

**ALIGNING INCENTIVES: THE CASE FOR
DELIVERY SYSTEM REFORM**

HEARING

BEFORE THE

COMMITTEE ON FINANCE

UNITED STATES SENATE

ONE HUNDRED TENTH CONGRESS

SECOND SESSION

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SEPTEMBER 16, 2008
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CONTENTS

OPENING STATEMENTS

	Page
Baucus, Hon. Max, a U.S. Senator from Montana, chairman, Committee on Finance	1
Grassley, Hon. Chuck, a U.S. Senator from Iowa	3

WITNESSES

Miller, Mark E., Ph.D., executive director, Medicare Payment Advisory Commission (MedPAC), Washington, DC	5
Steele, Glenn, Jr., M.D., Ph.D., president and chief executive officer, Geisinger Health System, Danville, PA	7
Berenson, Robert, M.D., senior fellow, The Urban Institute, Washington, DC ..	8
Campbell, Eric G., Ph.D., associate professor, Harvard University School of Medicine, Cambridge, MA	10

ALPHABETICAL LISTING AND APPENDIX MATERIAL

Baucus, Hon. Max: Opening statement	1
Berenson, Robert, M.D.: Testimony	8
Prepared statement	29
Campbell, Eric G., Ph.D.: Testimony	10
Prepared statement	41
Grassley, Hon. Chuck: Opening statement	3
Letter from Senator Grassley to James W. Wagner, dated September 16, 2008	45
Miller, Mark E., Ph.D.: Testimony	5
Prepared statement	55
Steele, Glenn, Jr., M.D., Ph.D.: Testimony	7
Prepared statement	73
Responses to questions from Senator Rockefeller	84

COMMUNICATIONS

Advanced Medical Technology Association (AdvaMed)	91
American Academy of Pediatrics	95
New York Academy of Medicine	100
Zimmer Holdings, Inc.	105

ALIGNING INCENTIVES: THE CASE FOR DELIVERY SYSTEM REFORM

TUESDAY, SEPTEMBER 16, 2008

U.S. SENATE,
COMMITTEE ON FINANCE,
Washington, DC.

The hearing was convened, pursuant to notice, at 10:04 a.m., in room SD-215, Dirksen Senate Office Building, Hon. Max Baucus (chairman of the committee) presiding.

Present: Senators Wyden, Grassley, Hatch, and Snowe.

Also present: Democratic Staff: Bill Dauster, Deputy Staff Director and General Counsel; Billy Wynne, Health Counsel; Neleen Eisinger, Professional Staff; Susan Hinck, Fellow; Renee Carter, Fellow; Matt Kazan, Intern; and Elise Stein, Detailee. Republican Staff: Mark Hayes, Health Policy Director and Chief Health Counsel; Michael Park, Health Policy Counsel; Emilia DiSanto, Special Counsel and Chief Investigator; Kristin Bass, Health Policy Advisor; Chris Armstrong, Investigator; and Lyndsey Arnold, Intern.

OPENING STATEMENT OF HON. MAX BAUCUS, A U.S. SENATOR FROM MONTANA, CHAIRMAN, COMMITTEE ON FINANCE

The CHAIRMAN. The committee will come to order.

John Donne wrote, "No man is an island entire of itself. Every man is a piece of the continent, a part of the main." But the way that America pays for health care is driving health care providers to become islands unto themselves. Fee-for-service payments encourage more patient encounters, and those are driving doctors and hospitals to become so many separate islands in a far-flung archipelago of care.

Patients are largely left at sea. Patients are left on their own to navigate between providers. As a result, patients receive duplicative tests, they receive inadvisable prescriptions, they undergo surgeries costing thousands of dollars, only to be ignored after they leave the hospital.

As a result, Americans waste more than 30 cents of every health care dollar in unnecessary and poor quality care. That amounts to more than \$600 billion a year, and that is one-third more than we spend on the entire Medicare program. That waste is simply unacceptable. It is unacceptable to American taxpayers, unacceptable to employers, and it is unacceptable to patients who expect more for their hard-earned dollars.

We need to focus our system and our dollars on coordinating patient care. In patients' many trips between separate caregivers on their isolated islands, money is being cast away. Today we look at

promising approaches to better integrate health care providers into a system that is truly patient-centered, and we consider how the ways that we pay for health care could help to bring about the reforms that we seek.

I have seen great successes in my home State of Montana. For example, the Billings Clinic is part of the Medicare Physician Group Practice Demonstration Program. This program is testing the payment method that measures and rewards quality, and it shares with providers the savings that they have achieved through better care coordination.

The program recently released the results of its second year. All 10 participants demonstrated improved quality, and most participants generated savings through disease management and other techniques. I am glad that Dr. Glenn Steele is here today because the Geisinger Health System is also a part of that program. The Billings Clinic and Geisinger demonstrate that we can achieve real system integration, even in rural areas.

Another strategy to improve integration is to take forceful steps to reduce avoidable hospital readmissions. Readmissions are occurring at an alarming rate. For example, nearly 1 in every 5 Medicare patients discharged after treatment for heart failure returns to the hospital within 30 days. Those readmissions cost Medicare and the American taxpayer nearly \$1 billion a year. Reducing the number of these potentially avoidable hospitalizations would greatly benefit patients and it would yield substantial savings as well.

Another area of concern is access to primary care. The Dartmouth Atlas tells us that areas of the country with higher proportions of primary care physicians spend less on health care, and patients get the same or better care.

Barbara Starfield of Johns Hopkins University has reported that people with a primary care physician have one-third lower costs of care, and they are nearly one-fifth less likely to die from their conditions. People are dying because they do not have a primary care doctor.

Unfortunately, when it comes to supply of primary care doctors, America lags well behind other industrialized nations. Only 36 percent of our physician workforce is primary care; in Australia, 56 percent is. So it is not surprising that Australia spends about half as much per person on health care as we do, and yet Australians can expect to live more than 3 years longer than Americans.

Fortunately, there is some cause for hope. Physician groups, the business community, and more recently patient and consumer groups, have worked diligently on proposals that reward high-quality delivery of primary care. Doctors offices can help achieve the kind of coordinated care that patients need. They can do so by adopting health IT, they can employ mid-level practitioners who can follow up with patients, they can implement clinical registries, and they can employ other strategies that work as well.

MedPAC has endorsed the testing of the patient-centered medical home model, and MedPAC would further recommend paying more for primary care services delivered by primary care providers. We need to increase the value that our health care places on primary care.

Today we will also explore the relationship between doctors, drug companies, and other manufacturers. Doctors provide an important service by assisting with the development of clinical protocols and researching new drugs and devices but, when physicians have financial relationships with manufacturers and facilities, it can compromise their independence and objectivity. Payers, plans, patients, and the general public deserve to know of these potential conflicts of interest, and additional information to be gathered to examine the effect that these conflicts may have on the referral patterns and the volume of services.

So let us find ways to connect health care's separate islands. Let us stop casting dollars on the waves as patients travel along the far-flung archipelago of care. Let us see if we can land on a system that centers health care where it belongs, with the patient.

Senator Grassley?

**OPENING STATEMENT OF HON. CHUCK GRASSLEY,
A U.S. SENATOR FROM IOWA**

Senator GRASSLEY. Thank you, Chairman Baucus. I thank our witnesses for their time that they put into this. We can all agree that any discussion of health care reform must include an examination of our health care delivery system. We have all heard that our health care delivery system has much room for improvement.

We can talk about rising costs, we can talk about little or no access for millions of people, we can talk about the need for improving quality, but if we do not examine the shortcomings in how the system actually delivers health care to people, we would be missing an essential part—and maybe some people would say the most important part—of the picture.

For example, patients do not receive the recommended care often enough, and they too often receive unnecessary care. This, of course, is the failure in how our care is delivered. Furthermore, for people who have coverage, volumes of health care services are provided in our system. This is quite evident by the amount that we spend on health care, but that does not necessarily mean that patients are receiving high quality or showing improved outcomes. That, too, is a result of how our system of health care delivery is organized.

When we look at the way health care is delivered in the United States, it explains quite a bit. Words commonly used to describe how our health care is delivered in America include words like “silo” or “fragmented” for a description. You also hear phrases like “lack of coordination,” “lack of accountability.” I have said it before: we should not be calling our health care delivery system a system in the first place.

But the system does not act this way just on its own. The way that we pay for health care drives the manner in which it is provided. This is a key point. Most of the problems with how health care is delivered today are the result of the payment system. Look at Medicare. The way Medicare pays providers creates incentives for quantity rather than the quality of health care, so we get a lot of quantity, but with quality suffering.

Here is another example. We all talk about how we need better coordinated care, but there are no incentives in the payment sys-

tem for providers to coordinate the patient's care with other providers. Since each type of Medicare provider is paid pursuant to a separate payment system, these payment silos result in fragmented delivery.

Another example is how the financial incentives affect the system. It is very disturbing, the reports showing the dwindling percentage of medical students who plan to become primary care physicians, perhaps as few as 2 percent of current medical students according to a new study by *The Journal of the American Medical Association*. Lack of sufficient financial incentives for primary care is a significant factor in this whole decline.

Financial relationships between health care providers and industry are another example of how financial incentives in our system affect delivery. There have been alarming reports of inappropriate financial relationships between pharmaceutical and medical device manufacturers and physicians.

Some industry-physician relationships do play a legitimate role in the development and dissemination of information on drugs and devices, particularly new ones. However, there are many questionable practices that result in inappropriate financial relationships between industry and physicians. Very few of these physician-industry relationships are transparent. They are hidden in the system. These inappropriate financial relationships can provide incentives for physicians to provide inappropriate health care.

In health care, like with most other things, you get what you pay for. If we want to make the system work better, then we must change the way health care delivery is financed. We have to change the financial incentives that are in the system until they are aligned with better care. We need incentives that will make our health care delivery system, in fact, a real system. These incentives should reward high quality and efficient care instead of simply more services, and some of questionable value.

These incentives should promote greater emphasis on primary care so that patients have better access to a provider who can coordinate care. These incentives should encourage providers like doctors and hospitals to work together to coordinate the care of patients as they transition from one setting to another. These incentives should make all providers involved in the care of patients accountable across the entire episode of care, and they should encourage physicians to involve the patient in his or her own care.

The Medicare Payment Advisory Commission—MedPAC, as we know it—recently made a number of recommendations to Congress on the system. Many of these reforms are currently being tested in both the public and private sector, and of course we ought to look forward to learning more about these reforms, and even doing it at today's hearing.

I would also like to hear about the successes and challenges of those innovators who are testing reforms, and I would especially like to learn more about what Congress could do to foster their development. We also look forward to hearing about drug and device industry and physician financial relationships, and implications that these relationships have on the health care delivery system.

So I believe then that public disclosure is the best safeguard against inappropriate financial relationships between the drug and

device industry and physicians. That is why I proposed the Physician's Payment Sunshine Act. So I am especially interested in hearing more about these relationships and what effect public disclosure might have on health care delivery.

Before closing, Mr. Chairman, I would also like to place a letter in the record that relates to the practice of medicine and medical research.

The CHAIRMAN. Without objection.

[The letter appears in the appendix on p. 45.]

The CHAIRMAN. Thank you, Senator.

I would now like to welcome our witnesses. First, we will hear from Dr. Mark Miller, executive director of the Medicare Payment Advisory Commission, otherwise known as MedPAC. Next, Dr. Glenn Steele is the president and CEO of Geisinger Health System. The third witness is Dr. Robert Berenson, a senior fellow at The Urban Institute. Our final witness will be Dr. Eric Campbell, who is associate professor at Harvard University School of Medicine.

All of your statements will be automatically included in the record, and I encourage you to limit your remarks to about 5 minutes.

We will start with you, Dr. Miller.

STATEMENT OF MARK E. MILLER, Ph.D., EXECUTIVE DIRECTOR, MEDICARE PAYMENT ADVISORY COMMISSION (MedPAC), WASHINGTON, DC

Dr. MILLER. Chairman Baucus, Ranking Member Grassley, distinguished committee members, thank you for inviting the Medicare Payment Advisory Commission here today to discuss delivery system reform ideas.

As we consider our policy advice to Congress, we keep certain principles in mind: assuring beneficiary access to quality care, paying providers fairly, and assuring that taxpayer dollars are spent wisely.

All of you are aware that Medicare is not sustainable on its current path. Medicare is growing faster than the budget, the economy, and beneficiary incomes. This increase in spending is not consistently accompanied by improvements in quality.

Our past reports have made recommendations related to payment updates, to improving the fairness of fee-for-service payments, rationalizing managed care payments, pay-for-performance policies, and developing comparative effectiveness information. All of these policies are important, but they are not sufficient.

Our current payment systems are part of the problem: they reward volume; they do not reward coordination, quality, or cost constraint. The commission's current thinking has led to recommendations on payment policies that would change the organization and delivery of care to achieve these goals.

I will highlight four recommendations from our most recent report. The first refers to rewarding primary care. Our fee-for-service system discourages primary care providers by under-valuing their services and rewarding volume. This has the upstream effect of discouraging students from choosing primary care, although obviously there are other parts of that decision.

There is evidence that a higher mix of primary care providers in our current supply of physicians can lower costs and improve quality. Our June report recommends redistributing a share of Medicare physician payments to services provided by clinicians who focus on primary care, and I can discuss that in the questioning.

The second idea is developing medical homes. A medical home is a clinical setting that serves as a central resource for a patient's ongoing care. The commission considers this idea worthy to be explored. Accordingly, the June report recommends that Medicare establish a voluntary pilot program to test whether beneficiaries with medical homes have better coordination, better quality of care, and lower cost. The report discusses the payment strategies and the medical home criteria, and I can take these on during questioning.

The two points I would like to emphasize with you are: it is imperative that this pilot be large enough to produce results in a short period of time, and it should focus on beneficiaries with multiple chronic conditions and medical homes that meet stringent criteria. This is necessary to provide a good proof of concept for the medical home idea.

The third idea I want to discuss is discouraging hospital readmissions. Medicare spends \$15 billion annually on readmissions within 30 days. Not all of these are avoidable, but there is evidence to suggest that during the hospitalization and at discharge, there are opportunities to improve care and avoid these readmissions.

There are wide variations in the rates of readmissions among hospitals, and there are strategies to avoid the readmissions. To this end, we have recommended a policy to reduce payments to hospitals with high risk-adjusted readmission rates for selected conditions. The commission recommends that this payment change be made in tandem with a previous recommendation we made on gain sharing, that is, change the rules to allow the hospitals to incent physicians to participate in reengineering inefficient care processes. The commission also recommends providing these hospitals and physicians with information that allows them to compare their readmission rates to other providers.

The fourth idea is a payment bundled around the hospitalization. That is, a single payment to cover the cost of the hospital, the physicians in the hospital, and providers of care following the hospitalizations, for example, for a 30-day period. The objective is to get a strong alignment of the incentives among the providers of care involved in the hospitalization and the immediate follow-up care.

Bundled payments can raise a host of implementation issues, and the commission has recommended that CMS conduct a pilot project here to test the bundled payment around the hospitalization for selected conditions.

