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TO: **Suppliers**

FROM: **Ascension**
Ascension Health
Ascension Health Resource and Supply Management Group, LLC
("The Resource Group")

DATE: **July 29, 2013**

RE: **Ascension Health's Position on Physician-Owned Distributors**

As the largest non-profit healthcare system in the United States, Ascension Health is dedicated to providing its patients safe and effective care, supporting the integrity of the U.S. healthcare system, and maintaining a commitment to purchasing the highest quality products and services at the best overall value. As a result, Ascension Health prohibits its affiliates and Health Ministries from purchasing items or services, including, but not limited to, pharmaceuticals, implants, instruments, and other devices from physician-owned distributors ("POD(s)") that are either owned or controlled by one or more physicians.

On March 26, 2013, the Office of the Inspector General ("OIG") released a special fraud alert ("Alert"), which focuses on the characteristics of PODs that the OIG believes pose the greatest risks of fraud and abuse and dangers to patient safety. This Alert reaffirms the OIG's longstanding belief that POD arrangements have a strong potential for improper inducements between and among the physician investors, the entities, the device vendors, and the device purchasers and, as such, should be closely scrutinized under the fraud and abuse laws, such as the Anti-Kickback Statute ("AKS") and Civil Monetary Penalties law ("CMP"). Penalties for violating AKS and CMP include felony conviction and criminal and/or civil fines. The Department of Health and Human Services may also exclude individuals or entities that violate these laws from participating in the Medicare and Medicaid programs.

Ascension Health has identified other legal and regulatory considerations that further create heightened concerns as they relate to purchase arrangements with PODS, including:

- The Federal Stark Law ("Stark"), given the U.S. Senate has requested Centers for Medicare and Medicaid Services ("CMS") to weigh in on the implications of POD arrangements under the Physician Payment Sunshine Act, the Patient Protection and Affordable Care Act, and Stark in reports from June 2011.
- The risks to a tax-exempt organizations under the Intermediate Sanctions Law, Section 4958 of the Internal Revenue Code, under which the Internal Revenue Service can impose sanctions on an "Excess Benefit Transaction" that involve "Disqualified Persons," such as a physician.
- Conflicts of interest policies, which may be implicated by POD arrangements and would be subject to ongoing compliance review by a hospital or health system.

Given OIG's recent confirmation of its continued concerns regarding the fraud and abuse dangers of PODs, OIG's intent to continue monitoring these relationships based on the 2012 and 2013 OIG Work Plans, the U.S. Senate's request for additional review of PODS by CMS, and the risks related to tax-exempt status and conflicts of interest, Ascension Health has determined that it will not purchase from or contract with PODs, directly or indirectly, for itself or on behalf of its affiliates and Health Ministries.

THE RESOURCE GROUP
Integrating Excellence and Stewardship

July 29, 2013

Dear [redacted]

The purpose of this communication is to provide Ascension Health's position regarding physician-owned distributor(s) ("POD(s)") in the attached document containing Ascension Health's Position on Physician-Owned Distributors and to request confirmation from your organization that it is not a POD as defined by the Office of Inspector General ("OIG") and that it does not utilize PODs as distributors of products and/or services to our Participants.

Please submit a confirming statement from your organization to verify that the company is not a POD and that it does not utilize PODs as distributors of products and/or services to our Participants. Formal confirmation should be communicated via email to Mike Elstro, Sourcing Manager, at michael.elstro@ascensionhealth.org. If your company is a POD or utilizes one or more PODs to service Participants of our organization, please contact Mike Elstro immediately and reference this memorandum.

Sincerely,

Michael D. Gray
Chief Strategy Officer
The Resource Group

Enclosure: Ascension Health's Position on Physician-Owned Distributors

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[redacted]

By **BEN EISLER** / **CBS NEWS** / *April 24, 2014, 6:30 AM*

Tapping into controversial back surgeries

Back pain is one of the most common reasons Americans go to the doctor, and one of the fastest growing treatments is spinal fusion surgery. From 2001 to 2011, the number of spinal fusions in U.S. hospitals increased 70 percent, making them more frequently performed than even hip replacements. The growth has been attributed in part to improved technology, an aging population, and a greater demand among older people for mobility. But it has also sparked a debate over whether some surgeons are performing spinal fusions that are unnecessary and potentially dangerous. The procedure fuses together two or more vertebrae often with metal rods and screws, and can result in paralysis or life-threatening complications.

X-ray of spinal fusion / **ASSOCIATION FOR MEDICAL ETHICS**

For decades, patients have had no insight into how likely their doctor is to recommend a spinal fusion, or whether they may be performing risky procedures that others would not consider appropriate. They had no way of knowing how many spinal fusions their doctor performed over a given period, what percentage of patients they performed the procedure on, and how that compared to their peers. This story makes much of that information public for the first time.

For this six month investigation, CBS News exclusively obtained part of a government database. We asked for, among other things, the number of spinal fusions each doctor in the country billed to Medicare from 2011-2012, under codes

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most commonly used for "degenerative" conditions that cause lower back pain. We put the entire database online and made it easily searchable by the public. We also provided guidance on how to interpret it and details about how it was compiled.

It is important to note that the data does not reveal whether any of the surgeries that a doctor performed were inappropriate, and includes many spinal fusions that are widely considered necessary. Still, experts say high numbers raise questions and serve as starting points for further investigation. We looked into some of the highest volume surgeons and found some were respected with unblemished records. Others were banned or suspended from hospitals or settled lawsuits alleging unnecessary procedures. All of them are still operating.

The data shows that a small group of doctors performed these procedures far more frequently than their peers. While the national average was 46 surgeries over the two year period, some did more than 460. While the average spine surgeon performed them on 7 percent of patients they saw, some did so on 35 percent. (Averages exclude doctors that performed 10 or fewer of these fusions. Medicare

proportionate e complicated that many doctors would not operate on. There is also a financial incentive to performing a spinal fusion. It can earn a surgeon thousands of dollars - and five times as much as less risky alternatives.

Some of the biggest concerns surround more complex fusions that join four or more vertebrae. The more vertebrae that a surgeon fuses, the more they are paid (all else being equal), but the risks increase for the patient as well. One study of complex fusions for stenosis (a narrowing of the spinal canal) found 1 in 20 led to life-threatening complications. When it came to these riskier surgeries, the discrepancy in the data was even larger. Some doctors performed more than 100, while the national average was less than 7. Overall, 5 percent of the surgeons did about 40 percent of the fusions on four or more vertebrae.

We shared these statistics with Dr. Daniel Resnick, Vice Chair of Neurosurgery at the University of Wisconsin School of Medicine and President of the Congress of Neurological Surgeons. He said they raise serious concerns, and suggest that while the majority of spine surgeons are careful about recommending fusions, some may be "operating outside of the generally agreed upon (based on common practice and literature supported guidelines) parameters."

Dr. Resnick added that Medicare, medical societies, and credentialing boards should use data like this to follow practice patterns and patient outcomes. He said surgeons with the highest numbers should be looked at closely and asked to explain themselves.

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[redacted]

By **BEN EISLER** / **CBS NEWS** / *April 24, 2014, 6:30 AM*

Tapping into controversial back surgeries

Look up a Surgeon

This database allows you to find and compare spinal fusion operating rates of surgeons nationwide. To start, **enter a doctor's last name in UPPER CASE**. If the number of patients that they operated on comes up blank, it was between 1 and 10 (Medicare redacted those counts to protect patient privacy). You can also download this spreadsheet with more detailed information. It can be sorted by total fusions and filtered by city or state.

The data includes procedures performed on Medicare patients from 2011-2012. Some of the country's highest volume surgeons discounted its value. They questioned the validity of the numbers and told us (for reasons listed below) that the data should not be used to compare them with their peers. Other doctors said it could be hugely beneficial to patients.

Dr. Sohail Mirza, Chair of Orthopaedics at Dartmouth-Hitchcock Medical Center, said if your surgeon performed significantly more of these fusions than others in your community, or did them on a far higher percentage of their patients, you should ask them why. You may also want to get another opinion. It could just mean they have a sizeable referral base because they are respected in the field, but it could also mean that they are doing surgeries that others would not consider appropriate.

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National Averages Per Surgeon

651

*Medicare patients **seen**, 2011-12*

43

*Medicare patients that surgeon performed a spinal **fusion** on, representing 7% of patients that they saw*

<7

*Medicare patients that surgeon performed a **complex fusion** on (4 or more vertebrae), representing 1% of patients they saw*

Text search is case sensitive. Leave fields blank to see the entire database (may cause longer load times).

LAST NAME includes Enter case-sensitive text

Powered by freeDive

SEE ALL RECORDS

How this database was compiled

We asked Medicare for details on the billing codes for spine surgery and the agency referred us to the American Medical Association, which forwarded us to the North American Spine Society (NASS). One of NASS's billing experts helped us identify the codes most commonly used for spinal fusions that treat degenerative conditions that cause lower back pain. Experts told us to focus on this subset of fusions because it is more controversial, and there is a debate over whether some of them are necessary.

NASS's expert then helped us develop a methodology for counting these surgeries. Specifically, any time CPT code 22558, 22585, 22586, 22612, 22614, 22630, 22632, 22633, or 22634 was billed, it was counted as one spinal fusion surgery. If multiple codes were billed on the same procedure, it was still counted as one surgery. When fusing more than two vertebrae, there are separate "add-on" codes to be billed once per additional vertebra, according to NASS. Any time CPT code 22585, 22614, 22632, or 22634 was duplicated (billed twice) on the same procedure, it was counted as a fusion on four or more vertebrae.

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We did not count surgeries where the physician was described as an assistant or team surgeon, or didn't finish the procedure, by excluding codes with modifiers 53, 55, 66, 73, 74, 80, 81, 82, AK, or AS. Doctors that did not have the specialty codes for neurosurgeons, orthopedic surgeons, or physical rehabilitation specialists were also removed from the dataset.

We sent the instructions to the Centers for Medicare and Medicaid Services (CMS). Michael Marquis, Christopher Powers, and Stephanie Bartee at CMS compiled a large spreadsheet with roughly 192,000 fusions by 6,000 doctors. It was the first time Medicare had released spinal fusion data and allowed the names of surgeons to be made public. No patient information was disclosed, and as stated above, counts between 1 and 10 were redacted to protect patient privacy. National averages were calculated among doctors that performed more than 10 total fusions. Fusions on beneficiaries in Medicare's Part C program were not included as those plans are run by private insurers.

Limitations to the data

The billing codes used to compile this database describe a technique - not a diagnosis. According to NASS, they are most commonly used for treating degenerative conditions, but may also be used for other purposes.

The billing codes do not indicate whether a fusion was inappropriate, and some widely accepted fusions (like those for spondylolisthesis, or a slipped disc) are billed for using these codes.

Billing can be confusing and there may be inconsistencies among surgeons in terms of the codes they use for fusions. There may also be billing errors.

Some surgeons may get more referrals, see more complicated cases and do more fusions as a result. These numbers do not take into account the severity of the conditions the surgeon is treating.

Since this just covers Medicare patients, physicians in areas with large elderly populations have higher numbers.

Some of these fusions may include the mid-back or neck, as some of the codes used extend up to that area

Some surgeons often perform "360 degree" fusions, which involve two surgeries (through the front and back). Their total number of fusions may be higher as a result, but the number of patients that they fused is not changed by this.

Some spine surgeons operate on other parts of the body as well. They may have lower numbers and bring down averages.

Residents, physician assistants, and others under a surgeon's supervision can file claims under that doctor's name. While this is not done for spinal fusion surgeries, it may artificially increase the number of patients that a doctor saw in the data.

To calculate averages for fusions on four or more vertebrae, we used 10 for each doctor with a redacted count. This was done to avoid overstating the differences between doctors performing many of these fusions and their peers.

As with all large datasets, there may be miscellaneous errors.

Incorrect address?

If you are a surgeon and your state (or full address in the spreadsheet) is incorrect, check the information you provided to the National Provider Identifier registry. If you have recently changed it, email us at spinesurgeons@cbsnews.com and we will update your information in the database.

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By **BEN EISLER** / **CBS NEWS** / *April 24, 2014, 6:30 AM*

Tapping into controversial back surgeries

Surgeons we looked into

Barbara Jo Smith has lived in Clarksville, Tennessee for her whole life. She grew up on a farm, riding horses and chasing her two brothers around. In 1999, she married her childhood sweetheart.

By age 45, Smith had developed debilitating back pain. She saw a chiropractor and a physical therapist, but neither seemed to help. So she went to Nashville spine surgeon Dr. David McCord.

Dr. David McCord / **YOUTUBE**

Dr. McCord's website calls him "A True Medical Pioneer in the Treatment of Spine Pain." A video claims "his insight is highly prized across the world," before patients offer praise, like "I have no idea where I would be today, had I not met Dr. McCord."

Dr. McCord recommended two spinal fusion surgeries for Barbara Jo Smith, two days apart. In May of 2010 he operated on her, using plates and screws to join three of her vertebrae. Five months later, she says her pain had only worsened. So she went back to Dr. McCord and he performed another spinal fusion.

Today, Barbara Jo Smith says her pain is "a hundred times worse" than before the surgeries, and that she has nerve problems she did not have before. "One foot feels

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like it's burning, the other feels like it's on ice," she says. "I'm 49 years old and I can't lift anything without dying."

There are always risks with surgery and a bad outcome is not necessarily the doctor's fault. But if an operation wasn't needed to begin with, it's a different story. When it comes to individual cases, surgeons can disagree about whether a spinal fusion is appropriate. So we asked two doctors to tell us, without commenting on Smith's case in particular, whether they generally recommend the procedure for the diagnosis she was given. Both said they do not.

Dr. Daniel Resnick, Vice Chair of Neurosurgery at the University of Wisconsin School of Medicine and President of the Congress of Neurological Surgeons, helps shape national guidelines for spine surgery. Dr. Sohail Mirza, Chair of Orthopaedics at Dartmouth-Hitchcock Medical Center, has published studies on spine surgery and what he considers the overtreatment of back pain. Both doctors said they generally recommend more conservative treatments for patients with Smith's diagnosis.

According to the Medicare database, Dr. McCord performed fusions on 96 patients from 2011-2012. He did them on 34 percent of patients he saw, almost the highest rate in the entire country. And he performed three or more of these surgeries on 20 different patients over that period - the most of any surgeon nationwide.

The number of patients that Dr. McCord has repeatedly operated on may be higher in part because he often performs "360 degree" fusions (as he did on Barbara Jo Smith). The technique involves two surgeries, through the front and back. But other doctors also use this method, and the 20 patients that Dr. McCord operated on three or more times was twice as many patients as any other surgeon nationwide, according to the Medicare database.

In 2012, Dr. McCord was banned from operating at Centennial Medical Center. A confidential report by the hospital reveals that a "hearing committee found that [Dr. McCord] had a pattern of performing spine surgeries on patients for whom surgery is not indicated." Internal and external reviews concluded that he was performing unnecessary hardware removal operations. Dr. McCord sued the hospital, accusing it of conducting a sham review process led by a surgeon that saw him as competition. The case was dismissed.

Dr. McCord's attorney says he will appeal. But it wasn't the first time his surgeries had come under scrutiny at Centennial. CBS News has learned that after a separate review in the late 1990s, Dr. McCord agreed to limit his number of surgeries and get second opinions before operating. He is still practicing at another hospital just blocks away.

Dr. McCord invited CBS News to his office but declined repeated requests for an
poke about
wrote: "we will
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The lawyer also said Dr. McCord has not settled or lost a malpractice lawsuit, and highlighted Dr. McCord's degrees from top universities. He said Dr. McCord was banned from Centennial because as an orthopedist, the neurosurgeons there did not like him (both specialties perform spine surgery).

The Medicare database indicates Dr. Omar Jimenez of Scottsbluff, Nebraska performed 325 spinal fusion surgeries - the third most nationwide. Through an attorney, Dr. Jimenez declined multiple interview requests for this story. The lawyer said that Dr. Jimenez performs many procedures because he works in a part of the country with few spine surgeons and receives many referrals. She also pointed out that some of the

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Dr. Omar Jimenez / **RWMC.COM**

fusions he performs require two surgeries, but should not be counted as such.

"Dr. Jimenez is well aware of and shares the general concern about unnecessary spinal surgeries," a statement reads. "Before a fusion is considered, he treats his patients conservatively with a course of care that might include NSAIDs, physical therapy and injections."

The attorney also objected to the use of billing codes to count spinal fusions for "degenerative" conditions that cause lower back pain. "It is simply not possible to discern the diagnosis(es) from the CPT code alone," she wrote.

It is true that the billing codes describe a technique - not a diagnosis. Some widely accepted fusions are billed for using these same codes. But while the data does not reveal whether any of the fusions that a doctor performed were inappropriate, experts say high numbers raise questions and serve as starting points for further investigation.

When we looked into Dr. Jimenez, we found that in 2006 he was suspended indefinitely by a network of five hospitals in Georgia. According to a confidential report obtained by CBS News, it concluded that he "pose[d] a threat to the life, health and safety of patients." There were concerns about, among other things, his "surgical competency and selection of procedures." Dr. Jimenez eventually left the hospital system and sued it for racial discrimination. He claimed the review committee made up lies to oust him and did not give him a hearing. The case was eventually dismissed.

Dr. Jimenez also settled two malpractice suits in Georgia, for $950,000 in 2006 and $375,000 in 2010, according to the state's medical board. One of the cases was brought by James McCall, a 44-year-old man with back and leg pain, McCall's attorney said. After Dr. Jimenez performed a fusion on three of his vertebrae, McCall suffered permanent nerve damage in his right leg, the complaint says. He could no longer lift his foot and would trip when walking, and his back and leg pain also remained. Dr. Jimenez denied wrongdoing.

We mentioned the hospital suspension and malpractice settlements to the attorney representing Dr. Jimenez, but she chose not to comment on them.

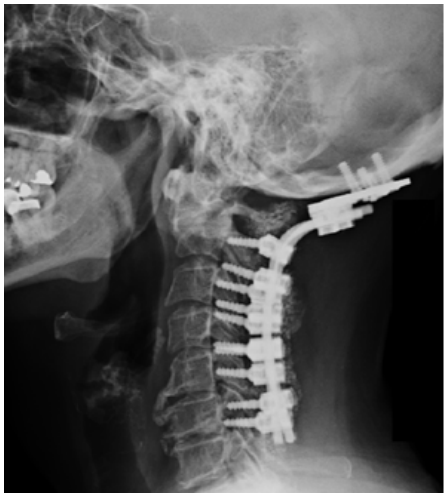
Dr. Ma hew Alexander / **DEPOSITION**

Some of the biggest concerns surround more complex fusions, on four or more vertebrae. A 2010 study in the Journal of the American Medical Association looked at complex fusions for lower back stenosis (a narrowing of the spinal canal) and found 1 in 20 led to life-threatening complications. The Medicare database indicates Dr. Mathew Alexander of Corpus Christi, Texas performed 97 fusion surgeries on four or more vertebrae - the sixth most in the country.

One of Dr. Alexander's patients, a 63-year-old hairdresser named Kimberly Keith, had pain in parts of her head, neck, and left arm. She tried physical therapy and a steroid injection, but neither helped. So in 2010, Dr. Alexander performed a spinal fusion from her skull through six of her vertebrae. The operation took five hours and in a deposition, Dr. Alexander said he had one or two other procedures earlier that day. Keith was billed more than $56,000 in surgical fees, but Dr. Alexander said they likely collected about a third of that amount.

Keith is now suing Dr. Alexander for allegedly aligning her neck crookedly and performing a more aggressive surgery than necessary. She has virtually no movement of her head, and it is stuck in a tilted position looking down and off to the right. Multiple doctors have said a corrective surgery would involve removing rods and screws that Dr. Alexander put in and entail significant risk. The case is

ongoing.



Kimberly Keith's x-ray after surgery / **HILLIARD MUNOZ GONZALES LLP**

Through a spokesperson, Dr. Alexander declined multiple interview requests. Even after we shared specific points for him to address, he chose not to respond. In a deposition, he said he believed Keith's spine was unstable, and without such an extensive operation she could have been paralyzed. He added that she had severe stenosis (a narrowing of the spinal canal) and a fracture in her second vertebra.

Dr. Alexander also said an imperfectly aligned neck is a risk of the surgery that cannot always be avoided. "There's no way you can hundred percent put a patient in neutral position...that's the best we can do for this type of operation."

In the deposition, Keith's attorney pressed Dr. Alexander on why he believed she had severe stenosis (a narrowing of the spinal canal) when multiple radiologists considered it mild or moderate. Dr. Alexander said he disagreed with their readings of the images. "I rely on the radiologist," he said. "But also as a neurosurgeon, we interpret the films, too."

Keith's attorney also asked why he fused the second, third, and fourth vertebrae in her neck, when none of the radiologists mentioned problems in that area. He said that when fusing two separate parts of the spine, it is common practice to include the vertebrae between them. "You have to incorporate the whole thing," he said, or she would "require further surgery down the road."

The Medicare data indicates that Dr. Richard Hynes of Melbourne, Florida performed 107 fusions on four or more vertebrae--the third most in the country. In 2006, a private health insurer dropped him and The B.A.C.K. Center (of which he is president) from its coverage network. "They say we're too aggressive, too expensive," he reportedly told a newspaper at the time. "Medical technology is expensive."

Dr. Richard Hynes / **THEBACKCENTER.NET**

Dr. Hynes filed an anti-trust lawsuit against the insurer's parent company, accusing it of excluding him because he was performing surgeries at a competing hospital. The case is ongoing.

In 2008, Dr. Hynes was sued for allegedly performing an unnecessary spinal fusion. After the operation, his 32-year-old patient developed an infection and required another spinal fusion, medical records show. According to her legal complaint, one of the surgeries damaged her intestine, forcing her to have part of it removed. Dr. Hynes settled the case, but denied wrongdoing.

According to the Florida Office of Insurance Regulation, five payments totaling more than $500,000 were made to former patients of Dr. Hynes by his insurance company from 2005-2012. Three of the cases challenged the necessity of spinal procedures performed by Dr. Hynes.

Through an attorney, Dr. Hynes declined our interview requests for this story. Even after we shared our specific findings, he chose not to respond. His lawyer only suggested we review a separate anti-trust lawsuit filed against Health First, the parent company of the insurer that dropped him from its network.

That case was filed by several physicians and group practices (not including Dr. Hynes). It alleges that the company has a near monopoly on healthcare services in the area, and intimidates doctors or obstructs their ability to practice medicine if they do not refer patients exclusively to its facilities. Health First has denied the allegations.

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[redacted]

By **BEN EISLER** / **CBS NEWS** / *April 24, 2014, 6:30 AM*

Tapping into controversial back surgeries

Response to Our Findings

We shared our findings with Dr. Daniel Resnick, Vice Chair of Neurosurgery at the University of Wisconsin School of Medicine and President of the Congress of Neurological Surgeons. He spoke on behalf of himself, not the organizations he is affiliated with.

Dr. Resnick said our findings concerned him. He said they suggest that while most doctors are careful about recommending a fusion, some may be "operating outside of the generally agreed upon (based on common practice and literature supported guidelines) parameters." He added that data on reoperation rates and complication rates should also be made public. That information is "critical to make any value judgments regarding the frequency of procedures performed," he said.

Dr. Resnick added that Medicare, medical societies, and credentialing bodies (including state medical boards and the American Board of Medical Specialties) should use databases like the one in this story to follow practice patterns and patient outcomes. He said surgeons with the highest numbers should be closely looked at and asked to explain themselves. But he said that won't happen without a source of funding, as the work is time consuming and entails legal risk.

Dr. Resnick also emphasized that there are many cases where spinal fusions are clearly necessary. The procedure is widely accepted for treating major spinal deformities (like scoliosis), fractures, tumors, infections, and spondylolisthesis

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(slipped disc) in the lower back. But some of the nation's top spine surgeons say they rarely perform it for simple back pain, degenerated discs (or "degenerative disc disease"), stenosis (a narrowing of the spinal canal), or a herniated disc.

More than 480,000 spinal fusions are performed in U.S hospitals each year, making them more common than even hip replacements. The annual cost of these surgeries is more than $12 billion, according to the Agency for Healthcare Research and Quality. Experts disagree about how many may be unnecessary, but Dr. Richard Deyo, a critic of the procedure and professor at Oregon Health and Science University believes it could be as much as half. For Medicare and Medicaid patients, taxpayers foot the bill.

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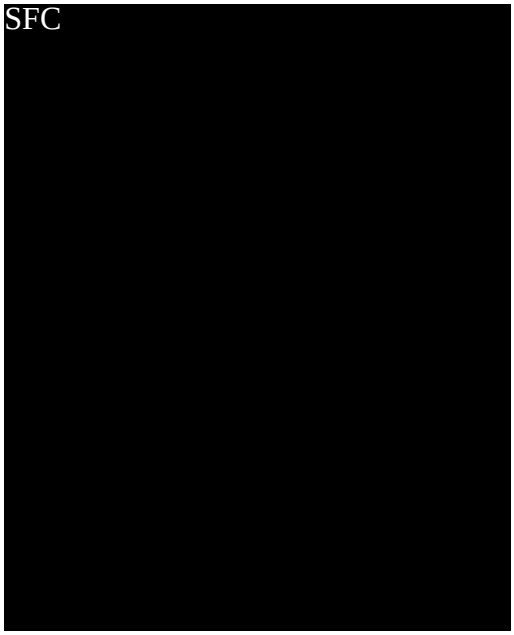

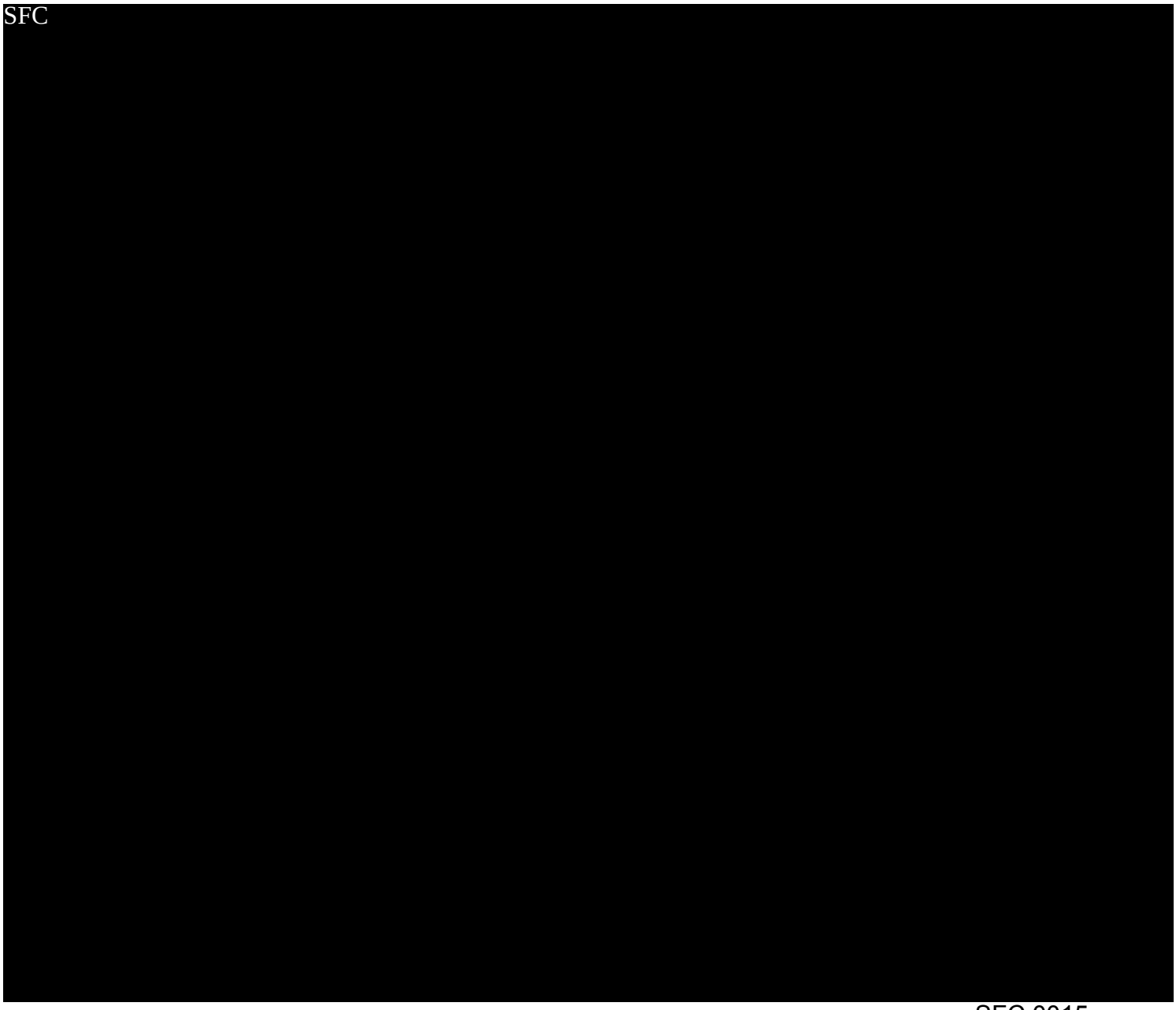

SFC 0015

Judge rejects Birmingham neurosurgeon's plea deal

By Tresa Baldas, Detroit Free Press *7:09 p.m. EDT October 2, 2015*

(Photo: Romain Blanquart/ Detroit Free Press)

In a rare move, a federal judge today refused to accept the guilty plea of a Birmingham neurosurgeon who admitted to performing unnecessary spinal surgeries on his patients and cheating insurers out of $11 million for them.

Under the terms of a plea deal, Dr. Aria Sabit faced a maximum of 11 years in prison.

But U.S. District Judge Paul Borman rejected that agreement — though without elaborating — and sent both sides back to the drawing board to come up with a different deal.

Sabit was scheduled to be sentenced today, but instead returned to jail with his fate still unknown because the judge refused to accept his plea deal — which is required before a criminal defendant can be sentenced.

More than a dozen of Sabit's victims attended the sentencing hearing but left with no closure.

Detroit attorney Brian McKeen, whose law firm represents two of Sabit's victims, applauded Borman's decision to reject the plea deal "until more facts are known especially with respect to how Dr. Sabit's misconduct has adversely affected his many victims.

"Regardless of the eventual outcome of the criminal case, I intend to continue on my quest to hold Dr. Sabit — and the hospitals that allowed these travesties to occur — fully accountable," McKeen said today.

DETROIT FREE PRESS

Birmingham doc admits to $11M fraud for unneeded surgeries

(http://www.freep.com/story/news/local/michigan/oakland/2015/05/22/spine-surgeon-pleads-guilty/27809373/)

Sabit's lawyer, Joseph Niskar, was not available for comment.

Sabit, 39, has been locked up since his arrest nearly a year ago. He tried to get released on bond, but Borman refused to let him out after declaring him a flight risk in January. Prosecutors had argued that Sabit would flee to his native Afghanistan — or somewhere else — to avoid prosecution. The defense said Sabit wouldn't do that, but Borman didn't take that chance and ordered him jailed pending the outcome of his case.

Sabit struck a deal with the federal government in May when he pleaded guilty to four counts of health care fraud, conspiracy and unlawful distribution of a controlled substance. He admitted that he convinced patients to undergo spinal fusion surgeries with medical stabilizing devices that he actually never used but billed public and private health care programs for it anyway. In some instances, Sabit admitted that he billed insurance programs for implants, when in fact the implants were tissue.

Since 2011, Sabit owned and operated the Michigan Brain and Spine Physicians Group with various locations in metro Detroit, including Southfield, Clinton Township and Dearborn.

According to the government, Sabit also admitted that, prior to moving to Michigan from California, he was involved in a kickback scheme in which he convinced a California hospital to buy spinal implant devices from a company that he was secretly involved in.

DETROIT FREE PRESS

Cancer doc Fata sobs, seeks mercy at sentencing

(http://www.freep.com/story/news/local/michigan/oakland/2015/07/10/fata-sentence-handed-down/29924303/)

Sabit surrendered his California medical license last summer after similar malpractice allegations. He also has forfeited his house and nearly $750,000 since his arrest.

Read or Share this story: http://on.freep.com/1RjY2Uu

JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE Friday, May 22, 2015

Detroit-Area Neurosurgeon Admits Causing Serious Bodily Injury to Patients in $11 Million Health Care Fraud Scheme

A Detroit-area neurosurgeon pleaded guilty today in two separate criminal cases that resulted in serious bodily injury to his patients and more than $11 million in Medicare, Medicaid and private insurance companies.

Assistant Attorney General Leslie R. Caldwell of the Justice Department's Criminal Division, U.S. Attorney Barbara L. McQuade of the Eastern District of Michigan, Special Agent in Charge Paul M. Abbate of the FBI's Detroit Field Office, Assistant Director in Charge David L. Bowdich of the FBI's Los Angeles Field Office, Special Agent in Charge Lamont Pugh III of the U.S. Department of Health and Human Service Office of Inspector General (HHS-OIG), Special Agent in Charge Glenn R. Ferry of the U.S. Department of Health and Human Services Office of Inspector General's (HHS-OIG) Los Angeles Region and Special Agent in Charge Marlon Miller of U.S. Immigration and Customs Enforcement's Homeland Security Investigations' (ICE-HSI) Detroit Field Office made the announcement.

"Disregarding his Hippocratic oath to do no harm, Dr. Sabit enriched himself by performing unnecessary, invasive spinal surgeries and implanting costly and unnecessary medical devices, all at the expense of his patients' health and welfare," said Assistant Attorney General Caldwell. "Doctors who sell their medical judgment and ethics for personal profit endanger the lives and safety of vulnerable patients who count on their advice to make life-altering decisions. The Criminal Division of the Department of Justice will continue to prioritize the prosecution of doctors whose criminal behavior puts patients at risk."

"This case of health care fraud is particularly egregious because Dr. Sabit caused serious bodily injury to his patients by acting out of his own greed instead of the best interests of his patients," said U.S. Attorney McQuade. "Not only did he steal $11 million in insurance proceeds, but he also betrayed his trust to patients by lying to them about the procedures that were medically necessary and that were actually performed."

Aria O. Sabit, M.D., 39, of Birmingham, Michigan, entered his guilty pleas in both criminal cases at a hearing before U.S. District Judge Paul D. Borman of the Eastern District of Michigan. Sabit pleaded guilty to four counts of health care fraud, one count of conspiracy to commit health care fraud and one count of unlawful distribution of a controlled substance, resulting in losses to Medicare, Medicaid and various private insurance companies. A sentencing hearing is scheduled for Sept. 15, 2015.

According to court documents, Sabit was a licensed neurosurgeon who owned and operated the Michigan Brain and Spine Physicians Group with various locations in the Eastern District of Michigan, including Southfield, Michigan, Clinton Township, Michigan, and Dearborn, Michigan, which opened in approximately April 2011.

During his guilty plea today, Sabit admitted that he derived significant profits by convincing patients to undergo spinal fusion surgeries with instrumentation (meaning specific medical devices designed to stabilize and strengthen the spine), which he never rendered, and subsequently billing public and private healthcare benefit

programs for those fraudulent services.

Sabit further admitted he operated on patients and dictated in his operative reports—that he knew would later be used to support his fraudulent insurance claims—that he had performed spinal fusion with instrumentation, which he never performed. This invasive surgery caused serious bodily injury to the patients. Sabit admitted that his operative reports and treatment records contained false statements about the procedures performed, and the instrumentation used in the procedures. Sabit also admitted that, on occasion, he would implant cortical bone dowels and falsely dictate in his operative reports that he had implanted instrumentation. Sabit, then fraudulently billed public and private health care programs for instrumentation, when in fact the implants were tissue. Sabit admitted he failed to render services in relation to lumbar and thoracic fusion surgeries, including in certain instances, billing for implants that were not provided.

Sabit also admitted that, prior to moving to Michigan, he was a resident of Ventura, California, and a licensed neurosurgeon in California. He admitted that in approximately February 2010, he became involved with Apex Medical Technologies LLC (Apex) while he was on the staff of a California hospital.

Apex was owned by another neurosurgeon and three non-physicians who operated Apex as a physician-owned distributorship and paid neurosurgeons lucrative illegal kickbacks tied directly to the volume and complexity of the surgeries that the surgeons performed, and the number of Apex spinal implant devices the surgeons used in their spine surgeries.

In exchange for the opportunity to invest in Apex and share in its profits, Sabit admitted that he agreed to convince his hospital to buy spinal implant devices from Apex and use a sufficient number of Apex spinal implant devices in his spine surgeries. Sabit further admitted that he and Apex's co-owners used Apex to operate an illegal kickback scheme. In doing so, they concealed Sabit's involvement in Apex from outsiders. Sabit then required the hospitals and surgical centers where he and his fellow neurosurgeon performed surgeries to purchase spinal implant devices from Apex.

Sabit admitted that his involvement in Apex, and the financial incentives provided to him by Apex and his co-conspirators, caused him to compromise his medical judgment and cause serious bodily injury to his patients by performing medically unnecessary spine surgeries on some of the patients in whom he implanted Apex spinal implant devices. Sabit admitted that on a few occasions, the money he made from using Apex spinal implant devices motivated him either to refer patients in for spine surgery who did not medically need surgery or refer his patients for more complex surgeries, such as multi-level spine fusions, that they did not need.

Sabit also admitted that the financial incentives provided to him by Apex and his co-conspirators caused him to "over instrument" his patients (meaning Sabit used more spinal implant devices than were medically necessary to treat his patients) in order to generate more sales revenue for Apex, which resulted in serious bodily injury to his patients.

The Michigan case was investigated by the FBI, HHS-OIG and ICE. The California case—which was subsequently transferred to the Eastern District of Michigan—was investigated by the FBI and HHS-OIG. The Michigan case is being prosecuted by Assistant U.S. Attorneys Regina R. McCullough and Philip A. Ross of the Eastern District of Michigan. The California case was brought as part of the Medicare Fraud Strike Force, under the supervision of the Criminal Division's Fraud Section and the U.S. Attorney's Office of the Eastern District of Michigan, and is being prosecuted by Senior Trial Attorney Jonathan T. Baum and Trial Attorneys Dustin Davis and Blanca Quintero of the Criminal Division's Fraud Section.

Sabit is also a defendant in two civil False Claims Act cases brought by the Department of Justice in the U.S. District Court of the Central District of California.

Since its inception in March 2007, the Medicare Fraud Strike Force, now operating in nine cities across the country, has charged nearly 2,100 defendants who have collectively billed the Medicare program for more than

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$6.5 billion. In addition, the HHS's Centers for Medicare and Medicaid Services, working in conjunction with the HHS-OIG, are taking steps to increase accountability and decrease the presence of fraudulent providers.

15-666
Healthcare Fraud

Criminal Division

Updated May 22, 2015

SFC 0019

McDermott Will & Emery

FCA Update

Exploring Recent Developments in False Claims Act Litigation, Enforcement and Compliance

"Operation Spinal Cap" Sees Former Hospital Executive, Physicians Charged for Their Roles in Kickback Scheme

BY CHELSEA M. RUTHERFORD ON DECEMBER 3, 2015

POSTED IN COMPLIANCE PROGRAM, GOVERNMENT INVESTIGATION, HEALTH CARE, PENALTIES

Last week, the Department of Justice (DOJ) announced charges against a former hospital CFO, two orthopedic surgeons, a chiropractor, and a health care marketer for their alleged roles in a series of fraudulent referral and billing schemes. According to the DOJ, these referral schemes paid illegal kickbacks to physicians for spinal surgery referrals and caused "nearly $600 million in fraudulent billings over an eight-year period." These charges underscore the federal government's recent emphasis on greater individual accountability for fraudulent healthcare schemes and the potential for those involved to face significant liability.

According to a statement from the U.S. Attorney's Office, the schemes generally involved paying tens of millions of dollars in kickbacks for referrals to two California hospitals, Pacific Hospital in Long Beach and Tri-City Regional Medical Center in Hawaiian Gardens, for spinal surgeries. Those hospitals then billed those surgeries to California's workers' compensation system, the U.S. Department of Labor, and workers' compensation insurers. The schemes implicated dozens of surgeons, orthopedic specialists, chiropractors, marketers, and other medical professionals.

These charges are the latest development in an ongoing coordinated government investigation dubbed "Operation Spinal Cap." The investigation is specifically focused on providers and other individuals who may have been involved in these spinal surgery-related schemes.

In early 2014, the ex-CEO of Pacific Hospital was indicted and pleaded guilty to paying illegal kickbacks and federal conspiracy charges. He was also the subject of a qui tam suit and a suit by the County of Los Angeles on state false claims grounds. According to those cases, the CEO used a network of shell corporations, physician-owned distributorships, and sham contracts to facilitate the referral and billing schemes.

Notably, not all improper kickback payments are clear-cut cash transactions. The schemes described above

are alleged to have used multiple vehicles for providing and concealing kickback payments, including

are alleged to have used multiple vehicles for providing and concealing kickback payments. For example, the U.S. Attorney's Office statement described several "bogus contracts" deployed as part of the Pacific Hospital referral scheme. These included agreements where physicians were paid for a "right to purchase" their medical practices, but the option was never exercised; operations-based agreements that compensated physicians at rates above fair market value; agreements for consulting or directorship work that was never performed; and even lease agreements that paid doctors for space that was never or rarely used. Corporations should be mindful of these improper arrangements when structuring their compliance programs and evaluating their financial relationships with physicians.

Pacific Hospital's former CFO, whose case was unsealed last Tuesday, was allegedly responsible for, among other things, tracking the referrals from and payments to physicians. He pleaded guilty to participating in a conspiracy that engaged in paying kickbacks in connection with a federal healthcare program and in mail fraud, among other charges. The charges brought against the individuals are varied. For example, one orthopedic surgeon was charged with filing a false tax return; his plea agreement admits he did not report his kickback payments as income on his taxes. Additionally, a health care marketer who admitted to recruiting doctors to make referrals pled guilty to conspiring to commit mail fraud.

While the crimes charged vary, they are consistent with the federal government's recent enhanced focus on individual actors and their roles in health care fraud schemes. The government's focus on individuals was notably described in Deputy Attorney General Sally Quillian Yates' recent memo, which focused on themes of cooperation and individual accountability for involvement in corporate crimes (see our former pieces on the Yates memo here and here.

A copy of the DOJ's Press Release on these charges can be found here.

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SOCIAL ISSUES
December 18, 2014

Americans Rate Nurses Highest on Honesty, Ethical Standards

by Rebecca Riffkin

Story Highlights

- *Nurses continue to be rated the most honest and ethical*
- *Members of Congress, car salespeople get lowest ratings*
- *Ratings of bankers and business executives declined this year*

WASHINGTON, D.C. -- In 2014, Americans say nurses have the highest honesty and ethical standards. Members of Congress and car salespeople were given the worst ratings among the 11 professions included in this year's poll. Eighty percent of Americans say nurses have "very high" or "high" standards of honesty and ethics, compared with a 7% rating for members of Congress and 8% for car salespeople.

U.S. Views on Honesty and Ethical Standards in Professions

Please tell me how you would rate the honesty and ethical standards of people in these different fields -- very high, high, average, low, or very low?

	% Very high or high	% Average	% Very low or low
Nurses	80	17	2
Medical doctors	65	29	7
Pharmacists	65	28	7
Police officers	48	31	20
Clergy	46	35	13
Bankers	23	49	26
Lawyers	21	45	34
Business executives	17	50	32
Advertising practitioners	10	44	42
Car salespeople	8	46	45
Members of Congress	7	30	61

Dec. 8-11, 2014
Rated in order of % Very high or high

GALLUP

Americans have been asked to rate the honesty and ethics of various professions annually since 1990, and periodically since 1976. Nurses have topped the list each year since they were first included in 1999, with the exception of 2001 when firefighters were included in response to their work during and after the 9/11 attacks. Since 2005, at least 80% of Americans have said nurses have high ethics and honesty. Two other medical professions -- medical doctors and pharmacists -- tie this year for second place at 65%, with police officers and clergy approaching 50%.

Historically, honesty and ethics ratings for members of Congress have generally not been positive, with the highest rating reaching 25% in 2001. Since 2009, Congress has ranked at or near the bottom of the list, usually tied with other poorly viewed professions like car salespeople and -- when they have been included -- lobbyists, telemarketers, HMO managers, stockbrokers and advertising practitioners.

Although members of Congress and car salespeople have similar percentages rating their honesty and ethics as "very high" or "high," members of Congress are much more likely to receive "low" or "very low" ratings (61%), compared with 45% for car salespeople. Last year, 66% of Americans rated Congress' honesty and ethics "low" or "very low," the worst Gallup has measured for any profession historically.

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Other relatively poorly rated professions, including advertising practitioners, lawyers, business executives and bankers are more likely to receive "average" than "low" honesty and ethical ratings. So while several of these professions rank about as low as members of Congress in terms of having high ethics, they are less likely than members of Congress to be viewed as having low ethics.

No Professions Improved in Ratings of High Honesty, Ethics Since 2013

Since 2013, all professions either dropped or stayed the same in the percentage of Americans who said they have high honesty and ethics. The only profession to show a small increase was lawyers, and this rise was small (one percentage point) and within the margin of error. The largest drops were among police officers, pharmacists and business executives. But medical doctors, bankers and advertising practitioners also saw drops.

U.S. Views on Honesty and Ethical Standards in Professions Compared With 2013

Please tell me how you would rate the honesty and ethical standards of people in these different fields -- very high, high, average, low, or very low?

	% 2014 very high or high	% 2013 very high or high	Difference (pct. pts.)
Nurses	80	82	-2
Medical doctors	65	69	-4
Pharmacists	65	70	-5
Police officers	48	54	-6
Clergy	46	47	-1
Bankers	23	27	-4
Lawyers	21	20	1
Business executives	17	22	-5
Advertising practitioners	10	14	-4
Car salespeople	8	9	-1
Members of Congress	7	8	-1

Dec. 8-11, 2014

GALLUP

Honesty and ethics ratings of police dropped six percentage points since last year, driven down by many fewer nonwhite Americans saying the police have high honesty and ethical standards. The clergy's 47% rating last year marked the first year that less than 50% of Americans said the clergy had high ethical and honesty standards -- and the current 46% rating is, by one percentage point, the lowest Gallup has measured for that

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profession to date.

Bottom Line

Americans continue to rate those in medical professions as having higher honesty and ethical standards than those in most other professions. Nurses have consistently been the top-rated profession -- although doctors and pharmacists also receive high ratings, despite the drops since 2013 in the percentage of Americans who say they have high ethics. The high ratings of medical professions this year is significant after the Ebola outbreak which infected a number of medical professionals both in the U.S. and in West Africa.

At the other end of the spectrum, in recent years, members of Congress have sunk to the same depths as car salespeople and advertising practitioners. However, in one respect, Congress is even worse, given the historically high percentages rating its members' honesty and ethics as being "low" or "very low." And although November's midterm elections did produce a significant change in membership for the new Congress that begins in January, there were also major shakeups in the 2006 and 2010 midterm elections with little improvement in the way Americans viewed the members who serve in that institution.

Previously in 2014, Gallup found that Americans continue to have low confidence in banks, and while Americans continue to have confidence in small businesses, big businesses do not earn a lot of confidence. This may be the result of Americans' views that bankers and business executives do not have high honesty and ethical standards, and the fact that their ratings dropped since last year.

The Trend Line: Nursing Is America's Most Ethical Profession

Survey Methods

Results for this Gallup poll are based on telephone interviews conducted Dec. 8-11, 2014, with a random sample of 805 adults, aged 18 and older, living in all 50 U.S. states and the District of Columbia. For results based on the total sample of national adults, the margin of sampling error is ±4 percentage points at the 95% confidence level.

Each sample of national adults includes a minimum quota of 50% cellphone respondents and 50% landline respondents, with additional minimum quotas by time zone within region. Landline and cellular telephone numbers are selected using random-digit-dial methods.

View complete question responses and trends.

Learn more about how Gallup Poll Social Series works.

RELEASE DATE: December 18, 2014

SOURCE: Gallup http://www.gallup.com/poll/180260/americans-rate-nurses-highest-honesty-ethical-standards.aspx

CONTACT: Gallup World Headquarters, 901 F Street, Washington, D.C., 20001, U.S.A

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SFC 0027

HCA

DEPARTMENT: Legal	**POLICY DESCRIPTION:** Relationships with Physician-Connected Vendors
PAGE: 1 of 7	**REPLACES POLICY DATED:** 3/15/08, 6/1/08, 8/1/08, 11/1/08, 6/15/09, 8/1/10; 11/1/12, 7/1/2014
EFFECTIVE DATE: July 1, 2014	**REFERENCE NUMBER:** LL.027
APPROVED BY: Ethics and Compliance Policy Committee	

SCOPE: This policy applies to HCA Holdings, Inc. and all of its Affiliated Entities and Facilities, including but not limited to, hospitals, ambulatory surgery centers, imaging centers, home health agencies, physician practices, service centers, and all Corporate Departments, Groups and Divisions, HealthTrust Purchasing Group ("HPG") and Parallon (collectively with HCA Holdings, Inc., the "Company").

"Affiliated Entities and Facilities" include any person or entity controlling, controlled by or under common Control with the Company.

Other capitalized terms used in this policy and not otherwise defined have the meaning given to them in the Definitions section below.

PURPOSE: The Office of Inspector General ("OIG") and the Centers for Medicare and Medicaid Services ("CMS") closely scrutinize purchases of items and services from Vendors that are owned in whole or in part by Physicians or that have compensation arrangements with Physicians. This policy is intended to guide such purchases in accordance with applicable laws.

POLICY:

1. **General**. The Company shall not purchase items and/or services from Physician-Connected Vendors unless all of the following requirements are satisfied:

   a. The arrangement is memorialized by a Fair Market Value Contract. (A Fair Market Value Contract is required regardless of whether the Physician(s) with which the Vendor is connected might refer to the component of the Company purchasing the item or service or any other component of the Company); and

   b. The arrangement complies with this policy, Policy LL.001, Policy LL.029, Policy MM.002, other applicable policies and applicable law.

2. **Policy LL.029**. Policy LL.029 prohibits the Company from purchasing certain covered products from certain Physician-Owned Vendors. This policy does not limit or alter the application of Policy LL.029. If Policy LL.029 prohibits the purchase of a particular product from a particular Vendor by a Purchasing Entity (as defined in Policy LL.029), then the Purchasing Entity must not purchase that product from that Vendor, even if the purchase would otherwise be permitted by this policy. Those responsible for purchasing products from Physician-Owned Vendors should also be familiar with Policy LL.029.

3. **Under Arrangements Agreements With Physician-Owned Vendors.** Under Arrangements Agreements with Physician-Owned Vendors may be prohibited by the federal Stark Law. Accordingly, any Under Arrangements Agreement with a Physician-Owned Vendor should be

reviewed and evaluated on a case-by-case basis with HCA Operations Counsel before the Company (or any component thereof) may agree to, or enter into, such arrangement.

4. **Exceptions**. Any exceptions to this policy must be approved in writing by the applicable Division President and the Company's Senior Vice President & Chief Ethics and Compliance Officer.

DEFINITIONS:

Approving Authority means the applicable Division President or Market President.

Control means the direct or indirect power to govern the management and policies of an entity; or the power or authority through a management agreement or otherwise to approve an entity's transactions.

Certification Form means the applicable, then-current Vendor Physician Ownership and Compensation Certification Form attached to this policy.

Designated Health Services means those services (such as inpatient and outpatient hospital services, radiology and certain other imaging services and radiation therapy services) that are subject to the general prohibition against self-referrals contained in the federal Stark Law.

Fair Market Value means the value in arm's-length transactions consistent with the price that an item or service would bring as the result of bona fide bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party. Usually, the fair market value price is the price at which bona fide sales have been consummated for items of like type, quality and quantity in a particular market or the compensation that has been included in bona fide service agreements with comparable terms, where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals.

Fair Market Value Contract means a written agreement, executed by the parties before items or services are provided or paid for, which: (a) specifies a purchase price consistent with Fair Market Value for the items and services to be provided; (b) contains representations, warranties and covenants on the part of the Vendor that are substantially similar to the representations, warranties and covenants set forth in Sections II and III of the Certification Form; (c) has been reviewed by the Legal Department and (d) otherwise satisfies the requirements of Policy LL.001. A Fair Market Value Contract will usually take the form of the appropriate Legal Department approved form. The term of a Fair Market Value contract should usually not exceed two (2) years.

Immediate Family Member of a person means that person's husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law,

son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; grandparent's or grandchild's spouse.

Ownership Interest means any direct or indirect ownership or investment interest whether through equity, debt or other means, including but not limited to stock, stock options, warrants, partnership shares, limited liability company memberships, as well as loans and bonds.

Physician means any person who is a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or chiropractor. The term "Physician" includes without limitation any person who is an Immediate Family Member of a person described in the immediately preceding sentence.

Physician-Connected Vendor means any Vendor that is a Physician-Owned Vendor and/or a Vendor with a Physician Compensation Arrangement.

Physician-Owned Vendor means any Vendor in which a Physician holds any Ownership Interest; excluding any Vendor that is a Publicly Traded Company.

Publicly Traded Company means a company that is publicly held and both:

(a) listed for trading on the New York Stock Exchange ("NYSE") or any regional exchange in which quotations are published on a daily basis, or are foreign securities listed on a recognized foreign, national or regional exchange in which quotations are published on a daily basis, or traded on the National Association of Securities Dealers Automated Quotation System ("NASDAQ"); AND

(b) had at least $75 million in stockholder's equity at the end of its most recent fiscal year or on average during the previous 3 fiscal years.

Under Arrangements Agreement means an agreement with a Physician-Owned Vendor where: (a) the Physician-Owned Vendor performs services for a Company affiliated entity or facility (such as a hospital); and (b) the Company affiliated entity or facility (such as a hospital), in turn, bills such services as Designated Health Services. Performing a service generally includes situations where the Physician-Owned Vendor provides both the equipment and personnel/technicians for the test or treatment provided to a patient or where the technical component is purchased. Examples may include, but are not limited to, the following services: cardiac catheterization, outpatient surgery, mobile PET, imaging, CT or MRI, radiation therapy (including cyberknife/gamma knife), cryotherapy, intraoperative monitoring, perfusion, sleep lab, etc.

Vendor means an entity doing business with, or seeking to sell items or services to, the Company.

HCA

DEPARTMENT: Legal	**POLICY DESCRIPTION:** Relationships with Physician-Connected Vendors
PAGE: 4 of 7	**REPLACES POLICY DATED:** 3/15/08, 6/1/08, 8/1/08, 11/1/08, 6/15/09, 8/1/10; 11/1/12, 7/1/2014
EFFECTIVE DATE: July 1, 2014	**REFERENCE NUMBER:** LL.027
APPROVED BY: Ethics and Compliance Policy Committee	

Vendor with a Physician-Compensation Arrangement means any Vendor that has a direct or indirect compensation arrangement with a Physician or a Physician-Owned Vendor. A Vendor that is a Publicly Traded Company may also be a Vendor with a Physician-Compensation Arrangement.

PROCEDURE:

A. **Determining Whether a Vendor is a Physician-Connected Vendor.**

1. **Certification Form.**

   a. Before entering into any new business relationship, or renewing any existing business arrangement, with a Vendor, the Company shall send the Certification Form to the Vendor for completion and execution.

   b. Supply Chain shall save a copy of all returned Certification Forms in a database accessible by Division Contract Managers and facility management, such as "OnBase."

   c. If a Vendor returns a Certification Form with Box "4" or "5" checked or with Box 7 marked "Yes," the Vendor will be considered a Physician-Connected Vendor. Subject to Policy LL.029 and subject to confirmation from the Legal Department that a prohibited Under Arrangements Agreement with a Physician-Owned Vendor is not involved, the Company must enter into a Fair Market Value Contract with the Vendor prior to purchasing from the Vendor, or paying the Vendor for, items or services. (If Box I.A is marked "Yes," please refer to Policy LL.029 to determine whether Policy LL.029 prohibits the purchase of Covered Product from the Vendor.)

   d. Each Vendor's Certification Form should be updated, completed and re-executed at least every year and within thirty (30) days of any change to the information provided on such form.

2. **Vendor's Failure or Refusal to Return a Fully Completed Certification Form.** The Company shall not purchase (or pay for) items or services from a Vendor which has not previously returned a fully completed and signed Certification Form, unless it otherwise complies with this policy. As provided above, existing Vendors may be asked to update their Certification Form. If a Vendor fails to return a fully completed and signed updated Certification Form within thirty (30) days of the request to do so, all purchases from the Vendor and all payments to the Vendor will be suspended until the Vendor returns a fully completed and signed Certification Form indicating that the Vendor is not a Physician-Connected Vendor or the parties enter into a Fair Market Value Contract that complies with this Policy.

3. **Conflicting Responses in Certification Forms.** If a Vendor provides more than one Certification Form and any one of the forms (as updated) indicates that the Vendor is a

Physician-Connected Vendor, then the Company must enter into a Fair Market Value Contract with the Vendor before any further items or services are ordered or provided or payments are made, unless Policy LL.029 is applicable or a prohibited Under Arrangements Agreement with a Physician-Owned Vendor is involved (in either of which cases the Company will not enter into or continue the arrangement). Until such a contract is executed by the parties or until the Vendor returns a fully completed and signed Certification Form indicating that the Vendor is not a Physician-Connected Vendor, the Company will not make payment to the Vendor for previously provided items or services.

4. **Current List of Physician Connected Vendors.** A current list of contracts with Physician-Connected Vendors will be maintained in a centralized database. The list will indicate whether the Vendor is a Physician-Owned Vendor, a Vendor with a Physician Compensation Arrangement or both.

B. **Determining Fair Market Value.**

1. **Methodologies for Determining Fair Market Value.** The Fair Market Value price to be paid for items and services provided by a Physician-Connected Vendor may be determined in any of the following manners:

   a. The entity or facility purchasing the item or service, or the conglomerate of entities purchasing the item or service together, may obtain an independent valuation from one of the HCA-approved third party appraisers.

   b. If the item or service is offered by a Vendor through a contract with HPG, and there is no exclusive provider language in that contract, the price, compensation and other economic terms agreed to with any other Vendor should be, in the aggregate for all the economic terms, consistent with and comparable to the fair market value terms agreed to by HPG. Any economic terms under consideration that are in the aggregate higher than HPG pricing must be reviewed by HPG and the Legal Department.

   c. If the item or service is not offered by a Vendor through a contract with HPG, the entity or facility purchasing the item or service, or the conglomerate of entities purchasing the item or service together, may obtain competitive bids for items or services similar in quantity, quality, type and availability from companies that are non-Physician-Connected Vendors through a Request for Proposal (RFP) bid process. No entity or facility may structure the request for pricing process in a way that would effectively limit the Vendors able to participate in the bid process to preferred or local Vendors. The price paid to a Physician-Connected Vendor should be at or lower than the average of the bids. If the price is higher than the average, documentation must be provided to HCA Operations Counsel, justifying the higher price (based upon quality, etc.). Documentation of the alternate bids and any other supporting information must

be maintained by the entity for the duration of the relationship with the Vendor plus five years.

2. **Updating Analysis of Fair Market Value.** Any fair market value analysis of any arrangement to purchase items or services from a Physician-Connected Vendor must be updated at least every two years.

C. **Verifying, Before Making Purchases or Payment, that a Fair Market Value Contract has been Executed.**

Before making purchases or payment to a Physician-Connected Vendor, if the item or service is not offered by the Vendor through a Fair Market Value Contract with HPG, Supply Chain will determine the Company affiliated facility (or facilities) with which the Vendor does business and will contact the CFO of the facility (or facilities) with a request for a copy of the Fair Market Value Contract reviewed by the Legal Department. If no such Fair Market Value Contract exists under which the proposed purchase is to occur, Supply Chain will notify the facility(ies) that a Fair Market Value Contract is necessary and no purchases or payments are to be made until one is obtained for each such facility.

D. **HPG Exclusive Agreements.**

Where the item or service supplied by the Vendor is or could be supplied through an existing contract between HPG and another Vendor, HPG must be contacted prior to entering into any contract with the Vendor. HPG will review its contract and advise whether the HPG agreement prohibits entities or facilities from executing contracts with any other Vendor for the same or similar items. If HPG determines that such an exclusive statement is included in the HPG contract, the entity or facility will not purchase items or services from the Vendor.

E. **Vendor Discovered to be Physician-Connected Vendor After Agreement to Purchase Items and Services.**

In very limited cases, the Company may learn that a Vendor is a Physician-Connected Vendor only after agreeing to purchase an item or service from the Vendor. The Company will enter into a Fair Market Value Contract with the Vendor that complies with this Policy before any further items or services are ordered or provided or payments are made. Until such a contract is executed by the parties, the Company will not make payment to the Vendor for previously provided items or services.

F. **Under Arrangements Agreements With Physician-Owned Vendors**.

Any Under Arrangements Agreement with a Physician-Owned Vendor should be reviewed and evaluated on a case-by-case basis with HCA Operations Counsel before it is entered into to determine if it is legally permissible.

G. **Approvals**.

HCA

DEPARTMENT: Legal	**POLICY DESCRIPTION:** Relationships with Physician-Connected Vendors
PAGE: 7 of 7	**REPLACES POLICY DATED:** 3/15/08, 6/1/08, 8/1/08, 11/1/08, 6/15/09, 8/1/10; 11/1/12, 7/1/2014
EFFECTIVE DATE: July 1, 2014	**REFERENCE NUMBER:** LL.027
APPROVED BY: Ethics and Compliance Policy Committee	

The purchase of items or services from a Physician-Connected Vendor must be approved by the Approving Authority. The CEO/Administrator of the Purchasing Entity (as defined in Policy LL.029) and the Division President or Division CFO will be required to certify at the time the Fair Market Value Contract is entered into that:

a. if a Covered Product (as defined in Policy LL.029) is involved, the Physician-Connected Vendor is not a Physician-Owned Business (as defined in Policy LL.029) or with respect to the Purchasing Entity (as defined in Policy LL.029) qualifies as an Exempt Physician-Owned Business (as defined in Policy LL.029) under Policy LL.029;

b. the items and/or services covered by the agreement are priced at Fair Market Value and such Fair Market Value has been determined consistent with Section B of this Policy LL.027 by either: (a) independent valuation from one of the Company approved third party appraisers, (b) confirmation that is consistent with and comparable to Fair Market Value terms agreed to by HPG for the item or service, or (c) an RFP bid process for items or services similar in quantity, quality, type and availability from non-Physician-Connected Vendors;

c. there are no agreements or understandings, whether written or oral, that condition the decision to purchase or the consideration paid on the volume or value of any referrals or other business generated among the parties, their owners or investors, or any other entity affiliated with the Company; and

e. the items and/or services to be purchased do not exceed those that are reasonable and necessary for the arrangement's commercially reasonable business purposes.

A form of such certificate is attached to this policy. A copy of this completed certificate is to be maintained with the agreement at the facility, with the original certificate to be forwarded to the Legal Department.

H. **Compliance Reporting**.
The Company shall follow appropriate procedures, outlined in Policy EC.025, for reporting any potential compliance issues and occurrences.

REFERENCES:
1. 42 U.S.C. § 1320a-7b;
2. Stark Law, 42 U.S.C. § 1395nn and implementing regulations;
3. General Statement on Agreements with Referral Sources - Approval Process Policy, LL.001

HCA

DEPARTMENT: Legal	**POLICY DESCRIPTION:** Relationships with Physician-Connected Vendors
PAGE: 8 of 7	**REPLACES POLICY DATED:** 3/15/08, 6/1/08, 8/1/08, 11/1/08, 6/15/09, 8/1/10; 11/1/12, 7/1/2014
EFFECTIVE DATE: July 1, 2014	**REFERENCE NUMBER:** LL.027
APPROVED BY: Ethics and Compliance Policy Committee	

4. Reporting Compliance Issues and Occurrences to the Corporate Office Policy, EC.025
5. Vendor Relationships Policy, MM.002
6. Company Code of Conduct
7. Prohibition on Purchasing Certain Products from Physician-Owned Businesses, LL.029

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VENDOR PHYSICIAN OWNERSHIP & COMPENSATION CERTIFICATION

Vendor: _____ Address: _____

_____

Service or Product Type(s):_____ City/State/Zip_____

_____

Organizational form: ☐ Corporation, profit ☐ Partnership ☐ Individual or Sole Proprietorship
☐ Corporation, non profit ☐ LLC ☐ LLP ☐ Other_____

The person, company, business or other entity named above ("Vendor") hereby certifies that the selection made below is true and accurate:

SECTION I: Vendor's Ownership Type. (Check only one box).

	1	Vendor is publicly traded, with less than $75 million dollars in stockholder's equity as of the end of its most recent fiscal year or on average during the previous 3 fiscal years (please attach Balance Sheet); and no physician* nor any immediate family member** of a physician is known to own, directly or indirectly, an ownership interest.
	2	Vendor is either: (a) not publicly traded, or (b) an individual or sole proprietorship, and in either case listed above at (a) or (b), no physician* or immediate family member** of a physician is known to own, directly or indirectly, an ownership interest.
	3	Vendor is publicly traded with at least $75 million dollars in stockholders' equity as of the end of its most recent fiscal year or on average during the previous 3 fiscal years (please attach evidence).
	4	Vendor is not publicly traded, and is: (a) an entity in which a physician* or immediate family member** of a physician owns, directly or indirectly, an ownership interest; (b) an individual or sole proprietorship which is owned by a physician* or an immediate family member** of a physician; or (c) a business that is affiliated with a Vendor described in preceding clauses (a) or (b) above, including but not limited to a parent entity, subsidiary, or other entity controlling, controlled by, or under common control with such a Vendor. "Control" means the direct or indirect power to govern the management and policies of an entity, or the power or authority through a management agreement or otherwise to approve an entity's transactions.
	5	Vendor is publicly traded, with less than $75 million dollars in stockholder's equity as of the end of its most recent fiscal year or on average during the previous 3 fiscal years, and a physician* or an immediate family member** of a physician is known to own, directly or indirectly, an ownership interest.

I.A. Does Vendor sell or intend to sell to HCA or its affiliates, facilities or entities, (i) implantable medical devices (including external fixation devices) and/or related instrumentation; (ii) pharmaceuticals; or (iii) biologics? ☐ Yes ☐ No *(Note: This answer should be used solely in analyzing whether Policy LL.029 prohibits the purchase of Covered Product from the Vendor. If the answer is marked "yes," please analyze whether Policy LL.029 prohibits the purchase of Covered Product from the Vendor).*

I.B. Initial next to the following statement to indicate your understanding and agreement:
_____ Vendor has read the OIG Special Fraud Alert: Physician-Owned Entities, dated March 26, 2013, and certifies that the Vendor's operations, ownership structure, and physician compensation arrangements are in compliance with the Special Fraud Alert and the federal Anti-Kickback Statute.

* Physician includes a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry or a chiropractor.
**An immediate family member means husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.

SECTION II (Box 7): Physician Compensation Arrangement.

Does the Vendor have compensation arrangement(s) with a physician, immediate family member of a physician, or an entity in which a physician or an immediate family member of a physician has an ownership interest?

☐ Yes ☐ No

Regardless of which box above is checked, please initial next to those statements below which are true and accurate as to each such current or future physician compensation arrangement of the Vendor.

_____ All physicians, immediate family members of physicians, and entities in which such persons have an ownership interest, if any, are and will be compensated or paid consistent with fair market value for commercially reasonable and legitimate services under a signed written agreement,.

_____ No physician, immediate family member of a physician, or entity in which such a person has an ownership interest, if any, is or will be compensated in any manner that varies with, or takes into account, the volume or value of referrals to, or other business generated by the physician for, any hospital, ASC or health care facility.

_____ Any consulting, product development or royalty agreement or similar arrangement with a physician, immediate family member of a physician, or entity in which such a person has an ownership interest, if any, expressly excludes from the compensation or royalty payment to a physician or immediate family member any revenues received by the Vendor by virtue of the use of any product, item or service in question by:

- the physician (or immediate family member),
- any practice group with which the physician (or any immediate family member) is affiliated,
- any member, employee or consultant of a practice group of which the physician (or any immediate family member) is affiliated,
- any hospital, ASC or health care facility with which the physician is affiliated or has medical staff privileges, and
- any individual or entity for which the physician has any actual or potential ability to influence procurement decisions for goods, items or services.

SECTION III: Current and Future Notice by Vendor;

Please initial next to the following statements to indicate your understanding and agreement:

_____ Vendor agrees that it will not offer, syndicate or add any additional Physician (or immediate family member) ownership interests in the Vendor without first notifying in advance Supply Chain Consolidated Service Center or other appropriate party at [**_phone**_____], of any such proposed change.

_____ Vendor further agrees to promptly notify Supply Chain Consolidated Service Center or other appropriate party at [**_phone**_____], of any other changes to the information provided on this Certification Form as soon as such changes are known, but in no event later than thirty (30) days of the change.

SSECTION IV: Current Agreements with HCA

Does Vendor have a current written, signed contract with any HCA affiliated entity?

☐ Yes ☐ No ☐ Contract is Pending

IF "yes," please attach a copy/copies to this certificate.

HCA CONTACT INFORMATION (HCA, National or Affiliate contact who is sending this request–Please complete contact information below)

Name of HCA Affiliated Entity/Contracting Party: _____

Contact Name: _____, Title_____, Phone Number_____

Fax completed Certificate to: _____.

To reply by fax, please send to **[____fax_____]**. If you have any questions about this form, please call **[____phone_____]**.

Please provide an accurate and complete copy of the Vendor's current organizational chart identifying all entities affiliated with Vendor, including but not limited to parent entities, subsidiaries, and other entities controlling, controlled by, or under common control with the Vendor.

Please complete each of the fields in the chart below with respect to any physician who (i) has a direct or indirect ownership interest in the Vendor, (ii) whose immediate family member(s) has a direct or indirect ownership interest in the Vendor, or (iii) is a member of the integrated group practice with any physician identified in (i) or (ii). For physicians named below because an immediate family member has a direct or indirect ownership interest in the Vendor, please indicate specifically whether the immediate family member is the physician's spouse or another immediate family member.

Name of Physician Owner	**State in which Physician is Licensed / Practicing**	**Tax ID or National Provider Identifier (NPI)**	**Name of Group Practice**	**Names of (and Tax ID/NPI) of All Other Physician Members of Physician's Group Practice**	**Affiliations, Privileges, or Referral Relationships with Any HCA Entity/Facility**

If your answer in Section II, Box 7 is "Yes" <u>but</u> you are unable to initial and make all (or any one of) the representations, warranties and covenants in Section II, Box 7, then please list the name of each physician who (or whose immediate family member(s)) has a compensation arrangement with the Vendor that <u>varies with the volume or value of referrals</u> to any hospital, ASC or health care facility, including any HCA affiliate, as well as the state in which that physician is licensed and/or practicing and the physician's Tax ID or NPI number.

Name of Physician with Compensation Arrangement that Varies with the Volume or Value of Referrals	**State in which Physician is Licensed / Practicing**	**Tax ID or National Provider Identifier**

Attach additional pages as necessary

VENDOR CERTIFICATION

The Vendor hereby certifies that it is not currently excluded or ineligible to participate in any Federal or State health care programs, that the information provided and contained herein is true and accurate, that Vendor will promptly notify the Company and update this certification in writing within thirty (30) days of any change in the information provided:

Name of Vendor: _____

Certified by: _____

Signature: _____ Date: _____

Name: _____ Phone: _____

Title*: _____
*If not an officer of the Vendor, please attach proof of authority to sign.

FORM
OF
CERTIFICATE

PURCHASING AGREEMENT

Certification by (a) CEO/Administrator of Purchasing Entity/Facility; and (b) Division President or Division CFO

Regarding the agreement between **Facility Legal Name** and **Vendor Legal Name**, ("Vendor"), effective _____, 20__ (the "Purchasing Agreement"), the undersigned hereby certifies that:

1) I have reviewed (a) Relationships with Physician-Connected Vendors Policy LL.027, (b) Prohibition on Purchasing Certain Products from Physician-Owned Businesses Policy LL.029 and (c) the Purchasing Agreement described above;
2) I have reviewed the Vendor Physician Ownership & Compensation Certification and verified that, if any Covered Products are the subject of the Purchasing Agreement, the Vendor is not a Physician-Owned Business or with respect to the Purchasing Entity the Vendor qualifies as an Exempt Physician-Owned Business, as those terms are defined under Prohibition on Purchasing Certain Products from Physician-Owned Businesses Policy LL.029;
3) The items and/or services covered by the Purchasing Agreement are priced at fair market value and such fair market value has been determined consistent with Section B of the Relationships with Physician-Connected Vendors Policy LL.027 by either: (a) independent valuation from one of the Company approved third party appraisers, (b) confirmation that the terms are consistent with and comparable to fair market value terms agreed to by HealthTrust Purchasing Group for the item or service, or (c) a Request for Proposal (RFP) bid process for items or services similar in quantity, quality, type and availability from non-Physician-Connected Vendors;
4) There are no agreements or understandings, whether written or oral, that condition the decision to purchase or the consideration paid on the volume or value of any referrals or other business generated among the parties, their owners or investors, or any other entity affiliated with HCA Holdings, Inc.;
5) The items and/or services to be purchased do not exceed those that are reasonable and necessary for the arrangement's commercially reasonable business purposes;
6) I have verified that the Vendor is not currently excluded or ineligible to participate in any Federal health care programs;
7) The Purchasing Agreement has been reviewed by HCA Operations Counsel for compliance with the Company's policies, including Agreements with Referral Sources Policy LL.001, Relationships with Physician-Connected Vendors Policy LL.027, and Prohibition on Purchasing Certain Products from Physician-Owned Businesses Policy LL.029.

CEO/Administrator of Purchasing Entity/Facility

By: _____

Name: _____

Title: _____

Date: _____

.

Division President or Division CFO

By: _____

Name: _____

Title: _____

Date: _____

HCA

DEPARTMENT: Legal	**POLICY DESCRIPTION:** Prohibition on Purchasing Certain Products from Physician-Owned Businesses
PAGE: 1 of 5	**REPLACES POLICY DATED:** 7/1/14
EFFECTIVE DATE: July 1, 2014	**REFERENCE NUMBER:** LL.029
APPROVED BY: Ethics and Compliance Policy Committee	

SCOPE: This policy applies to HCA Holdings, Inc. and all of its Affiliated Entities and Facilities, including but not limited to hospitals, ambulatory surgery centers, imaging centers, home health agencies, physician practices, service centers, and all Corporate Departments, Groups and Divisions, and Parallon (collectively with HCA Holdings, Inc., the "Company"). Notwithstanding the foregoing, this policy does not apply to HealthTrust Purchasing Group ("HPG") with respect to purchases made via HPG contracts by or on behalf of non-Company-affiliated entities and facilities.

"Affiliated Entities and Facilities" include any person or entity controlling, controlled by, or under common Control with the Company.

Other capitalized terms used in this policy and not otherwise defined have the meaning given to them in the Definitions section below.

PURPOSE: On March 26, 2013, the Office of Inspector General ("OIG") of the Department of Health and Human Services published "Special Fraud Alert: Physician-Owned Entities." The Special Fraud Alert focuses on certain physician-owned entities that derive revenue from selling, or arranging for the sale of, implantable medical devices. The Special Fraud Alert states that facilities and entities that purchase from such physician-owned entities may be at risk for violating the Federal Anti-Kickback law.

This policy is intended to prohibit the Company from purchasing certain covered products from certain physician-owned businesses.

This policy supplements the Relationships with Physician-Connected Vendors Policy, LL.027.

POLICY: A Purchasing Entity shall not purchase Covered Products from a business that is a Physician-Owned Business (either directly or indirectly through an agent such as HPG), unless the Physician-Owned Business is an Exempt Physician-Owned Business and the purchase complies with Relationships with Physician-Connected Vendors Policy LL.027.

HCA

DEPARTMENT: Legal	**POLICY DESCRIPTION:** Prohibition on Purchasing Certain Products from Physician-Owned Businesses
PAGE: 2 of 5	**REPLACES POLICY DATED:** 7/1/14
EFFECTIVE DATE: July 1, 2014	**REFERENCE NUMBER:** LL.029
APPROVED BY: Ethics and Compliance Policy Committee	

DEFINITIONS:

Active Medical Staff has the meaning given to it (or to a comparable term) in the governing documents (*e.g.*, the medical staff bylaws) of the organized medical staff of the applicable Purchasing Entity. In the event the governing documents do not use the term "Active Medical Staff" or a comparable term, HCA Operations Counsel will determine the category of the Purchasing Entity's medical staff to which this Policy applies. If the Purchasing Entity does not have an organized medical staff (*e.g.*, an HCAPS physician practice), then "Active Medical Staff" means those Physicians employed by, or engaged to provide services for or on behalf of, the Purchasing Entity, either directly or through their practice.

Certification Form means the applicable, then-current Vendor Physician Ownership and Compensation Certification Form referred to in Policy LL.027.

"Control" means the direct or indirect power to govern the management and policies of an entity or facility; or the power or authority through a management agreement or otherwise to approve an entity's or facility's transactions.

Covered Product means all or any of the following: (i) implantable medical devices (including external fixation devices) and/or related instrumentation; (ii) pharmaceuticals; and (iii) biologics.

Exempt Physician-Owned Business means, with the determination being made on a Purchasing Entity-by-Purchasing Entity basis, a Physician-Owned Business that:

(i) is a Publicly Traded Company (Note: Publicly Traded Companies are exempt with respect to all Purchasing Entities); or

(ii) with respect to any particular Purchasing Entity, none of the following Physicians are on the Active Medical Staff of the Purchasing Entity:

(a) Physicians holding an Ownership Interest in the Physician-Owned Business;

(b) Physicians whose spouse holds an Ownership Interest in the Physician-Owned Business; or

(c) Physicians who are members of any integrated group practice with any Physician described in (a) and/or (b).

Note: A Physician-Owned Business may be an Exempt Physician-Owned Business with respect to only certain Purchasing Entities. Purchasing Entities with respect to which the Physician-Owned Business is not an Exempt Physician-Owned Business shall not purchase Covered Products from the Physician-Owned Business.

HCA

DEPARTMENT: Legal	**POLICY DESCRIPTION:** Prohibition on Purchasing Certain Products from Physician-Owned Businesses
PAGE: 3 of 5	**REPLACES POLICY DATED:** 7/1/14
EFFECTIVE DATE: July 1, 2014	**REFERENCE NUMBER:** LL.029
APPROVED BY: Ethics and Compliance Policy Committee	

Ownership Interest means any direct or indirect ownership or investment interest, whether through equity, debt or other means, including but not limited to stock, stock options, warrants, partnership shares, limited liability company memberships, as well as loans and bonds.

Physician means any person who is a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or chiropractor.

Physician-Owned Business means (i) a business in which a Physician or a spouse of a Physician has any Ownership Interest, whether that business is operated as a sole proprietorship, partnership, corporation, limited liability company, limited liability partnership, or in any other form; or (ii) any business or entity controlling, controlled by, or under common Control with a business or entity identified in clause (i) above.

Publicly Traded Company means a company that is publicly held and both:

(a) listed for trading on the New York Stock Exchange ("NYSE") or any regional exchange in which quotations are published on a daily basis, or are foreign securities listed on a recognized foreign, national or regional exchange in which quotations are published on a daily basis, or traded on the National Association of Securities Dealers Automated Quotation System ("NASDAQ"); **AND**

(b) had at least $75 million in stockholder's equity at the end of its most recent fiscal year or on average during the previous 3 fiscal years.

Purchasing Entity means the Company Affiliated Entity or Facility that directly or indirectly is seeking to purchase, is purchasing, or on whose behalf will be purchased a Covered Product from a Physician-Owned Business.

PROCEDURE:

A. **General**

1. **Inquiry**. In accordance with Policy LL.027, before entering into any new business relationship and before the renewal of any existing business arrangement, the Company will send the Certification Form to the business for completion and execution. The Certification Form should be updated by the business every year and within thirty (30) days of any change to the information included on such form, in accordance with LL.027.

2. **Response to Certification Form**.

a. When a business returns a Certification Form indicating that it is a Physician-Owned Business, the Company will input the information from the form into the Physician-

Owned Business database described in Section A.5 below. The Company will also compare the information to the Active Medical Staff lists described in Section A.5 below.

b. If the information in the database and the lists indicates that the business is a Physician-Owned Business that is not an Exempt Physician-Owned Business with respect to the Purchasing Entity, the Purchasing Entity will not purchase Covered Products from the business, either directly or indirectly through an agent such as HPG.

c. Supply Chain will save a copy of the Certification Form in a database accessible by Division Contract Managers and facility management, such as "OnBase."

3. **Failure to Respond**. Until a fully completed Certification Form is signed and returned, the Company will not purchase Covered Products from the business.

4. **Conflicting Responses**. If a business provides more than one Certification Form indicating different or conflicting information, such as different physician ownership status, different Exempt Physician-Owned Business status, or different information regarding Covered Products, then the Company will suspend purchasing Covered Products from the business and all payments to the business for Covered Products until the Company obtains an appropriate and satisfactory clarifying response from the business.

5. **Physician-Owned Business Database and Active Medical Staff Lists**. The Company will maintain in a centralized database a record of each Physician-Owned Business that has submitted a Certification Form under Policy LL.027, regardless of whether the Physician-Owned Business has indicated a desire to sell Covered Products to the Company. The database will be based on the Certification Form(s) submitted by the Physician-Owned Business. With respect to each Physician-Owned Business, the database will include, without limitation, the name and Tax ID or National Provider Identifier ("NPI") of all the following Physicians: (i) any Physicians that have Ownership Interests in the Physician-Owned Business; (ii) any Physicians whose spouse has an Ownership Interest in the Physician-Owned Business and (iii) any Physicians who are members of any integrated group practice with any Physician identified in clauses (i) and/or (ii) above. The Company will also maintain, in centralized databases, a list of each Physician that is on the Active Medical Staff of each Affiliated Entity and Facility. Before purchasing from or entering into a purchase agreement with a Physician-Owned Business, the Purchasing Entity will review the database and the lists. The Purchasing Entity will not purchase Covered Products from a Physician-Owned Business in the database until such time as the Purchasing Entity confirms that the Physician-Owned Business is an Exempt Physician-Owned Business with respect to such Purchasing Entity by obtaining an updated Certification Form.

HCA

DEPARTMENT: Legal	**POLICY DESCRIPTION:** Prohibition on Purchasing Certain Products from Physician-Owned Businesses
PAGE: 5 of 5	**REPLACES POLICY DATED:** 7/1/14
EFFECTIVE DATE: July 1, 2014	**REFERENCE NUMBER:** LL.029
APPROVED BY: Ethics and Compliance Policy Committee	

B. **Compliance Reporting**. The Company shall follow appropriate procedures, outlined in Policy EC.025, for reporting any potential compliance issues and occurrences.

REFERENCES:

1. OIG Special Fraud Alert: Physician-Owned Entities (March 26, 2013)
2. OIG Letter "Response to Request for Guidance Regarding Certain Physician Investments in the Medical Device Industries" (October 6, 2006).
3. 42 U.S.C. § 1320a-7b;
4. 42 U.S.C. § 1395nn;
5. Relationships with Physician-Connected Vendors Policy, LL.027
6. Vendor Physician Ownership & Compensation Certification Form
7. Reporting Compliance Issues and Occurrences to the Corporate Office Policy, EC.025
8. Company Code of Conduct

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

AUG 13 2015

TO: Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services

FROM: Suzanne Murrin
Deputy Inspector General
for Evaluation and Inspections

SUBJECT: Memorandum Report: *Overlap Between Physician-Owned Hospitals and Physician-Owned Distributors*, OEI-01-14-00270

This memorandum provides the results of OIG's examination of overlap between physician-owned hospitals and physician-owned distributors (PODs) of spinal devices. This work follows up on our October 2013 report *Spinal Devices Supplied by Physician-Owned Distributors: Overview of Prevalence and Use* (OEI-01-11-00660), which found that PODs supplied the devices used in nearly one in five spinal fusion surgeries that were billed to Medicare.

METHODOLOGY

When we met with the Centers for Medicare & Medicaid Services (CMS) in September 2013 to discuss a draft of the report, CMS staff expressed interest in the overlap between owners of physician-owned hospitals and PODs of spinal devices. We agreed to analyze the extent to which such overlap exists. We used publicly available information (such as the Web sites for hospitals and PODs, as well as State business registration websites) and information from CMS's Provider Enrollment, Chain and Ownership System (PECOS) to attempt to determine whether a physician had an ownership interest in both a hospital and a POD that sold spinal devices to the hospital.

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

RESULTS

Using available information, we identified one physician with an ownership interest in both a hospital and a POD

During data collection for the original report, 119 hospitals self-identified as having purchased spinal devices from PODs. Of these 119 hospitals, 12 self-identified as physician-owned and reported that they purchased spinal devices from 12 PODs.[1] All of these hospitals self-identified as physician-owned on their Web sites, and five of them identified physician-owners by name.

We also researched the ownership of the 12 PODs from which the 12 physician-owned hospitals reported having bought spinal devices. Two of these PODs identified physician-owners by name on their Web sites. We identified the physician-owners of an additional three PODs from our review of State business registration websites.

Using the physician ownership information we gathered on hospitals and PODs, we identified one physician who had an ownership interest in both a hospital and a POD that supplied spinal devices to that hospital.[2] However, it is possible that additional physicians had such ownership interests that we could not detect using the available information.

Available information about ownership interests is limited and raises concerns about lack of transparency

The limited information that is available to identify physicians who have concurrent ownership interests in PODs and hospitals raises concern about transparency among Medicare providers and the vendors that sell them implantable devices. Transparency of ownership is important for the Department of Health and Human Services to ensure that providers do not violate the referral and billing prohibitions of the Stark Law (also known as the Physician Self-Referral Law) and that they comply with OIG exclusions and the Anti-Kickback Statute. Additionally, the transparency of ownership information may have implications for patient safety and quality of care. One of the primary criticisms of PODs is that ownership may affect physicians' clinical decisionmaking, such as influencing them to perform unnecessary surgeries or to choose a device in which they have a financial interest rather than another device that may be more appropriate for the patient.

In 2013, OIG released a Special Fraud Alert on Physician Owned Entities that described a number of characteristics of concern.[3] OIG is particularly concerned about PODs because—as the Special Fraud Alert stated—surgical implants "typically are 'physician

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[1] Two PODs sold spinal devices to multiple hospitals included in this analysis.

[2] This physician was listed as a physician-owner of a hospital both on the hospital's Web site and in CMS PECOS data.

[3] OIG, *Special Fraud Alert: Physician Owned Entities* (March 2013). Accessed at http://oig.hhs.gov/fraud/docs/alertsandbulletins/2013/POD_Special_Fraud_Alert.pdf on August 4, 2015.

preference items,' meaning that both the choice of brand and the type of device may be made or strongly influenced by the physician, rather than the hospital where the procedure is performed."[4] The alert echoes OIG guidance from 2006 that specifically addressed physician investments in manufacturers and distributors of medical devices. In that guidance, OIG acknowledged the "strong potential for improper inducements between and among the physician investors, the entities, device vendors, and device purchasers" and stated that such arrangements should be "closely scrutinized under fraud and abuse laws."[5]

CONCLUSION

This work demonstrates that there is limited transparency with regard to ownership information for PODs and, to a lesser extent, of hospitals. CMS's implementation of the Physician Payments Sunshine Act (Sunshine Act) may improve the information available to identify the physician-owners of PODs.[6] The Sunshine Act requires manufacturers and group purchasing organizations to report to CMS any ownership and investment interests that are held by physicians.[7] OIG will monitor CMS's Sunshine Act database and determine how best to assess its impact on transparency within Medicare.

This report is being issued directly in final form because it contains no recommendations. If you have comments or questions about this report, please provide them within 60 days. Please refer to report number OEI-01-14-00270 in all correspondence.

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[4] OIG, *Special Fraud Alert: Physician Owned Entities* (March 2013). Accessed at http://oig.hhs.gov/fraud/docs/alertsandbulletins/2013/POD_Special_Fraud_Alert.pdf on August 4, 2015.
[5] Ibid.
[6] Entities that are required by the Sunshine Act to report ownership interests are listed at http://www.cms.gov/OpenPayments/Program-Participants/Program-Participants.html. Accessed on July 7, 2015.
[7] 42 CFR §§ 403.900–403.914.

October 6, 1997

[Names and addresses of Requestors have been redacted]

Re: Advisory Opinion No. 97-5

Dear Sirs:

We are writing in response to your request for an advisory opinion on behalf of Radiology Group X and Hospital System A. The request asks whether an outpatient radiology imaging center joint venture owned by a medical group specializing in radiology and a hospital care provider (i) generates prohibited remuneration within the meaning of the anti-kickback statute, Section 1128B of the Social Security Act ("Act"); (ii) constitutes grounds for the imposition of an exclusion under Section 1128(b)(7) of the Act (as it applies to kickbacks); (iii) constitutes grounds for criminal sanctions under Section 1128B(b) of the Act; and/or (iv) satisfies the criteria set out in Section 1128B(b)(3) of the Act or associated regulations, 42 C.F.R. § 1001.952.

Radiology Group X and Hospital System A have certified that all of the information provided in the request, including all supplementary letters, is true and correct, and constitutes a complete description of the relevant facts and agreements among the parties regarding the joint venture ("Proposed Arrangement"). Radiology Group X and Hospital System A have also certified that upon our approval, they will undertake to effectuate the Proposed Arrangement.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed, this opinion is without force and effect.

Based on the information provided and subject to certain conditions described below, we have determined that the Proposed Arrangement does not meet any of the statutory or regulatory safe harbors set out in Section 1128B(b)(3) of the Act or 42 C.F.R. § 1001.952. However, we also conclude that the Proposed Arrangement would not generate prohibited remuneration within the meaning of the anti-kickback statute, Section

1128B of the Act, and therefore, does not constitute grounds for the imposition of either an exclusion under Section 1128(b)(7) of the Act (as it applies to kickbacks) or criminal sanctions under Section 1128B(b) of the Act.

This opinion may not be relied on by any person or entity other than the addressees and is further qualified as set out in Part III below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

Radiology Group X and Hospital System A have made the following representations with respect to the Proposed Arrangement. Radiology Group X and Hospital System A are collectively the "Requestors".