In closing, I would like to make a couple of points. The commission believes that the sustainability of the Medicare program depends in part on changing the payment system that is built around fragmented care and generating service volume. The tough nut is that the status quo is organized around the current payment system. Ideas like those put forward by the commission here today are designed to align the incentive of the providers to produce better coordination and improve quality of care for patients and cost re-

straint for the taxpayer. It is urgent that the Congress press forward on delivery system changes, and I look forward to your questions.

The CHAIRMAN. Thank you very much, Dr. Miller.

[The prepared statement of Dr. Miller appears in the appendix.]

The CHAIRMAN. Dr. Steele, you are next.

STATEMENT OF GLENN STEELE, JR., M.D., Ph.D., PRESIDENT AND CHIEF EXECUTIVE OFFICER, GEISINGER HEALTH SYSTEM, DANVILLE, PA

Dr. STEELE. Mr. Chairman, Senator Grassley, members of the committee, thank you for the opportunity to testify today.

My name is Glenn Steele. I am the CEO and president of Geisinger Health System. Geisinger is an integrated system which includes physicians, hospitals, outpatient health care facilities and programs, as well as a health care plan. We are located in central and northeastern Pennsylvania and serve a predominantly rural population of 2.6 million. We have a fully integrated electronic health record, and we lead our area's regional electronic health network.

Geisinger serves a population that is older, poorer, and sicker than the national average. Most of our patients have multiple chronic diseases: diabetes, high blood pressure, coronary artery disease, lung disease. We have been working aggressively over the past several years and committed significant resources to identifying ways to better care for this population and to reduce the costs.

One problem we have been tackling has to do with the great paradox in health care: getting paid for making mistakes. It does not mean that we intentionally make mistakes, but we are frequently rewarded financially when an outcome is not beneficial to the patient. For example, with few exceptions, if a patient develops a complication following surgery that might have been avoided by optimal care, we may receive more reimbursement than for comparable care without a complication. This does not happen in other industries. Purchase of a car, a computer, or even a home typically includes a warranty. Why should health care services be an exception?

In 2006, we started transforming care by testing and rewarding how we provided elective cardiac surgery, what is known as coronary artery bypass. We reviewed the American Heart Association and American College of Cardiology guidelines for cardiac surgery and we translated them into 40 verifiable process steps that could be implemented with each patient.

These behaviors were imbedded into our electronic health records so that we would be prompted or forced to meet each identified step or document the specific reason for an exception. We established one set price that included all the associated costs—pre-operative, operative, post-operative, and rehabilitation—and we did not charge for mistakes.

With our cardiac surgery outcome already well above the national average, implementing this program led to greater improvements in patient care. There was a reduction in complications of 21 percent, sternal infections were down 25 percent, readmissions

fell by 44 percent, and costs for treatment fell as well. Our average length of hospital stay decreased by half a day. Recently we have included hip replacement, cataract surgery, obesity surgery, care for babies from conception to birth, and heart catheterization. To date, we are showing success in each of these areas.

A second major problem has to do with the complexities a patient experiences in navigating through any health care problem. To address this, we have invested in programs and staff to support each patient's journey, placing dedicated nurses in targeted outpatient clinics.

Our version of medical home is called Proven Health Navigator, and our nurses are assigned to get to know their patients and their families, follow the patient's care, help them get access to specialists and social services, follow them into the hospital, follow them out of the hospital, contact them to confirm that they are taking the appropriate medications, and be available for advice 24/7. In our pilot program, initial hospital admissions for our sickest chronic disease patients were down by 24 percent, and our readmissions were down by 19 percent.

The pay-back on the resource investments for the health plan occurred within the first year; the benefit to the patients avoiding multiple hospital admissions and emergency department visits was priceless. Because this program has had such tremendous initial success, we have now expanded it to 35,000 additional Medicare patients.

In summary, we have unusual attributes that help us test and apply new methods of health care delivery, but what we are doing is not unique. Application of best practices can be shared and used by others. What we need to do is reward good clinical practice and not reward bad practice. Paying for readmitting a patient for an infection that should have been prevented is unacceptable.

National policies that address these reimbursement issues, particularly for Medicare patients, should be changed. Programs like medical home need to be recognized for their value and reimbursed appropriately. As we struggle together with adopting the right health care reform plan, at Geisinger we would be pleased to support your efforts in any way that we can.

Thanks again for the opportunity to testify.

The CHAIRMAN. Thank you very much, Doctor.

[The prepared statement of Dr. Steele appears in the appendix.]

The CHAIRMAN. Dr. Berenson?

**STATEMENT OF ROBERT BERENSON, M.D., SENIOR FELLOW,
THE URBAN INSTITUTE, WASHINGTON, DC**

Dr. BERENSON. Chairman Baucus, Senator Grassley, members of the committee, I very much appreciate the opportunity to provide testimony to the committee as it undertakes an important inquiry into the crucial topic of incentives to promote health care delivery reform.

It is a subject that I have been deeply involved with through most of my professional career as a general internist who practiced 20 years, a senior CMS official, and now as a senior fellow with The Urban Institute.

For more than 30 years, I have been in and around discussions of health care system reform. The idea of organizing physicians, hospitals, and other professionals and providers into integrated organizations better able to manage the complexity of patient needs has usually assumed the policy high ground. Integrated delivery systems can promote collaborative team-based care to better serve patients' complex care needs; promote adoption and quality enhancement of electronic health records; and sustained, systematic quality improvement in patient safety efforts.

Yet, research has found that in recent years physicians have been much more active in forming single specialty groups than in organizing and joining multi-specialty groups. Specialty consolidation provides more negotiating leverage with health insurers and permits the requisite organizational size and scope so that physicians can own and self-refer lucrative ancillary services, such as MRIs and PET scans.

Further, collaboration between hospitals and particular physician specialties has focused on developing and promoting profitable service lines rather than efficiently meeting the challenges of caring for an aging population.

A major problem is that, because they are dependent on current payment approaches, organizations are often penalized financially for undertaking activities that actually reduce costs. Incentives must be created to encourage physicians, other professionals, and institutional providers to become part of accountable care organizations, and then incentives must be created for those organizations to improve value for patients and purchasers.

Delivery system reform will not succeed if hospitals continue to be rewarded for increasing the volume of inpatient admissions and penalized for working with physicians and other clinicians to avoid hospitalizations for large numbers of patients with so-called ambulatory care-sensitive conditions.

We start with the problem of preventable readmissions, which MedPAC has estimated to cost as much as \$12 billion a year. Hospitals could administer dramatically improved discharge planning and patient education, assure that hospitals communicate with patients' regular practices, promptly push out discharge summaries to patients' physicians, and follow up with discharged patients by phone or in home visits shortly after the discharge to help coordinate patients' return to their home and community.

A crucial part of this enhanced transition planning needs to include detailed medication reconciliation. There are few policy initiatives that at the same time can improve the quality of care, enhance patient experience with care, and decrease system costs; reducing avoidable readmissions is one. Learning how to get these incentives right will help policy makers learn how to make more systematic payment changes to promote and enhance provider performance.

Value-based purchasing, which this committee has taken a lead on, should not only try to improve the quality and efficiency of provided services, but also try to change the kind and mix of services that patients receive. Medicare needs more geriatric care and, I would argue, fewer imaging services.

The Medicare Physician Fee Schedule, which is also used by most private plans, produces the wrong mix of services for patients being served. The result is that public and private fee schedules reward niche specialists disproportionately well at the expense of physicians who provide evaluation and management services or core surgical services.

Thus, distorted fee schedule prices not only contribute to shortages of primary care physicians, but to shortages of general surgeons as well. One result of the payment disparities is that medical students are advised to follow the “ROAD” to success—the road stands for the specialties of Radiology, Orthopedics (or Ophthalmology, depending on who’s telling the tale), Anesthesiology, and Dermatology—which, in addition to being highly remunerative, also support gentler lifestyles, usually without emergencies outside of regular work hours.

Fee schedule distortions not only result directly in excess spending related to a number of specific services, but also alter physician behavior to increase the volume of profitable services that do not overtly harm patients in order to increase practice revenues. A substantial body of evidence documents that countries and parts of the U.S. which rely more on primary care produce higher quality at lower cost than those with more reliance on specialty care.

Health delivery reform requires a stable primary care workforce, willing and able to take on the challenge of providing care to the growing share of the population with serious chronic conditions. Because of the long pipeline required to train physicians, Congress should address this issue immediately. Thank you.

The CHAIRMAN. Thank you very much, Doctor. I appreciate that.

[The prepared statement of Dr. Berenson appears in the appendix.]

The CHAIRMAN. Next, Dr. Campbell?

STATEMENT OF ERIC G. CAMPBELL, Ph.D., ASSOCIATE PROFESSOR, HARVARD UNIVERSITY SCHOOL OF MEDICINE, CAMBRIDGE, MA

Dr. CAMPBELL. Chairman Baucus, Senator Grassley, members of the committee, I am honored to testify today. My remarks today are related to physician–industry relationships.

A physician–industry relationship exists whenever a physician accepts anything from a pharmaceutical or device company, such as dinners in fancy restaurants, pens, drug samples, lunches, trips, and paid consultancies. These relationships create a tendency towards increased use of company procedures and high-cost drugs, sometimes with marginal benefits to patients. These relationships create hidden incentives to use procedures unnecessarily, thus potentially increasing the costs and threatening the quality of care.

Also, some forms of industry relationships can threaten the quality of the scientific literature, which in turn undermine the entire concept of evidence-based medicine and quality of care.

In the next few minutes, I would address four key points: first is that these relationships are highly prevalent; second is that they can have benefits and risks; third is that disclosure of industry relationships is highly variable; and fourth, increased disclosure of these relationships is advisable.

First, industry relationships are highly prevalent. A study published in the *New England Journal of Medicine* in 2007 found that 94 percent of all practicing physicians had some form of relationship with industry. These ranged from accepting food and beverages, gifts, to various kinds of payments. The study also found that 35 percent of physicians received payments for travel, and more than 25 percent received payments for consulting services.

In terms of their impact, the research has shown that certain relationships, especially research relationships between physicians, researchers, and industry, can and do facilitate the development of new drugs and medical devices. Many of the drugs and devices that are currently available to patients today would not exist had it not been for close relationships between physicians and industry.

At the same time, these relationships can have negative effects. For example, physicians who accept gifts from companies are more likely than those who do not accept gifts to prescribe company products. Gifts may also result in physicians prescribing higher-priced brand name drugs instead of cheaper, equally effective alternatives. This practice likely results in substantial increases in the cost of care. Free drug samples may further reinforce this behavior and perhaps stimulate the off-label use of medications, a behavior which often raises issues about patient safety.

Also, several leaders in medicine have suggested that industry support of academic research has led to substantial bias in the research literature, which is the yardstick by which we measure evidence-based practice and quality of care. Presently, the disclosure of industry relationships is highly variable. The most extensive disclosure systems are in medical schools and teaching hospitals; however, the vast majority of physicians do not practice in these settings.

Thus, there are no comprehensive data regarding the nature and extent of relationships between community-based physicians and industry. Several States have laws that require disclosure; however, these State-based systems are limited in number and there is concern regarding the quality of the data these systems produce.

Finally, increased disclosure of industry relationships is advisable. Without comprehensive data on physician–industry relationships, it is not possible to assess the overall impact that these have on the cost and quality of care that doctors provide and patients receive. Clearly, a comprehensive database that is linkable to claims and prescribing records would be a valuable asset for research and policy making.

For example, consider the use of radiologic services. Physicians vary in the extent to which they use expensive imaging equipment like MRIs. There are many possible reasons for why this variation exists. One potential explanation is that physicians who order MRIs at extremely high rates do so because they have an ownership position or other financial interest in a local imaging facility. Similar studies could be conducted related to the use of expensive surgical procedures and high-cost medications.

In conclusion, I believe that physician–industry relationships are ubiquitous in medicine. Because of the incomplete disclosure of relationships, there is a limited ability to scientifically study their overall impact on the care that patients receive. This knowledge

would be beneficial when considering which types of industry relationships should be allowed to continue at current levels, which should be constrained, and which should be eliminated. Failure to address these issues could overlook an important mechanism to controlling health care costs and improving quality of care in the future.

Thank you. I will answer any questions.

The CHAIRMAN. Thank you.

[The prepared statement of Dr. Campbell appears in the appendix.]

The CHAIRMAN. Dr. Campbell, I want to start off by asking if there is any disagreement generally among the panelists that we should move toward two subjects, one is a medical home concept, and the second question is, is there any disagreement among the panelists that we should move toward more bundling in our payment system?

If there is not a lot of disagreement on the concept, then my question is going to be, how do we get there most expeditiously? Is there anybody who disagrees in any significant way with the medical home concept or with moving toward—the problem is definition—bundling? Dr. Miller?

Dr. MILLER. No disagreement. Our point is, though, the concept just has to be tested before it goes wall-to-wall in Medicare.

The CHAIRMAN. Right. That is my question. My question is, how do we get there most expeditiously? I will begin with you, Dr. Steele, since you are doing a lot of this.

Dr. STEELE. Well, I think we have to look at our outcome. Right now, we have expanded to 30-some sites on our medical home version. That would be 35,000 Medicare patients. We have to ask questions. Is the effect that we have seen on the hospitalization rates going down, and the rehospitalization, is it durable? Have we just pent up demand? Have we pushed the patients into nursing homes?

So far we have seen no evidence of that, but it is an early experiment and it looks very, very promising. The other issue is, can we take this into a commercial product? There is certainly an age range pre-Medicare where a lot of us are facing the same kind of chronic diseases that we treat through the Medicare program. A big question for us, which I think is probably pertinent to Mark, is can we do this outside of the Geisinger-employed physician group?

In other words, is there a way of incenting this same kind of redesign of the practice with the insurance company having paid for a nurse to be imbedded into the practice outside of a Geisinger-employed community practice site? There are a lot of questions that hopefully will be of importance to Mark as he expands demonstration projects.

The CHAIRMAN. But what are your thoughts along those lines? How much can it be expanded, and what are some of the considerations we should address to get there?

Dr. STEELE. Well, first of all, I think we need electronic health records. I do not think that this could be done very easily without an electronic health record. The typical patient is 74, with four chronic diseases—a typical chronic disease would be type II diabe-

tes, congestive heart failure, hypertension, or reactive depression—and is taking 15 to 20 medications.

So this is blocking and tackling, Senator. If you can get to that patient before they get into florid failure, before they end up in the emergency room having to be admitted and given diuretics inpatient, what have you, and all of this has to do with knowing the information in real time. It is not waiting for the phone, waiting for the usual appointment. We think electronic health records are important. We think that redesigning the practice is important. We pay for it. We pay for it through the insurance company which is part of Geisinger, and pay for the provider group which is the other part of Geisinger.

The CHAIRMAN. Dr. Berenson, your thoughts?

Dr. BERENSON. Yes. I wanted to make a point about whether we should be equating the patient-centered medical home with chronic care management. My own view is that everybody should be in a patient-centered medical home. I want to give you an example. We have actually just recently published a paper in *Health Affairs* sort of reviewing the different definitions of patient-centered medical homes. One of my colleagues has given me permission to just very briefly recount something that happened while we were doing our work. She and I were at a conference together. She turned to me and said, I have leg pain. Why do I have leg pain? I gave her a curbside consult, suggested maybe she was developing early phlebitis.

What ensued over the next 3 weeks? She called her physician long-distance, had six phone call interactions and a number of missed calls, six e-mail interactions. Her physician arranged, on an emergency basis, to get to the vascular lab to diagnose her phlebitis. She had multiple anticoagulation tests and phone calls to go over it, and one office visit during that whole period. Her physician received reimbursement for one office visit, was functioning as a patient-centered medical home, provided impeccable care to my colleague.

Many physicians would not have done that under current payment models. So, there are physicians today who no longer take calls at night, they put an answering machine on at 5 o'clock at night and patients wind up going to the emergency room and getting admitted. Other doctors are up at 3 o'clock in the morning while wondering what people are doing at 3 o'clock in the morning. Some doctors are with their patients or are talking to the ER.

I think that may be about a medical home or it may be about flaws in our fee-for-service payment system. I do not think we can just reimburse for every e-mail or every phone call. It goes to thinking about more innovative approaches to paying, particularly in primary care. So I would urge us to think fairly broadly about this topic, not just equate it—and I agree with Dr. Steele. It is essential for improving care for chronic care management, but I think it has broader application.

The CHAIRMAN. Thank you very much.

Senator Grassley?

Senator GRASSLEY. Dr. Campbell, you noted that currently there is no national database of relationships between industry and physicians, no sunshine on these relationships and publicly available

data on industry relationships. So what are the risks caused by this lack of transparency and what effect does it have on health care delivery?

Dr. CAMPBELL. I think, first of all, the risks are that it is impossible for institutions to manage what they do not know about. Health plans and hospitals, if they do not know about these relationships, cannot manage these things. I think they create the risks I talked about before, about increased incentives towards over-use. It creates waste. It is possible that some portion of the variation in physician use of expensive medical procedures may in fact be related to the conflicts of interest or industry relationships that those physicians have. That was the first part.

Could you repeat your second part, Senator?

Senator GRASSLEY. Well, what effect would it have on the health care delivery system because of the lack of transparency?

Dr. CAMPBELL. Well, like I said, I think it is very difficult to manage what you do not know about. The other thing that it is doing, there is a very limited ability to study the impact of these things. If you do not have a database, you cannot do the research, which is essentially linking the relationships to the actual care that physicians provide to get a better understanding of their potential impact on the cost and quality of care.

Senator GRASSLEY. Let us go to Dr. Miller and Dr. Berenson, following on a little bit of what Senator Baucus has already talked about, because everybody seems to be talking about medical home being an answer to everything.

What I want to know is, how do we know it is not just the latest fad, much as gatekeepers were 10 years ago who were supposed to be doing the same thing?

Dr. MILLER. I think we do not know. I think what we are trying to push here is a test to make sure it does not become just a fad. Just to pick up with your question and some of the things that were said here, we feel very strongly that it may be that in the long run a medical home is the right solution for every patient, but the first step, in our view, is to prove that the concept works and to focus first on high opportunity—so, chronic conditions where you can do things like avoid hospitalizations, have criteria for the medical home such as things that were mentioned.

IT, something that Bob was talking about. Twenty-four hour access for the patient. Having a care management team. If you meet those criteria, then you get a per-member, per-month payment to help defray some of the costs that Bob was talking about that do not get covered—phone calls, e-mails.

But then the last component is to show that the performance actually has an impact. If this is working, then the medical home's panel of patients will have better quality and lower cost. If it is not working, then the idea should be pushed to the side and other solutions looked for. But if it does work the way some experience shows and some early research suggests, we could have something that would work here. But the idea is to test it so it is not just a fad.

I am sorry, just one last thing. What we have to resist is the notion that people will say, we are doing this now, just pay us. There is a lot of evidence that there are many practices that are not like the one that Bob is talking about. I am sorry, I will stop.

Senator GRASSLEY. Dr. Berenson?

Dr. BERENSON. Very briefly, I basically agree. We need to test a lot, and that is why I think it is important not to assume that we are going to solve—I would call it a crisis in primary care, given the kind of data that the chairman was talking about, how few physicians are going into primary care fields. We have to take that one on separately.

I mean, I think there are flaws in the Medicare Physician Fee Schedule which, as I said, is adopted by private plans as well. We need to deal with that as a separate action that needs to be addressed while we are understanding how the patient-centered medical home works and can be promoted.

Senator GRASSLEY. Dr. Miller, a short answer to this question: we have many examples where Medicare has led the private sector in delivery system changes. For example, the private sector stopped paying for “never” events and some hospital-acquired infections only after Medicare. Does Medicare have to take the lead in the delivery system reform?

Dr. MILLER. Yes.

Senator GRASSLEY. All right.

Dr. MILLER. And I have had many conversations with people in the private sector over the years. They have said, you need to lead on pay-for-performance so that we can follow. You need to lead on comparative effectiveness so we can use that information. I hear this all the time. I think Medicare should lead. The only thing I would add is, we should also set up structures that reward people who have already stepped in and started to try to make these changes, and certainly not stand in their way, the innovators in the system.

Senator GRASSLEY. Yes.

Senator Wyden?

Senator WYDEN. Thank you, Mr. Chairman. I think it has been an excellent panel. I would only say, with respect to the health care home, what we have done in the Healthy Americans Act is we made it an option for the patient and the consumer. In other words, it is not going to be drilled down their throat against their will, but plans would have to make it an option. I think, Dr. Miller, that is along the lines of what you want to have. Let us have some options, let us have some flexibility and make sure that this is tested.

Obviously what has emerged from this panel and our previous hearings is that the incentives that drive American health care today work against quality. I mean, Medicare in effect pays for quantity mostly rather than quality, and that is certainly true of the tax code as well. If you are really offering crummy quality health care in the United States in the private sector, do not sweat it because the private sector is going to get subsidized through the tax code for inefficiency.

So, as I look at the tools for rooting out a lot of the poor-quality care and driving down the cost, it seems to me we have to make it easier for patients to comparison shop. I would like to maybe start with you, Dr. Miller, and then you, Dr. Berenson. I do not think it is very easy for patients to comparison shop, either in

Medicare or in the private sector, for quality and cost. Do you agree with that?

Dr. MILLER. I agree. It is very difficult for a patient to look at information on a provider and make those kinds of choices. I have another thought behind this, if I can.

Senator WYDEN. Please.

Dr. MILLER. I think that there is some thought at the commission that says that this information does not just go to the patient. The information on quality and use of resources should also go to the provider so that they can see how they practice differently from one another, and then, if our payment systems put the right types of incentives in place, they can lead the patient in those decisions. But to your original question, there is probably a lot of work that needs to be done to synthesize this information to a form that patients can understand.

Senator WYDEN. Dr. Berenson?

Dr. BERENSON. I agree. Right now quality is not transparent to patients. I am quite skeptical that in the near term we are going to be able to have a robust set of measures that patients will be able to rely on. That is why I think a necessary strategy for delivery system reform is to encourage the Geisinger clinics to form, to have Billings Clinics and Geisinger Health Systems, I guess is what they are now called, so that you can have peer-on-peer quality improvement that may not be transparent as easily to consumers, but clearly you can get substantial quality improvement because the organization has a commitment. It is also, I would add, easier to array data at an organizational level than it is at a physician-by-physician level.

Senator WYDEN. Well, that really gets to my question for you, Dr. Steele, because I think that an approach like Geisinger which values quality rather than just in effect spending their time trying to shed bad risk, is going to flourish under the Healthy Americans Act. For example, what we do in this legislation is we create a website where consumers—all consumers, Medicare, private sector—can secure quality and cost information by zip code.

So what that means is, Medicare patients and, say, a worker with an employer-based package can look at all the alternatives. The worker can keep their employer package if that is what they want, but they would also be able to look at the alternatives.

So my question to you, Dr. Steele, is would it not be useful in delivery system reform to include changes that provide incentives to the consumer to comparison shop for private coverage?

Dr. STEELE. Yes. And I believe, as we develop our system, it is a combination of having the information available. If you go on our website, you can actually find our quality data. You can find our patient satisfaction data for each of our platforms, and it is not all good. I mean, we are constantly working to try to get things up to optimal.

But my experience with the citizens out there is, they get inundated by information and misinformation, so we are betting on the fact that you have to have access to the information and a trusted, long-term relationship. I think it is that combination, that is, the information and a trusted, long-term relationship, whether it is with a nurse, a doctor, or a PA, somebody that is living in their

community. That is the key engine, I believe, that is going to allow the right choices to be made.

Senator WYDEN. Thank you. I look forward to working with you, Doctor.

Thank you, Mr. Chairman.

Senator GRASSLEY. Senator Hatch?

Senator HATCH. Well, it is easier said than done, I have to say, but I appreciate the efforts that all of you are making.

Let me go to you, Dr. Campbell. Most drugs are administered either orally or intravenously. The information needed by physicians in administering a drug is fairly straightforward and can adequately be addressed through package labeling.

Now, on the other hand, the safety and effectiveness or outcome for most high-risk devices, particularly implants, is highly dependent on the physician being properly trained to use the specific device. In fact, the FDA takes into consideration physician training when approving many high-risk devices.

Do you feel that there should be a distinction between the valid education and training that needs to occur for devices versus drugs?

Dr. CAMPBELL. I think—for example, I saw the instruction manual for programming a pacemaker and a defibrillator, and it was about that thick and read like a textbook at MIT. I think there is absolutely no doubt that complex medical devices require intense periods of training, which require interactions between physicians and the company representatives to ensure that those devices are implanted safely and used safely. That may not be so with less intensive drugs. It may be so with more complex forms of chemotherapy and so on.

Senator HATCH. I agree.

Dr. Steele, I find Geisinger's Proven Care program refreshing and the results regarding patient outcomes thought-provoking. Now, what you said makes a lot of sense to me. I agree with you. I think you are on to something. However, I do have one question. How did Geisinger determine which complications were preventable? To me, there would have to be instances when medical issues would arise that were unavoidable and not the fault of the medical provider.

In addition, how difficult would it be for a national health care program like Medicare and Medicaid to implement such a program nationwide for, for instance, coronary artery bypass, grafts, hip replacements, or even cataract surgery? How would we be able to create a disease prevention model similar to the one you described in your testimony nationally? I appreciate your ideas regarding medical homes, but do you have any other suggestions or advice for members of the Finance Committee? I would like you to continue to work with us because I think we could benefit a great deal from your experiences.

Dr. STEELE. The first question is easier to answer than the second. What we started with, Senator, was a high-volume, high-cost, inpatient procedure-based treatment that already had the discipline, both on the cardiology and the cardiac surgery side, having defined what optimal outcomes should be.

So we basically took off the shelf what the metric should be, where we would say, we will not accept anything less than that, any complications. We avoided, for at least the near term—we have now added some high-volume procedures like, for instance, the care of the gastric bypass patients, where we have to determine on our own what's in or what's out in terms of complications. But we started with what was already consensus or evidence-based practice and looked at that metric.

Then we went back historically and looked at our complication rates and how we did against that metric, and our pricing strategy was to do a 50-percent discount from our historical complication rate. So we had to do twice as good in order to break even in the deal that we made with our own insurance company, and we were betting on the reengineering getting us above that in order to break even. That was kind of a financial incentive to get us where we wanted to go in terms of quality improvement.

Now, the second part of your question. I mean, I am not going to be able to give you a short answer. I think that there are areas of innovation that probably we should learn from. I do not think we are going to be able to do anything nationally through MedPAC that would get us immediately where Geisinger is. We have this unique anatomy, this unique culture, unique market. The rural market actually allows us some real advantages.

Senator HATCH. You remind me a lot of Intermountain Health Care.

Dr. STEELE. Exactly.

Senator HATCH. Very similar.

Dr. STEELE. Intermountain is a cohort. Intermountain is in our cohort. We are extraordinarily proud of being compared to them from time to time. They are superb, as you know.

Senator HATCH. Yes.

Dr. STEELE. But, I mean, I think how we translate our experience into an evolution—one thing that we think is terrific about the changes in the MedPAC incentives right now is moving towards episodes, moving in terms of bundled reimbursement. So I think that is moving in the right direction.

Senator HATCH. Well, thank you. I think my time is up.

The CHAIRMAN. I am kind of wondering how we pay for all this. We want to give more incentives in the right direction. We also know that in the next couple of years, at least, the Medicare trust fund costs are just going through the ceiling. So to what degree do we try to institute cost savings while removing—I know in the long term this is going to probably reduce costs. At least, that is the hope, with bundling, with medical home, comparative effectiveness, and other actions that we are taking.

I know a lot of people talk about giving greater reimbursement to primary care doctors and maybe changing the SGR system along those lines. The trouble is, the specialties are not going to want to give up what they have. They are going to fight tooth and nail on this, and so forth. So I am just trying to figure out how we squeeze all this together in a constructive way.

I do not know quite what my question is, except, how do we sort of get from here to there? I mean, we are paying so much on Medicare right now. Let us just start with Medicare. We want to give

more incentives in the direction that we think make more sense and encourage people to do things they should be doing. But how do we cut back in other areas? Dr. Steele, you seem to be thinking about this.

Dr. STEELE. We were taught a number of years ago that there was a choice between quality over here and cost reduction over here. I remember that discussion back in 1993, 1994. We are starting to get a hint that quality and value may actually cohabitate. Now, would that not be wonderful? I mean, if we assume that 50 percent of what we are doing, if you read the McGlynn articles and some of the other articles, is not based on best practice. If somehow you could move the system, incent the system to have less of that, conceptually you have to save some money somewhere.

Now, the other thing we found in our medical home which is interesting is, if you look at our costs per-member, per-month, there is a huge difference between the patients who are on medical home and the patients who are not on medical home. But some of that difference is mitigated, is neutralized by increased pharma costs.

So my guess is—we are going to look at this—that we are getting better compliance with those patients taking the pills that they should take, so there will be a trade-off. But I believe, if we are moving toward incenting the way the patient has the best chance of a good outcome, that we are actually going to find out that some of this quality and value cohabitates.

The CHAIRMAN. What do you think about that, Dr. Miller?

Dr. MILLER. Relative to some of the ideas that we have talked about today, in primary care, we are talking about something there that is budget-neutral, shifting dollars. Bob and I have had these conversations about whether we are paying too much for certain procedures within the fee schedule and the need to, at a minimum, reallocate those dollars.

The CHAIRMAN. Are you talking about cutting down the payment to the specialties?

Dr. MILLER. You know, I am sorry, yes.

The CHAIRMAN. How do you get them to either buy in or, if they do not buy in, are you just saying, let them squawk and that is just tough for them?