A. Parties to the Proposed Arrangement.

Hospital System A. Hospital System A operates three hospitals in State C: Hospital 1, Hospital 2, and Hospital 3. Hospital 1, located in State C, is licensed for 351 beds and is the largest hospital in the several counties surrounding City D. Hospital 1 has a full range of radiological equipment at its facility, including a CT scanner, ultrasound equipment, fluoroscopic radiographic equipment, nuclear radiographic equipment, and magnetic resonance imaging ("MRI") equipment. Hospital 1 will continue to operate its radiology department after the Proposed Arrangement is implemented.

Hospital System A employs three physicians directly or through its subsidiary organizations. These physicians will not make referrals to the Proposed Arrangement's joint venture imaging center, nor will any such referrals be accepted if made.

Radiology Group X. Radiology Group X is a medical group specializing in radiology. It is a State C professional corporation owned and controlled by five radiologists. Dr. Y, serves as the President of Radiology Group X.

The shareholders of Radiology Group X are also the members of Radiology Group X's affiliate, Company Z. Ownership and control interests in Radiology Group X and Company Z are identical. Company Z is a newly-formed State C limited liability company and one of the members of the Proposed Arrangement's joint venture company, Imaging Center [defined below].

Current Relationship Between Radiology Group X and Hospital 1. Radiology Group X and Hospital 1 have represented that they have an informal, unwritten arrangement whereby Radiology Group X provides professional radiology services to the hospital, while hospital employees provide the technical services. The hospital owns all of the radiological equipment and is responsible for employing qualified technicians. As part of

this arrangement, Radiology Group X's president, Dr. Y, serves as Hospital 1's Director of the Department of Radiology. His duties are set forth in the hospital's Medical and Dental Staff By-Laws. In addition, Hospital 1 provides Radiology Group X with space in its facility to perform radiologic interpretations.[1]

While there is no written agreement, the hospital has certified that the fair market value of the space used by Radiology Group X is substantially equal to the fair market value for compensation of Dr. Y's duties as the Director of the Department of Radiology. Further, the arrangements whereby Radiology Group X and Dr. Y provide services to Hospital 1 and Hospital 1 provides Radiology Group X with space in its facility are separate from, and not dependent on, the terms and conditions of the Proposed Arrangement.

B. Proposed Arrangement.

Radiology Group X, through its affiliate Company Z, and Hospital System A have proposed to enter into a joint venture to establish an outpatient radiology imaging center ("Imaging Center"). The Imaging Center will be located in the Village of E, at the western edge of City D. The Imaging Center will offer a full range of state-of-the-art imaging techniques, including X-ray equipment, fluoroscope equipment, a superconducting open MRI system, a computerized tomography scanner, and an ultrasound system.

The Imaging Center will be owned and operated by a State C limited liability company, Company B. The members of Company B will be Company Z and Hospital System A. Company Z and Hospital System A will make capital contributions of $204,000 and $196,000, respectively. In return, each member will receive voting and distribution rights proportional to its investment. Additional capital contributions will be apportioned to Company Z and Hospital System A based upon their respective ownership interests.[2]

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[1] Radiology Group X does not have any non-hospital based office space.

[2] If either member of Company B is unable or unwilling to make any part of an additional capital contribution, the other member has a right to make up the difference, treat such amount as either an additional capital contribution or as a loan, and adjust the

The Imaging Center will be staffed by employees hired by Company B. Radiology Group X radiologists will be the exclusive providers of professional services to the Imaging Center. The president of Radiology Group X, or his designee, will be in charge of supervising and administering all aspects of the clinical services rendered at the Imaging Center, including quality assurance. The Radiology Group X radiologists will not be employees of the Imaging Center, but will enter into a service provider agreement with Company B. Under the service agreement, Radiology Group X will not receive any compensation from the Imaging Center. Radiology Group X will bill patients and third-party payers, including Medicare and Medicaid, for the professional component of radiological services directly. The Imaging Center will bill separately its technical component to patients and third-party payers.

II. LEGAL ANALYSIS

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit or receive any remuneration to induce referrals of items or services reimbursed by Federal health care programs. 42 U.S.C. § 1320a-7b(b). Where remuneration is paid purposefully in exchange for referrals of items or services paid for by a Federal health care program, the kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration is to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 476 U.S. 988 (1985). Violations of the statute constitute a felony punishable by a maximum fine of $25,000, imprisonment up to five years or both. Conviction will also lead to automatic exclusion from Federal health care programs including Medicare and Medicaid.

The Office of Inspector General may also initiate an administrative proceeding to exclude an individual from Federal health care programs for fraud, kickbacks and other prohibited activities. Section 1128(b)(7) of the Act. Because both the criminal and administrative

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proportional percentages of ownership accordingly. For purposes of this opinion, we have assumed that any loan would be at fair market value.

sanctions related to the Proposed Arrangement are based on the anti-kickback statute, the analysis is the same under either provision.

Health care joint ventures in which investors are also sources of referrals or suppliers of items or services to the joint venture raise many questions under the anti-kickback statute. In 1989, the Office of Inspector General issued a "Special Fraud Alert" specifically discussing joint venture arrangements that may violate the anti-kickback statute.[3] In general, joint ventures between radiologists and health care providers in a position to order imaging services may be suspect, because distributions from the joint ventures may be disguised remuneration paid in return for referrals. Like any kickback scheme, these arrangements can lead to overutilization of such services, increased costs for Federal health care programs, corruption of professional judgment, and unfair competition.

A. The Proposed Joint Venture Does Not Meet the Safe Harbor For Investment Interests in Small Entities.

In 1991, the Department of Health and Human Services ("Department") published safe harbor regulations which define practices that are not subject to the anti-kickback statute because such arrangements would be unlikely to result in fraud or abuse. Failure to comply with a safe harbor provision does not make an arrangement per se illegal. Rather, the safe harbors set forth specific conditions that, if fully met, would assure the entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. The only safe harbor regulation potentially available to the Proposed Arrangement addresses investment interests in small entities. See 42 C.F.R. § 1001.952(a)(2).[4]

The safe harbor for investments in small entities has eight elements, each of which must be satisfied in order for the arrangement to qualify for the exception. The eight elements address three areas of concern in abusive joint ventures: (i) how investors are selected and retained; (ii) the nature of the business structure; and (iii) the financing and profit distributions. The eight elements are:

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[3] See Special Fraud Alert, "Joint Venture Arrangements" (OIG-89-4), reprinted in 59 Fed. Reg. 65373 (December 19, 1994).

[4] The Requestors had suggested that the "shared risk" statutory exception to the anti-kickback statute added by Section 216 of the Health Insurance Portability and Accountability Act, Pub. Law No. 104-191 (Aug. 21, 1996), potentially applied. That provision, however, applies only to contractual arrangements where a person supplying items or services is at risk for the cost or utilization of such items or services and is obligated to provide them, as in some managed care contracts.

- no more than forty percent of the investment interests may be held by investors who are in a position to make or influence referrals, furnish items or services, or generate business ("Interested Investors");

- interests offered to passive investors who are Interested Investors cannot be made on terms different from those offered to other investors;

- the terms on which an investment is offered to Interested Investors cannot take into account any previous or expected volume of referrals, services furnished, or amount of business generated from such investors;

- there is no requirement that a passive investor make referrals to, or otherwise generate business for, the entity as a condition of remaining an investor;

- the entity cannot market or furnish the items or services differently to passive investors and non-investors;

- no more than forty percent of the gross revenue of the entity may come from Interested Investors;

- the entity cannot loan or guarantee funds to an Interested Investor if the loan or guarantee is used to obtain the investment interest; and

- an investor's return on investment must be directly proportional to the amount of capital investment of that investor.

Strict compliance with all elements is required. See 56 Fed. Reg. 35952, 35954 (July 29, 1991).

The Proposed Arrangement fails to meet at least one of the eight elements. More than 40% of the investment interest is owned by persons who furnish items or services to the new venture; Radiology Group X owns 51% of the entity and will provide the professional services to the venture. Accordingly, the Proposed Arrangement does not meet the only relevant safe harbor.

B. The Proposed Arrangement Will Not Result in Prohibited Remuneration.

Even though the Proposed Arrangement does not fall within a safe harbor, it does not necessarily violate the anti-kickback statute. With respect to joint ventures, the major concern is that the profit distributions to investors in the joint venture, who are also referral sources to the joint venture, may potentially represent remuneration for those referrals. A related concern is that, where the investing parties have a referral relationship wholly apart from the joint venture, distributions from the joint venture could potentially represent remuneration to one party for referrals to the other party based on those independent relationships. Accordingly, all aspects of all relationships between the parties must be examined.

1. There Is No Prohibited Remuneration For Referrals To The Imaging Center.

Our initial inquiry is whether the distributions from the joint venture may be "disguised" remuneration for referrals by the investors to the joint venture. Based upon the information and representations provided, we find that neither Radiology Group X nor Hospital System A will be able to generate referrals to the joint venture.

A threshold issue is the proper characterization of Hospital System A's role in relationship to the joint venture. In many instances, hospitals are capable of influencing, and do influence, referrals to other health care providers, such as through discharge planning with respect to post-discharge care. In addition, hospitals are in a position to influence the flow of radiology work performed at the hospital, because the hospital controls to whom radiologic interpretations are referred. See Financial Arrangements Between Hospitals and Hospital-Based Physicians, OEI-09-89-00330, 1991. In this instance, however, and subject to the conditions set out below, we do not believe that the Hospital System A hospitals will be able to generate referrals to the Imaging Center.

First, Hospital System A has represented that its employed physicians will make no referrals to the Imaging Center, and the Imaging Center will not accept any referrals from those physicians. Second, Hospital System A has agreed that it will take no actions, either overt or covert, financial or otherwise, to induce its medical staff (i.e., any physician with admitting or staff privileges) to use the Imaging Center. Third, Hospital System A has agreed that it will inform the medical staff of the preceding agreement. Fourth, physician referrals to the Imaging Center will not be tracked by Hospital System A, its hospitals, Company Z, or Radiology Group X. Fifth, Hospital System A hospitals will continue to operate and use their own radiology units. In these circumstances, referrals from physicians with admitting or staff privileges at the Hospital System A hospitals would not be attributable to Hospital System A.

Moreover, the Radiology Group X radiologists are also unlikely to be able to generate an appreciable number of referrals to the Imaging Center. In general, radiologists do not order the radiological tests they perform; such tests are ordered by a patient's attending

physician. Although there may be situations in which a radiologist can recommend additional testing to the attending physician during the course of a consultation and, as a practical matter, indirectly generate some additional business, those tests must be approved by the patient's attending physician.[5] In these limited circumstances -- the recommendation of additional testing by a radiologist to an attending physician with whom the radiologist has no financial arrangements and pursuant to a bona fide medical consultation -- we conclude that a Radiology Group X radiologist's recommendation is not prohibited under the anti-kickback statute.[6]

In sum, since neither Radiology Group X nor Hospital System A will be in a position to generate or influence an appreciable number of referrals to the Imaging Center, the

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[5] See 61 Fed. Reg. 59490, 59497 (November 22, 1996) (with respect to when Medicare will cover diagnostic tests, the Health Care Financing Administration has stated, "we believe that the physician interpreting the diagnostic tests has an obligation to discuss any changes in or additions to the original order with the patient's physician.").

[6] Radiology Group X radiologists receive no remuneration from patients' attending physicians, and none of the attending physicians which refer to Radiology Group X have any financial relationships with Radiology Group X.

distributions of any profits would not constitute illegal remuneration in exchange for referrals.

2. There Is No Prohibited Remuneration For Referrals Outside Of The Joint Venture.

Radiology Group X derives a substantial amount of its revenues from its position as the exclusive provider of professional radiology services for Hospital 1.[7] This raises the possibility that the joint venture may be a vehicle by which Radiology Group X may indirectly reward Hospital System A for revenues Radiology Group X receives as a result of its arrangement with Hospital 1.[8]

In determining whether the joint venture may be a vehicle for illegally remunerating one investor for referrals to another investor, we examine initially whether the party making the referrals receives a disproportionate return on its investment compared to the return on the investment of the party receiving the referrals. Any excess or disproportionate return on the investment may be remuneration for referrals. Based on the facts and circumstances as represented by Radiology Group X and Hospital System A, both parties have made substantial financial investments in the venture, and control of the venture and

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[7] Radiology Group X radiologists are not in a position to make referrals to the Hospital System A hospitals for the same reasons that they cannot make appreciable referrals to the Imaging Center. Accordingly, the potential profit distributions from the Imaging Center to the Radiology Group X radiologists would not represent disguised remuneration for any possible referrals to Hospital System A hospitals.

[8] Specific problems with financial arrangements between hospital-based physicians, such as radiologists, and hospitals were discussed in a 1991 Management Advisory Report entitled Financial Arrangements Between Hospitals and Hospital-Based Physicians, OEI-09-89-00330 (1991).

distribution of profits will be in direct proportion to such investments. Thus, both parties' return on investment is commensurate with their undertakings and would not appear to include any "unearned" remuneration to Hospital 1 attributable to its arrangements with Radiology Group X. Accordingly, any profit distributions from the Proposed Arrangement would not appear to represent compensation to Hospital System A or Hospital 1 for their referrals to Radiology Group X.

Moreover, based on the representations by Radiology Group X and Hospital System A that the value of the premises and equipment provided to Radiology Group X are substantially equal to the value of Dr. Y's services to Hospital 1, we conclude that any profit distribution from the Imaging Center will not represent illegal remuneration for the use of space and equipment at Hospital 1.[9]

However, even in situations where each party's return is proportionate with its investment, the mere opportunity to invest (and consequently receive profit distributions) may in certain circumstances constitute illegal remuneration if offered in exchange for past or future referrals. Such situations may include arrangements where one or several investors in a joint venture control a sufficiently large stream of referrals to make the venture's financial success highly likely, or where one investor has an established track record with similar ventures or the financial investment required is so small that the investors have little or no real risk. By contrast, there are no such indicia that the Proposed Arrangement will generate any profits for its investors, since neither party is in a position to influence appreciable referrals to the joint venture nor has successfully operated a freestanding imaging center before. In light of the substantial financial investment being made by Hospital System A, we find no evidence that the mere opportunity to participate as an investor in the Imaging Center constitutes illegal remuneration to Hospital System A.

III. CONCLUSION

For the above reasons, we have determined that the Proposed Arrangement does not contain any prohibited remuneration within the meaning of the anti-kickback statute,

[9] We are not, however, making any independent finding as to the legality of the current arrangement between Radiology Group X and Hospital 1.

1128B of the Social Security Act ("Act"), and consequently does not constitute grounds for the imposition of either an exclusion under section 1128(b)(7) of the Act (as it applies to kickbacks) or criminal sanction under 1128B(b) of the Act.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to the Radiology Group X and Hospital System A, which are the Requestors of this opinion. This advisory opinion has no application, and cannot be relied upon, by any other individual or entity.

- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a Requestor to this opinion.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is herein expressed or implied with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Proposed Arrangement, including any laws relating to insurance or insurance contracts.

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- This advisory opinion is prospective only. It has no application to conduct which precedes the date of this opinion.

- This advisory opinion does not make any determination as to whether any amounts paid by one party to another are representative of fair market value.

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against the Requestors with respect to any action taken in good faith reliance upon this advisory opinion as long as all of the material facts have been fully, completely, and accurately presented, and the arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions

and issues raised in this advisory opinion and, where the public interest requires, modify or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against the Requestors with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion.

Sincerely,

/S/

D. McCarty Thornton
Chief Counsel to the Inspector General

ATTACHMENT 1.—LIST OF SUDS KNOWN TO BE REPROCESSED OR CONSIDERED FOR REPROCESSING—Continued

	Medical specialty	Device type	Regulation No.	Class	Product code	Risk [1,2,3,3*]	Critical/semi-critical/non-critical	Premarket exempt
227 ..	Surgery	Scissor Tips	878.4800, 884.4520, 874.4420	I	LRW, HDK, HDJ, JZB, KBD	2	C	Y
228 ..	Surgery	Laser Fiber Delivery Systems	878.4810 874.4500 886.4390 884.4550 886.4690	II	GEX EWG LLW HQF HHR HQB	1	C	N

1 = low risk according to RPS
2 = moderate risk according to RPS
3 = high risk according to RPS
3* = high risk due to neurological use

Dated: April 23, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–10413 Filed 4–23–03; 5:03 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Publication of OIG Special Advisory Bulletin on Contractual Joint Ventures

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice.

SUMMARY: The OIG periodically develops and issues guidance, including Special Advisory Bulletins, to alert and inform the health care industry about potential problems or areas of special interest. This **Federal Register** notice sets forth the recently issued OIG Special Advisory Bulletin addressing certain contractual joint venture arrangements.

FOR FURTHER INFORMATION CONTACT: Vicki Robinson or Joel Schaer, Office of Counsel to the Inspector General, (202) 619–0335.

SUPPLEMENTARY INFORMATION:

Special Advisory Bulletin: Contractual Joint Ventures (April 2003)

Introduction

This Special Advisory Bulletin addresses certain complex contractual arrangements for the provision of items and services previously identified as suspect in our 1989 Special Fraud Alert on Joint Venture Arrangements.[1] While much of the discussion in the 1989 Special Fraud Alert focused on investor referrals to newly formed entities, we observed that:

[t]he Office of Inspector General has become aware of a proliferation of arrangements between those in a position to refer business, such as physicians, and those providing items or services for which Medicare or Medicaid pays. Some examples of the items or services provided in these arrangements include clinical diagnostic laboratory services, durable medical equipment (DME), and other diagnostic services. Sometimes these deals are called ''joint ventures.'' *A joint venture may take a variety of forms: it may be a contractual arrangement between two or more parties to cooperate in providing services,* or it may involve the creation of a new legal entity by the parties, such as a limited partnership or closely held corporation, to provide such services. (Emphasis added.)

Notwithstanding that caution, the Office of Inspector General (OIG) is concerned that contractual joint venture arrangements are proliferating.[2]

A. Questionable Contractual Arrangements

The federal anti-kickback statute, section 1128B(b) of the Social Security Act (the Act), prohibits knowingly and willfully soliciting, receiving, offering, or paying anything of value to induce referrals of items or services payable by a federal health care program. Kickbacks are harmful because they can (1) distort medical decision-making, (2) cause overutilization, (3) increase costs to the federal health care programs, and (4) result in unfair competition by freezing out competitors unwilling to pay kickbacks. Both parties to an impermissible kickback transaction may be liable. Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to 5 years, or both. The OIG may also initiate administrative proceedings to exclude persons from the federal health care programs or to impose civil money penalties for kickback violations under sections 1128(b)(7) and 1128A(a)(7) of the Act.

This Special Advisory Bulletin focuses on questionable contractual arrangements where a health care provider in one line of business (hereafter referred to as the ''Owner'') expands into a related health care business by contracting with an existing provider of a related item or service (hereafter referred to as the ''Manager/Supplier'') to provide the new item or service to the Owner's existing patient population, including federal health care program patients. The Manager/Supplier not only manages the new line of business, but may also supply it with inventory, employees, space, billing, and other services. In other words, the Owner contracts out substantially the entire operation of the related line of business to the Manager/Supplier—otherwise a potential competitor—receiving in return the profits of the business as remuneration for its federal program referrals.

Some examples of potentially problematic contractual arrangements include the following:

[1] The 1989 Special Fraud Alert was reprinted in the **Federal Register** in 1994. *See* 59 FR 65372 (December 19, 1994). The Special Fraud Alert is also available on our Web page at *http://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html.*

[2] The kinds of contractual arrangements addressed in this Special Advisory Bulletin are sometimes referred to as ''joint ventures'' or ''contractual joint ventures'' or may be referenced by other terminology. For purposes of the analysis set forth in this Bulletin, a ''joint venture'' is any common enterprise with mutual economic benefit. The application of this Bulletin is not limited to ''joint ventures'' that meet technical qualifications under applicable state or common law.

• A hospital establishes a subsidiary to provide DME. The new subsidiary enters into a contract with an existing DME company to operate the new subsidiary and to provide the new subsidiary with DME inventory. The existing DME company already provides DME services comparable to those provided by the new hospital DME subsidiary and bills insurers and patients for them.

• A DME company sells nebulizers to federal health care beneficiaries. A mail order pharmacy suggests that the DME company form its own mail order pharmacy to provide nebulizer drugs. Through a management agreement, the mail order pharmacy runs the DME company's pharmacy, providing personnel, equipment, and space. The existing mail order pharmacy also sells all nebulizer drugs to the DME company's pharmacy for its inventory.

• A group of nephrologists establishes a wholly-owned company to provide home dialysis supplies to their dialysis patients. The new company contracts with an existing supplier of home dialysis supplies to operate the new company and provide all goods and services to the new company.

These problematic arrangements typically exhibit certain common elements. First, the Owner expands into a related line of business, which is dependent on referrals from, or other business generated by, the Owner's existing business.[3] The new business line may be organized as a part of the existing entity or as a separate subsidiary. Typically, the new business primarily serves the Owner's existing patient base.

Second, the Owner neither operates the new business itself nor commits substantial financial, capital, or human resources to the venture. Instead, it contracts out substantially all the operations of the new business. The Manager/Supplier typically agrees to provide not only management services, but also a range of other services, such as the inventory necessary to run the business, office and health care personnel, billing support, and space. While the Manager/Supplier essentially operates the business, the billing of insurers and patients is done in the name of the Owner. In many cases, the contractual arrangements result in either practical or legal exclusivity for the Manager/Supplier through inclusion of non-competition provisions or restrictions on access. While the contract terms of these arrangements may appear to place the Owner at financial risk, the Owner's actual business risk is minimal because of the Owner's ability to influence substantial referrals to the new business.

Third, the Manager/Supplier is an established provider of the same services as the Owner's new line of business. In other words, absent the contractual arrangement, the Manager/Supplier would be a competitor of the new line of business, providing items and services in its own right, billing insurers and patients in its own name, and collecting reimbursement.

Fourth, the Owner and the Manager/Supplier share in the economic benefit of the Owner's new business. The Manager/Supplier takes its share in the form of payments under the various contracts with the Owner; the Owner receives its share in the form of the residual profit from the new business.

Fifth, aggregate payments to the Manager/Supplier typically vary with the value or volume of business generated for the new business by the Owner. While in some arrangements certain payments are fixed (for example, the management fee), other payments, such as payments for goods and services supplied by the Manager/Supplier, will vary based on the number of goods and services provided. In other words, the aggregate payment to the Manager/Supplier from the whole arrangement will vary with referrals from the Owner. Likewise, the Owner's payments, that is, the difference between the net revenues from the new business and its expenses (including payments to the Manager/Supplier), also vary based on the Owner's referrals to the new business. Through these contractual payments, the parties are able to share the profits of the new line of business.

B. Safe Harbor Protection May Be Unavailable

Under the kickback statute, a number of statutory and regulatory ''safe harbors'' immunize certain arrangements that might otherwise violate the anti-kickback statute. (*See* 42 U.S.C. 1320a-7b(b)(3); 42 CFR 1001.952.) To qualify for safe harbor protection, an arrangement must fit squarely in one of these safe harbor provisions. Some parties attempt to carve otherwise problematic contracting arrangements into several different contracts for discrete items or services (*e.g.*, a management contract, a vendor contract, and a staffing contract), and then qualify each separate contract for protection under a ''safe harbor.'' Such efforts may be ineffectual and leave the parties subject to prosecution for the following reasons.

First, many of these questionable joint venture arrangements involve contracts pursuant to which the Manager/Suppliers agree to sell items and services to the Owners at a discounted price. However, where a discount is given as part of an overarching business arrangement, it cannot qualify for protection under the discount safe harbor. Simply put, the discount safe harbor does not protect—and has never protected—prices offered by a seller to a buyer in connection with a common enterprise. To be protected under the discount safe harbor, a price reduction must be based on an arms length transaction. (*See* 42 CFR 1001.952(h) under which ''the term *discount* means a reduction in the amount a buyer * * * is charged for an item or service based on an arms-length transaction.''). As we expressly stated in the preamble to the 1991 safe harbor regulations, the provision of items or services to a joint venture by a participant in the venture is not an ''arms length'' transaction:

> Another problem exists where an entity, which is both a provider and supplier of items or services and joint venture partner with referring physicians, makes discounts to the joint venture as a way to share its profits with the physician partners. Very often this entity furnishes items or services to the joint venture, and also acts as the joint venture's general partner or provides management services to the joint venture. * * * *These arrangements are not arms length transactions where the joint venture shops around for the best price on a good or service. Rather it has entered into a collusive arrangement with a particular provider or supplier of items or services that seeks to share its profits with referring physician partners. [We did] * * * not intend to protect these types of transactions which are sometimes made to appear as ''discounts''* * * (Emphasis added) (*See* 56 FR 35977; July 29, 1991).

In short, a discount is not based on arms length transaction if it is provided by a seller to a purchaser in connection with a common venture, regardless of whether the venture is memorialized in separate contracts.

Second, even if the various contracts could fit in one or more safe harbors, they would only protect the remuneration flowing from the Owner to the Manager/Supplier for actual services rendered. In the contractual arrangements that are the subject of this Bulletin, however, the illegal remuneration is often the difference between the money paid by the Owner to the Manager/Supplier and the

[3] The Owner's referrals may be direct or indirect and may include not only ordering or purchasing goods or services, but also ''arranging for'' or ''recommending'' goods and services. *See* section 1128B(b) of the Act. For example, a hospital may generate business for a DME company, notwithstanding that orders for specific DME items must be signed by a physician who may or may not be a hospital employee.

reimbursement received from the federal health care programs. By agreeing effectively to provide services it could otherwise provide in its own right for less than the available reimbursement, the Manager/Supplier is providing the Owner with the opportunity to generate a fee and a profit. The opportunity to generate a fee is itself remuneration that may implicate the anti-kickback statute.

C. Indicia of a Suspect Contractual Joint Venture

To help identify the suspect contractual joint ventures that are the focus of this Special Advisory Bulletin, we describe below some characteristics, which, taken separately or together, potentially indicate a prohibited arrangement. This list is illustrative, not exhaustive.

New Line of Business. The Owner typically seeks to expand into a health care service that can be provided to the Owner's existing patients. As illustrated in Part A, examples include, but are not limited to, hospitals expanding into DME services, DME companies expanding into the nebulizer pharmacy business, or nephrologists expanding into the home dialysis supply business.[4]

Captive Referral Base. The newly-created business predominantly or exclusively serves the Owner's existing patient base (or patients under the control or influence of the Owner). The Owner typically does not intend to expand the business to serve new customers (*i.e.*, customers not already served in its main business) and, therefore, makes no or few *bona fide* efforts to do so.

Little or No Bona Fide Business Risk. The Owner's primary contribution to the venture is referrals; it makes little or no financial or other investment in the business, delegating the entire operation to the Manager/Supplier, while retaining profits generated from its captive referral base. Residual business risks, such as nonpayment for services, are relatively ascertainable based on historical activity.

Status of the Manager/Supplier. The Manager/Supplier is a would-be competitor of the Owner's new line of business and would normally compete for the captive referrals. It has the capacity to provide virtually identical services in its own right and bill insurers and patients for them in its own name.

Scope of Services Provided by the Manager/Supplier. The Manager/Supplier provides all, or many, of the following key services:

- Day-to-day management;
- Billing services;
- Equipment;
- Personnel and related services;
- Office space;
- Training;
- Health care items, supplies, and services.[5]

In general, the greater the scope of services provided by the Manager/Supplier, the greater the likelihood that the arrangement is a contractual joint venture.

Remuneration. The practical effect of the arrangement, viewed in its entirety, is to provide the Owner the opportunity to bill insurers and patients for business otherwise provided by the Manager/Supplier. The remuneration from the venture to the Owner (*i.e.*, the profits of the venture) takes into account the value and volume of business the Owner generates.

Exclusivity. The parties may agree to a non-compete clause, barring the Owner from providing items or services to any patients other than those coming from Owner and/or barring the Manager/Supplier from providing services in its own right to the Owner's patients.

As noted above, these factors are illustrative, not exhaustive. The presence or absence of any one of these factors is not determinative of whether a particular arrangement is suspect. As indicated, this Special Advisory Bulletin is not intended to describe the entire universe of suspect contractual joint ventures. This Bulletin focuses on arrangements where substantially all of the operations of a new line of business are contracted out to a would-be competitor. Arrangements involving the delegation of fewer than substantially all services, or delegation to a party not otherwise in a position to bill for the identical services, may also raise concerns under the anti-kickback statute, depending on the circumstances.

The Office of Inspector General (OIG) was established at the Department of Health and Human Services by Congress in 1976 to identify and eliminate fraud, abuse, and waste in the department's programs and to promote efficiency and economy in departmental operations. The OIG carries out this mission through a nationwide program of audits, investigations, and inspections.

The Fraud and Abuse Control Program, established by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), authorized the OIG to provide guidance to the health care industry to prevent fraud and abuse and to promote the highest level of ethical and lawful conduct. To further these goals, the OIG issues Special Advisory Bulletins about industry practices or arrangements that potentially implicate the fraud and abuse authorities subject to enforcement by the OIG.

Dated: March 27, 2003.

Dennis J. Duquette,

Acting Principal Deputy Inspector General.

[FR Doc. 03–10626 Filed 4–29–03; 8:45 am]

BILLING CODE 4150–01–P

[4] These examples are illustrative only. This list is not intended to suggest that other analogous ventures are not equally suspect.

[5] The Manager/Supplier may also provide marketing services, although in many instances no such services are required since the Owner generates substantially all of the venture's business from its existing patient base.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; National Institute of Diabetes and Digestive and Kidney Diseases Information Clearinghouses Customer Satisfaction Survey

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management (OMB) for review and approval.

Proposed Collection

Title: NIDDK Information Clearinghouses Customer Satisfaction Survey. *Type of Information Request:* EXTENSION. The OMB control number 0925–0480 expires July 31, 2003. *Need and Use of Information Collection:* NIDDK is conducting a survey to evaluate the efficiency and effectiveness of services provided by NIDDK's three information clearinghouses: National Diabetes Information Clearinghouse, National Digestive Diseases Information Clearinghouse, National Kidney and Urologic Diseases Information Clearinghouse. The survey responds to Executive Order 12862, ''Setting Customer Service Standards,'' which requires agencies and departments to identify and survey their ''customers to determine the kind and quality of service they want and their level of satisfaction with existing service.'' *Frequency of Response:* On occasion.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL
WASHINGTON, DC 20201

Special Fraud Alert: Physician-Owned Entities

March 26, 2013

I. Introduction

This Special Fraud Alert addresses physician-owned entities that derive revenue from selling, or arranging for the sale of, implantable medical devices ordered by their physician-owners for use in procedures the physician-owners perform on their own patients at hospitals or ambulatory surgical centers (ASCs). These entities frequently are referred to as physician-owned distributorships, or "PODs."[1] The Office of Inspector General (OIG) has issued a number of guidance documents on the general subject of physician investments in entities to which they refer, including the 1989 Special Fraud Alert on Joint Venture Arrangements[2] and various other publications. OIG also provided guidance specifically addressing physician investments in medical device manufacturers and distributors in an October 6, 2006 letter.[3] In that letter, we noted "the strong potential for improper inducements between and among the physician investors, the entities, device vendors, and device purchasers" and stated that such ventures "should be closely scrutinized under the fraud and abuse laws."[4] This Special Fraud Alert focuses on the specific attributes and practices of PODs that we believe produce substantial fraud and abuse risk and pose dangers to patient safety.

II. The Anti-Kickback Statute

One purpose of the anti-kickback statute is to protect patients from inappropriate medical referrals or recommendations by health care professionals who may be unduly influenced by financial incentives. Section 1128B(b) of the Social Security Act (the Act) makes it a criminal

[1] The physician-owned entities addressed in this Special Fraud Alert are sometimes referred to as "physician-owned companies" or by other terminology. For purposes of this Special Fraud Alert, a "POD" is any physician-owned entity that derives revenue from selling, or arranging for the sale of, implantable medical devices and includes physician-owned entities that purport to design or manufacture, typically under contractual arrangements, their own medical devices or instrumentation. Although this Special Fraud Alert focuses on PODs that derive revenue from selling, or arranging for the sale of, implantable medical devices, the same principles would apply when evaluating arrangements involving other types of physician-owned entities.

[2] Special Fraud Alert: Joint Venture Arrangements (August 1989), *reprinted at* 59 Fed. Reg. 65,372, 65,374 (Dec. 19, 1994).

[3] Letter from Vicki Robinson, Chief, Industry Guidance Branch, Department of Health and Human Services, OIG, Response to Request for Guidance Regarding Certain Physician Investments in the Medical Device Industries (Oct. 6, 2006).

[4] Id.

offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce, or in return for, referrals of items or services reimbursable by a Federal health care program. When remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to 5 years, or both. Conviction will also lead to exclusion from Federal health care programs, including Medicare and Medicaid. OIG may also initiate administrative proceedings to exclude persons from the Federal health care programs or to impose civil money penalties for fraud, kickbacks, and other prohibited activities under sections 1128(b)(7) and 1128A(a)(7) of the Act.

III. Physician-Owned Distributorships

Longstanding OIG guidance makes clear that the opportunity for a referring physician to earn a profit, including through an investment in an entity for which he or she generates business, could constitute illegal remuneration under the anti-kickback statute. The anti-kickback statute is violated if even one purpose of the remuneration is to induce such referrals.

OIG has repeatedly expressed concerns about arrangements that exhibit questionable features with regard to the selection and retention of investors, the solicitation of capital contributions, and the distribution of profits. Such questionable features may include, but are not limited to: (1) selecting investors because they are in a position to generate substantial business for the entity, (2) requiring investors who cease practicing in the service area to divest their ownership interests, and (3) distributing extraordinary returns on investment compared to the level of risk involved.

PODs that exhibit any of these or other questionable features potentially raise four major concerns typically associated with kickbacks—corruption of medical judgment, overutilization, increased costs to the Federal health care programs and beneficiaries, and unfair competition. This is because the financial incentives PODs offer to their physician-owners may induce the physicians both to perform more procedures (or more extensive procedures) than are medically necessary and to use the devices the PODs sell in lieu of other, potentially more clinically appropriate, devices. We are particularly concerned about the presence of such financial incentives in the implantable medical device context because such devices typically are "physician preference items," meaning that both the choice of brand and the type of device may be made or strongly influenced by the physician, rather than being controlled by the hospital or ASC where the procedure is performed.

We do not believe that disclosure to a patient of the physician's financial interest in a POD is sufficient to address these concerns. As we noted in the preamble to the final regulation for the safe harbor relating to ASCs:

> …disclosure in and of itself does not provide sufficient assurance against fraud and abuse…[because] disclosure of financial interest is often part of a testimonial, i.e., a reason why the patient should patronize that facility. Thus, often patients

are not put on guard against the potential conflict of interest, i.e., the possible effect of financial considerations on the physician's medical judgment.

See 64 Fed. Reg. 63,518, 63,536 (Nov. 19, 1999). Although these statements were made with respect to ASCs, the same principles apply in the POD context.

OIG recognizes that the lawfulness of any particular POD under the anti-kickback statute depends on the intent of the parties. Such intent may be evidenced by a POD's characteristics, including the details of its legal structure; its operational safeguards; and the actual conduct of its investors, management entities, suppliers, and customers during the implementation phase and ongoing operations. Nonetheless, we believe that PODs are inherently suspect under the anti-kickback statute. We are particularly concerned when PODs, or their physician-owners, exhibit any of the following suspect characteristics:

- The size of the investment offered to each physician varies with the expected or actual volume or value of devices used by the physician.
- Distributions are not made in proportion to ownership interest, or physician-owners pay different prices for their ownership interests, because of the expected or actual volume or value of devices used by the physicians.
- Physician-owners condition their referrals to hospitals or ASCs on their purchase of the POD's devices through coercion or promises, for example, by stating or implying they will perform surgeries or refer patients elsewhere if a hospital or an ASC does not purchase devices from the POD, by promising or implying they will move surgeries to the hospital or ASC if it purchases devices from the POD, or by requiring a hospital or an ASC to enter into an exclusive purchase arrangement with the POD.
- Physician-owners are required, pressured, or actively encouraged to refer, recommend, or arrange for the purchase of the devices sold by the POD or, conversely, are threatened with, or experience, negative repercussions (e.g., decreased distributions, required divestiture) for failing to use the POD's devices for their patients.
- The POD retains the right to repurchase a physician-owner's interest for the physician's failure or inability (through relocation, retirement, or otherwise) to refer, recommend, or arrange for the purchase of the POD's devices.
- The POD is a shell entity that does not conduct appropriate product evaluations, maintain or manage sufficient inventory in its own facility, or employ or otherwise contract with personnel necessary for operations.
- The POD does not maintain continuous oversight of all distribution functions.
- When a hospital or an ASC requires physicians to disclose conflicts of interest, the POD's physician-owners either fail to inform the hospital or ASC of, or actively conceal through misrepresentations, their ownership interest in the POD.

These criteria are not intended to serve as a blueprint for how to structure a lawful POD, as an arrangement may not exhibit any of the above suspect characteristics and yet still be found to be unlawful. Other characteristics not listed above may increase the risk of fraud and abuse

associated with a particular POD or provide evidence of unlawful intent. For example, a POD that exclusively serves its physician-owners' patient base poses a higher risk of fraud and abuse than a POD that sells to hospitals and ASCs on the basis of referrals from nonowner physicians.

The anti-kickback statute is not a prohibition on the generation of profits; however, PODs that generate disproportionately high rates of return for physician-owners may trigger heightened scrutiny. Because the investment risk associated with PODs is often minimal, a high rate of return increases both the likelihood that one purpose of the arrangement is to enable the physician-owners to profit from their ability to dictate the implantable devices to be purchased for their patients and the potential that the physician-owner's medical judgment will be distorted by financial incentives. Our concerns are magnified in cases when the physician-owners: (1) are few in number, such that the volume or value of a particular physician-owner's recommendations or referrals closely correlates to that physician-owner's return on investment, or (2) alter their medical practice after or shortly before investing in the POD (for example, by performing more surgeries, or more extensive surgeries, or by switching to using their PODs' devices on an exclusive, or nearly exclusive basis).

We are aware that some PODs purport to design or manufacture their own devices. OIG does not wish to discourage innovation; however, claims—particularly unsubstantiated claims—by physician-owners regarding the superiority of devices designed or manufactured by their PODs do not disprove unlawful intent. The risk of fraud and abuse is particularly high in circumstances when such physicians-owners are the sole (or nearly the sole) users of the devices sold or manufactured by their PODs.

Finally, because the anti-kickback statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction, hospitals and ASCs that enter into arrangements with PODs also may be at risk under the statute. In evaluating these arrangements, OIG will consider whether one purpose underlying a hospital's or an ASC's decision to purchase devices from a POD is to maintain or secure referrals from the POD's physician-owners.

IV. Conclusion

OIG is concerned about the proliferation of PODs. This Special Fraud Alert reiterates our longstanding position that the opportunity for a referring physician to earn a profit, including through an investment in an entity for which he or she generates business, could constitute illegal remuneration under the anti-kickback statute. OIG views PODs as inherently suspect under the anti-kickback statute. Should a POD, or an actual or potential physician-owner, continue to have questions about the structure of a particular POD arrangement, the OIG Advisory Opinion process remains available. Information about the process may be found at: http://oig.hhs.gov/faqs/advisory-opinions-faq.asp.

To report suspected fraud involving physician-owned entities, contact the OIG Hotline at http://oig.hhs.gov/fraud/report-fraud/index.asp or by phone at 1-800-447-8477 (1-800-HHS-TIPS).

U.S. Department of Health and Human Services
Office of Inspector General

Spinal Devices Supplied By Physician-Owned Distributors: Overview of Prevalence and Use

Daniel R. Levinson
Inspector General

October 2013 | OEI-01-11-00660

EXECUTIVE SUMMARY: SPINAL DEVICES SUPPLIED BY PHYSICIAN-OWNED DISTRIBUTORS: OVERVIEW OF PREVALENCE AND USE
OEI-01-11-00660

WHY WE DID THIS STUDY

This report responds to a congressional request to determine the extent to which physician-owned distributorships (PODs) provide spinal devices to hospitals. PODs' physician-owners can include the surgeons who implant the PODs' devices; these owners have an opportunity to profit from using the devices their PODs sell. Critics of PODs claim that such ownership creates a conflict of interest that may affect physicians' clinical decisionmaking. PODs assert that their devices cost less than devices provided by other spinal device companies.

HOW WE DID THIS STUDY

We selected a sample of 1,000 claims billed to Medicare in fiscal year (FY) 2011 that included spinal fusion surgery. We asked each hospital associated with these claims to complete a questionnaire about its knowledge of physician ownership of spinal device suppliers. We also asked each hospital to complete a worksheet with details about the spinal devices used in each surgery in our sample.

WHAT WE FOUND

In FY 2011, PODs supplied devices used in nearly one in five spinal fusion surgeries billed to Medicare. Spinal surgeries that used POD devices used fewer devices but did not have lower per surgery device costs than surgeries that did not use POD devices. Among the hospitals in our sample, about a third reported buying spinal devices from PODs. When hospitals in our sample began buying from PODs, their rates of spinal surgery grew faster than the rate for hospitals overall. Finally, in FY 2012, surgeons performed more spinal surgeries at hospitals in our sample that purchased from PODs than at those that did not purchase from PODs.

WHAT WE CONCLUDE

PODs are a substantial presence in the spinal device market. Our findings raise questions about PODs' claim that their devices cost less than those of other suppliers. Surgeons performed more spinal surgeries at hospitals that purchased from PODs, and those hospitals experienced increased rates of growth in the number of spinal surgeries performed in comparison to the rate for hospitals that did not purchase from PODs. Taken together, these factors may increase the cost of spinal surgery to Medicare over time. Finally, hospitals' policies varied in whether they required physicians to disclose ownership interests in PODs to either the hospital or their patients. Thus the ability of hospitals and patients to identify potential conflicts of interest among these providers is reduced.

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OBJECTIVES

1. To determine the extent to which spinal fusion surgeries used spinal devices provided by physician-owned distributors (PODs).
2. To determine whether the cost and quantity of spinal devices used in spinal fusion surgeries differed when spinal devices were supplied by PODs.
3. To determine the extent to which hospitals associated with a sample of spinal fusion surgeries purchased spinal devices from PODs.
4. To determine whether the rates and complexities of spinal surgeries differed when hospitals associated with a sample of spinal fusion surgeries purchased spinal devices from PODs.

BACKGROUND

In fiscal year (FY) 2012, Medicare paid hospitals a total of $3.9 billion for 178,789 spinal surgeries. Medicare reimbursed hospitals an average of $21,613 for each of these surgeries. On average, Medicare reimbursed hospitals $10,289 for the least complicated spinal surgeries and $34,676 for the most complicated surgeries.

This report responds to a congressional request. The requestors expressed concerns about the growth of physician-owned distributorships and the potential adverse effect that these entities could have on Medicare beneficiaries and Federal health care programs. The requestors asked the Office of Inspector General (OIG) to examine a number of issues regarding PODs. In response, OIG stated that it would determine the extent to which PODs provide spinal devices to hospitals.

Overview of Physician-Owned Device Companies

Companies not owned by physicians most commonly supply spinal devices to hospitals through their staff or contracted sales representatives. These sales arrangements may also provide other services, such as operating-room technical support, inventory management, and coding assistance.

Some physicians, including surgeons who implant spinal devices, have ownership stakes in spinal device companies. For the remainder of this report, we will refer to such companies as PODs.

Physicians invest in a variety of POD arrangements. PODs vary in (1) whether their physician-investors practice in the hospitals to which they distribute devices, (2) whether they solely distribute devices or both manufacture and distribute their own devices, and (3) which services they

offer along with the purchase of their devices. Regardless of the business arrangement, PODs offer physician-investors the opportunity to profit from using the devices their PODs sell.

Controversy Over PODs

Benefits of PODs. PODs assert that they supply spinal devices at a lower cost than companies not owned by physicians. They claim to reduce costs to hospitals by lessening the need for sales representatives, procuring inventory from smaller manufacturers, and increasing competition in the market for devices.

Vulnerabilities of PODs. Critics of PODs claim that PODs create a conflict of interest that could affect physicians' clinical decisionmaking. Ownership may encourage surgeons to perform unnecessary and inappropriate spinal surgeries to drive sales for their companies. Critics claim that surgeons may also perform more spinal refusion surgeries, also known as revision surgeries. These surgeries sometimes involve removing previously implanted devices and replacing them with new devices. Critics claim that PODs may encourage surgeons to perform these surgeries.

PODs potentially raise legal concerns under the Anti-Kickback Statute. The statute makes it a criminal offense to knowingly and willfully offer remuneration to induce, or in return for, referrals of items of services reimbursable by a Federal health care program.[1] By its terms, the statute ascribes criminal liability to parties on both side of an impermissible "kickback" transaction.[2]

In 2013, OIG released a Special Fraud Alert on Physician Owned Entities. OIG stated that PODs are inherently suspect under the Anti-Kickback Statute and set forth a number of suspect characteristics about which it is concerned.[3] OIG is particularly concerned about PODs because surgical implants "typically are 'physician preference items,' meaning that both the choice of brand and the type of device may be made or strongly influenced by the physician, rather than the hospital where the procedure is performed."[4] The Fraud Alert echoes OIG guidance from 2006 that specifically addressed physician investments in medical device manufacturers and distributors. In that guidance, OIG acknowledged the "strong potential for improper inducements between and among the

[1] Section 1128B(b) of the Social Security Act.

[2] Ibid.

[3] OIG Special Fraud Alert, Physician Owned Entities (Mar. 2013). Accessed at http://oig.hhs.gov on May 13, 2013.

[4] Ibid.

physician investors, the entities, device vendors, and device purchasers" and stated that such arrangements should be "closely scrutinized under fraud and abuse laws."[5]

The Sunshine Act

Hospitals and patients may be unaware of physicians' investment in PODs. However, regulations that the Centers for Medicare & Medicaid Services (CMS) recently issued under the Physician Payments Sunshine Act will require PODs to become more transparent.[6] As of August 1, 2013, CMS requires manufacturers and group purchasing organizations to report all physician ownership and investment interests to CMS annually.[7] The regulations define group purchasing organizations as including most PODs, but CMS may determine, on a case-by-case basis, whether it considers a particular POD arrangement to be a group purchasing organization under the final rule.[8] CMS will make a database of compensated physicians publicly available.

Spinal Procedures and Devices Associated With Spinal Surgeries

Spinal surgery often involves implanting devices that immobilize or reduce pressure on the spine. Some of the indications for spinal surgery are disc degeneration, spinal stenosis, fractures, tumors, and vertebral instability.[9] Two common spinal procedures—spinal fusion and decompression—often involve implanting medical devices and biologics (such as bone grafts). Each spinal surgery may involve one or more spinal procedures.

Spinal Fusion Procedures. Spinal fusion is considered either simple or complex depending on the number of vertebrae fused. Simple spinal fusion joins two or three vertebrae to one another, often using both bone grafts and devices to immobilize the vertebrae. Complex spinal fusion involves fusing more than three vertebrae using similar devices and grafting techniques.[10]

Decompression Procedures. Decompression is performed to relieve pressure on the spinal cord and/or nerve roots. To do this, surgeons might remove bone spurs and part or all of a lamina, vertebra, or spinal disk.

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[5] Ibid.

[6] The Physician Payments Sunshine Act was part of the Patient Protection and Affordable Care Act, P.L. 111-148 § 6002, Social Security Act, § 1128G.

[7] 42 CFR § 403.906.

[8] 42 CFR § 403.902; 78 Fed Reg 9458, 9493 (Feb. 8, 2013).

[9] OrthoInfo, *Spinal Fusion*. Accessed at http://orthoinfo.aaos.org/ on Oct. 20, 2013.

[10] We defined "complex spinal fusion" and "simple spinal fusion" according to the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) procedure codes.

Surgeons might also use a device to expand the openings where nerves exit the spinal cord. Surgeons can perform a spinal fusion in conjunction with decompression, depending upon the extent of the decompression procedure and its impact on the stability of the spine.[11]

Spinal Devices. Spinal procedures may involve implanting a number of different spinal devices, including plates, screws, pedicle screws, rods, cap/set screws, and interbody cages. Plates and screws are used in conjunction with one another to properly align vertebrae. Surgeons stabilize the spine either by affixing the plate directly to the vertebral bone with screws or by inserting pedicle screws into adjacent vertebrae and connecting screws with rods. Cap/set screws are used to affix rods to pedicle screws. Interbody cages are implanted between vertebrae to host the bone graft used to fuse adjacent vertebrae. The interbody cage helps maintain height between vertebrae as the bone graft hardens.

Medicare Payment for Spinal Surgery Using Spinal Devices

Medicare covers only spinal implant surgery performed in the inpatient setting. It makes separate payments for surgeons' professional fees and for hospitals' facility charges. Medicare Part B pays surgeons under the Medicare Physician Fee Schedule. Medicare Part A pays the hospitals under the Inpatient Prospective Payment System (IPPS).

Under the IPPS, Medicare classifies each case into one of 747 medical severity diagnosis related groups (MS-DRG). These groups are based on the beneficiary's diagnoses and the procedures performed, as well as other factors reported by the hospital on the claim. Payment for the MS-DRG covers nearly all costs associated with the hospital stay, including any spinal devices implanted into the beneficiary.

[11] The Cleveland Clinic, *Spinal Decompression Surgery, Treatments and Procedures*. Accessed at http://my.clevelandclinic.org on Oct. 14, 2011.

METHODOLOGY

This study used Medicare claims and enrollment data, a review of the spinal devices implanted during a representative sample of spinal fusion surgeries billed to Medicare, and questionnaire responses from the hospitals that billed for Medicare for these surgeries. See Appendix A for a full discussion of our methodology.

Scope

This study is national in scope. For the purposes of this study, we defined "spinal surgery" as spinal decompression and spinal fusion. Our sample of claims included surgeries that involved a spinal fusion procedure and were billed to Medicare during FY 2011. We sampled such claims because surgeries involving spinal fusion were more likely to use implanted spinal devices than surgeries that involved only decompression. We did not make any judgment on the legality of hospitals' relationships with PODs or on the appropriateness of spinal surgeries performed by hospitals.

Sample Selection

We selected a simple random sample of 1,000 claims for spinal fusion surgery from Medicare's Standard Analytical File of 100-percent inpatient claims for FY 2011. After clearing the 615 hospitals associated with these claims with OIG's Office of Investigations, we removed 29 claims from 19 hospitals from our sample. Our data collection sample included 971 claims from 596 hospitals.

Data Collection

We administered a questionnaire to hospitals and asked them to complete an invoice worksheet using secure Web-based survey software. We made three attempts to obtain responses. Of the 596 hospitals that we asked to complete the questionnaire, 589 hospitals responded. These hospitals also provided invoice information for 963 of the 1,000 claims included in our sample.[12] Our overall response rate was 96 percent.

Hospital Questionnaire. We asked each hospital that billed for one or more spinal surgeries in our sample to answer a series of questions about the entities from which it purchases spinal devices. As part of those questions, we asked each hospital about its awareness of physician ownership among its suppliers of spinal devices. We defined "physician owners" as those with a partial or full ownership stake through private investment, excluding stock in a publicly traded company.

[12] Five of the hospitals in our sample refused to provide invoice information detailing spinal devices implanted during eight inpatient stays covered by Medicare. We will refer these hospitals to CMS.

Invoice Review. We asked each hospital to complete a worksheet for each of its spinal surgeries in our sample. The worksheet compiled detailed data about the spinal devices used for the surgery and the entities that supplied them to the hospital. We asked hospitals to substantiate the data they provided on the worksheets by sending us hard copies of supporting documents, such as invoices and purchase orders.

Data Analysis

We analyzed data from the invoice review and the hospital questionnaire responses to determine the extent to which spinal surgeries used spinal devices provided by PODs and whether the cost or quantity of spinal devices used in these surgeries differed for POD-provided devices.

To determine the extent to which hospitals associated with our sample of claims purchased spinal devices from PODs, we analyzed data from the questionnaire responses and the invoice review. We counted hospitals as purchasing from PODs if they self-identified as using PODs in the responses or invoice review or if we identified such purchasing by cross-referencing these two data sources.

We analyzed data from the questionnaire responses to explain why hospitals purchased spinal devices from PODs and determine the extent to which they had policies on physician disclosure of ownership in medical device companies.

To determine whether rates and complexities of spinal surgeries differed when hospitals purchased from PODs, we analyzed hospitals' Medicare claims to describe their spinal surgery caseloads both (1) before and after they began purchasing from PODs and (2) in FY 2012. We used three measures to describe the complexity of hospitals' caseloads: the percentage of spinal surgery caseload that was spinal fusion, the percentage that was complex spinal fusion, and the percentage that was refusion surgery.

Limitations

This study relies on Medicare claims and the hospital questionnaire responses, which were self-reported by hospitals. We did not independently verify these data. Certain findings are limited to the hospitals associated with our sample of claims and are not generalizable. We describe changes in utilization rates over time, but did not determine the cause of those changes. We relied on ICD-9-CM procedure codes reported by hospitals on Medicare claims to determine the type and complexity of spinal procedures. We also did not assess the clinical benefits or equivalency of POD devices and non-POD devices.

Standards

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

FINDINGS

In FY 2011, PODs supplied the devices used in nearly one in five spinal fusion surgeries billed to Medicare

PODs supplied spinal devices for 19 percent of the spinal fusion surgeries billed to Medicare in FY 2011. Of the surgeries that used POD devices, about two-thirds used a mix of such devices and devices that were not from PODs. About one-third of these surgeries used only POD devices.

The distribution of surgeries that used POD devices varied geographically (see Appendix C). Surgeries from California and Texas composed one quarter of the surgeries in our sample that used POD devices, with 14 and 11 percent, respectively. Just over a quarter were performed in Missouri (6 percent), Florida (6 percent), Pennsylvania (5 percent) Alabama (5 percent), and Georgia (5 percent).

Spinal fusion surgeries that used POD devices used fewer devices but did not have lower device costs

Critics of PODs argue that because PODs link surgeons' compensation to the number of devices they implant, they have the potential to increase the number of devices used during spinal surgeries. However, proponents of PODs claim that PODs reduce the cost of spinal devices by lessening the need for sales representatives and increasing competition in the spinal device market. Medicare payment is tied to the MS-DRG classification of the hospital stay, so any difference in device costs would not immediately affect the amount Medicare or the beneficiary paid for a given stay. However, Medicare payment to hospitals could change over time as device costs are factored into hospitals' Medicare reimbursement through cost reporting.

Surgeries that used POD devices used about two fewer devices per surgery than surgeries that did not use POD devices

Overall, surgeries that used POD devices implanted an average of 12.3 spinal devices compared to an average of 14.2 spinal devices for surgeries that did not implant POD devices. The number of devices implanted during complex spinal fusion surgeries accounts for this difference. Complex spinal fusion surgeries that used POD devices implanted an average of 16.5 devices compared to an average of 23 devices for complex spinal fusion surgeries that did not implant POD

devices.[13]

Device costs for surgeries that used POD devices were not lower than those for all other surgeries

We did not find a statistically significant difference between the average total device cost for spinal surgeries that used POD devices and those that that did not use POD devices.[14]

Furthermore, none of the six types of spinal devices we examined was less costly per unit when provided by PODs, and one was more costly when provided by PODs (see Table 1). Using data from the invoice review, we determined and compared the prices that hospitals paid PODs and distributors not owned by physicians for rods, cap/set screws, pedicle screws, interbody fusion devices, spinal plates, and other screws. We found no statistical difference between the price hospitals paid PODs and distributors not owned by physicians for rods, cap/set screws, pedicle screws, other screws, and interbody fusion devices. However, we found that hospitals paid $845 more for spinal plates from PODs. This difference could eventually raise a hospital's Medicare reimbursement through increased device costs in its cost reporting.

Table 1: Average Cost of Spinal Devices by Device Type

Device Type	Cost of POD Devices	Cost of Non-POD Devices	Statistically Significant Difference
Spinal plates *	$2,475	$1,630	$845
Other screws †	$699	$620	-
Interbody fusion devices, non-bone †	$2,821	$2,998	-
Pedicle screws †	$942	$892	-
Rods †	$345	$360	-
Cap/set screws †	$142	$148	-

Source: OIG analysis of hospital questionnaire responses and invoice worksheet data, 2013.
* Denotes a statistically significant difference at the p<.05 level.
† Denotes no statistically significant difference at the p<.05 level.

[13] Complex spinal fusion surgeries make up over a fifth both of surgeries that use POD devices and surgeries that do not use POD devices (21 and 25 percent, respectively).
[14] The average total device cost for surgeries that used POD devices was $11,601 and the average total device cost for surgeries that did not use POD devices was $11,383. The difference between these two averages is not statistically significant at the .05 level.

About a third of hospitals in our sample purchased spinal devices from PODs

Thirty-four percent of hospitals in our sample (203 of 589 hospitals) purchased spinal devices from PODs. About three-fifths, or 119, of those hospitals self-identified on the questionnaire responses as having purchased from PODs. We identified the remaining two-fifths, or 84 hospitals, by cross-referencing PODs that hospitals identified in their responses with device suppliers that hospitals reported on their invoice worksheets (see Table 2).

Table 2: Types of Hospitals in Our Sample

Hospital Type	Number of Hospitals
Hospitals that purchased from PODs	203
Self-identified hospitals	*119*
Cross-referenced hospitals	*84*
Hospitals that did not purchase from PODs	386
All hospitals in our sample	**589**

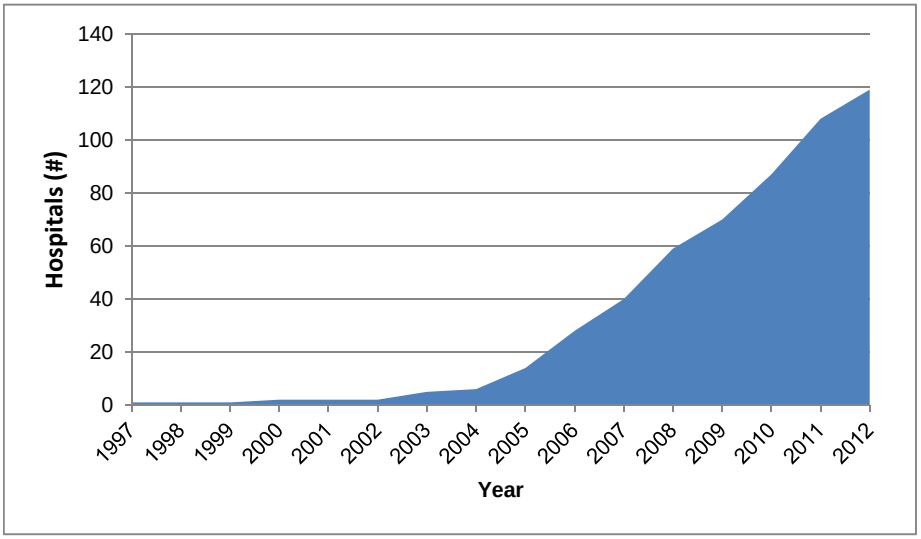
Source: OIG analysis of hospital questionnaire responses and invoice review, 2013.

The following analysis is limited to the 119 hospitals that reported in their questionnaire responses that they used PODs. We analyzed this subset of hospitals because our questionnaire collected additional details about hospitals' interactions with PODs only when hospitals self-identified as purchasing from PODs. We were unable to collect these details for the hospitals that we identified through our cross-reference as purchasing from PODs.

Most hospitals began purchasing spinal devices from PODs in the last 10 years

Hospitals reported purchasing from PODs as early as 1997. However, the majority (88 percent) of hospitals that purchased from PODs began doing so after 2005. Nearly half (41 percent) of hospitals that purchased from PODs began doing so recently, between 2010 and 2012 (see Chart 1 on the following page).

Chart 1: Hospitals in Our Sample That Purchased Spinal Devices From PODs, by Year



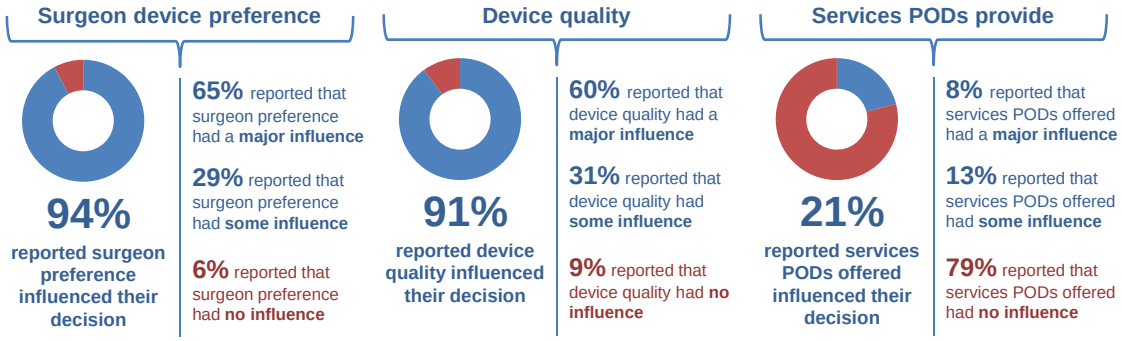
Source: OIG analysis of hospital questionnaire responses, 2013.

Hospitals identified surgeon preference as the strongest influence on their decisions to purchase spinal devices from PODs

Ninety-four percent of hospitals that purchased from PODs reported that surgeon preference influenced their decision to purchase from PODs. Surgeons often develop a preference for a company's devices after they gain familiarity and experience with that company's devices. Hospitals ranked surgeon preference over quality and effectiveness of devices as factors that influenced their decision to purchase spinal devices from PODs. About 90 percent of hospitals reported that quality and effectiveness also influenced their decision. Although about three quarters of hospitals that purchased devices from PODs reported that they received additional services from them, only about 20 percent of hospitals reported that those services influenced their decisions to purchase from PODs (see Figure 1 on the following page).[15]

[15] In addition to supplying devices, PODs and distributors not owned by physicians often provide services to hospitals, such as technical and administrative support. About three quarters of hospitals reported that they received technical support from PODs in the operating room. Thirty-one percent of hospitals received assistance from PODs to manage their inventory of spinal devices. Ten percent of hospitals received help from PODs with coding to bill for their devices. Non-physician owned companies offer similar services.

Figure 1: Factors That Influenced Hospitals' Decisions To Purchase From PODs



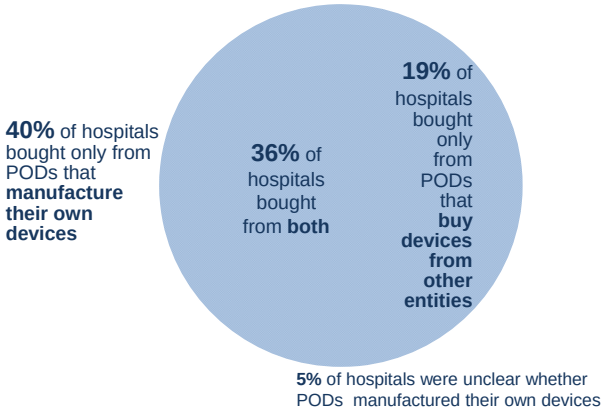
Source: OIG analysis of hospital questionnaire responses, 2013.

Many hospitals purchased spinal devices from PODs owned by physicians practicing in their hospitals

PODs are owned by physicians practicing inside or outside the hospitals they sell spinal devices to. About two-thirds of hospitals reported that they purchased from PODs owned by physicians practicing in their hospitals.

PODs also varied by whether they distributed devices that they manufactured or devices manufactured by others. Three-quarters of hospitals purchased spinal devices from PODs that manufactured their own devices (see Figure 2).

Figure 2: Hospitals' Use of PODs by PODs' Manufacturing Capabilities



Source: OIG analysis of hospital questionnaire responses, 2013.

Most hospitals did not purchase exclusively from PODs. Ninety-four percent of hospitals that purchased spinal devices from PODs also purchased devices from companies not owned by physicians.

Hospitals were not always aware of physician investment in spinal

device companies. About 40 percent of hospitals that purchased from PODs were uncertain whether one or more of their other suppliers were PODs.

Over half of hospitals had policies requiring physicians to disclose ownership stakes in device companies to the hospitals; far fewer required physicians to disclose to patients

Although Federal law does not require physicians to disclose ownership stakes in device companies to hospitals they practice in, 65 percent of hospitals had policies requiring them to do so. Disclosure policies can help hospitals and patients identify whether their physicians have potential conflicts of interest through investment in medical device companies.

Hospitals' disclosure policies varied. Some hospitals noted only requiring physicians to disclose ownership during the credentialing or hiring process. Furthermore, some hospitals noted that they required disclosure only from certain types of employees, such as managers and administrators.

Only 8 percent of hospitals that purchased from PODs reported that they required physicians to disclose to their patients whether they have ownership stake in the device companies they use.[16] Federal law does not require physicians to disclose such ownership to their patients.

When hospitals in our sample began purchasing devices from PODs, their rates of spinal surgery grew faster than the rate for hospitals overall

The presence of PODs may encourage surgeons to perform more surgeries or more complex surgeries to increase device sales. To explore this issue, we compared rates of spinal surgeries performed at hospitals in the sixth month before they started purchasing from PODs and in the sixth month after they started purchasing from PODs. We compared changes in these rates between two groups of hospitals: all hospitals that billed Medicare for spinal surgery and the hospitals in our sample that self-identified in the questionnaire responses that they

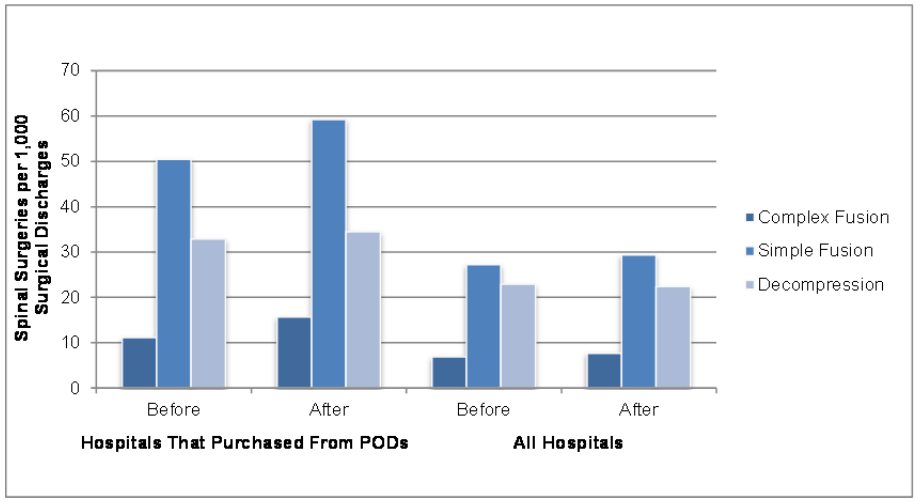
[16] In the questionnaire, we asked all 589 hospitals in our sample about their disclosure policies, regardless of whether they purchased from PODs. Overall, 60 percent of hospitals reported that they had policies in place to require physicians to disclose to the hospitals whether they have an ownership stake in medical device companies and 13 percent had policies requiring disclosure to patients.

purchased spinal devices from PODs.[17] We limit our consideration to these hospitals because they told us in the responses when they began purchasing from PODs. This analysis spans from FY 2004 to FY 2012.

The growth in the rate of spinal surgery after hospitals began purchasing from PODs was three times that for all hospitals

Hospitals' overall rate of spinal surgery—which includes spinal decompression only, spinal fusion, and spinal revision—grew more quickly for the group of hospitals in our sample that purchased from PODs. Before these hospitals started purchasing from PODs, they performed 95 spinal surgeries per 1,000 surgical discharges. This rate grew to 110 spinal surgeries per 1,000 surgical discharges after these hospitals began purchasing from PODs, an increase of 16 percent. Over matched time periods, the rate for hospitals overall grew by only 5 percent, from 57 to 60 spinal surgeries per 1,000 surgical discharges (see Chart 2).

Chart 2: Types of Spinal Surgeries Performed Before and After Hospitals Started Purchasing Spinal Devices From PODs



Source: OIG analysis of hospital questionnaire responses and the Medicare Standard Analytical File, 2013.

Furthermore, hospitals' rate of spinal fusions—surgeries that are more likely to use spinal devices—grew more than twice as fast among hospitals that used PODs compared to the rate for hospitals overall. The rate of spinal fusions among hospitals that used PODs increased by 21 percent (from 62 to 75 spinal fusions

[17] We excluded 17 of the 119 hospitals that self-identified that they used PODs from this analysis because we did not have claims data available for the periods before and after they began purchasing from PODs.

per 1,000 surgical discharges) compared to 9 percent at all hospitals (from 34 to 37 spinal fusions per 1,000 surgical discharges).

The complexity of hospitals' caseloads of spinal surgeries remained largely unchanged after they began purchasing from PODs

We used three measures to describe the complexity of hospitals' caseloads of spinal surgeries: the percentage of caseload that was spinal fusion, the percentage that was complex spinal fusion, and the percentage that was spinal refusion.

The complexity of the spinal surgery caseload at hospitals in our sample that used PODs shifted slightly after they began purchasing from PODs, but not across all measures. For example, the percentage of spine surgery (either simple or complex) that was spinal fusion shifted in favor of spinal fusions after hospitals began purchasing from PODs. Prior to hospitals' purchasing from PODs, spinal fusion and decompression-only accounted for 61 and 39 percent of their spine caseloads, respectively. After hospitals began purchasing from PODs, spinal fusion increased to 65 percent of their caseloads while decompression-only fell to 35 percent. For hospitals overall, spinal fusion increased slightly from 60 percent to 62 percent of their spinal caseloads over the same time periods. Examining growth in this measure also highlights the potential for increased device usage because spinal fusion, which fuses vertebrae together, is more likely to involve implanted devices than decompression-only.

Two other measures of complexity remained unchanged and decreased slightly, respectively, after hospitals began purchasing from PODs. The percentage of complex spinal fusion accounted for 14 percent of hospitals' spinal caseloads both before and after they began purchasing from PODs. At hospitals overall, the percentage of complex spinal fusion increased slightly, from 12 to 13 percent over the same time periods. The percentage of spinal refusion, which involves refusing a fusion that failed previously or fusing additional vertebrae after a previous surgery, decreased from 6 percent of spinal surgeries before hospitals started purchasing from PODs to 5 percent afterward. At hospitals overall, the percent of spinal refusion remained unchanged at 4 percent over the same time periods.

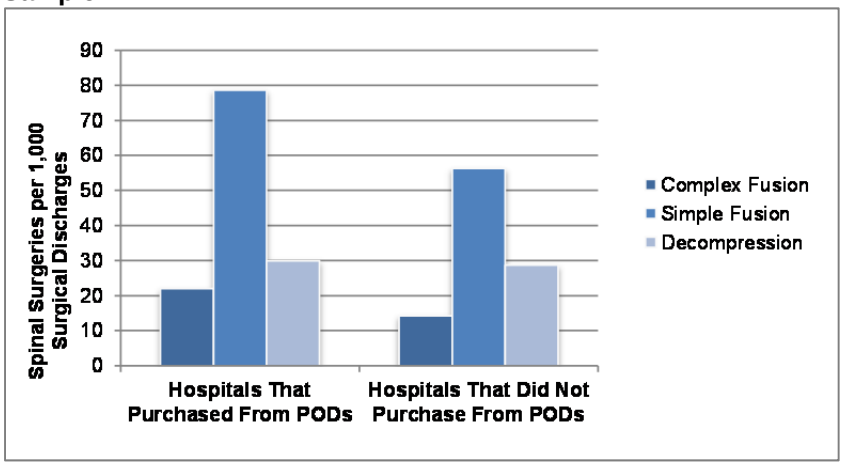
In FY 2012, hospitals in our sample that purchased from PODs performed more spinal surgeries than those that did not purchase from PODs

We compared hospitals' rates and caseloads of spinal surgery in FY 2012 between two groups of hospitals: the 203 hospitals in our sample that purchased from PODs and the 386 hospitals in our sample that did not purchase from PODs. For this analysis, hospitals that purchased from PODs included those that self-reported in the hospital questionnaire responses that they purchased from PODs and those we identified through our cross-referencing of data from the responses and invoice review.

Hospitals that purchased devices from PODs performed over a quarter more spinal surgeries than hospitals that did not purchase from PODs

Hospitals that did not purchase spinal devices from PODs performed 99 spinal surgeries per 1,000 surgical discharges in FY 2012. Hospitals that purchased spinal devices from PODs performed 28 percent more spinal surgeries, or 131 spinal surgeries per 1,000 surgical discharges (see Chart 3).

Chart 3: Type of Spinal Surgeries Performed in FY 2012 at Hospitals in Our Sample



Source: OIG analysis of hospital questionnaire responses, invoice review data, and the Medicare Standard Analytical File, 2013.

The complexity of hospitals' caseloads of spinal surgeries was slightly higher for hospitals that purchased devices from PODs than that for hospitals that did not purchase from PODs

On each of the three measures we used to describe the complexity of hospitals' caseloads, hospitals that purchased from PODs had a slightly more complex caseload than other hospitals.

First, hospitals in our sample that purchased from PODs performed more spinal fusion and less decompression-only surgery than hospitals that did not purchase from PODs. Spinal fusion made up 76 percent of the spinal surgery caseload at hospitals that purchased from PODs. It made up 69 percent of the caseload at hospitals that did not purchase from PODs. Conversely, decompression-only made up 25 percent of the spinal surgery caseload at hospitals that purchased form PODs and 31 percent of the caseload at hospitals that did not purchase from PODs.

The other measure of complexity that was slightly higher for hospitals that purchased from PODs was the percentage of caseload that was complex spinal fusion. At hospitals that purchased from PODs, complex spinal fusion made up 18 percent of the spinal surgery caseload compared to 16 percent at hospitals that did not purchase from PODs.

Our final measure of complexity, percentage of caseload that was spinal refusion, was similar between hospitals that purchased from PODs and those that did not purchase from PODs. Spinal refusion made up 7 percent of the caseloads at hospitals that purchased from PODs and 6 percent of the caseloads at hospitals that did not purchase from PODs.

CONCLUSION

PODs have a substantial presence in the spinal device market. PODs provided devices used in nearly a fifth of the spinal surgeries billed to Medicare in FY 2011, and over a third of the hospitals in our sample purchased spinal devices from PODs. Many of these hospitals began purchasing from PODs after 2009. Also, few hospitals in our sample required physicians to disclose their ownership in device companies, such as PODs, to their patients.

In FY 2012, hospitals that purchased from PODs performed more spinal surgeries and had slightly more complex spinal surgery caseloads than hospitals that did not purchase from PODs. After they began purchasing from PODs, hospitals experienced increased rates of growth in the number of spinal surgeries performed as compared to the growth rate for hospitals overall. Determining the cause for the increased rate of spinal procedures was beyond the scope of our review.

In addition, our findings raise questions about PODs' claims that their devices cost less than other suppliers. Within the device categories we examined, PODs' devices either cost the same as or more than devices from companies not owned by physicians. This, combined with the volume of spinal surgeries we found at hospitals that purchase from PODs, may increase the cost of spinal surgery to the Medicare program and beneficiaries over time. Further, hospitals inconsistently required physicians to disclose ownership interests in PODs to either the hospitals or their patients. Thus the ability of hospitals and patients to identify potential conflicts of interest among these providers is reduced.

The Sunshine Act may improve the ability of hospitals and patients to identify physicians' investment in device companies. The Act will require most PODs to report to CMS all physician ownership and investment interests.[18] CMS plans to list these companies and their payments on a publicly available Web site.

This report is being issued directly in final form because it contains no recommendations.

[18] 42 CFR§ 403.906.

APPENDIX A

Detailed Methodology

This study used Medicare claims and enrollment data, a review of the invoices for spinal devices implanted by a representative sample of spinal fusion surgeries billed to Medicare, and questionnaire responses from the hospitals that billed for Medicare for these surgeries.

Scope

This study is national in scope. For the purposes of this study, we defined "spinal surgery" as spinal decompression and spinal fusion. Our sample of claims included surgeries that involved a spinal fusion procedure and were billed to Medicare during FY 2011. We focused our sample on spinal fusion because surgeries involving these procedures were more likely to use implanted spinal devices than surgeries that involved only decompression. See Table A-1 for the complete list of procedures we used. We did not make any judgment on the legality of hospitals' relationships with PODs or on the appropriateness of spinal surgeries performed by surgeons.

Table A-1: ICD-9 Codes Used To Identify Spinal Surgeries

ICD-9 Procedure Code	ICD-9 Procedure Code Description
81.0 / 81.3	Spinal fusion/refusion
81.00 / 81.30	Spinal fusion/refusion, not otherwise specified
81.01 / 81.31	Atlas-axis spinal fusion/refusion
81.02 / 81.32	Other cervical fusion/refusion of the anterior column, anterior technique
81.03 / 81.33	Other cervical fusion/refusion of the posterior column, posterior technique
81.04 / 81.34	Dorsal and dorsolumbar fusion/refusion of the anterior column, anterior technique
81.05 / 81.35	Dorsal and dorsolumbar fusion/refusion of the posterior column, posterior technique
81.06 / 81.36	Lumbar and lumbosacral fusion/refusion of the anterior column, anterior technique
81.07 / 81.37	Lumbar and lumbosacral fusion/refusion of the posterior column, posterior technique
81.08 / 81.38	Lumbar and lumbosacral fusion/refusion of the anterior column, posterior technique
81.39	Refusion of spine, not elsewhere classified
81.62	Fusion or refusion of 2-3 vertebrae
81.63	Fusion or refusion of 4-8 vertebrae
81.64	Fusion or refusion of 9 vertebrae
84.51	Insertion of interbody spinal fusion device

Sample Selection

The sample universe for this file is all inpatient claims with discharge dates in FY 2011. We created our sampling frame by limiting the file to claims that reported one or more ICD-9-CM procedure codes for spinal fusion (see Table A-1 for the complete list of procedures we used). This resulted in population file of 127,547 claims for spinal surgery. From this file, we drew a simple random sample of 1,000 claims billed by 615 hospitals.

We used data from CMS's Certification and Survey Provider Enhanced Reporting (CASPER) database to get the name and address of each hospital in our sample and then forwarded these data to our Office of Investigations for review. As a result of this review, we removed 29 claims from 19 hospitals from our sample, leaving our data collection sample with 971 claims from 596 hospitals.

Data Collection

We administered the hospital questionnaire and asked hospitals to complete an invoice worksheet using secure Web-based survey software from November 2012 through February 2013. To initiate the data collection, we sent each hospital with a claim in our sample an invitation packet via a trackable delivery service. Each packet contained an invitation letter; a printed copy of the hospital questionnaire; a printed copy of the invoice review worksheet; detailed instructions, including a secure hyperlink and login credentials to the Web-based survey; and identifying information for the sampled claim(s) from that hospital. We made three attempts to obtain responses from hospitals. Of the 596 hospitals associated with claims in our data collection sample, 589 hospitals completed the questionnaire. These hospitals also provided invoice worksheet information for 963 of the 971 claims included in our sample.[19] Our overall response rate was 96 percent.

Hospital Questionnaire. We requested each hospital that billed for one or more spinal surgeries in our sample to answer a series of questions about the entities it purchases spinal devices from. We asked each hospital about its awareness of physician-ownership among its suppliers of spinal devices. In doing so, we differentiated between PODs owned by physicians practicing inside the hospital and those owned by physicians practicing outside the hospital. We defined physician-owners as those

[19] Five of the hospitals in our sample refused to provide invoice information detailing spinal devices implanted during eight inpatient stays covered by Medicare. We will refer these hospitals to CMS.

with a partial or full ownership stake through private investment, excluding stock in a publicly traded company.

If a hospital acknowledged purchasing from a POD, we asked it to identify the extent to which certain factors influenced its decision to purchase from a POD: cost savings on devices, quality of devices, clinical effectiveness, preference of surgeons, and additional services. We also asked whether PODs provided services to the hospital, including inventory management, operating room technical support, and coding assistance. We asked each hospital to estimate the date it began purchasing from a POD and asked that it identify the name and ownership structure (i.e., manufacturer, distributor, or unknown type of entity) of the POD(s) it purchased from. Finally, we asked whether the hospital was physician owned and asked about its policies on physician disclosure of ownership in medical device companies.

Invoice Review. We asked each hospital to complete a worksheet for each spinal surgery it had in our sample. To help hospitals identify each surgery, we provided them with the dates of admission from the claims and identified the beneficiaries treated with data from the Medicare Enrollment Database. The worksheet compiled detailed data about the spinal devices used for the surgery. These data included the number and types of devices implanted during the surgery and the price per device net of any manufacturer/distributor discounts or rebates. The worksheet also collected information about the entity that supplied the hospital with the devices, including what the entity's name was, whether the entity was a manufacturer or distributor, and whether the entity was a POD. We asked hospitals to substantiate the data they provided on the worksheet by sending us hard copies of supporting documents, such as invoices and purchase orders. In our analysis, we used only data substantiated by hospitals in this manner.

Pre-Test. Prior to our data collection effort, we pre-tested the hospital questionnaire and invoice review with four hospitals. We purposively selected one spinal procedure claim from each hospital and sent each hospital a test version of our invitation packet. We held a conference call with each hospital after it completed the pretest to discuss its experience with the questionnaire and invoice review and any recommendations for improvement that arose from the pretest. The pretest enabled us to improve our data collection instruments and gather data that informed our sampling plan.

Data Analysis

To determine the extent to which spinal surgeries used spinal devices provided by PODs and to determine whether the cost or quantity of spinal devices used in these surgeries differed for PODs, we used data from the invoice review. We supplemented the invoice review with data provided on the hospital questionnaire responses. Specifically, we cross-referenced PODs that hospitals reported in questionnaire responses to suppliers that hospitals reported on the invoice review to identify suppliers that hospitals may not have identified on the invoice review as being PODs. Our findings on spinal surgeries are generalizable to the population of surgeries involving spinal fusion and spinal revisions billed to Medicare during FY 2011.

To determine the extent to which hospitals associated with our claims sample purchased spinal devices from PODs, we used data from the questionnaire responses and the invoice review. We counted hospitals as purchasing from PODs if they self-identified as using PODs on the responses or invoice review or if we identified them through our cross-referencing of these two data sources. When hospitals reported publicly traded companies as PODs, we excluded those companies from our analysis. The responses identified 119 hospitals that reported purchasing spinal devices from PODs, and our cross-referencing identified a further 84 hospitals, for a total of 203 hospitals in our sample that purchased from PODs.

We also analyzed the questionnaire responses to learn why hospitals purchase spinal devices from PODs and determine the extent to which they have policies on physician disclosure of ownership in medical device companies. Our findings from this analysis are generalizable to the 119 hospitals in our sample that self-identified as using PODs in the responses.

To determine whether rates and complexities of spinal surgeries differed when hospitals purchased from PODs, we first categorized hospitals' spinal surgery claims by complexity of the surgical procedures reported on them. To do so, we used the ICD-9 procedure codes reported on the claims to classify them from least to most complex: decompression-only, simple spinal fusion, or complex spinal fusion. When the procedure codes on a claim reported multiple procedures, we classified that claim on the basis of the most complex procedure reported. For example, when a claim contained procedure codes for both decompression and simple fusion, we classified the claim as simple fusion. We also created a flag for increased complexity when simple or complex fusions were also spinal revisions (repeats or add-ons to prior fusion surgeries). We used these classifications to create rates by type of spinal surgery and three measures

to describe complexity of hospitals' spinal surgery caseloads: the percentage of caseload that was spinal fusion, the percentage that was complex spinal fusion, and the percentage that was spinal revision. We then conducted two separate analyses of hospitals' claims data.

Our first analysis compared the hospitals' caseload of spinal procedures performed before and after hospitals began purchasing devices from PODs. This analysis examined the rate and complexity of spine surgeries performed by hospitals that purchased from PODs in the sixth month before and in the sixth month after they began purchasing from PODs. As a comparison against these hospitals, we analyzed the spinal surgery caseload at all hospitals for the same before and after time periods. For example, if Hospital A started buying from PODs in March 2011, we calculated its rate of spine surgeries before it began purchasing from PODs using all spine surgeries performed by Hospital A in September 2010. We calculated the all-hospital rate using the rate of spine surgeries performed in September 2010, but across all hospitals, not only at Hospital A. Our findings from this analysis are generalizable only to the hospitals in our sample that self-identified as using PODs in the questionnaire responses and that also told us when they first began purchasing spinal devices from PODs. We excluded 17 of the 119 hospitals that self-identified that they used PODs from this analysis because we did not have claims data available for the periods before and after they began purchasing from PODs.

The second analysis compared the spinal surgery caseload during FY 2012 between the 203 hospitals in our sample that purchased from PODs and the remaining 386 hospitals that responded to the questionnaire. Similar to our first analysis, this analysis considered rate and complexity of surgeries for these two groups.

Limitations

This study relies on Medicare claims and the hospital questionnaire responses, which were self-reported by hospitals. We did not independently verify these data. Certain findings are limited to the hospitals associated with our sample of claims and are not generalizable. We describe changes in utilization rates over time, but did not determine the cause of those changes. We relied on ICD-9-CM procedure codes reported by hospitals on Medicare claims to determine the type and complexity of spinal procedures. We also did not assess the clinical benefits or equivalency of POD devices and non-POD devices.

Standards

This study was conducted in accordance with the Quality Standards for Inspection and Evaluation issued by the Council of the Inspectors General on Integrity and Efficiency.

APPENDIX B

Confidence Intervals

Variable	Unweighted N	Weighted N	Point Estimate	95% Confidence Interval	
				Lower Bound	Upper Bound
Percent of Surgeries Using PODs Devices	926	118,109	18.8%	16.3%	21.3%
Mean Number of Devices Used					
For POD Surgeries	174	22,193	12.3	11.2	13.4
For Non-POD Surgeries	752	95,915	14.2	13.5	15.0
For POD Complex Spinal Fusion Surgeries	36	4,592	16.5	13.5	19.4
For Non-POD Complex Spinal Fusion Surgeries	187	23,851	23.0	20.8	25.1
Mean Total Device Cost					
For POD Surgeries	174	22,193	$11,601	$10,448	$12,754
For Non-POD Surgeries	752	95,915	$11,383	$10,705	$12,062
Mean Cost of Devices For POD Surgeries					
Spinal plates	82	90	$2,475	$2,183	$2,768
Other screws	91	293	$699	$602	$795
Interbody fusion devices, non-bone	95	128	$2,821	$2,455	$3,187
Pedicle screws	63	206	$942	$836	$1,048
Rods	74	110	$345	$232	$458
Cap/set screws	60	302	$142	$119	$165
Mean Cost of Devices For Non-POD Surgeries					
Spinal plates	251	263	$1,630	$1,477	$1,784
Other screws	883	2,806	$620	$589	$652
Interbody fusion devices, non-bone	376	476	$2,998	$2,820	$3,177
Pedicle screws	557	1,693	$892	$856	$928
Rods	544	871	$360	$340	$380
Cap/set screws	365	2,261	$148	$135	$162

Source: OIG analysis of hospital questionnaire responses and invoice review data, 2013.

APPENDIX C

Distribution of Sampled Surgeries by State

State	Number of Spinal Surgeries	Number of Surgeries Using POD Devices	Percentage of Surgeries Using POD Devices
California	76	24	32%
Florida	73	11	15%
Texas	65	19	29%
Georgia	44	8	18%
North Carolina	42	5	12%
Pennsylvania	39	9	23%
Michigan	38	4	11%
Ohio	37	6	16%
Missouri	34	11	32%
Illinois	28	5	18%
Minnesota	26	2	8%
New York	26	6	23%
Alabama	25	9	36%
Tennessee	25	4	16%
Virginia	25	4	16%
Oklahoma	23	6	26%
South Carolina	22	3	14%
Indiana	21	3	14%
Kansas	19	1	5%
Maryland	19	2	11%
Colorado	17	3	18%
Massachusetts	16	1	6%
New Jersey	15	0	0%
Washington	15	1	7%
Kentucky	13	1	8%
Louisiana	13	0	0%
Connecticut	12	0	0%
Arizona	11	1	9%
Idaho	11	3	27%
Nevada	11	6	55%
Arkansas	8	1	13%
Mississippi	8	4	50%
Oregon	8	0	0%
Wisconsin	8	0	0%
Iowa	7	0	0%
Nebraska	6	2	33%
South Dakota	6	3	50%
Utah	6	3	50%
Delaware	4	0	0%
Montana	3	0	0%
North Dakota	3	0	0%
New Hampshire	3	0	0%
Wyoming	3	1	33%
Alaska	2	0	0%
Hawaii	2	0	0%
Maine	2	0	0%
New Mexico	2	1	50%
District of Columbia	1	0	0%
Rhode Island	1	0	0%
Vermont	1	1	100%
West Virginia	1	0	0%
Total	**926**	**174**	**19%**

Source: OIG analysis of hospital questionnaire responses and invoice review data, 2013.

ACKNOWLEDGMENTS

This report was prepared under the direction of Joyce Greenleaf, Regional Inspector General for Evaluation and Inspections in the Boston regional office; Kenneth Price, Deputy Regional Inspector General; and Russell Hereford, Deputy Regional Inspector General.

Jesse Valente served as the team leader for this study, and Alyson Cooper served as the lead analyst. Other Office of Evaluation and Inspections staff from the Boston regional office who contributed to this study include Tim Chettiath, Melissa Hafner, and Elizabeth Havener. Central office staff who provided support include Clarence Arnold, Heather Barton, Berivan Demir Neubert, and Christine Moritz.

Office of Inspector General

http://oig.hhs.gov

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

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The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

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Intermountain Healthcare

July 26, 2013

VIA ELECTRONIC MAIL [redacted] AND
FIRST CLASS U.S. MAIL (RETURN RECEIPT REQUESTED)

[redacted]

Re: Action Required: Intermountain Policy on Physician-Owned Device Companies

[redacted]

As you may know, on March 26, 2013, the OIG issued a "Special Fraud Alert: Physician-Owned Entities." A copy is attached for your reference. The Fraud Alert addresses physician-owned entities that derive revenue from "selling, or arranging for the sale of, implantable medical devices" and "includes physician-owned entities that purport to design or manufacture, typically under contractual arrangements, their own medical devices or instrumentation." The OIG refers to such entities as "PODs," but notes that the same principles would apply when evaluating arrangements involving other types of Physician-Owned Entities (POEs).

Prior guidance from the OIG on the subject of POEs had been equivocal, indicating only that such arrangements could potentially implicate the Federal Antikickback Statute and should be evaluated based on the particular facts and circumstances. By contrast, the Fraud Alert suggests heightened concern about POEs, which the OIG describes as "inherently suspect under the anti-kickback statute."

In response, under the direction of Intermountain's President and CEO, Intermountain has adopted an updated policy regarding contracting with POEs. A copy of the policy is attached for your reference.

The basic thrust of the policy is quite simple: Intermountain will no longer contract with POEs, and will also be discontinuing purchases from existing POEs.

Under the Policy, a POE includes any entity that is owned in any part by a physician or an immediate family member of a physician. There is no minimum percentage that needs to be reached to trigger the prohibition. "Ownership" can mean shares, partnership units, bonds and other forms of debt, or royalties based on purchases by the ordering physician.

[redacted]

We are writing you to reconfirm that you are not a POE under the Policy's definition, as you have previously represented. You will qualify as a POE if you have any owner who is a physician, or whose immediate family member is a physician. Under the Policy, "immediate family member" means husband or wife; birth or adoptive parent, child or sibling; stepparent, stepchild, stepbrother or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of grandparent or grandchild.

Please take a moment to review the Policy and, if you are not a POE, sign the attached attestation. **If Intermountain does not receive a signed copy of the attached attestation prior to August 9, 2013, Intermountain will initiate a process to terminate any further purchases from** [redacted] False or incomplete attestations will be taken seriously, and will be treated both as a breach of the purchase agreement between [redacted] and Intermountain and, depending on the facts, unprofessional conduct that may result in disciplinary action through the medical staff process.

We recognize that this Policy will change some existing arrangements, but believe that ultimately this is the right thing to do. We very much value your contribution over the years, and the contribution made by every supplier and physician at Intermountain in providing the care for which Intermountain is known.

If you have any questions about this letter or the Policy, please contact me at (801) 442-1502. Also, please contact Jeramy Green at (801) 442-3557 if you believe [redacted] does not qualify as a POE.

Sincerely,

Suzie Draper
Vice President of Business Ethics and Compliance
Intermountain Healthcare

cc: Dr. Brent Wallace, Chief Medical Officer, Intermountain Healthcare
Brent Johnson, Chief Purchasing Officer, Intermountain Healthcare
Jeramy Green, Esq., Intermountain Healthcare

Physician Owned Entities Financial Arrangements Policy

Policy Statement

Except as set forth in this Policy, Intermountain will not enter into any agreement to purchase from a Physician-Owned Entity any item or service other than a professional medical service personally furnished by a Physician or by an allied health professional employed by the Physician-Owned Entity under a Physician's supervision.

Scope

IHC Health Services, Inc.

Definitions

Immediate Family Member - Husband or wife; birth or adoptive parent, child or sibling; stepparent, stepchild, stepbrother or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of grandparent or grandchild.

Ownership or Investment Interest - Has the same meaning set forth in 42 C.F.R. § 411.354(b) or any successor regulation. For these purposes, ownership may be direct or indirect, and may be by means of equity or debt. There is no minimum percentage ownership below which this policy would not apply. Investments in publicly-traded securities or mutual funds are excluded from the definition so long as they meet the requirements of 42 C.F.R. § 411.356(a) or (b) or any successor regulation.

Royalty Interest - Payments made to the creator/owner of an item or intellectual property for each unit/copy of the property sold.

Physician - A doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor.

Physician-Owned Entity (POE) - Any entity in which a Physician or Immediate Family Member of a Physician holds an ownership, investment, or royalty interest if royalties are paid on purchases resulting from the royalty holder's order.

Provisions

1 If no Physician owner (or Physician who is an Immediate Family Member of any owner) of the POE is in a position to generate business for Intermountain, the prohibition does not apply. Utah-based physicians are presumed to be in a position to generate business for Intermountain.

1.1 Evidence that the POE satisfies provision 1 above must be submitted to and approved by the Anti-Kickback Statue (AKS) Committee before entering into any financial arrangement with the POE.

1.2 Intermountain may contract for an item or service meeting this exception so long as the contract:

1.2.1 is in writing;

1.2.2 is fully executed and effective prior to the first purchase;

1.2.3 includes a representation and warranty and ongoing covenant from the Physician-Owned Entity that the entity does not and will not have any of the following eight suspect characteristics identified in the Department of Health and Human Services' Office of Inspector General's "Special Fraud Alert: Physician-Owned Entities" or later related regulations or guidance;

- The size of the investment offered to each Physician varies with the expected or actual volume or value of devices used by the Physician.
- Distributions are not made in proportion to ownership interest, or Physician-owners pay different prices for their ownership interests, because of the expected or actual volume or value of devices used by the Physicians.
- Physician-owners condition their referrals to hospitals or ambulatory surgical centers (ASCs) on their purchase of the POE's devices through coercion or promises, for example, by stating or implying they will perform surgeries or refer patients elsewhere if a hospital or an ASC does not purchase devices from the POE, by promising or implying they will move surgeries to the hospital or ASC if it purchases devices from the POE, or by requiring a hospital or an ASC to enter into an

exclusive purchase arrangement with the POE.

- Physician-owners are required, pressured, or actively encouraged to refer, recommend, or arrange for the purchase of the devices sold by the POE or, conversely, are threatened with, or experience, negative repercussions (e.g., decreased distributions, required divestiture) for failing to use the POE's devices for their patients.
- The POE retains the right to repurchase a Physician-owner's interest for the Physician's failure or inability (through relocation, retirement, or otherwise) to refer, recommend, or arrange for the purchase of the POE's devices.
- The POE is a shell entity that does not conduct appropriate product evaluations, maintain or manage sufficient inventory in its own facility, or employ or otherwise contract with personnel necessary for operations.
- The POE does not maintain continuous oversight of all distribution functions.
- When a hospital or an ASC requires Physicians to disclose conflicts of interest, the POE's Physician-owners either fail to inform the hospital or ASC of, or actively conceal through misrepresentations, their ownership interest in the POE.

1.2.4 includes a representation and warranty and ongoing covenant that no Physician owner or Physician who is an Immediate Family Member of any owner of the POE is in a position to generate business for Intermountain, and requires immediate notice to Intermountain if that is no longer true; and

1.2.5 provides for the right of Intermountain to terminate the agreement no later than ten (10) days after any such notice.

2 An exception to this policy may also be made for disruptive technologies when approved by the Intermountain President/Chief Executive Officer, Chief Medical Officer, and General Counsel (see *Disruptive Technologies Exception Guideline*).

3 The Vice President of Business Ethics and Compliance works with Supply Chain Organization staff to terminate or non-renew existing arrangements that do not meet the requirements of this Policy in an orderly fashion, with first priority given to implantable medical devices.

Exceptions

None

Primary Sources

Special Fraud Alert: Physician-Owned Entities

42 C.F.R. § 411.354(b)

42 C.F.R. § 411.356(a) and (b)

Secondary Materials

"Physician Investment in Medical Device Manufacturers and Distributors" (Letter from the OIG) (Oct. 6, 2006)

Disruptive Technologies Exception Guideline

Effective Date:

SFC 0104

Intermountain Healthcare is an At-Will Employer. The terms of this policy do not, either directly or indirectly, constitute any form of employment contract or other binding agreement between any employee and Intermountain.

Contact Intermountain Healthcare's Legal Department for questions.

LHP
LHP Hospital Group, Inc.®

Culture · Collaboration · Capital

August 18, 2014

To: Spine Manufacturer/Vendor

From: Courtney Bohman, LHP Supply Chain Value Analysis Director CKB

Scott Remmich, LHP Director and Deputy Chief Compliance Officer SR

Re: Approved Spine Manufacturers/Vendors

It is of most importance to LHP that our patients are provided with the best medical options that are free from potential conflicts while maintaining the highest standard of quality, ethics, and compliance. With respect to the Special Fraud Alert released by the Office of Inspector General (OIG) whereby informing the healthcare community that Physician Owned Distributorships ("PODs") are inherently suspect of violating certain Federal statutes, LHP underwent internal investigation of the manufacturers/vendors utilized by our hospital system

In April, LHP directed the evaluation of twenty-five Spine manufacturers. As a result of this evaluation of the current manufacturer/distributor relationship, LHP has made the decision to mitigate risk via manufacturer elimination and standardization as a Company. The evaluation process utilized multiple data points provided by the manufacturer to arrive at a conclusion, including but not limited to ownership model.

We have approved the following manufacturers for use by the LHP medical staff:

- DePuy/Synthes Spine
- Globus Medical
- Integra Lifesciences
- Medtronic
- NuVasive
- OrthoFix
- Stryker
- Zimmer/Biomet

We began implementing this initiative system wide starting **August 1, 2014**. Contractual negotiation discussions will begin immediately if not already underway or completed.

All questions regarding this decision should be directed to courtney.bohman@lhphg.com.

Health Law @ MINTZ LEVIN
Mintz Levin Cohn Ferris Glovsky and Popeo PC

Health Law Alert

FEBRUARY 4, 2013

CMS Publishes Final Sunshine Act Rule; Data Collection to Begin on August 1, 2013

BY THOMAS S. CRANE, BRIAN P. DUNPHY, KAREN S. LOVITCH, AND KATE F. STEWART

The long-awaited final rule (the Final Rule) implementing the Physician Payments Sunshine Act (Sunshine Act) has arrived at the Federal Register. It amends key definitions and adds new terms; retains broad reporting provisions but includes new limitations; exempts certain continuing medical education (CME) payments from disclosure; and includes additional reporting guidance.

The Sunshine Act requires applicable manufacturers of drugs, devices, biologics, or medical supplies covered by Medicare, Medicaid, or the Children's Health Insurance Program (Manufacturers) to collect and report payments and other transfers of value to physicians and teaching hospitals. These requirements apply if a Manufacturer sells or distributes at least one covered drug, device, biologic, or medical supply (Covered Product). The Sunshine Act also requires Manufacturers and Group Purchasing Organizations (GPOs) to disclose ownership or investment interests held by physicians or their immediate family members.

Most importantly, the Final Rule requires Manufacturers and GPOs to begin collecting the required data on August 1, 2013 and to report the remaining calendar year 2013 data to the Centers for Medicare & Medicaid Services (CMS) by March 31, 2014.

The delay in publication of the Final Rule is well documented. CMS published the Proposed Rule in December 2011 and left many questions unanswered, as explained in our analysis of the Proposed Rule previously published in BNA's Health Care Fraud Report. It therefore comes as no surprise that CMS received more than 300 comments on the Proposed Rule. While awaiting publication of the Final Rule, Manufacturers and GPOs remained in the dark about many operational and implementation details and thus could not fully implement processes to comply with the Sunshine Act's data collection and reporting requirements.

The Final Rule provides Manufacturers and GPOs with long-awaited guidance in many areas and differs from the Proposed Rule in several key respects, some of which are discussed below. Mintz Levin also has prepared a chart that summarizes the differences between the Proposed Rule and the Final Rule.

Definitions – Changes and Additions

Among other things, the definitions determine to which entities and which products the Sunshine Act's disclosure obligations apply. The Final Rule includes important changes to the proposed definitions as well as several new terms.

- The definition of "applicable manufacturer" expressly excludes distributors or wholesalers that do not hold title to Covered Products. In addition, CMS clarified in the Final Rule that entities such as hospitals, hospital-based pharmacies, and laboratories that manufacture a

Covered Product solely for internal use or for use by their patients also do not qualify as Manufacturers.

  - The Final Rule adds the defined term "operating in the United States," which helps to establish whether an entity qualifies as a Manufacturer.
  - The Proposed Rule established that an entity under "common ownership" with a Manufacturer is also a Manufacturer, and the Final Rule sets the ownership threshold at five percent direct or indirect ownership of two entities by the same individual, individuals, entity, or entities. As discussed below, CMS placed limits on reporting requirements for entities under common ownership.

- The definition of "applicable group purchasing organization" includes entities that "operate in the United States" and purchase, arrange for, or negotiate the purchase of Covered Products for a group of individuals and entities, but (rather than "and," as stated in the Proposed Rule) "not for use by the entity itself." By making few changes, CMS retained a definition that includes physician-owned distributors (PODs).
- Whether a product is a "covered drug, device, biological, or medical supply" hinges partly on whether payments are "available" from Medicare, Medicaid, or the CHIP. To account for the wide variety of reimbursement structures used by these government health care programs, CMS clarified that payment is "available" through a fee schedule or formulary, or as part of a bundled payment.
- "Covered recipients" include physicians and teaching hospitals. In the Final Rule, CMS stated that it will publish a list of teaching hospitals 90 days before data collection begins. CMS also explained that "physicians" must be authorized to practice and have a current license.
- The Final Rule adds the term "indirect payments or other transfers of value," which means payments or other transfers of value made by a Manufacturer (or GPO) to a covered recipient (or a physician owner or investor) through a third party, where the Manufacturer (or GPO) "requires, instructs, directs, or otherwise causes the third party" to provide the payment or transfer of value to a covered recipient (or a physician owner or investor). Indirect payments need not be reported if a Manufacturer is unaware of the covered recipient's identity. According to CMS, the term "know" has the same meaning as in the False Claims Act, which includes actual knowledge of information, deliberate ignorance, or reckless disregard.
- The new phrase "payment or transfer of value" is defined, consistent with the Sunshine Act, to mean a transfer of anything of value. In contrast to long-standing interpretations of the Office of Inspector General for the Department of Health and Human Services in other contexts, CMS stated that a product has "value" for the purposes of the Final Rule if it has "discernible economic value on the open market."
- The new term "related to a covered drug, device, biological, or medical supply" means that a payment or other transfer of value is made in reference to or in connection with one or more Covered Products. This phrase is used in the Final Rule's new reporting limitations in 42 C.F.R. § 403.904(b).

Reporting of Payments or Transfers of Value

CMS significantly revised the general disclosure rule for Manufacturers. Manufacturers must disclose direct and indirect payments or other transfers of value to covered recipients, including payments to a third party, "at the request of or designated by the applicable manufacturer on behalf of a covered recipient." The Final Rule also defines several limits on reporting. First, Manufacturers for whom gross revenue from Covered Products constituted less than 10 percent of total (gross) revenue during the fiscal year preceding the reporting year must

SFC 0108

only report payments related to Covered Products. Second, Manufacturers that qualify as Manufacturers through common ownership must only report payments or transfers of value related to a Covered Product for which they provided "assistance or support" to the Manufacturer engaged in the production of the Covered Product. Third, Manufacturers with separate operating divisions that do not manufacture any Covered Products must only report payments to covered recipients related to the activities of these separate divisions if those payments or other transfers of value are related to a Covered Product.

Reporting Exceptions

The Sunshine Act includes fourteen exceptions from disclosure. We anticipate that the following exceptions will be used frequently:

- Payments of less than $10 need not be reported unless payments to a covered recipient exceed $100 annually. The $10 threshold will increase every year according to the consumer price index. CMS clarified that Manufacturers do not have to track incidental items worth less than $10 (e.g., pens and note pads) provided at large-scale conferences. Similarly, although not a defined exception, Manufacturers do not have to track or report food or drinks, such as buffet meals or coffee, made generally available at a conference or large-scale event.
- Educational materials and items (CMS added "items" in the Final Rule) intended for use by or with patients are not subject to the reporting requirements.
- Discounts and rebates are excluded from reporting, which is notable because discounts and rebates create something of value flowing from a Manufacturer to a covered recipient. The Final Rule surprisingly does not specify that credits and charge-backs should be considered as discounts.
- Samples intended for patient use, including coupons and vouchers that patients can use to obtain samples, are exempt from the Sunshine Act's requirements. The Final Rule makes clear that the term "samples" includes devices and medical supplies.

The Final Rule also establishes an exemption for certain payments related to speaking at accredited or certified CME programs because, according to CMS, such programs include safeguards "designed to reduce industry influence."

Required Information, Including the "Form" and "Nature" of Payments

The Final Rule specifies the contents of annual reports, including the information that Manufacturers must report for each payment or transfer of value (including payments to covered recipients through third parties). The Final Rule provides that Manufacturers under common ownership may submit a consolidated report. It also defines the procedures for submission of reports and a 45-day period for covered recipients to review and dispute data. Among other things, Manufacturers must report the "form" of payment, the "nature" of payment, and the names of up to five related Covered Products (or report "none") for each payment or transfer of value. CMS provided additional guidance in the Final Rule's Preamble related to the form and nature of payment categories that Manufacturers will find useful. The following information about the "form" and "nature" of payments is notable:

- Form of payment - Manufacturers must report the "form" that "best describes" the payment or transfer of value: cash; in-kind items or services; stock, stock option, or any other ownership interest; dividend, profit, or return on investment.
- Nature of payment - Manufacturers must categorize the "nature" of each payment or transfer of value to a covered recipient – or any separable part of that payment – into one of the seventeen categories defined in the Final Rule that "best describes" the payment or transfer of value (e.g., consulting, research, charitable contributions, food and beverages, and travel). CMS added new categories related to CME programs and "space rental or facility fees" for teaching hospitals only, and also eliminated the catchall category "Other."

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The four different "nature" categories related to education listed below are likely to lead to confusion when payments related to education are reported:

- compensation for speaking at an event other than a CME program;
- compensation for serving as faculty or as a speaker at an unaccredited and non-certified CME program (a new category);
- compensation for serving as faculty or as a speaker at an accredited or certified CME program (a new category); and
- education, unrelated to speaking.

The Final Rule includes special rules for reporting payments for research and food and beverages, and it provides for delayed publication of payments made under product research or development agreements and clinical investigations.

Reports of Physician Ownership

Manufacturers and GPOs must submit an annual report to CMS regarding all ownership and investment interests held by physicians or immediate family members of physicians during the preceding year. CMS explained that it defined an ownership or investment interest in a Manufacturer or GPO in a similar manner as defined in the physician self-referral regulation (referred to as the "Stark Law"). Manufacturers and GPOs do not have to report indirect ownership or investment interests held by physicians or immediate family members of physicians about which they do not know. While GPOs generally are not required to report payments to covered recipients, GPOs do need to report direct and indirect payments or transfers of value to physicians with an ownership or investment interest.

Penalties

The penalties for failing to comply with the Sunshine Act can be severe. Manufacturers or GPOs who fail to "timely, accurately, or completely" report the required information can be subject to a civil monetary penalty (CMP) ranging from $1,000 to $10,000 for each payment or transfer of value, or ownership or investment interest, not reported (up to $150,000) and from $10,000 to $100,000 for each "knowing" failure to report (up to $1,000,000). The CMPs are aggregated separately, and a Manufacturer or GPO could be subject to a maximum penalty of $1,150,000. In addition, CMS clarified that, for errors corrected during the review and correction period, Manufacturers will not be "subject to penalties for failure to report in instances when the original submission was made in good faith."

CMS explained that the mere reporting of payments should not lead to the conclusion that the parties involved were engaged in wrongdoing. However, CMS emphasized that compliance with the Sunshine Act's reporting requirements does not exempt Manufacturers, GPOs, covered recipients, and others from potential liability under the Anti-Kickback Statute or the False Claims Act.

Preemption

Like the Proposed Rule, the Final Rule acknowledged that preemption of state law took effect on January 1, 2012. Manufacturers should continue to carefully assess the extent to which the Sunshine Act preempts state laws, such as those in effect in Massachusetts.

Conclusion

Mintz Levin is continuing to review the Final Rule, and we will publish additional educational materials in the coming weeks. Please refer to our blog, www.healthlawpolicymatters.com, for updates and additional information.

* * *

The Final Rule will be published in the Federal Register on February 08, 2013.

SFC 0110

View our chart summarizing the differences between the Proposed Rule and the Final Rule.

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2637-0213-NAT-HL

SFC 0111

Subject: Purchases from Physician-Owned Intermediaries/Distributors	**Policy Number:** PROV-ICP-723	
Department: Supply Chain	☒ New ☐ Revised ☐ Reviewed	**Date:** 2/9/2012
Executive Sponsor: Vice President, General Counsel / Vice President, Chief Risk Officer	**Policy Owner:** Vice President, Supply Chain	
Approved by: John Koster, MD - President/CEO	**Implementation Date:** 2/9/2012	

Scope: This policy applies to all Providence Health & Services ("Providence") owned and majority owned entities. This is a management-level policy recommended by the Leadership Council and approved and signed by the President/CEO.

Purpose: The Office of Inspector General ("OIG") has expressed concern that physician investments in medical device and distribution entities should be closely scrutinized under the fraud and abuse laws. This policy is intended to prevent Providence from entering into relationships with such businesses.

Policy: Providence generally prohibits the purchase of items and services, including but not limited to pharmaceuticals, implants, instruments and other medical devices from any Physician Owned Vendor ("POV").

Providence is committed to acquiring the highest quality products and services at the lowest possible cost. In light of national scrutiny with respect to relationships between hospitals and physician-owned entities that supply items and services including implantable orthopedic and cardiac devices, among others, Providence will prohibit Providence entities from purchasing an item or service from a POV that is either owned or controlled by one or more physicians, or immediate family members of such physicians where such physician is a member of the medical staff of any Providence hospital or has a financial relationship with Providence.

Purchase under this policy does not include: professional service agreements (e.g., agreements with a physician or physician practice to provide services in emergency departments, radiology or as hospitalists or intensivists; leases entered into between Providence and POVs; or joint ventures or other legal entity between Providence and such POV or directly with a physician(s). Additionally, this policy is not intended to prevent the purchase of an item from a third party where a physician has sold rights to that third party and receives a royalty or other payment for those rights (e.g., where a physician has sold intellectual property rights to a manufacturer and that manufacturer in turn sells a product to Providence). Such arrangements discussed in this paragraph are covered under other policies and practices within Providence and the Department of Legal Affairs should be consulted with for any questions that arise.

Providence will not purchase pharmaceuticals, implants, instruments or other medical devices if any purpose of the purchase is to generate or maintain referrals from a physician who has, directly or indirectly, a financial interest in the utilization of the item purchased.

In rare circumstances an exception to this policy may be warranted. A request for an exception under this policy must be made through your ministry materiel management to the Office of Supply Chain

Management and should include details surrounding the arrangement to be considered, the parties involved and information known about the ownership interest by the physician(s). Such exception to this policy must be approved by the VP/Supply Chain, VP/Chief Risk Officer and VP/General Counsel.

No Providence entity may enter into any agreement, contract or other commitment ("contract(s)") for the purchase of items or services if it determines that the transaction is intended to influence the referral pattern from a physician who has, directly or indirectly, a financial interest in the utilization of the item or service to be purchased.

Where relationships with POVs are necessary, the relationship must be consistent with fair market value and satisfy all other applicable legal standards.

Contracts with POVs shall contain an ongoing obligation to disclose, during the term of the contract, any financial relationship (whether direct or indirect) involving physicians who are either employed by Providence or are a member of the medical staff of any Providence hospital or have a financial relationship with Providence and shall include provisions for the prompt termination of the business relationship in the event of a failure to disclose or the disclosure of a financial relationship which may be prohibited under this policy. The provisions of this section of the policy shall also apply to financial relationships with such physicians' immediate family members.

Definitions:

Immediate Family Member: includes an individual's spouse, parents, grandparents, children, grandchildren, great grandchildren, siblings (whether step, whole or half blood), and the spouses of children, grandchildren, great grandchildren and siblings.

Physician Owned Vendor: is defined as any entity which is owned or controlled by physicians who are on the medical staff of a Providence hospital or with which Providence has a financial relationship or an immediate family member of such physician

References:
PROV-GOV-208, Conflicts of Interest Policy

ORIGINAL

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

-vs-

D-1 ARIA OMAR SABIT, M.D.,
Defendant.
_____/

No. 14-20779 & 15-20311
HON. PAUL D. BORMAN

OFFENSE(S):

Case No. 14-20779
Counts One – Four:
18 U.S.C. §1347
(Health Care Fraud)

Count Five:
21 U.S.C. §841(a)(1)
(Unlawful Distribution of a Controlled Substance)

Case No. 15-20311
Count One:
Conspiracy to Commit Health Care Fraud
18. U.S.C. 1349

MAXIMUM PENALTY:

Case No. 14-20779
Counts One – Four:
Up to 20 Years' Imprisonment
Count Five:
Up to 20 Years' Imprisonment

Case No. 15-20311
Count One:
Up to 20 Years' Imprisonment

Defendant's Initials: AS

MAXIMUM FINE:

Case No. 14-20779
Counts One – Four:
$250,000

Count Five:
$1 Million Dollars

Case No. 15-20311
Count One: $250,000

RULE 11 PLEA AGREEMENT

Pursuant to Rule 11 of the Federal Rules of Criminal Procedure, defendant DR. ARIA OMAR SABIT and the government agree as follows:

1. GUILTY PLEA

A. Counts of Conviction – Case No. 14-20779

Defendant will enter a plea of guilty to **Counts One, Two, Three, Four and Five** of the First Superseding Information. Counts One through Four charges the defendant with conspiracy to commit health care fraud, in violation of 18 U.S.C. §1349. Defendant's offense resulted in serious bodily injury as defined by 18 U.S.C. §1365 and, therefore, the statutory maximum penalty for Count One is 20 years' imprisonment, a fine that is the greater of $250,000 or twice the pecuniary gain or loss pursuant to 18 U.S.C. §3571(d), and a three year term of supervised release.

Defendant's Initials: AS

Count Five charges the defendant with unlawful distribution of a controlled substance in violation of 21 U.S.C. §841(a)(1). The statutory maximum penalty is 20 years' imprisonment, a fine of $1,000,000, and a minimum three year term of supervised release.

Count of Conviction – Case No. 15-20311

Defendant will enter a plea of guilty to **Count One** of the Information. Count One charges the defendant with conspiracy to commit health care fraud, in violation of 18 U.S.C. §1349. Defendant's offense resulted in serious bodily injury as defined by 18 U.S.C. §1365 and, therefore, the statutory maximum penalty for Count One is 20 years' imprisonment, a fine that is the greater of $250,000 or twice the pecuniary gain or loss pursuant to 18 U.S.C. §3571(d), and a three year term of supervised release.

B. Elements of Offense – Case No. 14-20779

The elements of Counts One - Four are:

First: Defendant knowingly devised a scheme or artifice to defraud a health care benefit program in connection with the delivery of or payment for health care benefits, items, or services;

Second: Defendant executed or attempted to execute this scheme or artifice to defraud; and

Third: Defendant acted with intent to defraud.

The elements of Count Five are:

Defendant's Initials: AS

One: The defendant knowingly and intentionally distributed a controlled substance, to wit: a prescription for Roxicodone (oxycodone HCl) outside the course of legitimate medical practice and without medical necessity;

Two: At the time of such distribution, the defendant knew that the substance distributed was Roxicodone (oxycodone HCl).

The term "knowingly," as used to describe the alleged state of mind of a defendant, means that he was conscious and aware of his action, realized what he was doing or what was happening around him, and did not fail to act because of ignorance, mistake or accident.

Elements of the Offense – Case No. 15-20311

The elements of Count One of the Information are:

First: Two or more persons, in some way or manner, came to a mutual understanding to try to accomplish a common and unlawful plan to commit the crime of health care fraud, as charged in the Information; and,

Second: The defendant knowingly became a member of the conspiracy with the intent to advance it.

The elements of health care fraud, the object of the conspiracy alleged in Count One of the Information, are:

First: The defendant knowingly and willfully executed and attempted to execute a scheme to defraud any health care benefit program, and to obtain, by means of false or fraudulent pretenses, representations, or promises any of the money or property owned by, or in the control of, a health care benefit program, in connection with the delivery of and payment for health care

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benefits, items, or services;

Second: The scheme related to a material fact and included a material misrepresentation or concealment of a material fact; and,

Third: The defendant had the intent to defraud.

The term "knowingly," as used to described defendant's state of mind to commit the offense alleged in Count One of the Information, has the same meaning as it does for the offenses alleged in the First Superseding Information in Case No. 14-20779. The term "willfully," as used to describe defendant's precise mental state, means only that he acted with the intent to violate the law and not with any evil motive or bad purpose. The term "intent to defraud," as used to describe defendant's intent to commit the offense alleged in Count One of the Information, means that defendant only intended to do an act that the law proscribes.

C. Factual Basis for Guilty Plea – Case No. 14-20779

The following facts are a sufficient and accurate basis for defendant's guilty plea:

Dr. ARIA OMAR SABIT, M.D., was a Medical Doctor, specifically a neurosurgeon, licensed in the State of Michigan. ARIA OMAR SABIT, M.D., owned and operated a medical clinic, the Michigan Brain and Spine Physicians Group (MBSPG) with various locations in the Eastern District of Michigan. ARIA OMAR SABIT, M.D., was enrolled as a participating provider with

Defendant's Initials: AS

Medicare, Medicaid, and private insurance companies, including BCBSM. Sabit also obtained medical privileges at various hospitals in the Eastern District of Michigan, including but not limited to: Sinai Grace, Detroit Medical Center (DMC); McLaren Lapeer Regional Hospital, and Doctor's Hospital of Michigan.

From on or about January 2011, and continuing through on or about November 23, 2014, the exact dates being unknown, in Oakland and Lapeer Counties, in the Eastern District of Michigan, and elsewhere, the defendant ARIA OMAR SABIT, M.D., in connection with the delivery of and payment for health care benefits, items, and services, did knowingly and willfully execute, and attempt to execute, a scheme and artifice to defraud a health care benefit program affecting commerce, as defined in Title 18, United States Code, Section 24(b), that is Medicare, Medicaid, Auto Insurance Companies and private insurance companies, and to obtain by means of materially false and fraudulent pretenses, representations, and promises, money and property owned by and under the custody and control of Medicare, Medicaid, Auto Insurance Companies, and private insurance companies in connection with the delivery of and payment for health care benefits.

Beginning in approximately 2011, and continuing through November 2014, ARIA OMAR SABIT, M.D., derived significant profits by convincing patients to undergo spinal fusion surgeries with instrumentation, which he never rendered, by

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billing public and private healthcare benefit programs for those fraudulent services.

As part of the scheme, ARIA OMAR SABIT, M.D., would operate on the patient and dictate that he had performed a spinal fusion with instrumentation, which he never performed. This invasive surgery would cause serious bodily injury to the patient. In addition, ARIA OMAR SABIT'S, operative reports and treatment records contained false statements about the procedure performed, and the instrumentation used in the procedure. As part of the scheme, ARIA OMAR SABIT, M.D., would implant cortical bone dowels and dictate in his operative report that he had implanted instrumentation. ARIA OMAR SABIT, M.D., then fraudulently billed public and private health care programs for instrumentation, when in fact the implants were tissue. As part of this scheme to defraud, ARIA OMAR SABIT, M.D., failed to render services in relation to lumbar and thoracic fusion surgeries; including in certain instances, billing for implants that were in fact not provided.

Count One:

On or about February 29, 2012, Patient-1, whose initials are L.C., underwent a spinal surgery, performed by ARIA OMAR SABIT, M.D. The surgery was performed at Doctor's Hospital of Michigan which is located in Pontiac, Michigan. ARIA OMAR SABIT, M.D., produced an Operative Report for the surgery he purportedly performed on Patient-1. Included within the "Procedure Performed"

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and "Details of Operation" sections of the report, ARIA OMAR SABIT, M.D., indicated he, among other procedures, performed a fusion with instrumentation at the L4, L5 and S1 levels. ARIA OMAR SABIT, M.D., also noted in his operative report that he utilized the Zimmer transfacet screw system.

Subsequent diagnostic imaging confirmed ARIA OMAR SABIT, M.D failed to place instrumentation, specifically transfacet screws, in the spinal column of Paitent-1 and failed to perform a posterolateral fusion. Patient-1 was insured under Medicaid. ARIA OMAR SABIT, M.D., submitted claims or caused MBSPG to submit claims to Medicaid in the amount of $26,067 for the fusion and instrumentation portion of surgery he failed to perform on Patient-1.

Count Two:

On or about April 13, 2012, Patient-2, whose initials are C. D., underwent spinal surgery performed by ARIA OMAR SABIT, M.D. The surgery was performed at Sinai Grace Hospital, DMC, in Detroit, Michigan. SABIT produced an Operative Report for the surgery he purportedly performed on Patient-2. Included within the "Procedure Performed" and "Operative Procedure" sections of the report, ARIA OMAR SABIT, M.D. indicated he performed a fusion with instrumentation at the L4, L5 and S1 levels. The report also indicated ARIA OMAR SABIT, M.D., placed the Zimmer transfacet screw system at the L4-L5 and the L5-S1.

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Subsequent diagnostic imaging of Patient-2 confirmed ARIA OMAR SABIT, M.D failed to place instrumentation, specifically transfacet screws, in the spinal column of Paitent-2 and failed to perform a posterolateral fusion. Instead, Sabit implanted one cortical bone dowel which is comprised of tissue. Patient-2 was insured under Medicaid. ARIA OMAR SABIT, M.D., submitted claims or caused MBSPG to submit claims to Medicaid in the amount of $28,605 for the fusion and instrumentation portion of surgery he failed to perform on Patient-2.

Count Three:

On or about March 21, 2012, Patient-3, whose initials are C.S., underwent a spinal surgery performed by ARIA OMAR SABIT, M.D., the surgery was performed at Doctor's Hospital of Michigan, Pontiac, Michigan. SABIT produced an Operative Report for the surgery he purportedly performed on Patient-3. Included within the "Procedure Performed" and "Details of Operation" sections of the report, SABIT indicated he, among other procedures, performed a fusion with instrumentation at the L4-L5 level. The report further indicated that ARIA OMAR SABIT, M.D., utilized the Zimmer transfacet screw system and placed two transfacet screws at the L4-L5.

Subsequent diagnostic imaging of Patient-3 confirmed ARIA OMAR SABIT, M.D failed to place instrumentation, specifically transfacet screws, in the spinal

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column of Paitent-3 and failed to perform a posterolateral fusion. Patient-3 was insured by BCBSM health insurance. ARIA OMAR SABIT, M.D., submitted claims or, caused MBSPG to submit claims to BCBSM in the amount of $20,383 for the fusion surgery he performed on Patient-3.

Count Four:

On or about March 31, 2012, Patient-4, whose initials are S.R., underwent spinal surgery, performed by ARIA OMAR SABIT, M.D. The surgery was performed at McLaren Lapeer Regional Hospital, Lapeer, Michigan. ARIA OMAR SABIT, M.D., produced an Operative Report for the surgery he purportedly performed on Patient-4. Included within the "Procedure" and "Operation" sections of the report, SABIT indicated he, among other procedures, performed a fusion with instrumentation at the L4, L5, and S-1 levels. The report further indicated that ARIA OMAR SABIT, M.D., utilized the Zimmer transfacet screw system and placed transfacet screws at the L4-5 and the L5-S1.

Subsequent diagnostic imaging of Patient-4 confirmed ARIA OMAR SABIT, M.D failed to place instrumentation, specifically transfacet screws, in the spinal column of Paitent-4 and failed to perform a posterolateral fusion. Instead, Sabit implanted two cortical bone dowels which are comprised of tissue. Patient-4 was insured under Medicaid. ARIA OMAR SABIT, M.D., submitted claims or caused

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MBSPG to submit claims to Medicaid in the amount of $27,205 for the fusion and instrumentation portion of surgery he failed to perform on Patient-4.

Count Five:

On or about October 22, 2012, defendant, ARIA OMAR SABIT, M.D., did knowingly, intentionally, and unlawfully distribute a Schedule II prescription drug controlled substance, specifically Roxicodone (oxycodone HCl 30 mg.). DR. ARIA O. SABIT, M.D., committed this offense by writing a prescription to patient-5, whose initials are C.S., for a Schedule II controlled substance, specifically Roxicodone (oxycodone HCl 30 mg.) outside the course of professional practice and for no legitimate medical purpose, and transferred the prescription so it could be filled, in the name of Patient-5.

Factual Basis to Guilty Plea – Case No. 15-20311

Background

At all times relevant to the factual basis of Aria Omar Sabit, M.D.'s ("defendant") plea agreement:

a. Defendant was a neurosurgeon licensed to practice medicine in California and Michigan.

b. The Medicare Program ("Medicare") was a "federal health care benefit program" and a "federal health care program" as defined by Title 18,

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United States Codes, Section 24(b) and Title 42, United States Code, Section 1320a-7b(f), respectively.

c. Individuals who were insured by Medicare were known as Medicare "beneficiaries."

d. Medicare would not pay a claim for items or services provided to a beneficiary by either a neurosurgeon, hospital, or surgical center if the items or services were not medically necessary or if any part of the claim included items or services that were predicated on illegal kickback payments or otherwise resulted from a violation of Title 42, United States Code, Section 1320a-7b (the "Anti-Kickback Statute"). Moreover, any such claim that included items or services that resulted from a violation of the Anti-Kickback Statute constituted a false or fraudulent claim for purposes of Title 31, United States Code, Section 3729.

Defendant as a Medicare Provider

In or around 2009, defendant executed Medicare applications to either obtain or maintain enrollment in Medicare, and obtain a Medicare provider number. Defendant had to be enrolled in Medicare as a provider and assigned a Medicare provider number to submit claims for reimbursement to Medicare for items or

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services that defendant claimed that he provided to his Medicare beneficiary patients.

On or about November 17, 2009, defendant executed a Medicare document titled "Certification Statement for Individual Practitioners" in which defendant certified to Medicare that, among other things, (a) he "agree[ed] to abide by the Medicare laws, regulations, and programs instructions" that applied to him; (b) he understood "that payment of a claim by Medicare [was] conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark Law), and on [his] compliance with all applicable conditions of participation in Medicare"; and (c) that he would "not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare."

Conspiracy to Commit Health Care Fraud

Notwithstanding these certifications, between in or around February 2010, and in or around August 2012, defendant conspired with three non-physicians, Co-Conspirator 1 ("CC-1"), Co-Conspirator 2 ("CC-2"), and Co-Conspirator 3 ("CC-3"); neurosurgeon Co-Conspirator 4 (collectively "the Apex Co-conspirators"); and others to commit health care fraud. The Apex Co-Conspirators conspired to commit health care fraud by submitting and causing

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the hospitals and surgical centers where defendant and CC-4 performed spine surgeries to submit false and fraudulent claims to Medicare for items and services provided by defendant, CC-4, and others. Specifically, every spine surgery that defendant and CC-4 performed using spinal implant devices from Apex Medical Technologies, LLC ("Apex") was predicated on illegal kickback payments that defendant and CC-4 received from CC-1, CC-2, CC-3, and their co-conspirators, and defendant's fraudulent representations that he was compliant with the Anti-Kickback Statute and Medicare's laws, regulations, and program instructions at the time defendant and others provided the items and services and those items and services were billed to Medicare, in violation of Title 18, United States Code, Section 1349. Moreover, incentivized by this illegal kickback arrangement and his involvement in the conspiracy, defendant performed medically unnecessary surgeries that caused serious bodily injury to at least some of his patients. Defendant participated in this conspiracy while he performed spine surgery at hospitals and surgical centers located in both the Central District of California ("CDCA") and the Eastern District of Michigan ("EDMI").

Defendant's participation in this conspiracy began while he had staff privileges at a hospital located in CDCA, and agreed to use spinal implant devices from Apex in surgeries that he performed on his Medicare and other patients (the

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"California surgeries"). CC-1 and CC-2 managed Apex, and operated it as a physician-owned distributorship ("POD"), paying neurosurgeons who concealed their involvement in the POD lucrative kickbacks that CC-1, CC-2, and other POD members tied directly to the volume and complexity of the surgeries that the surgeons performed, and the number of POD spinal implant devices that the surgeons used in their spine surgeries.

The Apex Co-Conspirators told defendant that before they would permit him to invest in Apex, they would put him through an evaluation period during which they would monitor defendant's surgical volume and the number of Apex implant devices that defendant used in his spine surgeries. Once defendant satisfied the Apex Co-Conspirators that his surgical volume was sufficient and that he was committed to using Apex implant devices in his surgeries, the Apex Co-Conspirators told defendant that they would invite him to invest in Apex. Defendant recognized that taking a financial interest in Apex could incentivize him to compromise his medical judgment by causing him either to perform medically unnecessary spine surgeries or "over instrument" his patients by using spinal implant devices in his patients that the patients did not need. Nevertheless, defendant agreed to allow the Apex Co-Conspirators to evaluate him and use Apex

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spinal implant devices in the surgeries that he performed during the evaluation period.

Defendant understood that the Apex Co-Conspirators expected him to convince his hospitals and surgical centers to accept Apex as a vendor of spinal implant devices and purchase the implant devices that defendant used in his surgeries from Apex. Defendant also understood that if he told the hospitals and surgical centers that he had a financial interest in Apex, the hospitals and surgical centers would not accept Apex as a vendor and purchase its implant devices. As a result, defendant concealed his financial interest in Apex from the hospitals and surgical centers where he performed surgeries. In fact, when a nurse and a purchasing manager from a hospital asked defendant whether he had a financial interest in Apex, defendant lied and said he did not.

In or around April 2010, defendant performed the first of his California surgeries using Apex spinal implant devices. Shortly thereafter, defendant accepted an invitation to join Apex, but he soon learned that Apex was a front that he and the Apex Co-Conspirators used to operate an illegal kickback scheme. While defendant was involved with Apex, defendant and the Apex Co-Conspirators intentionally ignored Anti-Kickback Statute compliance advice that they received from legal counsel as well as guidelines contained within Apex's

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operating agreements that were supposedly designed to ensure "that all sales of spinal implant products compl[ied] with the Stark Law and the Anti-Kickback Statute" by engaging in a variety of conduct that directly violated the Anti-Kickback Statute. This conduct included, but was not limited to, the following:

a. Contrary to the advice of legal counsel, defendant and the Apex Co-Conspirators did not invest any money in Apex to capitalize its operations. Instead, to make it appear as if they were compliant with the advice of counsel and the safe harbors to the Anti-Kickback Statute, defendant and the Apex Co-Conspirators made nominal investments in Apex that they knew they would later receive – and did receive – back from Apex.

b. CC-1, CC-2, and CC-3 claimed that Apex was distinguishable from other PODs and, therefore, compliant with the Anti-Kickback Statute because Apex surgeons designed the spinal implant devices that they used in surgery. However, defendant and CC-4 designed few, if any, of Apex's spinal implant devices. Instead, CC-1, CC-2, and CC-3 simply purchased spinal implant devices from third-party manufacturers and repackaged and rebranded them as Apex devices.

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c. As a general rule, defendant and the Apex Co-Conspirators did not permit other surgeons to use Apex spinal implant devices or Apex to sell implant devices to hospitals and surgical centers other than the ones affiliated with defendant and CC-4. Apex generated revenue only by defendant and CC-4 referring their Medicare and other patients for surgery and then requiring the hospitals and surgical centers where they performed those surgeries to purchase the implant devices they used in the surgeries from Apex.

d. Defendant and the Apex Co-Conspirators shared equally in the profits generated from Apex's implant device sales. As a result, the Apex Co-Conspirators pressured defendant to use Apex spinal implant devices in all or almost all of his surgeries. Defendant understood that the Apex Co-Conspirators would remove him from Apex if his surgical volume decreased or if he curtailed or ended his use of Apex spinal implant devices.

In or around December 2010, defendant resigned his staff privileges at the hospital in CDCA.

In or around March 2011, defendant moved to Detroit, Michigan, and began performing spine surgeries on Medicare and other patients at hospitals and surgical centers located in EDMI (the "Michigan surgeries"). Defendant continued to use Apex spinal implant devices in the Michigan surgeries. Defendant also continued

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to conceal his financial interest in Apex from the EDMI hospitals and surgical centers where he performed the Michigan surgeries.

Over time, defendant curtailed his use of Apex implant devices, and the EDMI hospitals and surgical centers were slow or refused to pay Apex for the spinal implant devices that defendant used in the Michigan surgeries. In or around August 2012, the Apex Co-Conspirators expelled defendant from Apex.

Defendant's involvement in Apex and the financial incentives provided to him by the Apex Co-Conspirators and Apex caused defendant to compromise his medical judgment and abuse his position of trust as both a physician and a Medicare provider by performing medically unnecessary spine surgeries on at least some of the patients in whom he implanted Apex spinal implant devices. Motivated by the money that he made from using Apex spinal implant devices, on a few occasions, defendant referred patients in CDCA and EDMI for spine surgery who did not medically need surgery or defendant referred his patients for more complex surgeries, such as multi-level spine fusions.

Defendant also abused his position of trust as both a physician and Medicare provider by, at times, "over instrumenting" his patients. Specifically, the financial incentives provided to defendant by the Apex Co-Conspirators and Apex caused

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defendant to use more Apex spinal implant devices in surgery than were medically necessary to treat his patients in order to generate more sales revenue for Apex.

Defendant's performance of medically unnecessary surgeries and his use of medically unnecessary Apex spinal implant devices resulted in him causing serious bodily injury to his patients. Specifically, at least some of defendant's patients suffered extreme physical pain, protracted and obvious disfigurement, and protracted loss or impairment of the functioning of a body member as a result of defendant selecting them for and performing surgery on them.

Loss to Medicare

As a result of defendant's conduct, defendant, the Apex Co-Conspirators, and others submitted or caused the submission of approximately $11,243,118 in false and fraudulent claims to Medicare for items and services provided to defendant's Medicare patients. Medicare paid approximately $1,568,622 of these false and fraudulent claims.

Defendant makes this statement knowingly and voluntarily and because he is in fact guilty of the crimes charged.

2. SENTENCING GUIDELINES

A. Standard of Proof

The Court will find sentencing factors by a preponderance of the evidence.

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B. Agreed Guideline Range

There are no sentencing guideline disputes. Except as provided below, defendant's guideline range is estimated as follows as set forth on the attached worksheets: **108-135 months.** If the Court finds:

a) that defendant's criminal history category is higher than reflected on the attached worksheets, or

b) that the offense level should be higher because, after pleading guilty, defendant made any false statement to or withheld information from his probation officer; otherwise demonstrated a lack of acceptance of responsibility for his offense(s); or obstructed justice or committed any crime,

and if any such finding results in a guideline range higher than **108 – 135 months**, the higher guideline range becomes the agreed range. However, if the Court finds that defendant is a career offender, an armed career criminal, or a repeat and dangerous sex offender as defined under the sentencing guidelines or other federal law, and that finding is not already reflected in the attached worksheets, this paragraph does *not* authorize a corresponding increase in the agreed range.

Neither party may take a position concerning the applicable guidelines that is different than any position of that party as reflected in the attached worksheets,

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except as necessary to the Court's determination regarding subsections a) and b), above.

C. Relevant Conduct

The relevant conduct in this case includes the following:

Dr. ARIA OMAR SABIT, M.D., submitted claims or caused MBSPG to submit claims to public and private insurance health programs for approximately $3.3 million dollars which involved more than 142 patients. Sabit fraudulently submitted these claims for spinal fusion surgeries with instrumentation which he never performed.

3. SENTENCE

The Court will impose a sentence pursuant to 18 U.S.C. §3553, and in doing so must consider the sentencing guideline range.

A. Imprisonment

Pursuant to Federal Rule of Criminal Procedure 11(c)(1)(C) the sentence of imprisonment in this case may not exceed the top of the sentencing guideline range as determined by Paragraph 2B.

B. Supervised Release

Case No. 14-20779

A term of supervised release follows the term of imprisonment. The Court

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must impose a term of supervised release on Counts One – Four of no less than **two years.** With respect to Count Five, the parties agree the Court shall impose a **life time** term of supervised release, which includes the special condition that the defendant be restricted from employment, in any capacity, in the medical profession (this restriction will cover the practice of medicine, owning/operating a medical clinic, conducting any medical research, consulting as an expert, manufacture or participating in the manufacture of any medical devices, membership in any physician owned distributorships) and any employment in any capacity in any medical facility. The agreement concerning imprisonment described above in Paragraph 3A does not apply to any term of imprisonment that may result from any later revocation of supervised release.

Case No. 15-20311

A term of supervised release follows the term of imprisonment. The Court must impose a term of supervised release on Count One of the Information of not more than **three years**.

C. Special Assessment

Defendant will pay a special assessment of **$600.00** and must provide the government with a receipt for the payment before sentence is imposed.

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D. Fine

There is no agreement as to the amount of any fine that is to be imposed by the Court.

E. Restitution

The Court shall order restitution to every identifiable victim of defendant's offense, including but not limited to, the United States Department of Health and Human Services. The victims and the full amount of restitution in this case, shall be determined by the Court.

F. Forfeiture

Defendant agrees, pursuant to 18 U.S.C. § 982(a)(7) to the forfeiture of the following property as the properties constitute or represent gross proceeds of the above-described conduct to which the defendant is pleading guilty as charged in United States v. Sabit, (14-20779, Eastern District of Michigan) and United States v. Sabit, (Docket No. 15-20311 Rule 20 transfer from the Central District of California):

Real Property:

The defendant agrees to the forfeiture of the proceeds from the private sale of a residence located at:

- **3645 Lahser Road, Bloomfield Hills, Michigan,** and being more fully

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described as:

Lots 12 and 13, Assessor's Plat No. 2, as recorded in Liber 50, on Page 13 of Plats, Oakland County Records.
ALSO
The easterly portion of Lahser Road, lying between the user-defined and presently traveled width thereof and the Westerly lines of Lots 12 and 13 of Assessor's Plat No. 2, which portion is located and lying between the Northerly and Southerly lines, as extended, of Lots 12 and 13 of Assessor's Plat No. 2, of part of the West 1/2 of the Northwest 1/4 of Section 15, Town 2 North, Range 10 East, City of Bloomfield Hills, Oakland County Records.

Commonly known as: 3645 Lahser Road, Bloomfield Hills, MI 48304

Tax Parcel No: 19-15-151-005

Personal Property

- **$200,498.60 seized from Comerica Bank account number #623626608**
- **$251,192.97 seized from Comerica Bank account number 6823625725**
- **$251, 196.27 seized from Comerica Bank account number 6823625840**
- **$17,860.46 seized from PNC Bank account number 4263698533**

With respect to the above-described property, within this agreement, the defendant agrees to the entry of one or more orders of forfeiture of his interest in

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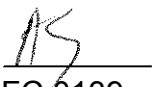
such property upon application by the United States at, or any time before, his sentencing in this case.

In entering into this agreement with respect to forfeiture, Defendant knowingly, voluntarily, and intelligently waives any challenge to the above-described forfeiture based upon the Excessive Fines Clause of the Eighth Amendment to the United States Constitution.

Defendant further agrees to hold the United States, its agents and employees harmless from any claims whatsoever in connection with the seizure and forfeiture of property covered by this Plea Agreement.

Defendant agrees that he will cooperate with the United States by taking whatever steps are necessary to deliver clear title to the Forfeited Property to the United States and will execute such legal documents as may be required to transfer title to the United States and by taking whatever steps are necessary to ensure that the Forfeited Property is not sold, disbursed, hidden, wasted or otherwise made unavailable for forfeiture. If any other person or entity has or claims any interest in such property, defendant will assist in obtaining a release of interest from any such other person or entity.

Defendant acknowledges that he understands that the forfeiture of assets is part of the sentence that may be imposed in this case and waives his right to

Defendant's Initials: 

challenge any failure by the court to advise him of his rights with respect to forfeiture, set forth in Fed.R.Crim.P. 11(b)(1)(J). Defendant also expressly waives his right to have a jury determine the forfeitability of his interest in the above identified property as provided by Rule 32.2(b)(4) of the Federal Rules of Criminal Procedure.

4. A. Use of Withdrawn Guilty Plea

If the Court allows defendant to withdraw his guilty plea for a "fair and just reason" pursuant to Fed. R. Crim. P. 11(d)(2)(B) , defendant waives his rights under Fed. R. Evid. 410, and the government may use his guilty plea, any statement made under oath at the change-of-plea hearing, and the factual basis statement in this plea agreement, against him in any proceeding.

B. Exclusion from the Medicare Program and Other Federal Health Care Programs

The defendant understands and acknowledges that as a result of this plea, the defendant will be excluded from Medicare, Medicaid, and all Federal health care programs. Defendant agrees to complete and execute all necessary documents provided by any department or agency of the federal government, including but not limited to the United States Department of Health and Human Services, to effectuate this exclusion within 60 days of receiving the documents. This exclusion will not affect defendant's right to apply for and receive benefits as a beneficiary under any

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Federal health care program, including Medicare and Medicaid.

5. OTHER CHARGES

If the Court accepts this agreement, the government will dismiss all remaining charges in this case.

6. EACH PARTY'S RIGHT TO WITHDRAW FROM THIS AGREEMENT

The government may withdraw from this agreement if the Court finds the correct guideline range to be different than is determined by Paragraph 2B.

Defendant may withdraw from this agreement, and may withdraw his guilty plea, if the Court decides to impose a sentence higher than the maximum allowed by Part 3. This is the only reason for which defendant may withdraw from this agreement. The Court shall advise defendant that if he does not withdraw his guilty plea under this circumstance, the Court may impose a sentence greater than the maximum allowed by Part 3.

7. CIVIL LIABILITY

By entering into this Agreement, the U.S. Attorney does not compromise any civil liability or administrative remedies, including but not limited to any tax liability, which defendant may have incurred or may incur as a result of his conduct and his plea of guilty to the charges specified in paragraph 1 of this Agreement.

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In light of the parties' intention to resolve all pertinent pending civil actions, including United States v. Reliance Medical Systems, et al, No. 14-cv-6979-DDP (C.D. Cal.) and U.S. ex rel. Savitch, et al. v. Sabit, et al., No. 13-cv-3363-DDP (C.D. Cal.), the parties agree that there will not be a separate restitution order as to defendant as part of the resolution of the ~~Information~~ and the Parties agree that the appropriate disposition of the civil cases does not include ~~a restitution order.~~

8. WAIVER OF APPEAL

Defendant waives any right he may have to appeal his conviction. If the sentence imposed does not exceed the maximum allowed by Part 3 of this agreement, defendant also waives any right he may have to appeal his sentence. If the sentence imposed is within the guideline range determined by Paragraph 2B the government agrees not to appeal the sentence, but retains its right to appeal any sentence below that range. Nothing in this waiver shall be construed to bar a claim of ineffective assistance of counsel, provided that the defendant properly raises such claim by collateral review under 28 U.S.C. § 2255.

9. CONSEQUENCES OF WITHDRAWAL OF GUILTY PLEA OR VACATION OF CONVICTION

If defendant is allowed to withdraw his guilty plea(s) or if any conviction entered pursuant to this agreement is vacated, the Court shall, on the government's request, reinstate any charges that were dismissed as part of this agreement. If

Defendant's Initials: _____

additional charges are filed against defendant within six months after the date the order vacating defendant's conviction or allowing him to withdraw his guilty plea(s) becomes final, which charges relate directly or indirectly to the conduct underlying the guilty plea(s) or to any conduct reflected in the attached worksheets, defendant waives his right to challenge the additional charges on the ground that they were not filed in a timely manner, including any claim that they were filed after the limitations period expired.

10. PARTIES TO PLEA AGREEMENT

Unless otherwise indicated, this agreement does not bind any government agency except the United States Attorney's Office for the Eastern District of Michigan and the Civil and Criminal Fraud Sections of the United States Department of Justice.

11. SCOPE OF PLEA AGREEMENT

This agreement, which includes all documents that it explicitly incorporates, is the complete agreement between the parties. This agreement supersedes all other promises, representations, understandings and agreements between the parties concerning the subject matter of this plea agreement that were made at any time before the guilty plea is entered in court. Thus, no oral or written promises made by the government to defendant or to the attorney for the defendant at any time before

Defendant's Initials: AS

defendant pleads guilty are binding except to the extent they have been explicitly incorporated into this agreement.

Notwithstanding the previous paragraph, if defendant has entered into a proffer agreement in writing or a cooperation agreement in writing with the government, this plea agreement does not supersede or abrogate the terms of any such prior written agreement.

This agreement also does not prevent any civil or administrative actions against defendant, or any forfeiture claim against any property, by the United States or any other party.

Defendant's Initials: AS

12. ACCEPTANCE OF AGREEMENT BY DEFENDANT

This plea offer expires unless it has been received, fully signed, in the Office of the United States Attorney by **5:00 P.M. on May 20, 2015**. The government reserves the right to modify or revoke this offer at any time before defendant pleads guilty.

w/permission DL

WAYNE F. PRATT
CHIEF, HEALTH CARE FRAUD UNIT
ASSISTANT UNITED STATES ATTORNEY

BARBARA L. MCQUADE
United States Attorney
w/permission RRM

GEJAA T. GOBENA
DEPUTY CHIEF
FRAUD SECTION
U.S. DEPARTMENT OF JUSTICE

REGINA R. MCCULLOUGH
DEPUTY CHIEF, HEALTH CARE FRAUD

PHILIP A. ROSS
ASSISTANT UNITED STATES ATTORNEY

JONATHAN T. BAUM
SENIOR TRIAL ATTORNEY
FRAUD SECTION

DUSTIN DAVIS
TRIAL ATTORNEY
FRAUD SECTION

BLANCA QUINTRO
TRIAL ATTORNEY
FRAUD SECTION

DATE: 5/22/15

Defendant's Initials: MS

BY SIGNING BELOW, DEFENDANT ACKNOWLEDGES THAT HE HAS READ (OR BEEN READ) THIS ENTIRE DOCUMENT, UNDERSTANDS IT, AND AGREES TO ITS TERMS. HE ALSO ACKNOWLEDGES THAT HE IS SATISFIED WITH HIS ATTORNEYS' ADVICE AND REPRESENTATION. DEFENDANT AGREES THAT HE HAS HAD A FULL AND COMPLETE OPPORTUNITY TO CONFER WITH HIS LAWYERS, AND HAS HAD ALL OF HIS QUESTIONS ANSWERED BY HIS LAWYERS.

JOSEPH NISKAR
ATTORNEY FOR DEFENDANT

ARIA OMAR SABIT, M.D.
DEFENDANT

DATE: 5/22/15

TIMOTHY LESSING
ATTORNEY FOR DEFENDANT

JOHNATHAN FRANK
ATTORNEY FOR DEFENDANT

DATE: 5/22/15

Defendant's Initials: AS

Defendant:	Aria Omar Sabit	Count:	
Docket No.:	14-20799	Statute(s):	18 U.S.C. 1347

WORKSHEET A (Offense Levels)

Complete one Worksheet A for each count of conviction (taking into account relevant conduct and treating each stipulated offense as a separate count of conviction) before applying the multiple-count rules in U.S.S.G. ch. 3, pt. D. However, in any case involving multiple counts of conviction, if the counts of conviction are all "closely related" to each other within the meaning of U.S.S.G. § 3D1.2(d), complete only a single Worksheet A.

1. BASE OFFENSE LEVEL AND SPECIFIC OFFENSE CHARACTERISTICS (U.S.S.G. ch. 2)

Guideline Section	Description	Levels
2B1.1(a)(1)	Health Care Fraud - serious bodily injury	7
2B1.1(b)(1)(I)	More than 11 million	+20
2B1.1(b)(7)	Federal Health Care Fraud Conviction	+3
2B1.1(b)(15)	Serious bodily injury	+2

2. ADJUSTMENTS (U.S.S.G. ch. 3, pts. A, B, C)

Guideline Section	Description	Levels
3B1.3	Abuse of Trust	+2

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3. ADJUSTED OFFENSE LEVEL

Enter the sum of the offense levels entered in Items 1 and 2. If this Worksheet A does not cover every count of conviction (taking into account relevant conduct and treating each stipulated offense as a separate count of conviction), complete one or more additional Worksheets A and a single Worksheet B.

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If this is the only Worksheet A, check this box and skip Worksheet B.

If the defendant has no criminal history, check this box and skip Worksheet C.

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WORKSHEET B (Multiple Counts)

Instructions (U.S.S.G. ch. 3, pt. D):

- Group the counts of conviction into distinct Groups of Closely Related Counts. "All counts involving substantially the same harm shall be grouped together into a single Group." (*See* U.S.S.G. § 3D1.2.)

- Determine the offense level applicable to each Group. (*See* U.S.S.G. § 3D1.3.)

- Determine the combined offense level by assigning "units" to each Group as follows (*see* U.S.S.G. § 3D1.4):

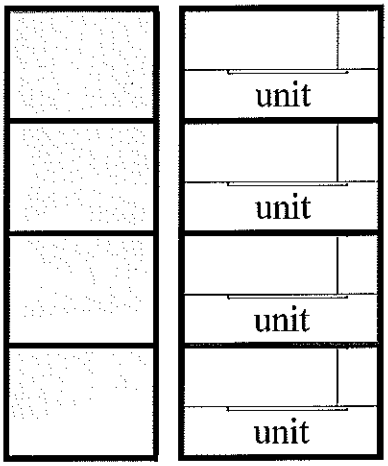
  - assign 1 unit to the Group with the highest offense level,
  - assign 1 unit to each additional Group that is equally serious as, or 1 to 4 levels less serious than, the Group with the highest offense level,
  - assign ½ unit to each Group that is 5 to 8 levels less serious than the Group with the highest offense level,
  - assign no units to each Group that is 9 or more levels less serious than the Group with the highest offense level.

1. **GROUP ONE:** COUNT(S) _____
   ADJUSTED OFFENSE LEVEL

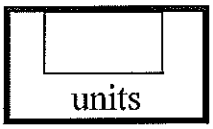
2. **GROUP TWO:** COUNT(S) _____
   ADJUSTED OFFENSE LEVEL

3. **GROUP THREE:** COUNT(S) _____
   ADJUSTED OFFENSE LEVEL

4. **GROUP FOUR:** COUNT(S) _____
   ADJUSTED OFFENSE LEVEL



5. **TOTAL UNITS**



Defendant:	Aria Omar Sabit	Count:	
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6. INCREASE IN OFFENSE LEVEL

1 unit ⟶ no increase
1 1/2 units ⟶ add 1 level
2 units ⟶ add 2 levels
2 1/2 – 3 units ⟶ add 3 levels
3 1/2 – 5 units ⟶ add 4 levels
> 5 levels ⟶ add 5 levels

1

7. ADJUSTED OFFENSE LEVEL OF GROUP WITH THE HIGHEST OFFENSE LEVEL

8. COMBINED ADJUSTED OFFENSE LEVEL

Enter the sum of the offense levels entered in Items 6 and 7.

Defendant:	Aria Omar Sabit	Count:	
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WORKSHEET C (Criminal History)

Date of defendant's commencement of the instant offense (taking into account relevant conduct and stipulated offenses):_____

1. PRIOR SENTENCES

Prior Sentence of Imprisonment Exceeding 13 Months (U.S.S.G. §§ 4A1.1(a)): **3 POINTS**

Enter 3 points for each prior adult sentence of imprisonment exceeding one year and one month that either (1) was imposed within 15 years of the defendant's commencement of the instant offenses (taking into account relevant conduct and stipulated offenses) or (2) resulted in the defendant's confinement during any part of that 15-year period. (*See* U.S.S.G. §§ 4A1.1(a), 4A1.2(d)(1), (e)(1).)

Prior Sentence of Imprisonment of at Least 60 Days (U.S.S.G. §§ 4A1.1(b)): **2 POINTS**

Enter 2 points for each prior sentence of imprisonment of at least 60 days not counted under U.S.S.G. § 4A1.1(a) that either (1) resulted from an offense committed after the defendant turned 18 and was imposed within 10 years of the defendant's commencement of the instant offense (taking into account relevant conduct and stipulated offenses) (*see* U.S.S.G. §§ 4A1.1(b), 4A1.2(e)(2)) or (2) resulted from an offense committed before the defendant turned 18 and resulted in the defendant's confinement during any part of the 5-year period preceding the defendant's commencement of the instant offense (*see* U.S.S.G. §§ 4A1.1(b), 4A1.2(d)(2)(A)).

Other Prior Sentences (U.S.S.G. §§ 4A1.1(c)): **1 POINT**

Enter 1 point for each prior sentence not counted under U.S.S.G. § 4A1.1(a) or (b) that either (1) resulted from an offense committed after the defendant turned 18 and was imposed within 10 years of the defendant's commencement of the instant offense (taking into account relevant conduct and stipulated offenses) (*see* U.S.S.G. §§ 4A1.1(c), 4A1.2(e)(2)) or (2) resulted from an offense committed before the defendant turned 18 and was imposed within 5 years of the defendant's commencement of the instant offense (taking into account relevant conduct and stipulated offenses) (*see* U.S.S.G. §§ 4A1.1(c), 4A1.2(d)(2)(B)). NOTE: No more than 4 points may be added under this item.

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Date of Imposition	Status*	Offense	Sentence	Release Date**	Points

* If the defendant committed the offense before turning 18, indicate whether he or she was sentenced as a juvenile (J) or as an adult (A).

** A release date is required in only two situations: (1) when a sentence covered under U.S.S.G. § 4A1.1(a) was imposed more than 15 years before the defendant's commencement of the instant offense (taking into account relevant conduct and stipulated offenses) but resulted in his or her confinement during any part of that 15-year period; or (2) when a sentence counted under U.S.S.G. § 4A1.1(b) was imposed for an offense committed before the defendant turned 18 but resulted in his or her confinement during any part of the 5-year period preceding his or her commencement of the instant offense (taking into account relevant conduct and stipulated offenses).

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2. COMMISSION OF INSTANT OFFENSE WHILE UNDER PRIOR SENTENCE (U.S.S.G. § 4A1.1(d))

Enter 2 points if the defendant committed any part of the instant offense (taking into account relevant conduct and stipulated offenses) while under any criminal justice sentence having a custodial or supervisory component, including probation, parole, supervised release, imprisonment, work release, and escape status. (*See* U.S.S.G. §§ 4A1.1(d), 4A1.2(m), (n).) List the type of control and identify the sentence from which it resulted.

3. PRIOR SENTENCE RESULTING FROM CRIME OF VIOLENCE (U.S.S.G. § 4A1.1(e))

Enter 1 point for each prior sentence resulting from a conviction for a crime of violence that did not receive any points under U.S.S.G. § 4A1.1(a), (b), or (c) because such sentence was considered related to another sentence resulting from a conviction for a crime of violence. But enter no points where the sentences are considered related because the offenses occurred on the same occasion. (*See* U.S.S.G. §§ 4A1.1(e), 4A1.2(p).) Identify the crimes of violence and briefly explain why the cases are considered related. NOTE: No more than 3 points may be added under this item.

4. TOTAL CRIMINAL HISTORY POINTS

Enter the sum of the criminal history points entered in Items 1-4.

5. CRIMINAL HISTORY CATEGORY

Total Criminal History Points	Criminal History Category
0-1	**I**
2-3	**II**
4-6	**III**
7-9	**IV**
10-12	**V**
≥13	**VI**

I

Defendant:	Aria Omar Sabit	Count:	
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WORKSHEET D (Guideline Range)

1. (COMBINED) ADJUSTED OFFENSE LEVEL

Enter the adjusted offense level entered in Item 3 of Worksheet A or the combined adjusted offense level entered in item 8 of Worksheet B. **34**

2. ADJUSTMENT FOR ACCEPTANCE OF RESPONSIBILITY (U.S.S.G. § 3E1.1) **-3**

3. TOTAL OFFENSE LEVEL

Enter the difference between Items 1 and 2. **31**

4. CRIMINAL HISTORY CATEGORY

Enter "I" if the defendant has no criminal history. Otherwise, enter the criminal history category entered in Item 6 of Worksheet C. **I**

5. CAREER OFFENDER/CRIMINAL LIVELIHOOD/ARMED CAREER CRIMINAL/DANGEROUS SEX OFFENDER (U.S.S.G. ch. 4, pt. B)

a. Total Offense Level: If the career offender provision (U.S.S.G. § 4B1.1), the criminal livelihood provision (U.S.S.G. § 4B1.3), the armed career criminal provision (U.S.S.G. § 4B1.4), or the dangerous sex offender provision (U.S.S.G. § 4B1.5) results in a total offense level higher than the total offense level entered in Item 3, enter the higher offense level total.

b. Criminal History Category: If the career offender provision (U.S.S.G. § 4B1.1), the armed career criminal provision (U.S.S.G. § 4B1.4), or the dangerous sex offender provision (U.S.S.G. § 4B1.5) results in a criminal history category higher than the criminal history category entered in Item 4, enter the higher criminal history category.

6. GUIDELINE RANGE FROM SENTENCING TABLE (U.S.S.G. CH. 5, PT. A)

Enter the guideline range in the Sentencing Table (*see* U.S.S.G. ch. 5, pt. A) produced by the total offense level entered in Item 3 or 5.a and the criminal history category entered in Item 4 or 5.b. **108 - 13+** months

Defendant:	Aria Omar Sabit	Count:	
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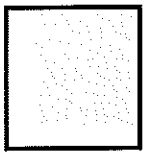
7. **STATUTORY RESTRICTIONS ON OR SUPERSESSION OF GUIDELINE RANGE**

If the maximum sentence authorized by statute is below, or a minimum sentence required by statute is above, the guideline range entered in Item 6, enter either the guideline range as restricted by statute or the sentence required by statute. (*See* U.S.S.G. § 5G1.1.) If the sentence on any count of conviction is required by statute to be consecutive to the sentence on any other count of conviction, explain why.



months

Defendant:	Aria Omar Sabit	Count:	
Docket No.:	14-20799	Statute(s):	18 U.S.C. 1347

WORKSHEET E (Authorized Guideline Sentences)

1. PROBATION

a. Imposition of a Term of Probation (U.S.S.G. § 5B1.1)

[X] 1. Probation is not authorized by the guidelines (minimum of guideline range ≥ 10 months or statute of conviction is a Class A or a Class B felony). If this box is checked, go to Item 2 (Split Sentence).

[ ] 2. Probation is authorized by the guidelines (minimum of guideline range = zero months).

[ ] 3. Probation is authorized by the guidelines, provided the court imposes a condition or combination of conditions requiring intermittent confinement, community confinement, or home detention satisfying the minimum of the guideline range (minimum of guideline range > 0 months but ≤ 9 months).

b. Length of Term of Probation (U.S.S.G. § 5B1.2)

[ ] 1. At least 1 year but not more than 5 years (total offense level ≥ 6)

[ ] 2. No more than 3 years (total offense level < 6).

c. Conditions of Probation (U.S.S.G. § 5B1.3)

2. SPLIT SENTENCE (U.S.S.G. § 5C1.1(C)(2), (D)(2))

[ ] a. A split sentence is not authorized (minimum of guideline range = 0 months or ≥ 15 months).

[ ] b. A split sentence is authorized (minimum of guideline range > 0 months but ≤ 12 months). The court may impose a sentence of imprisonment that includes a term of supervised release with a condition that substitutes community confinement or home detention for imprisonment, provided that at least one-half of the minimum of the guideline range is satisfied by imprisonment (if the minimum of the guideline range is 10 or 12 months), or that at least one month is satisfied by imprisonment (if the minimum of the guideline range is 1, 2, 3, 4, 6, 8, or 9 months). The authorized length of the term of supervised release is set forth below in Item 4.b.

3. IMPRISONMENT (U.S.S.G. CH. 5, PT. C)

A term of imprisonment is authorized by the guidelines if it is within the applicable guideline range (entered in Item 6 of Worksheet D). (*See* U.S.S.G. § 5C1.1.)

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4. SUPERVISED RELEASE (U.S.S.G. ch 5., pt. D)

a. Imposition of a Term of Supervised Release (U.S.S.G. § 5D1.1)

The court must impose a term of supervised release if it imposes a term of imprisonment of more than one year, or if it is required to do so by statute. The court may impose a term of supervised release if it imposes a term of imprisonment of one year or less.

b. Length of Term of Supervised Release (U.S.S.G. § 5D1.2)

☐ 1. At least 2 years but not more than 5 years, where the count of conviction is a Class A or a Class B felony, i.e., an offense carrying a maximum term of imprisonment ≥ 25 years.

☐ 2. At least 1 year but not more than 3 years, where the count of conviction is a Class C or a Class D felony, i.e., an offense carrying a maximum term of imprisonment ≥ 5 years but < 25 years.

☐ 3. 1 year, where the count of conviction is a Class E felony or a Class A misdemeanor, i.e., an offense carrying a maximum term of imprisonment > 6 months but < 5 years.

☒ 4. The statute of conviction requires a minimum term of supervised release of 5 years.

c. Conditions of Supervised Release (U.S.S.G. § 5D1.3)

The court must impose certain conditions of supervised release and may impose other conditions of supervised release.

5. RESTITUTION (U.S.S.G. § 5E1.1)

☒ 1. The court *must* order full restitution to the victim(s) of the offense(s) of conviction. (*See* 18 U.S.C. §§ 3556, 3663A, 3664.) The court will determine who the victims are and their restitution amounts.

☐ 2. The court *must* order full restitution to the victim(s) of the offense(s) of conviction. (*See* 18 U.S.C. §§ 3556, 3663A, 3664) The parties agree that full restitution is $_____.

Defendant:	Aria Omar Sabit	Count:	
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☐ 3. The parties agree that the court *may* order restitution to the victim(s) of the offense(s) of conviction in any amount up to and including $_____. (*See* 18 U.S.C. §§ 3663(a)(3), 3664.)

☐ 4. The parties agree that the court ***may also*** order restitution to persons other than the victim(s) of the offense(s) of conviction in any amount up to and including $_____. (*See* 18 U.S.C. §§ 3663(a)(1)(A), 3663A(a)(3), 3664.)

☐ 5. Restitution is not applicable.

6. FINE (U.S.S.G. § 5E1.2)

a. Fines for Individual Defendants

The court must impose a fine unless "the defendant establishes that he [or she] is unable to pay and is not likely to become able to pay any fine." (*See* U.S.S.G. § 5E1.2(a).) Generally, the fine authorized by the guidelines is limited to the range established in the Fine Table. (*See* U.S.S.G. § 5E1.2(b).) However, there are exceptions to this general rule. (*See* U.S.S.G. § 5E1.2(b), (c)(4).)

b. Fine Range from Fine Table (U.S.S.G. § 5E1.2(c)(3))

Minimum Fine	**Maximum Fine**
$_____	$1,000,000

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7. **SPECIAL ASSESSMENT(S) (U.S.S.G. § 5E1.3)**
The court must impose a special assessment on every count of conviction. The special assessments for individual defendants are:
- $100.00 for every count charging a felony ($400 for a corporation),
- $25.00 for every count charging a Class A misdemeanor ($125 for a corporation),
- $10.00 for every count charging a Class B misdemeanor ($50 for a corporation), and
- $5.00 for every count charging a Class C misdemeanor or an infraction ($25 for a corporation).

The defendant must pay a special assessment or special assessments in the total amount of $600.

8. **FORFEITURE (U.S.S.G. § 5E1.4)**

[X] Assets of the defendant will be forfeited.

[ ] Assets of the defendant will not be forfeited.

9. **ADDITIONAL APPLICABLE GUIDELINES, POLICY STATEMENTS, AND STATUTES**

List any additional applicable guideline, policy statement, or statute.

10. **UPWARD OR DOWNWARD DEPARTURE (U.S.S.G. ch. 5, pts. H & K)**
List any applicable aggravating or mitigating circumstance that might support a term of imprisonment above or below the applicable guideline range.

Physician Owned Distributors (PODs):

An Overview of Key Issues and Potential Areas for Congressional Oversight

An Inquiry by the Senate Finance Committee Minority Staff
U.S. Senator Orrin Hatch, (R-Utah), Ranking Member

June 2011

I. Background

Earlier this year, the Senate Finance Committee minority staff began an inquiry into the complicated issue of physician owned distributors (PODs), also known as physician owned companies or intermediaries. Since that time, committee staff has reviewed over 1000 pages of documents, spoken to over 50 people and uncovered many issues associated with the PODs that merit further review and consideration. This report is a summary of the Committee findings to date and an overview of the key issues identified which have implications for the health care system as a whole.

II. Overview

Business arrangements involving physician ownership of medical device companies and distributorships have been around in various forms for at least ten years. The basic arrangement involves medical device companies formed to give physicians who control the choice of what medical devices they implant in patients a share in the profits generated by the sale of such devices. The physician owners can then use their ability to generate referrals for hospitals to induce them to buy the medical devices from the companies in which the physicians have ownership. In effect, these entities act as a middleman entity that exists to give its physician investors the opportunity to profit from the sale and utilization of the medical devices they provide to hospitals. This is a significant shift away from what has typically been the model for the supply chain in the implant world.

The Implant Supply Chain

Implantable medical devices historically have been sold almost exclusively to hospitals and surgery centers directly by manufacturers through representatives who may be W-2 employees or may be 1099 independent contractors (independent sales agencies which the industry calls "distributors"). The manufacturer and its representatives provide services to the institution along with the implants, including order and delivery, stocking and restocking, sterilization, selection, delivery and deployment of external instrumentation, and assistance to surgeons in the operating room. In this instance, the medical device goes directly from the manufacturer to the entity where it is being used as the hospitals and surgery centers are equipped to manage the safety of the devices.

The Difference with PODs

PODs step into this supply chain as a middle man entity with no obvious nexus other than ownership by the ordering/referring physicians. Many PODs lack any operating history or experience (except to the extent that they are organized by and outsource their functions to a third-party entrepreneur/manager), and may not offer any or most of the existing suite of services outlined above, but at best offer (usually through a third-party manager) to replicate some of the services already performed by the manufacturer and its representatives. PODs also differ from the physician-owned providers of ancillary healthcare services. For those arrangements, the Office of Inspector General for (OIG) for the Department of Health and Human Services has historically advised that following guidance like its Special Fraud Alert on Joint Venture Arrangements may chart a path to compliant operation, in that the service providers are subject to state licensure, federal regulation and public oversight that is currently lacking for PODs.

III. Proliferation of PODs

As physicians continue to see dramatic reductions in reimbursements, increased demands on their time, hospital cost initiatives and growth in patient and procedure volumes, they are continuously looking for sustainable ancillary revenue sources. This has led to numerous models being implemented by physicians to provide such revenue sources, but foremost among them in the surgical arena appears to be the PODs. These entities first appeared primarily in California beginning around 2003. Currently, they appear to be limited to the orthopedic implant (spine and total joint) sector of the device industry, but appear to be quickly branching out into other areas such as cardiac implant (e.g., pacemakers and defilibrators).

While originally there were a handful of PODs primarily based in Northern California which first brought this issue to the forefront, it is the rapid proliferation of the PODs over the past 18-24 months which has raised a number of concerns regarding the structure of the PODs. No longer are there just a handful of PODs which are all operated under an organized structure or that share similar characteristics. The lure of financial incentives and lack of regulatory oversight appears to be driving huge increases in the number of PODs so that they are now a significant national presence. To date, the Committee has identified at least 20 states with multiple PODs that appear to be operational. Over 40 plus PODs have been identified in California alone. In particular, there seems to be a marked increase in rural areas where the POD distributor model is being used very aggressively.

IV. POD Business Models

There are three primary POD business models that have emerged over the past few years:

1) The Physician Distributor Model where the POD functions as a product distributor that arranges to buy implants from manufacturers and resell the implants to the hospitals where the physician investors refer their patients for implant procedures;

2) The Physician Manufacturer Model where the POD claims to be an implant manufacturer with development of implantable product produced by an outsourced manufacturer and then distributed by the POD; and

3) The Physician Group Purchasing Organization (GPO) model where the PODs have organized in an attempt to take advantage of the anti-kickback “safe harbor” for GPOs. This potentially could allow for the POD to aggregate the buying power of a large number of members to negotiate lower prices from a wide variety of manufacturers.

There are many different structural twists on these models and the following are some of the many examples of the variations on the POD models identified by the Committee:

1) Every physician investor receives a percentage of the money that their surgeries generate for the POD;

2) Each physician investor is compensated equally, irrespective of his or her individual usage;
3) An individual physician investor's usage is carved out from the profits he or she receives, but receives profit from the other physician investors' usage;
4) The POD's product use is limited to procedures that are not federally reimbursable;
5) The POD is organized to sell devices designed by the physician investors;
6) The POD includes a shell, or second corporation/entity (i.e., a construction company), which is used to facilitate payment to the physician investors so as to avoid direct payment from the POD that is selling the products to its physician investors; and
7) PODs that span multiple states such that physician investors from each state only profit from physician investor usage in the other state.

The typical structure of a POD is that a small group of individuals, who may or may not be physicians, establish a company to manufacture or distribute medical devices for implantation in primarily orthopedic (as of right now) surgeries. The company then seeks investors, primarily physicians who can generate referrals that benefit the company. The physicians are then offered either partnership or ownership interests in the company in return for a cash buy in of anywhere from $10,000 or more, and in return are promised the potential to earn returns at a far higher rate than they would get investing in more traditional investments. Numerous offering letters by some of these PODs obtained by the Committee present a compelling picture of the attraction of the POD to surgeon investors with claims of generous dividend returns of 25 percent or more, guarantees to increase patient load, and no real financial risk beyond the initial investment.

Most, if not all, of the products sold by PODs are sold to their own physician investors, and little or no business is obtained from physicians who have no affiliation with the POD. The business model is totally dependent upon hospitals agreeing to buy implants through the POD rather than directly from the manufacturer. This can be particularly troubling in instances where the physician investors of PODs are on the medical device or other related hospital committees that determine which products will be used at the hospital as physician could improperly influence the selection of a product in which he or she had a personal financial interest. The government, as evidenced by the "one purpose rule," has made clear that a physician's decision as to whether to use one product over another cannot in any way be based on the physician receiving payment for using a particular product. Therefore, even if the POD structure did lower healthcare costs, such an arrangement should not trump or justify violation of the anti-kickback statute or other Federal fraud and abuse laws.

All of the above models appear to be designed in a manner in which the physicians in the POD, in various levels of directness, profit from their use of the products they are selling. It may be possible to structure a POD that does not raise these issues and there appear to be some PODs that try to appropriately balance these competing interests. For example, if a POD was not permitted to do business with its own investors, their partners, or affiliated hospitals, presumably they would be acting as a traditional distributor and not be able to profit from their usage or the usage of other physician investors. However, even this structure would not prevent two separate PODs from using each other's products as a means to circumvent these rules.

V. Cost to the Federal Health Care Programs

One of the key assertions of the POD model is that they are lowering healthcare costs by providing products at a lower price than a medical device manufacturer or non-POD distributor. Opponents of the PODs claim this is a false metric because it does not take into account several critical and material factors in a true cost analysis, including the initial decision to operate on the patient and the number of revision surgeries necessary. Either of these factors could have a significantly larger impact on total healthcare costs in addition to calling into question whether it is in the best interest of the patient.

Proponents of the POD argue that the model allows them to engage in arms-length negotiations with the device manufacturer to secure a price for the product, which is usually lower than that which is offered to other purchasers, including hospitals. The POD is then able to share any savings with hospitals in which the device is eventually used. The POD is able to negotiate lower pricing because the manufacturer arguably then does not need to spend time or effort marketing its products. A POD in California has asserted that these savings are substantial and they issued a paper at the American Association of Orthopedic Surgeons annual meeting in 2009 which asserted that its model helped save the hospital they were affiliated with 34percent over a two-year period on the purchase of implantable devices, with total savings over one million dollars.

The very nature of PODs seem to create financial incentives for physician investors to use those devices that give them the greatest financial return and that, in the process, patient treatment decisions may be based on personal financial gain. This is especially troubling given numerous concerned allegations provided to the Committee that, due to their financial interest, physician investors in PODs may perform more procedures than are medically necessary or may use implants of inferior quality or that are not best suited for the procedure. One surgeon provided examples to the Committee of elderly patients in a POD area who were receiving eight to ten fusions in their back despite the serious health risks posed by these procedures. Another example was of an elderly patient who had a herniated disc and ended up receiving four fusion operations based on the recommendation of their surgeon who happened to be a member of a POD. Other surgeons provided examples of patients who had died from multiple operations.

Ancillary evidence concerning the rise in utilization of spinal fusion surgery and the costs of those surgeries seem to have an interesting correlation to the timeframe in which PODs have begun to become a more prevalent business model. A study published last April in the Journal of the American Medical Association cited a 15 fold increase in the number of spinal fusion surgeries for Medicare patients from 2002 to 2007. This same study went on to say that “it is unclear why more complex operations are increasing. It seems implausible that the number of patients with the most complex spinal pathology increased 15 fold in just six years. There is, however, a significant financial incentive to both hospitals and surgeons to perform the complex fusions and that may play a role.”

One example provided by the Quality Implant Coalition showed an example at one hospital based, on an analysis of its claims data, which showed that spinal fusion revision rates increased over 300 percent after a POD spinal product distributor moved into the hospital’s

area. That example was based on data from 2007, but numerous other anecdotal examples have alleged similarly dramatic increases in utilization after PODs entered the market, despite normal spine fusion procedure volume remaining constant. These actual and perceived increases raise significant questions of whether the physician investors decided to "re-do" a previously performed spinal fusion to utilize the POD's products, thereby increasing POD revenue and physician return on investment. This is of particular concern as it raises serious patient safety and ethical questions, not to mention potentially increasing Medicare and other health insurer costs.

VI. Implication of the POD Model on Hospitals, Physicians and Device Manufacturers

With the POD structure, the surgeon is acting as the seller, buyer, and person making the decision about what is best for the patient. On its face this appears to be entirely inconsistent with the fundamental tenets of healthcare compliance that have shaped the medical device industry over the last decade, and the POD structure has generated significant conflict of interest and anti-kickback concerns. However, in the absence of more clearly articulated guidance on the legality of these arrangements, those affiliated with this aspect of the medical device industry are faced with walking away from a significant amount of business that will be absorbed by companies who are willing to engage in this practice, or acquiesce to the POD structure that, in many cases, is potentially unethical and/or illegal.

Currently, there are two major national law firms that have weighed in significantly on the POD issue and they have come down squarely on opposite sides of the issue. Hooper, Lundy & Bookman, P.C., has been the most vocal proponent of the POD model arguing that the increase in these models has been because of "demonstrated savings to hospital customers alongside favorable returns on investment for physician and non-physician investors in such companies." They have opined at great length on the structure that they assert PODs must follow to make sure they are minimizing their regulatory risks and operating within the parameters of the federal fraud and abuse laws.

Conversely, Hogan Lovells (formerly Hogan & Hartson) has issued an extensive number of opinions articulating their analysis of why the POD models do not and cannot fit within the current fraud and abuse laws. Their view is that "we do not believe that physician ownership of physician owned intermediaries (POIs) reflect legitimate investments, and the evidence is that government fraud and abuse enforcement officials share our view. In fact, we believe close examination would reveal that most POIs essentially are shell entities, with no real infrastructure or capital investment, that have been developed for the unlawful purpose of directing remuneration to physicians for their ability to control the selection of surgical implants sold through the scheme. Moreover, unlike legitimate distributors and GPOs, POIs present an obvious and unavoidable potential for the patient and program abuses that the federal anti-kickback statute was specifically intended to prohibit."

It appears that hospitals and physicians, like medical device manufacturers, would benefit greatly from clear legal guidance regarding doing business with PODs. The most consistent comment from individuals interviewed by the Committee on this topic was "it was unclear to them if PODs were legal or illegal." As a result, potential physician investors typically choose the legal theory that best supports their inclination to join or refrain from joining a POD entity.

This lack of clarity seems to be the vastly disparate legal interpretations posited regarding PODs cited above and OIG's limited guidance on this issue to date.

In the absence of clarity, hospitals are in a position in which surgeons, who work in their hospital, generating income for the hospital, are approaching the hospital as a supplier and claiming that they are lowering healthcare costs by offering a lower price for products. This model seems inconsistent with the concepts of fraud and abuse law to think that a hospital can enter into a contract with their own physicians to purchase products that the hospital is paying for and that the physicians are selling and using. Hospitals, like manufacturers, have a responsibility to navigate their relationships with physicians with integrity such that a physician's ability to make more money based on the selection of products used does not enter into the equation of what is in the best interest of the patient. This obligation is greatly complicated by the threat of physician investors in PODs to take their practice and patients to another hospital if the hospital does not do business with them.

VII. Office of Inspector General Guidance

The OIG issued written guidance on this issue in 2006 expressing the need for careful review of these types of entities because of "the strong potential for improper inducements between and among the physician investors, the entities, device vendors, and device purchasers" which necessitates these arrangements being "closely scrutinized under the fraud and abuse laws." Additionally, in Congressional testimony two years later , an Office of Inspector General (OIG) representative articulated ongoing concerns that "physician ownership of medical device manufacturers and related businesses appear to be a growing trend in the medical device sector. These business ventures raise substantial concerns that a physician's return on investment from the venture may influence the physician's choice of device."

Combined, these appear to express strong concerns from OIG that a physician's financial interest in physician-owned implant supply chain companies, including PODs, could influence inappropriately the physician's choice of implantable medical device or the facility where s/he will perform procedures. Despite this expression of concern, there is abundant evidence, as noted above, that PODs have proliferated greatly in the last several years. This proliferation may have been enabled by the absence of policy statements, guidance, or visible enforcement proceedings that demonstrate with sufficient clarity and emphasis the extent of the government's concerns with the ways that PODs differ from physician joint ventures to provide legitimate (and regulated) health care services, the risks of abuse posed by PODs, and inherent suspicions about whether they serve any legitimate value.

A consistent theme among the multiple individuals interviewed by the Committee was that while OIG has acknowledged the risks of abuse that PODs pose, the lack of any recent or more specific guidance on this topic has allowed these entities to flourish as a result by citing that they are indeed following the basic guidance set forth by the OIG. This guidance does not appear to address all of the new permutations of the POD model and many of the models are being set up in such a way to purposefully circumvent the federal fraud and abuse laws designed to curb such behavior.

VIII. Physician-Payment Sunshine Law Implementation

It does not appear that the legislative history of the Sunshine Law fully contemplated the POD concept. However, the POD model at its basic level appears to be exactly the type of entities envisioned by the drafters of the Sunshine Law, which would require disclosure of the financial interests of their physician investors. Therefore, the Centers for Medicare & Medicaid Services (CMS) needs to closely examine the physician ownership and investment interests presented by PODs and ensure that those are addressed as they finalize the reporting requirements of the Sunshine Law. This would mean that the distribution model of these physician owned companies would need to be included as CMS develops a final definition of "applicable manufacturers" and "applicable GPOs." This would ensure consistent treatment of the three business models (physician-owned manufacturers, GPOs and distributors) that present similar policy and legal risks.