Dr. MILLER. Well, I would hope that some of the other ideas that we are talking about here, that when you have something that is more of an episode basis, which would include all of the providers that are involved in the chain of care for a given episode, if they have this incentive and they dig out the efficiencies that Glenn is talking about here, then all of the providers can participate in that outcome.

But to the point about whether we need to shift dollars within the Physician Fee Schedule, I am sorry, the blunt answer is, we are talking about taking it from one set of services and moving it to another.

The other thing you asked is, where does some of this money come from? It is not an answer, but also the philosophy behind the readmission policy is, we should not be paying for bad care. So the notion of taking the dollars out when that kind of care is provided is another strategy, and that is one—

The CHAIRMAN. Dr. Berenson, your thoughts?

Dr. BERENSON. Yes. I have done work with MedPAC. I guess my response would be, everybody is going to squawk when their fees are frozen or reduced. But there are flaws in how the relative value scale is developed which result in over-payment in the sense of payment far in excess of the production costs, which is supposed to be the basis for the RBRVS system in Medicare.

For example, imaging services had double-digit increases for many years. It is now beginning to moderate a little bit. Essentially, the volume of advanced imaging services like MRIs and CT scans doubled in a 5- to 6-year period. The fixed cost of the equipment is now being spread over a much larger volume of cases that they are doing, and yet the fees did not respond to that. Essentially, we were not getting the prices right.

So I understand the political dynamic, and that does not help your situation. But I think MedPAC has now identified, and CMS, I think, knows, a number of the technical areas that could be improved which would cause some redistribution within the fee schedule, not draconian cuts to anybody, but some redistribution.

The CHAIRMAN. All right. Thank you.

Senator Wyden?

Senator WYDEN. Thank you, Mr. Chairman.

Dr. Steele, I think the exchange you just had with the chairman was very insightful, because clearly we have to find a way to pay for these kinds of things. I want to ask you what I asked the head of the Congressional Budget Office, Dr. Peter Orszag, because I think that your comments indicate you are moving in that same direction. What Dr. Orszag has said to us when he has come up to testify in the past is that something like a third of all the health care spending today goes for treatments and services that are of little or no value. They are really not particularly good quality. That means it would be upwards of \$700 billion this year.

So I asked Dr. Orszag specifically this question. I said, Dr. Orszag, it seems to me that the only way to bend the cost curve down is to take two steps. The first is to demonstrate to our citizens how much all this inefficiency costs, particularly in terms of their take-home pay. The second is to put in health reform legislation incentives for them to select care on the basis of value. Dr. Orszag answered that question "yes." He said, that is the way you are going to bend the cost curve downward.

As a general rule, would you agree with what Dr. Orszag said?

Dr. STEELE. Absolutely. Our advantage, obviously—we are focused on an extraordinarily small universe, you are focused on the entire country. Our advantage is, we can sit down with our insurance leader over here, our provider leaders over here, and we can say, what is it we have to do to redesign our system and to incent to get the best possible outcome for either an acute problem that we handle with a patient coming in, with a citizen who is not sick yet, or with a patient with multiple chronic diseases? We can be very innovative.

Now, obviously what we want to do for Mark and his associates and for you all is to show whether those innovations actually create increased quality and decreased cost. So, I mean, my answer is yes. I feel our obligation is to be an engine of innovation that could be utilized, along with Intermountain, along with Billings, along with

a number of other committed, unusual systems to show whether these results are potentially scalable.

Senator WYDEN. Dr. Miller, were you stretching or did you want to comment on that?

Dr. MILLER. I wanted to comment, if you have the time. But the thing I would follow in that response is, he said sit down with the providers to see if you can create a product that is more efficient that you offer to the beneficiaries. So I am not saying no to your point, but I am just reinforcing, if we do not focus on how we pay providers and on information for providers, I do not think we can offer the choice to the beneficiary. I do not mean to put words in your mouth.

Senator WYDEN. I understand.

Can I just do one bit of clean-up with you, Dr. Berenson? You highlighted the need to improve the primary care workforce in your testimony. What we did in the Healthy Americans Act was include a care management fee for the primary care physicians as a way to kind of boost it, in effect. We legislated only two reimbursement increases, one for primary care and a second for chronic care coordination.

Any other ideas that you can think of with respect to boosting the primary care side of the ledger?

Dr. BERENSON. Yes. It is my observation—and I am not sure there is a lot of data, but I keep hearing anecdotes to suggest that one of the reasons for unnecessary health care spending is the absence of the patient's regular physician, usually the primary care physician, between the hours of about 9 p.m. at night and 7 a.m. in the morning. When the patient is going to the emergency room, the regular physician is not part of the decision-making. The ER doctor wants to clear the ER, and now there is a hospitalist who is more than happy to admit that patient to the hospital.

I think we should be providing increased payments to primary care, but one of the things we should be getting is a guarantee that those primary care physicians, through call relationships—they do not have to personally be on all night, but through reasonable call relationships—are going to be responsive during that important period of time. It works a lot easier in a larger organization, where you can even have nurses and others taking up some of that. It would work better if there was a link to an electronic health record so that that doctor at night knew what was going on, but we have absentee doctors during that time period. I just think that needs to be improved.

Senator WYDEN. It sounds too logical.

Thank you, Mr. Chairman.

The CHAIRMAN. Senator Hatch?

Senator HATCH. Thank you, Mr. Chairman.

Dr. Berenson, I read with interest your testimony advocating integrated health care systems. As you probably know, and I have been mentioning it here, Intermountain Health Care, which is headquartered in my own hometown of Salt Lake City, UT, specifically Dr. Brent James, whom I think everybody recognizes, has been quite involved in examining issues associated with health care quality. He has told me over and over again that 55 percent of health care expenditures may be attributable to waste.

In addition, IHC is one of the top-performing integrated health care systems in the country. Reimbursements for health care services are some of the lowest in the country, yet IHC has some of the best health care outcomes in the country. In contrast, Nevada, which is right next to Utah, has much higher reimbursement rates, yet some of the worst health care outcomes.

Last week our committee had a hearing on quality performance, and the witnesses talked about the advantages and disadvantages of pay-for-performance. I would like to have your thinking about pay-for-performance. Would it improve health care outcomes in an integrated health care system like Geisinger or Intermountain Health Care?

That is the question. I am simply not convinced that paying a provider more or less for providing health care services will make a significant difference. I would just like to know what your thinking is on this issue. After we hear from you, if there is time, I would also like to hear the opinions of, especially Dr. Steele.

Dr. BERENSON. It is a complicated topic.

Senator HATCH. Yes, it is.

Dr. BERENSON. I think there is a role for pay-for-performance but, for the most part, the way it has been conceived is to identify generally primary and secondary prevention activities and provide some marginal payments for performance of those. One can get some improvement in that area. What a marginal payment does not accomplish is changing the basic behavior, and especially addressing issues of overuse and misuse of services.

So, going back to my imaging example before, if you are paying a full payment for doing perhaps an unnecessary imaging procedure and 2 percent for not doing it, the provider is going to do it. We need to somehow have different incentives imbedded in the basic payment system, not just in the marginal payment.

So what I have heard Brent James say, and what I have heard others say, is that they undertake a program, one of the results of which is to reduce the need for hospitalization, and then the system loses revenue because you only get revenue during a hospitalization.

That is why I think an important first step—and Dr. Steele has some experience—is the PGP demo model, the physician group practice demonstration model that CMS has, which shares the savings with the organization if they are able to achieve savings. It internalizes to the organization the benefits of efficiency as opposed to letting a third-party payer benefit from the efficiency while you lose yourself.

So I think pay-for-performance has its role. I could use that rubric to describe what I am talking about, which is, for example, paying hospitals a reduced rate for readmissions within 30 days. Just do not pay a full DRG, pay a significantly reduced DRG. That imbeds the incentive in the basic payment system. It can be pay-for-performance, but it is not just using marginal payments.

Senator HATCH. All right. Would you care to add anything, Dr. Steele?

Dr. STEELE. Well, it is very complex. Just to add a little flesh on what Bob was mentioning, for our community practice commitment to taking better care of type II diabetic patients, coronary artery

disease patients, what have you, our practitioners themselves have decided that up to slightly less than 20 percent of their total cash compensation will be based on them achieving their goals for improving the care of these patients.

So their compensation has nothing to do then, up to that 20 percent level, with seeing more patients or doing more tests. It has to do with an actual performance metric which we are looking at to see if there is a connection to better outcome for those patients. So it has to be a significant incentive, not a marginal incentive.

The second thing is, we found that the doctors have to buy into it. The doctors, the nurses, the clerks, and all the people who are working have to be a part of this. There is a tremendous pride of purpose. But if you somehow combine the incentive with the pride of purpose and the professional, you get a lot out of it. If it is simply an intermediate marker that you define as a pay-for-performance metric, it can be gamed, and I think that is what we are all objecting to.

Senator HATCH. Mr. Chairman, can I ask just one other question that I would like to get out?

The CHAIRMAN. Sure.

Senator HATCH. Part of my prior life was defending in medical liability cases. Naturally, when they did away with the standard of practice in the community and came to the current changes in laws which made doctors have to explain every possible outcome in advance, which is impossible to do, and not every case goes to the jury, we spent a lot of time teaching doctors how to do everything they possibly could to have in their history that they literally took every precaution there was. We had to give that advice under those circumstances.

In the process, naturally we all want defensive medicine, but how is the medical liability litigation in this country impacting and creating a lot of unnecessary defensive medicine? Has that affected you, and how does that affect the total costs of these matters? We will go right across the board. Dr. Miller?

Dr. MILLER. I am not sure I can give you much of an answer. My sense of the literature on the defensive medicine broadly across the country is that it has an impact, but it is not a large explanatory variable like in the geographic variation that you see across the country. It is not a large factor in—

Senator HATCH. The AMA, basically, a number of years ago, estimated about \$60 billion a year. Now if the AMA estimates \$60 billion a year, can you imagine what it must really be? But you are saying you do not have a measurable—

Dr. MILLER. But to the extent there was some work done by the Dartmouth folks on looking at geographic variation, they did not think it was a large factor in explaining differences in the level of care across areas. They thought it had an impact, but a small impact.

Senator HATCH. I will talk to the practitioners here. Dr. Steele?

Dr. STEELE. Well, the biggest impact it has on us—you understand, let us just get to the core here. It costs us about \$145,000 per obstetrician for MedMal in Pennsylvania. You cannot have small practices with a small volume of deliveries in the small towns. Those practices closed down. So that is how it affects us. So

people have to go 30 miles from Tunkhannock down to Wilkes-Barre in order to deliver, even though there is a P&G plan up outside of Tunkhannock. That is how it affects us.

Senator HATCH. Some have to go farther than that.

Dr. STEELE. They have to go farther away, and those practices close down. The small hospitals that are dependent upon those practices are in deep stress.

The CHAIRMAN. So what are you saying?

Dr. STEELE. I mean, that is the main problem.

The CHAIRMAN. No. What are you saying about what, what is your practice with Geisinger? How do you incorporate those high MedMal premiums?

Dr. STEELE. Well, we subsidize. We cross-subsidize. I mean, we are doing well enough that we can keep those small practices going, even if they lose \$300,000 to \$400,000, if we decide that it is important to the community, important for the overall regional care that is delivered there. But I agree with Mark, there is no evidence that we have that that MedMal in itself and defensive practice leads to variation. There are other reasons for that variation which is much more important.

The CHAIRMAN. Thank you.

Senator HATCH. Dr. Berenson?

Dr. BERENSON. I was going to use a similar example to talk about the difficulties of trying to put a number on defensive medicine.

Senator HATCH. I am talking about unnecessary defensive medicine now.

Dr. BERENSON. Well, there is unnecessary defensive medicine. I still remember when I was an internist, going to my liability insurer seminar and being told, even if you know that your patient's rectal bleeding is from the hemorrhoids you can see, you need to refer that patient to a specialist for a colonoscopy because maybe there was an occult neoplasm. That is unnecessary. I ignored that advice. I basically said, I am going to continue to make that diagnosis and not refer. But different doctors make different decisions.

The example I was going to use was high-risk pregnancies. There is no question that in some jurisdictions community-based OBs no longer are doing those services and the patients are going to specialized high-risk pregnancy centers. On the one hand that is disrupting relationships, on the other hand perhaps the costs are coming down if the patients are now going to high-risk centers. Perhaps the costs are going up because those are more expensive centers to maintain. We do not know. I would agree with the overall assessment that there is a cost with the defensive medicine, but it is probably not anything like what the AMA had been putting out.

Senator HATCH. Dr. Campbell, you do not have any comment on it?

Dr. CAMPBELL. No.

Senator HATCH. I just wanted to ask that question because I think it is a much higher cost.

The CHAIRMAN. I have a question. Thank you, Senator, very much.

Dr. Miller said that hospitals with excessively high readmission rates should be penalized. The basic question I have of all of you

is, how do we implement ways other than that—maybe including that—to lower inappropriate readmission practices? I mean, I guess part of the incentive of the hospitals is, once they get their DRG they kick it out, kick the patient out. But as you said, Dr. Steele or Dr. Berenson, I have forgotten which, maybe the readmission DRG could be at a lower level, is one way. Then the question is, how do you coordinate with doctors and other providers once they are in the hospital, and also out of the hospital to lower the successive readmission?

Dr. MILLER. So in addition to the hospital penalty, is what your question is?

The CHAIRMAN. Yes.

Dr. MILLER. Yes. I think there are a couple of things that you can think about here. We have made recommendations elsewhere, and I am going to get you a silo solution, or at least a plan, and then get you to a bundled plan.

We have made recommendations, for example, to have impacts on the skilled nursing facilities payments when they have high readmission rates, so you have the actor who is sending the patient and the actor who is receiving the patient both at risk for a readmission, and you can kind of begin to implement things like that in a siloed system.

We did not do it in this particular recommendation, but the physicians in the hospital, their payments can also be considered if the readmission rates are very high. I already mentioned in the opening statement the notion of gain sharing as another mechanism to bring the physician into it, but then the objective, and I think what the commission is thinking about is, if you have a bundled payment that runs across those providers in the hospitalization—the hospital; the physician; in the first 30 days post-acute care, the physicians who see the patient—then you have all of their incentives going in the same direction in that they all want to avoid that readmission and they all want to avoid unnecessary services, consultations, that type of thing. That is kind of the thinking.

The CHAIRMAN. Dr. Steele?

Dr. STEELE. Yes. We deal with 17 non-Geisinger hospitals. These are small hospitals. I am sure you are familiar with the small hospitals in rural communities. One of the things that we are noticing now as our readmission rate dives down with our version of medical home, is stress on these small hospitals. They are important to us. We do not want to acquire them, but we want them healthy because we are trying to give as much care close to where patients live in the small towns of rural Pennsylvania as we can. It is a tough one. We are continuing to work with them because they are going to have to redefine themselves, and that is not easy to do. But I think that will be a very complex part of anything that successfully treats these patients.

The CHAIRMAN. And how will they have to redefine themselves, why, and in what way?