IX. Accountable Care Organizations

Another facet of the growth in PODs which needs to be taken into consideration is the extent to which the recently released Accountable Care Organization (ACO) regulations issued by CMS will provide an inadvertent loophole allowing the less reputable POD models to fall under the Stark and anti-kickback law waivers envisioned for ACOs. As such, it seems clear that CMS should take into account the POD models when developing the final ACO regulation to ensure that qualification and oversight of ACOs should protect against the abuses posed by PODs. The final rule should prohibit ACOs from purchasing products or services from entities that are owned by physicians participating in the ACO. Ownership would be deemed to exist if the physician receives any remuneration from the entity supplying the product or service. It should also be made clear that waivers of Stark and Anti-Kickback laws should not extend to PODs except where appropriate.

X. Conclusion

A number of legal and ethical concerns have been identified as a result of this initial inquiry into the POD models. The apparent lack of clear guidance from the government on this topic appears to be contributing to the potential for abuse in this area and it seems incumbent upon Congress to play a leadership role in bringing these issues to the forefront so they can be fully vetted and addressed. As such, the Committee is recommending that letters be sent to both OIG and CMS articulating many of the concerns cited above. We believe it is incumbent upon the Committee to work with OIG to address this rapidly evolving healthcare market issue by conducting an inquiry into PODs and their current structures and activities and develop recommendations for further action to effectively address the patient and program risks presented by PODs.

Statement of Scott Lederhaus, M.D.
President, Association for Medical Ethics

Hearing on Physician Owned Distributors:
Are They Harmful to Patients and Payers?

United States Senate Committee on Finance
November 17, 2015

Introduction

Chairman Hatch and committee members, it is an honor to be invited to testify before the Senate Committee on Finance's hearing on "Physician Owned Distributors: Are They Harmful to Patients and Payers?" As a neurosurgeon, spine surgeon and President of the Association for Medical Ethics, I have spent the last several years speaking out about the pervasive effect Physician Owned Distributorships of implantable medical devices, also known as PODs, on the medical community to my colleagues, patients and the media.

The Association for Medical Ethics is a grass roots group that was established by Ms. Gemma Cunningham and Dr. Charles Rosen at University of California, Irvine. The group formed in 2005 due to concerns regarding excessive and unnecessary spinal surgery being done in the United States. Initially consisting of orthopedic surgeons and neurosurgeons, the Association is now a national group and has expanded to include a variety of medical and surgical specialties. The members believe there is a need to address the rampant physician financial conflicts of interest contributing to the overuse and misuse of spine surgery in America. Dr. Charles Rosen was the only physician who testified in 2007 before Senate hearings about these abuses, which helped push through the Sunshine Act. Our current efforts have been directed towards the abuses and conflicts of interest with Physician Owned Distributors. I have been a member since 2007, a board member and now president of the group in 2014 and 2015.

In my testimony for the committee, I will define how PODs are affecting patients, physicians and the American medical community.

Understanding Physician Owned Distributors (PODs)

There are approximately 13.6 million patient visits for neck or low back conditions per year costing about $950 per patient per year. Between 49% and 70% of all adults will experience back pain during their lifetime and 12-30% of all adults have an active back problem. Back pain is the second most common reason adults consult a primary care provider and it is estimated that the total cost of spine related problems is approximately $90 billion per year with $10 to $20 billion in economic losses each year. Low back pain is the number one cause of disability in the United States and worldwide. Spinal fusion surgery is one of the most common surgical procedures done in the United States, roughly 500,000 operations per year. These 500,000 operations a year are where the opportunity arose for many spine surgeons to exploit the American medical system and endanger their patients.

Extensive spinal fusion surgery in the United States has exploded over the last decade often without indication and for no reason other than to enhance the income of some greedy and misguided spine surgeons. Outcomes are often poor. This behavior by some spine surgeons borders on criminal behavior, yet is largely ignored by most physicians and generally unrecognized by the public. The development of all types of spinal implants has dramatically increased over the last decade, enabling these spine surgeons to run amok by performing un-indicated multilevel spinal fusion operations. Due to the vast array of spinal implants now available – and the large amount of money to be made - spine surgeons have consciously and subconsciously loosened their "indications" for the use of these new implants. When you have a

hammer, everything looks like a nail. The profit from the "sale" of these screws, rods, and cages to the hospital is often more money to the surgeon than received for the surgical fee.

At present there are more types, shapes, sizes, materials and ways of putting implants into the spine from almost any direction; front, back or side, than ever before. The signature turn of the further explosion of operative spine procedures occurred when spine surgeons began performing operations to treat low back pain. Low back pain became the key ingredient for spinal fusion operations that initially seemed to make sense with limited and specific indications. However, over time the "surgical candidate" became anyone with a backache. Due to the evolution of thought processes regarding the treatment of back disorders, the spinal surgeon can now simply rationalize almost any back complaint as a surgical indication by grossly expanding the accepted criteria. Some patients may benefit by this shotgun approach, but the improvement may be more on the basis of luck than following evidenced-based medicine and good surgical guidelines.

Another reason for the surgical aggressiveness can be attributed to the continued financial cuts to a physician's income. Any cut in payments from Medicare directly translates into cuts in commercial insurance across the board. In order to maintain the same level of income, many doctors have made a conscious effort to see more patients and do more surgery, and some have become more "aggressive" with their surgical indications. The stage was set for some spine surgeons to enhance their income by increasing the numbers and levels of spine fusion procedures with the plethora of spinal implants available, particularly with the loosening of indications for spinal surgery.

With the further advent of PODs around 2003, doctors could now enhance their income far beyond what was imaginable prior to being involved in a POD. A POD is an entity whereby the physician purchases an ownership in an implant company. The POD buys the implants wholesale and then sells those implants to the hospital at retail. The surgeon inserts the POD implants into their patients and the doctor and POD organizers pocket the difference. Thus, the POD-docs can make additional income on each and every implant inserted in their patients creating obvious conflicts of interest. This has resulted in thousands of patients being treated by some overly aggressive spine surgeons, which have resulted in many un-indicated, multilevel spinal fusion operations, many of whom have suffered injuries, horrific infections and even death.

As a result of what my partners and I witnessed for years, we felt something had to do be done. I was compelled to notify the appropriate authorities and have some resolution to the horrible acts of neglect and malpractice that my partners and I witnessed on a regular basis. However, going after these individuals legally is a quagmire of issues, which is bogged down and largely impotent. The peer review (hospital physician oversight) process is generally useless and powerless. Too often, doctors who sit on peer review committees may choose to look the other way to avoid being tied up in legal proceedings. Hospital administrators often close their eyes to the abuses since the extensive spinal fusion operations bring huge profits into the hospital. The State Medical Boards have done little to protect the public.

What are the positions of our surgical societies and the American Medical Association on investing in PODs and conflicts of interest?

American Medical Association (AMA)
(http://www.amednews.com/article/20130408/government/130409964/7/). The American Medical Association (AMA) Code of Ethics, Opinion 8.06 issued in 2002 under Prescribing and Dispensing Drugs and Devices on the AMA website states: "Physicians may not accept any kind of payment or compensation from a drug company or device manufacturer for prescribing its products." "Furthermore, physicians should not be influenced in the prescribing of drugs, devices, or appliances by a direct or indirect financial interest in a firm or other supplier, regardless of whether the firm is a manufacturer, distributor, wholesaler, or re-packager of the products involved." (http://www.ama-assn.org//ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion806.page).

North American Spine Society (NASS): Ethical Stance on Industry and PODS
According to the North American Spine Society (NASS) Code of Ethics (http://www.spine.org/Pages/PracticePolicy/EthicsProfConduct/CodeofEthics.aspx) revised March 2012 states "A NASS member should not enter into any academic or consulting relationship with industry that might influence his or her care of patients. If a conflict or apparent conflict develops between the physician's financial interest and the physician's responsibilities to the patient, the conflict must be resolved to the patient's benefit. A NASS member must disclose to colleagues and patients, in a professional context, any financial relationships that he or she has with industry. A NASS member who fails to disclose financial or other significant relationships with industry in accordance with NASS' current Disclosure Policy is in violation of this Code of Ethics. NASS does not prevent or restrict its members from participating in a POD, but requires POD owners to disclose their ownership to their patients. Level 1 compliance for all NASS committee chairs and board members cannot have any POD involvement."

American Academy of Orthopedic Surgeons (AAOS): Ethical Stance on Industry
According to the American Academy of Orthopedic Surgeons (AAOS) Code of Ethics, revised 2011, section IIIC: (http://www.aaos.org/about/papers/ethics.asp). "When an orthopedic surgeon receives anything of value including royalties, from a manufacturer, the orthopedic surgeon must disclose this fact to the patient. It is unethical for an orthopedic surgeon to receive compensation (excluding royalties) from a manufacturer for using a particular device or product. Fair market reimbursement for reasonable administrative costs in conducting or participating in a scientifically sound research clinical trial is acceptable."

American Association of Neurological Surgeons (AANS): Ethical Stance on Industry
The American Association of Neurological Surgeons Position Statement: 2008 May 05
http://www.aans.org/~/link.aspx?_id=360DCEF0D6464BA3A086EF32819B1DD6&_z=z
Guidelines on Neurosurgeon-Industry Conflicts of Interest, Article 51297 states in their 2008 Code of Ethics: "It is unethical for a neurosurgeon to receive compensation of any kind from industry in exchange for using a particular device or medication in clinical practice. A neurosurgeon who has influence in selecting a particular product or service for an entity

(organization, institution) shall disclose any relationship with industry to colleagues, the institution and other affected entities. A "conflict of interest" occurs when a neurosurgeon or an immediate family member has, directly or indirectly, a financial interest or positional interest or other relationship with industry that could be perceived as influencing the neurosurgeon's obligation to act in the best interest of the patient."

California Association of Neurological Surgeons (CANS): California Association of Neurological Surgeons Newsletter, Volume 40, number 3, March 2013 and Volume 40, number 4, April 2013.
The California Association of Neurological Surgeons (CANS) in 2012 requested of "the AANS and the Congress of Neurological Surgeons (CNS) a Conflict of Interest Statement to include Physician Owned Distributorships (PODs)." CANS requested that the position statement should affirm that the neurosurgeon should disclose to the patient of his or her financial interest that is related to any aspect of the patient's evaluation and care related to the use of POD products.

AANS: Code of Ethics: Revised November 22, 2014
http://www.aans.org/en/About%20AANS/~/media/4A6862BB037742FF99B833D609D23B1E.ashx
The AANS finally included Physician Owned "Enterprise" in their updated Code of Ethics. "The AANS Member who has influence in selecting a particular device, product or service for an entity shall disclose any relationship(s) with industry to colleagues, the institution and other affected entities prior to the entity's selection or purchase of the device, product or service. If a AANS Member has a financial or ownership interest in a **physician-owned enterprise**, or any other entity that sells, or arranges to sell, implantable medical devices, and/or in a durable medical goods provider, imaging center, surgery center or other health care facility where the neurological surgeon's financial interest is not immediately obvious, the AANS Member **must disclose that financial interest to the patient and the institution where the patient is being treated**. The financial or ownership interest must be disclosed on a timely basis so as to allow the patient to take the interest(s) into account when making his or her health care decisions. The AANS Member has an obligation to be aware of the applicable laws regarding physician ownership, compensation and control of these entities. Disclosure of professionally-related commercial interests and any other interests that may influence clinical decision-making is required in communications to patients, the public and colleagues."

Dr. Gerald Rodts, 2010 Congress of Neurological Surgeon (CNS) President stated in his 2010 CNS Presidential Address: "**Findings of disk dehydration or degeneration at greater than or equal to 3 levels in a patient without deformity and only back pain do not justify a 3- or 4-level fusion. Without any medical evidence to support such extensive fusions, it is unethical to perform them**. **We all have a responsibility in our own practices, in our own hospitals and in our own communities to police ourselves**. **We need to get the issue out in the open and discuss it openly and honestly at regional or national neurosurgery meetings. It can no longer be the 800 pound gorilla in the room that everyone is ignoring."**
Dr. Gerald E. Rodts, M.D. 2010 CNS Presidential Address. Neurosurgical Pioneers: Foundation for Future Innovation. Clinical Neurosurgery, Volume 58, 2011. https://www.cns.org/sites/default/files/clinical_neuro/Chapter1_0.pdf

Summary of Ethical Problems with PODs

Every reputable physician association states that physicians must not be influenced in their choice of medical product by a financial interest. But it is difficult to believe that even physicians with the best of intentions could avoid being influenced in their choice of product and procedure by POD ownership. This conflict of interest is not the same as the financial incentive that exists in all fee-for-service medicine: its additive, and it's also qualitatively different. Not only is there potentially a lot more money involved for the physician-owners, but, the doctor's financial interest is likely to overwhelm any ability the hospital might otherwise have to exercise quality control. As Dr. James R. Bean, a former President of the American College of Neurosurgeons has said, "PODs invite an abuse that can neither be regulated nor prevented." Bean, "Are Physician-Owned Distributorships (PODs) Ethical," AANS Neurosurgeon, Volume 21, No. 2, 2012. And while disclosure to patients of such a conflict-of-interest is an ethical requirement, it is not sufficient. Relying on sound social science evidence, the HHS Office of Inspector General (OIG) has noted that patients often will perceive disclosure as a testimonial in favor of the procedure or product, Special Fraud Alert on Physician-Owned Entities (2013) **http://oig.hhs.gov/fraud/docs/alertsandbulletins/2013/POD_Special_Fraud_Alert.pdf** ; e.g.

It has been my experience that patients have no idea what an implant looks like, where they are made, what they are made of, what kind of quality they may be or what would be best for them. That decision is left to the spine surgeon. As a result patients are blindly willing to accept whatever implant the surgeon would decide to use regardless of the quality of those implants or where they are made. A patient has no idea what a POD is or how a POD might affect their treatment or outcome. So a disclosure by the physician of the POD implants to be used is nothing more than the physician telling their patients what they will be inserting into their spines.

Unfair competition, predatory pricing, and market distortion

In addition to the severe ethical problems posed by PODs, they adversely affect competition and distort the true price of healthcare services. On the basic question of competition, PODs eliminate it. Because implants are physician preference items, once physicians invest in a POD, the hospitals and ASCs where they perform their procedures either buy from the POD, or the physicians will take their cases elsewhere. Direct sale from an implant manufacturer to the facility is eliminated.

Moreover, through what might be described as "**Predatory Pricing**," PODs prevent the non-POD doctors from being able to compete on a level playing field when it comes to contract negotiations with insurance groups. Physicians whose income is supplemented by their self-referral earnings from a POD can agree to what would otherwise be unrealistically low insurance reimbursement rates for their physician services. Thus, the physicians who are members of a POD can simply eliminate competition between the POD and non-POD physicians by signing ridiculously low reimbursement healthcare contracts. This rewards the POD physicians, stifles competition and has nothing to do with good or competitive care, but only about money. It can

only hurt the market for health care services when inappropriate financial incentives hide the true costs that should be the basis for reimbursement rates and policies.

The OIG and PODs

I am not a lawyer, and fortunately the committee has not asked me here today to give legal advice. But you don't have to be a lawyer to understand something is illegal when the OIG describes self-referral to PODs as "inherently suspect" under the Federal health care programs anti-kickback law. According to OIG, the law is that if one purpose of offering a physician an opportunity to earn a return from a POD investment is to induce that doctor to order products from the POD, the law is violated. Can anyone seriously believe that there is any physician anywhere who has a POD ownership interest without at least "one purpose" being the financial reward from ordering POD products for his or her own patients?

I'm also not an economist. But you don't have to be an economist to understand that PODs don't save money when the OIG reports that from a study of almost 600 hospitals and almost 1,000 spinal fusion cases. *Physician-Owned Distributors of Spinal Devices: Overview of Prevalence and Utilization,* October 2013 **https://oig.hhs.gov/oei/reports/oei-01-11-00660.asp. The** OIG reported that the cost of implants purchased from PODs was not less, and in some cases was more, than from the purchase of non-POD devices. Also not surprising was the fact that the rate of growth of spinal surgeries at POD-purchasing hospitals was three times the rate at non-POD hospitals. POD Hospitals also performed 28% more surgeries than non-POD hospitals. If PODs present a serious conflict of interest, are "inherently suspect" under the anti-kickback law, don't save money and do lead to overutilization of medical services, it is hard to understand why any of them are still in business.

PODs in the real world

The poor judgment and extensive surgeries are not just theoretical. Physicians with ownership in PODs have caused real harm to patients. I have personally seen patients in consultation who have been the brunt of a POD surgeon. Examples are numerous: The 85-year-old man who has back pain undergoes a T8 to S1 (10 spinal levels) fusion with pedicle screws and rods up and down the spine to treat the back pain. Needless to say this not indicated or supported in the literature, but in most instances detrimental and can be lethal. The 45-year-old woman who has a single level herniated disc in her back with radiating leg pain who may benefit by a one hour, limited lumbar discectomy, but undergoes a two level lumbar fusion operation. The patient who has a multilevel lumbar fusion for suspected nerve root pain who does not improve only to find out the POD doctor did not examine their arthritic hips, which was the actual source of the pain. The patient who presents with carpal tunnel syndrome in the hand, yet gets a multiple level fusion in the neck. The patient who has mild spinal canal narrowing in the neck without any spinal cord compression, but is told they need a multilevel neck fusion to avoid becoming paralyzed. The patient with back pain who undergoes a three level lumbar fusion operation, which does not help the pain, undergoes additional levels of fusion with still no improvement, who then undergoes a sacro-iliac joint fusion, still without resolution of the pain, only then to be referred to a pain management physician who puts in a spinal cord stimulator to help with the pain.

Mr. John Carreyrou authored an article for the Wall Street Journal about Dr. Aria Sabit, a neurosurgeon in Ventura, Calif., who used Apex Medical implants through Reliance Medical. The same Reliance Medical implants from Mr. Bret Berry and Mr. Adam Pike who claimed they had no financial dealings with the doctors. According to the **Wall Street Journal articles by Mr. John Carreyrou on 7/25/13 ("Surgeons Eyed Over Deals With Medical-Device Makers") and 7/27/13, ("Does my Surgeon Profit From My Implants?"),** the Reliance Medical network of Mr. Pike and Mr. Berry eventually grew to comprise at least 11 PODs operating in six states: Utah, California, Texas, Louisiana, Florida and South Carolina. Thus, further evidence that Reliance Medical is a group of PODs that utilize one of their 26 LLC's for distribution purposes of the POD implants. Dr. Sabit worked in Ventura, Calif., for 17 months and somehow managed to acquire 30 malpractice lawsuits against him. It just so happened that in many of his cases he used Apex Medical Implants, which are Reliance Medical implants supplied by Mr. Pike, Mr. Berry and Mr. Hoffman (the owners and salesperson for Reliance Medical implants). The profits from Apex Medical POD included 20% of the proceeds each going to Mr. Adam Pike, Mr. Bret Berry, Mr. John Hoffman, Dr. Sean Xie (a neurosurgeon in Los Angeles who apparently trained with Dr. Sabit, as a co-owner in Apex POD) and Dr. Aria Sabit. Dr. Sabit's surgeries, often without indication and very extensive spine fusion procedures, caused injury to many patients including nerve root damage, spinal fluid leaks, failed fusions and life threatening infections to mention a few complications. Dr. Sabit reportedly was paid $400,000 in just over a year for the use of the Apex POD implants. These issues were discussed in the articles by Mr. Carreyrou. Thankfully, the Department of Justice has brought cases against Dr. Sabit and against Reliance, bringing both criminal charges and claims under the False Claims Act. E.g., United States District Court for the Eastern District of Michigan, United States of America v Aria O. Sabit" Filed 2/7/14 page 32 and 33, http://projects.scpr.org/longreads/selling-the-spine/docs/doj_investigation.pdf. The USA vs Reliance Medical Systems, Mr. Adam Pike, Mr. Brett Berry, Mr. John Hoffman and Dr. Aria Sabit is the first test case against a POD. However, what is really remarkable is that although OIG's report estimated that 20% of the spinal fusion operations done in America were done with POD implants in 2011, there currently do not appear to be any other enforcement cases.

Hospital systems react to POD controversy

Overtime, many hospital systems have recognized that PODs represent additional liability exposure and perhaps increased abuse, expense and inherent conflicts of interest. Especially following the OIG's 2013 Special Fraud Alert, many hospitals have taken the opinion that PODs are too risky and have eliminated them from their facilities. Some of the hospitals that no longer allow PODs are:

- Catholic Healthcare West, now Dignity Health (40 Hospitals)
- Scripps Hospital System in San Diego
- Martin Memorial Health System (Florida)
- Providence Health & Services (28 Hospitals)
- Loma Linda University
- University of California, Irvine
- The Memorial Care Health System in Orange County (6 Hospitals)
- Tenet Health Care (77 Hospitals in 14 states)
- Ascension Health (70 Hospitals, largest Catholic non-profit)
- Intermountain Healthcare (22 hospitals in Utah and Idaho)
- Hospital Corporation of America (HCA, 165 hospitals, 115 ASC's)

- Baylor Scott & White Health (43 hospitals in Texas)

It is encouraging that the private sector is stepping up to push back on PODs to fill the gap left by the absence of law enforcement. But there are still way too many hospitals that are dealing with PODs. The private sector alone is not enough to protect patients and the health care system.

Can there be an "Ethical POD?"

In a word, "no." Surgery involving implantable medical devices is one of the great medical innovations of the 20th Century. Millions of patients have received life-changing and life-prolonging relief from disabilities that crippled or killed previous generations. Physicians who provide this kind of care are justifiably proud of what they do. After long years of training to become specialists in these fields, many of the physicians in this country have been frustrated to watch as a health care system tries to "bend the cost curve" which continues to devalue their services. That the physicians of this country are looking for an alternative should then be of no surprise.

But PODs cannot be the answer. Giving physicians a financial interest in the implants they order for their own patients creates a conflict of interest that is quantitatively greater and qualitatively different from the choice of whether to treat a patient in the first place. Medical ethics largely places the decision of whether an inappropriate financial interest exists in the hands of the physician. However, it is difficult to believe that any physician could fail to be influenced in choice of products based on the financial interest involved, or choice of facility based on whether the facility will deal with the POD. PODs adversely affect competition and distort the true cost of health care products and services. And while decreased health care costs and better controlled utilization of health care services would not eliminate the conflict interest, unfair competition, or market distortion, the OIG's research demonstrates that PODs fail to deliver even on these.

Conclusion

In conclusion, my experience as a neurosurgeon these past 30+ years, and my observations of the world around me from my position as President of the Association for Medical Ethics, leads me to believe that physicians should not be permitted to profit from the implants they order for their own patients by investment in a POD. PODs present doctors with an ethical conflict that realistically can't be overcome. They create unfair competition among implant sellers, hospitals, and physicians. They distort the true cost of medical products and services. And even if they did so in the transparent light of day, the potential for harm to patients and the integrity of the physician-patient relationship can't be put at risk in this way. The only answer in my opinion is that PODs cannot be allowed.

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Supporting Addendum One

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Physician-Owned Distributors: The Wave of the Future or the End of the Model?

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ABSTRACT: New business entities called physician-owned distributors (PODs) have sprung up around the country. PODs are business entities that enhance the income of physicians who are investors via the recovery of money paid out for the implantation of medical devices in their patients. There have been a varying opinions among attorney groups and the Office of Inspector General as to their legality and what may constitute a legal entity. The legal opinion of attorneys employed by the major implant companies is that the PODs are illegal, whereas the legal opinion of those physicians setting up a POD is that the PODs are legal when properly and "legally" constructed. The Office of Inspector General has been watching these businesses as possible violations of the Stark Laws and kickbacks being paid out to the physician owners in the PODs. Some hospital groups have been prohibiting PODs from doing business in their hospitals because of fear of the excessive use of implants and possible kickback violations. These are confusing issues and as of this time there is no clear and concise model that can be considered legal, yet the PODs persist and are becoming more prevalent.

KEY WORDS: physician-owned distributors, PODs, OIG, kickbacks, Stark, safe harbors, alliance surgical distributors, omega solutions, implants, Sunshine Act, predatory pricing, False Claims Act, civil monetary penalty.

I. DEFINITION

Physician-owned distributors (PODs) are sometimes called physician-owned intermediaries or physician-owned companies by virtue of their place in the supply chain. PODs are groups of physicians, usually surgeons, who enter into a business relationship with a business entity that purchases implanted devices such as total joint prostheses or spinal hardware (i.e., pedicle screws, cages, and rods that the owner physician ordered for their cases). The physicians in the POD profit financially by participating in the sale of medical devices intended for implantation in their own patients, thus creating the opportunity for them to profit from their own referrals and implants.

II. INTENT AND DESIGN MODEL

Probably in large part because of the continued decline in reimbursement from Medicare and private payers, PODs have become increasingly widespread throughout the United States in an effort to increase physician income.[1] The design with which the PODs achieve their goal varies. The simplest model involves the POD business being set up by a entrepreneur, who could be a physician or nonphysician. The developer of this model then seeks investors who implant devices such as spinal implants, joint replacement,

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cardiac pacemakers, and spinal cord stimulators. The initial financial contribution to be a investor may vary, but it could exceed $50,000. The investor may own their implants, a percentage of the POD, or both. The hospital at which the surgery takes place pays the POD for the product after the investor implants the devices. The POD includes a shell—a second corporation or entity—that is used to facilitate payment to the investors, thus avoiding, direct payment from the POD which then sells its products to the physician investors. The investor may be involved as a solo physician in his own investment group or possibly could be involved in a small group of physicians who all share in the profits; both of these models are considered mini-PODs. Therefore, in most of these models there is a direct payment per implant to the POD.

III. CONFLICTS OF INTEREST

The Office of Inspector General (OIG) along with the Stark legislation have examined PODs as a source of kickbacks and conflicts of interest.[2,3] Kickbacks can be in the form of direct financial payments, consulting and royalty agreements, trips for doctors and their families, or consulting meetings. The conflict of interest is borne out in that an investor in a POD stands to make large sums of money for the implants used. The more extensive the surgery the higher the reimbursement, which may be a set up for egregious acts on the part of the surgeon. Unfortunately, all too often, greed becomes the determining factor in the extent of surgery and issues surrounding minimal or no indication for surgery.

IV. EXISTING LEGISLATION AGAINST THE POD MODEL

According to a OIG/Department of Health Services (DHS) Fraud and Abuse Alert from January 23, 1989,[2] noted that Congress did not intend to bar absolutely any investment by physicians in other health care entities but has included a "safe harbor" for investment interests in large public corporations. The OIG and DHS have done this to ensure that the companies are sufficiently large enough so that the return on investment is, at most, tangentially related to any referrals of items or services made by a shareholder. Therefore, under the proposed rule, referrals by physicians to entities in which they have any kind of investment interest (other than in large corporations available to the general public), such as limited partnerships, would be subject to prosecution.

Safe harbors' protection of medical business entities makes it possible that certain business arrangements might violate the antikickback laws. Thus, if the business qualifies as a safe harbor then the doctors involved do not have to worry about being accused of making money from referrals. To be a "legal" POD entity under the safe harbor regulations a number of legal issues would need to be satisfied to avoid being held accountable under antikickback regulations.

Safe harbor regulations allow for certain arrangements when the business entity, a POD in this case, is not publicly traded, derives less than 40% income from physician investors, be no more than 40% physician owned, receive no referrals from investing physicians, have terms for passive investors that are no different than those for physician

investors, and require payments to physicians that are not directly related to volume of referrals. Passive physician owners are not required to make referrals to the POD and physicians are not required to divest their interest if they retire or are no longer actively engaged in the practice of medicine in the POD market. It is doubtful if any of the PODs today would qualify as safe harbors because a large, publicly traded company does not fit the POD model. In general, then, safe harbor protection would not apply to a POD.

If the safe harbor classification does not apply, then the Ethics in Patient Referral Act (Stark law against self referrals) may apply. The theory behind the Stark law is to control unnecessary spending that arises from improper financial relationships with Federal programs. The statute applies to anyone who is connected financially under any federally funded health care program, not just Medicare or Medicaid. A physician is prohibited from referring Medicare-funded inpatient or outpatient services when the physician or anyone in their immediate family has a financial relationship with the associated hospital unless the relationship meets a Stark exception, for example, a possible indirect financial relationship.[4] To violate Stark laws, the *intent* to violate does not matter, whereas with antikickback regulations, *intent* to violate is critical.

Under the Stark law, anyone who fulfils either of the following criteria is potentially liable for prosecution:

> *A physician who has a "financial relationship," which is defined as (a) ownership of an entity, or (b) a compensation arrangement between physicians and the entity, including family members.*
>
> *The entity cannot make a claim to Medicare for a prohibited referral. This is done to prevent physicians from making referrals based on financial gain, thus preventing overutilization, which increases health care costs.*

Because PODs do not qualify as safe harbors, they must follow antikickback regulations and potentially Stark laws. A member of a POD then has to be concerned about whether the POD is a legal entity and if, as an investor, they would be potentially at fault for breaking these laws. The Stark laws prohibit Medicare payments for any hospital services *referred* by a physician with a prohibited financial relationship or who requires refunds are subject to penalties that increase with each new referral. This is especially true when the physician knows or should have known they are an investor in a POD. The Centers for Medicare and Medicaid Services has recognized the physician–POD–hospital connection and believe this is a *indirect financial relationship* under the Stark laws and would run afoul of the physician self-referral statute.[5] The Federal Register[5] reported that there is concern about possible program or patient abuse when physicians profit from the referrals they make to hospitals through physician-owned companies. In the *Federal Register* it is noted that many cases the physician investors bear little, if any, economic risk with respect to the medical devices. It is felt that some PODs serve little purpose other than providing physicians the opportunity to earn economic benefits in exchange for nothing more than ordering medical devices or other products that the physician investors use on their own patients. "The financial incentives paid to the phy-

sicians may foster an anticompetitive climate, raise quality of care concerns, and lead to overutilization of the device or other products to which the physician is linked."[5,6]

If the Stark restrictions are not enough, the False Claims Act (FCA) can also be a legal avenue against a investor. The FCA is the Federal government's primary civil enforcement tool for addressing health care fraud. Under the False Claims Act the government may enforce significant penalties against any person who *knowingly* submits a false claim for *unnecessary* medical services. Whistleblowers can report those violators who have defrauded the government, and many of the individuals who file these lawsuits are employees or former employees of the companies that committed the fraud. If there are violations of the antikickback or Stark laws, then there is a potential for a violation of the FCA, which is implicated in cases of the questionable medical necessity of procedures. In February 2008, Gregory Demske of the OIG stated that, "[PODs] will be closely scrutinized due to potential for abuse. These groups can be prosecuted under the Federal False Claims Act, Federal antikickback statute, or civil monitories penalty law."[7] The Civil Monetary Penalty (CMP) refers to device manufacturers paying a physician to recommend the specific device for use in hospital procedures. Therefore, a physician owner in a POD is walking a tight rope with respect to believing they can navigate the potential laws designed to punish those involved in health care fraud and abuse.

V. GOVERNMENT LEGAL ISSUES

A June 2011 inquiry by the Senate Finance Committee provided an overview of key issues and potential areas for congressional oversight. This investigative report noted that PODs began developing around 2003 and have branched out from orthopedics to spinal implants, cardiac pacemakers, and other implants.[8,9] It was noted that that there are multiple PODs in at least 20 states, with as many as 40 PODs in California alone.[1] On June 9, 2011, letters were sent to the US Department of Health and Human Services and the CMS, both of which were authored by Senator Orrin Hatch (ranking member of the Finance Committee), Senator Herb Kohl (chairman of the Special Committee on Aging), Senator Charles Grassley (ranking member of the Judiciary Committee), Senator Max Baucus (chairman of the Finance Committee), and Senator Bob Corker (ranking member of the Special Committee on Aging). The authors requested that PODs be included in the Sunshine Act as far as making public the payments made to physicians through these POD groups. In addition, the letters requested that the DHS and CMS address potential loopholes in the POD model that may relate to the upcoming accountable care organizations and any potential conflicts of interest, safety concerns, and the impact on health care, all of which are considered "troubling issues about PODs."[8]

VI. GETTING AROUND THE GOVERNMENT LEGAL ISSUES

Bill Lockyer, Attorney General for the State of California, issued a opinion letter in February 2006.[10] He stated that a physician may prescribe a medical device distributed by a

company in which a physician has an ownership provided that the return on investment is based on the physician's proportional ownership share and that the requisite disclosures are made. He goes on to point out that the company's profits are not dependent on the number of referrals that the physician has made if the physician complied with relevant patient disclosure requirements. The opinion mentions the Department of Health and Human Services regulations defining "financial interests" subject to the federal antikickback statue and that interest offered to passive investors would be no different that that offered to other investors. He states that the investment would be required to be lawful under the federal antikickback statute and implemented regulations. Regarding the Unfair Competition Law, which governs anticompetitive business practices as well as injuries to consumers, he notes that, "a business practice can be unfair if it offends and established public policy or is immoral, unethical, oppressive, unscrupulous, or substantially injurious to consumers."[11] The terms of financial interest, proportional return on investment, and passive investors are vague and not well defined in Lockyer's opinion letter. Despite his opinion, the Attorney General of the State of California has no jurisdiction over the federal laws regarding fraud and abuse, antikickback regulations, or the Stark laws.

Many of the attorney groups that argue that PODs are illegal generally have some connection to the medical device companies and thus argue in favor of the illegal nature of PODs.[12-14] No different are the attorney groups that argue that PODs are legal.[15,16] Thus, there seems to be no unbiased opinion when it comes to the legal views on either side of the argument. Hooper, Lundy & Bookman, a law firm in California that has worked with PODs, including Alliance Surgical Distributors, a POD owned by Dr. John Steinmann in Redlands, California; Omega Solutions, a POD in Fresno, California; and Atlas Medical in Southern California. Hooper, Lundy & Bookman have stated and recognize that a POD may be impacted by antikickback statutes and they point out that the OIG recognizes that these PODs are vulnerable to violations of antikickback laws, and the firm also states that, "following these guidelines does not guarantee the POD is lawful."[4] In an attempt to avoid the need for safe harbors, Hooper, Lundy & Bookman claim to have set up a potentially legal POD by using *indirect compensation* as a exception to the Stark self-referral laws: the products are sold at fair market value, and pricing competes with that of other companies. As reported by Orthopedics This Week,[17] the firm has established a 19 requirements that must be met for a POD to be considered a legal entity; these requirements will in effect make the POD as legal because it can meet the current restrictive federal laws. The Indirect Compensation Agreement is a Stark exception but is not relevant to the kickback laws. Therefore, the kickback laws can still be applied even with a Stark exception. Dr. Steinmann, owner of the POD Alliance Surgical Distributors, has opined that his model is a win–win for the doctor and hospital because he is able to supply the hospital with competitively priced implants and enable the physician members of the POD to enhance their income by using his model and his implants. His model does not take into account the surgeon who uses the POD implants and "saves the hospital money" but in actuality would increase costs by performing

extensive surgery that may not be needed. According to Hooper, Lundy & Bookman, using the 19 provisions, PODs can be as legal as possible although they still could be violating the antikickback laws.

The 19 steps for the formation of a POD[18] as required by Hooper, Lundy & Bookman include the following:

1. The company will hire and employ its own personnel.
2. The company will purchase products directly from manufacturers/distributors under its own contracts.
3. The company will sell products directly to its own customers such as hospitals or surgery centers under its own contracts.
4. The company will manage its own inventory.
5. The company will have its own distinct office and warehouse space for the operation of its own business.
6. Products will be shipped to the company by the manufacturer/distributor and will be separately warehoused by the company before resale to hospitals or surgery centers.
7. The company will hold any and all licenses or governmental approvals necessary for the operation of its business.
8. The investment price offered to physicians will not be based on the projected referrals from the physicians, nor will the amount being offered to physicians reflect the anticipated referrals generated from the physicians procedures.
9. No physician's investment interest will be subject to repurchase for failure to use the company's devices in their surgeries.
10. The investing physicians will not be pressured in any way to utilize the company's devices in their surgeries.
11. The investing physicians will not exert pressure on the hospitals or surgery centers to purchase the devices from the company.
12. The company will be adequately capitalized for its operations through the initial capital contributions of its members and the physician investments will not be nominal. The members' capital contributions will not come from the manufacturers or distributors that sell devices to the company, nor will the managers or its affiliates loan funds to the physician investor for their capital contributions.
13. The use of the devices will at all times be medically necessary.
14. The company will not bill patients or payers (including Medicare and Medi-Cal) for the devices.

15. The company will have written agreements with the manufacturers/distributors for purchase of the devices.
16. The company will have written agreements with the purchasers, hospitals, or surgery centers for the sale of the devices.
17. The purchasers, hospitals, or surgery centers will be charged a fixed price based on negotiations, which will not increase with the use of more devices.
18. The company will generally have a fixed list of prices that will be generally available to all purchasers, hospitals, or surgery centers.
19. However, the company may be willing to accept lower pricing if the purchaser dictates lower fixed pricing. The payments by the purchasers will not be higher than fair market value for the devices.

Omega Solutions was the distributor used by Dr. Vishal Makker, who was exposed by the *Wall Street Journal* in March,[17] April,[19] and June 2011[11]; the *Journal* highlighted that Makker was using implants from a POD and allegedly was performing multiple repeat surgeries while receiving $500,000 per year from Omega Solutions. As well, Makker's girlfriend was an Omega product representative. Omega Solutions closed its doors after the *Wall Street Journal* articles because the instrument manufacturers declined to do business with Omega any longer. Since the exposition of Dr. Makker the Oregon's Providence Health & Services Hospital, the Providence Health & Services have eliminated PODs from their 28 hospital system, which was implemented by John Koster, M.D. and President/CEO on February 9, 2012.

Regarding physician ownership in light of the OIG opinion mentioned earlier, Paul Hastings,[20] an attorney employed by Medtronic-Sofamore Danek, stated that, "this could be considered a 'referral,' which is applicable to the antikickback statutes. Return on investment to a physician from a medical device company to which the physician refers must be based solely on the value of the investment. The physician with a ownership must disclose the financial interest in writing to the patient at the time the referral is made. These referral companies may be permissible, but should not be considered a blanket permission to engage in such activities." Hastings concluding the following: (1) the physician must disclose ownership interest in writing to the patient; (2) physicians should remember that they must comply with the most restrictive federal laws, which may carry significant criminal penalties; (3) the return on investment must be solely on the value of the investment; (4) the attorney general seems to view solicitation by medical device companies of physicians as investors to be a potential violation of the California Unfair Competition Law (hospitals have to use the physician implants); and (5) the physician should be careful not to commit in any way to using a company's products or to enter into a arrangement that guarantees return based on the volume of referrals.

Thomas Bulleit,[17,21] an attorney in a firm that represents some large spinal implant companies, noted that PODs are entrepreneur-driven opportunities where doctors are

seduced into kicking in a "little bit of money" in exchange for shares of the company. "There is no purpose for these companies but to give the doctor's a return. …The anti-kickback statute is violated if one purpose of the financial reward to a doctor is to get him to order a particular product or refer patients to a particular hospital."

Mr. Kevin McAnaney,[22] a attorney who specializes in healthcare fraud, claims physician ownership of medical device companies is legal providing that the physicians are buying their shares at fair market value and that their profits are based on their percentage of ownership of interest and not on the volume of business they generate for the company. The problem would arise if the money made is directly tied to his usage of the product.

VII. THE STANCE OF GOVERNMENT TODAY

Advanced Medical Technology, an organization representing the code of ethics of interaction with health care professionals, headed by Stephen Ubl, requested clarification from the OIG regarding guidance for certain physician investments in medical device manufacturers and distributors.[23] The OIG has taken the stance of closely scrutinizing PODs under the fraud and abuse laws (Dept HHS, Oct 6, 2006). The OIG considers these arrangements ripe for potential violations of fraud and abuse and that these models will be observed closely. More recently the Senate Finance Committees[12] have strongly requested clarification on PODs to draw a line in the sand so everyone can understand what is "legal." "You can't possibly think this is OK," said Tom Scully, senior counsel at the law firm Alston & Bird who headed the Medicare program from 2001 to 2004. "I understand that the docs feel squeezed and want to make more money, but they're racing toward a cliff. This can't possibly hold up."[18]

In September 2011, Daniel Levinson, Inspector General of the OIG, gave the following response[24]:

> *We expect that our study will produce important information about PODs. We will consider this information in determining whether to issue additional guidance addressing physician-owned entities, including PODs. However, as we have discussed a wide variety of POD models are being utilized, and different POD models can raise varying levels of legal concern; thus, the answers to many of the important legal questions posed about PODs depend on the specific facts of the case. The Federal Anti-Kickback Statute is a criminal, intent-based statute that plays a central role in addressing improprieties in physician–industry relationships. The legality of any individual physician-owned entity under the Federal Anti-Kickback Statute is highly dependent on each entity's particular characteristics, including the details of its legal structure; its operational safeguards; and, importantly, the actual conduct of its investors, management entities, suppliers, and customers during the implementation phase and ongoing operations. For these reasons, the OIG's ability to issue guidance about the application of these business structures is limited.*

> *It has been OIG's longstanding view that the opportunity for a referring physician to earn a profit, including through an investment in an entity for which he or she generates business, could constitute an illegal inducement under the Federal Anti-Kickback Statute. When evaluating the legality of a such an investment, OIG would consider, among other factors, the terms under which a physician may invest in the entity and, conversely, the terms under which a physician owner may be required to divest his or her ownership interest; the actual return or projected return on the physician's investment; and the amount of revenues generated for the entity by its physician investors. OIG has repeatedly expressed this view, and listed these factors, in various guidance documents, including Special Fraud Alerts, advisory opinions, and published letters to the industry.*

It is clear from Levinson's response that there is no formal decision as to what constitutes a legal POD or whether a POD even can be legal. The "wait and watch," noncommittal attitude of the OIG continues to confuse proponents on either side.

VII.A. The Sunshine Act

The Sunshine Act, introduced in 2009 by Senators Chuck Grassley (R-IA) and Herb Kohl (D-WI),[25] requires manufacturers and group purchasing organizations to report a wide variety of payments to physicians and physician-owned entities. Penalties for not reporting include fines from $1,000 to $10,000 for each payment not reported, with a cap of $150,000 per year. For intentional failure to report, the penalties will be steeper, with fines of $10,000 to $100,000 for each payment not reported, with a cap of $1 million per year. For PODs, the Sunshine Act requires reporting physicians' ownership interests in private companies, including the dollar amount(s) invested, the current value, and any payment or transfer of value to the owner, including dividends or other payments. The information is to be published in a searchable website in 2013. The Sunshine Act alone does not imply that the PODs are illegal, only that items such as the dividends and payments are to be made public.

VII.B. The Stance of Some Hospital Groups

The Martin Memorial Health Systems in Stuart, Florida, have decided to stop doing business with PODs because in their opinion PODs are "inconsistent with the spirit and intent of the federal antikickback statute."[26] Other hospital groups are requiring their physician members to sign financial relationships with their suppliers to avoid antikickback and self-referral laws. The Scripps Hospital system in San Diego, California, has eliminated the use of PODs in their hospitals. According to Daniel Roach, Vice President of Compliance, except for very limited use the Catholic Healthcare West Hospital systems have eliminated PODs from their system of 40 hospitals throughout California, Arizona, and Nevada (Roach D, personal communication). As well, the 28-hospital

Providence Health & Services have eliminated PODs where Dr. Makker had performed surgery.

VIII. OTHER POD ISSUES NOT PREVIOUSLY CONSIDERED

VIII.A. Predatory Pricing

If one considers health plan contracts including capitated payment issues to the physicians who are investors in a POD, the POD physicians cannot be competed with. Over the years, physicians have been competing to the point of who will accept the bottom dollar on a contract. Now, with the POD model available, one can consider predatory pricing when it comes to contract negotiations. Without the monies paid from a POD, a non-POD physician has little or no power to compete with a physician or group of physicians who utilize a POD model. In theory, the POD physicians could survive without being paid any fees for services or capitated money to provide care for their patients from their contracted insurance groups. The POD physicians can generate more income than would be possible with any insurance payment plan. Thus, the POD physician essentially could work without compensation when it comes to the insurers and could dominate their local provider market. How could anyone who is not part of a POD compete with this model? This could be considered a violation California's unfair business practice under the Unfair Competition Law, section 17200.[20,27] The antitrust laws were enacted to promote competition. Now we have gone to the other extreme to eliminate competition by reducing payments to amounts so low as to consider the POD model being almost free services to insurers. Although this is a new concept, it is occurring. This essentially promotes those physicians who may egregiously perform extensive and nonindicated operations for the sake of enhancing income solely on the implants used. Gone are the days of lumbar discectomies when a multilevel fusion can be done instead. Thus, predatory pricing rewards those unscrupulous surgeons who have no sense of ethics or doing what is best for the patient.

VIII.B. Who Loses?

In a POD situation, if a surgeon performs more than that which needs to be done, the hospital loses because the costs of the implants generally are paid directly by the hospital. In some instances the costs may be paid by the health maintenance organization or insurance company, depending on the contracts the hospital may have with the insurer. In the instance of Medicare, the hospital loses because patients are admitted on a diagnosis-related group basis, multiple implants would be paid for by the hospital and Medicare would only pay based on the admitting diagnosis-related group. The other loser in this model is the patient, who unknowingly has submitted to a extensive operation with little or no indication for the treatment.

VIII.C. What Can Be Done?

It is doubtful that all physicians can be trusted enough to perform operations or provide services for only those patients who need surgery and do only what is best for their patients. There are too many financial enticements to keep those marginally ethical docs on the straight and narrow. It will be up to the hospitals to be proactive in their stance regarding PODs. At a minimum, hospitals should develop a conflict of interest statement that all physicians should sign. If a hospital's opinion is that the PODs do not coincide with the intent of the law, then it would be up to the individual hospital to decide whether or not PODs should be allowed at their facility. These efforts likely would eliminate the PODs ability to develop or gain a foothold at any given hospital.

VIII.D. Can a POD be Legal?

With the controversy regarding the legality of PODs, one must decide if sitting on the fence waiting for the federal government to formally declare PODs illegal or legal or if the risks of joining a POD are worth it. With time there may be more openly prosecuted cases involving PODs undergoing OIG investigations for fraud and abuse with surgeons performing egregious nonindicated, multilevel procedures.

It would seem that a POD cannot qualify for protection as a safe harbor. Thus, a indirect payment model, as a potential Stark exception, would be necessary, as outlined in part by Dr. Steinmann's 19-point compliance, with several important additions and differences.

1. The POD investors could only own a fixed, small percentage of the company and eliminate multiple small and individual or mini-PODs.
2. Reimbursement from a POD can be based only on the percentage ownership of a individual POD and not by individual use of a product.
3. A POD must have a large number of physician owners, perhaps 25 or more, all with equal percentages of ownership, who locally work in a close geographic area, so that one cannot construe that payment is based on volume as it would be in a smaller POD and an investor cannot choose heavy users throughout a large geographic area.
4. Any implant company potentially could compete for the business at any hospital from the POD.
5. The physician owners would not purchase specific implants because purchasing a implant would force a physician to use only one particular product that may be of inferior quality or not what would be best for the patient.
6. The POD would not accrue implants but would purchase implants from the most cost-conscious and quality options manufactured by any of the small or large implant companies.

7. Implants purchased by the hospital through any vendor would be no more expensive with a POD; a POD could not charge higher fees than other implant companies.
8. Each hospital that allows PODs must have a conflict of interest statement that each physician member of that hospital signs.
9. If any physician is egregiously performing nonindicated, multilevel operations (which would have to be monitored via a peer-review process and conflict of interest declaration at each hospital), those individuals would be eliminated from the POD and potentially reported for possible fraud and abuse prosecution.
10. The POD owner would have to declare in writing to their patients that they have a financial interest in the company.
11. There would be no need for passive investors because the POD models would not qualify as safe harbors.
12. Physician investors who retire or move out of the area of a particular POD would sell their interests back to the POD.
13. POD investors who care for non–federally funded insurance, including workers compensation, should follow these same guidelines to avoid egregious acts and kickbacks.

IX. CONCLUSION

The POD model as described by John Steinmann and others has been looked at legally by Hooper, Lundy & Bookman in California. Nevertheless, even this legal team, despite all efforts to develop a legal entity that complies with the most stringent federal legislation, recognizes and acknowledges that their efforts to make a legal POD still could be considered illegal under scrutiny by the federal government. It should be remembered that a legal opinion from an attorney or group of attorneys does not have legal jurisdiction over the OIG/DHS and the federally funded patients. It is ultimately up to the OIG and Fraud and Abuse to determine what is considered legal and what is deemed illegal and worthy of prosecution. For these reasons, one should be exceedingly careful when becoming involved in a POD. Only after a POD investor loses his license to practice medicine, incurs heavy fines, or faces potential prison time for egregious acts will these POD groups collapse, as they did in the case of the Omega Solutions group and Dr. Makker. Perhaps all hospitals should consider what the Stuart, Florida–based Martin Memorial Health Systems decided this year: stop doing business with such entities. Martin Memorial Health Systems told its staff that PODs are "inconsistent with the spirit and intent of the federal antikickback statute." If a legal POD could be devised with stringent guidelines then perhaps there is a place in the market for such a model. Without strict guidelines the POD model will be poorly defined and lead to fragmentation of structure, and we will be back to our current

dilemma of forming semilegal or entirely illegal PODs and dealing with predatory pricing and kickbacks. Continuing on as we are is not acceptable and will eventually require the OIG to take a firm stance for or against PODs. It is up to physicians to practice responsible, ethical surgery for the benefit of their patients. However, if a legal POD entity can be developed that satisfies all the stringent federal laws and restrictions it also could be a revenue source for physicians in these difficult economic times.

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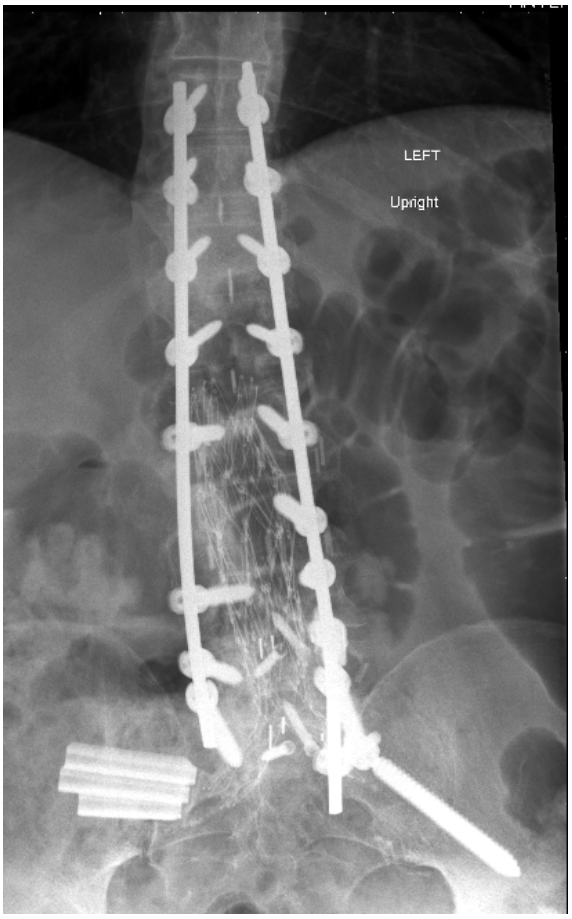
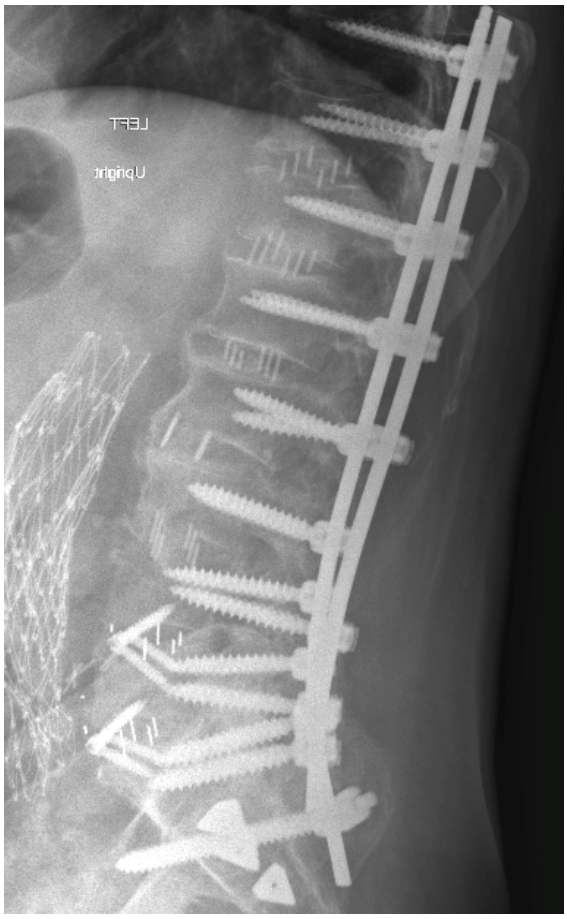
Supporting Addendum Two

T10-S1 fusion for low back pain and bilateral Sacro-iliac fusion





Shown is an extensive POD fusion to treat low back pain. Unfortunately, despite a total of four operations, the patient is in worse pain than prior to the surgeries. This is not a unique case.

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 402 and 403

Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 402 and 403

[CMS–5060–F]

RIN 0938–AR33

Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule will require applicable manufacturers of drugs, devices, biologicals, or medical supplies covered by Medicare, Medicaid or the Children's Health Insurance Program (CHIP) to report annually to the Secretary certain payments or transfers of value provided to physicians or teaching hospitals ("covered recipients"). In addition, applicable manufacturers and applicable group purchasing organizations (GPOs) are required to report annually certain physician ownership or investment interests. The Secretary is required to publish applicable manufacturers' and applicable GPOs' submitted payment and ownership information on a public Web site.

DATES: *Effective date:* These regulations are effective on April 9, 2013.

Compliance date: Applicable manufacturers and applicable group purchasing organizations must begin to collect the required data on August 1, 2013 and report the data to CMS by March 31, 2014.

FOR FURTHER INFORMATION CONTACT: Erica Breese, (202) 260–6079.

SUPPLEMENTARY INFORMATION:

I. Executive Summary and Background

A. Executive Summary for This Final Rule

1. Purpose

This final rule is necessary to implement the requirements in section 6002 of the Affordable Care Act, which added section 1128G to the Social Security Act (the Act). That provision requires applicable manufacturers of drugs, devices, biologicals, or medical supplies covered under title XVIII of the Act (Medicare) or a State plan under title XIX (Medicaid) or XXI of the Act (the Children's Health Insurance Program, or CHIP) to report annually to the Secretary certain payments or other transfers of value to physicians and teaching hospitals. Section 1128G of the Act also requires applicable manufacturers and applicable group purchasing organizations (GPOs) to report certain information regarding the ownership or investment interests held by physicians or the immediate family members of physicians in such entities.

We believe that these provisions of the Act were modeled largely on the recommendations of the Medicare Payment Advisory Commission (MedPAC), which voted in 2009 to recommend Congressional enactment of a new regulatory program. In addition, the Institute of Medicine (IOM) recommended implementing a national disclosure program for payments to health care providers and prescribers in the 2009 report titled, "Conflict of Interest in Medical Research, Education and Practice." Given these recommendations and other information on conflicts of interest that could affect treatment decisions, Congress enacted legislation establishing a national disclosure program with section 6002 of the Affordable Care Act. This final rule provides the implementing requirements for this program.

2. Summary of the Major Provisions

a. Transparency Reports

This rule finalizes requirements for applicable manufacturers to annually report certain payments or other transfers of value to covered recipients. The rule provides definitions of numerous terms, such as applicable manufacturer, and covered drug, device, biological, and medical supply. In addition, the rule also clarifies how applicable manufacturers should report and characterize payments or other transfers of value, including rules for research payments, and indirect payments provided to a covered recipient through a third party. The rule also finalizes which payments or other transfers of value are excluded from the reporting requirements.

In addition, the rule finalizes the requirements for applicable manufacturers and applicable GPOs to annually report information about certain ownership or investment interests held by physicians and the immediate family members of physicians in such entities, as well as payments and other transfers of value to such physicians. The rule details what constitutes an ownership or investment interest for purposes of the reporting requirements, and defines for whom they must be reported. The rule also clarifies the content for the ownership or investment interest report.

b. Report Submission, Correction, and Publication

The rule finalizes the processes and requirements for applicable manufacturers and applicable GPOs to submit their reports to CMS, including the specific data elements required to be included in the reports and the report format. The rule also details the processes for the review, dispute, and correction period when applicable manufacturers, applicable GPOs, covered recipients, and physician owners or investors are provided the opportunity to review, dispute, and propose corrections to reported payments or other transfers of value, or ownership or investment interests, attributed to them. In addition, the rule clarifies the information to be included on the publicly available Web site, as well as the usability of the public Web site. Finally, the rule includes details on the processes for reporting and publishing payments or other transfers of value which are eligible for delayed publication.

c. Penalties

The rule includes details regarding the statutorily authorized civil monetary penalties for failure to report payments or other transfers of value, or physician ownership or investment interests, including clarification of the instances when the penalties will be imposed.

d. Annual Report

The rule finalizes the details of the annual reports to Congress and the States.

e. Relation to State Laws

The rule clarifies the statutory requirements for the pre-emption of State laws.

3. Summary of Costs and Benefits

Based on the comments submitted, we anticipate that much of the total estimated burden of this final rule will fall on applicable manufacturers and applicable GPOs. We have estimated that the total cost of these provisions will be approximately $269 million in the first year and $180 million annually thereafter. We have no empirical ability to estimate the monetary benefits of this provision; however, there are nonmonetary benefits, which are difficult to quantify. Increased transparency regarding the extent and nature of relationships between physicians, teaching hospitals, and industry manufacturers will permit patients to make better informed decisions when choosing health care professionals and making treatment decisions, and deter inappropriate

financial relationships which can sometimes lead to increased health care costs. Additionally, increased transparency about the owners and investors in GPOs will allow purchasers to make better informed decisions and identify potential conflicts of interest with ordering physicians.

B. Background

1. Legislative Overview (Statutory Background)

Section 6002 of the Affordable Care Act added section 1128G to the Act, which requires applicable manufacturers of drugs, devices, biologicals, or medical supplies covered under Medicare or a State plan under Medicaid or CHIP to report annually to the Secretary certain payments or other transfers of value to physicians and teaching hospitals. Section 1128G of the Act also requires applicable manufacturers and applicable GPOs to report certain information regarding the ownership or investment interests held by physicians or the immediate family members of physicians in such entities.

Specifically, manufacturers of covered drugs, devices, biologicals, and medical supplies (applicable manufacturers) are required to submit on an annual basis the information required in section 1128G(a)(1) of the Act about certain payments or other transfers of value made to physicians and teaching hospitals (collectively called covered recipients) during the course of the preceding calendar year. Similarly, section 1128G(a)(2) of the Act requires applicable manufacturers and applicable GPOs to disclose any ownership or investment interests in such entities held by physicians or their immediate family members, as well as information on any payments or other transfers of value provided to such physician owners or investors. Applicable manufacturers must report the required payment and other transfer of value information annually to the Secretary of the Department of Health and Human Services (HHS) (the Secretary) in an electronic format. The statute also provides that applicable manufacturers and applicable GPOs must report annually to the Secretary the required information about physician ownership and investment interests, including information on any payments or other transfers of value provided to physician owners or investors, in an electronic format by the same date. Applicable manufacturers and applicable GPOs are subject to civil monetary penalties (CMPs) for failing to comply with the reporting requirements of the statute. The Secretary is required by statute to publish the reported data on a public Web site. The data must be downloadable, easily searchable, and aggregated. In addition, we must submit annual reports to the Congress and each State summarizing the data reported. Finally, section 1128G of the Act generally preempts State laws that require disclosure of the same type of information by manufacturers.

2. Transparency Overview

We recognize that collaboration among physicians, teaching hospitals, and industry manufacturers contributes to the design and delivery of life-saving drugs and devices and we received many comments supporting this statement. However, as discussed in the proposed rule and in the public comments submitted, payments from manufacturers to physicians and teaching hospitals can also introduce conflicts of interest that may influence research, education, and clinical decision-making in ways that compromise clinical integrity and patient care, and may lead to increased health care costs.

We recognize that disclosure alone is not sufficient to differentiate beneficial financial relationships from those that create conflict of interests or are otherwise improper. Moreover, financial ties alone do not signify an inappropriate relationship. However, transparency will shed light on the nature and extent of relationships, and will hopefully discourage the development of inappropriate relationships and help prevent the increased and potentially unnecessary health care costs that can arise from such conflicts. Given the intricacies of disclosure and the importance of discouraging inappropriate relationships without harming beneficial ones, we have worked closely with stakeholders to better understand the current scope of the interactions among physicians, teaching hospitals, and industry manufacturers. In addition to this feedback, we consulted with the HHS Inspector General, as required by the statute. Our conclusions and interpretations in the preamble are solely for purposes of this regulation and do not apply in other contexts.

II. Provisions of the Proposed Rule and Analysis of and Responses to Public Comments

In the December 19, 2011 proposed rule (76 FR 78742), we solicited public comment on a number of proposals regarding transparency reports and the reporting of physician ownership or investment interests. In response to our solicitation, we received approximately 373 timely public comments. Most of the public comments addressed provisions included in the proposed rule. We received some comments that were outside the scope of the proposed rule and, therefore, will not be addressed in this final rule. Summaries of the public comments that are within the scope of the proposals and our responses to those comments are set forth in the various sections of this final rule under the appropriate headings. In this final rule, we have organized the document by presenting our proposals, summarizing and responding to the public comments for the proposal(s), and describing our final policy.

The following sections outline the agency's directives concerning implementation of section 1128G of the Act, including clarification of the terms and definitions used in the statute, as well as procedures for the submission, review, and publication of the reported data. For terms undefined by the statute, we have provided definitions where appropriate to provide additional clarity, as well as explanations of how we interpret such terms. During the public comment period, we received numerous comments on how to approach and structure the final rule, such as providing additional examples and memorializing intentions in the regulatory text. We appreciate the comments and have endeavored to develop a final rule that allows for reporting flexibility while also providing sufficient detail, clarity, and standardized processes, in order to better ensure the accuracy of the published data. Throughout the final rule, time periods referenced in days are considered to be calendar days, unless otherwise noted.

A. Timing

This final rule has not been published in time for applicable manufacturers and applicable GPOs to begin collecting the information required in section 1128G of the Act on January 1, 2012, as provided in the statute. In the proposed rule, we indicated that we would not require applicable manufacturers and applicable GPOs to begin collecting the required information until after the publication of this final rule. We proposed a preparation period of 90 days. Additionally, we considered requiring the collection of data for part of 2012, to be reported to CMS by the statutory date of March 31, 2013. We also stated that we were considering requiring the collection of data for part of 2012, to be reported to CMS by the statutory date of March 31, 2013, and requested comments on the feasibility of a partial year collection.

Comment: Many commenters were concerned with the length of time applicable manufacturers and applicable GPOs would be given following publication of the final rule before the data collection requirements begin.

A number of these commenters suggested that the reporting requirements begin as quickly as possible following the publication of the final rule, in order to ensure that there is sufficient time for data to be collected for a partial year of 2012. These commenters recommended a 30-day preparation period. Conversely, many other commenters requested that the data collection requirement not begin until January 1, 2013, stating that the data collection requirement for collecting a partial year of data would be difficult and overly burdensome. Other commenters did not address the beginning date for data collection, but instead advocated for a longer preparation period than the proposed 90 days. The majority of these commenters requested an 180-day preparation period, but a few suggested longer, with the longest being 15 months. Some commenters also requested that regardless of the timing, data collection should begin at the beginning of a quarter and also explained that making systems changes during the last quarter of a year would be difficult.

Response: We appreciate these comments and agree that data collection needs to begin as soon as reasonably possible; however, to allow us time to address the important input we received from stakeholders during the rulemaking process, we announced in May 2012 that we would not require the collection of any data before January 1, 2013. We are finalizing that the data collection requirement will begin on August 1, 2013, allowing about an 180-day preparation period. We believe that this is a sufficient amount of time for applicable manufacturers and applicable GPOs to prepare.

Comment: A few commenters requested that CMS modify the reporting requirements for the first year. Some suggested easing the initial burden by phasing in reporting with a higher minimum dollar threshold, while others recommended collecting more data for 2012 by requiring retroactive reporting.

Response: We appreciate these comments, but we do not believe that we have authority to amend the reporting requirements for the first year. In addition, we believe that changing the reporting requirements for a single year would be operationally difficult, since both CMS and applicable manufacturers and applicable GPOs would have to develop systems and then change them after the first year. The statute sets forth the minimum threshold for reportable payments and does not appear to provide any authority for us to change it. We believe that because the threshold is provided in the statute itself, applicable manufacturers were given adequate notice of the threshold amount and should be able to prepare for it. We are also concerned that changing the threshold for 1 year would be confusing to users. With regard to retroactive reporting, we similarly believe that we do not have the authority to require this and will not adopt that approach.

After consideration of the public comments received and given the timing of the final rule, we are establishing that data collection will begin on August 1, 2013 and must be reported to us by March 31, 2014. There will be no retroactive reporting.

B. Transparency Reports

Section 1128G(a) of the Act outlines the transparency reporting requirements and consists of two paragraphs. The first, section 1128G(a)(1) of the Act, outlines the required reports from applicable manufacturers on payments or other transfers of value to covered recipients. The second, section 1128G(a)(2) of the Act, outlines the reporting requirements for applicable manufacturers and applicable GPOs concerning ownership and investment interests of physicians, and their immediate family members, as well as information on any payments or other transfers of value provided to such physician owners or investors. While there is some overlap between these submissions, we proposed that these two types of information be reported separately to ensure that the relevant reporting obligations of applicable manufacturers and applicable GPOs are clearly distinguished. We solicited comment on this general approach, but received no comments, so we are finalizing this provision as proposed.

Additionally, we also want to emphasize that compliance with the reporting requirements of section 1128G of the Act does not exempt applicable manufacturers, applicable GPOs, covered recipients, physician owners or investors, immediate family members, other entities, and other persons from any potential liability associated with payments or other transfers of value, or ownership or investment interests (for example, potential liability under the Federal Anti-Kickback statute or the False Claims Act). However, we also want to make clear that the inclusion of a payment or other transfer of value, or ownership or investment interest on the public database does not mean that any of the parties involved were engaged in any wrongdoing or illegal conduct.

1. Reports on Payments and Other Transfers of Value Under Section 1128G(a)(1) of the Act

a. Applicable Manufacturers

While the term applicable manufacturer was defined in section 1128G of the Act, we provided additional clarification in the proposed rule. In this section, we aim to even more clearly define the entities that will be required to report.

(1) Definition of Applicable Manufacturer

In the proposed rule we defined "applicable manufacturer" for the purposes of this regulation as an entity that is—

- Engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply for sale or distribution in the United States, or in a territory, possession, or commonwealth of the United States; or
- Under common ownership with an entity in the first paragraph of this definition, and which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological, or medical supply for sale or distribution in the United States, or in a territory, possession, or commonwealth of the United States.

In defining applicable manufacturer, we interpreted the statutory phrase "operating" in the United States, or in a territory, possession, or commonwealth of the United States in section 1128G(e)(2) of the Act, as "for sale or distribution" in the United States, or in a territory, possession, or commonwealth of the United States.

Comment: Many commenters expressed concern with CMS's interpretation of the phrase "applicable manufacturer." Specifically, many commenters suggested that the phrase "for sale or distribution" is overly broad and would apply to nearly any entity in the world involved in the manufacturing chain or marketing of a covered drug, device, biological, or medical supply (referred to generally for purposes of this rule as a "covered product") that is ultimately sold or distributed in the United States, even if such entity has no operations in the United States. These commenters

recommended that CMS retain the statutory language and define the phrase "operating" in the United States as having a physical location in the United States or conducting business activities in the United States. Several commenters agreed with and supported the proposed definition.

Response: We appreciate the comments and agree that the proposed definition may have inadvertently captured entities that operate wholly outside the United States, many of which may have little or no interaction with U.S. health care providers. We did not intend to capture foreign entities that may contribute to the manufacturing process of a covered product, but have no business presence in the United States. Accordingly, we have decided to revise the definition by retaining the statutory phrase operating in the United States, which we defined as having a physical location within the United States, or otherwise conducting activities within the United States or in a territory, possession, or commonwealth of the United States. We believe that any manufacturer, foreign or not, which operates in the United States (including by selling a product) must comply with the reporting requirements, regardless of where the product is physically manufactured. Therefore, under this final rule, entities based outside the United States that *do* have operations in the United States are subject to the reporting requirements. Additionally, we note that entities that have operations in the United States are not permitted to circumvent the reporting requirements by making payments to covered recipients indirectly through a foreign entity that has no operations in the United States. Such payments are considered to be made by the entity that is operating in the United States as an indirect payment or other transfer of value and must be reported as such, so long as the entity operating in the United States is aware of the identity of the covered recipients receiving the payments as required for all indirect payments or other transfers of value.

Comment: Many commenters recommended additional limitations on the scope of the definition of applicable manufacturer. A few commenters suggested CMS limit the definition to manufacturers directly involved in manufacturing of the final products, and not entities that supply components and raw materials. In addition, many commenters stated that the definition should not include hospitals or other entities that produce covered products for sale to or use by their own patients only. A few commenters provided similar comments that entities that produce or compound products or tests should be exempt from the definition. For example, many pharmacies compound medications in small batches for individual patients at the direction of a prescribing physician.

Response: We recognize that entities that only manufacture raw materials or components may differ from manufacturers of the final product, and we believe that the statutory framework already treats them differently. The definition of "applicable manufacturer" is dependent on the definition of "covered drug, device, biological or medical supply." Raw materials and components often do not meet the definition of covered drug, device, biological, or medical supply because payment is not available for them in their component form under Medicare, Medicaid or CHIP. Entities that only manufacture raw materials or components, which are not themselves covered products, will not be required to report unless they are under common ownership with an applicable manufacturer and assist such manufacturer with the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological, or medical supply. In the event a supplier of raw materials is under common ownership with an applicable manufacturer, it will be subject to the reporting requirements for entities under common ownership, including options for consolidated reporting with the applicable manufacturer.

In addition, we agree with the comments regarding hospitals, pharmacies, and laboratories that produce or manufacture materials and products solely for their own use or use by their patients. We believe that it was not the intent of the statute to include these entities as applicable manufacturers, since they are not listed in the statute as manufacturers. Given these considerations, we have revised the definition of applicable manufacturer to exclude entities such as hospitals, hospital-based pharmacies and laboratories that manufacture a covered product solely for use by or within the entity itself or by an entity's own patients. In addition, the definition of applicable manufacturer does not include pharmacies, including compounding pharmacies, that meet all of the following conditions: (1) Maintain establishments that comply with applicable local laws regulating the practice of pharmacy; (2) regularly engage in dispensing prescription drugs or devices upon prescriptions from licensed practitioners in the course of their professional practice; and (3) do not produce, prepare, propagate, compound, or convert drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail to individual patients.

Comment: Many commenters addressed whether distributors and wholesalers, including repackagers, relabelers, and kit assemblers, met the definition of applicable manufacturer. These entities were not specifically addressed in the proposed rule other than the recognition that there are other definitions of "manufacture," "manufacturer" and "manufacturing" with which industry may be familiar (such as those in 21 CFR 207.3, 21 CFR 210.3(b)(12), 21 CFR 820.3(o), and 42 U.S.C. 1396r–8(k)(5)). The commenters represented both sides—some advocated that these types of entities meet the definition, while others advocated that they do not. Some commenters noted that distributors and wholesalers purchase and often take the title to covered products and then sell them to providers. The distributor may or may not rebrand or repackage the product before resale. Commenters on both sides referred to other definitions of "manufacturer" and "manufacture" both in the Affordable Care Act and elsewhere, some of which specifically reference distributors and some of which did not, similar to the statutory definition in section 1128G(e)(9) of the Act. The advocates for including distributors and wholesalers state that because these entities are involved in "preparation" and "propagation" of covered products, they should be included based on the statutory definition. Conversely, other commenters stated that distributors and wholesalers stock multiple competing products, so they do not try to sway purchasing decisions in the same way as a manufacturer.

Response: We agree that distributors and wholesalers (which include repackagers, relabelers, and kit assemblers) that hold the title to a covered drug, device, biological or medical supply meet the definition of an applicable manufacturer for the purpose of this rule. We believe that distributors that hold the title to a covered product are similar to applicable manufacturers since both hold title to the product at some point in the production and distribution cycle. These entities will be subject to the same requirements as all other applicable manufacturers, as described in more detail in this section. Wholesalers or distributors that do *not*

hold the title of a covered product will not be subject to the reporting requirements, unless they are under common ownership with an applicable manufacturer and provide assistance or support with respect to a covered drug, device, biological, or medical supply. Finally, an applicable manufacturer that has product(s) with titles held by distributors does not need to report payments or other transfers of value made by the distributor or wholesaler to covered recipients, since these will be reported by the distributor or wholesaler. However, in the event that the applicable manufacturer makes payments or other transfers of value related to the product independently from the distributor or wholesaler (or through the distributor or wholesaler as a third party), then the applicable manufacturer would have to report these payments or other transfers of value.

(2) Limitations to the Definition of Applicable Manufacturer

In the preamble to the proposed rule, we clarified that the applicable manufacturer definition included entities that hold Food and Drug Administration (FDA) approval, licensure, or clearance for a covered drug, device, biological, or medical supply, even if they contract out the actual physical manufacturing of the product to another entity. We interpreted these entities as being "engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply." However, we did not address whether the entity manufacturing the product under contract is an applicable manufacturer. We also proposed that any manufacturer that meets the definition of applicable manufacturer by manufacturing at least one covered drug, device, biological or medical supply (as defined later in this section) would be considered an applicable manufacturer, even though it may also manufacture products that do not fall within that category.

Comment: A few commenters requested clarification on the reporting requirements for situations when the license-holder is not the manufacturer or the manufacturing process is contracted out. These commenters recommended that if an entity, which manufactures a covered product under contract, but does not market or distribute the product and is not an applicable manufacturer otherwise, then the entity does not meet the definition and does not need to report.

Response: We agree that additional clarification is necessary, although we recognize that it is difficult to anticipate all potential manufacturing arrangements. In general, we believe that our proposed position to require reporting by an entity that holds an FDA approval, licensure, or clearance for a covered product is appropriate. Such entities are clearly "engaged in the production, preparation, propagation, compounding, or conversion" of a covered product. We did not receive any comments on this and are finalizing it as proposed. For the contracted entity conducting the actual manufacturing, we believe that these entities fit into the definition of applicable manufacturer, since they are actually manufacturing a covered product and clearly are "engaged in the production, preparation, propagation, compounding, or conversion" of a product. Therefore, we are finalizing that entities that manufacture any covered product are applicable manufacturers, even if the manufacturer does not hold the FDA approval, licensure, or clearance. While we recognize that such entities do not necessarily market the product, we believe it is clear that they do manufacture it. However, we also understand that these manufacturers' business model may not be focused on covered products. Therefore, if an applicable manufacturer does not manufacture a covered drug, device, biological, or medical supply except pursuant to a written agreement to manufacture the covered product for another entity, does not hold the FDA approval, licensure or clearance for the product, *and* is not involved in the sale, marketing or distribution of the product, then the manufacturer is only required to report payments or other transfers of value *related to the covered product*. This is described in the regulatory text at § 403.904(b)(4). If an applicable manufacturer has this business arrangement for some products and also manufactures at least one covered product that does not meet these criteria, then the applicable manufacturer must report all payments or other transfers of value subject to the reporting requirements. We believe that this is consistent with our treatment of other manufacturers with business models that are not focused on covered products, as discussed in more detail in this section. Finally, no payment or other transfer of value should be reported more than one time by a single entity.

Comment: Several commenters also discussed CMS's proposed decision to require applicable manufacturers to report all payments or transfers of value to covered recipients rather than only payments related to covered drugs, devices, biologicals, and medical supplies. While a few commenters supported this proposal, others did not. Entities and organizations with only a small number of covered products believed that reporting all payments would be overly burdensome and recommended limiting the definition to manufacturers that obtain a certain percentage (generally 5 or 10 percent) of their sales or revenues from covered products.

Response: We stand by our decision to require reporting of all payments or transfers of value to covered recipients rather than only payments related to covered drugs, devices, biologicals, and medical supplies and discuss this decision more fully in section II.B.1.b of this final rule. We do not believe that all payments or other transfers of value are related to particular covered products, so we do not want an applicable manufacturer to avoid reporting by representing certain payments or other transfers of value to covered recipients as being unrelated to covered products.

However, we are sensitive to applicable manufacturers whose primary business focus is not the production of covered drugs, devices, biological or medical supplies, but may still produce one or a few covered products. We recognize that since so few of their products are covered, many of their competitors will not be subject to the reporting requirements, providing the competitors with a potential competitive advantage. Despite this recognition, we also do not believe that these entities should be exempt from all reporting, since other manufacturers of the same covered products with a different business model would be subject to reporting. We recognize that these applicable manufacturers could also classify payments or other transfers of value as unrelated to a covered drug, device, biological or medical supply in order to try to avoid the reporting requirements; however, we believe the burden on these applicable manufacturers of reporting all interactions related to all products (not just covered drugs, devices, biologicals, or medical supplies) outweighs this concern. Therefore, we have clarified the agency's position in § 403.904(b)(1) to allow applicable manufacturers with less than 10 percent of total (gross) revenues from covered drugs, devices, biologicals or medical supplies during the previous fiscal year to report only payments or other transfers of value specifically related to covered drugs, devices, biologicals or medical supplies.

The 10-percent threshold should be calculated based on the company's total (gross) annual revenue. Applicable manufacturers with less than 10 percent of total (gross) revenue from covered products during the previous year that have payments or other transfers of value to report must register with CMS and must attest that less than 10 percent of total (gross) revenues are from covered products, along with their attestation of the submitted data. We selected a 10-percent threshold based on the public comments that we received suggesting a range from 5 to 10 percent; we chose the higher percentage in order to reduce the reporting burden on a greater number of entities.

Comment: A few commenters also requested additional clarification on when an entity with no covered products becomes an applicable manufacturer because payment becomes available for one of the company's products under Medicare, Medicaid or CHIP (for example, because a manufacturer's only product received FDA approval). Most of the commenters simply requested clarification, since this was not addressed in the proposed rule. However, a commenter suggested that CMS should allow new applicable manufacturers a grace period (for example, 180 days) to allow the manufacturer time to prepare to comply with the data collection requirements.

Response: We agree that we should provide clarification on when a product becomes "covered" and, thus, when an applicable manufacturer who did not previously have any other covered products becomes subject to the data collection and reporting requirements under this rule. We will allow the applicable manufacturer a grace period of 180 days following a product becoming "covered" to begin complying with the data collection and reporting requirements. We believe this is appropriate because it is the same preparation period allowed after the publication of the final rule, allowing all new applicable manufacturers the same time to prepare for complying with the data collection and reporting requirements.

(3) Common Ownership

The definition of applicable manufacturer includes entities under common ownership with an applicable manufacturer. We proposed to define "common ownership" as when the same individual, individuals, entity, or entities, directly or indirectly, own any portion of two or more entities. This would apply to a range of corporate arrangements, including, but not limited to, parent companies and subsidiaries and brother/sister corporations. In addition, we also included an alternate interpretation that would limit the common ownership definition to circumstances where the same individual, individuals, entity, or entities own 5 percent or more of total ownership in two or more entities. This would be subject to the same requirements as the definition described previously, but would only apply to common interests of 5 percent or more.

Regarding how applicable manufacturers under common ownership will submit reports, we proposed that if two or more entities individually met the proposed definition of an applicable manufacturer under paragraph (1) of the definition, the entities should report separately under section 1128G of the Act. However, if only one company under common ownership met the proposed definition of applicable manufacturer under paragraph (1) of the proposed definition, and the other company is required to report under paragraph (2) of the definition, then the affected entities can choose whether or not to report together. Additionally, we proposed that a payment or other transfer of value provided to a covered recipient in accordance with a joint venture or other cooperative agreement between two or more applicable manufacturers must be reported in the name of the applicable manufacturer that actually furnished the payment or other transfer of value to the covered recipient, unless the terms of a written agreement between the applicable manufacturers specifically require otherwise, so long as the agreement requires that all payments or other transfers of value in accordance with the arrangement are reported by one of the applicable manufacturers.

Comment: Many commenters did not support the agency's definition of common ownership. These commenters generally recommended that a threshold greater than the proposed alternative of 5 percent be applied to determine common ownership. The commenters that support a higher threshold generally advocated for a "common control" standard, which is traditionally a greater ownership percentage of 50 to 80 percent, rather than an affiliate status, which is generally around 5 percent. Conversely, some commenters supported the proposed definition, as well as the 5 percent alternative.

Response: We appreciate the comments and have decided to finalize the 5-percent ownership threshold for common ownership. We recognize that this is a lower threshold than many of the commenters recommended; however, we believe this is appropriate. We believe that had Congress intended to establish a "common control" standard, it would have used that term, rather than "common ownership." Similarly, a 5-percent threshold for common ownership is used elsewhere in the Act, in other CMS regulations, and is one with which entities are familiar. For example, section 1124(a)(3) of the Act defines the term "person with an ownership or control interest," in part, as a person who has a direct or indirect ownership interest in an entity of at least 5 percent. We also believe that clarifying when an entity under common ownership has to report (as explained in this section) will help reduce the number of entities under common ownership reporting.

Comment: Many commenters also requested additional clarification on how the agency was interpreting "assistance and support" for entities under common ownership, since only entities under common ownership which provide "assistance and support" for the listed manufacturing activities need to report. These commenters varied in their suggestions, but most advocated a narrow interpretation, such as only those involved in sales and marketing or those entities integral or necessary to the manufacturing process. In addition, some commenters questioned whether separate operating divisions, which are not related to covered products, such as the animal health division or over-the-counter drugs division, need to report. The commenters advocated that reporting of these divisions would be confusing, since they are unrelated to covered products.

Response: We appreciate these comments and agree that we should provide greater clarification to help identify the entities under common ownership which are required to report. We define "assistance and support" as being necessary or integral to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered product. For example, an entity under common ownership which produces the active ingredient for a covered drug and provides it to the applicable manufacturer for inclusion in the final product would be considered necessary to the manufacturing of that product, since the applicable manufacturer could not produce the drug without the active ingredient. Conversely, an entity under common ownership that only aids the applicable manufacturer with human resources administrative functions would not be deemed necessary or integral to the production, preparation, propagation,

compounding, conversion, marketing, promotion, sale, or distribution of covered products, since human resources functions are not directly involved with any of these manufacturing processes.

In general, we believe that all payments or other transfers of value related to covered products should be reported, but that we should minimize the reporting of payments or other transfers of value unrelated to covered products. The final rule does not require entities under common ownership to report when they are not necessary or integral to manufacturing, and are not applicable manufacturers in and of themselves. However, an indirect payment or other transfer of value made to a covered recipient through an entity under common ownership that is not necessary or integral to the manufacturing process must still be reported as required for indirect payments or other transfers of value. In addition, we believe that entities under common ownership that are necessary or integral to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale or distribution of a covered product should not have to report all payments or other transfers of value that the entities provide to covered recipients, and § 403.904(b)(2) of this final rule states that they only need to report payments or other transfers of value that are related to covered products.

Finally, with regard to applicable manufacturers that have separate operating divisions that only produce non-covered products and do not meet the definition of providing "assistance and support," we believe that such divisions only need to report payments or other transfers of value that are related to a covered drug, device, biological or medical supply as stated in § 403.904(b)(3). We believe that the vast majority of payments or other transfers of value will not be related to covered products. To prevent applicable manufacturers from diverting payments through these divisions in order to avoid the reporting requirements, we are finalizing that all payments or other transfers of value made by these divisions that are related to covered products must be reported. This includes payments or other transfers of value made directly by the operating division, as well as payments or other transfers of value made indirectly by the applicable manufacturer through the separate operating division, as the latter payments are required to be reported as indirect payments or other transfers of value.

Comment: Many commenters advocated that CMS should allow entities more flexibility to submit consolidated reports, regardless of whether an entity meets the definition of applicable manufacturer under paragraph 1 or 2 of the proposed definition and at the company or operating division level. These commenters explained that manufacturers may have complicated corporate structures and reporting systems and suggested that the agency provide additional flexibility in reporting. Additionally, the commenters noted that consumers may not be familiar with the names of manufacturers' smaller divisions and, therefore, publication of the data under the names of the smaller divisions could limit the usefulness of the published data to consumers. Other commenters agreed with increased flexibility, but advocated that the reports should clearly state what entities are included in the report, including reporting which payments were made by which entity.

Response: We agree that entities should have more flexibility to report together or separately. Therefore, we clarified in § 403.908(d) that applicable manufacturers under paragraph 1 of the definition that are under common ownership with separate entities that are also applicable manufacturers under paragraph 1 may, but are not required to, file a consolidated report for all of the entities. Additionally, as we stated in the proposed rule, applicable manufacturers under paragraph 1 of the definition of applicable manufacturer and an entity (or entities) under common ownership with such manufacturer under paragraph 2 of the definition also may, but are not required to, file a consolidated report. We believe that this will make reporting less burdensome to entities and will provide more clarity to consumers. However, we are concerned that it will not be clear to CMS or consumers which companies are under common ownership and are either reporting together or separately. Therefore, if multiple applicable manufacturers (under paragraph 1 and/or 2 of the definition) submit a consolidated report, we are requiring that the report must provide information specified by CMS to identify each applicable manufacturer and entity (or entities) under common ownership that the report covers. Additionally, applicable manufacturers submitting consolidated reports must specify on an individual payment line which entity made which discrete payment or other transfer of value. We believe this method is more useful for consumers since it clarifies the specific entity making the payment. We also believe that this method provides significantly more clarity for covered recipients when reviewing their payments or other transfers of value, allowing them to better review the information submitted on their behalf. Regardless of whether applicable manufacturers file separate or consolidated reports, § 403.908(d)(1)(iv) and (d)(2)(ii) clarify that in no case shall a single payment or other transfer of value be reported more than once by multiple applicable manufacturers (under common ownership or not). Each transaction between an applicable manufacturer and a covered recipient must be reported only one time. Also, to support our ability to improve identity and data matching, regardless of whether applicable manufacturers file separate or consolidated reports, all covered recipients included in the report must be individually, uniquely and consistently identified. The same individual, if present on multiple payment lines within the same report, must have the same unique identifiers for all occurrences within the report. For example, the same name and National Provider Identifier (NPI) (as required to be reported in this final rule) should be used consistently for all payment lines and any subsequent updates for the same individual. Finally, we did not receive any comments on our proposed reporting method for joint ventures and co-promotions, so we have finalized these provisions as proposed, which required reporting by the applicable manufacturer that actually made the payment or other transfer of value (unless decided by the parties to report differently) and that the payment or other transfer of value was only reported once.

In sum, after consideration of the public comments received, we are revising the interpretation of what it means that an entity is "operating in" the United States. We are finalizing the position that applicable manufacturers must report all payments or other transfers of value, but clarifying that manufacturers with less than 10 percent of their gross revenue coming from covered products only have to report payments related to covered products. In addition, we are also finalizing the definition of common ownership to require a threshold of 5 percent or more common ownership interest and providing additional clarification on the requirements for reporting by entities under common ownership. Finally, we are allowing additional flexibility for

applicable manufacturers (under paragraph 1 and/or 2 of the definition) to report separately or together depending on their internal structure.

b. Covered Drug, Device, Biological, or Medical Supply

The data collection and reporting requirements are limited to applicable manufacturers of a "covered drug, device, biological, or medical supply." The phrase "covered drug, device, biological, or medical supply" is defined in section 1128G(e)(5) of the Act as any drug, biological product, device, or medical supply for which payment is "available" under Medicare, Medicaid, or CHIP. Because there are numerous payment mechanisms in Medicare, Medicaid and CHIP, we proposed that drugs, devices, biologicals, or medical supplies for which payment is available through a composite payment rate, as well as those reimbursed separately, are considered to be covered products under section 1128G of the Act. We were particularly concerned about inadvertently excluding items, such as implantable devices, for which payment may be available only as part of a bundled payment.

We proposed to define "covered drug, device, biological, or medical supply" as: any drug, device, biological, or medical supply for which payment is available under Title XVIII of the Act or under a State plan under Title XIX or XXI (or a waiver of such plan), either separately, as part of a fee schedule payment, or as part of a composite payment rate (for example, the hospital inpatient prospective payment system or the hospital outpatient prospective payment system).

The proposed definition included two exceptions to limit the entities reporting. We proposed to limit drugs and biologicals in the definition of "covered drug, device, biological, and medical supply," to drugs and biologicals that, by law, require a prescription to be dispensed, thus excluding drugs and biologicals that are considered "over-the-counter" (OTC). Similarly, we proposed an additional limitation to the definition as it pertains to devices and medical supplies, which would limit them to those devices (including medical supplies that are devices) that, by law, require premarket approval by or notification to FDA. This would exclude many Class I devices and certain Class II devices, which are exempt from premarket notification requirements under 21 U.S.C. 360(l) or (m), such as tongue depressors and elastic bandages.

Beyond coverage, the proposed rule also discussed what payments or other transfers of value must be reported. In the proposed rule, we specifically stated that manufacturers who manufacture both non-covered products (such as OTC drugs) *and* at least one product that falls within the definition of a covered drug, device, biological or medical supply would be required to report *all* payments or transfers of value to covered recipients required by section 1128G of the Act (whether or not associated with a covered drug, device, biological or medical supply).

Comment: Many commenters inquired about the definition of covered drug, device, biological, or medical supply. Many commenters supported the proposed definition, particularly the proposed limitations, which did not receive any opposition. However, a few commenters sought clarification on how the two parts of the definition work together. These commenters sought clarification, for example, on whether a drug or biological that requires a prescription to be dispensed or a device that requires premarket approval or clearance, but for which payment is not available under Medicare, Medicaid or CHIP, would be a covered product.