Dr. STEELE. Well, if they have fewer admissions, they are going to have to give care in a different manner, and they are going to have to actually probably look at their fixed cost structure. Now, as you are well aware, a lot of these hospitals are the largest generator of employment for the small towns.

The CHAIRMAN. Right.

Dr. STEELE. So, it is not easy. I think the key thing, though, is to do the right thing for the patients and to be sensitive about the effect that it has on some of these wonderful, but very small, very close to the margin, rural community hospitals.

The CHAIRMAN. Dr. Berenson?

Dr. BERENSON. Yes. I have a suggestion about how small hospitals can redefine themselves, and that is by essentially becoming the locus for the chronic care management activities. Small practices, I do not think, will have the capability of doing what Geisinger does in terms of developing collaborative teams, having dedicated nurse managers for specific chronic conditions, having a very active social service activity. We want to have those doctors doing primary care, availability/access to care for their medical care.

It is the hospital, in my view, that can help organize that support activity to house the disease management nurses, to get a part of the chronic care management. So, instead of a health plan contracting with a disease management company and being on the phone three States over or in some call center somewhere, you actually locate it in the community.

The North Carolina Medicaid program has that kind of model, where you have primary care physicians in a medical home, but they support community-based nurses either at hospitals or in health departments to do the coordination so that they, in effect, have virtual teams. I think that community hospitals could be doing some of that activity.

The CHAIRMAN. Your thoughts about CMS and implementing some of these demonstrations or pilot projects and so forth. I think to some degree next year, in our health care reform legislation, we are going to be delegating a lot to CMS to implement some of these changes. It is an open-ended question. Just, what guidance do you have for this committee in dealing with CMS so that CMS does what it should be doing?

Dr. MILLER. At least a couple of things I think are imbedded in our testimony and the report, and my comments. On the medical home and on the bundled payments plus 30 days, I chose this word carefully, but it is subtle and so it may be missed, is the notion of a pilot so that you set standards for what the success rate is, for the success of the test. If the test is successful, then you can roll out another wave and kind of move forward. That is one thought.

A second thought on the medical home is, and I will be very direct about this, we think more money should be devoted to testing that concept so that you can get results quickly and figure out whether this thing is going to work or not outside of a network environment like Glenn has going there.

So we would encourage more money and the notion that, if you set the standards high for multiple chronic conditions and some of the conditions for the medical homes that we talk about in the testimony, you can get a good test and then figure out what is needed going forward. So pilot concepts, a little more money on the medical home, and then set the criteria fairly high to get the thing tested.

The CHAIRMAN. Do you think the medical home should focus on chronic care as opposed to everybody?

Dr. MILLER. I would say initially to test this concept, absolutely, yes. If you are going to see an impact, you are going to see it there, in multiple chronic condition patients where you can avoid the hospitalization, which I think is where the money is.

The CHAIRMAN. All right. Other thoughts about what we tell CMS.

Dr. BERENSON. Well, I just wanted, having been a senior official at CMS for 3 years at the last part of the Clinton administration, I am very sensitive to how overworked and understaffed CMS is. There is data that suggests the complement of staff is about the same now as it was 25 years ago, with many more responsibilities. It is simply stretched.

So my understanding third-hand—well, when we say, to be a value-based purchaser, not just putting a formula into the *Federal Register*, but actually doing what is required for things like the durable medical equipment competitive pricing, involves enough staff, and with some new skills sets, to be able to handle something like that. I just do not think right now, if we really want to seriously move to being a much more nimble value purchaser, that CMS has adequate staff or skill sets, and that needs special attention.

The CHAIRMAN. Dr. Steele?

Dr. STEELE. Yes. I think you start where the money is. We have all heard the 80/20 rule: 20 percent of the patients are using 80 percent. That is where, I think, Mark, you and I agree. George Halvorson has been talking about it for a long time out of Kaiser. We are experimenting with that group. So I would say, what would be the ideal outcome for that cohort of patients that has the highest utilization, and then how do we get there? How do we incent for that?

The other thing, quite frankly, is that, in 1966 when the Medicare law was written, it starts out by saying that we do not want to influence the care that is given throughout our country. We have come a long way.

The CHAIRMAN. We sure have.

Dr. STEELE. That is the original sin, so we have to get through that.

The CHAIRMAN. Thank you all very much. This has been a very constructive hearing. I appreciate it.

[Whereupon, at 11:31 a.m., the hearing was concluded.]

A P P E N D I X

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

Testimony of Robert A. Berenson, M.D.
Senior Fellow, the Urban Institute

Before

The United States Senate Committee on Finance
Hearing on
“Aligning Incentives: The Case for Delivery System Reform

Sept 16, 2008

Chairman Baucus, Senator Grassley, and Member of the Committee:

I very much appreciate the opportunity to provide testimony to the Committee as it undertakes an important inquiry into the crucial topic of incentives to promote health care delivery system reform. It is a subject that I have been deeply involved with through most of my professional career. I practiced general internal medicine for over twenty years, twelve of which were in a small group practice I co-founded located a few blocks from here. I have been medical director of a D.C. area preferred provider organization and helped organize and oversee two physician-owned independent practice associations.

In the latter part of the Clinton Administration, I had operational responsibility for provider payment systems at the Centers for Medicare and Medicaid Services (CMS) and was in charge of contracting with Medicare Advantage plans. In recent years, as a Senior Fellow at the Urban Institute, I have been studying the effects of the Medicare Physician Fee Schedule as well as important innovations that offer promise to improve how care is provided to Medicare beneficiaries and the American public, including the Patient-Centered Medical Home.

For the more than 30 years that I have been in and around discussions of health care system reform, the idea of organizing physicians, hospitals, and other professionals and providers into integrated and accountable organizations better able to manage the complexity of patient needs has usually assumed the policy high ground. The original concept of health maintenance organizations, developed by Paul Elwood and colleagues, assumed the development of integrated physician groups, and Alain Enthoven's vision of managed competition assumed replacement of unaccountable and independent physicians and hospitals with organizations that were better able to improve quality and manage costs. Over the years, these organizations have been variously labeled "multispecialty group practices," "integrated delivery networks," "physician-hospital organizations," "accountable health organizations" and "organized delivery systems," or other term to reflect changing fashion and nuanced differences in their configurations.

Proponents of this form of health care delivery have pointed to real-world examples of organizations that exemplify the best of breed and the potential of new organizational forms to improve care. Indeed, for most of my career, the same organizations have been cited: the Permanente Medical Group, the Mayo Clinic, Intermountain Healthcare, and the Geisinger Clinic, now the Geisinger Health System. Recently, there has been one interesting addition to the list of cutting-edge organizations that are reengineering how health care is being delivered to improve value – the Veterans Health Administration -- which demonstrates that government programs also can get it right.

As others on the panel are better able to discuss, integrated delivery systems can promote collaborative team-based care to better serve patients' complex care needs especially in the area of chronic care management; promote adoption and enhancement of electronic health records, including patient access to a personalized health record via customized

Web portals, and can mount and sustain systematic quality improvement and patient safety efforts.

And at a time when health care costs are rising at a pace that robs workers of well-earned wage increases because their employers must first pay the price of double-digit premium increases and is beginning to threaten the fiscal sustainability of the Medicare and Medicaid programs, offer the potential of reducing costs, while maintaining or even improving quality. A major problem is that because they are dependent on current payment approaches, these organizations are often penalized financially for undertaking activities that reduce costs. The result is that the potential of these organizations is not being realized.

It is striking that the same exemplary organizations that have been prominently identified over a number of decades as leaders are the same ones at the cutting edge of care improvement today. I have pondered why there has been relatively little uptake nationally into this form of health care delivery.

With colleagues at The Center for Studying Health System Change (HSC), I have conducted research documenting that in recent years physicians have been much more active in forming single specialty groups than in organizing and joining multispecialty groups. Single specialty consolidation provides them more negotiating leverage with health insurers and permits the requisite organizational size and scope to be able to own and self-refer lucrative ancillary services, such as MRI and PET scans.¹ Similarly, HSC has found that collaboration between hospitals and particular physician specialties, often in joint ventures based around construction of new facilities, has focused on developing and promoting profitable service lines and not on meeting the challenges of caring for an aging population and the challenge of patients with multiple chronic illnesses.

This understandable but unfortunate orientation, in my view, reflects distorted incentives, the subject of today's hearing, and explains much of why the organization of health care delivery actually is actually heading in the wrong direction, despite the occasional success stories of excellent organizations like Geisinger. Although I think altering these incentives will go a long way to changing the direction of change, I first want to offer a few observations of some other barriers I think stand in the way of adoption of integrated care models of health care delivery.

Merging Different Cultures

Organization of health care professionals and institutional providers does not occur naturally or easily. Forming and supporting the types of multidisciplinary, collaborative teamwork that lies at the heart of integrated care delivery requires altering the cultures of physicians, other professionals, and hospitals, all of which have developed mostly in hard siloes over many decades. Battling for their share of the health care dollar and coming

¹ Robert A. Berenson, Thomas Bodenheimer, Hoangmai H. Pham. Specialty-Service Lines: Salvos in the New Medical Arms Race, *Health Affairs*, Web Exclusive, 25(5), 2006, W:337-W343.

from their separate cultures with different attitudes towards basic approaches to how care should be delivered, tensions have arisen between primary care physicians and specialists, between physicians and other professionals such as nurse practitioners, and between physicians and hospital administrators.

Indeed, one of the harmful effects of having separate payment systems for each category of provider is to reinforce the cultural differences that already exist across the spectrum of providers which need to work together in patients' best interests. In practical terms, this means that even if the incentives become better aligned, developing organizations that can surmount long-standing disputes and cultural differences requires unique leadership and communication skills, not only at the top of the organization but in other senior management positions.

Need for New Organizational Ethics

A particular challenge for development of accountable care systems is taking on the culture in which most physicians have been nurtured in their medical education and practice environments. That culture in effect emphasizes heroic individualism, which often has well served patient's needs. However, this emphasis represents a distorted view of professional ethics emphasizing autonomy and independence, deference to other professionals' independence, and resistance to collaboration, transparency, and accountability. Physicians as professionals are taught to adhere to standards of care, whether or not adherence to those standards actually produce the desired results. Less emphasis is given to focusing on how to actually contribute to collaborative efforts to produce outcomes that best serve the interests of their patients and the public.

A modified professional ethics that emphasizes collaboration, accountability for performance, responsibility for conserving finite financial resources, while preserving the core element of professionalism – fidelity to the patient's best interests, ideally grounded in a mutually trusting relationship – has been promulgated.² It may be that integrated care organizations with appropriate physician leadership actually may be in a better position to follow this revised and updated set of ethical principles than many individual practices that unfortunately now seem inordinately focused on income maximization.

If the health care system begins to rely much more on the expansion of integrated provider systems, there is need to assure that the organizations adopt codes of ethics specific to their unique roles while assuring fidelity to serving patients' best interests. Further, policy makers need to assure the public that any recognition and support of accountable health systems as separate entities supported by their own, unique payment approaches vigilantly guard against the possibility that some of these organizations would have unsavory conflicts of interests and would not do their share to serve the underinsured and uninsured. In moving from a system relying on siloed physicians and

² ABIM Foundation, ACP-ASIM Foundation, European Federation of Internal Medicine. Medical professionalism in the new millennium: a physician charter. *Ann Intern Med.* 2002;136:243-246.

hospitals to one relying on integrated organizations, the public needs assurance that their interests as patients and as citizens are being protected.

Building on the Responsiveness That Characterize Many Small Practices

Another barrier that many multispecialty medical groups face, I believe, is that many patients prefer the familiarity, convenience, responsiveness, and trust they often find in community-based small practices to the more structured but often more imposing and less responsive environments that may characterize organizations with centralized clinics located some distance from where patients live and work. Even if the accountable delivery systems can document better performance on objective, but inherently limited, measures of quality and make the health care dollar go farther, patients may appropriately give priority in their own health care choices to small, “relationship-centered” practices.

Some multispecialty groups, such as Geisinger and the Billings Clinic in the Chairman’s home state, include in their networks primary care physicians practicing in community locations outside of the main hubs in which many of the group’s physicians, especially specialists, practice. Recent developments in health information technology, with interoperable electronic health records offer the very real potential that organizations can retain the patient responsiveness that characterize decentralized small practices while taking advantage of the organized group capabilities for expert referral networks, chronic care management support, quality improvement activities, pharmacy management, and other benefits that derive from what inelegantly has been called “systemness.”

Altering Payment Incentives

Although these and other challenges faced by current and would-be accountable delivery systems will not disappear if public and private payers altered their basic payment approaches, I agree with many others that the current incentives embedded in current common payment approaches have made it very difficult for integrated physician and hospital systems to succeed and to realize their potential. Their ability to increase value for patients and society are not rewarded, and their need to respond to current payment incentives undercuts what they are configured to accomplish.

In short, incentives must be created to encourage physicians, other professionals and institutional providers to become part of accountable care organizations, and then incentives must be created for those organizations to improve value for purchasers. As a prime example, whether or not the kinds of organizations I have described develop broadly throughout the country, delivery system reform of any kind will not succeed if hospitals continue to be rewarded for increasing the volume of inpatient admissions and penalized for working with physicians and other clinicians to avoid hospitalization for large numbers of patients with so-called “ambulatory care-sensitive conditions.”

If these patients receive appropriate ambulatory care, many would not need to be hospitalized, but currently hospitals have no financial interest in joining collaborative efforts to develop the needed alternative delivery approaches that would among other

things reduce the number of hospitalizations they experience. A primary objective for delivery system reform should be that hospitals assume their proper role as essential and valued community assets with a mission to improve community health instead of continuing to rely on revenue-maximizing strategies built of profitable service lines, regardless of population needs.

Decreasing Preventable Readmissions

The perversity of current payment approaches is well demonstrated in the problem of avoidable hospital readmissions. MedPAC, which has done important work on this topic, has found that about 18 percent of all-cause Medicare admissions result in readmission, accounting for \$15 billion in spending annually. MedPAC further found that Medicare spends about \$12 billion on these potentially preventable readmissions. Researchers at 3M have found comparably disturbing findings for patients with commercial insurance. Although harder to document, the need for readmission shortly after discharge suggests poor quality that might compromise patients' long-term health and well-being; surely some patients die before they can be readmitted.

Virtually all payers provide hospitals entirely new payments for a readmission, even one that takes place on the same day. (Sometimes, as in Medicare, payment is denied on a case-by-case basis if medical review determines there was a quality of care problem that led to the readmission.) Perhaps the most striking finding of all in this research is that about half of Medicare patients who experience a readmission within 30 days have not had a visit with a physician or other provider in the interim between discharge and readmission. Patients who are sick enough to have needed a hospitalization or have undergone a major procedure requiring an inpatient stay are then "lost in transition," with, apparently, no one taking responsibility for their care in the crucial, initial post-hospital days.