Response: We are pleased with the support for the proposed definition, including the limitations, and have finalized them. In addition, we agree with the commenters regarding a need for clarification concerning the relationship between the parts of the definition. We had intended the interpretation of the definition to require that a product must meet both parts of the definition in order to be considered covered. In order to make this more clear, we have revised the definition to clearly state that a covered drug, device, biological or medical supply is one for which payment is available under Medicare, Medicaid or CHIP *and* which, requires a prescription to be dispensed (in the case of a drug or biological) or premarket approval by or notification to the FDA (in the case of a device or a medical supply that is a device). For example, a device which is of a type that requires premarket notification, but for which payment is not available under Medicare, Medicaid, or CHIP, would not be a covered device under the program. Finally, we do not intend to capture *all* items that require FDA premarket approval or premarket notification and for which payment is available under Medicare, Medicaid, or CHIP; rather, we only intend to include items that meet these criteria *and* that are devices (or medical supplies that are devices). For example, the definition is not intended to include products that require premarket approval or premarket notification, but that are regulated by the FDA solely as a food.

Comment: Many commenters requested additional clarification and details concerning the meaning of payment being "available" under Medicare, Medicaid or CHIP. Some commenters inquired whether the availability of payment referred only to those items that have been approved or cleared by FDA. Other commenters suggested that the definition should only include payments for products which are reimbursed separately, and not through a bundled payment. Finally, a few commenters inquired whether the proposed definition referred to payment availability on a single basis (for example, as a result of an appeal) or if payment was regularly available.

Response: We agree with the comments that additional clarification of the meaning of "availability" of payment would be useful. The statute provides that in order to be a covered product, payment must be available under Medicare, Medicaid or CHIP. While the statute does not discuss FDA approval, clearance or notification, most products for which payment is available under Medicare, Medicaid or CHIP will have received FDA approval or clearance. However, we note that there may be exceptions. For example, payment may be available under Medicare for certain investigative devices that receive an investigational device exemption (IDE) from the FDA and are classified as a Category B device, in accordance with 42 CFR part 405 Subpart B. In addition, payment may be available under Medicaid for certain drug products described in section 1927(k)(2) of the Act, that have not been approved by the FDA, but were commercially used or sold in the United States before the date of the enactment of the Drug Amendments of 1962 (or which are identical, similar, or related within the meaning of 21 CFR 310.6(b)(1) to such drugs) *and* have not been the subject of a final determination by the Secretary that they are a "new drug." While we understand that a bright line test would be useful, limiting covered products to those that have received FDA approval or clearance (or for which notification has been provided to the FDA) would not be comprehensive. We believe that manufacturers are generally aware when payment is available for their drugs, devices, biologicals, or medical supplies under a Federal health care program.

In addition, we do not agree with the suggestions to interpret payment availability as being limited to those provided separately, rather than through a bundled payment. We recognize that

it is not always clear whether a product is paid through a bundle, making it difficult to establish whether payment is available. We also recognize that this expands the number of products meeting the definition of covered drug, device, biological or medical supply. However, bundled payments constitute a significant portion of Medicare reimbursement and excluding products that are reimbursed only as part of bundled payments would exclude manufacturers of products who have historically had significant relationships with physicians and teaching hospitals. For example, we believe it would be inappropriate to exclude implanted devices that are reimbursed through the hospital inpatient prospective payment system (IPPS) or the outpatient prospective payment system (OPPS), as well as chronic kidney disease drugs and products reimbursed through the end stage renal disease (ESRD) bundled payment system. As a result, the final rule adopts the proposal to include products which are reimbursed separately or as part of a bundled payment. We note that because there was some confusion about the phrase "composite payment rate" in the proposed rule, we have replaced it with the phrase "bundled payment" and continue to interpret that as meaning IPPS, OPPS, and other prospective payment systems.

Comment: Many commenters also requested clarification on what products constituted a device or medical supply. The proposed rule did not define these terms, so commenters provided recommendations for ways to clarify the terms, such as limiting them to product classes or providing definitions. Additionally, commenters questioned whether specific products would or would not be considered a "device" or "medical supply" for the purposes of the reporting requirements.

Response: We appreciate the comments and note that covered devices and medical supplies are limited to those devices and medical supplies for which payment is available under Medicare, Medicaid or CHIP, and are of the type that require premarket notification to or premarket approval by the FDA. We believe that this provides applicable manufacturers with a clear sense of the devices and medical supplies that constitute covered devices and medicals supplies, as well as those that do not. For example, FDA defines the devices (including certain medical supplies) that are exempted from the premarket notification requirements. This information can be found in 21 CFR parts 862 through 892 and is publicly available on the FDA's Web site.[1]

Comment: A few commenters suggested that reporting on all payments or other transfers of value, including those related to products under development, is too broad. These commenters recommended that only payments or other transfers of value related to covered products should be reported. Similarly, other commenters requested that payments or other transfers of value for certain products, such as veterinary drugs, be excluded since the relationships related to such products are not intended to be included by the statute.

Response: As noted previously, we are finalizing the proposal that, in most circumstances, applicable manufacturers must report payments or other transfers of value to covered recipients regardless of whether they are related to a covered product. We believe that not all payments or other transfers of value will be related to specific drugs, devices, biologicals, or medical supplies, but they nevertheless represent a financial relationship between an applicable manufacturer and a covered recipient that has the potential to affect medical judgment and must be reported under the requirements in section 1128G of the Act. Additionally, we are concerned that limiting the reporting requirements to payments or other transfers of value related to covered products would create loopholes that would allow entities to avoid reporting of certain payments or other transfers of value. However, we do understand that payments related to products that will never become covered by Medicare, Medicaid or CHIP (such as animal health products) may unnecessarily increase the scope of reporting. Therefore, we have limited the reporting requirements to address this situation, as well as other situations described previously in the discussion of the limitations to the definition of "applicable manufacturer," where requiring an applicable manufacturer to report payments related to non-covered products would be unnecessarily burdensome and not particularly useful to the public. We are finalizing that separate divisions that manufacture only non-covered products do not need to report payments or other transfers of values unless the payments or other transfers of value are in fact related to covered products (see the applicable manufacturer and payments or other transfers of value sections of this final rule). Similarly, we do not intend to capture payments made to a veterinary school that may be associated with a teaching hospital.

[1] List of exempt products: *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/315.cfm*.

c. Covered Recipients

Under section 1128G(a)(1) of the Act, applicable manufacturers are required to disclose certain payments or other transfers of value made to covered recipients, or to entities or individuals at the request of, or designated on behalf of, a covered recipient. Section 1128G(e)(6) of the Act defines "covered recipient" as: (1) a physician, other than a physician who is an employee of an applicable manufacturer; or (2) a teaching hospital. As required by section 1128G(e)(11) of the Act, we proposed to define "physician" as having the meaning set forth in section 1861(r) of the Act, which includes doctors of medicine and osteopathy, dentists, podiatrists, optometrists, and chiropractors, who are legally authorized to practice by the State in which they practice.

The statute excludes from the definition of covered recipient a physician who is an employee of the applicable manufacturer, as defined in section 1877(h)(2) of the Act. Section 1877(h)(2) defines "employee" as an individual who would be considered to be an employee of an entity under the usual common law rules applicable in determining the employer-employee relationship (as applied for purposes of section 3121(d)(2) of the Internal Revenue Code of 1986). We note that these common law rules are discussed in 20 CFR 404.1007 and 26 CFR 31.3121(d) through 1(c).

Finally, we proposed to define the term "teaching hospital" by linking it to Medicare graduate medical education (GME). The proposed rule defined teaching hospital as any institution that received payments under section 1886(d)(5)(B) of the Act (indirect medical education (IME)); section 1886(h) of the Act (direct GME); or section 1886(s) of the Act (psychiatric hospital IME) during the most recent year for which such information is available.

Comment: Many commenters recommended changes to the proposed definition of physician. Some commenters requested that CMS expand the definition of physician to include other entities with prescribing privileges. Other commenters inquired about whether residents would be considered physicians. Some commenters requested that the definition exclude physicians who are not actively engaged in (or who do not

"perform") the practice of medicine, which would include physicians not acting solely within their role as a physician, as well as medical researchers. They refer to the phrase in the statutory definition that a physician is an individual licensed in the State "in which he performs such function or action." Other commenters recommended that the reporting requirements should be limited to physicians enrolled in Medicare, Medicaid or CHIP, on the basis of recent reimbursement or expected reimbursement. Finally, a few commenters recommended that CMS establish an "opt-out" function for physicians to declare that they have opted out, and no payments would appear on the public Web site attributed to them.

Response: We appreciate the comments, but we will not expand the definition to include other provider types nor will we limit the definition to exclude those clearly intended in the statutory definition. The statute defines the term "physician" as having the same meaning as in section 1861(r) of the Act. We recognize that, as a result, we will not be able to fully capture financial relationships between industry and prescribers, specifically non-physician prescribers such as nurse practitioners. However, to the extent that applicable manufacturers make payments or other transfers of value to non-physician prescribers to be passed through to a physician, they would be indirect payments to the physician and would have to be reported under the name of the physician.

Additionally, we believe that the definition hinges on whether a physician is "legally authorized" to practice, so all physicians (including all providers types listed in the statutory definition) that have a current license to practice will be considered covered recipients. By holding a current license to practice, the physician is legally authorized to practice regardless of the extent to which they do so.

Payments or other transfers of value to residents (including residents in medicine, osteopathy, dentistry, podiatry, optometry and chiropractic) will not be required to be reported for purposes of this regulation. We recognize that some States require or allow residents to obtain licenses to practice, whereas other States do not require or allow residents to obtain them. We do not want to treat residents differently depending on their State of residency by requiring reporting on payments to residents in only those States that require or allow residents to have a license. Moreover, we believe it will be difficult for us to accurately identify residents and ensure that payments or other transfers of value are attributed across applicable manufacturers appropriately because many of them do not have a NPI and/or State professional license number (used for physician identification, discussed later in this section). Due to the operational and data accuracy concerns regarding aggregation of payments or other transfers of value to residents, many of whom have neither an NPI nor a State professional license number, applicable manufacturers will not be required to report such payments or other transfers of value.

With regard to the comment that the term "physician" should be limited to those enrolled in Medicare, we believe such an interpretation would be contrary to the language of the statute. In contrast to the statutory requirement that products are limited to those for which payment is available under Medicare, Medicaid or CHIP, the statute did not indicate that physician covered recipients be limited to those enrolled in Medicare, Medicaid or CHIP.

Finally, while we appreciate the interest in allowing physicians the opportunity to "opt-out" of the reporting requirements, we do not believe it would be possible to implement a system of this kind. We believe it would be overly burdensome for both CMS and applicable manufacturers to track who has opted out and ensure that no payments or other transfers of value are made to those individuals. Additionally, we would need to create a system to reconcile any payments reported as having been made to physicians stating that they have opted out. We believe that a physician who wants to opt out should simply refuse all payments or other transfers of value from manufacturers, and will, accordingly, not be included on the public Web site (unless they hold ownership or investment interests in an applicable manufacturer or applicable GPO).

Comment: Many commenters addressed the exclusion for employees of applicable manufacturers from the definition of physician covered recipient. A few commenters recommended revising the definition to ensure that only "bona fide" employee relationships are excluded from reporting, similar to the language in the employee exception in the Anti-Kickback Statute in section 1128(b)(3)(B) of the Act and the corresponding HHS OIG regulation at 42 CFR 1001.952(i). Other commenters questioned whether employees of agents of the applicable manufacturer would be included in the exception. The commenters also noted that the language in the proposed rule indicated that the exception included physicians employed by *an* applicable manufacturer, so it was not limited to employees of the applicable manufacturer making and reporting the payment or other transfer of value. In addition to these more general definitional comments, we also received numerous comments recommending other situations (such as physicians who serve as medical directors or retirees) that should be included in the employee exception.

Response: We appreciate the comments and have clarified the definition of covered recipient to ensure that only bona fide employment relationships are included in the employee exclusion. We are concerned that in the absence of this clarification, applicable manufacturers could circumvent the reporting requirements by styling a physician as an "employee" and not reporting payments made to such a physician. Additionally, we did not intend to allow the exception for employees to include physician employees at any applicable manufacturer, rather than only the reporting applicable manufacturer itself. The proposed rule incorrectly quoted the statute, which in section 1128G(e)(6)(B) of the Act states that the term covered recipient "does not include a physician who is an employee of *the* applicable manufacturer." For the final rule, we have reverted to the statutory language. Additionally, regarding employees of agents of the applicable manufacturer, we do not intend these individuals to be included in the exception, since they are not employees of the applicable manufacturer. However, as discussed in the section on indirect payments (section II.B.1.k of this final rule), we do not believe that payments or other transfers of value to legal agents of an applicable manufacturer that happen to have physicians on staff constitutes a payment or other transfer of value for the purposes of this rule.

We appreciate the comments regarding other situations that commenters would like to see included in the employee exclusion, such as an applicable manufacturer's board members and medical directors. However, we believe that whether such individuals fall within the statutory definition of employee in section 1877(h)(2) of the Act, which defines employee by referencing common law rules used to determine the employer-employee relationship for Internal Revenue Service purposes, will require

a case-specific analysis. Therefore, we are not able to adopt a bright-line policy that all board members or medical directors are (or are not) bona fide employees for purposes of the reporting exclusion.

Similarly, with regard to the comments suggesting that prospective employees and retirees should treated as employees for purposes of being excluded from the reporting requirements, we believe that whether such individuals fall within the statutory definition of employee in section 1877(h)(2) of the Act will require a case-specific analysis. Therefore, we are unable to state that payments to such physicians, such as recruiting costs paid to prospective employees, do not need to be reported.

Comment: We received significant support for our proposed definition of teaching hospital. However, some commenters recommended that CMS clarify that payments or other transfers of value to non-healthcare departments at universities affiliated with teaching hospitals should not be included in the reporting requirements.

Response: We have decided to finalize the proposed definition. As explained in the proposed rule, we recognize that this definition may not capture hospitals with accredited medical residency programs that do not receive IME or direct GME payments; however, we are unable to include these hospitals since we cannot readily identify them based on Medicare payment data. Finally, we do agree; payments to non-healthcare departments of universities affiliated with teaching hospitals should not be included in reporting requirements. However, any payments or other transfers of value made through these departments to a covered recipient as indirect payments or other transfers of value must be reported as required for indirect payments.

d. Identification of Covered Recipients

In order to accurately identify and distinguish covered recipients, section 1128G(a)(1) of the Act requires that applicable manufacturers report the covered recipient's name and business address, and for physician covered recipients, the physician's NPI, and specialty. The collection of this information is necessary for applicable manufacturers, in order to distinguish individual covered recipients when reporting to CMS, and for CMS, in order to be able to aggregate the data. This section outlines the comments received regarding identification of both physician and teaching hospital covered recipients.

(1) Identification of Physicians

Section 1128G of the Act requires that applicable manufacturers report a physician covered recipient's name, business address, NPI and specialty. This information will be used to distinguish physicians and allow us to match physicians across applicable manufacturers. We proposed that applicable manufacturers use the National Plan & Provider Enumeration System (NPPES), which we currently maintain and update on the public Web site, to assist with identifying physician covered recipients. The NPPES Web site includes a database of physician NPIs and has an NPI Registry function that allows applicable manufacturers to look up individual physician's NPIs.[2] The full database can be downloaded from the CMS Web site.[3] We proposed that if the physician NPI was not available in NPPES, the applicable manufacturer would be responsible for obtaining the physician's individual NPI directly from the physician, if the physician has an NPI. Other than NPI, in the proposed rule, we considered whether we should require, under the discretion granted in section 1128G(a)(1)(A)(viii) of the Act, that applicable manufacturers report another unique identifier, such as State professional license number, for physicians who are identified, but do not have an NPI.

Comment: A number of commenters provided input on the processes and requirements for applicable manufacturers to report the NPI for a physician. Some commenters noted that reporting a physician covered recipient's NPI is complicated, since not all physicians have an NPI and manufacturers typically do not collect such information. Additionally, a few commenters did not support the requirement that applicable manufacturers must obtain an NPI from a physician, if it was not readily available in the NPPES database. They explained it would be difficult to obtain and questioned how an applicable manufacturer would really know if a physician did not have an NPI. Some other commenters requested clarification that if an applicable manufacturer cannot identify an NPI for a physician then the NPI field can be left blank. Beyond determining a physician's NPI, a few commenters recommended that CMS clarify that physicians are not required to provide their NPI when requested and that applicable manufacturers should state that it will not be made public. Finally, some commenters recommended that CMS should require physicians to obtain NPIs to ensure that all physicians have one.

Response: We appreciate the comments, but want to reiterate that reporting a physician covered recipient's NPI is a statutory requirement, so the agency does not have flexibility to waive the requirement. Similarly, we do not believe that section 1128G of the Act provides the agency with authority to require all physicians to obtain an NPI. We agree that it may be difficult for an applicable manufacturer to definitively know whether a physician does not have an NPI; however we believe it is reasonable for the applicable manufacturer to bear responsibility for determining a physician covered recipient's NPI (or lack thereof). Applicable manufacturers should be able to demonstrate that they made a good faith effort to obtain an NPI for the physician. We believe that a good faith effort includes, but is not limited to, specifically requesting an NPI from the physician, checking the NPPES database, and calling the NPPES help desk. This statute does not impose requirements on covered recipients, so we do not believe we can require physicians to disclose their NPI to applicable manufacturers when requested; however, we strongly encourage physicians to provide this information because it is essential for matching payments or other transfers of value to physicians accurately. We believe it is in the best interest of all parties (applicable manufacturers, physician covered recipients, consumers and others) that payments be attributed to the correct physician, and we hope that physicians will be willing to provide their NPI to applicable manufacturers to make this possible, especially since their NPI will not be made public on the public Web site. If, after a good faith effort, the applicable manufacturer cannot determine an NPI for a physician covered recipient, or a physician does not have an NPI, we agree with the commenters and have finalized that the NPI field may be left blank to indicate that the applicable manufacturer could not identify an NPI for the physician covered recipient. However, if we determine that a physician covered recipient does have an NPI, we may inform the applicable manufacturer and require the applicable manufacturer to re-submit the data including the NPI and re-attest to the updated data. Additionally, not reporting an NPI for physician covered

[2] NPI Registry can be found at: *https://nppes.cms.hhs.gov/NPPES/NPIRegistryHome.do.*

[3] Database can be downloaded at *http://nppes.viva-it.com/NPI_Files.html.*

recipients that do have an NPI will be considered inaccurate reporting, which may be subject to penalties. Finally, we want to reiterate that only one *individual* NPI (not a group NPI) may be reported for each physician, and that applicable manufacturers should use the NPI listed in NPPES, if a dispute arises. Also as required by statute, physician-covered recipient's NPIs will *not* be included on the public Web site.

Comment: Some commenters discussed the proposal to allow reporting of an alternative identifier for physicians without an NPI. Many of these commenters supported reporting a State professional license number as an alternative to an NPI. Conversely, a few advocated that CMS not require an additional alternative unique identifier, whether it is a State professional license number or another identifier. Some commenters that supported State professional license number recommended that CMS should allow State professional license number instead of NPI at the discretion of the applicable manufacturer, since they believe it is could be burdensome for the applicable manufacturer to find the NPI.

Response: We agree that obtaining a unique identifier is particularly important for physicians who do not have an NPI or for whom an NPI cannot be reasonably identified. Without this information, it will be difficult for us to ensure that payments are attributed to the appropriate physician and to aggregate payments accurately. We believe that the more unique identifiers supplied for a physician covered recipient, the more accurate the data will be, since they are essential for us to appropriately match data about the same physician within and across reports, and publish data appropriately on the public Web site. Therefore, pursuant to the discretion granted in section 1128G(a)(1)(A)(viii) of the Act, we will finalize that applicable manufacturers *must* report the State(s) and appropriate State professional license number(s) for at least one (but multiple will be accepted) State where the physician maintains a license for all physician covered recipients, regardless of whether the applicable manufacturer has identified an NPI for the physician covered recipient or not. While this is slightly broader than what was proposed in the proposed rule, we believe (based on the comments) that reporting applicable State professional license numbers for all physician covered recipients, rather than only the subset that do not have NPIs, will significantly improve data accuracy and will not represent a significant additional burden on applicable manufacturers. Many commenters indicated that applicable manufacturers maintain this information already. Moreover, we believe that any additional burden associated with collecting and reporting physicians' State professional license numbers will be outweighed by the increased accuracy of the data attributing payments or other transfers of value to physician covered recipients.

Comment: Many commenters discussed the proposal that applicable manufacturers use NPPES to identify physician covered recipients. Many commenters did not support requiring applicable manufacturers to use the information listed in NPPES, rather than what was in their internal files, particularly for specialty and business address. The commenters explained that the data in NPPES is not as accurate in some cases, as their internal databases and information. Similarly, some commenters did not believe it made sense to report information from NPPES back to CMS. Many commenters also discussed how applicable manufacturers should use NPPES. These commenters inquired whether there would be point in time (such as 90 days before the reporting year) when the NPIs in the database would be finalized and no longer changed, and whether manufacturers could rely on it. A few commenters recommended that applicable manufacturers should be notified of changes in NPPES. For example, a commenter advocated that CMS should keep past "versions" of NPPES in case of an audit. In addition, some commenters stated that NPPES is not user friendly and CMS should be responsible for improving it. Finally, a few commenters requested that CMS create a list of physician covered recipients rather than using NPPES.

Response: We appreciate the comments on NPPES and note that we did not intend to require applicable manufacturers to specifically or solely use NPPES in order to obtain the NPI of a covered recipient. Applicable manufacturers may obtain physician NPI information (or any other information) in any manner they see fit, as long as they report NPIs accurately as required. This may include matching NPIs obtained elsewhere with the NPIs provided in NPPES. The NPPES database is continually updated, so it is difficult to set a point in time to freeze the database for a reporting year or notify applicable manufacturers of all changes. Applicable manufacturers may rely on NPI information in NPPES as of 90 days before the beginning of the reporting year.

However, just because an NPI is not listed in NPPES does not mean that the applicable manufacturer does not need to make a good faith effort to obtain the NPI or that the payment should not be reported. While it is not possible to keep past "versions" of NPPES due to the continual updates, we would like to point out that each provider entry is date stamped to include the date the entry was created, as well as the date of each update, which will help establish the information available at a particular time. Beyond the specific concerns regarding using NPPES, we understand that NPPES is not perfect, but the agency is working to improve it. In addition, we do not believe it is appropriate for us to create a new system specifically for this program, as it would be duplicative and unnecessary.

Finally, while we are sensitive to the request for a physician covered recipient list, we do not believe it is a viable option. Any list of physicians would be created based on NPPES, since it is the most comprehensive database available. However, as stated in this section, NPPES is not complete since not all physicians meeting the definition of covered recipient have an NPI. We also do not want the reporting requirements to be based on a list, which will be difficult to maintain and invariably include mistakes and inaccuracies. Instead, the statute that requires reporting of payments to physicians who meet the statutory definition. We believe applicable manufacturers are in the best position to identify the individuals with whom they have financial relationships who meet this definition.

(2) Identification of Teaching Hospitals

Regarding the identification of teaching hospitals, we proposed to publish a list of hospital covered recipients (that is, those hospitals that received Medicare direct GME or IME payments during the last calendar year for which such information is available) on the CMS Web site once per year. We proposed to do so since it may not be immediately apparent to applicable manufacturers whether a particular hospital meets our definition of a teaching hospital, and there is no currently published database that includes this information. We proposed that the list of teaching hospital covered recipients should include the name and address of each teaching hospital.

Comment: Many commenters supported CMS's proposal to publish a list of teaching hospitals, but recommended that the agency provide additional details regarding the list. The

commenters suggested that CMS publish the list prior to the beginning of the reporting year and ensure that applicable manufacturers will be able to download the list. The majority of these commenters recommended that the list be published 90 days before the end of the year, but the comments varied. Additionally, some commenters requested that CMS clarify that applicable manufacturers could rely on the teaching hospital list for the entire year and that entities not included on the list would not be covered recipients for the whole data collection year. They also advocated that the list should remove hospitals classified in error. Finally, a few commenters also requested that the list contain additional information to help clarify corporate identities (such as inclusion of a tax identification number (TIN) or an OSCAR number), as well as an institutional contact or officer for all hospitals.

Response: We agree that the teaching hospital list will be useful for applicable manufacturers and appreciate the comments making suggestions for how to improve the list. We will publish the list once annually and make it available publicly and for download at least 90 days before the beginning of the reporting year, or for the first reporting year, at least 90 days prior to the start of data collection. Applicable manufacturers can rely on the list for the entirety of the data collection year. The list will include all hospitals that CMS had recorded as receiving a payment under one of the defined Medicare direct GME or IME programs. The list will include hospital TINs to provide more specific information on hospitals with complex corporate identities. Finally, we will not include an institutional contact, since we do not have this information readily available and do not believe it is integral to the success of the program.

e. Payments or Other Transfers of Value

Section 1128G(a)(1)(A) of the Act requires that applicable manufacturers report a "payment or other transfer of value" made to a covered recipient or "to an entity or individual at the request of or designated on behalf of a covered recipient." Under Section 1128G(a)(1)(B), if an applicable manufacturer makes a payment or other transfer of value to an entity or individual at the request of or designated on behalf of a covered recipient, the applicable manufacturer must disclose the payment or other transfer of value under the name of the covered recipient. Section 1128G(e)(10)(A) of the statute defines "payment or other transfer of value" broadly as "a transfer of anything of value."

We would like to clarify that we interpret payments or other transfers of value to an entity or individual at the request of or designated on behalf of a covered recipient to refer to a situation in which an entity or individual receives and keeps the payment that was made on behalf of (or at the request of) the covered recipient and the covered recipient does not receive the payment or other transfer of value. Rather, the covered recipient directs the payment or other transfer of value and does not receive the payment personally. Such payments or other transfers of value to third party recipients are somewhat different than indirect payments to a covered recipient made through a third party (discussed in section II.B.1.k. of this final rule). Indirect payments or other transfers of value are made to an entity or individual (that is, a third party) to be passed through to a covered recipient. In the case of indirect payments or other transfers of value, we believe that the applicable manufacturer will generally direct the payment path.

We proposed that payments or transfers of value made to an individual or entity at the request of or designated on behalf of a covered recipient included payments or other transfers of value provided to a physician (or physicians) through a physician group or practice. We proposed that payments or other transfers of value provided through a group or practice should be reported individually under the name(s) of the physician covered recipient(s).

When reporting payments or other transfers of value made at the request of, or designated on behalf of a covered recipient, we proposed that applicable manufacturers should report the payment or other transfers of value in the name of the covered recipient, but include the entity or individual that received the payment at the request of or designated on behalf of the covered recipient. We believed that reporting the entity or individual paid would maximize transparency about the details of the payment or other transfer of value, by allowing end users to discern whether a covered recipient actually received the payment, and if not, where the payment went. Additionally, we proposed that we did not believe it was feasible to provide a review period for these entities before the data is made public. Instead, we explained that review by the covered recipient was sufficient.

Comment: Many commenters requested additional information on how to determine the amount and value of a payment or other transfer of value since neither the statute nor the proposed rule provided much guidance. While some commenters recommended specific options, such as interpreting value as discernible economic value on the open market, the majority advocated that the applicable manufacturers be allowed flexibility to determine whether a payment or other transfer of value has a cognizable economic value, and if so, to allow flexibility to determine such value. Several commenters also recommended that if a payment or other transfer of value does not have a measurable economic value to a covered recipient, then it does not need to be reported. In addition, a few commenters requested clarification on how to handle tax and other additional payments, such as shipping. Finally, a few commenters recommended that CMS clarify that goods purchased for market value should not be reportable.

Response: We appreciate the comments and agree that more information will be useful for applicable manufacturers. In general, for purposes of this rule only, we interpret value similarly to many comments as the discernible economic value on the open market in the United States. However, we agree and support that applicable manufacturers should be allowed flexibility to determine value, so we do not plan to create numerous rules for calculating value. We have outlined a few guidelines to help manufacturers. First, payments or other transfers of value that do not have a "discernible" economic value for the covered recipient specifically, but nevertheless have a discernible economic value generally must be reported. For example, an applicable manufacturer may provide a physician with a textbook that the physician already owns. Since it is a duplicate, it may not have a value to the physician; however, the textbook does have an economic value, so it must be reported. Second, even if a covered recipient does not formally request the payment or other transfer of value, it still must be reported. Similarly, when calculating value we believe that all aspects of a payment or transfer of value, such as tax or shipping, should be included in the reported value. Finally, all applicable manufacturers must make a reasonable, good faith effort to determine the value of a payment or other transfer of value. The methodology used and assumptions made by the applicable manufacturer may be included in the applicable manufacturer's voluntary assumptions document (discussed in section II.B.1.h.

of this final rule). Finally, we added the statutory definition of "payment or other transfer of value" to the regulatory text to ensure consistency with the statute.

Comment: A few commenters stated that applicable manufacturers should not report payments or other transfers of value provided to a group practice as if the payment or other transfer of value had been provided to all members of the group.

Response: We agree that payments or other transfers of value being provided to a specific physician through a group practice should not necessarily be attributed to all physicians in that group. However, we also do not want payments or other transfers of value to go unreported because they were provided to a group or practice rather than to a specific physician. This was the intent of our proposal for reporting payments to group practices. We have finalized that payments provided to a group or practice (or multiple covered recipients generally) should be attributed to the individual physician covered recipients who requested the payment, on whose behalf the payment was made, or who are intended to benefit from the payment or other transfer of value. This means that the payment or other transfer of value does not necessarily need to be reported in the name of all members of a practice. For example, if an applicable manufacturer donates a set of dermatology textbooks to a group practice, we believe that applicable manufacturers should attribute the transfer of value to only the dermatologists at the practice by dividing the cost equally across all dermatologists. We intend for applicable manufacturers to divide payments or other transfers of value in a manner that most fairly represents the situation. For example, many payments or other transfers of value may need to be divided evenly, whereas others may need to be divided in a different manner to represent who requested the payment, on whose behalf the payment was made, or who was intended to benefit from the payment or other transfer of value. We agree with the commenters that this approach attributes payments more fairly, since some physicians in a group practice may not make use of a payment or other transfer of value and may have concerns about such payments or other transfers of value being attributed to them.

Comment: A few commenters requested clarification of the reporting requirements for payments or other transfers of value provided through a covered recipient to another covered recipient. We did not address this specific situation in the proposed rule. These commenters generally refer to a situation when a payment is provided to a physician covered recipient, but made through a teaching hospital covered recipient.

Response: We appreciate the comments and agree that this is an area of potential confusion, so we believe that clarification is necessary. While the comments are generally limited to payments or other transfers of value to a physician through a teaching hospital, we provide clarification more generally. However, we recognize that the majority of payments to one covered recipient through another will likely involve a physician and teaching hospital.

Payments provided to one covered recipient, but directed by the applicable manufacturer to another specific covered recipient should be reported in name of the covered recipient that ultimately received the payment because the intermediate covered recipient was merely passing through the payment. For example, if an applicable manufacturer provides a payment to a teaching hospital intended for a physician employee of the teaching hospital, then the payment should be reported in the name of the physician covered recipient, since that is who ultimately received the payment. In addition, a payment provided directly to a physician covered recipient should be reported in the name of the physician, regardless of whether the physician is an employee of a teaching hospital, since the payment was provided to the physician and not the teaching hospital. In order to prevent double counting, payments provided in these circumstances should not also be reported in the name of the intermediate covered recipient. If the payment or other transfer of value was not passed through in its entirety, then the applicable manufacturer should report separately the portion of the payment or other transfer of value retained by the teaching hospital covered recipient and the portion passed through to the physician covered recipient. If the payment or other transfer of value was not passed through at all, the applicable manufacturer should report it in its entirety in the name of the teaching hospital. We note that the rules regarding research-related payments made to teaching hospital covered recipients differ somewhat and are discussed further in the section on research herein.

Comment: A few commenters recommended that CMS set a limit for the total amount a physician can receive annually.

Response: This statute does not afford us the authority to limit the payments or other transfers of value made to covered recipients. The statute requires applicable manufacturers to report the relationships, but does not limit or ban them in any way. This is a transparency initiative, and inclusion on the public Web site does not indicate that the relationships are necessarily improper or illegal.

Comment: There were a number of comments, some which supported reporting the name of the entity or individual that received the payment and others opposing this approach. However the most common suggestion was to only report the name of entities that receive the payment, rather than individuals, due to privacy concerns. Additionally, a few commenters stated that the applicable manufacturer may not know the amount if it was at the request or designated on behalf of a covered recipient.

Response: We appreciate the comments and continue to believe that reporting the name of the entity which received the payment at the request of or designated on behalf of a covered recipient is beneficial. However, we agree that reporting the name of an individual that received the payment could be problematic. We will finalize that applicable manufacturers must report, in the name of the covered recipient, all payments or other transfers of value made at the request of or designated on behalf of a covered recipient, as well as the name of the entity that received the payment or other transfer of value. In the event that a payment was provided to an individual, at the request of or designated on behalf of a covered recipient, the individual's name does not need to be reported. Instead, the applicable manufacturer should report simply "individual" in the field for entity paid.

Finally, we do not agree with the comment that the applicable manufacturer may not know the amount of the payment. We believe that because the applicable manufacturer is making the payment, it should know the amount being provided. We believe regardless of what entity received the payment or other transfer of value, the details are available to the applicable manufacturer.

Comment: Many commenters recommended that CMS should provide entities receiving payments or other transfers of value at the request of or designated on behalf of a covered recipient (as a third-party recipient) should have the opportunity to review and correct the information. However,

other commenters supported the CMS proposal.

Response: While we appreciate the interest in allowing these entities the opportunity for review, dispute and proposing corrections, we do not believe there is a viable method for administering it. The agency will not have any information on the entities beyond their name, so we will not be able to match an entity across applicable manufacturers. More importantly, since the entities will not be readily identifiable groups or individuals (such as physicians), the agency will have no means to validate the identity of an individual signing on to the Web site and stating that he or she is from a specific entity. Additionally, we believe a covered recipient will be able to review these payments or other transfers of value sufficiently since they should be aware of the payment or other transfer of value made at their request or designated on their behalf. As explained in this section, we have decided to only require reporting and publication of the name of entities (and not individuals) that received payments or other transfers of value at the request of or designated on behalf of covered recipients. We believe this should alleviate some of the concerns regarding review and correction because personal payments to an individual will not be made public on the Web site. Given these considerations, we will finalize that review and correction for entities which receive a payment at the request of or designated on behalf of a covered recipient will be done by the covered recipient, rather than the entity.

Comment: Numerous commenters noted various situations when a payment or other transfer of value may be at the request of or designated on behalf of a covered recipient. In some cases, a covered recipient may direct the payment elsewhere; conversely, in others, the covered recipient may simply waive the payment and the applicable manufacturer provides it to a third-party recipient of their choosing. In addition, there are also models when a covered recipient does not have any claim to the payment and it is automatically provided elsewhere (such as a charity) on his/her behalf. The commenters recommended various methods to report these situations, including categorizing some as non-reportable.

Response: We appreciate these comments and recognize that there are various circumstances where a payment will be made at the request of or on behalf of a covered recipient, which will all be slightly different. In general, we do not believe it will be possible to create rules for each situation. Instead, we are providing the following general guidelines and information on how we intend to interpret the phrases "at the request of" and "designated on behalf of."

If a covered recipient directs that an applicable manufacturer provide a payment or other transfer of value to a specific entity or individual, rather than receiving it personally, then the payment is being made "at the request" of such covered recipient and must be reported as described in this section (under the name of the covered recipient, but also including the name of the entity paid or "individual," in the case of an individual). For example, in the event that a covered recipient directs an applicable manufacturer to donate a payment or other transfer of value—to which he would have otherwise been entitled—to a particular charity, the applicable manufacturer must report the payment in the name of the covered recipient and provide the name of the charity that received the payment at the covered recipient's request. However, if a covered recipient decides to neither accept the payment or other transfer of value nor request that it be directed to another individual or entity, then the payment or other transfer of value that was offered by the applicable manufacturer does not need to be reported. In this situation, there is nothing to report because no reportable payment or other transfer of value was made to a covered recipient or to an individual or entity at the request of or designated on behalf of a covered recipient.

In addition, we interpret "designated on behalf of a covered recipient" as when a covered recipient does not receive a payment or other transfer of value, but the applicable manufacturer provides the payment or other transfer of value to another entity or individual in the name of the covered recipient. For example, a covered recipient may waive his payment, and the applicable manufacturer nevertheless donates the payment to a charity "on behalf of" the covered recipient. We recognize that this could result in a covered recipient who waived a payment nevertheless having a payment reported in his or her name; therefore, we encourage covered recipients to make very clear to applicable manufacturers whether they would like their waived fee to be paid to another individual or entity—

After consideration of the public comments received, we are finalizing that reporting of payments or other transfers of value at the request of or designated on behalf of a covered recipient should be reported, but should include the name of the entity paid or that another individual received the payment. The covered recipient will have the opportunity to review and correct the payment on behalf of the entity or individual that received the payment.

f. Payment and Other Transfer of Value Report Content

The specific categories of information required to be reported for each payment or other transfer of value provided to a covered recipient are set forth in section 1128G(a)(1)(A) of the Act. In the proposed rule, we provided explanations and details on how we proposed that applicable manufacturers report some of this information to CMS. This section outlines the comments we received on the data elements.

(1) Name

We proposed that applicable manufacturers should report the first name, last name, and middle initial for physician covered recipients.

Comment: A few commenters stated that not all physicians have middle names and not all existing systems include middle name or initial, so they recommended middle initial not be reported.

Response: We appreciate the comments, but believe that given the number of physicians with the same first and last name, reporting a middle initial will be important when identifying and distinguishing physician covered recipients and aggregating payments across applicable manufacturers. While we recognize that not all physicians have middle names, we believe that this information should be reported whenever possible. As required in § 403.904(c)(1), applicable manufacturers must report the middle initial of a physician covered recipient as listed in NPPES, but will not be penalized for leaving the field blank if it is not available in NPPES or if the physician does not have a middle name. Additionally, as stated previously, we hope that applicable manufacturers provide as much identifying detail as possible on physician covered recipients to ensure we can attribute payments appropriately. In order to ensure that physician covered recipients are appropriately matched across applicable manufacturers and to their own data during the review and correction period, we will require applicable manufacturers to report a physician covered recipient's name as listed in NPPES.

(2) Business Address

We proposed that applicable manufacturers should report the full street address. For teaching hospital covered recipients, we proposed using only the address included in the CMS-published list of teaching hospitals. For physician covered recipients, we proposed that applicable manufacturers report the physician's primary practice location address, since this is more easily recognizable to end users of the data.

Comment: A few commenters recommended that CMS allow applicable manufacturers to use the address kept on file for a physician covered recipient, rather than the address in NPPES, since the address on file may be more accurate than the NPPES address. Regarding NPPES, a few commenters also suggested that CMS should require physicians to keep their address updated. Some commenters recommended reporting the address used for correspondence, rather than business location. Finally, a few commenters discussed that providing the full street address for the business address field for each payment or other transfer of value will increase the data elements significantly.

Response: We appreciate the comments. We agree that (unlike with a physician covered recipient's name) applicable manufacturers do *not* need to use NPPES when reporting addresses. In the proposed rule, we simply wanted to be clear that it was available and explain what field to use, if an applicable manufacturer chose to use NPPES. Regarding the requirement to keep addresses updated, we encourage physicians to keep their NPPES profiles updated, but we do not believe that we have the authority to force all physicians to do so.

We also have finalized our proposal to require the primary practice location address to be reported as the business address. We realize that a physician can be associated with multiple addresses, but we believe that primary practice location is the most recognizable to consumers. However, we understand that it may be difficult for an applicable manufacturer to know which address represents the primary practice location, so we plan to not penalize applicable manufacturers for providing the incorrect address, as long as applicable manufacturer reports a legitimate business address for the covered recipient.

Finally, we appreciate the comment that the reporting of a full street address (as opposed to a portion of the address, such as City and State) will require a significant amount of data to be submitted. We agree that we want to minimize the data submitted; however, we believe that full street address is important since in large urban areas there may be multiple physicians with the same name in the same city, so we will continue to require reporting of full street business address.

(3) Specialty and NPI

In the proposed rule, we stated that, as required by the statute, applicable manufacturers are required to report the specialty and NPI for physician covered recipients. We suggested that applicable manufacturers use the "provider taxonomy" field when reporting physician specialty. We proposed that applicable manufacturers only report a single specialty and use only the specialties available for the "provider taxonomy" field in NPPES. More details on these terms are available online.[4] For NPI, we proposed that applicable manufacturers report the physician's individual NPI, rather than any group NPI, with which the physician may be associated.

Comment: Many commenters addressed the requirements for reporting physician specialty and NPI. Some commenters recommended that applicable manufacturers be able to use their own internal files for reporting specialty, rather than NPPES. They were concerned that specialty in NPPES may not be accurate and could lead to concerns about off-label marketing. Regarding the NPPES list, a few commenters recommended that CMS include the nine recognized American Dental Association (ADA) specialties. Some commenters also requested clarification on whether applicable manufacturers should report both the specialty name and the associated NPPES code. In addition, a few commenters recommended that CMS allow methods for an applicable manufacturer to provide more context regarding physician specialty, such as reporting multiple specialties with one listed as primary or allowing a statement justifying specialty choice.

Response: We appreciate the comments and agree that applicable manufacturers may use their internal information when reporting specialty. However, the NPPES "provider taxonomy" list (as referenced previously) should be used as the list of accepted specialties since consistency in the names of reported specialties is important for facilitating aggregation of the data. We note that the NPPES list does include the nine recognized ADA specialties. When reporting specialty, applicable manufacturers should list both the specialty name and code to ensure consistency.

Additionally, we do not believe applicable manufacturers need to provide more information when reporting physician covered recipient specialty. We believe that a single specialty should be sufficient and that allowing applicable manufacturers to provide a justification of physician specialty would be too much information to be beneficial.

(4) Date of Payment

In the proposed rule, we required applicable manufacturers to provide the date on which a payment or transfer of value was provided to the covered recipient. We recognized that some payments or other transfers of value might be provided over multiple dates, such as a consulting agreement with monthly payments. We proposed that applicable manufacturers use their discretion as to whether to report the total payment on the date of the first payment as a single line item, or to report each individual payment as a separate line item.

Comment: Many commenters supported the proposed requirements for reporting the date(s) of payment. These comments appreciated the flexibility since applicable manufacturers may use different tracking systems. However, some commenters requested additional flexibility on how to report the payment date. For example, some commenters suggested that applicable manufacturers should have flexibility, depending on their individual systems, to report the date a flight actually occurred or the date the trip was booked, as long as this information is reported consistently within a category. Additionally, the commenters recommended that CMS clarify how to report payments which may happen across a reporting year.

Response: We appreciate the comments and have finalized the proposal that applicable manufacturers have the flexibility to report payments made over multiple dates either separately or as a single line item for the first payment date. In addition, we will allow flexibility for what specific date to report for a nature of payment category. We believe that the methodology employed should be consistent within a single nature of payment category. For example, for all flights, applicable manufacturers should report dates in a consistent manner (such as the flight

[4] Health care provider taxonomy codes are available through a link on the NPPES Web site: *https://nppes.cms.hhs.gov/NPPES/StaticForward.do?forward=static.instructions.*

date or ticket purchase date). In addition, the aggregated payments should not cross years, so for payments which span multiple years, the amount paid in a given year must be reported for that reporting year. Similarly, the date of payment methodology should not be used to move payments from one reporting year to another. Applicable manufacturers are encouraged to include information on the methods they used for reporting date of payment or other transfer of value in their assumptions document. When reporting the date of payment for bundled small payments (as described in § 403.904(i)(2)(iv)), applicable manufacturers should report the date of payment as the date of the first small payment or other transfer of value made to the covered recipient.

(5) Context

Comment: Some commenters recommended that CMS allow applicable manufacturers to voluntarily report contextual information about each payment or other transfer of value and make the information publicly available. CMS did not propose including this in the proposed rule.

Response: We agree that information on the context of a payment or other transfer of value could be useful. We believe it could help the public better understand the relationships between the industry and covered recipients. In addition to consumers, we believe contextual information will be useful for covered recipients when reviewing the payments or other transfers of value. Hopefully, the context will provide information to help the covered recipient assess the accuracy of the payment. However, we do not want this information to overwhelm users or significantly increase the data reported, so will limit the amount of data that can be reported in that field. Section 403.904(c)(12) allows applicable manufacturers to provide brief contextual information for each payment or other transfer of value, but does not require them to do so.

(6) Related Covered Drug, Device, Biological or Medical Supply

Section 1128G(a)(1)(A)(vii) of the Act requires applicable manufacturers to report the name of the covered drug, device, biological or medical supply associated with that payment, if the payment is related to "marketing, education, or research" of a particular covered drug, device, biological, or medical supply. We proposed that in cases when a payment or other transfer of value is reasonably associated with a specific drug, device, biological or medical supply, the name of the specific product must be reported. We realize that not every financial relationship between an applicable manufacturer and a covered recipient is explicitly linked to a particular covered drug, device, biological or medical supply, but many are, and we proposed that those must be reported.

When reporting a related product, we proposed that applicable manufacturers could report only one covered drug, device, biological or medical supply as related to a payment or other transfer of value, even though there arguably may be multiple covered products related to the payment. However, we considered, as an alternative, allowing applicable manufacturers to report multiple covered drugs, devices, biologicals or medical supplies as related to a single payment or other transfer of value. We believed that reporting of multiple covered drugs, devices, biologicals, and medical supplies may be easier for applicable manufacturers since many financial relationships are not specific to one product only, but could make aggregating payments by product difficult.

With regard to reporting a product name, we proposed that the applicable manufacturer should report the name under which the product is marketed, since this name is probably most recognizable to the consumer. In the event that a covered drug, device, biological or medical supply does not yet have a market name, we proposed the applicable manufacturer should report the scientific name.

Comment: Many commenters questioned how and when to report an associated product. A number of these commenters discussed whether a product name should be reported for payments associated with non-covered products (such as pre-commercial or OTC drugs) and recommended only requiring reporting of a product when the payment is related to "marketing, education, or research." Many commenters also recommended that CMS allow the reporting of "n/a" or "none" in instances when a product is not associated or when associated with a non-covered product. Similarly, a few commenters recommended that applicable manufacturers should not have to report an associated product for research on a new indication of a covered product.

A few commenters provided more specific requirements, such as only reporting a covered product for a payment or other transfer of value, when there is a written agreement or an understanding with the covered recipient that the product will be named. Similarly, some commenters suggested that CMS should allow flexibility to report business purpose, in addition to product family or a single product.

Response: We appreciate the comments and agree that it is important to provide additional information on when and how a related product should be reported. Section 1128G(a)(1)(A)(vii) of the Act requires that "if a payment or other transfer of value is related to marketing, education, or research specific to a covered drug, device, biological, or medical supply," applicable manufacturers must report the name of the covered product. We believe that many financial relationships between applicable manufacturers and covered recipients are related to marketing, education or research associated with a particular product, often a covered product. Therefore, we will finalize that applicable manufacturers must report a related product name for all payments or transfers of value, unless the payment or other transfer of value is not related to a covered product. However, we do not believe applicable manufacturers should be required to report the name of associated non-covered products, since this may be misleading to consumers and would provide information that is beyond the goal of the statute. However, we do believe it is useful to know the extent of payments or other transfers of value that are not associated with *any* product or not associated with a *covered* product. This distinction will not be possible if applicable manufacturers leave the associated products fields blank in cases when it is not applicable. Given this interest, the final rule directs applicable manufacturers to fill in associated product fields as appropriate. Instead, if the payment or other transfer of value is not related to at least one covered product, then applicable manufacturers should report "none." Conversely, if the payment or other transfer of value is related to a specific product, which is not a covered product, then applicable manufacturers are to report "non-covered product." Finally, if the payment or other transfer of value is related to at least one covered product, as well as at least one non-covered product, then applicable manufacturers must report the covered products by name (as required), and may include non-covered products in one of the fields for reporting associated product.

Comment: Many comments addressed the number of associated products that may be reported for each payment or other transfer of value. Several commenters supported allowing

reporting of only a single product, whereas several others supported allowing applicable manufacturers to report multiple products as being associated with the a payment or other transfer of value. The commenters who advocated reporting multiple products explained that often a financial relationship is associated with multiple products, and it would be misleading to attribute it to a single product. Conversely, some commenters were sympathetic to the need to aggregate the payments or other transfers of value by product. As a compromise, some of these commenters suggested reporting a single product would be sufficient, as long as we allowed applicable manufacturers to report "multiple," as well. Other commenters recommended that CMS allow reporting of up to five products. However, these comments cautioned that aggregation by product should not give the impression that there were multiple interactions. A commenter recommended requiring applicable manufacturers to report a percentage of the interaction to be attributed to each product listed. The comments also addressed what product name should be used. Many commenters advocated that applicable manufacturers should be allowed to report the product category or therapeutic area rather than the product-specific name. Many commenters recommending this method referenced implantable devices, since consumers may not know the specific name of the device that had been implanted during a medical procedure. Many devices are given a complex name and number combination, which consumers may not know. For example, a patient may be aware that she received a hip implant manufactured by company A, but may not know the specific model number of the implant. Similarly, some commenters recommended slight changes to the name required to be reported, such as using the clinicaltrials.gov name for drugs without a name or allowing reporting of the generic name. Finally, a few commenters suggested that we require reporting of National Drug Code (NDC), as well as brand and generic name.

Response: We appreciate the comments and agree that reporting multiple products will likely improve the accuracy of the database in a way that is more beneficial than the difficulty in aggregating by product. Therefore, we will finalize that applicable manufacturers may report up to five related covered products for each interaction. If the interaction was related to more than five products, an applicable manufacturer should report the five products which were most closely related to the payment or other transfer of value. Additionally, when aggregating payments or other transfers of value by product, we will not represent a single interaction related to multiple products as multiple interactions. However, we do not agree that the applicable manufacturer should report the percentage of the interaction dedicated to each product. We believe this will be burdensome to the applicable manufacturers and would not be beneficial to consumers, since it will greatly increase the volume of the data.

We also agree that we should allow greater flexibility in reporting the product name, particularly for devices where the product name is less recognizable to consumers. For drugs and biologicals, we are finalizing that applicable manufacturers must report the market name of the product and must include the NDC (if any). If a market name is not yet available, applicable manufacturers should use the name registered on clinicaltrials.gov. We believe that reporting the NDC will greatly help CMS aggregating the data by product. However, if there is no NDC available for a product, it does not have to be reported. For devices and medical supplies, § 403.904(c)(8)(ii) allows reporting of either the name under which the device or medical supply is marketed, or the therapeutic area or product category. We believe that reporting devices and medical supplies in this manner is appropriate, since device names are less known to consumers and a single product may actually be comprised of multiple devices. Conversely, we believe that the names of drugs and biologicals are more readily available to consumers, since they are often listed on a prescription.

(7) Form of Payment and Nature of Payment

The statute requires reporting on both the form of payment and the nature of payment for each payment or transfer of value made by an applicable manufacturer to a covered recipient. The statute provides a list of categories for both the form of payment and nature of payment and gives the Secretary discretion to add additional categories.

Section 1128G(a)(1)(A)(v) of the Act includes the following form of payment categories:

- Cash or a cash equivalent.
- In-kind items or services.
- Stock, a stock option, or any other ownership interest, dividend, profit, or other return on investment.
- Any other form of payment or other transfer of value.

Section 1128G(a)(1)(A)(vi) of the Act includes the following nature of payment categories:

- Consulting fees.
- Compensation for services other than consulting.
- Honoraria.
- Gift.
- Entertainment.
- Food.
- Travel (including the specified destinations).
- Education.
- Research.
- Charitable contribution.
- Royalty or license.
- Current or prospective ownership o investment interest.
- Direct compensation for serving as faculty or as a speaker for a medical education program.
- Grant.
- Any other nature of the payment or other transfer of value.

In this section, we discuss the general policies for reporting the form of payment and the nature of payment, rather than the specific categories, which will be discussed in sections II.B.1.g and h. of this final rule.

In the proposed rule, we proposed that the categories within both the form of payment and the nature of payment should be defined as distinct from one another. Additionally, if a payment or other transfer of value for an activity is associated with multiple categories, such as travel to a meeting under a consulting contract, we proposed that the travel expenses should remain distinct from the consulting fee expenses and both categories would need to be reported to accurately describe the relationship. In these cases, we proposed that for each payment or other transfer of value reported, applicable manufacturers may only report a single nature of payment and a single form of payment. For example, if a physician received meals and travel in association with a consulting fee, we proposed that each segregable payment be reported separately in the appropriate category. The applicable manufacturer would have to report three separate line items, one for consulting fees, one for meals and one for travel. The amount of the payment would be based on the amount of the consulting fee, and the payments for the meals and travel. For lump sum payments or other transfers of value, we proposed that the applicable manufacturer break out the distinct parts of the payment that fall into multiple categories for both form of payment and nature of payment. We also solicited comment on an alternative approach of allowing a payment or other transfer of value for an activity that is

associated with multiple segregable categories to be reported as a single lump sum, rather than separately by each segregable category.

Finally, in the proposed rule we also discussed the interpretations of various forms of payment and natures of payment categories. We did not define the categories individually and instead proposed that they would have their dictionary definitions.

Comment: Many commenters addressed our proposed method for reporting form of payment and nature of payment. A number of these commenters supported our proposed method of reporting a single form of payment and a single nature of payment for each reported payment, whereas others supported the alternative of reporting multiple forms of payment and natures of payment for a single payment. The commenters supporting multiple forms of payment and natures of payment recommended that the applicable manufacturer should be allowed flexibility to report, but should explain their decisions and methodology for reporting form and nature of payment in the assumptions document. Additionally, a few commenters suggested that the applicable manufacturer should be allowed to report lump payments, but should be required to produce segregated payments in an audit. Finally, a few commenters recommended that CMS allow applicable manufacturers to report additional details beyond form of payment and nature of payment to allow end users to understand that not all reported relationships are payments.

Response: We appreciate the comments and believe they provided important background on the processes of reporting. However, we have finalized these provisions as proposed. We believe that flexibility in the reporting requirements is important to aid applicable manufacturers with different systems. However, we believe that there should also be consistency in the way payments or other transfers of value are reported across applicable manufacturers, particularly when describing and classifying payments or other transfers of value. We believe that a single form of payment and a single nature of payment for each line item characterizes a payment or other transfer of value much differently than reporting multiple forms of payment and natures of payment for a lump sum payment. We are concerned that allowing this flexibility will be confusing to covered recipients and end users, since they will not be able to readily tell a specific applicable manufacturer's method for reporting the payment or other transfer of value, since the assumptions document will not be made public. We also believe that a flexible method would create additional disputes because a covered recipient would not know what was included in a single line item, since some line items would be separated, whereas others would be aggregated. Additionally, a State with a similar reporting requirement for manufacturers that allows the reporting of secondary natures of payment stated in its public comment that reporting entities seldom use the secondary field, indicating that a single field should be sufficient.

With regard to choosing the appropriate nature of payment, we agree that if a payment could fit within multiple possible categories, applicable manufacturers should have flexibility to select the category that best described the payment, in accordance with their own documented methodology. However, this should not be used to bundle payments of separate categories into a single payment. For example, a meal should be reported as a meal, even if associated with travel or a consulting contract. Additionally, serving as a faculty for a medical education program should be reported separately from a consulting contract, even if the medical education program speech was similar in content to the consulting services provided by the covered recipient.

Comment: A number of commenters generally questioned the form of payment and nature of payment categories. Many commenters requested that CMS develop precise definitions, and a few commenters provided recommended definitions. However, in the event that the agency does retain the dictionary definitions, some commenters suggested that CMS should ensure that the dictionary definitions are sufficient to provide clarity. Additionally, a few commenters recommended that CMS publish and allow for Q&As to further clarify the categories. A few commenters provided additional categories for CMS to add, whereas others recommended methods for categorizing payments or other transfers of value to explain the details of the payment. For example, a commenter recommended that we create separate reporting categories for payments or other transfers of value made directly and indirectly. Finally, a few commenters recommended that we should consider form of payment as "payment type" or the modality used to transfer value, whereas we should consider nature of payment as "payment nature" or the reason the payment was made.

Response: We appreciate the comments and have carefully considered the best way to provide additional context to the categories. Given the very specific statutory requirements, we are unable to fully reconfigure the categories; while the Secretary is granted discretion to add forms of payment and natures of payment, she is not given discretion to remove or collapse them. However, we appreciate the clarification on form of payment being considered the modality used to transfer value and nature of payment being the reason the payment was made. We believe these classifications should help applicable manufacturers when assigning categories, and will help us provide more accurate guidance on the categories.

In order to provide additional information we have provided general discussions and additional contextual information, particularly for the nature of payment categories, since we believe most comments were concerned with the nature of payment categories. We provide additional details in the following two sections of this final rule dedicated to form of payment and nature of payment.

g. Form of Payment

Section 1128G(a)(1)(A)(v) of the Act lists forms of payment that applicable manufacturers must use to describe payments or other transfers of value. Applicable manufacturers must assign each individual payment or other transfer of value, or separate parts of a payment, to one and only one of these categories. In the proposed rule, we did not add any forms of payment beyond those outlined in the statute because we believed what is provided in the statute was sufficient to describe payments and other transfers of value. Additionally, as explained, we proposed that each form of payment be defined by the term's dictionary definition, since we believed that these terms are understandable as written.

Comment: We received a few comments supporting the categories, as well as a few recommending small changes to the categories. A few commenters advocated adding a category for "grant" to make clear that it was not personal income. Another few commenters recommended separating stock, stock option, or any other investment interest from dividend, profit or other return on investment, since they are materially different. These commenters explained that stocks, stock options, and investment interests are different from dividends, profits, and return on investments

because the former are actively granted to a covered recipient while the latter are earned on existing investments. Finally, regarding the definitions, a few commenters suggested that CMS use standard legal definitions.

Response: We appreciate the comments and agree that the forms of payment categories are sufficient. However, we do agree that the "stock, stock option, or any other ownership investment interest, dividend, profit or other return on investment" category should be divided into two categories. We agree that the categories are different and separating them would create additional specificity in the categories, without changing them significantly. Conversely, we do not agree that grant should be a form of payment. Instead, we believe "grant" should remain as a nature of payment (as included in the statute), since it best describes a reason a covered recipient might receive a payment. After consideration of the public comments received, we are finalizing the proposal to break the category of "stock, stock option, or any other ownership investment interest, dividend, profit or other return on investment" category into two categories, but otherwise will not be adding any additional categories to form of payment. We agree that stock, stock options, and other ownership investment interests are different than dividends, profits and other returns of investment, so separating these categories may provide additional clarity to consumers. We do not believe that this changes the way forms of payments will be reported, since the categories existed previously, we are simply providing more clarity and specificity to the categories. We believe the dictionary definitions are sufficient, particularly since these terms are generally understandable to consumers.

h. Nature of Payment

Section 1128G(a)(1)(A)(vi) of the Act lists the categories for the nature of payment or other transfer of value that applicable manufacturers must use to describe each payment. In the proposed rule, we encouraged applicable manufacturers to consider the purpose and the manner of the payment or other transfer of value; if a payment could conceivably fall into more than one category, we proposed that applicable manufacturers should make reasonable determinations about the nature of payment reported for the payment or transfer of value. Additionally, as explained, we believed that the nature of payment categories have meanings to the general public that are familiar to the industry and proposed defining each nature of payment category by its dictionary definition.

Comment: Many commenters discussed the nature of payment categories, including our proposed method for defining the categories. A few commenters recommended that CMS provide more guidance on how these categories should be applied. For example, one commenter recommended that CMS rank the categories and if multiple categories could apply to a single payment or other transfer of value, the applicable manufacturer should report it in the "higher" ranked category. Another commenter requested that CMS break the categories into two groups: those made in exchange for value (such as services or intellectual property rights) and those made without any expectation of benefit. Beyond categorizing payments or other transfers of value, many commenters requested additional guidance on the definitions for the nature of payment categories. We also received a few recommendations for additional nature of payment categories. For example, a few commenters recommended including a category for agreements to appear as an "author" of an industry ghost-written publication. Another commenter recommended that we include a category for space or facility fee for events at a teaching hospital.

Response: We appreciate the comments. However, we believe that providing precise definitions for applicable manufacturers to use in categorizing nature of payments will be too restrictive. Applicable manufacturers are required to report all payments or other transfers of value, unless they specifically fall within an exception. The nature of payment categories are simply used to *describe* these payments or other transfers of value. We believe precise definitions could make these descriptors less useful and could make reporting more challenging for applicable manufacturers. For example, if a payment or other transfer of value that the applicable manufacturer generally would classify as a consulting fee does not meet our precise definition, the applicable manufacturer would be forced to report it in another category, which would likely be less accurate than the consulting fee category. The relationships between applicable manufacturers and covered recipients are extremely diverse; we are concerned that providing specific, narrow definitions would not encompass every situation, forcing applicable manufacturers to describe payments or other transfers of value by less specific categories that do not accurately describe the relationship. Additionally, since all payments or transfers of value must be reported, we do not believe we should rank the categories and indicate some as more desirable or beneficial than others. Instead, we believe that the nature of payment categories are descriptors and that applicable manufacturers should select the most appropriate description. However, we do understand the interest in consistency to enhance of the usefulness of the data, so we will provide some additional explanations for the categories.

Finally, we appreciate the recommended additional categories. We have tried to limit the number of additional categories as much as possible, so we have only added categories for those recommendations that we believe cannot be described by existing nature of payment categories. For example, we believe that agreement to appear as an author of a ghostwritten article is an important relationship that should be reported, but believe there are sufficient existing nature of payment categories, such as compensation for services other than consulting, which can be used to describe the relationship. Conversely, regarding space rentals, we do agree that this represents a specific relationship between a covered recipient (likely a teaching hospital) and an applicable manufacturer that cannot be accurately described by the existing nature of payment categories. We understand that space rental or facility fees are commonly part of hosting an event at a hospital and believe that including them in another category would inflate the amount in that category. Similarly, the statutory nature of payment categories are mostly directed towards physician covered recipients, so it is important to consider the common relationships between teaching hospital covered recipients and applicable manufacturers. Given these considerations, we will add space rental and facilities fees as a nature of payment category under our authority in section 1128G(a)(1)(A)(vi)(XV) of the Act, but will not add appearing as an author for a ghostwritten article.

We are providing some additional explanation of the nature of payment categories to provide additional context. These explanations are not exhaustive (unless specified as such), but rather are intended to provide additional guidance to applicable manufacturers when they are categorizing payments. Additionally, we will discuss research in a separate section in light of the additional complexities in reporting research-related payments or other transfers of

value, which warrants additional consideration.

(1) Charitable Contributions

In the proposed rule, we stated that charitable contributions to, at the request of, or on behalf of covered recipients by applicable manufacturers must be reported. For purposes of the reporting requirement, a charitable contribution is any payment or transfer of value made to an organization with tax-exempt status under the Internal Revenue Code of 1986, but only if it is not more specifically described by one of the other nature or payment categories. We did not receive any comments on the definition of charitable contribution and intend to finalize it as proposed.

Comment: Many commenters questioned how to report payments or other transfers of value for when a covered recipient (usually a physician) does not receive a payment personally and instead the payment is provided to a charity. In these situations, the covered recipient may or may not choose the charity and may be waiving his or her customary fee.

Response: We appreciate the comments and understand these payments or other transfers of value can be complicated. We discussed general guidelines for reporting payments through another covered recipient in the payments or other transfer of value section of the final rule, but will provide additional detail in this section for situations when a payment or other transfer of value is directed to charity. We believe that the "charitable contribution" nature of payment category should be used only in situations when an applicable manufacturer makes a payment or other transfer of value to a charity on behalf of a covered recipient and not in exchange for any service or benefit. For example, in circumstances where a physician provides consulting services to an applicable manufacturer, but requests that his payment for the services be made to a charity, this would not be a charitable contribution for purposes of this rule because the payment was not provided by the applicable manufacturer as a charitable contribution, but rather as a directed consulting fee. This payment would be reported as a consulting fee with the physician as the covered recipient, but the entity paid would be the charity.

Additionally, we note that in the cases of teaching hospital covered recipients that have tax-exempt status under the Internal Revenue Code of 1986, payments or other transfers of value made to these organizations (other than payments or other transfers of value made for expected services or benefits, such as consulting services or rental of space in a hospital for an event) would be considered and reported as charitable contributions for purposes of this rule.

(2) Food and Beverage

When reporting food and beverage, we proposed that in group settings, such as the office of a group practice, where it is more difficult to keep track of which covered recipients actually partook in the food and beverage provided by an applicable manufacturer, the applicable manufacturer should report the cost per covered recipient receiving the meal even if the covered recipient does not actually partake of the meal.

Comment: Numerous commenters questioned our proposed allocation method for food and beverage. The majority of commenters recommended that we revise our proposed allocation methodology, but we did receive some support for it. Many commenters recommended various options for dividing the cost of group meals; however, there were some common themes in the recommendations. The majority of these commenters recommended that applicable manufacturers should report the amount based on the cost per participant (including, for example, support staff members who are not covered recipients), rather than the cost per covered recipient. Many commenters also strongly recommended that we should not attribute meals to *all* covered recipients in a practice because it may be difficult for applicable manufacturers to identify all the physicians within a practice, and this methodology could implicate concerns of off-label marketing in large multispecialty practices. These commenters suggested that the cost of a meal should only be attributed to physicians who actually partook of the food. They suggested that it would not be unduly burdensome to keep track of which physicians actually participated in the meal. Some commenters also recommended that CMS allow applicable manufacturers flexibility in allocating the value of meals depending on their internal systems or that the value should be based on the amount actually received. Finally, a few commenters recommended that CMS provide covered recipients with the opportunity to "opt-out" of interactions with applicable manufacturers, including meals, and attest that they never partake in such meals.

Beyond the allocation method, we received significant support for our proposal that applicable manufacturers do not need to report any offerings of buffet meals, snacks or coffee at booths at conferences or other similar events where it would be difficult for applicable manufacturers to definitively establish the identities of the individuals who accept the offerings. However, a few commenters also recommended that meals that are dropped off at a physician's office should also be excluded, as well as meals when the attendees are outside the control of an applicable manufacturer.

Response: We appreciate the comments and understand that reporting payments or other transfers of value that fall under the "food" nature of payment category is quite complicated, both in terms of calculating the value of the payments and determining who should be reported as having received payments. We believe that while reporting the transactions accurately is important, tracking exactly what a person ate or drank may not be practical for purposes of the reporting requirements. We have considered how to improve accuracy in reporting, while ensuring that the reporting requirements for this nature of payment are not overly burdensome. For meals in a group setting (other than buffet meals provided at conferences or other similar large-scale settings), we will require applicable manufacturers to report the per person cost (not the per covered recipient cost) of the food or beverage for each covered recipient *who actually partakes in the meals* (that is, actually ate or drank a portion of the offerings). In other words, applicable manufacturers should divide the total value of the food provided by the number of people who actually partook in the food and beverage including both covered recipients and non-covered recipients (such as support staff). If the per person cost exceeds the minimum threshold amount, then the applicable manufacturer must report the food or beverage as a payment or other transfer of value for each covered recipient who actually participated in the group meal by eating or drinking a food or beverage item. For example, a sales representative brings a catered lunch costing $165 to a 10-physician group practice. Six of the ten physicians and five support staff participate in the meal. Because the meal cost $15 per participant ($165/11 participants = $15), the meal needs to be reported for the 6 physicians who participated in it. However, the meal does not need to be reported for the 4

other physicians in the group who did not participate in the meal (that is, did not eat or drink any of the offerings). Additionally, if the total cost of the meal was $100, making the cost per participant less than $10, then the meal would not have to be reported since it was below the minimum threshold. We decided to make this modification to the proposed rule because we agree with commenters that for the purposes of this rule this method will more accurately reflect the actual transaction, and will not unfairly attribute a payment to a physician who did not partake in it. Additionally, we believe this approach will reduce disputes between applicable manufacturers and physicians, since food-related payments or other transfers of value will not be attributed to physicians that did not actually receive them. Finally, this method does not require the reporting of meals eaten by support staff, for the purposes of this reporting requirement. However, we recognize that in other contexts, transfers of value to a physician's office support staff (which may include meals) may constitute transfers of value to the physician.

While we appreciate the importance of flexibility, we believe that we need to set out the attribution methodology in order to ensure as much consistency as possible. If we did not provide a methodology, it could result in very different amounts being reporting across applicable manufacturers and could lead to increased disputes since covered recipients would not know how a particular applicable manufacturer attributed the value of a meal. We believe that there must be some consistency across applicable manufacturers in this complicated area, so we have finalized the position that applicable manufacturers must report the cost per participant for covered recipients in attendance.

Regarding meals that are dropped off at a covered recipient's office (for example, by a sales representative) and other meals where the attendees are not controlled or selected by the applicable manufacturer, we believe that these situations nevertheless constitute payments or other transfers of value to a covered recipient, so they must be reported. Applicable manufacturers are responsible for keeping track of food and beverages provided to covered recipients and must use the same attribution method for all meals as described previously regardless of whether the manufacturer's representative remained in the office for the entire meal.

We also appreciate the comments regarding allowing covered recipients the opportunity to opt-out from receiving meals; however, we believe that this would be operationally difficult for CMS. We would need to track the covered recipients and would have to develop a method of arbitration if an applicable manufacturer reports a meal for a physician who has opted-out. We believe that covered recipients who do not want to receive meals simply should make clear to applicable manufacturers that they do not accept them. The finalized methodology will no longer attribute meals to physicians who do not attend the meal, so a physician who does not want to receive meals should not attend or accept them.

Finally, we appreciate the support regarding offerings of buffet meals, snacks, or coffee at conferences or other large-scale events where it would be difficult for applicable manufacturers to definitively establish the identities of the physicians who partake in the food or beverage. Accordingly, we have finalized that food and beverage provided at conferences in settings where it would be difficult to establish the identities of people partaking in the food do not need to be reported. This applies to situations when an applicable manufacturer provides a large buffet meal, snacks or coffee which are made available to all conference attendees and where it would be difficult to establish the identities of the physicians who partook in the meal or snack. We do not intend this to apply to meals provided to select individual attendees at a conference where the sponsoring applicable manufacturer can establish identity of the attendees.

(3) Direct Compensation for Serving as a Faculty or as a Speaker for a Medical Education Program

In the proposed rule, we interpreted this category broadly to encompass all instances in which applicable manufacturers pay physicians to serve as speakers, and not just those situations involving "medical education programs." We acknowledged that this interpretation does not allow for differentiation between continuing education accredited speaking engagements, and all other speaking engagements.

Comment: Many comments addressed our proposed interpretation of this category, particularly regarding its relationship to accredited and/or certified continuing medical and dental education.

A few commenters supported our interpretation to include all speaking engagements in one category; however, numerous others were concerned about payments for accredited and/or certified continuing education-related speaking engagements and recommended that they be treated differently than unaccredited and/or certified continuing education speaking engagements. Many of these commenters provided significant background information on accredited and certified continuing education. Accredited Continuing Medical Education (CME) refers to CME activities that have been deemed to meet the requirements and standards of a CME accrediting body, as authorized by the Accreditation Council for Continuing Medical Education (ACCME). Certified CME refers to CME activities that carry credit offered by the grantors of CME credit (the American Osteopathic Association (AOA), the American Academy of Family Physicians (AAFP), and the American Medical Association (AMA)). Continuing dental education is similarly accredited through the American Dental Association's Continuing Education Recognition Program (ADA CERP).

These commenters explained that accredited and certified continuing education speaker payments will generally not be made directly by an applicable manufacturer to a covered recipient, as this category suggests, due to the accreditation requirements. Some commenters suggested that these be reported in another "indirect" speaking engagement category. Conversely, other commenters recommended that this category be limited to accredited and certified continuing education payments, and that compensation for other speaking engagements should be described by other natures or payments.

Response: We appreciate the comments and agree that it is important that CMS clarify this category. We understand the importance of continuing medical education and discuss the requirements for reporting it generally in section II.B.1.k. of the final rule, dedicated to indirect payments or other transfers of value. We agree that given the title of this nature of payment category, which was set out in the statute itself, it should not include compensation for accredited or certified continuing education payments. However, we do not believe that all payments to physicians for serving as speakers at an accredited or certified continuing education program should be granted a blanket exclusion (as discussed in the indirect payment section), so we have added an additional nature of payment category for serving as a faculty or speaker at an accredited or certified continuing education event, at § 403.904(e)(2)(xv). This category, named "compensation for

serving as faculty or as a speaker for an accredited or certified continuing education event," includes all accredited or certified continuing education payments that are not excluded by the conditions set forth in § 403.904(g)(1)(i) through (iii), and further discussed in section II.B.1.k. of this final rule. Additionally, we also renamed the category for direct compensation to include speaking engagements at unaccredited and non-certified continuing education events at § 403.904(e)(xiv). We recognize that not all payments or other transfers of value related to unaccredited and non-certified continuing education will be provided directly. Therefore, we retitled the category as "compensation for serving as a faculty or as a speaker for an unaccredited and non-certified continuing education program." This renamed category includes all other instances when an applicable manufacturer provides compensation to a covered recipient for serving as a speaker or faculty at an unaccredited and non-certified education event, regardless of whether the payment was provided directly or indirectly. Finally, the nature of payment category for "compensation for services other than consulting" at § 403.904(e)(2)(ii) now explicitly includes payments or other transfers of value for speaking engagements that are not for continuing education.

We believe this reporting strategy appropriately separates accredited and certified continuing education from unaccredited and non-certified continuing education, so that consumers can better understand the nature of the payment received by a covered recipient. Accredited and certified continuing education that complies with applicable standards of the accrediting and certifying entities generally includes safeguards designed to reduce industry influence, so we believe that, when reportable (that is, when the payments or transfers of value do not meet the conditions delineated at § 403.904(g)(1)(i) through (iii)), payments or transfers of value made to support accredited and certified continuing medical education should remain in a distinct category from unaccredited or non-certified continuing education. We also believe that educational speaking engagements should be separated from all other speaking engagements, promotional or otherwise, to have separated them appropriately. Finally, we believe the renaming of the statutory nature of payment category for "direct compensation for serving as a faculty or as a speaker for a medical education program" to include indirect compensation as well, provides applicable manufacturers flexibility to describe payments or other transfers of value more accurately.

(4) Other

In the proposed rule, we added a nature of payment category, titled "other," to serve as a catch all for payments or other transfers of value that do not fit into one of the listed natures of payment.

Comment: Many commenters recommended that CMS remove the proposed additional nature of payment category "other."

Response: We appreciate the comments and agree that an "other" category could dilute the usefulness of the nature of payment categories. Therefore, the final rule omits "other" category from the nature of payment categories at § 403.904(e). However, all payments or transfers of value from applicable manufacturers to covered recipients (other than those excluded under section 1128G(e)(10) of the Act) must be reported. Any payments or transfers of value that are not specifically excluded, must be reported and described based on the nature of payment categories included in the final rule. Applicable manufacturers are required to report each payment under the nature of payment category that most closely describes the payment; the absence of a nature of payment category that closely describes the payment does not constitute a basis for not reporting an otherwise reportable payment or other transfer of value. Failure to report such a payment may result in the imposition of a civil monetary penalty on the applicable manufacturer.

(5) Other Nature of Payment Categories

Although we did not address these categories in the proposed rule, we received comments requesting additional information on these categories and what CMS intends them to include. In the following sections, we have provided additional guidance on how we interpret the categories. Once again, this is not intended to define the categories, but rather to provide additional information for applicable manufacturers when considering the categories.

(A) Consulting Fees

This category is intended to include fees paid by an applicable manufacturer to a covered recipient for services traditionally viewed as consulting services. While we believe there is likely variation, we believe that consulting services are typically provided under a written agreement and in response to a legitimate need by the applicable manufacturer. Similarly, we believe there is often a connection between the competence of the covered recipient paid and the purpose of the arrangement, as well as a reasonable number of individuals hired to achieve the intended purpose.

(B) Compensation for Services Other than Consulting

This category is intended to capture compensation for activities or services that are not traditionally considered consulting services, but are provided by a covered recipient to an applicable manufacturer. As discussed in the section on direct compensation for serving as a faculty or as a speaker for a medical education program, this category should include payments or other transfers of value for speaking engagements that are not related to continuing education, such as promotional or marketing activities.

(C) Honoraria

We believe this category is similar to "compensation for services other than consulting." However, honoraria are distinguishable in that they are generally provided for services for which custom prohibits a price from being set.

(D) Gift

This category is a general category, which will often include anything provided to a covered recipient that does not fit into another category. For example, the provision of small trinkets (above the minimum threshold) would need to be reported as a "gift" since they are not included in any other category. However, provision of tickets to a professional sporting event should not be reported as a "gift" since this transaction is better described by the nature of payment category "entertainment" even if the provision of the tickets was a gift.

(E) Entertainment

This category is intended to include, but is not limited to, attendance at recreational, cultural, sporting or other events that would generally have a cost.

(F) Travel and Lodging

This category includes travel, including any means of transportation, as well as lodging. As required in section 1128G(a)(1)(A)(vi)(VII) of the Act, the destination, including City, State and country must be reported.

(G) Education

We believe this category generally includes payments or transfers of value for classes, activities, programs or events that involve the imparting or acquiring of particular knowledge or skills, such as those used for a profession. As stated in the section on indirect payments or other transfers of value, we do not intend to capture the *attendees* at accredited or certified continuing education events whose fees have been subsidized through the CME organization by an applicable manufacturer (as opposed to payments for speakers at such events); however, we believe that any travel or meals provided by an applicable manufacturer to specified covered recipients associated with these events must be reported under the appropriate nature of payment categories.

(H) Royalty or License

This category includes, but is not limited to, the right to use patents, copyrights, other intellectual property and trade secrets, including methods and processes. We believe this may be pursuant to a written agreement and could entail various payment schedules (such as scheduled or milestones methods). Applicable manufacturers may report total aggregated payment amounts for payments made under a single agreement, in order to consolidate reporting.

(I) Current or Prospective Ownership or Investment Interests

We believe this category includes ownership or investment interests currently held by the covered recipient, as well as ownership interests or investment that the covered recipient has not yet exercised. Details on current ownership or investment interests is discussed in the section of the final rule dedicated to reporting ownership or investment interests of physicians.

(J) Grant

This category generally refers to payments to covered recipients in support of a specific cause or activity.

(6) Nature of Payment Categories

Based on the comments, and the discussion and justifications included in this section, we will allow applicable manufacturers to report the following categories in the nature of payment field to describe payments or other transfers of value. However, as stated previously, all payments or other transfers of value must be reported, unless excluded, even if they do not explicitly fit into one of the outlined nature of payment categories. Applicable manufacturers must select the nature of payment category that best describes the payment or other transfer of value. The nature of payment categories in the final rule are as follows:

- Consulting fee.
- Compensation for services other than consulting, including serving as faculty or as a speaker at an event other than a continuing education program.
- Honoraria.
- Gift.
- Entertainment.
- Food and beverage.
- Travel and lodging (including the specified destinations).
- Education.
- Research.
- Charitable contribution.
- Royalty or license.
- Current or prospective ownership or investment interest.
- Compensation for serving as faculty or as a speaker for an unaccredited and non-certified continuing education program.
- Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program.
- Grant.
- Space rental or facility fees.

(7) Assumptions Document

In order to monitor how applicable manufacturers were classifying payments or other transfer of value, we proposed that applicable manufacturers could submit along with their data a document describing the assumptions used when categorizing the natures of payments. We proposed that submission of the assumptions document would be voluntary and would not be made public. We explained that the documents could aid the agency in offering further guidance to applicable manufacturers regarding how natures of payment should be classified.

Comment: A few commenters questioned the CMS proposal to allow applicable manufacturers to submit an assumptions document in order to ensure consistency in the reporting and selection of categories. Many of these commenters supported the submission of the assumptions document; however, the commenters varied as to whether the assumptions documents should be mandatory. Some commenters recommended that it be mandatory, while others supported that it be voluntary. Additionally, the commenters also both supported and opposed the proposal not to make the assumptions document public. A few commenters expressed that the assumptions documents should not be published on the public Web site and should also not be subject to a Freedom of Information Act (FOIA) request. Conversely, other commenters recommended that even if the assumptions documents were not made public, they should be available to covered recipients upon request to help mitigate disputes.

Beyond the publication of the assumptions document, some commenters discussed the expected content for the assumptions document, as well as how CMS intends to use the documents. Regarding the content of the assumptions document, a few commenters recommended that applicable manufacturers may include other reporting assumptions and methodologies, beyond natures of payment, such as determining whether an interaction constitutes a payment or other transfer of value. Other commenters recommended that CMS create its own assumptions document for applicable manufacturers to use when characterizing payments or other transfers of value. Finally, a few commenters recommended that CMS clarify that it intends to review the submitted assumptions documents and does not plan to use them for purposes of prosecution for failure to report.

Response: We appreciate the comments, and given the support for the assumptions document, we are finalizing the voluntary submission of an assumptions document in this final rule. As discussed in the section of the preamble to this final rule on payments or other transfers of value (section II.B.1.F. of this final rule), applicable manufacturers may include in the assumptions document assumptions and methodologies other than only those employed when classifying nature of payment categories. Furthermore, applicable GPOs reporting under section 1128G(a)(2) of the Act may also submit an assumptions document. The assumptions document may include the applicable GPO's assumptions when categorizing nature of payment categories for any information submitted on payments or other transfers of value provided to physician owners or investors (as required in section 1128G(a)(2)(C) of the Act) or any other assumptions or methodologies the applicable GPO wishes to include.

After review of the comments, we continue to believe that submission of the assumptions document should be voluntary and that the contents of the assumptions documents submitted should not be made public. We believe that they will likely contain significant detailed information, which will not necessarily be consumer friendly, so it could be overwhelming on the public Web site. We encourage applicable

manufacturers to be as clear and specific as possible with regard to the information submitted within the assumptions document. If a statement within the assumptions document pertains to a particular section of the report, applicable manufacturers should explicitly refer to that section in the assumptions document. Additionally, we do not believe that we should provide the assumptions documents to covered recipients. This would be difficult for the agency to track and would greatly reduce the confidentiality of the documents. Applicable manufacturers may provide their assumptions document to covered recipients upon the request of covered recipients independently from CMS. To the extent an assumptions document is requested under the FOIA, we would follow our predisclosure notification procedures at 45 CFR 5.65(d) and seek the submitter's input on the applicability of FOIA Exemption 4, which protects trade secrets and commercial or financial information that is obtained from a person and is privileged or confidential.

The agency intends to carefully review the assumptions documents to determine whether we need to publish more detailed guidance to assist applicable manufacturers in classifying the nature of payment categories, or other assumptions or methodologies included in the assumptions document. Additionally, we intend to provide assistance to applicable manufacturers to help classify payments or other transfers of value and hope that such guidance will be useful. Finally, we do not intend to use the assumptions document for prosecution, but acknowledge that the reporting based on the assumptions would be open to prosecution. Other HHS divisions, the Department of Justice (DOJ), or the Office of the Inspector General (OIG) could request access to the documents as part of an audit or investigation into an applicable manufacturer or applicable GPO.

i. Research

We received numerous comments on our proposed methods for reporting and presenting research-related payments. We recognize that reporting payments or other transfers of value for research activities is extremely complicated, since many research activities include large payment amounts which are spread across numerous activities and parties, and acknowledge that our proposed method did not fully address this complexity. We understand the need for a simple and clear reporting process, which allows the agency to accurately present research payments to consumers. We appreciate the comments and have revised the system to try to improve the process and ensure that the research is reported in a manner that most accurately describes the research relationship. A summary of the comments and our finalized process are outlined in this section.

(1) Scope of Research

In the proposed rule, we proposed to limit the research category to bona fide research activities, including clinical investigations that are subject to a written agreement or contract between the applicable manufacturer and the organization conducting the research *and* a research protocol. We based this criteria on the method used to identify payments eligible for delayed publication.

Comment: We received a number of suggestions from commenters about which types of research payments should be reportable. Many commenters recommended including a definition of research and suggested many different definitions. Additionally, some commenters recommended that CMS provide information on what constitutes a research protocol or written agreement. These commenters stated that not all research has a "research protocol" and recommended that the agency interpret the term broadly or not require that one exist in order for a payment to be described as research. For example, clinical research for devices is often different from clinical drug research and does not require a research protocol. Finally, many commenters recommended that CMS exclude certain research-related payments from the reporting requirements altogether, such as payments related to pre-clinical research, indirect research, or research by Principal Investigators (PI) not practicing medicine, due to the importance of research-related relationships in developing new treatments and products.

Additionally, a few comments addressed how to handle payments that could conceivably be related to research, but do not meet the definition of research. In the proposed rule, we solicited comments on the preferred method for these payments and the comments were mixed. Some recommended that CMS create another nature of payment category for these payments (such as one titled "other research"); others recommended that CMS require applicable manufacturers to report the payment in another category.

Response: We appreciate the comments and agree that we should provide additional information and clarification about what constitutes research and what research-related payments must be reported. Based on suggestions in the comments received, we have decided to define research based on the Public Health Service Act definition of research in 42 CFR 50.603; this definition defines research as: "a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. This term encompasses basic and applied research and product development." We believe this definition includes pre-clinical research and FDA Phases I–IV research, as well as investigator-initiated investigations. We have finalized that payments reported as research should be made in connection with an activity that meets the definition. In addition, we agree that requiring both a written agreement or contract *and* a research protocol is limiting for some types research, so we are finalizing that if a payment falls within the nature of payment category for research, it only needs to be subject to a written agreement or contract *or* a research protocol. This may include an unbroken chain of agreements (instead of a single agreement between the applicable manufacturer and the covered recipient) which link the applicable manufacturer with the covered recipient because we understand that many applicable manufacturers use other entities such as contract research organizations (CROs) (as defined in 21 CFR 312.3(b)), or site management organizations (SMOs) to manage their clinical research activities. For example, agreements between an applicable manufacturer and a CRO, between a CRO and an SMO, and then between an SMO and a teaching hospital would be considered a continuous chain of agreements from the applicable manufacturer to a covered recipient and would be considered a research agreement.

Regarding reporting of research-related payments which do not meet the definition of research, applicable manufacturers should report using the other categories available. We believe that the categories are sufficiently broad to provide applicable manufacturers options; for example, we believe the grant category could be used to sufficiently describe some of the transactions.

We also seek to respond to comments about which research-related payments should be reportable. In general, we believe that any payments related to the definition of research discussed previously should be reportable. We

recognize that research is important and have allowed research to be reported in a manner that acknowledges its special role. Given this consideration, we do not believe we should further limit the scope of research payments to be reported. Many of the comments sought to limit the reporting of research related payment in significant ways, such as only reporting direct research. However, we believe Congress clearly intended research-related payments or other transfers of value to be included in the reporting requirements, based on the inclusion of "research" as a nature of payment, the statutory definition of "clinical investigation," and the procedures for delayed reporting for certain research-related payments or other transfers of value. We believe that excluding payments or other transfers of value related to clinical research or indirect research from the reporting requirements would be inconsistent with the intent of Congress. We do agree that pre-clinical research is slightly different, so we have outlined reporting requirements tailored to its unique structure which are discussed more in this section.

Additionally, as explained in the section on covered recipients, we do not believe the statute limits the reporting requirements to licensed physicians who regularly treat patients, so we plan to require reporting of research payments to PIs who meet the definition of "physician," even if they do not regularly treat patients. Finally, material transfers (such as provision of a protein) to a researcher for discovery collaboration does not need to be reported when not part of a commercial or marketing plan and precedes the development of a new product. We believe for the purposes of this regulation that due to the early stage of the research process, the transferred material does not have independent value.

(2) Reporting Research Payments

We also understand that research payments are unique and should be reported differently than other payments or other transfers of value. We proposed special rules to report research payments, including a rule to separate the classification of research payments to clarify whether the payment or other transfer of value went indirectly or directly to the covered recipient. When reporting payments or other transfers of value designated as research, we proposed that applicable manufacturers must report the payment or other transfer of value as either "indirect research" or "direct research." Additionally, we proposed that the payment or other transfer of value (whether direct or indirect research) should be reported individually under the names and NPIs of physician covered recipients serving as principal investigators. For indirect payments, this included the physician covered recipient(s) serving as principal investigator(s) who would ultimately receive payments from the clinic, hospital, or other research institution, assuming the applicable manufacturer is aware of the identity of the principal investigator(s). Finally, we proposed that for both direct and indirect research, applicable manufacturers must report the entire payment amount for each research payment (whether to the covered recipient or research institution), rather than the specific amount that was provided to the covered recipient.

Comment: A significant number of comments addressed the method proposed for reporting research payments. While there was some support for our proposed methods, the majority of the commenters did not support it and recommended a new method. Many commenters stated that allocating 100 percent of the research payment to the physician PI would be misleading, even if the payment amount was not aggregated into the physician's total payments. Similarly, many commenters did not support reporting a single payment multiple times, which some commenters feared could lead to double counting of research payments. These commenters provided numerous recommendations for how to report and present research related payments. The most common recommendation was to report research in a separate reporting template, which would include a single line item for each payment. The payment would include both the entity paid (such as the research institution) and list the name of the principal investigator. There were some variations in the recommendations, including reporting only the amount the PI received and that the applicable manufacturer must control the selection of the PI; however, the majority of comments followed this basic process. A few commenters also requested that applicable manufacturers should be allowed to report context of research or additional information on the research payment. Finally, a few commenters recommended that research payments be presented separately on the public Web site to clearly delineate them as a research-related payment or other transfer of value.

Response: We appreciate the comments and agree that reporting of research-related payments should be more representative of the actual payment stream for research. Applicable manufacturers must report research-related payments that ultimately are paid, in whole or in part, to a covered recipient (physician or teaching hospital). We have finalized that applicable manufacturers must report research payments separately in a different template, since we will be requiring the reporting of modified information. Applicable manufacturers will not be responsible for indicating whether a payment was direct or indirect. We have adopted a procedure similar to the process outlined in many of the comments, where a single research payment is reported once and includes the entity paid, as well as the name of the principal investigator(s). Applicable manufacturers must report each research payment once as a single interaction. They must report the name of the individual or entity (regardless of whether it is a covered recipient) that received the payment for the research services, as well as the principal investigator(s). When reporting the entity or individual that received the payment, we intend for the applicable manufacturer to report the entity or individual that received the payment, either directly from the applicable manufacturer or indirectly through a CRO or SMO. We believe that the recipient of the payment could include individual principal investigators, teaching hospitals, nonteaching hospitals or clinics. We intend for the principal investigator(s) to include the individual(s) conducting the research or providing the services on behalf of the research institution.

As discussed regarding the reporting elements for all payments or other transfers of value, in order to better identify and match covered recipients, the same identifying information will be required to be reported for each PI meeting the definition of covered recipient.

The applicable manufacturer shall be required to report the following for each research-related payment that ultimately is paid, in whole or in part, to a covered recipient (physician or teaching hospital):

- Name of research institution/other entity or individual receiving payment (regardless of whether a covered recipient)

++ If paid directly to a physician covered recipient, list the individual's name, NPI, State professional license number(s) and associated State names for at least one State where the physician maintains a professional license, specialty, and primary business address of the physician(s).

++ If paid directly to a teaching hospital covered recipient, list name and primary business address of the teaching hospital.

++ If paid to a non-covered recipient (such as a non-teaching hospital or clinic), list name and primary business address of the entity.

- Total amount of research payment.
- Name of study.
- Name(s) of related covered drug, device, biological or medical supply (same requirements as for all payments or other transfers of value) and NDC (if any).
- Principal investigator(s) (including name, NPI, State professional license number(s) and associated States for at least one State where the physician maintains a professional license, specialty, and primary business address);
- Context of research (optional).
- ClinicalTrials.gov identifier (optional).

We believe reporting this information for each research payment will better capture the nature of the research relationship, creating a simpler reporting mechanism for the applicable manufacturers to report payments and allowing end users a more accurate understanding of the relationship. We believe the study name will provide information on the research topics, but we have also included an optional field allowing applicable manufacturers to provide additional contextual information on or the objectives of the research. We intend this to be used similarly to the additional context allowed for reporting all payments or other transfers of value. Additionally, we also will allow applicable manufacturers to provide the ClinicalTrials.gov Identifier to allow consumers the ability to obtain more information on the study from ClinicalTrials.gov. However, we recognize that not all research studies will be posted on ClinicalTrials.gov, so this category will be optional. Finally, this represents the information required to be reported for each research-related payment or other transfer of value, but the agency may identify other optional fields, such as information on publications related to the research, in order to provide additional information and background on the public Web site.

For pre-clinical research, we finalize slightly modified reporting requirements since such early stage research is often not connected to a specific product. We intend pre-clinical research to include laboratory and animal research that is carried out prior to beginning any studies in humans, including FDA's defined phases of investigation. For pre-clinical research, applicable manufacturers only have to report the name of the research institution, principal investigator(s) (including name, NPI, State professional license number(s), specialty and business address), and the total amount of the payment, so they do not need to report an associated product, or study name.

We are also finalizing guidelines for what should be included in the total research payment amount. The amount should include the aggregated amount of any payments for services included in the written agreement/research protocol. We envision that this would include the costs associated with patient care, including diagnostics, exams, laboratory expenses, time spent by health care professionals treating the patient and managing the study, and the provision of study drugs, devices, biologicals, and medical supplies or other in-kind items. The payment amount should not include any payments for activities which are separate or segregable from the written agreement or research protocol or are paid through a method different than that of the research. For example, payments made directly to a physician for serving on a study steering committee or data monitoring committee that are not a part of the larger research payment should be reported separately. Payments for medical research writing and/or publication would be included in the research payment, if the activity was included in the written agreement or research protocol and paid as a part of the research payment. In addition to research payments, we also believe that meals and travel should be reported separately (under the food and travel nature of payment categories) unless included in written agreement or research protocol and paid for through the large research contract.

We realize that reporting requirements for research will be somewhat different than the procedure outlined for other natures of payment, but we believe that this is appropriate for research-related payments or other transfers of value. As several comments pointed out, due to the flow of research payments from sponsor to research institution, an applicable manufacturer might not know the specific details or amounts of how the larger research payment was spent. We do not intend for applicable manufacturers to be required to itemize each research payment, since they are usually large payments obligated to general administration of the study and the applicable manufacturer may not be aware of the daily activities. Additionally, we do not require the reporting of payments to non-covered recipients that are not passed on to covered recipients. For example, if an applicable manufacturer paid separately for a non-covered recipient to travel to a meeting, then it would not need to be reported. However, if an applicable manufacturers paid separately for a covered recipient (regardless of whether the individual was a PI or not) to travel to a meeting, then the travel would have to be reported in the name of the covered recipient traveling.

When reporting research payments, we also acknowledge that research payments are generally different than other payments and may not represent a payment to the covered recipient. For physician covered recipients whom are paid by a third party and not directly by the manufacturer, we will list research studies separately from all other payments provided to the covered recipient. For teaching hospitals, we will publish all research payments which went to the hospital as a research institution. These will be listed separately from other payments to the hospital, but will include both the study amount and study name.

We believe that presenting research payments in this method reflects the fact that research payments are unique and do not necessarily represent a personal payment to physicians; however, it still allows for research payments to be reported as intended by Congress, but in a less burdensome way for applicable manufacturers. In light of the public comments received, we believe that the modifications represent a better, more accurate method of reporting research payments.

j. Exclusions

Section 1128G(e)(10) of the Act excludes specific types of payments or other transfers of value from the reporting requirements.

Comment: We received numerous comments on the exclusions section of the proposed rule. Many of the comments focused on the statutory exclusions and the explanations CMS provided in the proposed rule. Beyond these comments, we also received numerous recommendations for additional exclusion categories to be included in the final rule. The recommended exclusions covered numerous specific relationships between applicable manufacturers and covered recipients, some related to healthcare, such as paying a physician at an on-site clinic, whereas others did not, such as campaign contributions to physicians running for political office.

Response: We appreciate these recommendations, but do not believe that we have the statutory authority to add exclusions beyond what was outlined in the statute. The statute expressly provides the Secretary discretion to require the reporting of additional information of payments or other transfers or value, and ownership or investment interests, but it does not provide a similar authority to add exclusion categories. We have finalized our policy that the exclusions will be defined by their dictionary definitions, but plan to provide additional clarification in response to the comments in this section. We believe that some of the recommended exclusions could be included in some of the statutory exclusions, so we have provided additional information to clarify our interpretation of these categories.

(1) Existing Personal Relationships

In the proposed rule we stated that we did not intend to require reporting of purely personal transfers of value (for example, if one spouse, who works for an applicable manufacturer, gives a present to the other spouse who is a covered recipient), and we solicited comments on this proposal.

Comment: Many commenters supported our intention to exclude payments or other transfers of value between individuals who happen to have existing personal relationships and recommended that it be included as a listed exclusion. A few commenters also recommended specific requirements, such as to include relationships between family members, to limit to bona fide relationships or to mirror the Federal employee exemption.

Response: We appreciate the comments and do not intend existing personal relationships to be reported, so we have finalized this provision in § 403.904(i)(14).

(2) Payments or Other Transfers of Value of Less Than $10

Small payments or other transfers of value, which the statute defines as payments or other transfers of value less than $10, do not need to be reported, except when the total annual value of payments or other transfers of value provided to a covered recipient exceeds $100. As required by section 1128G of the Act, for subsequent calendar years, the dollar amounts specified will be increased by the same percentage as the percentage increase in the consumer price index (CPI) for all urban consumers (all items; U.S. city average) for the 12-month period ending with June of the previous year. In the proposed rule, we proposed that applicable manufacturers should not report to CMS any payments or other transfers of value less than $10 individually and all small payments or transfers of value in the same nature of payment category should be reported as one total amount for that category. We believed this would simplify reporting for applicable manufacturers and prevent the reporting of payments less than $10 individually. Given the timing of this final rule, we have decided to begin increasing the de minimis thresholds for reporting in CY 2014, and retain the statutory de minimis thresholds ($10 and $100) for reporting in CY 2013. We believe this simplifies reporting for the first year of data collection by employing simple numbers as thresholds. Also because these were the statutory thresholds, we believe applicable manufacturers should be prepared to collect data and report using these thresholds for CY 2013.

Comment: We received various comments on small payments or other transfers of value. Some commenters indicated that our proposed method for reporting small payments together might (for some applicable manufacturers) be more difficult than reporting small payments individually; these commenters recommended that CMS allow applicable manufacturers discretion in their reporting mechanism. Some commenters also recommended that CMS not change the thresholds within a single reporting year. Beyond comments on reporting of small payments, many commenters also addressed the small payment or transfer of value exclusion more generally. Many commenters questioned the thresholds and indicated that they were too low and recommended various higher thresholds. Similarly, some commenters recommended that CMS consider methods within the statutory requirements to reduce the number of small payments being reported. Finally, many commenters supported CMS's proposal to not report food and beverages at conferences and indicated that CMS should extend this to other items provided at conferences (both above and below the $10 threshold).

Response: We appreciate the comments and agree that applicable manufacturers should have discretion when reporting small payments. We had proposed requiring applicable manufacturers to bundle payments in order to reduce burden, but we do not want to require that method if some applicable manufacturers actually believe it to be more burdensome. Therefore, we will finalize that applicable manufacturers have flexibility in reporting small payments. They may either report them individually or bundled with other small payments or other transfers of value in the same nature of payment category, as long as applicable manufacturers are reporting consistently and clearly indicating the method they are using. Additionally, we agree that the de minimis thresholds should not change within a reporting year and will be constant for the entire year. For example, for the entirety of data collection in 2014, the thresholds will be those adjusted based on CPI published in June 2013. We will report the new de minimis value with the reporting template for the next reporting year.

We appreciate the comments on the threshold for small payments and understand that they may be low for some stakeholders. Nevertheless, the thresholds were mandated by the statute, and we do not have discretion to change them. However, we recognize that we do not want the database to be overwhelmed by small payments. We have considered options for reducing the number of small payments, but we believe that we do not have authority to change the reporting requirements for small payments or other transfers of value.

Regarding reporting of payment or other transfers of value at conferences or similar events, we appreciate the comments and have provided additional guidelines expanding on the proposed rule. In general, we will finalize that these guidelines will apply to conference and similar events, as well as events open to the public. We believe that at events open to the public, it will be extremely difficult for applicable manufacturer to identify physician covered recipients. Therefore, we will finalize that small incidental items that are under $10 (such as pens and note pads) that are provided at large-scale conferences and similar large-scale events will be exempted from the reporting requirements, including the need to track them for aggregation purposes. While these small payments are excluded by statute, the $100 aggregate payment requirement generally requires the tracking of small payments in order to determine whether covered recipients received more than $100 annually. For these covered recipients, we believe it would be difficult for applicable manufacturers to track who receives these small items at conferences or similar events, due to the nature and disparate attendance at large-scale conferences or similar events. Additionally, this method is consistent with our decision to not require

reporting of food and beverage at large-scale conferences. We note that payments or other transfers of value of $10 or more (for calendar year (CY) 2013) need to be tracked and reported even when provided at large-scale conferences or similar events. We believe that if an applicable manufacturer is handing out an item above the threshold, they should be able to track who received the payment since it is a more significant transfer.

Finally, we will not be providing a standard template for reporting by entities that organize and oversee events and conferences. These event and conference vendors are not applicable manufacturers, so we do not believe we should have any contact with them or impose requirements on them. We recognize that applicable manufacturers and their vendors will need to devise business practices to meet the requirements; however, we believe that many of the interactions at large-scale conferences and similar events will not be reportable, so we do not believe this will be excessively burdensome.

(3) Educational Materials That Directly Benefit Patients or are Intended For Patient Use

In the proposed rule, we explained that this exclusion was limited to materials (including, but not limited to, written or electronic materials) and did not include services or other items. Additionally, we considered whether certain materials provided by applicable manufacturers to covered recipients for their own education, but which are not actually given to patients (for example, medical textbooks), should be interpreted as educational materials that "directly benefit patients."

Comment: Many commenters addressed this exclusion, particularly questioning the meaning of "materials." A few commenters stated that "materials" should be interpreted more broadly to include "programs, services, and items" since many applicable manufacturers provide services and items to patients in order to support disease management or increase medication adherence. These items are generally provided to patients through covered recipients. Finally, a few commenters also asked for clarification on what form these materials needed to be in and whether overhead costs for educational materials, such as time and printing, were included in the exclusion.

Response: We appreciate the comments and agree that "materials" should be interpreted somewhat more broadly for purposes of this exclusion. We understand that patient education is important and recognize that it may take a form other than written material, especially in the device context. For example, a device manufacturer may give a physician an anatomical model to help explain to patients how a procedure would work. We agree that such an item, which is given to physicians for the purpose of educating patients, falls within the exclusion. Similarly, if a manufacturer provides educational materials to a physician on a flash drive to be distributed to patients, the flash drive would also be included in the exclusion. However, if the drive was provided as a gift alongside the materials, then it would have to be reported, since it was secondary to the materials. Similarly, we believe that overhead expenses, such as printing and time, should be included in the exclusion as long as they are directly related to the development of the materials, which directly benefit patients or are intended for patient use.

Comment: Numerous commenters questioned CMS's interpretation of "directly benefit patients or are intended for patient use." These commenters had mixed reactions to CMS's proposed interpretation. Some recommended that all materials provided to educate physicians (such as textbooks or journals) should be included in the exclusion, since educating the physician benefits patients. Others suggested that these should not be included, since they do not benefit patients directly. Some commenters also recommended that materials that are used "for or with" patients, but not taken home (such as anatomical models or wall charts) should be included in the exclusion because they are intended for patient use. Finally, a few commenters recommended that all materials intended for patients should be included in the exclusion.

Response: We appreciate the comments and agree that additional clarification is required. We agree that items that are educational to covered recipients (such as medical textbooks and journal reprints), but are not intended for patient use are important for physicians; however, we do not believe that these materials fall within the statutory exclusion. Although these items may have downstream benefits for a patient, we believe they are not directly beneficial to patients, nor are they intended for patient use, as required by section 1128G(e)(10)(B)(iii) of the Act. Therefore, we will finalize that educational materials provided to covered recipients for their own education, but that do not "directly" benefit patients, do not fall within the exclusion and are therefore subject to the reporting requirements. Conversely, we have finalized that this exclusion does encompass materials, such as wall models and anatomical models which are ultimately intended to be used with a patient. In addition, we believe that pursuant to the statutory text, the exclusion is limited to educational materials only, and not marketing or promotional materials.

(4) Discounts and Rebates

Discounts and rebates for covered drugs, devices, biologicals, and medical supplies provided by applicable manufacturers to covered recipients are excluded from reporting under section 1128G(e)(10)(B)(vii) of the Act.

We did not receive any comments on this exclusion, so we have finalized it as proposed.

(5) In-Kind Items for the Provision of Charity Care

In the proposed rule, we defined "in-kind items for the provision of charity care" as items provided to a covered recipient for one or more patients who cannot pay, where the covered recipient neither receives, nor expects to receive, payment because of the patient's inability to pay. Any items provided by the applicable manufacturer to a covered recipient that meet the definition of in-kind items for the provision of charity care, are excluded from reporting. This does not include the provision of in-kind items to a covered recipient, even if the covered recipient is a charitable organization, for the care of *all* of the covered recipient's patients (both those who can and cannot pay). If a payment or other transfer of value is not an in-kind item and/or not for the provision of charity care, as defined, then the payment must be reported as required under section 1128G of the Act.

Comment: Many commenters provided recommendations on the charity care exclusion. These comments fell in two categories: first, on the interpretation of a patient's ability to pay, and second, on the interpretation of in-kind items. Regarding a patient's ability to pay, the commenters generally supported the proposed interpretation, but recommended that CMS provide additional clarification that a patient's ability to pay includes whether the patient can afford the copayment or coinsurance, but not the entire visit. Additionally, a few commenters recommended that ability to pay should be based on whether payment will be a significant burden to a patient. Regarding in-kind items, the

commenters discussed whether payments to a covered recipient and/or a third party should be excluded if used to support charities or other charitable activities, such as patient assistance programs. Finally, a few commenters advocated that this exclusion should be based on the mission of the organization receiving the items, rather than what actually happened to them, since it will be impossible for applicable manufacturers to track the uses of these items.

Response: We appreciate the comments and agree that an analysis of a patient's ability to pay should include whether the patient can afford his or her copayment or coinsurance and whether the patient has insurance to cover the care. We intend this exclusion to include in-kind items given to covered recipients to provide care to patients who are unable to pay, or for whom payment would be a significant hardship.

Finally, we do not intend applicable manufacturers to be responsible for tracking each individual item provided to a covered recipient to ensure it is provided to a patient unable to pay. We believe it is sufficient for the applicable manufacturer and covered recipient to agree in writing that the covered recipient will use the in-kind items only for charity care.

Secondly, we believe that the statutory text for this exclusion (section 1128G(e)(10)(B)(viii) of the Act) clearly states that the exclusion should only apply to "in-kind items" and not all payments, so we have finalized that only in-kind items will be included in the exclusion, which does not include financial support for charitable covered recipients. However, we recognize that some payments made to charitable third parties may at some point indirectly benefit a covered recipient. We believe that these payments or other transfers of value should be reported based on the reporting requirements for indirect payments or other transfers of value. However, we believe that charitable contributions made directly to or intended for a covered recipient should be reported as a charitable contribution.

(6) Product Samples

Even though this exclusion was not specifically discussed in the proposed rule, we received comments on the exclusion for product samples from section 1128G(e)(10)(B)(ii) of the Act which states that "product samples that are not intended to be sold and are intended for patient use" are excluded from the reporting requirements.

Comment: Many commenters recommend that CMS clarify the boundaries of the exclusion and interpret it widely to include samples beyond traditional drug samples, such as single use or disposable devices, demonstration devices, and evaluation equipment. A few commenters also recommended that the exclusion should include products used for research studies, as well as coupons and vouchers. Finally, a commenter stated that an applicable manufacturer may not know what actually happens to samples and should not be required to track them.

Response: We appreciate the comments and agree that further clarification is necessary. We believe that the statutory text is clear that this exclusion applies to products intended for patient use; therefore, any drug, device, biological or medical supply provided as a sample to a covered recipient that is intended for use by patients will be included in the exclusion. Given this interpretation, as long as single use or disposable devices, demonstration devices or evaluation equipment provided to a covered recipient are intended for patient use, they will be included in the exclusion. Otherwise, we believe these items may be excluded from the reporting requirements under the exclusions for short term loans, as explained in that section. In addition, we believe that products used for research studies should be included as a part of the larger research payment. Regarding coupons and vouchers, we believe they fall within the exclusion, so we have finalized that all coupons and vouchers for the applicable manufacturer's products that are intended for patient use to defray the costs of covered drugs, devices, biologicals or medical supplies will be included in this exclusion category. For the purposes of this rule, we believe such coupons and vouchers are materially similar to samples. Finally, we do not believe the applicable manufacturer should be responsible for tracking what actually happens to samples. Instead, we believe that as long as the applicable manufacturer and covered recipient agree in writing that the products will be provided to patients, which is commonplace in the industry, the provision of samples can be excluded.

(7) Short Term Loans

This exclusion was also not addressed in detail in the proposed rule; however we did receive some comments recommending clarifications. Section 1128G(e)(10)(b)(iv) of the Act excludes "the loan of a covered device for a short-term trial period, not to exceed 90 days, to permit evaluation of the covered device by the covered recipient."

Comment: A few commenters recommended that we include loans of a broad range of devices (including medical supplies) such as both covered and non-covered devices, as well as a short-term supply of disposable devices. Additionally, some commenters requested clarification on the timing of the 90-day loan period and what to report if the loan goes beyond 90 days. We also received a comment to shorten the loan period to 60 days.

Response: We appreciate the comments and agree that this exclusion can include a broad range of devices. We have finalized that this exclusion may include loans for covered devices, as well as those under development. We also have finalized that this will include a supply of disposable or single use devices (including medical supplies) intended to last for no more than 90 days. We believe that these products should be treated similarly to non-disposable devices and, therefore, should be included in the exclusion. However, we do not believe that applicable manufacturers should be allowed to provide an unlimited supply of these products and still fall within the exclusion, so we are establishing a 90-day supply as the limit. If an applicable manufacturer provides a specific disposable or single use device for more than 90 days (even if provided over multiple dates), the products provided beyond the 90-day supply will be subject to the reporting requirements.

For a single product the total number of days for the loan should not exceed 90 days for the entire year, regardless of whether the 90 days were consecutive. We believe that this aligns with the intention of the statute to limit the loan period to 90 days and not allow a new loan to start at the end of the previous loan period, thus avoiding the reporting requirements. In the event that the loan of a non-disposable device exceeds 90 days (for the entire calendar year), the applicable manufacturer should start reporting as if the loan began on day 91. We do not believe that reporting the prior 90 days as a payment or other transfer of value would greatly increase the payment value which would be misleading to consumers. Additionally, if a device is purchased within 90 days, the applicable manufacturer does not need to report the loan since the loan was less than 90 days. The loan period is statutorily defined, so we do not have the authority to lower it, but appreciate the input that 90 days should be more than sufficient for the loan period.

(8) Contractual Warranty

While this exclusion was not addressed in the proposed rule, we received a few comments on it. Section 1128G(e)(10)(B)(v) excludes "items and services provided under a contractual warranty, including the replacement of a covered device, where he terms of the warranty are set forth in the purchase or lease agreement for the covered device."

Comment: Some commenters recommended that CMS allow the exclusion to extend to items and services provided under a contractual warranty, regardless of whether or not the warranty period had expired. These comments stated that often applicable manufacturers grant the terms of a warranty even after the period has expired. Additionally, a few commenters recommended that the exclusion should include other product contracts, such as product sale agreements, maintenance service agreements, and technical support agreements. Finally, a few commenters also recommended that replacement products as a part of a product recall should be included in this category.

Response: We appreciate the comments and agree that it is not materially different for an applicable manufacturer to grant the terms of a contractual warranty before the period expires or afterwards. We have finalized that as long as the contract warranty specified the terms prior to expiration and the terms do not change, then the exclusions may extend to items and services provided outside the expiration period. We believe the exclusion should extend beyond the express time period of the warranty, since the warranty terms, and thus the relationship, are the same before or after the expiration period and it will be misleading to consumers to only include a portion of the relationships.

In addition, we agree that there are numerous other contractual agreements that are similar to a warranty agreement, but are not specifically excluded. We believe that service or maintenance agreements are so similar to warranty agreements that it may be difficult to consumers and applicable manufacturers to meaningfully separate. We also believe the replacement products in the case of a product recall are materially similar and should be included. Given the similarities, we have finalized that items and services provided under a contractual service or maintenance agreement will also be subject to the exclusion.

(9) Covered Recipient Acting as a Patient

While this exclusion was not addressed specifically the proposed rule, we received a few comments on it. Section 1128G(e)(10)(B)(vi) of the Act excludes "a transfer or anything of value to a covered recipient when the covered recipient is a patient and not acting in the professional capacity of a covered recipient."

Comment: A few commenters recommended that CMS include in this exclusion situations when a covered recipient is a subject in a research study.

Response: We appreciate the comments and agree that a covered recipients participating as a subject (and not in a professional capacity) in a research study is the same as being a patient and, should be included in the exclusion.

(10) Provision of Healthcare

Although the exclusion was not discussed in detail in the proposed rule, we did receive a few comments. Section 1128G(e)(10)(B)(x) excludes "in the case of an applicable manufacturer who offers a self-insured plan, payments for the provision of health care to employees under the plan."

Comment: A few commenters recommended that CMS clarify that this exclusion includes the provision of health care to both covered recipients and their families covered under the self-insured plan. Similarly, received few commenters discussed other situations, outside a self-insured plan when an applicable manufacturer may reimburse a physician for provision of health care services to employees.

Response: We appreciate the comments and agree that payments to covered recipients for services rendered to family members receiving care under a self-insured plan should also be excluded from the reporting requirements. Similarly, we believe that the provision of healthcare to employees should extend beyond that offered under a self-insured plan. We understand that applicable manufacturers, both self-insured and otherwise, may provide healthcare services to employees beyond traditional insurance. We believe that for the purposes of this exclusion there is little material difference between the provision of healthcare under a self-insured plan and provision of healthcare outside a self-insured plan. We have finalized that this category encompasses other situations, beyond a self-insured plan, when an applicable manufacturer makes a payment to a covered recipient as part of healthcare services provided to the manufacturer's employees or their family, such as at an on-site clinic or at a health fair.

(11) Nonmedical Professional

This exclusion was not specifically addressed in the proposed rule and we did not receive specific comments on it, and we have finalized it as proposed. Section 1128G(e)(10)(B)(xi) of the Act excludes "in the case of a covered recipient who is a licensed nonmedical professional, a transfer of anything of value to the covered recipient if the transfer is solely for the non-medical professional services of such licensed nonmedical professional."

(12) Civil or Criminal Action or Administrative Proceeding

Although this exclusion was not specifically addressed in the proposed rule, we did receive a few comments on it. Section 1128G(e)(10)(B)(xii) of the Act excludes "in the case of a covered recipient who is a physician, a transfer of anything of value to the covered recipient if the transfer is payment solely for the services of a covered recipient with respect to a civil or criminal action or an administrative proceeding."

Comment: A few commenters recommended that CMS clarify the exclusion to include specific legal proceedings or arrangements, such as legal defense, prosecution, settlement or judgment of a civil or criminal action and arbitration or other legal action.

Response: We appreciate the comments and agree that the agency can help clarify this exclusion. We will finalize that other specific legal relationships will be included in the exclusion. We believe that there are numerous legal proceedings that require physician involvement and we plan to exclude all of them, in order to allow for clear, consistent reporting requirements for applicable manufacturers, covered recipients, and consumers.

k. Indirect Payments or Other Transfers of Value Through a Third Party

Section 1128G(e)(10)(A) of the Act also excludes the reporting of payments or other transfers of value that an applicable manufacturer makes indirectly to a covered recipient through a third party where the applicable manufacturer is unaware of the identity of the covered recipient. However, any payment or other transfer of value provided to a covered recipient through a third party, whether or not the third party is under common ownership with an applicable manufacturer or operating in the U.S., must be reported if the

applicable manufacturer is aware of the covered recipient's identity.

In the proposed rule, we proposed that indirect payments are excludable when an applicable manufacturer is unaware of the identity of the covered recipient and explained that an applicable manufacturer is unaware of the identity if the applicable manufacturer does not know (as defined in § 403.902) the identity of the covered recipient. The definition of "know" in § 403.902 provides that a person, with respect to information, has actual knowledge of the information, acts in deliberate ignorance of the information, or acts in reckless disregard of the truth or falsity of the information. This standard is consistent with the knowledge standard set forth in many laws, including the False Claims Act, and we believed it is one with which many applicable manufacturers are already familiar.

Comment: Numerous commenters discussed when an applicable manufacturer should be required to report indirect payments to covered recipients made through a third party. Many commenters recommended additional interpretations to further clarify when an indirect payment is reportable. A few commenters recommended that all indirect payments should be excluded from the reporting requirements; however, some other commenters supported the reporting of indirect payments. Similarly, some commenters requested that payments or other transfers of value made through certain third parties, such as medical professional societies, be carved out of the third party reporting requirements such that payments to covered recipients made through these entities would not be reportable.

Many commenters did not advocate excluding all indirect payments, but instead recommended ways to limit which indirect payments would be reported. One common recommendation was to limit the reporting of indirect payments to those under control of the applicable manufacturer. Commenters described this concept in various ways, but generally suggested that reporting should be limited to when an applicable manufacturer has control of the selection of the recipient of the payment, and not merely when they are aware of the covered recipient's identity.

Another common comment was that indirect payments or other transfers of value should only be reported if they are at the request of or designated on behalf of a covered recipient. These commenters stated that this was the statutory intent for reporting indirect payments given the language requiring reporting of payments made at the request of or designated on behalf of a covered recipient to a third party recipient. A subset of these commenters recommended that in order for a payment to be reportable, the applicable manufacturer must notify both the covered recipient and the third party that the payment will be reported and receive concurrence that it is accurate. Finally, a few commenters recommended that the applicable manufacturer must require, instruct or direct the third party to provide a payment or other transfer or value (or a portion of one) to a covered recipient(s).

Response: We appreciate the comments and agree that CMS should consider ways to further clarify when an indirect payment or other transfer of value should be reported. In addition, we intend that this exclusion refers to both payments and other transfers of value, despite references in the proposed rule to only transfers of value.

We do not agree that all indirect payments or other transfers of value should be excluded from the reporting requirements. Section 1128G(e)(10)(A) of the Act states that the exclusion of indirect payments or other transfers made through a third party is limited to situations "where the applicable manufacturer is unaware if the identity of the covered recipient." This indicates that indirect payments or other transfers of value where the applicable manufacturer *is aware* of the identity of the covered recipient must be reported, and only those where the applicable manufacturer is unaware of the identity are excluded. Moreover, we believe that excluding from the reporting requirements all payments made through a third party would create a significant loophole by allowing manufacturers to funnel payments through a third party and not report them; such a loophole would significantly undermine the intent of the reporting requirements. Additionally, we do not believe that we have statutory authority to carve out otherwise reportable indirect payments made through particular third parties, such as medical professional societies.

With regard to the recommendation that indirect payments should only be reported when under the control of the applicable manufacturer, we believe that controlling the selection of a recipient is different than being aware of the identity of the recipient. Congress based the exclusion on an applicable manufacturer being unaware of a covered recipient's identity, not on the applicable manufacturer lacking control over the selection of the covered recipient. Accordingly, we do not believe that Congress intended lack of control to be the basis for the indirect payment exclusion. Additionally, we believe that receiving a payment or other transfers of value from an applicable manufacturer could lead to conflicts of interest, even in the event that the applicable manufacturer does not directly control the selection of the covered recipient.

Similarly, we also do not believe that the statutory language suggests that indirect payments or other transfers of value are only reportable if they are made at the request of or designated on behalf of a covered recipient. The parenthetical reference in section 1128G(a)(1)(A) of the Act refers to payments or other transfers of value made to an entity or individual other than a covered recipient on behalf of or at the request of a covered recipient. We believe this situation is different from one in which a payment is provided to a third party and passed through to a covered recipient, as referenced in the exclusion in section 1128G(e)(10)(A) of the Act. In situations where a covered recipient requests that a payment or other transfer of value be provided to a third party, and the third party in turn provides the payment or other transfer of value to the covered recipient, the payment must be reported under the name of the covered recipient.

We agree with the comments that we should provide some guidance on when indirect payments must be reported. We understand that there are circumstances where an applicable manufacturer makes a payment to a third party, which will be passed indirectly to a covered recipient, unbeknownst to the applicable manufacturer. For example, an applicable manufacturer could make a payment to a consulting firm for professional services and the consulting firm incidentally employs a physician on the project. The applicable manufacturer's payment was ultimately transmitted, at least in part, to a physician covered recipient, but not because the applicable manufacturer directed that the payment be made to a specific physician, or to any physician at all. We believe that in these situations, it would be misleading to require reporting of the relationship, since the applicable manufacturer did not intend or expect that a covered recipient would receive any portion of the payment or other transfer of value.

In order to address this concern and clarify when an indirect payment must be reported, we have provided for the purposes of these regulations a definition of "indirect payments or other transfers of value" in § 403.902.

The definition states that an indirect payment or other transfer of value is one that an applicable manufacturer requires, instructs, or directs to be provided to a covered recipient, regardless of whether the applicable manufacturer specifies the specific covered recipient. For example, if an applicable manufacturer provided an unrestricted donation to a physician professional organization to use at the organization's discretion, and the organization chose to use the donation to make grants to physicians, those grants would not constitute "indirect payments" because the applicable manufacturer did not require, instruct, or direct the organization to use the donation for grants to physicians. The physician professional association could have used the donation for another purpose at its discretion. In this situation, the applicable manufacturer would not be required to report the donation, even if a portion of the payment or other transfer of value was ultimately provided to a covered recipient as a grant (or some other type of payment or other transfer of value). However, if an applicable manufacturer gave money to a medical professional society earmarked for the purpose of funding awards or grants for physicians, the awards or grants would constitute indirect payments to covered recipients and would be subject to the reporting requirements. In another example, an applicable manufacturer may provide a general payment to a clinic for one of its employed physicians to review materials. In this case, the applicable manufacturer directed that the payment be provided to a physician covered recipient, so it would constitute an indirect payment and would be a reportable indirect payment or other transfer of value.

Comment: A number of commenters recommended alternative definitions of "aware." For example, many commenters recommended that we use a standard of "actual knowledge" or "constructive knowledge," rather than the False Claims Act standard. Additionally, many commenters also discussed an applicable manufacturer's affirmative duty to investigate the identities of covered recipients. The commenters suggested that applicable manufacturers should not have an affirmative duty to determine the identity of a covered recipient, but that the proposed definition of awareness meant that applicable manufacturers would have an affirmative duty. These commenters stated that an applicable manufacturer would be in reckless disregard, if it knew that a payment or other transfer of value went to a covered recipient, but did not specifically know the identity of the covered recipient.

Similarly, some commenters also discussed the language in the proposed rule that attributes awareness of the identity of the covered recipient by an agent of the applicable manufacturer to the applicable manufacturer. Commenters both supported and opposed the proposal. Some of these commenters recommended that CMS provide additional information on how the agency interpreted "agent."

Finally, many commenters also recommended that CMS apply some sort of time restriction on the awareness requirement. The proposed rule did not specify whether there was a specific time period for awareness of the identity of the covered recipient, so the commenter requested clarification. Many of the commenters recommended that an applicable manufacturer must be aware of the identity of a covered recipient at the time of payment. Whereas, other comments provided slight variations, such as awareness at the time the payment is committed or agreed upon, but in general the majority of commenters focused on the time of payment.

Response: We appreciate the comments on alternative interpretations of the statutory tem "unaware"; however, we have decided to finalize our proposed definition that an applicable manufacturer is "unaware" if it does not know the identity of a covered recipient, and that "know" means that the manufacturer has actual knowledge of the identity or acts in deliberate ignorance or reckless disregard of the identity. We appreciate the concerns about the knowledge standard, but we are concerned that the actual knowledge standard suggested by several commenters is too limiting. An actual knowledge standard could potentially allow applicable manufacturers to direct payments to a limited category or subset of individuals and avoid the reporting requirements by not knowing the names of the specific covered recipients and claiming a lack of actual knowledge. We believe that by clarifying that applicable manufacturers must only report indirect payments or other transfers of value that they direct or instruct third parties to pay to covered recipients, we will address some of the commenters' concerns about the broader knowledge standard. Therefore, if a payment meets the definition of an indirect payment or other transfer of value in § 403.902, then the payment can only be excluded from the reporting requirements if the applicable manufacturer did not "know" the identity of the covered recipient, as defined in § 403.902. However, we want to clarify that, for purposes of this rule only, we will not consider an applicable manufacturer to be acting in deliberate ignorance or reckless disregard of a covered recipient's identity in situations when the reason a payment or other transfer of value is being made through a third party is that the identity of the covered recipient remains anonymous. For example, an applicable manufacturer may hire a market research firm to conduct a double-blinded market research study, which includes paying physicians $50 for responding to a set of questions. The applicable manufacturer clearly intends a portion of the payment to be provided to physicians, but given that the reason for the third party's involvement is specifically to maintain the anonymity of the respondents and sponsor, we do not intend this to be considered a reportable indirect payment or other transfer of value.

We recognize that by finalizing the proposed definition, applicable manufacturers may still feel they have an affirmative duty to determine the identity of covered recipients. However, our intention with this definition is to prevent applicable manufacturers from directing payments to a discrete set of covered recipients whose identities the manufacturer may not actually know, but could easily ascertain. For example, we believe that a manufacturer that directs a third party to make payments to the top billing cardiologists in a certain city or the chiefs of staff of a certain class of hospitals should be required to report these payments, even though they do not have actual knowledge of the identities of such individuals. However, we do not require reporting of every payment that an applicable manufacturer makes through a third party that is ultimately provided to a covered recipient; rather, the intent is to require reporting of indirect payments where applicable manufacturers know or should know the identity of the covered recipients who receive them.

We appreciate the comments regarding awareness of an agent of an applicable manufacturer of the identity of a covered recipient; however, we have finalized the requirements as proposed. We understand that awareness by an agent is somewhat different than awareness of the applicable manufacturer, but believe the reporting of indirect payments in this situation is warranted. Otherwise, applicable manufacturers could structure their business model, so that

payments are funneled through an agent that selects the recipients. However, we do not intend the concept of an agent of the applicable manufacturer to be merely any third party with a connection to the applicable manufacturer. Instead, we intend the term to refer to legal agents acting on behalf of the applicable manufacturer.

Finally, we agree that applicable manufacturers should not be responsible for tracking and reporting indirect payments or other transfers of value indefinitely. However, we do not agree that the time period for awareness of the identity of the covered recipient should be limited to the time the applicable manufacturer made the payment to the third party. We are concerned that this would allow applicable manufacturers to funnel payments or other transfers of value to third parties, and thereafter direct them to specific covered recipients, thus potentially avoiding the reporting requirements. Additionally, we believe there are multiple dates which could be reported, such as the date the applicable manufacturer decides to make the payment, or the date the payment is sent to or received by the third party, making it difficult to standardize a policy. After reviewing the comments, we will finalize that for the purposes of this exclusion, an applicable manufacturer must be unaware of the identity of a covered recipient during the reporting year and the second quarter of the subsequent year following the transfer of the payment from the third party to the covered recipient. Therefore, if an applicable manufacturer becomes aware of the identity of a covered recipient on or before June 30th of the year following the year in which the payment is made by the third party to the covered recipient, then the payment or other transfer of value must be reported. For example, an applicable manufacturer makes a payment to a medical professional society in March 2013 with instructions to use the money to provide grants to physicians. This payment meets the definition of an indirect payment, since the applicable manufacturer earmarked the payment for the physician grants. The professional society selects and makes payments to the grantees in April 2013 and alerts the sponsoring applicable manufacturer to the grant recipients in June 2013. Since the applicable manufacturer became aware of the identity of the covered recipients receiving the grants during the reporting year in which the payment was made, the payment or other transfer of value must be reported. Similarly, if the payment was made in November 2013, and the professional society provided the names of the grantees to the applicable manufacturer in April 2014, the payment would be reportable as part of the applicable manufacturer's report for CY 2014.

In determining this standard, we sought a definite time period, since the applicable manufacturer may not know the selection and payment process of the third party making the actual payment to the covered recipient. We also sought a uniform cut off point for all payments or other transfers of value in a reporting year, rather than a rolling time period, which would be based on the date of payment (such as 6 or 12 months after the date of payment). We believe a rolling date would be difficult due to the reasons outlined previously regarding inconsistency in the date of payment, as well as due to operational difficulties for both CMS and applicable manufacturers to track the awareness standard for each payment or other transfer of value. In order to set a date which applied to an entire year, we needed to set a date beyond the end of the reporting calendar year (December 31), which allows some time for indirect payments or other transfers of value made late in the year to be finalized. However, we did not want to set a time period which was too long and would require applicable manufacturers to report indirect payments that were made several years prior. We believe that two quarters beyond the end of the payment reporting year is sufficient for payments or other transfers of value made late in the year.

Comment: Several commenters questioned the process for reporting indirect payments, which was not addressed in detail in the proposed rule. A few commenters suggested that applicable manufacturers should be required to label all payments as direct or indirect and report the entity paid. Similarly, some commenters recommended that CMS clarify the amount of information that a third party should be required to provide to applicable manufacturers regarding indirect payments or other transfer of value. These commenters expressed that it would be burdensome for third parties to provide detailed information to applicable manufacturers regarding the recipients of payments made using the manufacturer's funding. Finally, a few commenters also inquired about the process for reporting payments when multiple applicable manufacturers contribute to a specific payment or other transfer of value. For example, multiple applicable manufacturers may fund a single speaker.

Response: We appreciate the comments and agree that providing more detail is necessary. However, we do not believe it is necessary to significantly change the reporting requirements for indirect payments. Given the unfavorable comments submitted regarding the proposal to classify research payments as direct or indirect, we believe that it would be similarly confusing to classify *all* payments or other transfers of value as either direct or indirect. Additionally, we do not believe it is necessary or appropriate for CMS to provide any requirements on the information third parties should or should not report. Applicable manufacturers will need to work with the third parties through which they make payments to covered recipients to ensure that the third parties are taking the appropriate steps to track the indirect payments. We recognize that this will, in some cases, require the third parties to put in place new tracking systems, but we believe that in many cases, such tracking systems already exist. For example, we believe that physician professional societies generally keep track of the physicians to whom they provide industry-funded grants and may not need to put new accounting systems in place in order for applicable manufacturers to be able to comply with the reporting requirements of this rule. Finally, we seek to clarify the situation when multiple applicable manufacturers provide a payment or other transfer of value to a covered recipient through a third party. We intend to allow for flexibility because we want to ensure that no payment or other transfer of value is captured twice. Applicable manufacturers and third parties may work together to determine the best method for reporting the payment or other transfers of value, as long as the payment or other transfer of value gets reported. We believe payments or other transfers of value made through a third party to a covered recipient using funds from multiple applicable manufacturers will be limited, since the companies will be required to report only those payments or other transfers of value directed to covered recipients and not unrestricted, non-earmarked payments.

Comment: Numerous commenters questioned the reporting on indirect payments or other transfers of value for education, particularly accredited or certified continuing education (both CME and continuing dental education). A large number of these commenters recommended that accredited or certified continuing education payments

to speakers (and payments for supporting materials) should not be reported because there are safeguards already in place, and they are not direct payments or other transfers of value to a covered recipient. Many of these commenters also stated that requiring that the reporting of payments or other transfers of value related to continuing education would be detrimental to continuing education and would reduce the funding for and attendance at continuing education programs. Additionally, some of these commenters also strongly indicated that they believe that Congress did not intend to require applicable manufacturers to report payments related to accredited or certified continuing education programs. However, we did receive some comments supporting the reporting of accredited or certified continuing education-related payments or other transfers of value, particularly when the sponsor provides suggestions to the CME vendor for potential faculty or speakers at a CME program. No commenters recommended that payments made to subsidize the costs of attendees of continuing education programs (as opposed to payments for faculty or speakers) should be reported.

Beyond accredited or certified continuing education, these comments were mixed on whether unaccredited and non-certified speaking engagements should be reported. A few commenters also addressed other types of education, such as Risk Evaluation and Mitigation Strategies (REMS), suggesting that since they were required by FDA, sponsorship of REMS education should be exempted from the reporting requirements.

Response: We appreciate the comments and agree that industry support for accredited or certified continuing education is a unique relationship. The accrediting and certifying bodies, including ACCME, AOA, AMA, AAFP, and ADA CERP, and the industry standards for commercial support, create important and necessary safeguards prohibiting the involvement of the sponsor in the educational content. However, we believe that even with this separation, the sponsor may still influence the selection of faculty by offering suggestions to the accredited or certified continuing education provider; although the continuing education provider may not be required to follow these suggestions, we believe that it may often be impossible to distinguish when a suggestion is influential and when it is not.

We have finalized at § 403.904(g)(1) that an indirect payment made to a speaker at a continuing education program is not an indirect payment or other transfer of value for the purposes of this rule and, therefore, does not need to be reported, when all of the following conditions are met: (1) The program meets the accreditation or certification requirements and standards of the ACCME, AOA, AMA, AAFP or ADA CERP; (2) the applicable manufacturer does not select the covered recipient speaker nor does it provide the third party vendor with a distinct, identifiable set of individuals to be considered as speakers for the accredited or certified continuing education program; and (3) the applicable manufacturer does not directly pay the covered recipient speaker. We believe that when applicable manufacturers suggest speakers, they are directing or targeting their funding to the speakers, so these payments will be considered indirect payments for purposes of this rule. Conversely, when they do not suggest speakers, they are allowing the continuing education provider full discretion over the CME programming, so the payment or other transfer of value will not be considered an indirect payment for purposes of these reporting requirements. Additionally, since industry support of CME programs that meets all three requirements discussed previously will not be considered indirect payments or other transfers of value for the purposes of reporting, the awareness standards for indirect payments are not applicable to such support. We believe that this approach will greatly reduce the number of payments to speakers at accredited or certified continuing education programs that must be reported. Applicable manufacturers will not be responsible for reporting payments made to CME vendors that are used to subsidize attendees' tuition fees for continuing education events. However, as explained in the discussion of the nature of payment categories, payments or other transfers of value associated with attendance of an event (such as travel and meals) must be reported as required.

With regard to unaccredited and non-certified education, we believe that since this type of education program does not require the same safeguards as an accredited and certified program, payments or transfers of value should be reported as required for any other payment or other transfer of value. If the payment or other transfer of value is made indirectly, it will be subject to the same reporting requirements for all indirect payments. The details for how to report both accredited or certified, and unaccredited or non-certified continuing education payments or other transfers of value are discussed in section II.B.1.h. of this final rule, dedicated to nature of payment categories.

Finally, we do not agree with comments that payments related to REMS with elements to assure safe use that require prescriber education should have a blanket exclusion from the reporting requirements. We recognize that REMS are required by FDA for some prescription drug products to ensure that the benefits of a drug outweigh the risks and that REMS often requires a sponsor to inform or educate health care providers about the risks associated with a product. However, we believe that payments made in connection with prescriber education required by REMS should be reportable on the same basis as other education payments. For example, if a sponsor directs the choice of a program speaker, or pays for covered recipients' meals or transportation to a REMS educational program, such payments would be reportable. However, applicable manufacturers are not required to report the provision of written materials that have been approved by FDA for distribution to physicians, such as Dear Healthcare Provider letters. Other REMS educational materials may be excluded if they fall within the exclusion for materials intended for patient use described in § 403.904(i)(4).

2. Reports on Physician Ownership and Investment Interests Under Section 1128G(a)(2) of the Act

Section 1128G(a)(2) of the Act requires applicable manufacturers, as well as applicable GPOs, to report to the Secretary, in electronic form, certain information concerning ownership and investment interests held by physicians or their immediate family members in such applicable manufacturers and applicable GPOs, and payments or other transfers of value to such physician owners or investors. In the proposed rule, we proposed that applicable GPOs were only required to report under section 1128G(a)(2) of the Act.

Comment: A few commenters suggested that Congress intended applicable GPOs to report under section 1128G(a)(1) of the Act, as well as under section 1128G(a)(2) of the Act. These commenters supported their interpretation with the introductory language of section 1128G(a)(2) stating that "[i]n addition to the requirement under paragraph (1)(A)" regarding reporting of payments to covered recipients, applicable manufacturers and applicable GPOs must report information regarding physician ownership and investment interests.

Response: We appreciate the comment but do not agree that applicable GPOs are required to report under section 1128G(a)(1) of the Act. While the phrasing in section 1128(a)(2) could be phrased more clearly, we do not believe it suggests that applicable GPOs need to report under both sections. Applicable GPOs are not mentioned in section 1128G(a)(1) at all, indicating that Congress did not intend for them to be subject to the requirements of that section. Additionally, other sections of the statute, such as the definition of payment or other transfer of value (section 1128G(e)(10) of the Act), only refer to applicable manufacturers when discussing payments or other transfers of value separately from ownership of investment interests.

a. Reporting Entities

(1) Applicable Manufacturers

Section 1128G(a)(2) of the Act includes applicable manufacturers as defined for section 1128G(a)(1) of the Act, as entities subject to the reporting requirements in section 1128G(a)(2) of the Act.

(2) Applicable Group Purchasing Organizations

Section 1128G(a)(2) of the Act also includes applicable GPOs as entities required to submit reports on physician ownership or investment interests; these reports are also required to include payments or other transfers of value provided to the applicable GPO's physician owners or investors. Section 1128G(e)(1) of the Act defines "applicable group purchasing organization" as "a group purchasing organization (as defined by the Secretary) that purchases, arranges for or negotiates the purchase of a covered drug, device, biological, or medical supply, which is operating in the United States, or in a territory, commonwealth or possession of the United States."

We proposed to define "applicable GPOs" as an entity that: (1) operates in the United States, or in a territory, possession or commonwealth of the United States; and (2) purchases, arranges for or negotiates the purchase of a covered drug, device, biological, or medical supply for a group of individuals or entities, and not solely for use by the entity itself.

We proposed that the definition will not include entities that buy covered drugs, devices, biologicals, or medical supplies solely for their own use, such as some large practices or hospitals (including those owned by physicians). Rather, it is our intent to capture entities (including physician-owned entities) that purchase, arrange for or negotiate the purchase of covered drugs, devices, biologicals, or medical supplies for resale or distribution to others. Additionally, we also interpreted the statute to encompass not only more traditional GPOs that negotiate contracts for their members, but also entities that purchase covered drugs, devices, biologicals, and medical supplies for resale or distribution to groups of individuals or entities. These interpretations would include, for example, physician owned distributors (PODs) of covered drugs, devices, biologicals, and medical supplies.

Comment: A number of commenter supported the definition of "applicable GPOs," particularly the inclusion of PODs. However, some commenters suggested revisions to the definition in order to capture additional PODs. For example, these comments included removing the reference to "group" in the definition, as well as limiting the exclusion for entities that purchase the products for their own use to only those entities that are the end users of the device based on billing under the same provider or supplier number as the entities that purchased the product. The commenters suggested that this would capture both fee-based and buy-and-sell POD models. Finally, a few commenters recommended that CMS issue a few clarifications, including allowing reselling in case of shortages and explicitly including commonly owned entities purchasing together as "own use."

Response: We appreciate the comments, but do not agree with the recommended changes to the definition to include additional PODs. While we appreciate the need to include as many PODs as possible, we are concerned that removing the word "group" from the definition would be contrary to the statutory phrase "group purchasing organization" which clearly implies that in order to be a GPO, the entity must be purchasing for a group. Therefore, we are not going to remove the word "group" from the definition. We are also concerned that hospitals and large group practices may not always purchase under the same provider or supplier number with which they bill, making it difficult to determine the end user by billing number. Therefore, we will not be changing the language in the definition to require use of the same provider or supplier number. Based on these considerations, we have decided to finalize the proposed definition. We recognize that this definition may not include every POD model; however, we intend for it to capture as many PODs as possible, while still aligning with the statutory language. Finally, we do not intend our definition to apply to rare and circumstantial resale of a product in response to a documented drug shortage. Similarly, we believe that bulk purchasing of covered products for commonly owned entities, which will be used only by those entities, would be considered "own use."

b. Physician Owners or Investors

Section 1128G(a)(2) of the Act differs from section 1128G(a)(1) of the Act in that section 1128G(a)(2) of the Act does not use the term "covered recipient" as defined in 1128G(e)(6) of the Act, which explicitly excludes payments or other transfers of value to employees of an applicable manufacturer from the reporting requirements. Instead, section 1128G(a)(2) of the Act uses the term "physician" as defined in section 1861(r) of the Act. Based on this definition of "physician," we proposed that the requirement to report physician ownership and investment interests includes any physician, regardless of whether the physician is an employee of the applicable manufacturer or applicable GPO. We did not receive any comments on this interpretation, and we will finalize it.

Additionally, as required by statute, ownership and investment interests of immediate family members of physicians must also be reported under this provision. In the proposed rule, we defined immediate family member as one of the following (as defined for purposes of section 1877(a) of the Act at 42 CFR 411.351):

- Spouse.
- Natural or adoptive parent, child, or sibling.
- Stepparent, stepchild, stepbrother, or stepsister.
- Father-, mother-, daughter-, son-, brother-, or sister-in-law.
- Grandparent or grandchild.
- Spouse of a grandparent or grandchild.

In the proposed rule, we also stated that in cases when the ownership or investment interest is held by an immediate family member of a physician, applicable manufacturers and applicable GPOs should report not only the required information for the physician, but also that the ownership or investment interest is held by an immediate family member of the physician. We considered whether to require the reporting of the immediate family member's relationship to the physician, as well as the immediate family member's name, but did not propose to require it.

Comment: A few commenters recommended that ownership or investment interests held by immediate family members of physicians should not be reported at all. Similarly, a few other commenters advocated that CMS employ a narrower definition of "immediate family member."

Response: We appreciate the comments; however, both the requirement to report ownership or investment interests of immediate family members of physicians, as well as the proposed definition of immediate family member, are required by statute. Section 1128G(a)(2) requires the reporting of ownership or investment interests held by an immediate family member of a physician and states that "immediate family member" is defined as it is for purposes of section 1877(a) of the Act, which is codified at 42 CFR 411.351. Given the statutory requirements, we have finalized the definition as proposed.

Comment: Many commenters supported *not* reporting the name and relationship of the immediate family member. However, a few commenters suggested that applicable manufacturers should not be required to report the name or relationship of immediate family members, but applicable GPOs should be required to report the information. Additionally, some commenters requested that CMS clarify expectations for how applicable manufacturers and applicable GPOs should obtain ownership or investment interest information. A few commenters also recommended that CMS should not require physicians to disclose this information and applicable manufacturers may rely on the representations by owners or investors regarding immediate family members. Finally, a few commenters recommended that in the event that multiple family members hold an ownership or investment interest in a specific entity, then the applicable manufacturer or applicable GPO should only report the ownership or investment interest in aggregate.

Response: We appreciate the comments and agree that applicable manufacturers and applicable GPOs should not report the name and relationship of immediate family members of physicians holding ownership or investment interests in such entities. However, we do not agree that this standard should be applied differently for applicable manufacturers and applicable GPOs since we believe the privacy for immediate family members is the same regardless of the entity at issue.

Regarding the requirements for obtaining information on ownership or investment interests, we have revised the definition to help clarify situations when the applicable manufacturer or applicable GPO does not know that a reportable ownership or investment interest exists. We do not have the authority to require physicians or owners or investors to report this information; however, we believe that an applicable manufacturer or applicable GPO may inquire about these relationships. These situations are discussed more fully in the section on the definition of "ownership or investment interests."

Finally, we also agree that applicable manufacturers and applicable GPOs may report a specific ownership or investment interest in aggregate across multiple family members. Since we are finalizing that applicable manufacturers and applicable GPOs do not need to report the name or relationship for an immediate family member holding an ownership or investment interest in such entity, we do not believe the reported interests need to be on the individual level and instead can be aggregated across multiple immediate family members. However, we intend that applicable manufacturers and applicable GPOs can only aggregate interests when multiple immediate family members have ownership or investment interests with the same terms (as reported pursuant to § 403.906(b)(5)) and the value reported includes the total value of all the immediate family member's interests.

c. Ownership or Investment Interests

We proposed to define an ownership or investment interest in an applicable manufacturer or applicable GPO in a similar manner as in the physician self-referral regulation (42 CFR 411.354(b)). Specifically, we proposed to define an ownership or investment interest as one that may be direct or indirect, and through debt, equity, or other means. We further proposed that ownership or investment interest includes, but is not limited to, stock, stock options (other than those received as compensation, until they are exercised), partnership shares, limited liability company memberships, as well as loans, bonds, or other financial instruments that are secured with an entity's property or revenue or a portion of that property of revenue. As required by statute, we proposed that an ownership or investment interest shall not include an ownership or investment interest in a publicly traded security or mutual fund, as described in section 1877(c) of the Act. Additionally, we proposed that ownership or investment interest must not include the following:

- An interest in an applicable manufacturer or applicable GPO that arises from a retirement plan offered by that applicable manufacturer or applicable GPO to the physician (or a member of his or her immediate family) through the physician's (or immediate family member's) employment with that applicable manufacturer or applicable GPO;
- Stock options and convertible securities received as compensation, until the stock options are exercised or the convertible securities are converted to equity;
- An unsecured loan subordinated to a credit facility.

Comment: Some commenters recommended that CMS only require that applicable manufacturers and applicable GPOs report direct ownership or investment interests, rather than both direct and indirect interests. However, the commenters also recommended a few limitations in the event the agency decided to require reporting of indirect ownership or investment interests. These recommendations included setting a minimum threshold amount for ownership interests, following the knowledge requirements in the physician self-referral regulation, and requiring that the physician has sole control of the interest. Beyond indirect ownership interests, a few commenters also recommended that CMS require reporting of stock options as ownership or investment interests when they are granted, rather than only when exercised. Similarly, a few commenters recommended that CMS not distinguish between ownership or investment interests arising from a retirement plan and stock options once exercised.

Response: We appreciate the comments. However, we do not agree that applicable manufacturers and applicable GPOs should only report direct ownership or investment interests. Section 1128G(a)(2) of the Act requires that applicable manufacturers and applicable GPOs report "any ownership or investment interest * * * held by a physician." We believe that "any ownership or investment interest" encompasses both direct and indirect interests, since indirect ownership or investment interests are also true interests. However, we do agree that there should be some limitation on indirect ownership or investment interests. We appreciate the comments on ways to limit reporting of indirect ownership or investment interests. We believe that limiting ownership or investment interests to those when the

physician has sole control and right to receive the proceeds is too narrow. We believe this will eliminate a significant number of ownership or investment interests, greatly reducing those reported. Similarly, we believe that setting a threshold for indirect ownership or investment interest creates an incentive to structure relationships to remain below the threshold. However, we do understand that there should be some limitations. We have decided to finalize the recommendation that aligns with the physician self-referral rule in that applicable manufacturers and applicable GPOs will not have to report ownership or investment interests held by physicians or their immediate family members if they did not know about such interests. We agree that this limitation is warranted, since it is impossible for an applicable manufacturer or applicable GPO to report an indirect ownership or investment interest that is unknown to it. Additionally, we believe that many stakeholders are already familiar with this standard from the physician self-referral regulation. Therefore, we have finalized that applicable manufacturers and applicable GPOs do not have to report indirect ownership or investment interests held by physicians or immediate family members of physicians about which they do not know (as defined for the purposes of this rule).

Finally, we understand the concerns regarding stock options received as compensation and requiring reporting of options when granted, rather than when exercised. However, we believe that stock options before they are exercised are traditionally considered compensation, rather than an ownership or investment interest, so we do not believe that we should require them to be reported as held ownership or investment interests. This is consistent with the definition in the physician self-referral regulation. However, we note stock options will need to be reported when granted under sections 1128G(a)(1) and 1128G(a)(2)(C) of the Act as a payment or other transfer of value. Reporting under sections 1128G(a)(1) and 1128G(a)(2)(C) may not include all stock options that are granted to physicians. For example, stock options that are granted to a physician who is an employee of the applicable manufacturer and is not already an existing owner or investor of that entity would not be reported; however, we believe reporting under sections 1128G(a)(1) and 1128G(a)(2)C) will capture a significant portion of stock options when granted.

d. Physician Ownership or Investment Report Content

Under section 1128G(a)(2) of the Act, applicable manufacturers and applicable GPOs are required to report information about each ownership or investment interest held by physician owners or investors (or their immediate family member(s)).

As required in section 1128G(a)(2) of the Act, we proposed that the applicable manufacturer or applicable GPOs should report the name, address, NPI, and specialty of the physician owner or investor, as well as the dollar amount invested and the value and terms of the ownership or investment interest. Section 1128G(a)(2)(C) of the Act requires the reporting of "[a]ny payment or other transfer of value provided to a physician holding such an ownership or investment interest (or to an entity or individual at the request of or designated on behalf of a physician holding such an ownership interest) * * *" Applicable manufacturers and applicable GPOs must report all the information required in section 1128G(a)(1)(A) of the Act for those physicians who hold ownership or investment interests in such entity. With regard to reporting payments and transfers of value to physician owners or investors, we proposed that applicable manufacturers and applicable GPOs follow the procedures outlined in this preamble for reporting payments and other transfers of value.

We also noted that there was some overlap between the requirements for reporting payments or other transfers of value and reporting ownership or investment interests. In order to help manage the overlap, we proposed that applicable manufacturers submit one report for all their payments and other transfers of value and another for all their physician ownership or investment interests. To comply with section 1128G(a)(2)(C) of the Act, we proposed that applicable manufacturers report the payments or other transfers of value provided to physician owners or investors (regardless of whether the physician owner is a covered recipient) in the report for payments and other transfers of value, but should note that the covered recipient receiving the payment or other transfers of value is a physician owner or investor.

Since applicable GPOs are not subject to the reporting requirements in section 1128G(a)(1) of the Act, we believe there is less of a potential for duplicative reporting. However, we proposed that when an applicable GPO has payments or other transfers of value to report for physician owners or investors, the applicable GPOs should use the data elements outlined in section II.B.1.f. of the final rule on payments and other transfers of value report contents.

Comment: A few commenters discussed the content of physician ownership or investment interest reports. The commenters specifically recommended that CMS not require the reporting of the "terms" of the ownership or investment interest.

Response: We appreciate the comments. However, we are unable to waive reporting of the terms of an ownership or investment interest, since it is a statutory requirement. Because we did not receive any comments on other aspects, we will finalize these provisions to align with the reporting requirements for payments or other transfers of value reports to the extent the requirements overlap. For example, applicable manufacturers and applicable GPOs should report both physician NPI and State professional license number(s) for at least one State where the physician maintains a license (including the name of the applicable State) to ensure that the agency is able to attribute ownership and investment interests to the appropriate physician. Similarly, requirements for reporting name, primary business address and specialty should also be the same as described for reporting payments or other transfers of value. Finally, as described in the section on the assumptions document, both applicable manufacturers and applicable GPOs may submit an assumptions document including information on their assumptions and methodologies when reporting payments or other transfers of value, or ownership or investment interests.

Comment: We also received a few comments concerning the potential for duplicative reporting due to the overlap between the two sections. The comments requested clarification of the proposed rule but did not have any specific recommendation or advocate any particular changes.

Response: We appreciate the comments and seek to clarify as much as possible; however, we have finalized these provisions as proposed. Applicable manufacturers must report all payments or other transfers of value to covered recipients and physician owners or investors, including the provision of ownership and investment interests. In the event that a physician receives an ownership or investment interest in a given year, an applicable manufacturer should report it as a payment or other transfer of value (under section 1128G(a)(1) of the Act), as well as a standing ownership or

investment interest (under section 1128G(a)(2) of the Act).

Additionally, an individual may be both a covered recipient and a physician owner or investor, so an applicable manufacturer should only report a payment or other transfer of value once, regardless of whether the individual is a covered recipient, a physician owner or investor, or both. The payment or other transfer of value and all the additional required information must be reported in the "payments or other transfers of value" reporting template; however for physician owners or investor (regardless of whether the physician is a covered recipient) the applicable manufacturer should mark that that payment or other transfer of value was provided to a physician owner or investor. All payments or other transfer of value should only be reported once regardless of whether it is required to be reported under section 1128G(a)(1) and/or section 1128G(a)(2)(C) of the Act.

C. Report Submission and Review

The statute requires the Secretary to establish procedures for applicable manufacturers and applicable GPOs to submit the required information and for the Secretary to make such information submitted available to the public. We recognize that these regulations require applicable manufacturers and applicable GPOs to collect and submit large amounts of new data, so we have tried to finalize flexible processes for data collection and submission. However, we also recognize that in order to accept and aggregate the data effectively and efficiently, there needs to be system standardization.

1. Prior to Submission

In the proposed rule, we considered that prior to submission of data to CMS, applicable manufacturers and applicable GPOs would provide each covered recipient or physician owner or investor with information regarding the information that the applicable manufacturer plans to report to CMS on the covered recipient's or physician owner or investor's behalf. While we did not propose to require this type of pre-review, we recommended that applicable manufacturers and applicable GPOs provide it.

Comment: Several commenters supported the pre-submission review. However, the commenters were divided over whether to require it or leave it voluntary. Many commenters stated that there simply was not time between the end of the data collection year and the data of submission to facilitate the review; whereas some commenters recommended it, stating it would greatly reduce disputes and inaccuracies in the data.

Response: We appreciate the comments and agree that pre-submission review would help ensure the accuracy of the data. However, we have finalized that CMS will not administer or manage a pre-submission review process and will not make it mandatory. We recommend that applicable manufacturers voluntarily provide covered recipients the opportunity to review the data prior to submission to CMS, but doing so is not mandatory. We understand that the processes and systems of applicable manufacturers and applicable GPOs may not allow for a review of this capacity. Similarly, since there is a post-submission review period, we do not believe that it is worth the additional burden for applicable manufacturers and applicable GPOs to make significant system changes in order to provide a pre-submission review. However, we do believe a pre-submission review could be extremely useful and recommend that applicable manufacturers and applicable GPOs consider ways that they could administer a pre-submission review external to CMS. Because CMS is not requiring the review, we do not feel it is appropriate for CMS to prescribe the process and standardize it; nevertheless, we believe that ongoing notice throughout the year of any reportable interactions would be ideal.

2. Report Submission

Applicable manufacturers and applicable GPOs are statutorily required to submit their reports for the preceding calendar year electronically to CMS on March 31, 2013 and on the 90th day of each calendar year thereafter. We proposed to interpret "on" March 31, 2013 or the 90th of the each year thereafter as "by" March 31, 2013 or the 90th of each year thereafter and intend to allow applicable manufacturers and applicable GPOs to submit data prior to this date to provide applicable manufacturers and applicable GPOs with more flexibility for submission. We did not receive any comments on this interpretation and have finalized it as proposed; however, as discussed in the timing section, because of the publication date of this final rule, reports including 2013 data will not be due until March 31, 2014.

a. Registration

In the proposed rule, we proposed that only applicable manufacturers that have payments or other transfers of value and/or physician ownership or investment interests to disclose for the previous calendar year must register and submit reports. Similarly, we proposed that only applicable GPOs with physician owners or investors would be required to register and submit information. For applicable manufacturers and applicable GPOs that did have information to disclose, we proposed that applicable manufacturers and applicable GPOs register with us prior to submission to facilitate communication. We proposed the registration process would require the applicable manufacturer or applicable GPO to designate a point of contact, which we would use for communications related to the submitted data. Alternatively, we considered requiring that all applicable manufacturers and applicable GPOs register with CMS, regardless of whether they had information to report, in order help us better understand the extent of these relationships and ensure compliance with the reporting requirements.

Comment: Many commenters supported the registration requirement, but disagreed on which entities should be required to register. Some commenters supported the proposal to require registration only by those entities with payments or other transfers of value or ownership or investment interests to report; other commenters recommended that CMS employ the alternative and require all entities that meet the definition of applicable manufacturer or applicable GPOs to register.

Response: Given the comments received, we believe that we do not need to require all entities that meet the definition of applicable manufacturer or applicable GPO to register and have finalized the position as proposed. Because the statute only requires the reporting of payments or other transfers of value, we will not require action by entities without payments or other transfers of value to report. All applicable manufacturers with payments or other transfers of value to report under paragraph 1 of the definition must register individually, regardless of whether they intend to be part of a consolidated report being submitted by another applicable manufacturer. We believe this will better allow CMS to ensure that applicable manufacturers required to report are reporting under the reporting requirements. However, applicable manufacturers that are submitting data as a part of a consolidated report under another applicable manufacturer may indicate during registration that they intend to be part of the consolidated report to be submitted by another

applicable manufacturer, allowing CMS to approximate the number of consolidated reports to anticipate. Additionally, as stated in the applicable manufacturer section, the reporting entity submitting a consolidated report must indicate all the applicable manufacturers for which it is reporting. Similarly, applicable manufacturers that are reporting separately must each register individually.

Comment: A few commenters discussed reporting of the point of contact, specifically recommending that two points of contact be provided for a single applicable manufacturer or applicable GPO.

Response: We agree that establishing and maintaining appropriate points of contact are important because it is essential that we be able to contact applicable manufacturers and applicable GPOs in the event that questions arise regarding their submission. We believe that requiring a second point of contact to serve as a backup will be beneficial and ensure that CMS can contact applicable manufacturers and applicable GPOs. We are finalizing that applicable manufacturers and applicable GPOs must indicate two points of contact when they register to allow for a primary and backup point of contact for each reporting entity. In order to ensure that the points of contact are up to date in the CMS system, applicable manufacturers and applicable GPOs will be able to change them as appropriate (subject to CMS user security protocols).

We did not receive any comments on our proposed timing for registration, so we have finalized those provisions as proposed. We proposed that applicable manufacturers or applicable GPOs with payments or other transfers of value to report must register prior to the deadline for data submission for data for the preceding calendar year for every annual reporting cycle. We intend applicable manufacturers and applicable GPOs to register sufficiently prior to the deadline in order to allow registration to be completed appropriately. Applicable manufacturers or applicable GPOs will be able to choose to submit the data immediately after completing the registration process successfully. We proposed to open the registration process at the beginning of the calendar year, giving applicable manufacturers and applicable GPOs time to register and submit their data; however, we may open registration earlier to allow additional time.

b. File Format

We also received several comments of the format of the data and process for submission to CMS. We proposed that applicable manufacturers and applicable GPOs submit their data electronically in a comma-separated value (CSV) format and solicited comments on and suggestions for alternatives to that format. Additionally, we proposed that each line item in the dataset should represent a unique payment or other transfer of value, or a unique ownership or investment interest. In the event that a single file does not have sufficient volume for all the data required, then we proposed the applicable manufacturer or applicable GPO could submit as many files as necessary to provide the entirety of its data.

Comment: Many commenters recommended that CMS create a standardized format and template and allow stakeholders an opportunity to review. Additionally, a few commenters supported the use of CSV files, whereas a few other commenters recommended using Pipe Line Delineated files rather than CSV files. These commenters explained that since some numbers are presented with comma separators (for example, $100,000), CSV files may be problematic. Similarly, a few commenters recommended that CMS establish a uniform naming system for applicable manufacturers.

Besides the format of the report, we also received comments on the organization and submission of the data. A few commenters recommended that CMS accept submission of data multiple times throughout the year, such as quarterly or ongoing, and allow extensions. Conversely, other commenters recommended allowing applicable manufacturers to submit multiple reports, organized by topic or individual. Finally to receive the data, a few commenters recommended that CMS develop a data exchange and data portal to accept files.

Response: We appreciate the comments and agree that CMS should provide applicable manufacturers and applicable GPOs with reporting templates and more details on reporting. However, we do not believe it is necessary or beneficial to provide this information in regulation, in order to allow the agency more flexibility to make changes in response to feedback from stakeholders. If we intend to make changes to the reporting template or other details for reporting (which we envision could happen particularly as the program evolves in early years), we will provide them at least 90 days prior to first day of data collection for the next reporting year. In providing revised templates, we will also comply with the requirements of the Paperwork Reduction Act to seek public comments on the proposed changes to the information collections, as required by law. This will allow applicable manufacturers and applicable GPOs to make any necessary changes to prepare for the next reporting year. This is the same time as the date by which we will publish the list of teaching hospitals.

We appreciate the comments on the organization of the submitted files, but per the statute, we will only allow submission of a single report consisting of the entire reporting period (for example CY 2014). We will only be collecting and staging data for public posting in accordance with annual submissions, so we will not be accepting ongoing or quarterly submissions. We believe that not only is annual publication sufficient for end users, but also allows for a single review and dispute period prior to publicly publishing the data, which is operationally easier for all parties. In addition, submission extensions will not be granted. After receiving all the submitted data, we will need to process all the data to aggregate across manufacturers and applicable GPOs and provide a single review and dispute period to correct submitted data prior to public posting. Late data will be considered failure to report and may be subject to penalties. Similarly, as required in the regulations, applicable manufacturers and applicable GPOs should not aggregate any payments or other transfers of value, or ownership or investment interests (except as described for small payments or other transfers of value). All reported transactions must be at the individual payment or other transfer of value, or ownership or investment interest level and do not intend applicable manufacturers or applicable GPOs to organize or group specific transactions. Finally, we appreciate the comments regarding a data exchange portal and agree that CMS should create an electronic system for accepting the data. We plan to publish additional information along with greater detail on the submission process.

c. Attestation Process

In the proposed rule, we proposed that annually, following the submission of data, an authorized representative from each applicable manufacturer and applicable GPO will be required to submit a signed attestation certifying the timeliness, accuracy, and completeness of the data submitted to the best of the

signer's knowledge and belief. We specified that such attestations must be signed by the chief executive officer, chief financial officer or chief compliance officer.

Comment: The majority of commenters supported the attestation requirement. However, a few commenters recommended revising the attestation to certify that the entity made a reasonable effort to ensure that data meets regulatory requirements. These commenters explained that the reporting requirements are, in their view, complicated, so it would be impossible to know whether the data submitted was accurate. Similarly, a few commenters suggested that CMS allow other officers (at the discretion of the reporting entity) to attest.

Response: We appreciate the comments, but we continue to believe that applicable manufacturers and applicable GPOs can and should be confident that the data is accurate. We recognize that the reporting requirements require significant data to be collected, but the majority of comments supported the language without revision, suggesting that reporting entities can be confident in their data. Additionally, the penalties are significantly less for unknowing errors, so the statute provides safeguards for unexpected errors. Finally, we do understand that applicable manufacturers and applicable GPOs may have different business structures. We do not want to confine applicable manufacturers and applicable GPOs with regard to which officers must attest, so we have finalized that other officers will be allowed to attest, as designated by the company.

We also seek to clarify the timing of the attestation requirement. Applicable manufacturers and applicable GPOs must provide an attestation for their data at the time of original submission for it to be considered submitted; however, they will also be required to provide an attestation any time the data is changed or updated. The most recent data for which there is an attestation will be considered the official data submission from the applicable manufacturer or applicable GPO. Data without such attestation will not be considered an official submission for purposes of reporting under section 1128G of the Act. This is discussed in more detail in the section on dispute resolution. However, we believe this may alleviate some of the concerns of applicable manufacturers regarding the difficulty in knowing whether the data submitted originally will be appropriately amended during the review and correction period.

Finally, as discussed in the section on applicable manufacturers, applicable manufacturers for which covered drugs, devices, biologicals, or medical supplies represent less than 10 percent of total (gross) revenue for the preceding year that have payments or other transfers of value to report, as a part of the attestation process, must attest that less than ten percent of total (gross) revenue in the immediately preceding year came from covered drugs, devices, biological, or medical supplies. We also note that for consolidated reports, the applicable manufacturer that submitted the consolidated report will be required to attest on behalf of all the entities included in the consolidated report. Applicable manufacturers that have reportable payments or other transfers of value that are submitted through a consolidated report by another applicable manufacturer will be required to register with CMS, but will not be required to attest. Accordingly we encourage applicable manufacturers considering submitting a consolidated report to fully consider the ramifications of doing so, particularly the applicable manufacturer actually attesting on behalf of all the entities included in the consolidated report.

3. Report Content

We have outlined the fields of information to be included when reporting payments or other transfers of value and physician ownership and investment interests. Some changes have been made below based on comments submitted; however, these decisions and changes are discussed throughout the final rule. The asterisks indicate the additional information that we will require under the discretion provided by the statute.

For each payment and other transfer of value, the following information is required:

- Applicable manufacturer's name.
- Covered recipient's—

++ Name (for physicians only, provide name as listed in NPPES, including first and last name, and middle initial and suffix (if applicable));

++ Specialty (for physicians only);

++ Primary business street address (practice location);

++ NPI (for physicians only, as listed in NPPES);

++ State professional license number(s) for at least one State where the physician maintains a license, including the applicable State where the license(s) is held; *

- Amount of payment or other transfer of value in U.S. dollars.
- Date of payment or other transfer of value.
- Form of payment or other transfer of value.
- Nature of payment or other transfer of value.
- Name(s) of the related covered drug, device, biological, or medical supply, as applicable.
- NDCs of related covered drugs and biologicals, if any. *
- Name of entity that received the payment or other transfer of value, if not provided to the covered recipient directly. *
- Whether the payment or other transfer of value was provided to a physician holding ownership or investment interests in the applicable manufacturer. (Yes or No response).
- Statement providing additional context for the payment or other transfer of value (optional). *

For each research-related payment or other transfer of value, the following information is required:

- Applicable manufacturer's name.
- Name of research institution/entity receiving payment.
- Total amount of research payment.
- Name of study.
- Name(s) of related covered drug, device, biological or medical supply (same requirements as for all payments or other transfers of value).
- NDCs of related covered drugs and biologicals, if any. *
- Principal investigator(s) (including name (as listed in NPPES), NPI (as listed in NPPES), State professional license number(s) for at least one State where the physician maintains a license including the applicable State where the license(s) is held, specialty and primary business address).
- Context of research (optional).
- ClinicalTrials.gov identifier (optional).
- Whether the payment or other transfer of value should be granted a delay in publication because it was made pursuant to a product research agreement, development agreement, or clinical investigation. (Yes or No response).

For each physician ownership or investment interest, the following information is required:

- Applicable manufacturer's or applicable GPO's name.
- Physician owner or investor's—

++ Name (as listed in NPPES, including first and last name, middle initial, and suffix (if applicable));

++ Specialty;

++ Primary business street address (practice location);

++ NPI (as listed in NPPES);

++ State professional license number for at least one State where the physician maintains a license including

the applicable State where the license(s) is held; * and

- Whether the ownership or investment interest is held by the physician, or an immediate family member of the physician.
- Dollar amount invested.
- Value and terms of each ownership or investment interest.
- Any payments or other transfers of value provided to the physician owner or investor, including the following (applicable manufacturers should report this information with their other payments or other transfers of value, and indicate that the covered recipient is a physician investor or owner):

++ Amount of payment or other transfer of value in U.S. dollars.

++ Date of payment or other transfer of value.

++ Form of payment or other transfer of value.

++ Nature of payment or other transfer of value.

++ Name(s) of related covered drugs, devices, biologicals, or medical supplies.

++ NDCs of related covered drugs and biologicals, if any. *

++ Name of entity that received the payment or other transfer of value, if not provided to the physician owner or investor directly. *

++ Statement providing additional context for the payment or other transfer of value (optional).*

4. 45-Day Review Period for Applicable Manufacturers, Applicable GPOs, Covered Recipients, and Physician Owners or Investors

Section 1128G(c)(1)(C)(ix) of the Act requires that the Secretary allow applicable manufacturers, applicable GPOs, covered recipients, and physician owners or investors the opportunity to review the data submitted for a period of at least 45-days prior to the data being made available to the public. This section outlines the comments received on the processes for and length of this review and correction period.

a. Notification of Review and Correction Period

In the proposed rule, we stated that we would notify covered recipients and physician owners or investors about the review and correction period in a few ways. We proposed to allow, but not require, covered recipients, and physician owners or investors to register with CMS to ensure they receive communication about the processes for review. Additionally, we proposed to notify physicians and hospitals through CMS's list-serves and by posting the information publicly (for example: on the CMS Web site or in the **Federal Register**). We also considered an alternative method, in which we would require applicable manufacturers and applicable GPOs to collect and report whether the covered recipient, or physician owner or investor would like to be notified by USPS or email of the processes for their review, as well as the individual's email address, if indicated. We received numerous comments on this which are described later in this section.

Finally, we proposed that the notification to physicians and teaching hospitals would be provided annually to announce the review and correction period, and would include the specific instructions for performing this review. We did not receive any comments on this provision, so we have decided to finalize it as proposed.

Comment: Many commenters addressed how to notify physicians and teaching hospitals of the opportunity to review payments or other transfers of value or ownership or investment interests that were attributed to them in reports submitted by applicable manufacturers or applicable GPOs. Some of these commenters supported the methods outlined in the proposed rule and provided other suggestions. Many commenters requested that physicians and teaching hospitals be notified personally of the processes for review and correction. Some of these commenters recommended the alternative method of collecting contact information (applicable manufacturers and applicable GPOs providing preferred method of communication), while others recommended another method or simply stated that CMS should notify physicians and teaching hospitals, but supported flexibility in the notification method. Conversely, many other commenters indicated that the proposed alternative would be overly burdensome, and recommended that CMS notify physicians and teaching hospitals in another manner. Finally, some commenters recommended more ongoing approaches to notification and allowing review to happen multiple times throughout the year.

Response: We appreciate the comments and have tried to balance the necessity to notify physicians and teaching hospitals with the desire to avoid adding any additional burden on applicable manufacturers and applicable GPOs. We have also considered what is operationally possible and concluded that we will notify physicians and teaching hospitals, as proposed, using email list serves, online postings (including both on the CMS Web site and the **Federal Register**) and directly (likely by email) to any physicians or teaching hospitals that have registered with CMS ahead of time. We strongly recommend that all covered recipients and physician owners or investors register. Although registration is not mandatory for these entities, in order for covered recipients to be able to review the data attributed to them, they will be required to register so we can appropriately match them to their data. In addition to the methods proposed, we plan to work with physician professional societies and provide the information to applicable manufacturers and applicable GPOs to provide voluntarily to covered recipients and physician owners or investors. We understand that these methods do not constitute direct, personal notification, but believe that these methods are sufficient and significantly more cost effective for both CMS, and applicable manufacturers and applicable GPOs.

Finally, we note that since applicable manufacturers and applicable GPOs only submit data for the previous calendar year to CMS once annually, the agency may not provide ongoing notifications to covered recipients or physician owners or investors for data submitted on their behalf outside of the formal period (such as in response to a dispute). Similarly, we will only provide for one formal review and correction period prior to the publication of that year's data. We discuss our plans to allow for updates to submitted data or submission of data previously omitted, as well as additional time to review and dispute, later in this section, but the formal review and correction period will only happen once annually prior to the next publication on the public Web site.

b. Length of Review and Correction Period

Section 1128G(c)(1)(D) of the Act requires that CMS provide a review and correction period of "not less than 45 days." We proposed a 45-day review period to maximize the time for the agency to aggregate and publish the data. Additionally to facilitate the review, we proposed that applicable manufacturers, applicable GPOs, covered recipients, and physician owners and investors would sign into a secure Web site to view the data submitted. We proposed that only the current and previous years would be available for review and correction. For example, during the 45-day review period in 2015, applicable manufacturers, applicable GPOs, covered recipients, and physician owners or investors would be able to

review and amend the data submitted for 2013 and 2014. During the 2016 review, 2014 and 2015 would be available for changes.

Comment: Many commenters requested a longer review period, particularly to allow for additional time to resolve disputes. Many of these commenters recommended a 60- or 90-day review period and asked that the review period include a distinct phase to resolve disputes. These commenters stated that this was particularly important for disputes which may be initiated towards the end of the review and correction period.

Response: We appreciate the comments and are sympathetic to the need to provide time for review and correction and tried to maximize the time as much as possible. However, time constraints restrict flexibility in this area given the statutory date for publication of the submitted data on the public Web site. In finalizing the proposal, we tried to balance providing appropriate time for review which allows us sufficient time to process the data for review and publication. Following the first year of reporting, in which we must publish the data within approximately 6 months of receiving the data, we must thereafter publish the data within 90 days of the last day for data submission (March 31), so a 90-day review period is not feasible. Similarly, we also believe that a 60-day review period would not leave us enough time to aggregate the data and prepare it for publication within 90 days of data submission. Nevertheless, we do agree that there should be a distinct phase for correcting data to resolve disputes since we recognize that it is not practical to resolve disputes initiated at the end of the review and correction period, within the time allotted. We believe that there should be a distinct period after the review and correction period specifically for correcting data to resolve potential disputes.

Given these constraints, we have finalized a 45-day review and correction period, during which covered recipients and physician owners and investors may register and then sign into the CMS secure Web site and review the data submitted by applicable manufacturers and applicable GPOs on their behalf and choose to dispute certain payments or other transfers of value, or ownership of investment interests. As soon as a dispute is initiated, applicable manufacturers or applicable GPOs may begin resolving the dispute and correcting the data. Following the end of the review and correction period, applicable manufacturers and applicable GPOs will have an additional 15 days to correct data for purposes of resolving disputes, and after which they may submit (and provide attestation for) updated data to CMS to finalize their data submission. Undisputed data will be finalized for publication after the close of the annual 45-day review and correction period. Regarding the 15-day period for resolving and correcting disputes following the 45-day review period, we recognize that 15 days is not much time for applicable manufacturers and applicable GPOs to resolve disputes submitted late in the review and correction period. Because we do not believe that we have the authority to shorten the period when covered recipients and physician owners and investors can review and submit corrections to the data, the 15-day period to correct data and resolve disputes must be after the 45-day review and correction period. Extending the 15-day dispute resolution period would not allow us sufficient time to prepare for public posting and we cannot delay public posting for the review and correction period. Only data changes initiated during the 45-day review and correction period and resolved by the end of the 15-day period for dispute resolution will be captured in the initial publication of the current reporting year of data on the public Web site. Disputes submitted earlier in the review and correction period will have more time to be resolved. In order to try to maximize the successful resolution of disputes and have more accurate data for publication, we plan to encourage covered recipients and physician owners and investors to register with the CMS system, review their data and if necessary, initiate disputes as soon as possible within the 45-day review and correction period to maximize the likelihood of successful resolution and accurate data available for publication.

We also note that covered recipients and physicians owners and investors will have the opportunity to review and submit corrections for data updated by applicable manufacturers and applicable GPOs (either in response to a dispute, omission, or other error). There is no limit to the number of times a particular transaction can be reviewed and disputed.

Comment: Many commenters also discussed the processes for the review and correction period, including what data would be available during the 45-day period. The majority of these commenters supported the secure Web site to view the data and recommended that CMS determine a process to validate the identities of the applicable manufacturers. Regarding the data available, many commenters recommended that CMS allow review and correction of more data, beyond the 2 previous years. Additionally, a few commenters recommended that for data granted delayed publication, CMS should allow review and correction of the data in the year the data is submitted, rather than the year it will be published. These commenters explained that it will be easier for covered recipients and physician owners and investors to review and correct the data immediately after the payment was made, rather than up to four years later.

Response: We appreciate the comments on the review and correction process and what data should be available for review during the review and correction period. Regarding the review and correction process, we have finalized our proposal of facilitating the process on a CMS-secure Web site. We are working to develop a system to allow secure registration, data submission, data review and submission of corrections processes. Applicable manufacturers and applicable GPOs will only be able to access and review the data they submitted or that was submitted for them within a consolidated report submitted by another covered entity; covered recipients and physician owners and investors will only be granted access to data regarding payments or other transfers of value and/or ownership or investment interests submitted on their behalf. We agree that we will need to validate the identities of individuals signing on to the Web site and plan to employ a system that will allow for secure user identification and authorization. We also plan to allow physicians and teaching hospitals to register prior to the start of the annual formal review and correction period to establish their profile, allowing them immediate access to the information at the beginning of the formal review and correction period. The secure user-based authentication requires that the actual individual register and interact with the system to ensure the utmost security of the data. The registration process will also help us collect additional information from the covered recipients and physician owners or investors to ensure that only the appropriate data is available to them and able to be aggregated and presented to the appropriate individual.

Beyond the process for accessing the information, we do not agree that more than 2 years of data should be available for review and correction. While we believe that covered recipients and physician owners and investors should have appropriate opportunity to review the data, we believe that the data should

be finalized and no longer open to disputes and updates after a certain time period. As discussed later in this section, we have worked to improve the review and correction processes to allow covered recipients and physician owners and investors the opportunity to review and correct their data and resolve disputes with applicable manufacturers and applicable GPOs throughout the year. Given this increased flexibility, we believe that allowing only the review of the previous year's data (submitted in that year) provides covered recipients and physician owners and investors sufficient time to review and, if necessary, correct disputes.

Additionally, we agree that all data from the previous reporting year, including data granted delayed publication should be available for review during the review and correction period following the reporting year. For example, a payment or transfer of value granted delayed publication, but made in 2014 and reported in 2015, would be made available to the covered recipient for review and correction in 2015, but would not be published until the appropriate time for release. We believe covered recipients and physician owners and investors, as well as applicable manufacturers and applicable GPOs will be better able to review and correct the data during the period of time immediately following the transaction, rather than years afterward when the data is about to be published. Finally, we intend to provide additional information and guidance on the reporting requirements and timing of data review and correction to help applicable manufacturers, applicable GPOs, covered recipients and physician owners or investors understand how transactions should be reported.

c. Dispute Resolution

In the proposed rule, we provided information on the public presentation of disputed, but unresolved transactions. We proposed that if an applicable manufacturer or applicable GPO, and covered recipient, or physician owner or investor have contradictory information that cannot be resolved by the parties involved, then the data would be identified as contradictory and both the original submission from the applicable manufacturer or applicable GPO, and the modified information provided by the covered recipient or physician owner or investor, would appear in the final publicly available Web site. We also proposed that for aggregation purposes, we would use the contradictory data, as corrected by the covered recipient or physician owner or investor, for any aggregated totals.

We also received numerous comments on the proposed process for dispute resolution. In the proposed rule, we stated that we should not be actively involved in arbitrating disputes between applicable manufacturers or applicable GPOs, and covered recipients, or physician owners or investors regarding the receipt, classification or amount of any payment or other transfer of value, or ownership or investment interest. We proposed that covered recipients, and physician owners or investors may request from us the contact information for a specific applicable manufacturer or applicable GPO, in the event of a potential dispute over the reported data. However, it would be the responsibility of the covered recipient, or physician owner or investor, to contact and resolve the dispute with the applicable manufacturer or applicable GPO. We proposed that at least one of any entity involved (applicable manufacturer, applicable GPO, covered recipient, or physician owner or investor) must report to CMS that a payment or other transfer of value, or ownership or investment interest is disputed and the results of that dispute.

Regarding the timing for submitting disputes, we proposed that the 45-day review period is the primary opportunity to correct errors or contest the data submitted by applicable manufacturers and applicable GPOs to CMS. Once the 45-day review period has passed and the parties have identified all changes or disputes and we have made or noted them all, we proposed that neither applicable manufacturers, applicable GPOs, covered recipients, nor physician owners or investors would be permitted to amend the data for that calendar year. We also proposed that applicable manufacturers, applicable GPOs, covered recipients, or physician owners or investors alert us as soon as possible regarding any errors or omissions, but these changes may not be made until the data is updated for the following reporting year. At that time, all parties would once again have an opportunity to review and amend the data. However, we proposed that we would have the option to make changes to the data at any time (for example, to correct mathematical mistakes).

Comment: Commenters had mixed reactions to the proposal that CMS not play a central role in mediating disputes. Many commenters stated that CMS should manage the process to ensure it is standardized and intervene in situations when disputes cannot be resolved. Conversely, many other commenters supported that CMS should not be involved and that it should be at the discretion of the disputing parties. Many commenters also recommended options for resolution, such as engaging a third party to mediate the disputes or developing an appeals process.

Several commenters recommended that CMS allow applicable manufacturers and applicable GPOs discretion over which payments or other transfers of value or ownership or investment interests to resolve. A few of these commenters noted that the statute only requires that CMS grant a review and correction period, but not that all disputes must be resolved. Conversely, a few commenters recommended that CMS impose a materiality threshold, and applicable manufacturers and applicable GPOs would not be required to resolve disputes below the threshold. Additionally, a few commenters recommended that applicable manufacturers and applicable GPOs should be responsible for reporting the resolution of disputes to CMS since they are subject to penalties for incorrect reporting. Most of these commenters recommended that applicable manufacturers and applicable GPOs should be allowed to re-certify the data after the dispute resolution. Finally, a few commenters discussed how the post-submission review process would interact with a pre-submission review.