This lack of attention results from the current of siloed payment system, which penalizes no one for faulty "handoffs." Hospitals take no responsibility for the patient post-discharge and achieve entirely new inpatient payments when the patient needs to be readmitted within days. Similarly, under public and private payer fee schedules, physicians do not receive payment for reassuming responsibility for the patient post-discharge outside of a face-to-face visit. But office-based physicians who often do not go to the hospital any more to care for their own hospitalized patients may not even know that the patient has been discharged, much less the details of their clinical status and care recommendations, which may have been handled by a hospitalist. The hospitalists, for their part, may feel no responsibility for communicating the patient's discharge status to the patients' regular physicians, who after all has been absent during the hospital stay.

Hospitals could administer dramatically improved discharge planning and patient education, assure that hospitalists communicate with patients' regular practices, promptly "push out" discharge summaries to patients' physicians, and follow up with patients by phone or in person in home visits shortly after discharge to help coordinate patient's return to their home and community. A crucial part of this enhanced transition planning

needs to include detailed medication reconciliation with patients and their families because patients understandably are often confused about what which set of medications they are supposed to be on – the one prescribed in the hospital or the one that they had been on prior to hospitalization.

Simply, hospitals should not receive a full DRG payment in Medicare for readmissions that occur within short periods of time for large numbers of diagnoses that are amenable to better transition activities that would result in reduced rates of readmissions. One can think of it as robust pay-for-performance but able to be implemented without major new data collection requirements. And patients' regular physicians should be reimbursed, even fee-for-service -- for their activities outside of standard visits to assure a high quality transition and resumption of their patient responsibilities, possibly as a Patient-Centered Medical Home.

There are few policy initiatives which at the same time can improve quality of care, enhance patient experience with care, and decrease system costs. Reducing avoidable readmissions is one. Learning how to get these incentives right, initially even relying on siloed providers, will help policy makers learn how to make more systematic payment changes to promote enhanced provider performance.

The Need to Internalize Savings to Provider Organizations

Altered incentives can be a key to enhancing provider willingness to become more vigilant, not only to improve care transitions but also to reduce inappropriate provision of many services, to reduce errors, and to implement chronic care management programs to better support patients with complex health care needs. Diagnosis Related Group (DRG)-based case rates for hospitals and sixty day, episode-based case rates for home health agencies provide models for payment approaches that internalize to the organization the rewards for increasing efficiency.

A number of case studies have documented examples of organizations that have initiated programs improving quality and decreasing costs for patients and payers only to find that they could not sustain the direct costs of running the program and the decreased revenues that resulted from their success. Payment approaches need to reward rather than penalize cost reducing behavior. In this regard, the approach used in the Medicare Physician Group Practice (PGP) Demonstration – the “shared savings” approach that permits the group and Medicare to share in financial savings when the group successfully reduces total Part A and B spending – seems most practical for adoption initially for large organizations, especially for the kinds of integrated ones I discussed initially, but also for hospitals who might be allowed to share savings with physicians through gainsharing approaches.

It is time to move away from a “one size fits all” payment system relying on a Medicare Fee Schedule for physicians and Prospective Payment based on DRGs for hospitals. Over time approaches that derive from the PGP approach to shared savings might include forms of direct capitation to large provider organizations but without relying on private

health plans intermediaries. These alternatives need to be adopted and emphasized by traditional Medicare as a way to encourage accountable care organization development, while initially maintaining a parallel system for providers who have not decided to integrate. If anything, these new payment constructs might be tilted gently to encourage accountable care systems, for example by maintaining some form of expenditure cap on physicians receiving fee-for-service payments according to the Medicare Fee Schedule, while exempting physicians in integrated systems, because their performance is subject to the discipline of the shared savings or capitation incentives. The main point is that integrated delivery networks should be supported with payment systems developed specifically to take advantage of the added value they provide.

Payment Reforms for Non-Integrated Providers

On the expectation that even with new payment approaches that reward the development of accountable care organizations most physicians and hospitals initially will remain independent and not part of integrated systems, current payment methods used in Medicare and commercial insurance need to be altered. In the short run, paying “smarter” can reduce costs directly. In addition, new payment approaches that better align physician and hospital payment incentives might foster collaborative experience that could result in an interest in more formal collaborations to establish real integrated organizations.

One approach to encourage the internalization of cost-saving efficiencies and promoting greater collaboration between hospitals and physicians lies in bundled payments, for example combining Part A and Part B payments associated with a surgical procedure and its accompanying hospital stay. Bundling makes policy sense and needs to be vigorously tested.

At the same time, I have a concern about how the bundling of Part A and Part B services should occur. That is, bundling approaches need to also consider the appropriateness of the services being paid for, albeit now in a bundled manner. Health services research, especially the important work on appropriateness conducted at Rand and the decades of work on practice variation conducted by Jack Wennberg and colleagues at Dartmouth, document that even services provided expertly and efficiently may not have been needed in the first place. Bundled payment approaches, for example for cardiac procedures, need not only consider price and quality, but also appropriateness of those procedures for the patients in whom it is being provided.

In this regard, condition-specific, episode-based payment for physician services and bundled payments for physician and hospital services has inherent appeal, again because it internalizes to the providers the benefits of improved efficiency, in contrast to pure fee-for-service. There are, however, important implementation issues regarding bundling services involving procedures. Any episode-based payment system should guard against the inherent bias that exists in fee-for-service toward over provision of discretionary procedures. Although the costs of an episode needs to take into account the direct and substantial costs associated with providing the procedure, the valuation of condition-

specific episodes should attempt to reduce payment differentials that reward clinical decisions to provide the procedural intervention in preference to other strategies that do not include the procedural intervention. As an example, the payment for treating an episode of back pain that involves a surgical procedure should not be orders of magnitude more than payments that rely on conservative approaches to pain management.

Further, as with all episode or time period-based payment approaches, clinically sophisticated case-mix adjustment is needed to prevent perverse outcomes, such as physicians giving preference to less severe patients within a cohort with a particular condition or “over-diagnosing” relatively minor complaints to generate compensable episodes. All payment approaches present “gaming” opportunities; the work of developing payment bundles and episodes needs to actively protect against such behavior. Fortunately, in recent years, we now have much more sophisticated approaches to case-mix adjustment such that payment approaches, including capitation, that often did not work very well in the past should be more successful if adopted now.

The Need to Revise the Medicare Physician Fee Schedule

The Committee deserves credit for actively promoting the concept of Value-Based Purchasing (VBP) for Medicare. CMS is making progress in promoting VBP concepts for a range of provider types. However, some have interpreted VBP in a restricted fashion -- focusing on the quality and costs of the services being provided and not considering more broadly whether beneficiaries are receiving the right kind and mix of services, which should be a core concept in considerations of value. VBP has attempted to reward providers through public recognition and add-on payments, mostly for improving the provision of primary and secondary prevention activities. While useful, this approach does little to address the problems of misuse and overuse of services that create serious cost and quality problems in Medicare and, indeed, that affect the entire population.

At a programmatic level, the logic of Value-Based Purchasing would be to ask, for example, whether Medicare beneficiaries need more advanced imaging studies or more geriatricians to serve the increasing number of beneficiaries with complex chronic conditions and geriatric syndromes such as falls and memory loss. The current Physician Fee Schedule, based on estimates of the costs of production of the more than 6000 carefully defined services for which physicians submit claims, provides payment signals that have produced many years of double-digit annual increases in advanced imaging services and exponentially increasing rates of increases for some other discretionary tests and procedures, while evaluation and management services provided by primary care physicians, nurse practitioners and physician assistants have been increasing quite slowly. This suggests that current policy is producing a mismatch between beneficiary needs and the mix of services that are being provided to them.

Further, many of the activities that comprise chronic care coordination cannot be specifically reimbursed easily by fee-for-service. Patient-Centered Medical Home demonstrations by Medicare and private payers are beginning and will help policy

makers shape payment policy to support practice activities that better assist patients faced with the complexity of multiple prescriptions and often conflicting advice from different physicians, while reducing unnecessary emergency room visits and avoidable hospitalizations.

In the meantime, there is need to correct the current distortions in public and private fee schedule prices that not only produce the wrong mix of services for patients, but also frustrate efforts to develop integrated care organizations. Despite the promise of the Resource-Based Relative Value Scale to better reward so-called evaluation and management services compared to procedures and tests, the Medicare Fee Schedule, which is also a guide for health plan schedules, continues to pay more generously for tests and some procedures than for basic evaluation and management services, some of which are provided not just by primary care physicians but also by other important specialties. For example, a recent *Wall Street Journal* article described how current fee schedule values has contributed to shortages of neuro-ophthalmologists, who do not perform profitable tests or procedures to cross-subsidize the lengthy, expert evaluations that lie at the heart of their professional activities.³

The result is that public and private fee schedules reward niche specialists disproportionately well, at the expense of physicians who provide evaluation and management services or core surgical services. Thus, distorted fee schedule prices not only contribute to shortages of primary care physicians, including family physicians and general internists, but to a shortage of general surgeons as well. One result of the payment disparities in most public and private fee schedules is that medical students are advised to “follow the **road** to success,” that is, enter the specialties of Radiology, Orthopedics, Anesthesiology, and Dermatology, which in addition to being highly remunerative also support gentler lifestyles usually without emergencies outside of regular work hours.⁴

In short, the problems with the Medicare Fee Schedule are not limited to figuring out how to finance the financial shortfall created by overriding fee cuts that otherwise would take place according to the Sustainable Growth Rate (SGR) formula, although that naturally has been Congress’s primary focus. MedPAC has now identified a number of reasons for mis-pricing within the RBRVS-based fee schedule. These distortions not only result directly in excess spending related to a number of specific services but also alter physician behavior to increase the volume of profitable services that do not overly harm patients in order to increase practice revenues.

In other words, reducing prices where appropriate would not only save money directly but, in some situations, as with advanced imaging, would also reduce the financial stimulus to physicians to provide services when the clinical indications are equivocal or even nonexistent. Some of the savings from reducing overpriced services are needed to better support evaluation and management and other generalist services; however, some

³ V. Fuhrmans, “Medical Specialties Hit By A Growing Pay Gap,” *Wall Street Journal*, May 13, 2008.

⁴ In some versions of this advice the “O” stands for Ophthalmology

of the savings should be able to partly mitigate the financial hole created by the SGR score.

Fee schedule reform is also needed to further the objective of promoting the expansion of multispecialty medical groups, rather than single specialty groups, a change conducive to delivery system change as discussed earlier. Multispecialty groups have a different mix of primary care and specialty physicians than the unorganized fee-for-service sector. Current fee schedule payment disparities make it more difficult for multispecialty groups to recruit highly paid fee-for-service specialties or to narrow incomes for physicians to develop the needed collaboration and collegiality across specialties; highly remunerated fee-for-service niche specialists can do much better financially by staying out of multispecialty groups.

Combined with the impending shortage of primary care physicians, multispecialty groups face a challenge in recruiting the right balance of generalists to specialists. The well-known, successful groups may be able to recruit successfully and are helped by the fact that younger physicians are more likely to seek employment relationships rather than want to enter private practice. Nevertheless, the paucity of new multispecialty groups in recent years results partly from the major income disparities that make recruitment and collaboration within a multispecialty group problematic.

The Impending Crisis in Access to Primary Care

Whatever the blue print for delivery system reform, it is likely to fail unless immediate steps are taken to address the likely collapse of the primary care physician workforce infrastructure in many parts of the country. Primary care physicians have not been responsible for the volume increases in Medicare physician services yet have experienced the same payment freezes as those who have generated the increases. Baby boomer family physicians and general internists are approaching retirement along with many of their patients, while younger primary care physicians, who will find themselves in greater demand because of primary care shortages, will feel little personal commitment to serving Medicare patients, especially if Congress continues to flat-line their payments. Virtually no geriatricians are going into practice despite the manifest need for their expertise.

The trends to decreased family practice and general internal medicine residencies are stark, and many programs survive only by the entry of foreign-born graduates of overseas medical schools. So we are robbing developing countries of vital and needed professional workforce while ignoring the opportunity to develop an indigenous workforce more attuned to issues of health disparities and cultural competence.

A substantial body of evidence documents that countries and parts of the U.S. which rely more on primary care produce higher quality at lower costs than those with more reliance on specialty care.⁵ One study specifically showed a linear decrease in Medicare spending

⁵ B. Starfield, L. Shi, and J. Macinko, "Contribution of Primary Care to Health Systems and Health," *The Milbank Quarterly*, Vol. 83 (3), 2005, 457:502.

along with an increase in the supply of primary care physicians, as well as higher quality of care scores. In contrast, the supply of specialists was associated with more spending and poorer care.⁶

No matter what specific delivery system reform initiatives this Committee chooses to promote, whether those that would seek to promote development of accountable care organizations or others, there will be need for a stable primary care workforce willing and able to take on the challenge of providing care to the growing share of the population, with serious chronic conditions. Because of the long pipeline required to train physicians, Congress needs to address this issue immediately. Without action to alter the payment disparities inherent in the Medicare Physician Fee Schedule and, possibly, to refine graduate medical education payments to academic health centers to alter the mix of residents the federal government supports, efforts to reform health care delivery to improve quality and reduce costs will likely fail.

⁶ K. Baicker and A. Chandra, "Medicare Spending, the Physician Workforce, and Beneficiaries' Quality of Care," *Health Affairs*, 2004, W4:184-97



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Congressional Testimony

September 16, 2008

Chairman Baucus, Senator Grassley and members of the Committee, I am honored to testify today. My name is Eric Campbell. I am an Associate Professor of Medicine at the Institute for Health Policy at Massachusetts General Hospital and Harvard Medical School. However, my statements do not necessarily represent the opinions of the institutions in which I work.

My remarks today are related to physician-industry relationships. A physician-industry relationship exists whenever a physician accepts anything from a pharmaceutical or device company such as dinners at fancy restaurants, pens, drug samples, lunches, trips and paid consultancies. These relationships are believed to create a tendency towards increased use of specific procedures and high cost drugs, sometimes with marginal benefits to patients. These relationships create hidden incentives to use procedures unnecessarily, thus potentially increasing costs and threatening quality of care. Also, some forms of industry relationships can threaten the quality of the scientific literature which in turn undermines the entire concept of evidence-based medicine and quality of care.

In the next few minutes I will to address four key topics.

1. **Physician-industry relationships are highly prevalent.**
2. **Physician-industry relationships can have both negative and positive effects.**
3. **Disclosure of industry relationships are highly variable.**
4. **Increased disclosure of industry relationships is advisable.**

Let me briefly address each of these topics.

First, **physician-industry relationships are highly prevalent.** A study published in the *New England Journal of Medicine* in 2007 found that among practicing physicians 94% had at least one industry relationship. These ranged from accepting food and beverages, gifts, drug samples and payments of various kinds. This study also found that 35% received reimbursements for travel and more than 25% received consulting payments.

In terms of their impact, physician-industry relationships can have negative and positive effects. Research has shown that certain types of relationships between physician researchers and industry facilitate the development of new drugs and medical devices. Many of the drugs and medical devices currently available to patients today would not exist had it not been for close relationships between physician researchers and industry.

At the same time, physician-industry relationships can have negative effects. For example, physicians who accept gifts from companies are more likely than those who do not accept gifts to prescribe company products. Gifts may also result in physicians prescribing higher priced, brand name drugs instead of cheaper, equally effective

alternatives. This practice likely results in substantial increases in the costs of health care. Free drug samples may further reinforce this behavior and stimulate the off label use of medications—a behavior which often raises issues concerns about patient safety. Also, several leaders in medicine have suggested that industry support of academic research has led to substantial bias in the research literature which is the yardstick by which we measure evidence based practice and thus, quality of care.

Presently the disclosure of industry relationships is highly variable. The most extensive systems of disclosure are in medical schools and teaching hospitals. However, the vast majority of physicians do not practice in these settings. Thus, there is no comprehensive data regarding the nature and extent of relationships between community based physicians and industry.

Several states have laws that require companies to disclose gifts and payments to physicians. However, these state-based systems are limited in number and there is concern regarding the quality of the data these systems produce.

Finally, increased disclosure of industry relationships is advisable. Without comprehensive data on physician-industry relationships, it is not possible to assess the overall impact these have on the cost and quality of care. Clearly, a comprehensive database that is linkable to claims and prescribing records would be a valuable asset for research and policy making.

For example, consider the use radiological services. Physicians vary in the extent to which they use expensive imaging equipment like MRIs. There are many possible explanations for why this variation exists. One explanation is that physicians who order MRIs at extremely high rates do so because they have an ownership position or other financial interest in a local imaging facility. Similar studies could be conducted related to the use of expensive surgical procedures and high cost medicines.

In conclusion, I believe physician-industry relationships are ubiquitous in medicine. Because of the incomplete disclosure of relationships there is a limited ability to scientifically study their overall impact on the care patients receive. This knowledge would be beneficial when considering which types of industry relationships should be allowed to continue at current levels, which should be constrained and which should be eliminated. Failure to address these issues could overlook an important mechanism to controlling health care costs and improving the quality of care.

Thank you.

SUBMITTED BY SENATOR GRASSLEY

United States Senate

COMMITTEE ON FINANCE
WASHINGTON, DC 20510-6200

September 16, 2008

Via Electronic Transmission

James W. Wagner, Ph.D.
President
Emory University
201 Dowman Drive
Atlanta, GA 30322

Dear Dr. Wagner:

The United States Senate Committee on Finance (Committee) has jurisdiction over the Medicare and Medicaid programs and, accordingly, a responsibility to the more than 80 million Americans who receive health care coverage under these programs. As Ranking Member of the Committee, I have a duty to protect the health of Medicare and Medicaid beneficiaries and safeguard taxpayer dollars appropriated for these programs. The actions taken by key experts often have profound impact upon the decisions made by taxpayer funded programs like Medicare and Medicaid and the way that patients are treated and funds expended.

Moreover, and as has been detailed in several studies and news reports, funding by pharmaceutical companies may influence scientific studies, continuing medical education, and the prescribing patterns of doctors. Because I am concerned that there has been little transparency on this matter, I have sent letters to almost two dozen research universities across the United States. In these letters, I asked questions about the conflict of interest disclosure forms signed by some of their faculty. Universities typically require doctors to report their related outside income, but I am concerned that these requirements are disregarded sometimes.

I have also been taking a keen interest in the almost \$24 billion annually appropriated to the National Institutes of Health (NIH) to fund grants at various institutions such as yours. As you know, institutions are required to manage a grantee's conflicts of interest.¹ But I am learning that this task is made difficult because physicians do not consistently report all the payments received from drug companies.

To bring some greater transparency to this issue, Senator Kohl and I introduced the Physician Payments Sunshine Act (Act). This Act will require pharmaceutical companies to report publicly any payments that they make to doctors, within certain parameters.

¹ Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought, 42 C.F.R. 50 (1995).

The purpose of this letter is to assess the implementation of financial disclosure policies at Emory University (Emory/the University). In response to my letter of October 25, 2007, Emory provided me with the financial disclosure reports that Dr. Charles Nemeroff filed with Emory during the period of January 2000 through June 2007. Dr. Nemeroff is the Reunette W. Harris Professor and Chairman of the Department of Psychiatry and Behavioral Sciences at Emory and is one of the most widely published experts in the field of psychiatry.

My staff investigators carefully reviewed each of Dr. Nemeroff's disclosure forms and detailed the payments disclosed. I then asked that Emory confirm the accuracy of the information my staff compiled. In March 2008, Emory clarified previous statements and provided a chart of Dr. Nemeroff's outside income. This chart contained several reports of, among other things, Dr. Nemeroff's outside consulting that my staff did not find in his disclosure forms filed with Emory.

In addition, I contacted executives at several major pharmaceutical and device companies (the Companies) and asked them to list the payments that they made to Dr. Nemeroff during the years 2000 through 2007. These companies voluntarily and cooperatively reported additional payments that Dr. Nemeroff does not appear to have disclosed to Emory. For example, Dr. Nemeroff disclosed receiving \$7,500 in 2005 from Pfizer. But Pfizer reported to me that it paid Dr. Nemeroff \$138,000 in speaker honoraria (at least 40 speaking engagements) and consulting fees that same year. Based upon the information provided to me from both Emory and the Companies, it also appears that Dr. Nemeroff failed to disclose the vast majority of the over \$900,000 that he received in speaking fees and expenses related to talks he has given on behalf of GlaxoSmithKline (GSK).

Because Dr. Nemeroff's disclosures to Emory differ dramatically from those that I received from the Companies, I am attaching a chart that best represents a few of the disclosures made to me by the Companies. Specifically, the attached chart contains columns showing some of the payments disclosed by Dr. Nemeroff in March 2008 contrasted with the amounts reported to me by the Companies. However, I understand that some discrepancies may exist because Emory is uncertain if the disclosures were made during a calendar year or academic year.

INSTITUTIONAL AND NIH POLICIES

The disclosure policies at Emory, and in particular those of the school of medicine, allow faculty members to engage in private consulting up to 20 percent of their professional effort—known as the “20% effort” policy. However, consulting agreements by Emory faculty must have the prior approval of the Chair, Dean, and if necessary, the Conflict of Interest (COI) Committee. Pfizer reported to me that it paid Dr. Nemeroff approximately \$536,500 during the years of 2000 through 2007 for numerous speaking engagements and consulting activities. However, based upon the documents provided to the Committee by the Companies, Dr. Nemeroff did not report the existence of this financial relationship until 2004 when he reported receiving \$15,000 from Pfizer.

Pfizer's lawyers informed my staff that, because of inconsistencies in its databases, Pfizer's report on payments to Dr. Nemeroff do not always have the proper date for which Dr. Nemeroff provided a service. Still, Pfizer reported that it paid Dr. Nemeroff \$95,000 in 2004 for over 25 speaking engagements. This number is dramatically greater than the \$15,000 Dr. Nemeroff reported. Further, from 2005 until the present, Dr. Nemeroff appears to have underestimated the amount he received for the dozens of speaking engagements he gave on behalf of Pfizer.

Moreover and based upon my staff's review of Emory documents, I note that in May 2004 the COI Committee conducted a review² of Dr. Nemeroff's outside activities. Specifically, the COI Committee examined whether or not Dr. Nemeroff had any potential conflicts related to all company research grants that were ongoing in 2003 and 2004. The COI Committee's report found several instances in which Dr. Nemeroff violated Emory's Conflict of Interest policies. Some of the findings include that Dr. Nemeroff:

- received consulting fees and traveling expenses from multiple companies including Abbot, Astra Zeneca, GSK, Neurocrine Biosciences, and Wyeth-Ayerst and that he did not follow procedures regarding the review of his consulting agreements.
- failed to disclose his potential financial conflicts of interest in his Annual Disclosure Form for 2002-2003, his Sponsored Projects Approval Forms, his Institutional Review Board (IRB) forms, and his Institutional Animal Care and Use Committee (IACUC)³ forms.
- reported that he had no financial interest with the sponsor (Merck) of a trial⁴ on his IRB form, the IRB renewal form and the Sponsored Projects Approval form. However, the COI Committee determined that Dr. Nemeroff received \$40,000 and \$48,000 from Merck in 2002 and 2003, respectively.
- indicated no financial interest with the sponsor (Eli Lilly) of a trial⁵ on his IRB and Sponsored Project Approval Form. During the final review of the COI Committee's report, Dr. Nemeroff admitted receiving \$16,159 in fees and expenses in 2002 and \$6,000 in 2003 from Eli Lilly.

² Memorandum to Dr. Thomas J. Lawley, Dean of the Emory University School of Medicine, dated May 26, 2004.

³ The Institutional Animal Care and Use Committee (IACUC) is a self-regulating entity that, according to U.S. federal law, must be established by institutions that use laboratory animals for research or instructional purposes to oversee and evaluate all aspects of the institution's animal care and use program.

⁴ Clinical Trial using Existing Clinical Specimens sponsored by Merck, Measurement of Cerebrospinal Fluid Substance P Concentrations in Depression and Anxiety, began July 2002, end date of 2004.

⁵ Clinical Trial Sponsored by Eli Lilly, Open Label Treatment with Duloxetine Hydrochloride for stabilizing patients with Major Depression, began December 2002, end date December of 2004.

- failed to disclose his relationship with Eli Lilly to the COI Committee and the IACUC regarding a trial⁶ sponsored by Eli Lilly. This was a breach of the conflict of interest policy and potentially a violation of IACUC procedures.
- did not indicate a potential conflict with the sponsor (Janssen) of a grant.⁷ Accordingly, the grant did not receive a conflict of interest review.
- failed to indicate possible conflicts regarding a trial⁸ sponsored by Janssen to the IRB and the COI Committee. The COI Committee determined that this was a serious omission.

In June 2004, the very next month after the COI Committee's review of Dr. Nemeroff's possible conflicts, it sent a letter to Dr. Nemeroff detailing its findings.⁹ The COI Committee wrote:

The [COI] Committee concluded that you did not follow procedures and policies regarding the review of your consulting agreements and that you failed to disclose your potential conflicts of interest in research in your Annual Disclosure Form for 2002-2003, your Sponsored Projects Approval Forms, and your IRB and IACUC forms...

You must notify the [COI] Committee in writing whether any of your federally funded research involves compounds that are produced by companies with whom you have consulting relationships. Under federal regulations, these grants must be reviewed in light of your relationships with the companies. If conflicts are found, the University is required to notify the funding agency as to whether the conflicts can be managed.

Due to the many violations of the Conflict of Interest, consulting, and other policies and your leadership position as a Department Chair, which may implicate institutional conflicts of interest, a copy of this letter and its related files will be referred to the Dean for evaluation under the Research Misconduct Policy.¹⁰

However, it appears that the COI Committee review did not capture Dr. Nemeroff's other potential conflicts of interest with other companies. This appears to be the case because Dr. Nemeroff failed to report to Emory the money he received from

⁶ Non-clinical Research Grant sponsored by Eli Lilly, the Role of the Neurotensin System in the Antipsychotic Properties of Olanzapine, budget start September 29, 2000, project end September 28, 2003.

⁷ Clinical Trial sponsored by Janssen, Six Month, Double Blind, Randomized Trial to Evaluate Effects of Risperdone and Olanzapine in Subject with Schizophrenia or Schizoaffective Disorder, project start April 16, 2002, ended December 31, 2003.

⁸ Clinical Trial sponsored by Janssen, Neurocognitive and Functional Imaging Study of Comparative Effects of Risperdal and Zyprexa on Schizophrenia, project start March 1, 1999, ended December 1, 2003.

⁹ Confidential Memo to Dr. Charles B. Nemeroff, MD, PhD, from Conflict of Interest Committee, dated June 24, 2004.

¹⁰ Id.

Pfizer and GSK. Based upon the information that I received from the Companies, it appears that Dr. Nemeroff did not report over \$95,000 in fees from Pfizer in 2002, and he dramatically underreported his speaking fees and expenses from GSK for 2002. Additionally, Dr. Nemeroff reported \$15,000 in fees and expenses from GSK that year, but GSK reported to me that they paid him over \$230,000 in 2002.

Based upon my staff's review of the material received from Emory, the COI Committee's review did not include an examination of Dr. Nemeroff's numerous NIH grants for possible violations of federal regulations on conflicts of interest. But federal regulations place several requirements on a university/hospital when its researchers receive NIH grants.¹¹ These regulations are intended to ensure a level of objectivity in publicly funded research, and state in pertinent part that NIH investigators must disclose to their institution any "significant financial interest"¹² that may appear to affect the results of a study. NIH interprets "significant financial interest" to mean at least \$10,000 in value or five percent ownership in a single entity.

I am also concerned that Dr. Nemeroff's actions or lack thereof may have placed Emory in violation of federal disclosure regulations regarding at least two NIH grants. First, from 2001 to late 2004, Dr. Nemeroff was the primary investigator on an NIH grant that studied whether fluoxetine is effective for treating psychological problems in adults who are the victims of child abuse.¹³ Eli Lilly sells a brand name of fluoxetine called Prozac. Regarding an Eli Lilly sponsored clinical trial, the COI Committee reported:

In an email to NAME REDACTED dated March 3, 2004, Dr. Nemeroff reported that he consults with Lilly 2-3 times per year and receives \$3,000 per visit. He claims that his remuneration does not exceed \$10,000....During the final review of this report, Dr. Nemeroff notified the [COI] Committee on March 19, 2004, that he received the following for consulting fees and travel expenses from Lilly: \$16,159.28 in 2002 and \$6,000 in 2003.

The COI Committee also found that Dr. Nemeroff indicated that he had no financial interests on his IRB application for this Eli Lilly trial in 2002 and again in 2003. Further in the Sponsored Projects Approval Form, Dr. Nemeroff answered "no" in response to whether he had a financial interest in Eli Lilly. However, the COI Committee found that Dr. Nemeroff's "failure to indicate his potential conflict of interest to the IRB and COI Committee was a violation of the COI policies and potentially the IRB policies."

During the same years that Dr. Nemeroff was found to have violated COI policies on his Eli Lilly grant, he was the primary investigator on an NIH grant that studied Eli

¹¹ Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought, 42 C.F.R. 50 (1995). See also <http://grants.nih.gov/grants/partners/0706NIHExtramuralNexus.pdf>.

¹² "Significant Financial Interest" is defined by the regulation as anything of monetary value, including but not limited to: salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); intellectual property rights (e.g., patents, copyrights and royalties from such rights).

¹³ Fluoxetine in Child Abuse, NIH Grant 5M01RR000039, start Oct 1974, end Nov 2004.

Lilly's drug Prozac. However, Dr. Nemeroff did not disclose the payments Eli Lilly made to him until 2004—two years later. Further, because Dr. Nemeroff did not follow IRB policies on his Eli Lilly sponsored trial, I am concerned that he may have done the same on the IRB form for this NIH grant.

Moreover, from December 2000 through November 2002, Dr. Nemeroff led an NIH sponsored study of Paxil, a drug manufactured by GSK.¹⁴ Dr. Nemeroff disclosed payments from GSK for activities including consulting and speaking during 2000 and 2001, but did not reveal the amount(s) of the payments.