Response: We appreciate the comments and agree that effective and accurate resolution of disputes is essential to the program. After reviewing the comments, we believe that we do have a responsibility to facilitate the capability for correcting the data and resolving disputes among the parties. However, we maintain that we should not be actively engaged in mediating dispute resolutions. The relationship exists between the applicable manufacturer or applicable GPO, and the covered recipient or physician owner or investor, so these parties should be involved in the resolution of the dispute, not CMS. We believe that we are not the appropriate party to mediate the disputes. However, we do plan to provide the opportunity for covered recipients, or physician owners or inventors to review and correct the data submitted on their behalf. We also plan to monitor the rate of disputes and resolutions, including whether an applicable manufacturer or applicable GPO has an abnormally high number of disputes or has an abnormally high rate of unresolved disputes.

When covered recipients and physician owners or investors register and sign on to the secure CMS Web site,

all payments or other transfers of value, and all ownership or investment interests, submitted on their behalf will be available for review. The covered recipient or physician owner or investor will be responsible for reviewing each payment or other transfer of value, or ownership or investment interest, and will be able to initiate a dispute on a particular transaction, if he/she chooses. If a covered recipient or physician owner or investor decides to initiate a dispute, he or she will be directed to fill out electronic fields detailing the dispute, including the proposed corrections. The system will automatically flag that the transaction was disputed and the system will notify the appropriate applicable manufacturer or applicable GPO of the dispute, detailing the information submitted by the disputing covered recipient or physician owner or investor. The applicable manufacturer or applicable GPO and physician or teaching hospital will then be responsible for resolving the dispute, after which the applicable manufacturer or applicable GPO will be responsible for submitting corrected data and re-attesting to the new data by the end of the 15-day resolution period. If a dispute cannot be resolved in this time, the parties may and should continue to work to reach resolution and update the data. However, we will continue to move forward with publishing the original and attested data, but will mark it as disputed.

If an applicable manufacturer or applicable GPO submits updated data to resolve dispute(s), the applicable manufacturer or applicable GPO must re-attest to the timeliness, accuracy, and completeness of the data, as required during the original data submission. If an applicable manufacturer or applicable GPO does not update its data at the end of the correction period, then its original attestation will be used. We recognize that this requirement adds a second attestation for applicable manufacturers and applicable GPOs that submit updated data, but we believe it is important that all the data presented on the public Web site be subject to the same attestation requirements. We also believe applicable manufacturers and applicable GPOs will appreciate the opportunity to re-attest in response to any updates to the data changed during the review and correction period.

Additionally, we do not agree that the statute does not require applicable manufacturers and applicable GPOs to resolve disputes. We believe that by requiring a review and correction period, Congress intended any disputes identified to be resolved; however, we do recognize that there may be situations when the cost of initiating and resolving a dispute may not be worth the potential benefits. We intend to monitor the volume and terms of disputes and resolutions, and plan to provide additional guidance regarding situations when the cost of resolving a dispute may outweigh the benefits. Finally, since we are neither requiring, nor managing the pre-submission review process, we do not believe there should be any connection between any pre-submission processes and the CMS processes for data submission and review and correction. For example, we will not restrict a physician who reviewed and approved a payment in the pre-submission review from disputing such payment or other transfer of value during the CMS process for review and correction, since we will not know whether the physician received an opportunity to pre-review the payments or the result of his/her pre-review.

Comment: Numerous commenters opposed CMS's proposed approach for presenting disputed data. Many commenters stated that it would be misleading to end users of the data to include both accounts. However, they differed in their preferred options for presenting unresolved transactions. Several commenters recommended that disputed transactions should be flagged as disputed, but only one account of the transaction be included. The majority of these commenters suggested that the information, as submitted by the applicable manufacturer or applicable GPO, should be the account of the transaction published, since they are the entities with the reporting requirements and subject to penalties. Other commenters recommended that the unresolved data should not be published until it has been resolved. Beyond the data reported, a few commenters recommended that CMS outline incentives for resolving disputes in order to ensure that applicable manufacturers, applicable GPOs, covered recipients and physician owners and investors participate in the dispute resolution process.

Response: We appreciate the comments and agree that publishing both accounts of a disputed transaction would be misleading. Although we believe publishing both accounts would provide the details of the dispute thereby providing the greatest transparency, we believe that this level of detail would not be useful for end users of the data. We also agree that any disputed transactions that have not yet been resolved should be labeled as such, but that only a single account of the transaction should be listed on the public Web site.

We also do not agree that disputed transactions should not be published publicly until they are resolved. We believe that this method would potentially create an incentive for covered recipients and physician owners or investors to dispute each transaction of the public Web site to prevent them from being made public. We also believe that publication of disputed transactions will incentivize the parties to resolve disputes in a timely manner. We do not believe that any additional incentives are necessary. We believe that the interest to only publish accurate and undisputed information will push all parties to actively resolve disputes.

Therefore, we will finalize that on the public Web site, payments or other transfers of value or ownership or investment interests that cannot be resolved by the end of the 15-day resolution period will be marked as "disputed," but the applicable manufacturer's or applicable GPO's most recent attested data subject to the dispute will be the only account of the information published. We believe publishing the most recent attested account by the applicable manufacturer or applicable GPO (rather than the corrected account provided by the covered recipient or physician owner or investor during the review and correction period) is appropriate because applicable manufacturers and applicable GPOs are responsible for collecting, reporting, and attesting to the accuracy of the information and are subject to penalties for failure to report. The parties may continue to resolve disputes after the close of the resolution period and after the data has been published publicly, or may leave the data as disputed; however, we discouraged leaving data as disputed and advocate for timely dispute resolution.

Comment: Several commenters did not support the 45-day review period being the only opportunity to review and correct the data and recommended that review and correction be available more frequently. Many commenters also recommended that CMS allow for changes to be made more than once annually to ensure that mistakes are identified and corrected on the public Web site as soon as possible. Finally, a few commenters also recommended that applicable manufacturers, applicable GPOs, covered recipients, and physician owners or investors should not have to report mistakes immediately, but allow time to investigate the mistake internally.

Response: We appreciate the comments on updating the public Web site and agree that we have a responsibility to allow for updates to the data more frequently than once a year during the formal 45-day review and correction period and 15-day resolution period, particularly given the short time period for the data to be reviewed and updated. We believe that some disputes will not be resolved in time for updated data to be included in the public data release for that reporting year, but will be resolved and require changes thereafter. These should not be incorrectly listed on the Web site for a whole year, when they have in fact been resolved. Nevertheless, we also believe that we do not have the resources to make continual changes to the Web site and should not be required to continually update the data. We will update the current and a previous year's data at least once annually, beyond the initial data publication following the submission of the data.

Similarly, we also believe that covered recipients, and physician owners or investors should be allowed to review and dispute the contents of the public Web site throughout the year. After registering with the CMS system, physicians and teaching hospitals, and physician owners and investors may sign in to the system to review or dispute officially submitted and attested transactions any time during the year. However, any disputes and subsequent updates initiated and resolved outside the 45-day review and correction period and 15-day resolution period may not be reflected on the public Web site until the next update of the data. We believe this fairly allows covered recipients and physician owners or investors control over reviewing and correcting their data at all times, but does not require us to make continual changes to the published data. This system will also allow covered recipients and physician owners and investors the opportunity to easily and efficiently review (and dispute, if necessary) data updated and re-submitted by an applicable manufacturer or applicable GPO.

Finally, we also understand applicable manufacturers, applicable GPOs, covered recipients, and physician owners or investors may want to investigate errors internally before notifying CMS of errors or omissions. However, we believe that errors and changes need to be reported to us as soon as possible so that we have the most accurate information possible. We believe that covered recipients and physician owners or investors should use the CMS review and correction processes to report errors and begin to resolve them with applicable manufacturers and applicable GPOs as quickly as possible. It will be the responsibility of the applicable manufacturer or applicable GPO that submitted and attested to the data to submit any updates, including errors and omissions, immediately after confirming that an update is needed or an error needs to be corrected; failure to do so may be considered incomplete reporting and may give rise to penalties.

D. Public Availability

Under the statute, we are required to publish on a publicly available Web site the data reported by applicable manufacturers and applicable GPOs for CY 2012 by September 30, 2013. For each year thereafter, we must publish the data for the preceding calendar year by June 30th. Given the timing of the final rule, no data will be collected for CY 2012, so the first data publication will be in 2014 for data collected in 2013.

In the proposed rule, we noted that section 4 of Executive Order 13563 calls upon agencies to consider approaches that "maintain flexibility and freedom of choice for the public," including the "provision of information to the public in a form that is clear and intelligible." We requested comment on how to structure this Web site for ultimate usability and proposed, as required by statute, that the Web site will include information on any enforcement activities taken under section 1128G of the Act for the previous year; background or other helpful information on relationships between the drug and device industry and physicians and teaching hospitals; and publication of information on payments or other transfers of value that were granted delayed reporting.

Comment: Numerous commenters provided feedback on the public Web site, particularly the development of the Web site. Many commenters called upon CMS to solicit stakeholder assistance in the development of the public Web site and that stakeholders should be given the opportunity to comment on the Web site content prior to it being finalized. A few commenters also recommended various methods to better develop the Web site, such as reviewing existing Web sites with similar information as examples. Finally, a few other commenters requested that CMS provide more information on the public Web site in the final rule.

Response: We appreciate the comments and agree that stakeholder input is essential to the success of the public Web site. We plan to engage stakeholders regarding the content of the Web site, since we recognize that stakeholders and the public must be a part of the development process. We agree that it is important that the final Web site is user-friendly and provide accurate and understandable information to the public. In order to regain flexibility over the details of the Web site and allow the opportunity to work with stakeholders on development, we have only provided general information on the public Web site in the final rule. We believe that it is important that we have flexibility to make changes to the Web site as they are identified, but do plan to engage the public on the future development. We intend to release additional information about the Web site through education and outreach to the stakeholder community.

Comment: In response to our request for comment on the structure of the public Web site, we received numerous comments recommending specific information to be included, as well as the Web site's capabilities. Some commenters recommended that specific information and research should be included on the Web site as background or contextual information, particularly including details of the reporting requirements and the benefits of relationships between manufacturers and physicians and teaching hospitals. Additionally, some other commenters recommended that CMS link to other Web sites, such as physician codes of conducts or a manufacturer's published data.

Regarding the capabilities of the Web site, some commenters recommended that the data should be easily searchable and downloadable. Other commenters recommended specific file structures and details for the data, for public use, as well as use by researchers, including allowing researchers to obtain information that is not publicly available.

Response: We appreciate the comments and agree that both the information included and capabilities of the Web site are extremely important. We support many of the recommendations and have provided general plans for the information to be presented, as well as the capabilities of the Web site. We plan to ensure that the public Web site accurately and completely describes the nature of relationships between physicians and teaching hospitals, and the industry, including an explanation of beneficial interactions. In addition, we plan to provide information to stakeholders regarding the data submission, review, dispute, dispute resolution and other

applicable operational processes. As proposed, the Web site will clearly state that disclosure of a payment or other transfer of value on the Web site does not indicate that the payment was legitimate nor does it necessarily indicate a conflict of interest or any wrongdoing. We appreciate the support of this language and plan to emphasize it on the Web site. We also plan to provide Frequently Asked Questions (FAQs) and other methods to help users find and understand this important contextual information.

While we appreciate that there is similar information available from industry and stakeholders that may be beneficial to include on the public Web site, we also want to try to reduce the promotional or company specific information on the Web site, so we will need to assess the best way to include this information, if at all. Finally, we are also cognizant that the Web site will include a significant amount of information and are considering the best way to provide sufficient context without overwhelming the consumer.

As required by statute, we plan to aggregate the data submitted and publish the data on a Web site that is searchable across multiple fields and available for downloads. In addition, we plan to establish mechanisms for researchers who may want information that is not publicly available. We believe that the data included in the database is primarily important for consumers, but understand that it also provides numerous opportunities for research on provider-industry relationships. We plan to provide opportunities to download the data that support researchers, as well as consumers, since we believe that research on this information is an important benefit of any transparency initiative.

1. Data Elements

In the proposed rule, we listed the data elements that would be available on the public Web site. We did not receive any comments on these, so we have finalized them as proposed. As required by statute, a physician's NPI will *not* be published on the public Web site. In these lists, we have included any necessary changes as required by other sections of the final rule. The asterisks indicate the additional information that we will publish under the discretion provided by the statute. As required in section 1128G(c)(1)(C)(ii) of the Act, at a minimum the following information on payments and other transfers of value would be included on the public Web site in a format that is searchable, downloadable, understandable, and able to be aggregated:

- Applicable manufacturer's name.
- Covered recipient's—
  - ++ Name;
  - ++ Specialty (physician only); and
  - ++ Primary business street address (practice location).
- Amount of payment or other transfer of value in U.S. dollars.
- Date of payment or other transfer of value.
- Form of payment or other transfer of value.
- Nature of payment or other transfer of value.
- Name(s) of the related covered drugs, devices, biologicals, or medical supplies, as applicable.
- NDCs of related covered drugs and biologicals, if any.*
- Name of the entity that received the payment or other transfer of value, if not provided to the covered recipient directly.
- Statement providing additional context for the payment or other transfer of value (optional).*

For research payments or other transfers of value, at a minimum the following research related information will be available on the public Web site:

- Name of research institution/entity receiving payment.
- Total amount of research payment.
- Name of study.
- Name(s) of the related covered drugs, devices, biologicals or medical supplies.
- NDCs of related covered drugs and biologicals, if any.*
- Principal investigator(s) (including name, specialty and primary business address).
- Context of research.
- ClinicalTrials.gov identifier (optional).

For physician ownership and investment interests, at a minimum the following information would be included on the public Web site in a format that is searchable, downloadable, understandable, and able to be aggregated:

- Applicable manufacturer's or applicable GPO's name.
- Physician owner or investor's—
  - ++ Name;
  - ++ Specialty; and
  - ++ Primary business street address.
- Whether the ownership or investment interest is held by the physician or an immediate family member of the physician.
- Dollar amount invested.
- Value and terms of each ownership or investment interest.
- Any payment or other transfer of value provided to the physician owner or investor, including:
  - ++ Amount of payment or other transfer of value in U.S. dollars.
  - ++ Date of payment or other transfer of value.
  - ++ Form of payment or other transfer of value.
  - ++ Nature of payment or other transfer of value.
  - ++ Name(s) of the related covered drugs, devices, biologicals, or medical supplies, as applicable.
  - ++ NDCs of related covered drugs and biologicals, if any.*
  - ++ Name of the entity that received the payment or other transfer of value, if not provided to the physician directly.
  - ++ Statement providing additional context for the payment or other transfer of value (optional).*

E. Delayed Publication for Payments Made Under Product Research or Development Agreements and Clinical Investigations

Section 1128G(c)(1)(E) of the Act provides for delayed publication of payments or other transfers of value from applicable manufacturers to covered recipients made pursuant to certain kinds of product research or development agreements and in connection with clinical investigations. This provision seeks to balance the need for confidentiality of proprietary information with the need for public transparency of payments to covered recipients that could affect prescribing habits or research outcomes.

In the proposed rule, we proposed that payments or other transfers of value would be granted delayed publication only if they were made in the context of a relationship for bona fide research or clinical investigation activities. We proposed that the "product research or development agreement" referenced in the statute included a written statement or contract between the applicable manufacturer and covered recipient, as well as a written research protocol.

Section 1128G(c)(1)(E) of the Act provides specific situations when delayed publication of payments or other transfers of value is appropriate, including the following:

- Research in connection with a potential new medical technology or a new application of an existing medical technology.
- The development of a new drug, device, biological, or medical supply.
- In connection with a clinical investigation regarding a new drug, device, biological, or medical supply.

In the proposed rule, we noted the difficulty in separating medical technology from the definition of covered drug, device, biological or medical supply and proposed to

consider "medical technology" broadly to include any drug, device, biological, or medical supply. Similarly, due to the overlap between the terms "research" and "development," we proposed to treat them similarly in this provision. In the proposed rule, we noted that the definition of clinical investigations in section 1128G(e)(3) of the Act is distinct from both "research" and "development" for the purposes of section 1128G the Act. We noted that this definition may also differ from those that applicable manufacturers may be familiar with in 21 CFR 312.3 and 812.3.

Given these interpretations, we proposed that delayed publication should apply to payments to covered recipients for services in connection with research on, or development of, new drugs, devices, biologicals, or medical supplies, as well as new applications of existing drugs, devices, biologicals, or medical supplies. Conversely, we proposed limiting delayed publication for payments in connection with clinical investigations to *new* drugs, devices, biologicals, or medical supplies, but not new applications of existing drugs, devices, biologicals, or medical supplies.

Finally, the statute also requires that information about payments and other transfers of value that are delayed from publication must be made publicly available on the first publication date after the earlier of either: (1) the approval, licensure or clearance by the FDA of the covered drug, device, biological or medical supply; or (2) 4 calendar years after the date of payment or other transfer of value.

Comment: Numerous commenters provided input on these interpretations and proposals. Some commenters recommended that CMS expand the situations when a payment or other transfer of value may be granted delayed publication. For example, a few commenters suggested that all research-related payments or other transfers of value should be granted a delay in publication, regardless of the product under consideration. Some commenters also explained that research on non-covered products should also be granted delayed publication, including pre-clinical research, which is often not expressly connected to a product. Conversely, other commenters recommended that CMS narrow the situations when a payment or other transfer of value is granted delayed publication. For example, a few commenters suggested interpreting medical technology as a subset of covered drugs, devices, biologicals or medical supplies, which would include only devices or even only a subset of devices. A few commenters also recommended that CMS not allow any delayed publication for payments or other transfers of value related to new applications of existing products. Finally, a few other commenters requested that CMS allow for delayed publication of sensitive payments or other transfers of value that are not related to research, such as business development activities.

Response: We appreciate these comments. However, we believe that our proposal strikes a good balance for granting certain payments or other transfers of value a delay in publication. In order to provide additional context to stakeholders, we seek to clarify our interpretation of the proposed requirements for delayed publication.

All payments or other transfers of value that are related to research, as defined in § 403.902, and are made pursuant to a written research agreement for research related to *new* products will be granted a delay. However, payments or other transfers of value related to research for new applications of products already on the market will be treated differently due to the statutory distinction between new products and new applications of existing products. Pursuant to the statute, payments related to research on new applications of existing products will be granted a delay only if the research does not meet the definition of "clinical investigation." We recognize that clinical investigations are a subset of research; however, we believe that the statute clearly differentiates them for purposes of delayed publication from research and development, and indicates that payments or other transfers of value made in connection with clinical investigations (as defined in section 1128G(e)(3) of the Act) related to new applications of existing products should not be granted a delay. Given the broad scope of the statutory definition of "clinical investigation," we believe this includes Phases I through IV clinical research for drugs and biologicals, and approval trials for devices (including medical supplies). We also amended the regulatory definition to include biologicals and medical supplies, as well as drugs and devices, since all product types should be treated similarly.

We recognize that the interpretation of the meaning of a new product (as opposed to a new application of an existing product) for the purposes of section 1128G of the Act may differ from other definitions, such as the definition of new drug in 21 U.S.C. 355. For purposes of determining eligibility for delayed publication under section 1128G(c)(1)(E) of the Act, new generic products will be considered new products, including drugs receiving approval under an Abbreviated New Drug Application, and devices under the 510(k) process.

Finally, while we recognize the potentially sensitive nature of business development activities, we do not believe that the statute grants us the ability to granted delays for payment types other than research.

Regarding the written agreement and research protocol, we discussed numerous comments on these requirements earlier in the research section, particularly regarding the requirement that a research study must be subject to both a written agreement and a research protocol. We have finalized the same requirements for payments or other transfers of value granted delayed publication. In general, a payment or other transfer of value can only be granted delayed publication if the payment meets the definition of research and could be reported under the "research" nature of payment category. Any related payments or other transfers of value that would not be reported as a part of the research nature of payment category, pursuant to the discussion in section II.B.1.i. of this final rule, will not be granted delayed publication.

Comment: Commenters specifically recommended that 4 years is not enough time for full development of a product, and that payments should only be published after FDA approval, licensure or clearance.

Response: We appreciate the comments, but the timelines are clearly delineated in section 1128G(c)(1)(E) of the Act. We do not have the authority to alter them. Additionally, we believe Congress clearly intended that all payments should be included on the public Web site, even if a product never received FDA approval, licensure or clearance.

1. Process for Reporting Payments or Other Transfers of Value Granted Delayed Publication

We received numerous comments on our proposed method for notification to CMS which payments or other transfers of value are eligible for delayed publication on the public Web site, as well as additional methods for reporting the information to CMS. We proposed that applicable manufacturers should indicate on their reports whether or not a payment or other transfer of value should be granted a delay from publication. In addition, we proposed that payments or other transfers of value

subject to delayed reporting need to be reported each year with a continued indication that publication should remain delayed and any updated information on the payment or other transfer of value, as necessary. Further, we proposed that following FDA approval, licensure or clearance, applicable manufacturers must indicate in their next annual submission that the payment should no longer be granted a delay and should be published in the current reporting cycle. Finally, we proposed that if a report includes a date of payment 4 years prior to the current year, then the payment or other transfer of value would be automatically published, regardless of whether the applicable manufacturer indicates that the payment should be delayed.

Comment: A few commenters requested clarification on whether applicable manufacturers would be required to indicate that a payment or other transfer of value should be granted delayed publication. Other commenters provided alternative methods for reporting payments or other transfers of value eligible for delayed publication. For example, some commenters recommended that applicable manufacturers should only report the payment or other transfer of value to CMS in the year it was made and then again in the year it is to be published. Similarly, other commenters recommended that applicable manufacturers should only report payments or other transfers of value in the year they are to be published. In addition, a few commenters expressed concern about confidentiality and recommended that applicable manufacturers should not be required to report the identifying details of the payment or other transfer of value until the payment was scheduled to be published. Beyond identifying details, some commenters recommended that CMS allow applicable manufacturers to report "research and development" for the product name, rather than the product, in order to better protect proprietary interests. Similarly, commenters recommended that CMS never require the collection of research protocols in order to ensure a payment or other transfer of value should be granted delayed publication.

Response: We appreciate the comments and agree that applicable manufacturers are not *required* to indicate that payments or other transfers of value are eligible for delayed publication and may instead choose not to indicate eligibility for the delay. However, if a manufacturer does not indicate that a payment or other transfer of value is eligible for delayed publication, it will be published immediately on the next publication date.

We also appreciate the comments regarding alternative methods for reporting payments or other transfers of value granted delayed publication; however, we believe that the proposed method is preferable. We believe that continual reporting is beneficial because it will allow us to ensure that payments or other transfers of value made more than four years earlier will be published appropriately. Otherwise, payments or other transfers of value from the same applicable manufacturer may be stored in various places. Additionally, we believe it will be difficult for us to enforce and audit payments or other transfers of value eligible for delayed publication if they are not reported until they are scheduled to be published. Nevertheless, we understand the confidentiality concerns, particularly for new products that have not yet been granted FDA approval, licensure, or clearance. However, after reviewing the comments, we believe that allowing applicable manufacturers to report in a different manner and allowing special considerations for certain research payments or other transfers of value makes the reporting requirements significantly more complicated. Additionally, section 1128G(c)(1)(E)(ii) of the Act requires CMS to keep the information submitted confidential prior to publication. We believe that creating separate requirements is too burdensome particularly when the statute and regulations already provide for confidentiality. We do not intend applicable manufacturers to provide research protocols or other such agreements to CMS for verification. Finally, pursuant to the statute, information reported by applicable manufacturers that is subject to delayed publication under section 1128G(c)(1)(E) of the Act shall be considered confidential and shall not be subject to disclosure under 5 U.S.C. 552, or any other similar Federal, State or local law, until after the date on which the information is made available to the public via publication on the Web site.

F. Penalties

Section 1128G(b) of the Act authorizes the imposition of CMPs for failures to report required information on a timely basis in accordance with the regulations. If an applicable manufacturer or applicable GPO fails to submit the required information, then the applicable manufacturer or applicable GPO will be subject to a CMP of at least $1,000, but no more than $10,000, for each payment or other transfer of value, or ownership or investment interest not reported as required. The maximum total CMP with respect to each annual submission for failure to report is $150,000. For knowing failure to submit required information in a timely manner, an applicable manufacturer or applicable GPO will be subject to a CMP of at least $10,000, but no more than $100,000, for each payment or other transfer of value, or ownership or investment interest not reported as required. The maximum total CMP with respect to each annual submission for a knowing failure to report is $1,000,000.

In the proposed rule, we outlined the penalty amounts as required by statute for failure to report and knowing failure to report. In addition, we proposed that all CMPs would be collected and imposed in the same manner as the CMPs collected and imposed under section 1128A of the Act. Additionally, we proposed that the procedures in 42 CFR part 402 subpart A would apply with regard to imposition and appeal of CMPs. Similarly, we defined the term "knowingly" based on the meaning in the False Claims Act, 31 U.S.C. 3729(b), as required by statute. Finally, we also proposed that a CMP may be imposed for failure to report information in a timely, accurate, or complete manner.

In the proposed rule, we outlined the factors that we would consider when determining the amount of a CMP, as well as when the maximum CMP would be imposed. We did not receive any comments on these factors, so we have decided to finalize these provisions as proposed. The factors to be considered include, but are not limited to, the following:

- The length of time the applicable manufacturer or applicable GPO failed to report, including the length of time the applicable manufacturer and applicable GPO knew of the payment or other transfer of value, or ownership or investment interest.
- Amount of the payment or other transfer of value or the value of the ownership or investment interest the applicable manufacturer or applicable GPO failed to report.
- Level of culpability.
- Nature and amount of information reported in error.
- Degree of diligence exercised in correcting information reported in error.

Finally, we proposed that in order to facilitate audits and enforcement, applicable manufacturers and applicable GPOs must maintain all books, records, documents, and other materials sufficient to enable an audit, evaluation or inspection of the applicable manufacturer's or applicable

GPO's compliance with the requirements in section 1128G of the Act and the implementing regulations. We proposed that applicable manufacturers and applicable GPOs must maintain these books, records, documents, and other materials for a period of at least 5 years from the date the payment or other transfer of value, or ownership or investment interest is published publicly on the Web site.

Comment: A few commenters discussed the proposed penalties for failure to report. These commenters generally supported higher CMP amounts for knowing failures to report. However, a few of these commenters suggested that the penalties were too low. The commenters also recommended that penalties should be imposed for inaccurate reporting, as well as omitted transactions.

Beyond the structure of the penalties, a few commenters also requested additional information on how CMS planned to enforce the program. They requested information on which agencies would be responsible for enforcement, as well as the enforcement mechanisms. Finally, a few commenters requested clarification on when the maximum penalty would be imposed and recommended that errors corrected during the review and correction period would not be subject to penalties.

Response: We appreciate the comments. However, we cannot change the amount or terms of the penalties, since they were authorized by statute. Section 1128G(b) of the Act outlines the CMP amounts and requires that they are imposed and collected in the same manner as those in section 1128A of the Act. Nevertheless, we do agree that the penalties should be imposed for inaccurate reporting. We have finalized our proposal that a CMP may be imposed for failure to report information in a timely, accurate, or complete manner. This includes failure to report timely or accurately an entire transaction, as well as failure to report timely or accurately certain fields related to a transaction. For example, this could entail reporting an erroneous payment amount or not reporting that an ownership or investment interest was held by an immediate family member of a physician. In order to clarify this, we have revised the regulation text in 42 CFR 402.105 to include the same text regarding reporting in a timely, accurate, or complete manner. In addition, we have revised the regulation text at § 402.105 and § 403.912 to clarify that the penalties imposed for failures to report and knowing failures to report will be aggregated separately and are subject to separate aggregate totals, with a maximum combined annual total of $1,150,000. Finally, we also realized that in the proposed rule we did not refer to the procedures for collection of CMPs in 42 CFR part 402 subpart B, so we are clarifying in this final rule that the procedures in 42 CFR part 402 subpart A and subpart B will apply with regard to imposition, appeal, and collection of CMPs.

Regarding corrections made during the review and correction, and dispute resolution periods, we want applicable manufacturers and applicable GPOs to correct any errors they have submitted without fear of alerting CMS to errors that will be subject to penalties; however, we do not want to allow applicable manufacturers to submit grossly inaccurate or incomplete data by the original submission date without risk of sanction. Therefore, we are requiring applicable manufacturers and applicable GPOs to attest the timeliness, accuracy, and completeness of their original submission to CMS prior to the review and correction period. Applicable manufacturers and applicable GPOs should make a good faith effort to ensure that the original data submitted to CMS is correct. We do not intend that errors corrected during the review and correction, and dispute resolution periods will be subject to penalties for failure to report in instances when the original submission was made in good faith. As noted earlier, applicable manufacturers and applicable GPOs will be required to re-attest after the submission of updated or new data. Outside this period, any errors or omissions will be considered failures to report timely, accurately, or completely, and will be subject to penalties. Additionally, both CMS and the HHS OIG are authorized to impose CMPs and both agencies will have the ability to investigate failures to report timely, accurately or completely.

Finally, in light of the increased flexibility for consolidated reports, we have clarified how penalties will be enforced for applicable manufacturers submitting consolidated reports. As explained previously, for consolidated reports, the applicable manufacturer that submitted the consolidated report will be required to attest on behalf of all the entities included in the consolidated report. Therefore, the applicable manufacturer actually submitting the consolidated report and signing the attestation will be subject to the maximum penalties (based on unknowing and knowing failures to report) for each individual applicable manufacturer included in the consolidated report. For example, an applicable manufacturer submitted a consolidated report for itself (Company A) and two other applicable manufacturers (Subsidiary B and C). We discover six instances of a failure to report a payment or other transfer of value in Company A's submission (each penalized at $10,000), seven instances of a knowing failure to report in Subsidiary B's submission (each penalized at $100,000) and finally nine knowing instances of failure to report (each penalized at $100,000) in Subsidiary C's submission. Company A, as the submitter and attester of the data, would be subject to a penalty of $60,000 for Company A's failure to report, $700,000 for Subsidiary B and $900,000 for Subsidiary C. To be clear, Company A would be subject to the penalties for knowing failure to report from both Subsidiary B's and Subsidiary C's submissions even though the penalties together exceed $1,000,000, because we interpret the maximum to apply individually to each applicable manufacturer's submission, even if the submission is contained within a consolidated report. We believe this appropriately handles the penalty requirements for applicable manufacturers submitting consolidated reports, since each applicable manufacturer should be subject to the same maximum penalties regardless of whether it submits individually, or as a part of a consolidated report. Two applicable manufacturers submitting a consolidated report should not be subject to lower penalties than two applicable manufacturers not submitting a consolidated report. Additionally, because the applicable manufacturer submitting the consolidated report is the entity attesting to the data, we believe it is fair that it be subject to the CMPs for each applicable manufacturer included in the consolidated report. Therefore, as noted previously we encourage applicable manufacturers considering consolidated reports to fully assess the requirements and potential penalties.

Comment: A few commenters discussed the retention period; in particular, many of them stated that the 5-year retention period was too long. A few other commenters recommended that the 5 years should begin on the date of first submission, rather than the date of publication. These commenters explained that retention based on date of publication would require applicable manufacturers and applicable GPOs to retain some records for longer than 5 years. Finally, a few commenters questioned whether the 5-year retention requirement was considered absolute in terms of liability.

Response: We appreciate the comments, but do not agree that 5 years is too long. We believe that 5 years is sufficient, since it is less than other retention requirements with which applicable manufacturers and applicable GPOs may be familiar. In addition, we believe that the retention period should begin at the date of publication. While we understand this policy may require the records to be retained for up to 9 years, we believe this information is essential for audits, and given the confidentiality requirements for data granted delayed publication, these activities may not be possible until after the data is published. If the date of retention began when the data was reported, in some cases there may be less than a year between when the data was published and the end of the retention period, which we do not believe is sufficient time to allow for audits, penalties, and appeals. Given these decisions, we have finalized the retention requirements as proposed. Finally, the requirements set forth in this final rule are in addition to, and do not limit, any other applicable requirements that may obligate applicable manufacturers or applicable GPOs to retain and allow access to records.

G. Annual Reports

We are required to submit annual reports to the Congress and the States. The Report to Congress is due annually on April 1st, beginning April 1, 2013, and shall include aggregated information on each applicable manufacturer and applicable GPO submitted during the preceding calendar year, as well as any enforcement action taken and any penalties paid. Similarly, we must report information submitted during the previous year to States annually by September 30, 2013 and June 30 for each year thereafter. In the preamble to the proposed rule, we explained that since we will not receive data for the prior year until the 90th day of each year, the data submitted that year will not be ready for the April 1st report. Instead, we proposed that we report to the Congress information submitted by applicable manufacturers and applicable GPOs during the preceding year.

Finally, we proposed that the State reports would be State-specific and include summary information on the data submitted regarding covered recipients and physician owners or investors in that State. Since these reports are due later in the year than the Report to Congress, we proposed that the reports would include data collected during the previous calendar year which was submitted in the current year. We also proposed that neither the Congressional nor State reports will include any payments or other transfers of value that were not published under the delayed publication requirements in section 1128G(c)(1)(E) of the Act. We did not receive any comments on these provisions and have finalized them as proposed.

Comment: A few commenters did not support the proposed timing for the Congressional report and instead recommended that CMS publish the Congressional report along with the publication of the data. Additionally, a few commenters recommended that CMS provide more information on the content of the Congressional reports. Particularly, they recommended that the report provides aggregate spending across applicable manufacturers and applicable GPOs, including aggregate spending for payments or other transfers of value granted delayed publication. Finally, a few commenters also recommended that CMS establish a process for sharing information across government agencies, such as OIG and the Department of Justice (DOJ).

Response: We appreciate the comments. We agree that the annual Congressional report should include summary statistics on the annual aggregate totals across applicable manufacturers and applicable GPOs. We also agree that inclusion of the aggregate total of payments or other transfers of value would be useful for oversight of the program. We plan to include this information in our annual Congressional report; however, in general we believe that we should not include specific details in the final rule to allow us flexibility to include and present information as appropriate. We also plan to work closely with other Federal agencies, since we recognize that other agencies are involved in similar activities. However, the purpose of this program is not to prosecute reporting entities, but to promote transparency.

Regarding the timing of the Congressional report, we recognize the awkwardness of the timing, but note that the report could be submitted early since it is only required *by* April 1st. We do not believe we have the authority to change the statutory deadline in regulation, but will try to publish the report as soon as possible.

Based on the timing of the publication of the final rule we have finalized that the Report to Congress will be submitted annually on April 1st, beginning April 1, 2015, and will include aggregated information submitted by each applicable manufacturer and applicable GPO submitted during the preceding calendar year (that is, data collected in CY 2013 and submitted in March of 2014), as well as any enforcement actions taken and any penalties paid.

H. Relation to State Laws

Section 1128G(d)(3) of the Act preempts any State or local laws requiring reporting, in any format, of the same type of information concerning payments or other transfers of value made by applicable manufacturers to covered recipients. No State or local government may require the separate reporting of any information regarding a payment or other transfer of value that is required to be reported under section 1128G(a) of the Act, unless such information is being collected by a Federal, State or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight.

Comment: A few commenters discussed the relation of section 1128G of the Act to relevant State laws. These commenters strongly supported preemption, but requested information on how CMS interpreted the timing, given the missed statutory deadline. Many commenters also requested that CMS identify what elements of current State laws will be preempted. Additionally, these commenters recommended clarifying the statutory language to prevent preemption from being applied too narrowly to successfully consolidate reporting. A few commenters explained that a broad interpretation of the exceptions to preemption, particularly "other public health purposes or health oversight purposes" could require applicable manufacturers and applicable GPOs to report the same information to States, as well as the Federal program. These commenters recommended that CMS clarify these terms to prevent them from being interpreted so broadly to not allow for any preemption.

Response: We appreciate the comments and acknowledge that the statute seems to provide that preemption of State or local transparency and disclosure laws is effective for payments or other transfers of value made on or after January 1, 2012. We understand that the delay in publication of the rule implementing section 1128G of the Act, which was to be published by October 1, 2011, has led to uncertainty regarding when preemption actually becomes effective. We urge manufacturers to continue to report under State or local disclosure laws until the requirements under the Federal rule take effect.

We also seek to provide some additional guidelines to clarify the preemption requirements; however, we note that preemption determinations will need to be analyzed on a case-by-case basis.

We interpret "type of information" for purposes of the preemption clause at 1128G(d)(3)(A) of the Act, to refer to the categories of information for each payments or other transfer of value required to be reported under the statute at 1128G(a)(1)(A)(i) through (viii) of the Act and § 403.904(c) of the regulations. We believe this is consistent with the statutory exception from preemption in section 1128G(d)(3)(B)(i) of the Act pertaining to the reporting to States and localities of information not of the type required to be disclosed under Federal law. Thus, State and local entities may require reporting of nonrequired categories of information for payments or other transfers of value reported to CMS, which are not required under Federal law. This includes payment categories excluded by the Federal law (including those listed at section 1128G(e)(10)(B) of the Act), with the exception of those that do not meet the minimum dollar threshold set forth in section 1128G(e)(10)(B)(i) of the Act. In addition, States and localities may require reporting of payments or other transfers of value not required to be reported at all under the Federal law. For example, they may require the reporting of payments to non-covered recipients or by nonapplicable manufacturers. We believe this is consistent with the statutory exceptions from preemption in section 1128G(d)(3)(B)(iii) of the Act.

Finally, we understand the concern over other public health and oversight activities; however, this language is required by statute, so we cannot expressly change it. However, these exceptions cannot be used to avoid preemption. If a Federal, State or local government agency seeks to collect information reportable under this regulation for public health and/or oversight purposes and specifically needs the information for a purpose other than transparency, then such collection will not be preempted. However, if the purpose of the collection does not meet this exception and in actuality seeks to achieve the same transparency goal as the collection required under section 1128G of the Act, we believe such a collection would be preempted, and the States or localities can obtain the information they want from the Federal program.

We have finalized the proposed discussion of public health agencies. We intend such agencies to include those that are charged with preventing or controlling disease, injury or disability and/or with conducting oversight activities authorized by law, including audits, investigations, inspections, licensure or disciplinary actions, or other activities necessary for oversight of the health care system.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. The information collections contained in this rulemaking are numerous and somewhat complex. We plan to obtain approval for the information collections in a step-wise fashion as we develop our system for receiving and displaying the required information and for allowing covered recipients and physician owners or investors to review the reported data prior to display on our Web site. Below, we provide an outline of the information collections and the current status of our requests for OMB approval.

A. Recordkeeping and Reporting of Payments or Other Transfers of Value and Physician Ownership and Investment Interests (§ 403.904, § 403.906, § 403.908(a),(b),(d),(f) and (g), § 403.912(e))

Section 403.904 requires applicable manufacturers of covered drugs, devices, biologicals, and medical supplies to report annually to CMS all payments and other transfers of value to physicians and teaching hospitals (collectively, covered recipients). This includes special reporting rules for research-related payments. Section 403.906 requires applicable manufacturers and applicable GPOs to report ownership and investment interests held by physicians or the immediate family members of physicians in such entities. This information is to be aggregated and posted publicly by CMS on a searchable Web site. Annually, under § 403.908(g) applicable manufacturers and applicable GPOs will be able to review and correct the data provided in any reporting period during the 45 day period to review and correction period. Under § 403.912(e), applicable manufacturers and applicable GPOs must retain records to support their reports for 5 years from the date when the information is publicly posted on the CMS Web site. This is, in some cases, a recordkeeping requirement of at most about 9 years for payments or other transfers of value eligible for delayed publication. In our proposed rule, we requested comment on the information required in the proposed regulation, but did not include all the data elements we expected applicable manufacturers and applicable GPO's to report, nor did we include detailed information about the mechanism for submission, amendment, or correction. For this reason, we are publishing a 60-day notice elsewhere in today's **Federal Register** seeking public comment on the information collection. As part of the process, we will be seeking public comment on templates that contain the data specifications for the system we will be building.

B. Registration for Applicable Manufacturers and Applicable GPOs (§ 403.908(c))

As required by § 403.908(c), any applicable manufacturer or applicable GPO that is required to report under this subpart must register with CMS within 90 days of the end of the calendar year for which a report is required. During registration, two points of contact must be provided, as well as other information. Registration is required once, but upon filing the annual reports the system will prompt applicable manufacturers and applicable GPOs to confirm that the registration information (for example, points of contact) is still accurate. If it is not accurate, the applicable manufacturers and applicable GPOs will be prompted to provide updated information. We have yet to seek OMB approval for the information collections associated with these provisions. We plan to seek public comment consistent with the requirement of the Paperwork Reduction Act and request OMB approval at a later date. Consistent with 5 CFR part 1320, these provisions will not be effective until OMB approves the collection of information.

C. Attestation (§ 403.908(e))

As required by § 403.908(e), each report, including corrections, must include a certification that the information reported is timely, accurate, and complete. We have yet to seek OMB approval for the information collections associated with these provisions. We plan to seek public comment consistent with the requirement of the Paperwork Reduction Act and request OMB approval at a later date. Consistent with 5 CFR part 1320, these provisions will not be effective until OMB approves the collection of information.

D. Assumptions Document (§ 403.908(f))

Under (§ 403.908(f)), applicable manufacturers and applicable GPOs may submit an assumptions document with their reports. This document can set out the assumptions and methodologies used to produce the reports. It will not be made available to the public, covered recipients or physician owners or investors, but it will provide CMS with information to help identify areas where additional guidance and clarity is needed. This is a voluntary collection and CMS does not plan to request that it be submitted in any particular way. We have yet to seek OMB approval for the information collections associated with these provisions. We plan to seek public comment consistent with the requirement of the Paperwork Reduction Act and request OMB approval at a later date. Consistent with 5 CFR part 1320, these provisions will not be effective until OMB approves the collection of information.

E. Information Collections Regarding Review and Correction by Physicians and Teaching Hospitals (§ 403.908(g))

As required by section 1128G of the Act, applicable manufacturers, applicable GPOs, covered recipients, and physician owners or investors must have an opportunity to review and submit corrections to the information submitted for a period of not less than 45-days before CMS makes the information available to the public. To accomplish this review, we plan to ask covered recipients and physician owners and investors that would like to review the information to register with CMS using the CMS Enterprise Portal and associated identity and access management system. Once registered, they will be able to access a secure Web site that allows them to submit or review data securely. We have yet to seek OMB approval for the information collections associated with these provisions. We plan to seek public comment consistent with the requirement of the Paperwork Reduction Act and request OMB approval at a later date. Consistent with 5 CFR part 1320, these provisions will not be effective until OMB approves the collection of information.

F. Notice of Resolved Disputes by Applicable Manufacturers and Applicable GPOs (§ 403.908(g)(4))

Under § 403.908(g)(4), applicable manufacturers and applicable GPOs must notify CMS of resolved disputes. We have not yet established the content or form of this notice, and therefore we have yet to seek OMB approval for the information collections associated with these provisions. We plan to seek public comment consistent with the requirement of the Paperwork Reduction Act and request OMB approval at a later date. Consistent with 5 CFR part 1320, these provisions will not be effective until OMB approves the collection of information.

G. Notice of Errors or Omissions (§ 403.908(h))

Under § 403.908(h), applicable manufacturers and applicable GPOs must notify CMS immediately upon discovering errors or omissions in their reports. We have not yet established the content or form of this notice, and therefore we have yet to seek OMB approval for the information collections associated with these provisions. We plan to seek public comment consistent with the requirement of the Paperwork Reduction Act and request OMB approval at a later date. Consistent with 5 CFR part 1320, these provisions will not be effective until OMB approves the collection of information.

IV. Regulatory Impact Analysis

A. Statement of Need

This final rule is necessary to implement the requirements in section 1128G of the Act (as added by section 6002 of the Affordable Care Act), which requires applicable manufacturers of covered drugs, devices, biologicals, and medical supplies to report annually to the Secretary all payments and other transfers of value to physicians and teaching hospitals (collectively, covered recipients). Section 1128G of the Act also requires applicable manufacturers and applicable GPOs to report ownership and investment interests held by physicians or the immediate family members of physicians in such entities.

These provisions of the Act were modeled largely on the recommendations of the MedPAC, which voted in 2009 to recommend Congressional enactment of a new regulatory program. The problem addressed, as stated by MedPAC, is that "at least some" drug and device manufacturer interactions with physicians "are associated with rapid prescribing of new, more expensive drugs and with physician requests that such drugs be added to hospital formularies," as well as "concern that manufacturers' influence over physicians' education may skew the information physicians receive." MedPAC went on to say that "there is no doubt that those relationships should be transparent," while pointing out that "transparency does not imply that all—or even most—of these financial ties undermine physician-patient relationships."[5] While a few comments discussed the reliability of the data used for the MedPAC report, we believe that the overall conclusions of the report are valid and continue to see the report's findings as a reason to promote transparency.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and promoting flexibility. Section 4 of Executive Order 13563 calls upon agencies to consider approaches that "maintain flexibility and freedom of choice for the public," including the "provision of information to the public in a form that is clear and intelligible." A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate that this rulemaking is "economically significant" as measured by the $100 million threshold. Accordingly, we have prepared a Regulatory Impact Analysis that presents estimated costs and benefits of the rulemaking. We solicited comments on all assumptions and estimates in this regulatory impact analysis, including some assumptions and estimates that were presented in the Collection of Information Requirements section of the proposed rule. As is standard practice in

[5] All quotes from pages 315–316 of "Public reporting of physicians' financial relationships" at *http://www.medpac.gov/chapters/Mar09_Ch05.pdf.*

meeting these various requirements for regulatory analysis, this section of the final rule addresses all of them together.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. Under the RFA, "small entities" are those that fall below size thresholds set by the Small Business Administration, or are not-for-profit organizations or governmental jurisdictions with a population of less than 50,000. We did not receive any comments on these aspects of the RFA, so have finalized it as proposed. For purposes of the RFA, we estimate that the majority of teaching hospitals and physicians, and most applicable manufacturers and applicable GPOs are small entities under either the size or not-for-profit standard. According to the Small Business Administration size standards [6] the threshold size standard for "small" pharmaceutical manufacturers is 750 employees, for biological products, and surgical equipment, surgical supplies, and electromedical/electrotherapeutic apparatus manufacturers is 500 employees and for drug and medical equipment wholesalers is 100 employees. We estimate that approximately 75 percent of applicable manufacturers and applicable GPOs are smaller than these size standards. In this final rule, we assume that applicable manufacturers that do not have payments or other transfers of value or physician ownership or investment interests to report do not need to submit a report. We believe that many small applicable manufacturers and applicable GPOs will have no relationships, thus will not have to report, so the burden on them will be negligible. For small entities with financial relationships to report, we believe that they will only have a small number to report, making the reporting process significantly less burdensome. We believe that the average burden of the reporting requirements will be about $80,000 in the first year (the sum of 0.25 FTEs of compliance officer at $48 hourly rate and 1 administrative support FTE at $26 hourly rate times 40 hours and 52 weeks) for smaller manufacturers, and even less in subsequent years. This amount is far below the 3 percent of revenues that HHS uses as a threshold for "significant impact" under the RFA, so these regulations will not have a significant effect on these small entities. For example, if a firm with only 100 employees generates annual revenues of $200,000 per employee, or $20 million, a cost of $80,000 would be less than 0.5 percent of the revenues. Firms this small would potentially face costs considerably less than $80,000, and hence an even lower effect.

As previously noted, most teaching hospitals and physicians are small entities under the RFA, since most teaching hospitals are not-for-profit and some have revenues below $34.5 million. We estimate that 95 percent of physician practices have revenues under $10 million. We believe the regulatory effects of this provision on physicians and teaching hospitals are relatively minor. Physicians and teaching hospitals are provided with the opportunity to review and correct this information, but are not involved in the data collection or reporting processes. We estimated that this review would take 1 hour from the individual physicians and 5 hours for the supporting staff to perform the duty to maintain records and review the reports annually. For teaching hospitals, it is estimated that on average 40 hours of compliance officer and 80 hours of supporting staff would needed. Given that their review will take such a small amount of their time annually, the costs faced by physicians and teaching hospitals are not substantial. As a result, we believe that the cost burden of this review and correction period will be far below the 3 percent threshold for "significant impact." Therefore, we have determined that this proposed rule will not have a significant economic impact on a substantial number of small entities in any category of entities it affects.

In addition, as stated in the proposed rule, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. In the proposed rule, we stated that we did not believe that any of the affected teaching hospitals are small rural hospitals, so did not believe that the rule had a significant impact on the operations of small rural hospitals. We did not receive any comments on this, so we have determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any single year of $100 million in 1995 dollars, updated annually for inflation. In early 2013, that threshold is approximately $139 million. The estimates presented in this section of this rule exceed this threshold and as a result, we have provided a detailed assessment of the anticipated costs and benefits in section V.C.4. of this final rule. Reporting under section 1128G of the Act is required by law, so we are limited as to policy options. Section IV.D. of this final rule, as well as other parts of the preamble, provide detailed additional information on the alternatives we considered.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. While this final rule does preempt certain elements of State law, the regulatory standard simply follows the express preemption provision in the statute. Because of this and the fact that this regulation does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable. We offer a more detailed discussion of preemption in § 403.914 of this final rule.

C. Anticipated Effects

The regulatory impact of this provision includes applicable manufacturers and applicable GPOs collection and submitting this information to CMS, and physician and teaching hospital review and correction period. The costs of these requirements are outlined in section III. of this final rule. We estimate a total cost of about $269 million for the first year of reporting, followed by about $180 million in the second year and annually thereafter.

1. Effects on Applicable Manufacturers and Applicable GPOs

For applicable manufacturers, only those that made reportable payments or other transfers of value, or have physicians (or immediate family members of physicians) holding ownership and investment interests, will be required to submit reports. Similarly, only applicable GPOs that have ownership or investment interests held by physicians (or immediate family members of physicians) would be required to submit reports. We estimate that approximately 1,150 applicable

[6] *http://www.sba.gov/sites/default/files/Size_Standards_Table.pdf.*

manufacturers, (150 drug and biologic manufacturers, and 1,000 device and medical supply manufacturers), and approximately 420 applicable GPOs would submit reports. We based these estimates on the number of manufacturers reporting in States with similar transparency provisions, as well as the number of manufacturers registered with FDA. The number of drug manufacturers is based on reporting in Massachusetts, Minnesota, and Vermont, whereas the number of device manufacturers is based on reporting in Massachusetts and Vermont, since Minnesota does not require device manufacturers to report. Because the State laws have higher payment thresholds and are specific to the physicians in the State, we estimated that the number of manufacturers reporting would be greater under section 1128G of the Act, so we increased the State reporting numbers by 50 percent. For device manufacturers, we also used data from the FDA to identify the total number of manufacturers to use as a ceiling for our estimate, combining the two data sources we increased the State reporting numbers by 75 percent. We believe that device manufacturers are often smaller and more region specific, which is why we increased the State estimates by a greater percentage. We did not receive comments on the number of reporting entities, except for information on the number of device manufacturers reporting in Vermont, where the legislature amended the transparency scheme in 2009 to include reporting by device manufacturers, so have finalized these assumptions.

It is difficult to establish with precision the number of GPOs, as proposed, because the definition of GPO includes some physician owned distributorships (PODs). However, we did rely on a recent report by the Senate Finance Committee which identified 20 States with multiple PODs and more than 40 PODs in California.[7]. When we extrapolate these estimates to the national level, taking into account the disproportionately higher number in California, we estimate that there are approximately 260 PODs currently in the U.S. We further estimate that there are an additional 160 GPOs, which have some form of physician ownership or investment. This is based on a review of what little literature exists and discussions with knowledgeable persons. Our research found that there are approximately 800 GPOs and that approximately 20 percent of GPOs have at least one physician owner or investor. We did not receive comments on the number of GPOs, so have finalized these assumptions.

In the public comments, we received comments on the estimated costs of the reporting requirements, but not the individual activities associated with them. Given these comments, we have revised the estimates, but have not revised the activities the FTEs will be required to perform, since we believe they accurately portray the requirements. Coordinating the data collection will require ensuring that all payments and other transfers of value are attributed to the correct covered recipient and reported in the manner required in this final rule. These estimates include our aggregate estimate of the overall time required to build and maintain the reporting systems (including the development of new information technology systems), train appropriate staff, obtain NPI and other information from the NPPES system (and if necessary supplement that information), establish whether any owners or investors have physicians as immediate family members (if necessary), organize the data for submission to CMS (within the organization and with any third party vendors), register with CMS and submit the required data, review the aggregated data that CMS produces, respond to any physician or teaching hospital queries during the review process, and resubmit and re-attest to certain disputed information (if necessary). Finally, it also includes any time required to maintain records, as required. However, we believe that much of this information will be collected and stored already for financial reasons, so we do not anticipate a significant burden. It allows for time applicable manufacturers and applicable GPOs may sometimes use for "pre-submission" reviews but assumes that would be rarely used, and only for complex cases. It also includes the time that applicable manufacturers may elect to spend to submit with their data a document describing their assumptions and methodology for categorizing the nature of payments. The estimates also include a downward adjustment to reflect the potential time savings that would accrue to applicable manufacturers who register with the CMS system and thus have the ability to query CMS, receive informal guidance through a listserv or other methods of providing technical assistance, and ultimately obtain useful information on low cost methods of compliance.

Comment: Several commenters stated that the current cost estimation for applicable manufactures and applicable GPOs to comply with the reporting requirements are too low, and CMS should increase the FTE estimates.

Response: We agree with the comment and have increased our estimates of the average FTE burden associated with the manufacturer and GPO reporting requirements. However, we believe that applicable manufacturers and applicable GPOs vary in their readiness to comply with the reporting requirements. Some companies have existing reporting systems in place, which can be used to comply with the government requirements. These systems track the wide range of financial interactions between the company, and physicians and teaching hospitals. Additionally, the efforts and workload varies with the size of the company as larger manufacturers will have more transactions, so may need more FTEs accordingly. As in the proposed rule, we estimated the impact based on all sizes of companies, recognizing that there are a few very large companies for which this would be a low estimate, but there are small companies which may need fewer FTEs. Additionally, we also took into account the finalized provisions that applicable manufacturers with less than 10 percent of gross revenues coming from covered products would only have to report payments or other transfers of value related to covered products, rather than all products. This will greatly reduce the reporting burden for these manufacturers, so we have considered them small companies for reporting purposes. Finally, we separated the FTE estimates to include a full time compliance officer, as well as multiple support staff for bookkeeping, accounting, and auditing; this change in approach yields a lower average cost per FTE than we estimated in the PRA.

We estimate that, for year 1, on average, smaller applicable manufacturers will have to dedicate 25 percent of an FTE employee (mainly in the range of zero to 50 percent), whereas larger applicable manufacturers may have to dedicate 1 to 10 FTE employees to comply with the reporting requirements (we assume 2 FTEs on average). Furthermore, we estimated that reporting activities will be conducted by the managerial staff and supporting staffs, the compliance or similar level of staffs will oversee the reporting activities, which will largely be supported by staff involved with bookkeeping, accounting and auditing. Since there are many more small companies, we estimate that on average, 0.5 FTEs of compliance officer and 2 FTEs of supporting staff would be needed for each applicable manufacturer in the first year (2 FTEs of

compliance officer and 8 FTEs of supporting staffs in 150 larger firms and 0.25 FTEs of compliance officer and 1 FTE of supporting staffs in 1,000 smaller firms). We appreciate that this is considerable simplification of a far more complex distribution of firms, but we believe that it captures the distribution in manufacturing sectors where a relative handful of firms have sales in the billions of dollars annually over a wide range of products, and a far larger number have annual sales in low millions of dollars annually for just a few products, with practices regarding financial relationships with physicians varying widely within each group and, in many cases by product or product class.

Therefore, for applicable manufacturers, the revised cost estimation assumes a compliance officer (0.5 full-time equivalents (FTEs)) and 2 FTEs of bookkeeping, accounting and auditing staff support in the first year. In the second year and thereafter, we reduced the estimates, since we believe the system will be more automated. In year 2 and thereafter we assumed 0.375 FTEs (780 hours) of a compliance officer and 1.5 FTEs (3,120 hours) of bookkeeping, accounting, and auditing support. Compared with the estimates we provided in the proposed rule, the total first-year FTE increased from 1.74 to 2.5 FTEs for applicable manufacturers. It should be noted that this is an average cost while the large manufacturers may need more and the small manufacturers may need less FTEs.

The greater staff time for year 1 represents time for applicable manufacturers to alter their systems to collect and report this data. We estimate that once procedures and systems are modified, costs would be 25 percent lower, which reduces this value to an average of 0.375 FTEs of compliance officer and 1.5 FTEs of support staff in year 2 and annually thereafter. We emphasize that these are very rough estimates. The actual burdens could easily average 25 percent lower or higher, and would depend on manufacturers' changes in practices after the regulations are made final. Some may welcome the new transparency; others may decide to change or eliminate their current practices. Our assumption that smaller firms could in some cases incur no new costs assumes that some do not now have any such financial relationships and that this proportion would grow as some firms decide that the benefits of such relationships are less than the costs of reporting. Other smaller firms with only a few products and only a few financial relationships might well already have systems in place that essentially meet the proposed requirements or that could do so with minimal effort.

We anticipate it would be less burdensome for an applicable GPO to comply with these proposed reporting requirements, since we believe companies will have fewer relationships with physician owners or investors (or immediate family members). This will make it much easier for applicable GPOs to match ownership and investment interests to the appropriate physicians (or family members). Based on discussions with officials of some GPOs and industry observers, we estimate that it would take from 5 to 25 percent of a FTE staff member, depending on the size of the applicable GPO. We assume that applicable GPOs already know the ownership and investment interests of its major investors, so the burden of these requirements include any changes to internal procedures to record and report the information. Also again, we have not found any empirical studies to better inform this estimate. Accordingly, we estimate that on average, an applicable GPO would dedicate 10 percent of an FTE (208 hours) of compliance officer and 0.25 FTEs (520 hours) of support staff to reporting under this section for year 1, followed by 25-percent reductions in both the compliance officer's time and support staff's time for year 2 and annually thereafter. Compared with the estimates we provided in the proposed rule, the total first-year FTE estimates increased from 0.1 FTE (208 hours) to 0.35 (728 hours) for GPOs.

While many individuals within the applicable manufacturer or applicable GPO may contribute to the data collection and reporting, we believe that majority of the work will be performed by the support staff and overseen by a compliance officer. According to the Bureau of Labor Statistics Occupational Employment Statistics, in May 2011, the average hourly rates for a compliance officer and bookkeeping, accounting and auditing staff in the pharmaceutical and medicine manufacturing field was $35.75 and $19.84, respectively. We applied a 33 percent increase to this amount to account for fringe benefits, making the total hourly compensation $47.55 and $26.39, respectively. The total number of hours for applicable manufacturers (including the hours for compliance officers and support staff) during year 1 would be 5,980,000 (1,150 applicable manufacturers × 100 hours (2.5 FTEs) × 52 weeks). For year 2 and subsequent years, we estimate a total of 4,485,000 hours (1,150 applicable manufacturers × 75 hours (1.875 FTEs) × 52 weeks). On average, this equals 4,983,333 hours annually for all applicable manufacturers for the first 3 years. The total number of hours for applicable GPOs (including the hours for compliance officers and support staff) for year 1 would be 305,760 (420 applicable GPOs × 14 hours (0.35 FTE) × 52 weeks) and for year 2 would be 229,320 hours (420 applicable GPOs × 10.5 hours (0.2625 FTEs) 52 weeks). For the first 3 years in total, applicable GPOs will spend on average 254,800 hours annually.

The following tables provide our total cost estimates for applicable manufacturers and applicable GPOs to comply with the data collection requirements in section 1128G of the Act such as collecting information, responding to inquiries, developing reports, and submitting reports to CMS. In total, we estimate that for applicable manufacturers and applicable GPOs required to report, it will cost $193,037,104 for year 1 and will cost $144,777,828 for year 2 and annually thereafter. For the first 3 years, this averages to a cost of $160,864,253 annually. All estimates are in 2011 dollars.

We note that Tables 1A and 1B contain revised estimated labor costs. The original cost estimates were included in the December 19, 2011 proposed rule (76 FR 78742).

TABLE 1A—YEAR 1 ESTIMATED LABOR COSTS FOR APPLICABLE MANUFACTURERS AND APPLICABLE GPOS

	Estimated reporting organizations	Estimated hours per reporting organization	Hourly rate	Average total cost per organization	Total cost
Compliance officer in AM	1,150	1,040	$48	$49,452	$56,869,800
Supporting staffs in AM	1,150	4,160	26	109,782	126,249,760
Compliance officer in Applicable GPOs	420	208	48	9,890	4,153,968

TABLE 1A—YEAR 1 ESTIMATED LABOR COSTS FOR APPLICABLE MANUFACTURERS AND APPLICABLE GPOS—Continued

	Estimated reporting organizations	Estimated hours per reporting organization	Hourly rate	Average total cost per organization	Total cost
Supporting staffs in Applicable GPOs	420	520	26	13,723	5,763,576
Total					193,037,104

TABLE 1B—YEAR 2 AND SUBSEQUENT YEAR ESTIMATED LABOR COSTS FOR APPLICABLE MANUFACTURERS AND APPLICABLE GPOS

[Annual]

	Estimated reporting organizations	Estimated hours per reporting organization	Hourly rate	Average total cost per organization	Total cost
Compliance officer in AM	1,150	780	$48	$37,089	$42,652,350
Supporting staffs in AM	1,150	3,120	26	82,337	94,687,320
Compliance officer in Applicable GPOs	420	156	48	7,418	3,115,476
Supporting staffs in Applicable GPOs	420	390	26	10,292	4,322,682
Total					144,777,828

In addition to FTE costs, we also assume that there would be some infrastructure costs associated with the reporting requirements under section 1128G of the Act. We acknowledge a substantial amount of uncertainty in these estimates. For example, we do not know how many companies will be using existing systems and technology to comply with the requirements and how many will be obtaining new equipment and technology; in both cases, there will be opportunity costs of using the systems for the reporting required by this rule, but with new systems, there might be higher-set-up costs. We also envision that companies of varying size will have different infrastructure needs, so have selected an average amount based on CMS infrastructure estimates of the requirements. We estimate that in year 1 the infrastructure costs for applicable manufacturers will be $10,000. This represents an average of $4,000 for small companies (estimated to be 1000 companies) and $50,000 for large companies (estimated to be 150 companies). We assume that the majority of these costs will be infrastructure costs, such as purchasing equipment and initial training, but assume that some costs will be required to maintain the systems. Therefore, we estimate that in year 2 and annually thereafter, applicable manufacturers will spend about $1,000 annually to maintain their systems. This represents 10 percent of the original infrastructure, which we believe is reasonable given CMS's experience with system maintenance. We note that this only covers the system and equipment maintenance and not the staff time to comply with the reporting requirements.

For applicable GPOs, we assume the infrastructure costs associated with the reporting requirements will be lower than that for applicable manufacturers. We assume that the applicable GPO costs will be roughly 20 percent of those for applicable manufacturers. This is based on the fact that estimated FTE costs for applicable GPOs are roughly 20 percent of that of applicable manufacturers. Therefore, we estimate that in year 1 the infrastructure costs for applicable GPOs will be $2,000. Similarly, we estimate that maintenance costs will be 10 percent of the initial cost, so in year 2 and beyond the maintenance costs for applicable GPOs will be $200. Table 2A and 2B contain the estimated infrastructure costs for applicable manufacturers and applicable GOPs in year 1 and year 2 and thereafter, respectively. We further assume that the combined infrastructure and maintenance costs per burden hour will be the same for physicians and teaching hospitals as for GPOs.

We note, and discuss in the benefits section later in this section, that the costs of applicable manufacturers may be partially offset because many companies are already required to report to States with similar disclosure requirements, but would no longer be required to report the same information to States after the final rule is issued. In addition, a few large companies are already reporting similar information on a national level in order to comply with Corporate Integrity Agreements (CIAs) with HHS OIG. These companies may not have to invest as much as we estimated earlier in this section to comply with the requirements in section 1128G of the Act. However, given the differing requirements for each State and CIA, and broad scope of section 1128G of the Act, we do not believe it is possible to approximate any lessened burden for entities already reporting.

Because applicable manufacturers have some influence in getting their products on a Part D plan formulary, obtaining billing codes, or getting Medicaid coverage, they have some control over whether Medicare, Medicaid and CHIP payments are available for their products. If applicable manufacturers were to stop accepting such payments so as to avoid reporting requirements, it would reduce the rule-induced cost that they bear themselves, but might negatively affect the well-being of Medicare, Medicaid and CHIP patients who no longer have coverage for a full range of medical products. However, because these public programs represent a very large patient population, we do not anticipate that applicable manufacturers will refrain from participating in the programs just to avoid reporting requirements.

TABLE 2A—YEAR 1 ESTIMATED INFRASTRUCTURE COSTS FOR APPLICABLE MANUFACTURERS AND APPLICABLE GPOS

	Organizations	Annual cost	Total cost
Large Applicable Manufacturers	150	$50,000	$7,500,000
Small Applicable Manufacturers	1000	4,000	4,000,000
Applicable GPOs	420	2,000	840,000
Total			12,340,000

TABLE 2B—YEAR 2 AND SUBSEQUENT YEAR ESTIMATED INFRASTRUCTURE COSTS FOR APPLICABLE MANUFACTURERS AND APPLICABLE GPOS

[Annual]

	Organizations	Annual cost	Total cost
Large Applicable Manufacturers	150	$5,000	$750,000
Small Applicable Manufacturers	1000	400	400,000
Applicable GPOs	420	200	84,000
Total			1,234,000

2. Effects on Physicians and Teaching Hospitals

We also have estimated costs for physicians and teaching hospitals, since they would have an opportunity to review and correct the data submitted by applicable manufacturers. The statute uses the definition of physician in section 1861(r) of the Act, which includes doctors of medicine and osteopathy, dentists, dental surgeons, podiatrists, optometrists and licensed chiropractors. Using the Bureau of Labor Statistics Occupational Outlook Handbook, we estimate that information may be available for as many as 897,700 physicians. However, we believe that not all physicians will have relationships with applicable manufacturers or applicable GPOs. In the proposed rule, we assumed that roughly 75 percent of physicians would have relationships. However, based on feedback we received from stakeholders, including a private firm with data of roughly 50 companies currently reporting, we now estimate that less than 50 percent of the physicians have transactions with industry. We assume that 50 percent of physicians have no relationships with applicable manufacturers or applicable GPOs, which reduces our universe of affected physicians to approximately 448,850. Further, stakeholders have expressed that many physicians maintain relationships with applicable manufacturers that are relatively insignificant from a financial point of view, so we estimate that many physicians will not devote any time to reviewing and correct the aggregated reports from CMS. We estimate that only 50 percent of the remaining 448,850 physicians will review the report, which reduces our universe of affected physicians to 224,425 for year 1. For year 2, we anticipate that there would be a further reduction in the number of physicians choosing to review the data because they would be familiar with the type of information on the database, so we reduced the number of physicians reviewing by another 25 percent, to 168,319 physicians. We also reduced the amount of time it would take the physicians choosing to review the information, since we believe they will be familiar with the review, correction and dispute process. For teaching hospitals, we know that about 1,100 hospitals receive Medicare GME or IME payments, all of which are defined as teaching hospitals for this provision. We believe that the vast majority of teaching hospitals would have at least one financial relationship with an applicable manufacturer, so we did not apply any adjustments to this estimate. We also anticipate that there would not be a reduction in the number of teaching hospitals that review the information after the first year because teaching hospitals probably have more complex financial relationships.

See the Table 3 for a breakdown of this calculation. In the proposed rule, we mistakenly omitted dental surgeons from the table, so have added estimates for them in the final rule. The definition of physician at section 1861(r) of the Act explicitly includes them.

TABLE 3—NUMBER OF PHYSICIANS BY TYPE

Physician type	Number
Doctor of Medicine/Doctor of Osteopathy	660,000
Doctor of Dental Medicine	155,700
Doctor of Podiatric Medicine	12,000
Doctor of Optometry	35,000
Licensed Chiropractors	*35,000
Total	897,700
Adjustment for Physicians with no reports (only 50% had transaction with industry)	448,850
Adjustment for Physicians who do not review reports (Year 1—reduction by 50%)	224,425
Adjustment for Physicians who do not review reports (Year 2—reduction by 25%)	168,319

*Reduced from 50,000 in BLS to account for licensure.

We received numerous comments on the cost estimations for physicians and teaching hospitals, and have responded to them and revised our cost estimates accordingly.

Comment: Several commenters questioned the time and cost estimation for physicians. Specifically, the commenters stated that the time allotted for the physicians to review the data is too short, since physicians will need to maintain records in order to review the information submitted on their behalf accurately. Similarly, several commenters noted that the current hourly rate for the physician ($75) is low.

Response: We agree with commenters that the physicians and teaching hospitals may need to maintain ongoing records of the activities for verification purposes, so have increased the time dedicated to the physician and teaching hospital review. However, we assume that most of these recordkeeping activities will fall on the duty of the office assistants, but the physician may need to review the records. The hours of bookkeeping are added in the revised cost estimation for physician and teaching hospital accordingly. Additionally, we agree that the physician hourly rate should be increased. The hourly rate for physicians in the final rule is updated to $137 per hour, which is based on the most recent data from Bureau of Labor Statistics (BLS).

Comment: A few commenters questioned CMS's cost estimate of 10 hours of compliance officer in teaching hospitals, which state that teaching hospitals will need more time to review the transactions and maintain records to facilitate the review.

Response: We agree with commenters that teaching hospitals will likely need more time for their review. The hospital compliance officer's annual hours have been increased from 10 hours to 40 hours. In addition, we revised the cost estimation to include 80 hours of administrative supporting staff at teaching hospitals to maintain the records. The role of the compliance officer will be review and oversight, while the administrative supporting staff will conduct the recordkeeping.

In response to the comments, even though there is no requirement for physician and teaching hospitals to review the reports or maintain records of interaction, we estimated the covered recipients may maintain records to facilitate reviews. In the final rule, we estimated the supporting staffs such as bookkeeping, accounting, and auditing would perform the tasks while the compliance officer would oversee the review process.

When reviewing the information reported, physicians and teaching hospitals are allowed to review the information attributed to them by applicable manufacturers and applicable GPOs that submitted data to CMS. A number of commenters suggested that physicians and teaching hospitals would spend some time during the year maintaining records to facilitate their review. In response to this feedback, we added estimates for recordkeeping for physicians and teaching hospitals and assumed that support staff would perform these functions. We estimate that on average, physicians would need 1 hour annually to review the information reported. For physicians that choose to review the information, this would range from a few minutes for physicians with few relationships with applicable manufacturers, to at most 10 or 20 hours for the small number of physicians who have lengthy disputes over a payment or other transfer of value, or ownership or investment interest. In addition, we also estimated 5 hours annually of supporting staff for each physician to help them to maintain records to facilitate the review. We believe that teaching hospitals will have to review more payments or other transfers of value and have more complex relationships, so we estimate that, on average, it would take a representative, such as a compliance officer, from a teaching hospital 40 hours annually to review the submitted data, ranging from 10 hours for small teaching hospitals that receive few payments or other transfer of value, to 200 hours for teaching hospitals that have lengthy disputes. In addition, we also estimated 80 hours annually of administrative support staff for each teaching hospital to help them maintain their records.

The Bureau of Labor Statistics Occupational Employment Statistics publishes data on hourly compensation for Healthcare Practitioners and Technical Occupations in physicians' offices. The average hourly rate for physicians and surgeons is $103.32,[8] which rises to $137 with 33-percent fringe benefits. This average includes physicians, who account for about half of the employment in this category. In the proposed rule, we used an estimate for the hourly wage that included other provider types, but having received numerous comments that the resulting wage was too low, we increased the estimate for this final RIA. The average hourly rate for the supporting staff is $16.35 which rises to $21.75 with 33 percent fringe benefits. The total number of hours for physicians (including supporting staffs in physician offices) would be 1,346,550 (224,425 × 6 hours) for year 1 and 757,436 hours (168,319 × 4.5 hours) for year 2, which averages to 953,807 hours annually for the first 3 years. The total estimated cost for the review and correction period for physicians and the supporting staffs in year 1 is $55,152,444. For year 2 and annually thereafter, the estimated cost for physician and supporting staffs to conduct review and correction is $31,023,250. For the first 3 years, the average cost for all physicians review and correction will be $39,066,314 annually.

For teaching hospitals, as explained, we expect a compliance officer to review the payments and other transfers of value with supporting staff to maintain any necessary records. Since this review could be done by employees with multiple titles, we used the Bureau of Labor Statistics Occupational Employment Statistics reported compensation for Management Occupations at General Medical and Surgical Hospitals in 2010. The hourly average rate for compliance officer in hospitals is $32.94 or $43.81 when fringe benefit costs are applied. The average hourly rate for the supporting staff in a teaching hospital is $16.22 which rises to $21.57 with 33 percent fringe benefits. For year 1, the total number of hours would be 132,000 (1,100 × 120 hours). For year 2 this would decrease to 99,000 hours (1,100 × 90 hours). For the first 3 years, the average number of hours for teaching hospitals will be 110,000 annually. The total estimated cost for the review and correction period for teaching hospitals is $3,825,800 for year 1 and $2,869,350 for year 2 and annually thereafter. On average, the cost for all teaching hospitals will be $3,188,167 annually for the first 3 years.

We note that Tables 4A and 4B contain revised cost estimates. The original cost estimates were included in the proposed rule (76 FR 78742).

[8] *http://www.bls.gov/oes/current/naics4_621100.htm.*

TABLE 4A—YEAR 1 ESTIMATED COSTS FOR PHYSICIANS AND TEACHING HOSPITALS

	Estimated number of entities reviewing	Estimated hours for review	Hourly rate	Average total cost per entity	Total cost
Physicians	224,425	1.00	$137	$137	$30,746,225
Physicians Support staffs	224,425	5.00	22	109	24,406,219
Compliance officer, Teaching Hospitals	1,100	40.00	44	1,752	1,927,640
Administrative supporting staffs in teaching Hospitals	1,100	80.00	22	1,726	1,898,160
Total					58,978,244

TABLE 4B—YEAR 2 AND SUBSEQUENT YEAR ESTIMATED COSTS FOR PHYSICIANS AND TEACHING HOSPITALS

[Annual]

	Estimated number of entities reviewing	Estimated hours for review	Hourly rate	Average total cost per entity	Total cost
Physicians	168,319	0.75	$137	$103	$17,294,751
Physicians Support staffs	168,319	3.75	22	82	13,728,498
Compliance officer, Teaching Hospitals	1,100	30.00	44	1,314	1,445,730
Administrative supporting staffs in teaching Hospitals	1,100	60.00	22	1,294	1,423,620
Total					33,892,600

For purposes of analysis, we also include estimates of the infrastructure costs for physicians and teaching hospitals, which may need to purchase and maintain equipment for internal tracking purposes. We assume that the combined infrastructure and maintenance costs for teaching hospitals will be the same as those for GPOs. For physicians, we assume a total cost of $2 million in the first year, and 10 percent thereafter.

TABLE 5A—YEAR 1 ESTIMATED INFRASTRUCTURE COSTS FOR PHYSICIANS AND TEACHING HOSPITALS

	Number	Annual cost	Total cost
Physicians	224,425		$2,000,000
Teaching Hospitals	1,100	2,000	2,200,000
Total			4,200,000

TABLE 5B—YEAR 2 AND SUBSEQUENT YEAR ESTIMATED INFRASTRUCTURE COSTS FOR PHYSICIANS AND TEACHING HOSPITALS

	Number	Annual cost	Total cost
Physicians	168,319		$200,000
Teaching Hospitals	1,100	$200	220,000
Total			420,000

3. Effects of Third Parties

We also received some comments on including estimates for entities that were not included in the proposed rule. We have provided the comment, as well as our response.

Comment: Many commenters suggested that the costs of recordkeeping for third parties, such as contract research organizations or professional associations that receive indirect payments or other transfers of value, should be included in the cost estimation.

Response: In the final rule, we have clarified the requirements for third parties which received payments at the request of, or on behalf of, covered recipients (§ 403.904(c)(10)), as well as the requirements for third parties which receive and make indirect payments to covered recipients (§ 403.904(i)(1)). We believe these revisions will help clarify and minimize any reporting requirements that third parties viewed as burdensome to them, but we maintain that the requirements in section 1128G of the Act do not impose significant burden on third parties, since they are neither required to report nor review. However, we recognize that some business models may require third parties to report recipients of payments back to applicable manufacturers, so we have included in the final rule estimates on the burden for third parties. We estimate that 58 third parties will incur costs under this final rule. We assume that there will be significantly fewer third parties than applicable manufacturers affected by these provisions, so we reduced the number of applicable manufacturers by 95 percent to obtain the number of third

parties as 5 percent the number of applicable manufacturers. Given the range of entities that could be third parties, we believe it is difficult to estimate the hourly rate for these entities. We assume that the role will be similar to that of compliance officers in applicable manufacturers and applicable GPOs, since it may require them to track similar relationships. Therefore, we estimate the hourly rate for third parties will be $47.55 ($35.75, plus a 33 percent increase for fringe benefits), which is the same hourly rate described in section IV.C.1. the final rule for a compliance officer at an applicable manufacturer or applicable GPO. As described, we do not believe these requirements set significant burden on third parties, since they are neither required to report nor review. We estimate that third parties may need to spend 40 hours in year 1 on tasks that are associated with the reporting requirements. Similarly to other estimates, we decreased this estimate by 25 percent in year 2 (for a total of 30 hours) to account for increased familiarity with the systems. In total, third parties will dedicate 2,320 hours in year 1 and 1,740 hours in year 2 with a total cost of $110,316 in year 1 and $82,737 in year 2.

In summary, the first year and subsequent year annual costs are presented in the following tables.

TABLE 6A—TOTAL YEAR 1 ESTIMATED COSTS

	Labor costs ($)	Infrastructure costs ($)	Total cost ($)
Applicable Manufacturers	183,119,560	11,500,000	194,619,560
Applicable GPOs	9,917,544	840,000	10,757,544
Third-Parties	110,316	.....	110,316
Physicians	55,152,444	2,000,000	57,152,444
Teaching Hospitals	3,825,800	2,200,000	6,025,800
Total	252,125,664	16,540,000	268,665,664

TABLE 6B—TOTAL COSTS, YEAR 2, AND SUBSEQUENT YEARS

[Annual]

	Labor costs ($)	Infrastructure costs ($)	Total cost ($)
Applicable Manufacturers	137,339,670	1,150,000	138,489,670
Applicable GPOs	7,438,158	84,000	7,522,158
Third-Party Recordkeeping	82,737	.....	82,737
Physicians	31,023,250	200,000	31,223,250
Teaching Hospitals	2,869,350	220,000	3,089,350
Total	178,753,165	1,654,000	180,407,165

4. Effects on the Medicare, Medicaid, and CHIP

Although the Department proposes to administer this program through the CMS, the final rule would have no direct effects on the Medicare, Medicaid, and CHIP. Reporting is required for physicians and teaching hospitals regardless of their association with Medicare, Medicaid, or CHIP. Manufacturers are identified by whether the company has a product eligible for payment by Medicare, Medicaid or CHIP, but this does not affect whether or not the product may be covered under titles XVIII, XIX, or XXI of the Act. We will incur some costs in administering the program. However, as required by statute, we will be able to use any funds collected from the CMPs assessed under this rule to support the program, decreasing the agency funding required.

5. Benefits

We outlined numerous benefits in the proposed rule and received numerous comments supporting these benefits. We appreciate these comments. Collaboration among physicians, teaching hospitals, and industry manufacturers can contribute to the design and delivery of life-saving drugs and devices. While collaboration is beneficial to the continued innovation and improvement of our health care system, some payments from manufacturers to physicians and teaching hospitals can introduce conflicts of interests that may influence research, education, and clinical decision-making in ways that compromise clinical integrity and patient care, and lead to increased program costs. It is important to understand the extent and nature of relationships between physicians, teaching hospitals, and industry manufacturers through increased transparency, and to permit patients to make better informed decisions when choosing health care professionals and making treatment decisions. Additionally, it is important to develop a system that encourages constructive collaboration, while also discouraging relationships that threaten the underlying integrity of the health care system.

Both the Institute of Medicine and other experts, such as MedPAC, have noted the recent increases in both the amount and scope of industry involvement in medical research, education, and clinical practice has led to considerable scrutiny and recommended enhanced disclosure and transparency to discourage the inappropriate use of financial incentives and lessen the risk of such incentives interfering with medical judgment and patient care. We recognize that disclosure is not sufficient to differentiate beneficial, legitimate financial relationships from those that create a conflict of interest or are otherwise improper. However, transparency can shed light on the nature and extent of relationships, and

discourage inappropriate conflicts of interest.[9]

We have no empirical basis for estimating the frequency of such problems, the likelihood that transparent reporting will reduce them, or the likely resulting effects on reducing the costs of medical care. Although a few States do have similar reporting requirements, determining the benefits based on their experiences is difficult. Transparency does not identify which relationships are conflicts of interests or whether public reporting dissuaded a relationship from forming, making it difficult to assess the benefits of public reporting. We plan to continue considering methods to use the data collected to identify any changes in these relationships as a result of public reporting. However, we observe, that the costs for preparing reports are small in relation to the size of the affected industry sectors.

Finally, section 1128G(d)(3) of the Act preempts State laws requiring the reporting of the same type of information as required by section 1128G(a) of the Act. Applicable manufacturers and applicable GPOs subject to State requirements would not have to comply with multiple State requirements, and instead would only have to comply with a single Federal requirement with regard to the types of information required to be reported under 1128G(a) of the Act. This benefits applicable manufacturers and applicable GPOs by allowing them to comply with a single set of reporting requirements for this information, lessening the potential for multiple, conflicting State requirements. This benefit may also lead to potential cost-savings, since a single reporting system for reporting this information is less burdensome than multiple programs.

D. Alternatives Considered

Reporting under section 1128G of the Act is required by law, which limits the other policy options available. Section 1128G of the Act encourages transparency of financial relationships between physicians and teaching hospitals, and the pharmaceutical and device industry. Although, many of these relationships are beneficial, close relationships between manufacturers and prescribing providers can lead to conflicts of interests that may affect clinical decision-making. Increased transparency of these relationships tries to discourage inappropriate relationships, while maintaining the beneficial relationships. Public reporting and publication is the only statutorily permissible option for obtaining this transparency and achieving the intentions of this provision. In developing this final rule, we tried to minimize the burden on reporting entities by trying to simplify the reporting requirements as much as possible within the statutory requirements and in response to public comment.

The statute is prescriptive as to the types of information required to be reported, and the ways in which it is required to be reported; however wherever possible we tried to allow flexibility in the reporting requirements. For example, we note the following:

- We did not require the submission of an assumptions document for nature of payment categories, but allow applicable manufacturers and applicable GPOs to submit this voluntarily.
- The Secretary is allowed discretion to require the reporting of additional information, but we tried to use this discretion as sparingly as possible, in large part because of the strong desire expressed by stakeholders that we not expand reporting categories. For example, we considered asking applicable manufacturers and applicable GPOs to report the method of preferred communication and email address for physicians and teaching hospitals with which they have relationships, but based on the comments that this would be burdensome, we did not finalize it. In order to reduce the burden further, we could have not added any additional reporting categories (such as requiring State professional license number or NDC (if any)); however, we believe that all the additional reporting elements are necessary for the successful administration of the program and have tried to provide sufficient explanation of each decision.
- We limited the definition of covered drug, device, biological, and medical supply to reduce the number of entities meeting the definition of applicable manufacturer and applicable GPO. We proposed limiting covered drugs and biologicals to those that require a prescription to be dispensed and limiting covered devices (including medical supplies that are devices) to those that require premarket approval by or notification to the FDA. The comments strongly supported these limitations, so we have finalized them in the final rule.
- In the proposed rule, we defined "common ownership" as covering any ownership portion of two or more entities, but are finalizing an alternate interpretation that would limit the common ownership definition to circumstances where the same individual, individuals, entity, or entities own 5 percent or more of total ownership in two or more entities. Additionally, we provided further guidance on the phrase "assistance and support" in order to limit the number of entities under common ownership reporting. We could have employed a higher threshold of common ownership to further lower the burden; however, as explained in section II.B.1.a.(3). of this final rule, we believe that 5 percent is a standard threshold.
- In the proposed rule, we considered whether we should require that applicable manufacturers report another unique identifier, such as State license number, for physicians who are identified but do not have an NPI. Such an approach would provide additional information by which to cross-reference physicians who do not have an NPI, but the approach could also cause confusion if the additional information is not captured in a consistent manner. We received numerous comments on this provision and finalized the reporting of State professional license number for all physician covered recipients. The comments and rationale for this decision is discussed in section II.B.1.d.(1) of the preamble to this final rule.
- The Congress gave the Secretary authority to define a GPO and also specified that such organizations would include organizations that purchase covered drugs, devices, biologicals, and medical supplies, as well as organizations that arrange for or negotiate the purchase of covered drugs, devices, biologicals, and medical supplies. Therefore, we interpret the statute to encompass entities that purchase covered drugs, devices, biological, and medical supplies for resale or distribution to groups of individuals or entities. This would include physician owned distributors (PODs) of covered drugs, devices, biological, and medical supplies. We received numerous comments on this proposal and finalized the definition as proposed (see section II.B.2.a.(2). of the preamble of this final rule).
- We also finalized limitations that will reduce the reporting requirements for applicable manufacturers that only manufacture a few covered products. Applicable manufacturers with less than 10 percent of revenues from covered products do not need to report all payments or other transfers of value as proposed. This will greatly reduce the

[9] Information on the IOM recommendations may be found here: *http://www.iom.edu/Reports/2009/Conflict-of-Interest-in-Medical-Research-Education-and-Practice.aspx.*

burden of reporting for these entities, allowing them greater flexibility. We could have lowered the burden by including additional limitations to reporting by certain applicable manufacturers, but believe that the statute did not provide much flexibility to do so.

• We have finalized, as required by statute, a 45-day review period during which applicable manufacturers and GPOs, covered recipients, and physician owners or investors can review the data before it is made available to the public. In response to the comments, we have considered the best methods to administer this review, as well as any dispute resolution processes. We have finalized a dispute resolution system which will allow covered recipients and physician owners or investors to more easily review the information submitted on their behalf and a more streamline process to initiate disputes, as necessary.

Finally, it is important to evaluate and monitor if the changes reflected in this rule achieve the goal of improving transparency and accountability between health care providers and drug manufacturers. We will evaluate over time, and encourage others to evaluate, the effects of this rule on Medicaid enrollment, on Federal, State, and enrollee costs, and on health outcomes.

E. Accounting Statement

The Office of Management and Budget, in Circular A–4, requires an accounting Statement for rules with significant economic impacts. The table that follows shows the estimated costs annualized over a 10-year period. The estimated costs are $269 million in year 1 and $180 million in year 2. We assume that future outlay costs may be similar to those costs experienced in year 2. We envision that the number of financial relationships required to be reported will remain similar, so the cost of reporting the information will not change significantly.

TABLE 7—ACCOUNTING STATEMENT

Category	Primary estimate	Year dollars	Discount rate (percent)	Period covered
Annualized Monetized Costs	$192	2011	7	2013–2022
	190	2011	3	2013–2022
Benefits	Public reporting of the extent and nature of relationships between physicians, teaching hospitals, and industry manufacturers through increased transparency will permit patients to make better informed decisions when choosing health care professionals and making treatment decisions, and deter inappropriate financial relationships.			

F. Conclusions

Section 1128G of the Act requires applicable manufacturers to report annually to CMS certain payments or transfers of value provided to physicians or teaching hospitals. In addition, applicable GPOs are required to report annually certain physician ownership interests. We estimate that the impact of these reporting requirements will be about $269 million for the first year of reporting, and $180 million for the second year and annually thereafter. As we have indicated throughout, these are rough estimates and subject to considerable uncertainty. Better estimates might well be 25 percent higher or lower. Nonetheless, we believe that the public comment period offers an excellent opportunity for all stakeholders to consider alternatives and to present quantitative or qualitative information that will enable us to both improve the effectiveness and lower the costs of the final rule. Therefore, we solicited comment on the analysis and assumptions provided throughout this preamble and in the alternatives section of the regulatory impact analysis in particular.

Many of the comments received discuss our assumptions for the costs of collecting this information. Because this rule involves the collection of data, the vast majority of the financial impact is included in the collection of information requirements. Therefore earlier in the preamble of this final rule, we summarize and respond to the comments regarding our cost assumptions.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 402

Administrative practice and procedure, Medicaid, Medicare, Penalties.

42 CFR Part 403

Grant programs-health, Health insurance, Hospitals, Intergovernmental relations, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 402—CIVIL MONEY PENALTIES, ASSESSMENTS, AND EXCLUSIONS

Subpart A—General Provisions

■ 1. The authority citation for part 402 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 2. Section 402.1 is amended as follows:

■ A. In paragraph (c) introductory text, by removing the reference "(c)(33)" and adding the reference "(c)(34)" in its place.

■ B. Adding a new paragraph (c)(34).

The addition reads as follows:

§ 402.1 Basis and scope.

* * * * *

(c) * * *

(34) Section 1128G (b) (1) and (2)– Any applicable manufacturer or applicable group purchasing organization that fails to timely, accurately, or completely report a payment or other transfer of value or an ownership or investment interest to CMS, as required under part 403, subpart I, of this chapter.

* * * * *

■ 3. Section 402.105 is amended as follows:

■ A. In paragraph (a), by removing the reference to "paragraphs (b) through (g)" and adding the reference "paragraphs (b) through (h)" in its place.

■ B. Adding paragraphs (d)(5) and (h).

The additions read as follows:

§ 402.105 Amount of penalty.

* * * * *

(d) * * *

(5) CMS or OIG may impose a penalty of not more than $10,000 for each failure of an applicable manufacturer or an applicable group purchasing organization to report timely, accurately, or completely a payment or other transfer of value or an ownership or investment interest (§ 402.1(c)(34)). The total penalty imposed with respect to failures to report in an annual submission of information will not exceed $150,000.

* * * * *

(h) *$100,000.* CMS or OIG may impose a penalty of not more than $100,000 for each knowing failure of an applicable manufacturer or an applicable group purchasing organization to report timely, accurately or completely a payment or other transfer of value or an ownership or investment interest (§ 402.1(c)(34)). The total penalty imposed with respect to knowing failures to report in an annual submission of information will not exceed $1,000,000.

PART 403—SPECIAL PROGRAMS AND PROJECTS

■ 4. The authority citation for part 403 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 5. A new subpart I is added to part 403 to read as follows:

Subpart I—Transparency Reports and Reporting of Physician Ownership or Investment Interests

Sec.

Subpart I—Transparency Reports and Reporting of Physician Ownership or Investment Interests

§ 403.900 Purpose and scope.

The regulations in this subpart implement section 1128G of the Act. These regulations apply to applicable manufacturers and applicable group purchasing organizations and describe the requirements and procedures for applicable manufacturers to report payments or other transfers of value provided to covered recipients, as well as for applicable manufacturers and applicable group purchasing organizations to report ownership or investment interests held by physicians or immediate family members of physicians in such entities.

§ 403.902 Definitions.

For purposes of this subpart, the following definitions apply:

Applicable group purchasing organization means an entity that:

(1) Operates in the United States; and

(2) Purchases, arranges for or negotiates the purchase of a covered drug, device, biological, or medical supply for a group of individuals or entities, but not solely for use by the entity itself.

Applicable manufacturer means an entity that is operating in the United States and that falls within one of the following categories:

(1) An entity that is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply, but not if such covered drug, device, biological or medical supply is solely for use by or within the entity itself or by the entity's own patients. This definition does not include distributors or wholesalers (including, but not limited to, repackagers, relabelers, and kit assemblers) that do not hold title to any covered drug, device, biological or medical supply.

(2) An entity under common ownership with an entity in paragraph (1) of this definition, which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological or medical supply.

Assistance and support means providing a service or services that are necessary or integral to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological or medical supply.

Charitable contribution includes, but is not limited to, any payment or transfer of value made to an organization with tax-exempt status under the Internal Revenue Code of 1986, which is not provided in exchange for any goods, items or services.

Charity care means services provided by a covered recipient specifically for a patient who is unable to pay for such services or for whom payment would be a significant hardship, where the covered recipient neither receives, nor expects to receive, payment because of the patient's inability to pay.

Clinical investigation means any experiment involving one or more human subjects, or materials derived from human subjects, in which a drug, device, biological or medical supply is administered, dispensed or used.

Common ownership refers to circumstances where the same individual, individuals, entity, or entities directly or indirectly own 5 percent or more total ownership of two entities. This includes, but is not limited to, parent corporations, direct and indirect subsidiaries, and brother or sister corporations.

Covered device means any device for which payment is available under Title XVIII of the Act or under a State plan under Title XIX or XXI of the Act (or a waiver of such plan), either separately (such as through a fee schedule) or as part of a bundled payment (for example, under the hospital inpatient prospective payment system or the hospital outpatient prospective payment system) and which is of the type that, by law, requires premarket approval by or premarket notification to the Food and Drug Administration (FDA).

Covered drug, device, biological, or medical supply means any drug, device, biological, or medical supply for which payment is available under Title XVIII of the Act or under a State plan under Title XIX or XXI of the Act (or a waiver of such plan), either separately (such as through a fee schedule or formulary) or as part of a bundled payment (for example, under the hospital inpatient prospective payment system or the hospital outpatient prospective payment system) and which is of the type that in the case of a—

(1) Drug or biological, by law, requires a prescription to be dispensed; or

(2) Device (including a medical supply that is a device), by law, requires premarket approval by or premarket notification to the FDA.

Covered recipient means— (1) Any physician, except for a physician who is a bona fide employee of the applicable manufacturer that is reporting the payment; or

(2) A teaching hospital, which is any institution that received a payment under 1886(d)(5)(B), 1886(h), or 1886(s) of the Act during the last calendar year for which such information is available.

Employee means an individual who is considered to be "employed by" or an "employee" of an entity if the individual would be considered to be an employee of the entity under the usual common law rules applicable in determining the employer-employee relationship (as applied for purposes of

section 3121(d)(2) of the Internal Revenue Code of 1986).

Immediate family member means any of the following:

(1) Spouse.

(2) Natural or adoptive parent, child, or sibling.

(3) Stepparent, stepchild, stepbrother, or stepsister.

(4) Father-, mother-, daughter-, son-, brother-, or sister-in-law.

(5) Grandparent or grandchild.

(6) Spouse of a grandparent or grandchild.

Indirect payments or other transfers of value refer to payments or other transfers of value made by an applicable manufacturer (or an applicable group purchasing organization) to a covered recipient (or a physician owner or investor) through a third party, where the applicable manufacturer (or applicable group purchasing organization) requires, instructs, directs, or otherwise causes the third party to provide the payment or transfer of value, in whole or in part, to a covered recipient(s) (or a physician owner or investor).

Know, knowing, or knowingly—(1) Means that a person, with respect to information—

(i) Has actual knowledge of the information;

(ii) Acts in deliberate ignorance of the truth or falsity of the information; or

(iii) Acts in reckless disregard of the truth or falsity of the information; and

(2) Requires no proof of a specific intent to defraud.

NPPES stands for the National Plan & Provider Enumeration System.

Operating in the United States means that an entity—

(1) Has a physical location within the United States or in a territory, possession, or commonwealth of the United States; or

(2) Otherwise conducts activities within the United States or in a territory, possession, or commonwealth of the United States, either directly or through a legally-authorized agent.

Ownership or investment interest—(1) Includes, but is not limited to the following:

(i) Stock, stock option(s) (other than those received as compensation, until they are exercised).

(ii) Partnership share(s);

(iii) Limited liability company membership(s).

(iv) Loans, bonds, or other financial instruments that are secured with an entity's property or revenue or a portion of that property or revenue.

(2) May be direct or indirect and through debt, equity or other means.

(3) *Exceptions.* The following are not ownership or investment interests for the purposes of this section:

(i) An ownership or investment interest in a publicly traded security or mutual fund, as described in section 1877(c) of the Act.

(ii) An interest in an applicable manufacturer or applicable group purchasing organization that arises from a retirement plan offered by the applicable manufacturer or applicable group purchasing organization to the physician (or a member of his or her immediate family) through the physician's (or immediate family member's) employment with that applicable manufacturer or applicable group purchasing organization.

(iii) Stock options and convertible securities received as compensation, until the stock options are exercised or the convertible securities are converted to equity.

(iv) An unsecured loan subordinated to a credit facility.

(v) An ownership or investment interest if an applicable manufacturer or applicable group purchasing organization did not know, as defined in this section, about such ownership or investment interest.

Payment or other transfer of value means a transfer of anything of value.

Physician has the same meaning given that term in section 1861(r) of the Act.

Related to a covered drug, device, biological, or medical supply means that a payment or other transfer of value is made in reference to or in connection with one or more covered drugs, devices, biologicals, or medical supplies.

Research includes a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. This term encompasses basic and applied research and product development.

Third party means another individual or entity, regardless of whether such individual or entity is operating in the United States.

§ 403.904 Reports of payments or other transfers of value to covered recipients.

(a) *General rule.* (1) Direct and indirect payments or other transfers of value provided by an applicable manufacturer to a covered recipient during the preceding calendar year, and direct and indirect payments or other transfers of value provided to a third party at the request of or designated by the applicable manufacturer on behalf of a covered recipient during the preceding calendar year, must be reported by the applicable manufacturer to CMS on an annual basis.

(2) For CY 2013, only payments or other transfers of value made on or after August 1, 2013 must be reported to CMS.

(b) *Limitations.* Certain limitations on reporting apply in the following circumstances:

(1) Applicable manufacturers for whom total (gross) revenues from covered drugs, devices, biologicals, or medical supplies constituted less than 10 percent of total (gross) revenue during the fiscal year preceding the reporting year are only required to report payments or other transfers of value that are related to one or more covered drugs, devices, biologicals or medical supplies.

(2) Applicable manufacturers under paragraph (2) of the definition in § 403.902 are only required to report payments or other transfers of value that are related to a covered drug, device, biological, or medical supply for which they provided assistance or support to an applicable manufacturer under paragraph (1) of the definition.

(3) Applicable manufacturers under either paragraph (1) or (2) of the definition in § 403.902 that have separate operating divisions that do not manufacture any covered drugs, devices, biologicals, or medical supplies (for example, animal health divisions) are only required to report payments to covered recipients related to the activities of these separate divisions if those payments or other transfers of value are related to a covered drug, device, biological, or medical supply. This includes reporting of payments or other transfers of value that are related to covered drugs, devices, biologicals, or medical supplies made by applicable manufacturers to covered recipients through these operating divisions.

(4) Applicable manufacturers that do not manufacture a covered drug, device, biological, or medical supply except when under a written agreement to manufacture the covered drug, device, biological, or medical supply for another entity, do not hold the FDA approval, licensure, or clearance for the covered drug, device, biological, or medical supply, and are not involved in the sale, marketing, or distribution of the product, are only required to report payments or other transfers of value that are related to one or more covered drugs, devices, biologicals, or medical supplies.

(c) *Required information to report.* A report must contain all of the following information for each payment or other transfer of value:

(1) *Name of the covered recipient.* For physician covered recipients, the name must be as listed in the National Plan & Provider Enumeration System (if applicable) and include first and last name, middle initial, and suffix (for all that apply).

(2) *Address of the covered recipient.* Primary business address of the covered recipient, including all the following:

(i) Street address.

(ii) Suite or office number (if applicable).

(iii) City.

(iv) State.

(v) ZIP code.

(3) *Identifiers for physician covered recipients.* In the case of a covered recipient who is a physician, the following identifiers:

(i) The specialty.

(ii) National Provider Identifier (if applicable and as listed in the NPPES). If a National Provider Identifier cannot be identified for a physician, the field may be left blank, indicating that the applicable manufacturer could not find one.

(iii) State professional license number(s) (for at least one State where the physician maintains a license), and the State(s) in which the license is held.

(4) *Amount of payment or other transfer of value.* A payment or other transfer of value made to a group of covered recipients should be distributed appropriately among the individual covered recipients who requested the payment, on whose behalf the payment was made, or who are intended to benefit from the payment or other transfer of value.

(5) *Date of payment or transfer of value.* The date of each payment or other transfer of value.

(i) For payments or other transfers of value made over multiple dates (rather than as a lump sum), applicable manufacturers may choose whether to report each payment or other transfer of value as separate line item using the dates the payments or other transfers of value were each made, or as a single line item for the total payment or other transfer of value using the first payment date as the reported date.

(ii) For small payments or other transfers of value reported as a single line item, applicable manufacturers must report the date that the first bundled small payment or other transfer of value was provided to the covered recipient.

(6) *Form of payment or transfer of value.* The form of each payment or other transfer of value, as described in paragraph (d) of this section.

(7) *Nature of payment or transfer of value.* The nature of each payment or other transfer of value, as described in paragraph (e) of this section.

(8) *Related covered drug, device, biological or medical supply.* The name(s) of the related covered drugs, devices, biologicals, or medical supplies, unless the payment or other transfer of value is not related to a particular covered drug, device, biological or medical supply. Applicable manufacturers may report up to five covered drugs, devices, biologicals or medical supplies related to each payment or other transfer of value. If the payment or other transfer of value was related to more than five covered drugs, devices, biologicals, or medical supplies, the applicable manufacturer should report the five covered drugs, devices, biologicals, or medical supplies that were most closely related to the payment or other transfer of value.

(i) For drugs and biologicals, applicable manufacturers must report the name under which the drug or biological is or was marketed and the relevant National Drug Code(s), if any. If the marketed name has not yet been selected, the applicable manufacturer must indicate the name registered on clinicaltrials.gov.

(ii) For devices and medical supplies, applicable manufacturers must report at least one of the following:

(A) The name under which the device or medical supply is or was marketed.

(B) The therapeutic area or product category for the device or medical supply.

(iii) If the payment or other transfer of value is not related to a covered drug, device, biological or medical supply, but is related to a specific non-covered product, applicable manufacturers must indicate "non-covered product."

(iv) If the payment or other transfer of value is not related to any drug, device, biological, or medical supply (covered or not), applicable manufacturers must indicate "none."

(v) If the payment or other transfer of value is related to at least one covered drug, device, biological, and medical supply and at least one non-covered drug, device, biological, or medical supply, applicable manufacturers must report the name(s) of the covered drug, device, biological or medical supply (as required by paragraphs (c)(8)(i) and (ii) of this section) and may indicate "non-covered products" in addition.

(9) *Eligibility for delayed publication.* Applicable manufacturers must indicate whether a payment or other transfer of value is eligible for delayed publication, as described in § 403.910.

(10) *Payments to third parties.* (i) If the payment or other transfer of value was provided to a third party at the request of or designated on behalf of a covered recipient, the payment or transfer of value must be reported in the name of that covered recipient.

(ii) If the payment or other transfer of value was provided to a third party at the request of or designated on behalf of a covered recipient, the name of the entity that received the payment or other transfer of value (if made to an entity) or indicate "individual" (if made to an individual). If a covered recipient performed a service, but neither accepted the offered payment or other transfer of value nor requested that it be made to a third party, the applicable manufacturer is not required to report the offered payment or other transfer of value unless the applicable manufacturer nonetheless provided it to a third party and designated such payment or other transfer of value as having been provided on behalf of the covered recipient.

(11) *Payments or transfers of value to physician owners or investors.* Must indicate whether the payment or other transfer of value was provided to a physician or the immediate family of the physician who holds an ownership or investment interest (as defined § 403.902) in the applicable manufacturer.

(12) *Additional information or context for payment or transfer of value.* May provide a statement with additional context for the payment or other transfer of value.

(d) *Reporting the form of payment or other transfer of value.* An applicable manufacturer must report each payment or transfer of value, or separable part of that payment or transfer of value, as taking one of the following forms of payment that best describes the form of the payment or other transfer of value, or separable part of that payment or other transfer of value.

(1) Cash or cash equivalent.

(2) In-kind items or services.

(3) Stock, stock option, or any other ownership interest.

(4) Dividend, profit or other return on investment.

(e) *Reporting the nature of the payment or other transfer of value.* (1) *General rule.* The categories describing the nature of a payment or other transfer of value are mutually exclusive for the purposes of reporting under subpart I of this part.

(2) *Rules for categorizing natures of payment.* An applicable manufacturer must categorize each payment or other transfer of value, or separable part of that payment or transfer of value, with one of the categories listed in paragraphs (e)(2)(i) through (xvii) of this

section, using the designation that best describes the nature of the payment or other transfer of value, or separable part of that payment or other transfer of value. If a payment or other transfer of value could reasonably be considered as falling within more than one category, the applicable manufacturer should select one category that it deems to most accurately describe the nature of the payment or transfer of value.

(i) Consulting fee.

(ii) Compensation for services other than consulting, including serving as faculty or as a speaker at an event other than a continuing education program.

(iii) Honoraria.

(iv) Gift.

(v) Entertainment.

(vi) Food and beverage.

(vii) Travel and lodging (including the specified destinations).

(viii) Education.

(ix) Research.

(x) Charitable contribution.

(xii) Royalty or license.

(xiii) Current or prospective ownership or investment interest.

(xiv) Compensation for serving as faculty or as a speaker for an unaccredited and non-certified continuing education program.

(xv) Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program.

(xvi) Grant.

(xvii) Space rental or facility fees (teaching hospital only).

(f) *Special rules for research payments.* All payments or other transfers of value made in connection with an activity that meets the definition of research in this section and that are subject to a written agreement, a research protocol, or both, must be reported under these special rules.

(1) Research-related payments or other transfers of value to covered recipients (either physicians or teaching hospitals), including research-related payments or other transfers of value made indirectly to a covered recipient through a third party, must be reported to CMS separately from other payments or transfers of value, and must include the following information (in lieu of the information required by § 403.904(c)):

(i) Name of the research institution, individual or entity receiving the payment or other transfer of value.

(A) If paid to a physician covered recipient, all of the following must be provided:

(*1*) The physician's name as listed in the NPPES (if applicable).

(*2*) National Provider Identifier.

(*3*) State professional license number(s) (for at least one State where the physician maintains a license) and State(s) in which the license is held.

(*4*) Specialty.

(*5*) Primary business address of the physician(s).

(B) If paid to a teaching hospital covered recipient, list the name and primary business address of teaching hospital.

(C) If paid to a non-covered recipient (such as a non-teaching hospital or clinic), list the name and primary business address of the entity.

(ii) Total amount of the research payment, including all research-related costs for activities outlined in a written agreement, research protocol, or both.

(iii) Name of the research study.

(iv) Name(s) of any related covered drugs, devices, biologicals, or medical supplies (subject to the requirements specified in paragraph (c)(8) of this section) and for drugs and biologicals, the relevant National Drug Code(s), if any.

(v) Information about each physician covered recipient principal investigator (if applicable) set forth in paragraph (f)(1)(i)(A) of this section.

(vi) Contextual information for research (optional).

(vii) ClinicalTrials.gov identifier (optional).

(2) For pre-clinical studies (before any human studies have begun), only report the following information:

(i) Research entity name (as required in paragraph (f)(1)(i) of this section).

(ii) Total amount of payment (as required in paragraph (f)(1)(ii) of this section).

(ii) Principal investigator(s) (as required in paragraph (f)(1)(v) of this section).

(g) *Special rules for payments or other transfers of value related to continuing education programs.* (1) Payments or other transfers of value provided as compensation for speaking at a continuing education program are not required to be reported, if all of the following conditions are met:

(i) The event at which the covered recipient is speaking meets the accreditation or certification requirements and standards for continuing education of one of the following:

(A) The Accreditation Council for Continuing Medical Education.

(B) The American Academy of Family Physicians.

(C) The American Dental Association's Continuing Education Recognition Program.

(D) The American Medical Association.

(E) The American Osteopathic Association.

(ii) The applicable manufacturer does not pay the covered recipient speaker directly.

(iii) The applicable manufacturer does not select the covered recipient speaker or provide the third party (such as a continuing education vendor) with a distinct, identifiable set of individuals to be considered as speakers for the continuing education program.

(2) Payments or other transfers of value that do not meet all of the requirements in paragraph (g)(1) must be reported as required by this section.

(i) Payments or other transfers of value that meet the requirements in paragraph (g)(1)(i) of this section, but not also (g)(1)(ii) or (g)(1)(iii) of this section or both, must be reported under the nature of payment category "Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program."

(ii) Payments or other transfers of value that do not meet the requirements in paragraph (g)(1)(i) of this section should be reported under the nature of payment category "Compensation for serving as a faculty or as a speaker for a unaccredited and non-certified continuing education program."

(iii) Payments or other transfers of value for speaking engagements not related to medical education should be reported under the nature of payment category "Compensation for services other than consulting, including serving as a speaker at an event other than a continuing education program."

(h) *Special rules for reporting food and beverage.* (1) When allocating the cost of food and beverage among covered recipients in a group setting where the cost of each individual covered recipient's meal is not separately identifiable, such as a platter provided to physicians in a group practice setting, applicable manufacturers must calculate the value per person by dividing the entire cost of the food or beverage by the total number of individuals who partook in the meal (including both covered recipients and non-covered recipients, such as office staff). The per person value of the meal must be reported as a payment or other transfer of value only for covered recipients who actually partook in the food or beverage.

(2) Applicable manufacturers are not required to report or track buffet meals, snacks, soft drinks, or coffee made generally available to all participants of a large-scale conference or similar large-scale event.

(i) *Exclusions from reporting.* The following are excluded from the

reporting requirements specified in this section:

(1) Indirect payments or other transfers of value (as defined in § 403.902), where the applicable manufacturer is unaware of the identity of the covered recipient. An applicable manufacturer is unaware of the identity of a covered recipient if the applicable manufacturer does not know (as defined in § 403.902) the identity of the covered recipient during the reporting year or by the end of the second quarter of the following reporting year.

(2)(i) For CY 2013, payments or other transfers of value less than $10, unless the aggregate amount transferred to, requested by, or designated on behalf of the covered recipient exceeds $100 in a calendar year.

(ii) For CY 2014 and subsequent calendar years, to determine if transfers of value are excluded under this section, the dollar amounts specified in paragraph (i)(2)(i) of this section must be increased by the same percentage as the percentage increase in the consumer price index for all urban consumers (all items; U.S. city average) for the 12-month period ending with June of the previous year. CMS will publish the values for the next reporting year 90 days before the beginning of the reporting year.

(iii) Payments or other transfers of value of less than $10 in CY 2013 (or less than the amount described in paragraph (i)(2)(ii) of this section for CY 2014 and subsequent calendar years) provided at large-scale conferences and similar large-scale events, as well as events open to the public, do not need to be reported nor included for purposes of the $100 aggregate threshold in CY 2013 (or the aggregate threshold calculated in accordance paragraph (i)(2)(ii) of this section for CY 2014 and subsequent calendar years), even if the aggregate total for a covered recipient exceeds the aggregate threshold for the calendar year.

(iv) When reporting payments or other transfers of value under the $10 threshold for CY 2013 (or under the amount described in paragraph (i)(2)(ii) of this section for CY 2014 and subsequent calendar years) for covered recipients that exceed the aggregate threshold for the reporting year, applicable manufacturers may (but are not required to) report all small payments to a particular covered recipient that fall within the same nature of payment category as a single payment or other transfer of value.

(3) Product samples, including coupons and vouchers that can be used by a patient to obtain samples, which are not intended to be sold and are intended for patient use.

(4) Educational materials and items that directly benefit patients or are intended to be used by or with patients, including the value of an applicable manufacturer's services to educate patients regarding a covered drug, device, biological, or medical supply.

(5) The loan of a covered device or a device under development, or the provision of a limited quantity of medical supplies for a short-term trial period, not to exceed a loan period of 90 days or a quantity of 90 days of average daily use, to permit evaluation of the device or medical supply by the covered recipient.

(6) Items or services provided under a contractual warranty (including service or maintenance agreements), whether or not the warranty period has expired, including the replacement of a covered device, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device.

(7) A transfer of anything of value to a physician covered recipient when the covered recipient is a patient, research subject or participant in data collection for research, and not acting in the professional capacity of a covered recipient.

(8) Discounts, including rebates.

(9) In-kind items used for the provision of charity care.

(10) A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security or mutual fund.

(11) In the case of an applicable manufacturer who offers a self-insured plan or directly reimburses for healthcare expenses, payments for the provision of health care to employees and their families.

(12) In the case of a covered recipient who is a licensed non-medical professional, a transfer of anything of value to the covered recipient if the transfer is payment solely for the non-medical professional services of the licensed non-medical professional.

(13) In the case of a covered recipient who is a physician, a transfer of anything of value to the covered recipient if the transfer is payment solely for the services of the covered recipient with respect to an administrative proceeding, legal defense, prosecution, or settlement or judgment of a civil or criminal action and arbitration.

(14) A payment or transfer of value to a covered recipient if the payment or transfer of value is made solely in the context of a personal, non-business-related relationship.

§ 403.906 Reports of physician ownership and investment interests.

(a) *General rule.* (1) Each applicable manufacturer and applicable group purchasing organization must report to CMS on an annual basis all ownership and investment interests in the applicable manufacturer or applicable group purchasing organization that were held by a physician or an immediate family member of a physician during the preceding calendar year.

(2) For CY 2013, only ownership or investment interests held on or after August 1, 2013 must be reported to CMS.

(b) *Identifying information.* Reports on physician ownership and investment interests must include the following identifying information:

(1) Name of the physician (as listed in the National Plan & Provider Enumeration System (if applicable), including first and last name, middle initial, and suffix (for all that apply), and an indication of whether the ownership or investment interest was held by the physician or an immediate family member of the physician.

(2) Primary business address of the physician, including the following:

(i) Street address.

(ii) Suite or office number (if applicable).

(iii) City.

(iv) State.

(v) ZIP code.

(3) The following information for the physician (regardless of whether the ownership or investment interest is held by an immediate family member of the physician):

(i) The specialty.

(ii) National Provider Identifier (if applicable and as listed in NPPES).

(iii) State professional license number(s) (for at least one State where the physician maintains a license), and the State(s) in which the license is held.

(4) Dollar amount invested by each physician or immediate family member of the physician.

(5) Value and terms of each ownership or investment interest.

(6) Direct and indirect payments or other transfers of value provided to a physician holding an ownership or investment interest, and direct and indirect payments or other transfers of value provided to a third party at the request of or designated by the applicable manufacturer or applicable group purchasing organization on behalf of a physician owner or investor, must be reported by the applicable manufacturer or applicable group purchasing organization in accordance with the requirements for reporting payments or other transfers of value in

§ 403.904(c) through (i). The terms "applicable manufacturer and applicable group purchasing organization" must be substituted for "applicable manufacturer," and "physician owner or investor" must be substituted for "covered recipient" in each place they appear.

§ 403.908 Procedures for electronic submission of reports.

(a) *File format.* Reports required under this subpart must be electronically submitted to CMS by March 31, 2014, and by the 90th day of each subsequent calendar year.

(b) *General rules.* (1) If an applicable manufacturer made no reportable payments or transfers of value in the previous calendar year, nor had any reportable ownership or investment interests held by a physician or a physician's immediate family member (as defined in § 403.902) during the previous calendar year, the applicable manufacturer is not required to file a report.

(2) If an applicable group purchasing organization had no reportable ownership or investment interests held by a physician or physician's immediate family member during the previous calendar year, the applicable group purchasing organization is not required to file a report.

(c) *Registration.* (1) Applicable manufacturers that have reportable payments or other transfers of value, ownership or investment interests, or both, are required to report under this subpart and must register with CMS within 90 days of the end of the calendar year for which a report is required.

(2) Applicable group purchasing organizations that have reportable ownership or investment interests are required to report under this subpart and must register with CMS within 90 days of the end of the calendar year for which a report is required.

(3) During registration, applicable manufacturers and applicable group purchasing organizations must name two points of contact with appropriate contact information.

(d) *Other rules.* (1) *Consolidated reports.* (i) An applicable manufacturer under paragraph (1) of the definition that is under common ownership with separate entities that are also applicable manufacturers under paragraph (1) of the definition may, but is not required to, file a consolidated report of all the payments or other transfers of value to covered recipients, and physician ownership or investment interests, for all of the entities.

(ii) An applicable manufacturer under paragraph (1) of the definition of applicable manufacturer and an entity (or entities) under common ownership with the applicable manufacturer under paragraph (2) of the definition of applicable manufacturer may, but are not required to, file a consolidated report of all the payments or other transfers of value to covered recipients, and physician ownership or investment interests.

(iii) If multiple applicable manufacturers (under paragraph (1) or (2) of the definition or both paragraphs of the definition) submit a consolidated report, the report must provide the names of each applicable manufacturer and entity (or entities) under common ownership that the report covers, and the report must identify the specific entity that provided each payment.

(iv) A single payment or other transfer of value reported in a consolidated report must only be reported once by one applicable manufacturer.

(v) The applicable manufacturer submitting a consolidated report on behalf of itself and other applicable manufacturers under common ownership, as permitted under this paragraph, is liable for civil monetary penalties imposed on each of the applicable manufacturers whose reportable payments or other transfers of value were included in the consolidated report, up to the annual maximum amount specified in § 403.912(c) for each individual applicable manufacturer included in the report.

(2) *Joint ventures.* If a payment or other transfer of value is provided in accordance with a joint venture or other cooperative agreement between two or more applicable manufacturers, the payment or other transfer of value must be reported—

(i) In the name of the applicable manufacturer that actually furnished the payment or other transfer of value to the covered recipient, unless the terms of a written agreement between the applicable manufacturers specifically require otherwise, so long as the agreement requires that all payments or other transfers of value in accordance with the arrangement are reported by one of the applicable manufacturers; and

(ii) Only once by one applicable manufacturer.

(e) *Attestation.* Each report, including any subsequent corrections to a filed report, must include an attestation by the Chief Executive Officer, Chief Financial Officer, Chief Compliance Officer, or other Officer of the applicable manufacturer or applicable group purchasing organization that the information reported is timely, accurate, and complete to the best of his or her knowledge and belief. For applicable manufacturers choosing to submit a consolidated report in accordance with paragraph (d)(1) of this section, the applicable manufacturer submitting the consolidated report must attest on behalf of itself, in addition to each of the other applicable manufacturers included in the consolidated report.

(f) *Assumptions document.* Applicable manufacturers and applicable group purchasing organizations may submit an assumptions document, explaining the reasonable assumptions made and methodologies used when reporting payments or other transfers of value, or ownership or investment interests. The assumptions documents will not be made available to covered recipients, physician owners or investors, or the public.

(g) *45-day review period for review and error correction.* (1) *General rule.* Applicable manufacturers, applicable group purchasing organizations, covered recipients, and physician owners or investors must have an opportunity to review and submit corrections to the information submitted for a period of not less than 45-days before CMS makes the information available to the public. In no case may this 45-day period for review and submission of corrections prevent the information from being made available to the public.

(2) *Notification.* CMS notifies the applicable manufacturers, applicable group purchasing organizations, covered recipients, and physician owners or investors when the reported information is ready for review.

(i) Applicable manufacturers and applicable group purchasing organizations are notified through the points of contact they identified during registration.

(ii) Physicians and teaching hospitals—

(A) Are notified using an online posting and notifications on CMS's listserves.

(B) May also register with CMS to receive notification about the review processes.

(iii) The 45-day review period begins on the date specified in the online notification.

(3) *Process.* (i) An applicable manufacturer, applicable group purchasing organization, covered recipient or a physician owner or investor may log into a secure Web site to view only the information reported specifically about itself.

(ii) Covered recipients and physician owners or investors are able to review

data submitted about them for the previous reporting year.

(iii) If the applicable manufacturer, applicable group purchasing organization, covered recipient, or physician owner or investor agrees with the information reported, the applicable manufacturer, applicable group purchasing organization, covered recipient, or physician owner or investor may electronically certify that the information reported is accurate.

(iv) If a covered recipient or physician owner or investor disagrees with the information reported, the covered recipient or physician owner or investor can initiate a dispute, which is sent to the appropriate applicable manufacturer or applicable group purchasing organization to be resolved between the parties.

(v) Covered recipients and physician owners or investors may initiate disputes at any time after the 45-day period begins, but before the end of the calendar year, but any changes resulting from disputes initiated outside the 45-day period, may not be made until the next time the data is refreshed.

(4) *Data disputes.* (i) In order to be corrected prior to the publication of the data, applicable manufacturers and applicable group purchasing organizations must notify CMS of resolved disputes and changes to the information submitted by no later than 15 days after the end of the 45-day period (that is, 60 days after the 45-day review period begins).

(ii) Disputes which are not resolved by 15 days after the end of the review and correction period, may still be resolved, but any changes resulting from the disputes may be made until the next time the data is refreshed.

(iii) If the dispute is not resolved by 15 days after the end of the 45-day review and correction period, CMS publicly reports and aggregates the applicable manufacturer's or applicable group purchasing organization's version of the payment or other transfer of value, or ownership or investment interest data, but marks the payment or other transfer of value or ownership or investment interest as disputed.

(h) *Errors or omissions.* (1) If an applicable manufacturer or applicable group purchasing organization discovers an error or omission in its annual report, it must submit corrected information to CMS immediately upon confirmation of the error or omission.

(2) Upon receipt, CMS notifies the affected covered recipient or physician owner or investor that the additional information has been submitted and is available for review. CMS updates the Web site at least once annually with corrected information.

§ 403.910 Delayed publication for payments made under product research or development agreements and clinical investigations.

(a) *General rule.* Certain research payments or other transfers of value made to a covered recipient by an applicable manufacturer under a product research or development agreement may be delayed from publication on the Web site. Publication of a payment or other transfer of value is delayed when made in connection with the following instances:

(1) Research on or development of a new drug, device, biological, or medical supply, or a new application of an existing drug, device, biological, or medical supply.

(2) Clinical investigations regarding a new drug, device, biological, or medical supply.

(b) *Research or development agreement.* The research or development agreement must include a written agreement, a research protocol, or both between the applicable manufacturer and covered recipient.

(c) *Date of publication.* Payments or other transfers of value eligible for delayed publication must be reported to CMS (in the manner required in § 403.904(f)) on the first reporting date following the year in which they occur, but CMS does not publicly post the payment until the first annual publication date after the earlier of the following:

(1) The date of the approval, licensure or clearance of the covered drug, device, biological, or medical supply by FDA.

(2) Four calendar years after the date the payment or other transfer of value was made.

(d) *Notification of delayed publication.* (1) An applicable manufacturer must indicate on its research report to CMS whether a payment or other transfer of value is eligible for a delay in publication. The absence of this indication in the report will result in CMS posting all payments publicly in the first year of public reporting.

(2) An applicable manufacturer must continue to indicate annually in its report that FDA approval, licensure, or clearance of the new drug, device, biological or medical supply to which the payment or other transfer of value is related, is pending.

(3) An applicable manufacturer must notify CMS during subsequent annual submissions, if the new drug, device, biological or medical supply, to which the payment is related (or the new application of the existing drug, device, biological, or medical supply), is approved by the FDA.

(4) Failure to notify CMS when FDA approval occurs may be considered failure to report, and the applicable manufacturer may be subject to civil monetary penalties.

(5) If, after 4 years from the date of a payment first appearing in a report to CMS, there is an indication in a report that the payment is subject to delayed reporting, it is reported regardless of the indication.

(e) *Confidentiality.* Information submitted and eligible for delayed publication is considered confidential and will not be subject to disclosure under 5 U.S.C. 552, or any similar Federal, State, or local law, until on or after the date on which the information made available to the public as required in this section.

§ 403.912 Penalties for failure to report.

(a) *Failure to report.* (1) Any applicable manufacturer or applicable group purchasing organization that fails to timely, accurately or completely report the information required in accordance with the rules established under this subpart is subject to a civil monetary penalty of not less than $1,000, but not more than $10,000, for each payment or other transfer of value or ownership or investment interest not reported timely, accurately, or completely.

(2) The total amount of civil monetary penalties imposed on each applicable manufacturer or applicable group purchasing organization (regardless of whether the applicable manufacturer was a part of a consolidated report) with respect to failures to report in an annual submission of information will not exceed $150,000.

(b) *Knowing failure to report.* (1) Any applicable manufacturer or applicable group purchasing organization that knowingly fails to timely, accurately or completely report the information required in accordance with the rules established under this subpart is subject to a civil monetary penalty of not less than $10,000, but not more than $100,000, for each payment or other transfer of value or ownership or investment interest not reported timely, accurately, or completely.

(2) The total amount of civil monetary penalties imposed on each applicable manufacturer or group purchasing organization (regardless of whether the applicable manufacturer was a part of a consolidated report) with respect to knowing failures to report in an annual submission of information will not exceed $1,000,000.

(c) *Total annual civil monetary penalties.* The amount of civil monetary penalties imposed on each applicable manufacturer or applicable group purchasing organization under paragraphs (a)(1) and (b)(1) of this section are—

(1) Aggregated separately;

(2) Subject to separate aggregate totals under paragraphs (a)(2) and (b)(2) of this section, with a maximum combined annual total of $1,150,000.

(d) *Determinations regarding the amount of civil monetary penalties.* In determining the amount of the civil monetary penalty, factors to be considered include, but are not limited to, the following:

(1) The length of time the applicable manufacturer or applicable group purchasing organization failed to report, including the length of time the applicable manufacturer or applicable group purchasing organization knew of the payment or other transfer of value, or ownership or investment interest.

(2) Amount of the payment the applicable manufacturer or applicable group purchasing organization failed to report.

(3) Level of culpability.

(4) Nature and amount of information reported in error.

(5) Degree of diligence exercised in correcting information reported in error.

(e) *Record retention and audits.* (1) *Maintenance of records.* (i) Applicable manufacturers and applicable group purchasing organizations must maintain all books, contracts, records, documents, and other evidence sufficient to enable the audit, evaluation, and inspection of the applicable manufacturer's or applicable group purchasing organization's compliance with the requirement to timely, accurately or completely submit information in accordance with the rules established under this subpart.

(ii) The items described in paragraph (e)(1)(i) of this section must be maintained for a period of at least 5 years from the date the payment or other transfer of value, or ownership or investment interest is published publicly on the Web site.

(2) *Audit.* HHS, CMS, OIG or their designees may audit, inspect, investigate and evaluate any books, contracts, records, documents, and other evidence of applicable manufacturers and applicable group purchasing organizations that pertain to their compliance with the requirement to timely, accurately or completely submit information in accordance with the rules established under this subpart.

(3) The requirements in this subpart are in addition to, and do not limit, any other applicable requirements that may obligate applicable manufacturers or applicable group purchasing organizations to retain and allow access to records.

(f) *Use of funds.* Funds collected by the Secretary as a result of the imposition of a civil monetary penalty under this section must be used to carry out the operation of this subpart.

(g) *Notice, hearings, appeals, and collection.* Civil monetary penalties imposed under this section are subject to the provisions set forth in subparts A and B of part 402 of this chapter, including those pertaining to notice, opportunity for a hearing, appeals procedures, and collection of penalties.

§ 403.914 Preemption of State laws.

(a) *General rule.* In the case of a payment or other transfer of value provided by an applicable manufacturer to a covered recipient, this subpart preempts any statute or regulation of a State or political subdivision of a State that requires an applicable manufacturer to disclose or report, in any format, the type of information regarding the payment or other transfer of value required to be reported under this subpart.

(b) *Information collected for public health purposes.* (1) Information required to be reported to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes must still be reported to appropriate Federal, State, or local governmental agencies, regardless of whether the same information is required to be reported under this subpart.

(2) Governmental agencies include, but are not limited to, the following:

(i) Agencies that are charged with preventing or controlling disease, injury, disability.

(ii) Agencies that conduct oversight activities authorized by law, including audits, investigations, inspections, licensure or disciplinary actions, or other activities necessary for oversight of the health care system.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: July 2, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: *January 23, 2013.*

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

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Supplier Code of Conduct

Trinity Health is committed to complying with all laws and regulations that apply to our health care ministry and operating in a manner consistent with the highest professional and ethical standards. As a Trinity Health supplier[1], you play an integral role in helping us achieve these goals. We have created this Supplier Code of Conduct to communicate the minimum standards by which all Trinity Health suppliers are expected to conduct themselves when providing goods or services to our system. Please note that Trinity Health organizations or departments may establish guidelines that are more restrictive than those described in this document. It is your responsibility to share this Supplier Code of Conduct with all personnel who may be engaged in conducting business activities with a Trinity Health organization.

Gifts – Trinity Health recognizes that the cost of gifts, including meals, entertainment, and social activities provided by suppliers is ultimately borne in the cost of products and services we purchase. Consistent with our mission to be faithful stewards of our resources, Trinity Health discourages suppliers from providing any gifts or other items of value to our colleagues, physicians or contractors working in Trinity Health facilities ("Trinity Health Personnel"). The following items are never acceptable:

- Gifts given to Trinity Health Personnel for the purpose of influencing a purchasing and contracting decision;
- Gifts that reasonably could be perceived as a bribe, payoff, deal, or any other attempt to gain a competitive advantage;
- Cash or items redeemable for cash such as checks, gift cards, stocks, etc.;
- Gifts to or from government representatives;
- Gifts or other incentives given for the purpose of encouraging or rewarding patient referrals;
- Gifts that may violate a law or regulation.

Trinity Health expects all supplier representatives in the pharmaceutical, medical supply and device industries to adhere to the codes of conduct on interactions with healthcare professionals as published by the Pharmaceutical Research and Manufacturers of America (PhRMA) and Advanced Medical Technology Association (AdvaMed), as applicable.

All Supplier representatives should be familiar with Trinity Health's policy on relationships with suppliers and other business partners as follows:

Entertainment and Social Activities – Trinity Health colleagues may not accept gifts that involve entertainment or social activities, such as free or discounted tickets to sporting events, theatre or concert events, golf outings, travel and lodging, etc. Trinity Health colleagues may attend an entertainment or social event with a supplier provided Trinity Health colleagues, not the supplier, pays their own cost (e.g. the face value of a sporting event ticket) to attend such events.

Meals – In general, Trinity Health discourages colleagues from accepting meals and refreshments paid by suppliers. Trinity Health colleagues may accept an occasional meal or refreshments, paid by a supplier provided the following requirements are met:

(1) Such events are infrequent, which as a general rule means no more than 1-2 times per year.
(2) The event immediately precedes or follows a legitimate business meeting (e.g. discussion of business topics involving Trinity Health).

[1] The term "Supplier" is used herein to refer to all vendors, independent contractors, agents, and other business partners providing goods or services to Trinity Health organizations.

(3) The setting for the meal is appropriate to discussing business matters (e.g. office or restaurant) and the host is present.
(4) The supplier's expense is modest which, as a general rule, means the cost of meals and refreshments does not exceed $50.
(5) Trinity Health does not incur additional travel or overnight lodging costs as a result of a colleagues participation in a meal offered by a supplier.

The above requirements do not apply to meals and refreshments provided in connection with a conference or other educational program sponsored by a supplier for the benefit of all attendees.

Sponsored Events – Trinity Health colleagues may attend supplier-sponsored local or out-of-town programs, workshops, seminars and conferences that have a legitimate educational purpose or otherwise support a Trinity Health business objective (e.g. product training) provided such events are infrequent (i.e. no more than once annually) and Trinity Health, not the supplier, pays for any related travel and overnight lodging costs.

Fundraising – As a tax-exempt, charitable organization, Trinity Health may solicit charitable contributions to support our health care ministries. Only Trinity Health foundations or specific departments responsible for fundraising activities may solicit such gifts. Trinity Health colleagues with responsibilities for ongoing business relationships with suppliers, including the negotiation or selection of suppliers, are prohibited from solicitation and fund-raising activities with suppliers.

Other than legitimate fund-raising activities as described above, Trinity Health colleagues are not allowed to solicit gifts, entertainment or meals from suppliers at any time. Suppliers who encounter situations where Trinity Health colleagues are in violation of this policy are expected to **contact the Trinity Health Integrity Line at 1-866-477-4661**.

Conflicts of Interest – Conflicts of interest, in which a Trinity Health colleagues' relationship with a supplier conflicts, or could appear to conflict, with Trinity Health's business interests, must be avoided. We recognize there are circumstances in which a member of a Trinity Health colleagues' family or household may work for a supplier. Trinity Health requires our colleagues to disclose such relationships in a timely manner. We also expect our suppliers to bring any actual, potential, or perceived conflicts of interest to the attention of a Trinity Health high-level representative, other than the person who has a relationship with the supplier. Trinity Health colleagues are not permitted to work for a supplier if Trinity Health is a customer of the Supplier.

Compliance with Laws – Suppliers are required to conduct their business activities in compliance with all applicable laws and regulations, including laws that are applicable to individuals and entities receiving Medicare, Medicaid and other federal funds.

Privacy and Security – Federal and state laws require Trinity Health and our suppliers to maintain the privacy and security of Trinity Health personal health information ("PHI"). Suppliers are responsible for ensuring that all supplier personnel who provide services to Trinity Health are aware of and familiar with the requirements of both the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules and, where applicable, those state laws that provide more stringent protection of PHI. If your business relationship with Trinity Health will require access to or usage of PHI, you will be required to sign a Business Associate Agreement with us.

Infection Control Policies – Supplier personnel whose activities require access to direct patient care environments are required to adhere to Trinity Health infection control policies applicable to the organizations visited.

Eligibility to Participate in Federal and State Health Care Programs – Trinity Health will not conduct business with any supplier excluded, debarred, or ineligible to participate in federal or state health care programs such as Medicare and Medicaid, or whose officers, directors or employees are excluded from participating in federal or state health care programs. Suppliers are responsible for taking all necessary steps to ensure personnel involved in providing goods and services to Trinity Health, directly or indirectly, remain eligible to participate in federal and state health care programs.

Fraud, Waste and Abuse ("FWA") – Trinity Health will promptly investigate any reports of alleged violations of law, regulations or Trinity Health policies involving a supplier or a supplier's personnel, including allegations of FWA involving federal or state health care programs. Suppliers are expected to fully cooperate in such investigations and, where appropriate, in taking corrective actions in response to confirmed violations. The Federal False Claims Act and similar state laws make it a crime to present a false claim to the government for payment. These laws also protect "whistleblowers" – people who report noncompliance or fraud, or who assist in investigations, from retaliation. Trinity Health policy prohibits retaliation of any kind against individuals exercising their rights under the Federal False Claims Act or similar state laws.

Deficit Reduction Act of 2005 ("DRA") Requirements – The DRA requires Trinity Health to provide detailed information to its employees, contractors and agents regarding the Federal False Claims Act and applicable state false claims laws. Suppliers are responsible for reviewing the False Claims Act Information section of the Trinity Health *Code of Conduct* available at http://www.trinity-health.org/documents/codeofconduct.pdf and for sharing this information with your employees conducting business with Trinity Health.

Environmental Purchasing Policy – Trinity Health is committed to purchasing products and services whose environmental impacts are healthier for the environment and human health. Trinity Health expects suppliers to develop price competitive, environmentally sound, and safe products and services that help us achieve these objectives.

Supplier Diversity Program – Trinity Health has a long tradition of support for programs that foster diversity in our organization, and in our communities. Where applicable, Trinity Health expects its suppliers to mirror our commitment, through subcontracting opportunities with diverse businesses and providing information to Trinity Health on supplier diversity when requested.

Visitation Policy – When visiting Trinity Health facilities, suppliers must comply with applicable Trinity Health Supplier visitation policy, which is available at facilities upon request. Supplier representatives are required to schedule appointments and must register prior to visiting any Trinity Health medical facility. Representatives will be required to state the area to be visited, and visits must be restricted to those location(s) only. Visitor badges provided by the facility must be worn at all times.

Product Samples – With the exception of drug samples provided to a physician office or clinic, supplier product samples may not be provided without the advance review and approval of Trinity Health Supply Chain Management.

Publicity – Suppliers are not permitted to distribute advertising, press releases, or any other general public announcement regarding its products or services to Trinity Health facilities unless you have obtained prior written authorization from an authorized Trinity Health management employee.

Business Record Retention – Trinity Health requires suppliers to retain and make available records related to business with Trinity Health in accordance with applicable law, regulation, and contract requirements.

Government Contractor Requirements – Trinity Health is not a federal government contractor; however, some of our individual affiliates may be federal government contractors. For those Trinity Health affiliates which are a federal government contractor, supplier acknowledges that the clauses regarding equal employment opportunity and affirmative action contained in 41 CFR 60-1.4(a), 41 CFR 60-300.5(a), and 41 CFR 60-741.5(a) shall apply. These regulations prohibit discrimination against all individuals based on their race, color, religion, sex, or national origin. Moreover, these regulations require that covered federal government contractors and subcontractors take affirmative action to employ and advance in employment individuals without regard to race, color, religion, sex, national origin, protected veteran status or disability.

Physician Owned Distributorships – Trinity Health will not purchase or enter into agreements for the purchase of products or supplies, including, but not limited to pharmaceuticals, implants, instruments and other medical devices, from Physician-Owned Distributorships ("PODs") or similar entities that maintain ownership or investment interests held by physicians and/or immediate family members of physicians on the medical staff of a Trinity Health organization. Suppliers are required to disclose to Trinity Health any such ownership or investment interests in their companies.

Resources – For more information on Trinity Health's policies, visit Trinity Health's Supply Chain Management web site at http://www.trinity-health.org/supply-chain-management.

Trinity Health Code of Conduct and Integrity & Compliance Line – The Trinity Health *Code of Conduct* describes behaviors and conduct expected of all Trinity Health Personnel. The *Code of Conduct* is available at http://www.trinity-health.org/documents/codeofconduct.pdf. Suppliers may use the Integrity & Compliance Line to report any actual or suspected violations of this Code of Conduct including FWA matters, safety concerns, or other matters, on an anonymous basis without fear of retaliation. The Integrity Line is available 24 hours a day, 365 days a year at **1-866-477-4661**. Suppliers may also file reports online at www.mycompliancereport.com. When prompted for an access ID, please use THO to designate Trinity Health.

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http://www.wsj.com/articles/detroit-neurosurgeon-aria-sabit-arrested-for-alleged-insurance-fraud-1416878290

U.S.

Detroit Neurosurgeon Aria Sabit Arrested for Alleged Insurance Fraud

Criminal Complaint Alleges Sabit Billed for Spine Surgeries He Didn't Actually Perform or Were Medically Unnecessary

By **JOHN CARREYROU**

Nov. 24, 2014 8:18 p.m. ET

A Detroit-area neurosurgeon was arrested Monday for allegedly defrauding federal and private health-insurance programs by billing for spine surgeries that he either didn't perform or that were medically unnecessary, according to a criminal complaint unsealed in federal court.

The surgeon, Aria Sabit, was sued by the Justice Department in civil court in September over similar allegations. Dr. Sabit was the subject of a 2013 Page One article in The Wall Street Journal revealing that he profited from the implants he used in dozens of surgeries at a California hospital, some with tragic outcomes.

Dr. Sabit's lawyer, Mark Kriger, said his client will enter a not guilty plea. No plea has been entered yet.

Dr. Sabit, who relocated from California to Michigan in early 2011, allegedly misled four different Michigan patients into thinking that he fused their spinal vertebrae when he actually performed no such procedure, according to the new criminal complaint.

Between the beginning of 2011 and June 2014, Dr. Sabit billed Medicare, Medicaid and Blue Cross Blue Shield of Michigan a total of $32.8 million, the complaint alleges. Of the $1.8 million he collected from them, $1.2 million was paid out by Medicare and Medicaid.

Dr. Sabit was ordered held without bond until a Dec. 1 hearing and could face 10 or more

years in prison if convicted.

Dr. Sabit was born in Afghanistan and obtained U.S. citizenship last year. The government's complaint alleges that he was "statutorily ineligible for naturalization" at the time because he knowingly committed health-care fraud and failed to disclose it.

Before moving to Michigan, Dr. Sabit operated at a hospital in Ventura, Calif., where he used spinal implants supplied by a company he had an ownership stake in. One California Medicare patient he operated on died from postoperative complications, according to the civil complaint the Justice Department filed in September. Dr. Sabit surrendered his California medical license last summer under a settlement with the state's medical board.

Federal prosecutors asked that Dr. Sabit be held in jail pending trial, citing an attempt he made in September to fly to Dubai via Atlanta. While interviewing Dr. Sabit at Atlanta's Hartsfield International Airport, customs officers found a plastic bag in his luggage containing a ruby and a 3.6-carat emerald, according to the complaint. Dr. Sabit told the agents that he was involved in the mining business in Afghanistan.

Write to John Carreyrou at john.carreyrou@wsj.com

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U.S.

Justice Department Sues Surgeon Aria Sabit Over Spinal Operations

Suit Alleges Surgeon and Network of Implant Distributorships Defrauded Medicare

By **JOHN CARREYROU**

Updated Sept. 10, 2014 12:36 p.m. ET

The Justice Department sued a neurosurgeon and the operators of a network of doctor-owned implant distributorships, alleging they defrauded Medicare of millions of dollars with unnecessary spinal surgeries.

The neurosurgeon, Dr. Aria Sabit, and the distributorship network, Reliance Medical Systems LLC, were the subject of a 2013 Page One article in The Wall Street Journal detailing that Dr. Sabit profited from implants he used in dozens of surgeries at a California hospital, some with tragic outcomes.

Dr. Sabit declined to comment for that article, and his lawyer didn't respond to inquiries Tuesday on the government suit. Patric Hooper, an attorney representing Reliance and its founders, said his clients "did absolutely nothing wrong" and added: "We are going to defend this thing aggressively."

The government built the civil case using cooperating witnesses wearing wires.

In one of two complaints it filed in a Los Angeles federal court, the Justice Department alleged that the Reliance network's two founders, Adam Pike and Bret Berry, operated

14 spinal-implant distributorships and parceled out ownership stakes in them to 35 surgeons who agreed to use Reliance implants.

Those ownership interests—and the monthly profit distributions that came with them—created incentives for the surgeons to perform "surgeries using Reliance implants that were not medically necessary, or that were more extensive than what was necessary," the government said in one of the complaints.

Messrs. Pike and Berry and a third non-surgeon associate together earned about $43 million from the arrangement between June 2007 and December 2012, the government alleged. Mr. Hooper disputed that figure, saying Messrs. Pike and Berry earned "much less."

Messrs. Pike and Berry paid a group of four surgeons with ownership interests in two of the implant distributorships a total of $5.9 million, according to the government.

Dr. Sabit, one of those four surgeons, had a 20% interest in a distributorship called Apex Medical Technologies and earned $438,570 from it between May 2010 and June 2012, the government alleged.

During the first eight months of that period, Dr. Sabit worked at Community Memorial Hospital in Ventura, Calif., and performed 130 spinal-fusion surgeries. The hospital paid Apex $1.4 million for the implants Dr. Sabit used in those surgeries, the government said; Apex, in turn, paid Dr. Sabit $264,957.

Community Memorial Hospital received at least $8.4 million from Medicare for the fusion surgeries Dr. Sabit performed on Medicare patients there while he was an Apex co-owner, the suit alleged; Dr. Sabit himself received $808,876 from Medicare for those surgeries.

Community Memorial Hospital didn't respond to inquiries.

One Medicare patient Dr. Sabit operated on died from postoperative complications, according to the government complaint. Dr. Sabit performed a surgery to fuse a number of the patient's vertebrae, "even though the indications for fusion were completely absent," the suit alleged.

Mr. Hooper, the Reliance attorney, said the alleged malpractice acts committed by Dr. Sabit were separate and had nothing to do with Reliance.

"Medical malpractice should not be the subject of an action under the False Claims Act,"

he said.

Dr. Sabit surrendered his California medical license last month under a settlement with the state's medical board, after the board alleged that he committed gross acts of negligence while treating five patients in Ventura and made false representations in their medical charts. As part of the settlement, Dr. Sabit agreed to give up his right to contest those charges.

Dr. Sabit still has a medical license in Michigan, where he relocated after California, and can still treat Medicare patients there because the Centers for Medicare and Medicaid Services hasn't excluded him from the program.

The Justice Department's complaints against Reliance and Dr. Sabit quote from government recordings of conversations involving Messrs. Pike and Berry. In one of those conversations in July 2011, the government said, Mr. Pike said he was interested in recruiting surgeons who would appreciate "this nice income" that in "the first month or two" could "buy their [kids'] college education."

Mr. Hooper said Messrs. Pike and Berry "do not recall" the conversations, adding: "I'm sure words were taken out of context."

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U.S.

Surgeons Eyed Over Deals With Medical-Device Makers

Justice Department Investigation Shines Light on Federal Authorities' Broader Scrutiny of Physician-Owned Distributorships

By **JOHN CARREYROU**

July 25, 2013 11:01 p.m. ET

Ten months after an Afghan-born surgeon named Aria Sabit arrived in Ventura, Calif., local hospital staffers noticed he suddenly developed a preference for an obscure brand of spinal implants for many of his surgeries. Soon his volume of operations increased, with sometimes-tragic results.

By the time he moved on less than a year later in late 2010, he had become embroiled in investigations by the California medical board and the Food and Drug Administration and more than two dozen medical malpractice lawsuits, including 12 involving surgeries he did with the new implants.

Now, the Department of Justice is investigating Dr. Sabit because it has emerged that he had an ownership interest in the company that distributed, and profited from, the surgical devices he switched to, people familiar with the matter say.

Federal prosecutors' scrutiny of Dr. Sabit is part of a broader civil investigation into a network of physician-owned spinal-implant distributorships operated by two former

SFC 0275

Dr. Aria Sabit, a spinal surgeon, testifying in a deposition last year. GLICKMAN & GLICKMAN

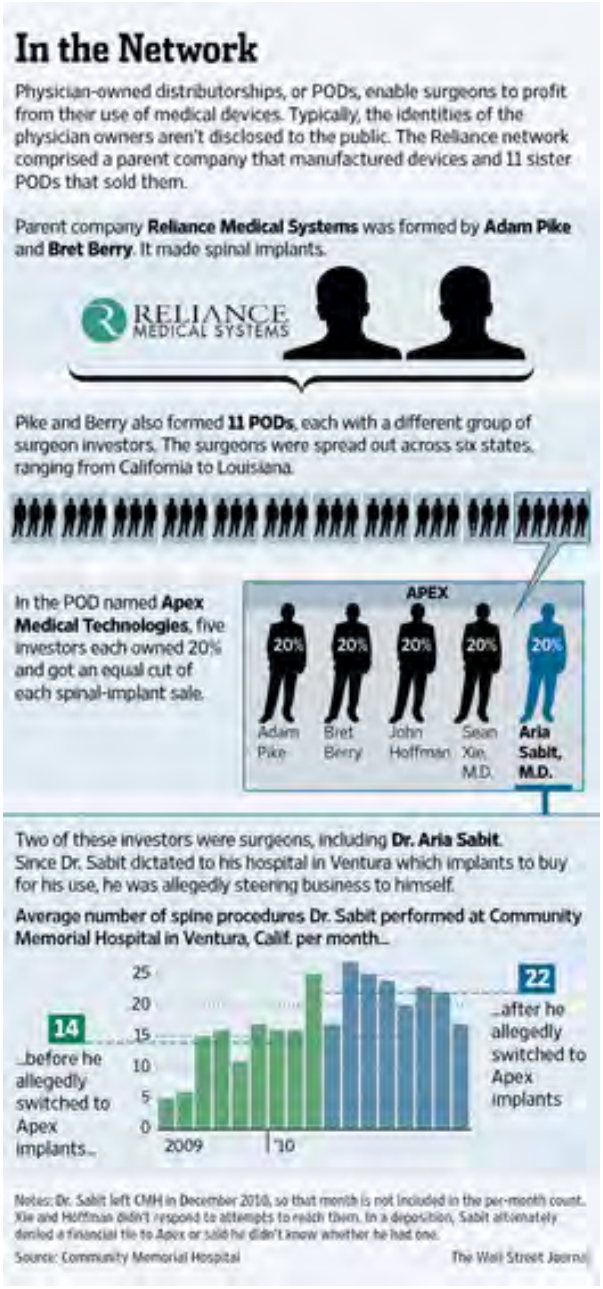
The late Lillian Kaulback was operated on by Dr. Sabit in October 2010 with Apex implants. KEVIN REYNOLDS

medical-device company employees, the people with knowledge of the matter say. This network, which was run out of Utah and comprised at least 11 physician-owned distributorships in six states, generated tens of millions of dollars in profits for its

investors over six years.

Physician-owned distributorships, or PODs, have proliferated in medicine. Distributorships, whether owned by physicians or not, act as intermediaries between medical-device makers and hospitals: In exchange for marketing and stocking devices, the distributors get a cut of each sale. When surgeons own the distributorship, that commission goes into their pockets. And since surgeons often dictate to their hospitals which devices to buy, they can effectively steer business to themselves.

Depending on how they are set up, such entities can be legal. But in March, the Department of Health and Human Services' Office of Inspector General issued a special fraud alert about PODs, warning that they "pose dangers to patient safety" by inducing surgeons to do more procedures than necessary and to favor devices they profit from



over more "clinically appropriate" ones.

In Dr. Sabit's case, the Justice Department has been looking into whether his financial interest in the implants caused him to over-operate or contributed to a spate of alleged patient complications. Twenty-eight former patients or their families have sued Dr. Sabit in Ventura Superior Court, alleging negligent acts ranging from misplacing implants in their spines to performing surgeries that were unnecessarily extensive. Dr. Sabit has settled 11 of the suits, one has been dismissed and 16 are still pending against him.

Through his attorneys, Dr. Sabit, who is now practicing medicine in Michigan, declined to comment, citing the malpractice lawsuits and California's medical privacy laws. He has denied the suits' allegations in court filings and, in a deposition, blamed a surgeon who recruited him to Ventura for encouraging patients to sue him. Dr. Sabit has sued that surgeon and the Ventura hospital for wrongful termination.

In his malpractice depositions, Dr. Sabit has alternately denied receiving any monetary benefit from the implants he used in his surgeries or said he didn't know whether he did.

However, a person with knowledge of the matter says Dr. Sabit owned one-fifth of a spinal-implant distributor called Apex Medical Technologies LLC from May 2010 to August 2012. Over that period, which includes eight months of his tenure in Ventura, he received profit distributions from Apex that averaged about $12,000 per month, this person says.

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- Does My Surgeon Profit From My Implants? (/articles/SB10001424127887323971204578626021375815096)
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SFC 0278

Dr. Sabit, 39, was born in Kabul, Afghanistan, but his family fled the country in 1979 during the Soviet invasion. In a deposition, he said they lived in a tent in Pakistan for four years until they emigrated to the U.S.

The family settled in Arlington, Va. Dr. Sabit's father, Abdul Jabbar Sabit, got a job as a reporter for Voice of America. He returned to Afghanistan after the fall of the Taliban and served as Afghanistan's attorney general from 2006 to 2008.

Dr. Sabit attended college and medical school at Virginia Commonwealth University and did his neurosurgery residency at the University of Medicine and Dentistry of New Jersey. He was recruited to Ventura by Moustapha Abou-Samra, a Syrian-born neurosurgeon who had practiced in the middle-class community north of Los Angeles for more than three decades.

Dr. Sabit raised eyebrows at Ventura's Community Memorial Hospital soon after he arrived in June 2009. An avid weight lifter, he said in one of his malpractice depositions that he used supplements such as creatine to build muscle mass. People who worked with him say he was physically intimidating. In the operating room, he played loud heavy-metal music, several hospital nurses have testified.

At first, Dr. Abou-Samra portrayed his recruit as a young star on the cutting edge of neurosurgery who could perform sophisticated spinal procedures CMH had previously been forced to refer out to academic medical centers, several Ventura doctors say. Dr. Abou-Samra didn't return calls for comment. A spokesman for CMH declined to comment for this article.

Though he was fresh from his residency, Dr. Sabit said in a deposition that he quickly became one of the hospital's busiest surgeons and was billing four times as much as Dr. Abou-Samra within a year. He said this created tensions with Dr. Abou-Samra. During 18 months at CMH, Dr. Sabit performed 371 procedures, including 306 spine operations, according to a list of his cases the hospital provided in the malpractice litigation.

Dr. Sabit prided himself on working fast, according to Joan Kruse, a CMH nurse deposed in the malpractice litigation. "He would grab instruments. He'd shove them into the wound," she testified. "I've never seen any neurosurgeon be that rough and brutal with" tissue "that close to the spinal cord," she said.

In one of his depositions, Dr. Sabit said he found Ms. Kruse to be "very disagreeable" and had asked that she be barred from his surgeries.

Dr. Sabit used a variety of spinal-implant brands during his first 10 months in Ventura, but he switched to Apex in April 2010, according to Marilyn Harris, CMH's director of surgical services. In her deposition in the malpractice litigation, Ms. Harris said the switch prompted speculation at the hospital that Dr. Sabit had joined a POD and was profiting from his use of Apex implants.

Dr. Sabit denied to Ms. Harris that this was the case, and later testified he couldn't recall when he began using Apex products. Ms. Harris testified that he showed up in her office unannounced and told her: "I don't even know what a POD is. I'm not part of a POD." Ms. Harris said "he was in a heightened state of anxiety" and "very emphatic."

However, a person with knowledge of the matter says that Apex was in fact a POD and that Dr. Sabit purchased a one-fifth stake in it in May 2010, after a short trial period.

Apex was created by two men, Adam Pike and Bret Berry. Following a model they replicated at least 11 times across six states, Messrs. Pike and Berry recruited Dr. Sabit and a neurosurgeon in Los Angeles to become partners with them in Apex. Each surgeon bought a 20% interest in the company, with the remaining 60% going to Messrs. Pike and Berry and one of their business associates.

The two men are veterans of the medical-device industry who partnered up to create their own spinal-implant company, Reliance Medical Systems. From offices in Bountiful, Utah, Reliance contracts with machine shops to manufacture replicas of bigger companies' products that it sells under its own brand. The practice is legal under a streamlined FDA approval process for medical devices deemed "substantially equivalent" to ones already on the market.

To get their products adopted, Messrs. Pike and Berry created a series of distributorships similar to Apex and sold ownership stakes to groups of surgeons across the country, according to a person familiar with the operation. Each surgeon received a monthly profit distribution, this person said. The more Reliance implants the surgeons put in patients' backs, the more business their distributorship did and the more they earned.

Under California's anti-kickback statute, it is illegal to pay doctors to induce patient referrals, or for doctors to accept such payments. The practice is also illegal under federal law if the patients are insured by health programs such as Medicare. According to the people familiar with its civil probe, the Justice Department is examining whether the distributorships Messrs. Pike and Berry created were effectively kickback mechanisms to induce surgeons to use Reliance implants.

SFC 0280

The answer to that question hinges in part on whether the amount Dr. Sabit and the other surgeons paid for their distributorship stakes is too small to be considered a real investment, given the size of their returns, which in some cases reached $50,000 a month.

Federal prosecutors are looking into whether Dr. Sabit's financial interest in Apex made him more prone to operate or to do bigger and riskier surgeries than necessary, the people familiar with the matter say.

The printout of Dr. Sabit's surgeries at CMH shows that, before allegedly switching to Apex, he averaged 14 spine procedures a month and spine surgeries accounted for 76% of his operations. After he allegedly switched to Apex, he averaged 22 spine procedures a month and their share of his case load rose to 87%.

In a court filing, Dr. Sabit has pointed to deposition testimony from CMH Chief Executive Officer Gary Wilde, in which Mr. Wilde stated, "we believed that the vast majority of cases Dr. Sabit did were appropriate."

It is unclear how many patients Dr. Sabit used Apex implants on. Of the 28 patients who sued, he implanted Apex hardware in 12 of them, according to the malpractice depositions and people familiar with the matter. None of those suits allege that the Apex implants were defective.

A spokesperson for Reliance says the fact that Dr. Sabit didn't use Apex on more than half of the plaintiffs shows that there is no causal relationship between his use of Apex and the suits. "It is wholly inaccurate to assume that these claims are a result of the use of Apex products. To the best of our knowledge, there have never been any allegations by patients or doctors about faulty Apex products," the spokesperson said.

One of the patients Dr. Sabit operated on using Apex was Guanda Dusette, a 72-year-old retired nurse. Jack Padour, Ms. Dusette's primary-care doctor, says he referred her to Dr. Sabit after she complained of persistent back pain. Dr. Sabit proposed removing part of two disks in her spine, a relatively routine procedure designed to take pressure off the nerve root, Dr. Padour says.

Dr. Sabit operated on Ms. Dusette on July 8, 2010. However, the surgery he performed turned out to be much more extensive: Using Apex implants, he fused together eight vertebral levels in her spine, Dr. Padour says.

After the surgery, Ms. Dusette was "in agonizing pain," according to Dr. Padour. The

metal screws and rods Dr. Sabit had drilled into her spine began coming loose, and the rods pressed against the skin of her back from the inside, according to Dr. Padour and Ms. Dusette's attorney.

Ms. Dusette was re-operated on at Cedars-Sinai Medical Center in Los Angeles, where all the hardware Dr. Sabit implanted was taken out, Dr. Padour says. She subsequently sued both Dr. Sabit and CMH. She recently reached a confidential settlement with the hospital, but her case against Dr. Sabit is still pending. Dr. Sabit has denied her suit's allegations.

Outside the hospital, Dr. Sabit's surgical outcomes caught the attention of Gary Proffett, the medical director of a physician association called SeaView that coordinates patients' care on behalf of health plans. Of 75 SeaView patients operated on by Dr. Sabit over his 18-month tenure in Ventura, 28 developed major complications, including two who died, Dr. Proffett said in an interview. Dr. Proffett reported the SeaView complications and deaths to the California Medical Board.

Many of Dr. Sabit's post-surgical complications involved infections, according to depositions by several nurses and Cary Savitch, an infectious diseases doctor at CMH.

Dr. Sabit has disputed this. In a court filing, he said CMH's infections control nurse "performed an exhaustive review of my infection rate" and concluded that it "was normal and acceptable."

One alleged victim of infection was Lillian Kaulback, an overweight woman in her late 60s with a number of health issues, ranging from diabetes to a history of ankle, shoulder and knee surgeries. Dr. Sabit operated on her on Oct. 7, 2010, using Apex implants to fuse three vertebral levels in her spine, according to several people familiar with her case.

A person close to Ms. Kaulback says she was mobile and active before her surgery, playing bingo, attending family functions and going to a local club to watch couples dance. After the surgery, she never walked again and was in and out of the intensive care unit, this person says.

Dr. Savitch, who treated Ms. Kaulback after her surgery, recalled in his deposition that she had a big wound on her back that "was open" and "dripping pus" and had "six different bugs growing from" it.

To his astonishment, Dr. Sabit closed the infected wound and didn't document it in Ms.

Kaulback's medical chart, Dr. Savitch testified. "Whenever you have an infected wound, you need it to drain...The last thing you do is close it," he said.

The wound opened back up the following day, according to Dr. Savitch's deposition. The person close to Ms. Kaulback says she was eventually transferred to a nursing home, where she spent six months in acute pain. She died there on May 31, 2011.

Ms. Kaulback's son has filed a wrongful-death suit against Dr. Sabit and CMH. The case is pending. Dr. Sabit and CMH have denied the suit's allegations.

In their depositions, Ms. Kruse and other nurses testified that Dr. Sabit was cavalier about keeping the operating field sterile and would sometimes contaminate it by not scrubbing in properly or by letting his hair dangle over an open wound.

The Reliance spokesperson said, "There is absolutely no connection between allegations of infection and Reliance's products or its sterilization procedures."

When CMH confronted him about alleged post-surgical infections among his patients, Dr. Sabit blamed one of the hospital's two operating rooms, which he argued in a letter wasn't kept sufficiently clean and sterile.

On Dec. 3, 2010, CMH suspended Dr. Sabit. Mr. Wilde, the CEO, handed him a letter stating that the hospital had decided "immediate action must be taken to protect the life or well-being of patients." The letter said the suspension was based in part on Dr. Sabit's alleged negligent treatment of two unidentified patients. In a subsequent court filing, a senior CMH staffer said one of those two patients died.

Dr. Sabit filed his own statement with the court in which he denied being negligent and said "there was no medical basis at all for the summary suspension." Instead, Dr. Sabit wrote, Dr. Abou-Samra and the hospital had conspired to suspend him so Dr. Abou-Samra could fire him and "avoid paying me the huge bonuses he would otherwise have to pay."

After Dr. Sabit threatened to sue the hospital, CMH reinstated him on Dec. 7, 2010. But Dr. Abou-Samra refused to let him rejoin his practice, so Dr. Sabit voluntarily resigned his hospital privileges on Dec. 21, 2010.

Following Dr. Sabit's departure, the California medical board launched an investigation, according to several CMH doctors and nurses interviewed by the board. A spokeswoman for the medical board declined to comment. The FDA also sent investigators to Ventura

and audited Reliance's operations in Utah in May 2011. The results of the audit weren't made public. The Reliance spokesperson said: "Our products, which are certified by a third-party, meet the strict sterilization procedures and protocols established by the FDA."

Reliance discontinued its relationship with Dr. Sabit in August 2012 and stopped operating Apex as a POD, according to a person with knowledge of the company's operations. It has since bought out the ownership interests of surgeons in its other PODs but continues to pay many of them consulting fees, this person says.

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HEALTH

Taking Double Cut, Surgeons Implant Their Own Devices

By **JOHN CARREYROU** And **TOM MCGINTY**
October 8, 2011

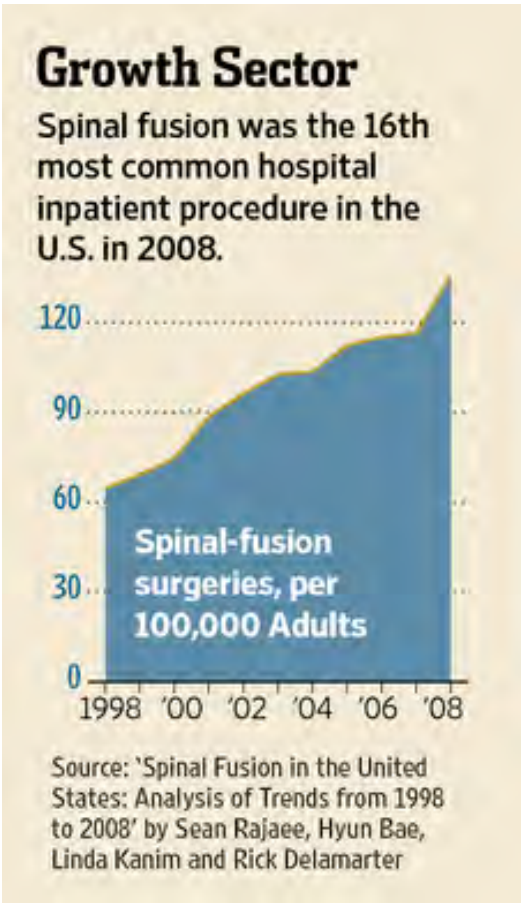
JACKSON, Miss.—On April 7, a 48-year-old Baptist preacher named Gary Steve Moore had spinal-fusion surgery at St. Dominic Hospital here. Hours later, he was dead.

Mr. Moore had been suffering from a degenerating disk in his lower back. Two spine surgeons who later reviewed his medical records say his history of heart disease and bowel obstructions made him a poor candidate for a 360-degree spinal fusion, a complex operation that involved opening up both his abdomen and his back.

His neurosurgeon, Adam Lewis, felt that "surgery was indicated" given Mr. Moore's worsening back pain and the fact that more conservative treatments he had tried, such as physical therapy, had provided no relief, says Dr. Lewis's lawyer, Whit Johnson.

However, there was one element of the surgery that Dr. Lewis didn't mention to the patient, according to his widow: The surgeon was part-owner of the company, Spinal USA, that makes the devices he implanted in Mr. Moore's spine.

Dr. Lewis's part-ownership of a medical-device company is far from unique in the world of back surgery. Rather than use spinal implants from third-party manufacturers, scores of surgeons have started their own device makers to churn out similar designs,



putting themselves in a position to benefit financially from the hardware they insert into patients.

Critics of such arrangements say they give surgeons an incentive to do more operations, and that the conflict of interest has led to a spate of unnecessary back surgeries that waste health-care dollars and often do patients more harm than good. "Patients are having huge operations that are un-indicated because of this," says Scott Lederhaus, a neurosurgeon in Pomona, Calif., and member of the Association for Medical Ethics, an organization of doctors that focuses on conflicts of interest.

Dr. Lewis's lawyer says his client's financial interest in Spinal USA had nothing to do with his decision to operate on Mr. Moore. Dr. Lewis used Spinal USA implants because he helped design them and believed they "were the best on the market for the procedure," not because he stood to profit from them, says Mr. Johnson. He says Dr. Lewis "is truly sorry about Mr. Moore's death."

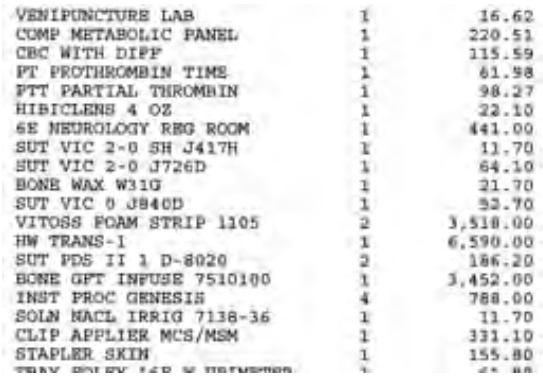
Spinal-fusion surgery, which involves fusing together vertebrae, is used to treat a variety of back problems, particularly serious ones such as spinal fractures and scoliosis. It went from being the 37th most common hospital inpatient procedure in the U.S. in 1998 to the 16th most common in 2008, according to a study to be published soon in the journal Spine. It now accounts for around $10 billion a year in U.S. medical spending.

Spine surgeons began implanting plates, rods and screws in patients' backs in the early 1990s. A federal antikickback law prohibits medical-device makers from paying surgeons to use their products. Mindful of the law, big device makers entered into partnerships with spinal surgeons, paying them consulting fees and royalties for help designing their products. In some cases, surgeons receiving payments would use that company's devices exclusively and would author research favorable to those products, company documents obtained by congressional investigators show.

Eventually, some entrepreneurial surgeons started making their own hardware.

MORE

Read the itemized hospital bill for Mr. Moore's surgery.



VENIPUNCTURE LAB	1	16.62
COMP METABOLIC PANEL	1	220.51
CBC WITH DIFF	1	115.59
PT PROTHROMBIN TIME	1	61.98
PTT PARTIAL THROMBIN	1	98.27
HIBICLENS 4 OZ	1	22.10
6E NEUROLOGY REG ROOM	1	441.00
SUT VIC 2-0 SH J417H	1	11.70
SUT VIC 2-0 J726D	1	64.10
BONE WAX W31G	1	21.70
SUT VIC 0 J840D	1	52.70
VITOSS FOAM STRIP 1105	2	3,518.00
HW TRANS-1	1	6,590.00
SUT PDS II 1 D-8020	2	186.20
BONE GFT INFUSE 7510100	1	3,452.00
INST PROC GENESIS	4	788.00
SOLN NACL IRRIG 7138-36	1	11.70
CLIP APPLIER MCS/MSM	1	331.10
STAPLER SKIN	1	155.80

Read the warning letter the Food and Drug Administration sent to Spinal USA in 2007.

Medicare Records Reveal Troubling Trail of Surgeries (3/29/11)

Top Spine Surgeons Reap Royalties, Medicare Bounty (12/20/11)

Surgeons often get to choose what devices they use, so some hospitals had no choice but to buy their products.

In addition to Dr. Lewis's Spinal USA, spinal-implant manufacturers created and co-owned by surgeons include Titan Spine in Mequon, Wis.; X-spine in Miamisburg, Ohio; and Innovasis in Salt Lake City. Surgeon Peter Ullrich, chief executive of Titan Spine, says he uses its products when he operates. X-spine and Innovasis didn't respond to requests for comment.

The Food and Drug Administration has a less stringent approval process for medical devices nearly identical to ones on the market. Surgeons only have to submit mechanical-testing data attesting that their implants are "substantially equivalent" to existing ones. The FDA usually gives its green light within 90 days.

Surgeon-owned implant makers, including Spinal USA, say they reduce health-care costs because their companies don't have marketing expenses and sales staffs, and they charge hospitals less than established medical-device makers do.

But the inherent conflict of interest is fueling concern. In June, five U.S. senators asked the Inspector General of the Department of Health and Human Services to open an investigation into physician-owned device companies, citing concerns that the surgeons involved have a financial incentive to "perform more procedures than are medically necessary."

A report provided to the agency by Utah Sen. Orrin Hatch, the senior Republican on the Senate Finance Committee, identified at least 20 states where surgeon-owned implant companies are present, and warned that they were spreading from spine surgery to other areas of medicine such as hip, knee and cardiac surgery.

Dr. Lewis, the Jackson, Miss., neurosurgeon, has long had financial ties to device makers. From 2004 to 2006, he received payments from Blackstone Medical Inc.,

Neurosurgeon Adam Lewis at his Jackson, Miss. office. THE CLARION-LEDGER

according to his lawyer, Mr. Johnson.

A whistleblower lawsuit filed against Blackstone in a Massachusetts federal court by one of its former sales representative and a former distributor of its products alleges that the payments of up to $8,000 a month were to induce Dr. Lewis and other surgeons to use the company's devices, in violation of the federal antikickback statute, rendering Medicare reimbursement claims fraudulent.

Mr. Johnson says the payments were legitimate consulting fees his client received for helping Blackstone develop two products. Blackstone has denied the allegations, and the case is pending.

St. Dominic Hospital, where Dr. Lewis performs most of his surgeries, says it temporarily stopped doing business with Blackstone in September 2006 when the company declined to provide it with information about its financial relationships with any hospital staff members. Blackstone has since been acquired by another company.

Dr. Lewis teamed up that same year with a former medical-device salesman and two other spine surgeons in Jackson and Hattiesburg, Miss. to manufacture their own devices. Their company, Spinal USA, is based in Pearl, Miss.

In the spring of 2007, FDA inspectors paid a surprise visit to Spinal USA's offices. They assessed the company with 14 violations, ranging from failing to maintain master records for its devices to having no system in place to track and label them, according to a warning letter the agency issued to the company. The violations were "symptomatic of serious problems," the warning letter stated.

A spokesman for Spinal USA says its rapid growth caused it to run afoul of FDA procedures. He says the company hired an experienced manager to oversee quality control in February 2008, and a second FDA inspection that September cleared the company of the violations. During a third visit in December 2010, FDA inspectors found

problems with the way Spinal USA was storing bone products, which the company also addressed.

In the summer of 2007, Dr. Lewis and his partners recruited four spine surgeons in Huntsville, Ala. to invest in the company. Those surgeons, Gilbert Aust, Cyrus Ghavam, Morris Seymour and Larry Parker, switched to using Spinal USA implants in most of their surgeries, according to a local representative for a big medical-device maker.

Four more Huntsville spine surgeons subsequently joined Spinal USA, giving the company a relationship with eight of Huntsville's current 15 spine surgeons. Spinal USA also expanded to Mobile, Ala., where it recruited two surgeons.

Dr. Aust, who is chairman of Spinal USA, confirmed that he and Drs. Ghavam, Seymour and Parker are investors. The company declined to comment on its other surgeon investors.

At Huntsville Hospital, one of the city's two hospitals, 351 spinal-fusion surgeries were performed on Medicare patients in 2009, up from 333 in 2006, before Spinal USA came to town, a Wall Street Journal analysis of Medicare claims data shows. At Crestwood Medical Center, the city's other hospital, there were 187 such operations on Medicare patients in 2009, up from 107 in 2006, the analysis shows. Huntsville Hospital says it spent $5.6 million on Spinal USA products in its most recent fiscal year.

Dr. Aust attributes the surgery increases to more spine surgeons coming to town and to an aging local population.

Spinal USA's surgeon-owners sometimes operate on patients whose spines already contain implants made by other manufacturers, placed during prior surgeries. At times, as they insert additional Spinal USA devices, they remove some hardware made by the other manufacturers and replace it with Spinal USA products.

Dr. Aust says he performs such hardware replacements for medical reasons, not financial ones. He says he doesn't see anything wrong with the fact that they benefit him financially by contributing to Spinal USA's sales. "I know some people in the profession don't think it's ethical, but I just don't see it," he says.

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The federal antikickback law doesn't specifically address the issue of surgeons using medical devices made by companies they co-own, but HHS's Office of the Inspector General has issued regulatory guidance for complying with the statute: Among other things, it advises that no more than 40% of a company be owned "by investors who are in a position" to "generate business" for it.

Dr. Aust says he and Spinal USA's other surgeon investors own "the majority of the company," but are working on lining up outside investors. The Spinal USA spokesman says its surgeon owners are in compliance with federal laws because their shares of profits are proportional to their ownership stakes, not to how much business they generate through their surgeries. He adds that more than 60% of the company's business is generated by surgeons who aren't owners.

Spinal USA declines to say how much its surgeon owners earn from the company. But a filing in the personal bankruptcy case of spine surgeon Michael Molleston, one of its investors, says Dr. Molleston received $26,000 a month from Spinal USA as of Nov. 19, 2008, when the filing was made. Dr. Molleston couldn't be reached for comment.

The company says it generates more than $20 million in annual revenues. Its spokesman notes, however, that its owners also are "personally responsible for debts of the company."

Medicare data show Dr. Lewis in Jackson performs spinal fusions more frequently than many of his peers. In 2008 and 2009, he performed 278 spinal fusions on Medicare patients, tenth most in the nation, according to the Journal's analysis of Medicare claims data. In 150 of those cases, or 54%, the patients' diagnosis was degenerative disks.

On March 25, Mr. Moore went to see Dr. Lewis complaining of lower-back pain. After reviewing a magnetic resonance imaging of Mr. Moore's spine, taken a few weeks earlier, Dr. Lewis concluded that he suffered from a degenerative disk at the base of his spinal column, his medical records indicate.

Mr. Johnson, Dr. Lewis's lawyer, says that, in addition to physical therapy, Mr. Moore already had tried chiropractic care, pain medication and steroid injections, to no avail, and his back pain was "significantly interfering with his lifestyle."

Dr. Lewis scheduled surgery—a 360-degree fusion. The procedure involves cutting open a patient's abdomen and back and fusing the vertebrae from front and rear, rather than from just one side.

Spinal implants Dr. Lewis used on Mr. Moore. THE WALL STREET JOURNAL

Many people over age 55 show evidence of disk degeneration, even if they feel no pain, studies have shown. Advocates of treating back problems conservatively say pain associated with disk degeneration can be alleviated by physical therapy and rarely requires surgery. Other surgeons say fusion surgery can relieve pain from the condition.

Two spine surgeons who have reviewed Mr. Moore's medical records and films for the Journal say his disk's deterioration looked mild and did not require a 360-degree fusion. One of them, Charles Rosen, president of the Association for Medical Ethics and a spine surgeon at the University of California, Irvine School of Medicine, contends: "No operation of any kind could be justified." The other surgeon says a less aggressive procedure might have been warranted, although the patient's records don't suggest it was needed.

Both surgeons say Mr. Moore was a poor candidate for the 360-degree fusion because he had had 11 abdominal surgeries for an obstructed bowel. He also suffered from diabetes and had had a stent implanted to treat his heart disease.

Mr. Johnson, Dr. Lewis's lawyer, says "different doctors can have different opinions about the best treatment option, but that doesn't make one right and one wrong." He says Mr. Moore wanted the surgery, and he had been cleared by other specialists who deemed him capable of withstanding the operation.

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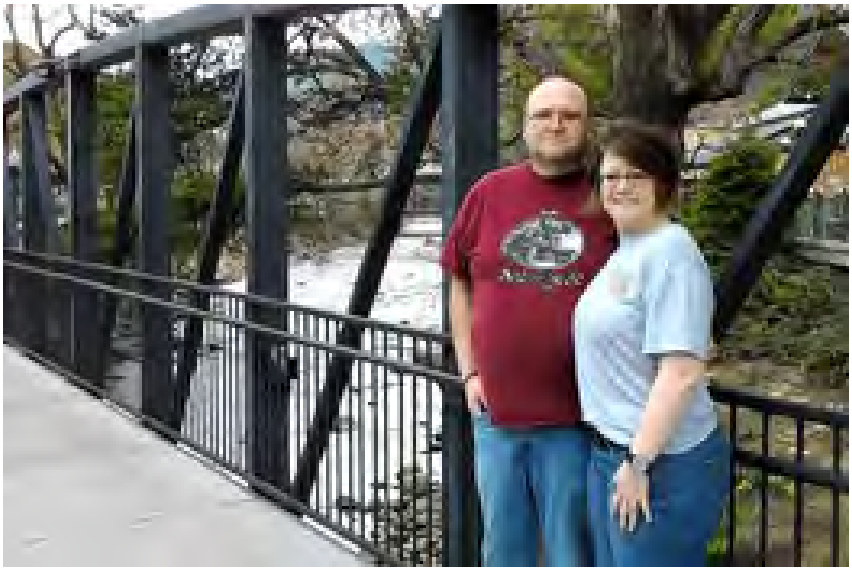

Gary Steve Moore and his wife, Kasey, in February 2011. Mr. Moore died April 7, hours after neurosurgeon Adam Lewis operated on his spine. KASEY MOORE

At St. Dominic Hospital, where the surgery was scheduled, a peer-review committee in 2010 had asked the hospital's chief of neurosurgery, John Lancon, to compile a report on 360-degree fusions of the lower spine following a series of complications involving the procedure, including two deaths, according to one person familiar with the matter. One of the patients who died had been operated on by Dr. Lewis, this person says. Dr. Lancon's report concluded that the risks of the surgery outweighed the benefits in most instances it was performed at the hospital, this person says.

Mr. Johnson says Dr. Lewis believes any deaths that followed 360-degree spinal fusions he performed "were from unrelated health issues" that developed after the surgeries. He declines to comment on any cases other than Mr. Moore's.

The peer-review committee decided to form a working group to review such cases before surgery, but under pressure from hospital management, shifted to reviewing the cases only after the surgeries were performed, the person familiar with the situation says. Consequently, Mr. Moore's surgery wasn't reviewed beforehand. St. Dominic's declined to comment on the matter, saying its peer-review process is confidential.

During the surgery on Mr. Moore, Dr. Lewis implanted a titanium Spinal USA cage and a Spinal USA plate with four screws. St. Dominic's charged the Moores $13,960 for the implants. Spinal USA itself would have received no more than $6,640 under the hospital's price-capping policy. Dr. Lewis received $11,514 in surgical fees.

After the surgery, Mr. Moore was feverish and nauseous, says Kasey Moore, his widow. Soon he was gasping for air. Doctors and nurses tried to revive him for 40 minutes. He

was pronounced dead at 5 p.m. In a discharge summary, Dr. Lewis wrote that Mr. Moore's heart gave out suddenly.

Neurosurgeons nationwide are sued for medical malpractice, on average, about once every two years. Dr. Lewis has been sued for malpractice 18 times since 2002. He has won two cases at trial, lost one, and 10 have been dismissed. Another five are pending, including one wrongful-death suit. (Mr. Moore's family has not sued.) His operating privileges at St. Dominic's have been suspended twice, court records show.

Mr. Johnson, his lawyer, says Dr. Lewis has never been in trouble with Mississippi's medical board, and most of the suits filed against him have proven to be without merit. Dr. Lewis is appealing the one case he lost at trial, in which a jury in May returned a $553,000 verdict. Mr. Johnson says Dr. Lewis's suspensions occurred because he fell behind on patient charts.

Zoe Musick, Dr. Lewis's sister and his practice administrator, says his surgeries are always medically necessary and his financial interest in Spinal USA doesn't influence his decisions on whether or not to operate.

Dr. Lewis never told the Moores of his involvement in Spinal USA, according to Ms. Moore. A treatment authorization signed by Mr. Moore says patients might be referred to "a health care facility" with which their physician could have a "financial relationship." It says nothing about medical devices.

Ms. Moore says she would have liked to know that Dr. Lewis stood to profit from the implants he planned to insert in her husband's back. "It might have caused me to ask: Is the surgery really necessary, or is he out to make more money?" she says.

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