However, GSK reported to me that it paid Dr. Nemeroff over \$190,918 in speaking fees and expenses in 2000. That year, Dr. Nemeroff gave over 50 different speaking engagements on Paxil. In 2001, GSK paid Dr. Nemeroff \$135,460 in speaking fees and expenses. That year, Dr. Nemeroff spoke about Paxil over 25 different times at restaurants around the country. In 2002, Dr. Nemeroff disclosed \$15,000 in payments from GSK, but GSK reported to me that it paid Dr. Nemeroff over \$232,000. Again, most of this work involved speaking about Paxil.

Based upon a review of the documents provided to me by Emory, it is very clear that university officials have attempted to address Dr. Nemeroff's outside consulting in 2000, 2004, and 2006. For example, following several reports in the *Wall Street Journal* in 2006 concerning Dr. Nemeroff's failure to report his outside income in a journal article, Dr. Nemeroff agreed to limit much of his outside activity. Specifically, on two separate occasions, Dr. Nemeroff wrote to the Dean of the medical school and the Executive Vice President for Health Affairs that he would no longer engage in promotional lectures on behalf of companies. Dr. Nemeroff wrote in pertinent part that:

I have already resigned from all industry-sponsored speakers' bureaus and have made it clear that I will not engage in "promotional" lectures on behalf of companies about their products.¹⁵

I will also not participate in any pharmaceutical-sponsored "promotional" lectures or speaker's bureaus.¹⁶

However, the Companies' reports available to me seem to contradict these statements. For instance, Eli Lilly reported two payments to Dr. Nemeroff for speaking in 2007 – \$4,000 on April 4, 2007 and \$5,500 on June 20, 2007. Pfizer reported one speaking honoraria to Dr. Nemeroff on April 13, 2007, in the amount of \$1500.

¹⁴ Paroxetine—Treatment of Exaggerated Platelet Reactivity with Major Depression (NIH Grant 5M01RR000039).

¹⁵ Letter to Michael M.E. Johns, MD, Executive Vice President for Health Affairs and Thomas J. Lawley, MD, Dean Emory School of Medicine, signed by Charles B. Nemeroff, MD, PhD, Reunette W. Harris Professor and Chair, dated November 20, 2006.

¹⁶ Letter to Michael M.E. Johns, MD, Executive Vice President for Health Affairs and Thomas J. Lawley, MD, Dean Emory School of Medicine, signed by Charles B. Nemeroff, MD, PhD, Reunette W. Harris Professor and Chair, dated December 21, 2006.

In light of the information set forth above, I ask for your continued cooperation in examining conflicts of interest. In my opinion, universities across the United States must be able to rely on the representations of their faculty to ensure the integrity of medicine, academia, and the grant-making process. At the same time, should the Physician Payments Sunshine Act become law, institutions like yours will be able to access a database that will set forth the payments made to all doctors, including your faculty members.

Accordingly, I request that Emory respond to the following questions and requests for information. For each response, please repeat the enumerated request and follow with the appropriate answer.

- 1) For each of the NIH grants received by Dr. Nemeroff, please confirm that he reported to Emory's designated official "the existence of [a] conflicting interest." Please provide separate responses for each grant received for the period from January 1, 2000 to the present, and provide any supporting documentation for each grant identified.
- 2) For each grant identified above, please explain how Emory ensured "that the interest has been managed, reduced, or eliminated." Please provide an individual response for each grant that Dr. Nemeroff received from January 1, 2000 to the present, and provide any documentation to support each claim.
- 3) For each grant identified above, please provide the amount of money paid directly to Dr. Nemeroff for "salary". Please detail this information by grant number, year, and salary amount.
- 4) Please provide and update on any reports of research misconduct or reviews of the discrepancies in disclosures by Dr. Nemeroff, including what action, if any, Emory is/will consider.
- 5) Please provide any reports on research misconduct regarding Dr. Nemeroff.
- 6) Please report whether a determination can be made as to whether or not Dr. Nemeroff violated guidelines governing clinical trials and the need to report conflicts of interest to an IRB. Please respond by naming each clinical trial for which Dr. Nemeroff was the principal investigator, along with confirmation that conflicts of interest were reported, if possible.
- 7) Please provide any notifications to the Office of Human Research Protection regarding potential violations of human subject research protection and research by Dr. Nemeroff. This request covers the period of 2000 through 2007.
- 8) Please provide any notifications and/or communications to the NIH regarding conflicts of interest and research by Dr. Nemeroff. This request covers the period of 2000 through 2007.

- 9) Please provide a total dollar figure for all NIH monies annually received by Emory. This request covers the period of 2000 through 2007.
- 10) Please provide a list of all NIH grants received by Emory. This request covers the period of 2000 through 2007. For each grant please provide the following:
 - a. Primary Investigator;
 - b. Grant Title;
 - c. Grant number;
 - d. Brief description; and
 - e. Amount of Award.

Thank you again for your continued cooperation and assistance in this matter. As you know, in cooperating with the Committee's review, no documents, records, data or information related to these matters shall be destroyed, modified, removed or otherwise made inaccessible to the Committee.

I look forward to hearing from you by no later than October 7, 2008. All documents responsive to this request should be sent electronically in PDF format to Brian_Downey@finance-rep.senate.gov. If you have any questions, please do not hesitate to contact Paul Thacker at (202) 224-4515.

Sincerely,



Charles E. Grassley
Ranking Member

Attachment

**Selected Disclosures by Dr. Nemeroff and Related Information Reported by
Pharmaceutical Companies and Device Manufacturers**

Year	Company	Disclosure Filed in March 2008	Amount Company Reported
2000	Bristol Myers Squibb	No amount provided	\$15,277
	GlaxoSmithKline	No amount provided ^a	\$190,918
	Johnson & Johnson/Janssen	Not reported	\$71,319
	Eli Lilly	No amount provided	\$1,000
	Merck	No amount provided	n/a
	Pfizer	Not reported	\$2,500
	2001	Bristol Myers Squibb	No amount provided
GlaxoSmithKline		No amount provided ^a	\$135,460
Johnson & Johnson/Janssen		Not reported	\$32,000
Merck		No amount provided	n/a
Pfizer		Not reported	\$15,000
2002	Bristol-Myers Squibb	\$10,000	\$10,869
	Cyberonics	\$50,000	n/a
	GlaxoSmithKline	\$15,000	\$232,248
	Johnson & Johnson/Janssen	\$38,239	\$38,761
	Eli Lilly	\$16,159	\$16,427
	Otsuka	\$65,000	n/a
	Merck	\$40,000	n/a
	Pfizer	Not reported	\$95,500
	2003	Bristol-Myers Squibb	No amount provided ^b
Cyberonics		Not reported	\$50,000
GlaxoSmithKline		Not reported	\$119,756
Johnson & Johnson/Janssen		\$25,000	\$25,641
Eli Lilly		\$6,000	\$6,892
Merck		\$48,000	n/a
Pfizer		Not reported	\$112,000
2004	GlaxoSmithKline	\$9,999	\$171,031
	Otsuka	\$50,000	n/a
	Cyberonics	\$50,000	n/a
	Johnson & Johnson/Janssen	Not reported	\$13,500

Year	Company	Disclosure Filed in March 2008	Amount Company Reported
	Eli Lilly	Not reported	\$8,000
	Merck	\$56,000	n/a
	Pfizer	\$15,000	\$95,000
2005	Cyberonics	<\$75,000	\$75,000
	GlaxoSmithKline	\$9,999	\$78,097
	Eli Lilly	No amount provided	\$5,500
	Otsuka	\$50,000	n/a
	Pfizer	\$7,500	\$138,000
2006	AstraZeneca	\$4,000	\$4,150
	Cyberonics	<\$75,000	\$75,000
	GlaxoSmithKline	No amount provided ^c	\$32,978
	Pfizer	\$5,000	\$76,500
2007	Cyberonics/Intermed	<\$75,000	\$5,000
	Johnson & Johnson	No amount provided	\$3,750
	Eli Lilly	Not reported	\$9,500
	Pfizer	Not reported	\$1,500

^a Consulting agreement for two weekends a year.

^b Consulting agreement for \$500 per hour or \$5000 per day.

^c Speaker's Bureau, \$3500 per talk; \$5250 for rotating speakers series.

Note 1: Based on reports to the Committee by Emory, Dr. Nemeroff disclosed receiving over \$1.2 million in payments from pharmaceutical companies and device manufacturers during the period of January 2000 through June 2007. However, this number is obviously an underestimate. In many cases, Dr. Nemeroff only disclosed the name of a company, but did not report an amount. And in many cases, Dr. Nemeroff failed to report even the existence of a relationship. Information reported by the pharmaceutical companies and device manufacturers the Committee contacted indicate that they made additional payments that are not reflected in Dr. Nemeroff's disclosures.

Note 2: When a Physician named a company in a disclosure but did not provide an amount, the text reads "no amount reported." When a Physician did not list the company in the disclosure, the column reads "not reported." The Committee contacted several companies for payment information and the notation "n/a" (not available) reflects that a company was not contacted.

Report to the Congress:
Reforming the Delivery System

September 16, 2008

Statement of
Mark E Miller, Ph.D.

Executive Director
Medicare Payment Advisory Commission

Before the
Committee on Finance
U.S. Senate

Chairman Baucus, Ranking Member Grassley, distinguished Committee members. I am Mark Miller, executive director of the Medicare Payment Advisory Commission (MedPAC). I appreciate the opportunity to be here with you this morning to discuss MedPAC's views on delivery system reform as embodied in our June Report to the Congress.

The health care delivery system we see today is not a true system: care coordination is rare, specialist care is favored over primary care, quality of care is often poor, and costs are high and increasing at an unsustainable rate. Part of the problem is that Medicare's fee-for-service (FFS) payment systems create separate payment "silos" (e.g., inpatient, physician). They do not encourage coordination among providers within each silo or among different types of providers across payment silos. We must now move beyond those limitations—creating new payment systems that will encourage providers to change how they interact with each other. Providers need to increase care coordination and be jointly accountable for quality and resource use. The objective is a delivery system that is focused on the beneficiary, improves quality, and controls spending.

Medicare has not been the sole cause of the problem, nor should it be the only participant in the solution. Other private and public payers will need to change payment systems as well to bring about the conditions needed to change the broader health care delivery system. But Medicare should not wait for others to act first—it can lead the way to broader system reform.

Why is fundamental change needed?

The Medicare program should provide its beneficiaries with access to appropriate, high quality care while spending the money entrusted to it by the taxpayers as carefully as possible. But too often that goal is not being realized and we see evidence of poor quality care and spending growth that threatens the program's fiscal sustainability.

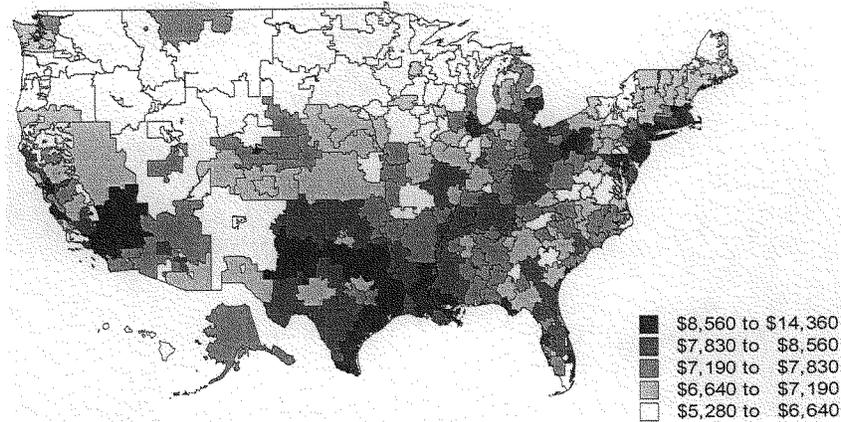
Poor quality

Many studies show serious quality problems in the American health care system. McGlynn found that participants received about half of the recommended care (McGlynn et al 2003). Schoen found wide variation across states in hospital admissions for ambulatory-care-sensitive conditions (i.e., admissions that are potentially preventable with improved ambulatory care) (Schoen et al 2006). In *Crossing the Quality Chasm*, the Institute of

Medicine pointed out that there were serious shortcomings in quality as well as the absence of real progress toward restructuring health care systems to address both quality and cost concerns (IOM 2001).

At the same time that Americans are not receiving enough of the recommended care, the care they are receiving may not be appropriate. For 30 years, researchers at Dartmouth's Center for the Evaluative Clinical Sciences have documented the wide variation across the United States in Medicare spending and rates of service use (see Figure 1). It is important to understand that variation is not driven by differences in the payment rates across the country but instead by the use of services. Dartmouth finds most of the variation is caused by differing rates of use for supply-sensitive services, that is, services whose use is likely driven by a geographic area's supply of specialists and technology (Wennberg et al. 2002). Areas with a higher proportion of primary care to specialty care physicians also show higher use of services.

Figure 1. Total Medicare spending by Hospital Referral Region



Source: Dartmouth Atlas of Health Care, 2005 Medicare claims data.

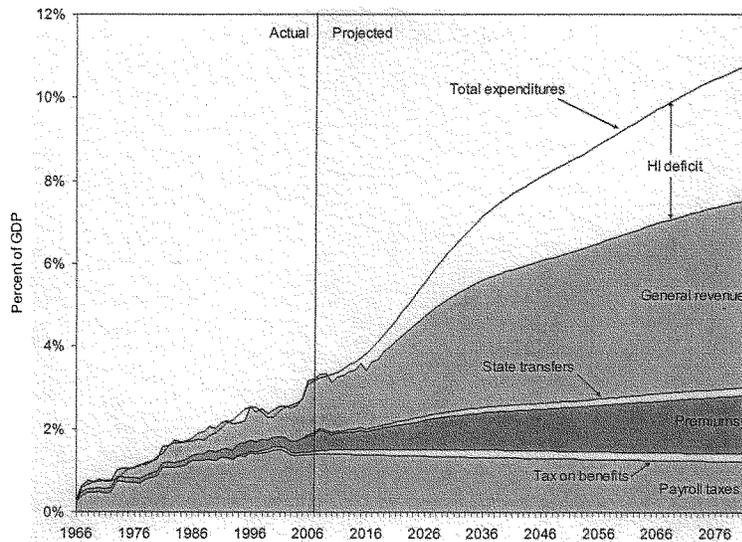
The higher rates of use are often not associated with better outcomes or quality and instead suggest inefficiencies. In fact, a recent analysis by Davis and Schoen shows at the state level that no relationship exists between health care spending per capita and mortality amenable to medical care, that an inverse relationship exists between spending and rankings on quality of

care, and that high correlations exist between spending and both preventable hospitalizations and hospitalizations for ambulatory-care-sensitive conditions (Davis and Schoen 2007). These findings point to inefficient spending patterns and opportunities for improvement.

Sustainability concerns

This inefficiency is contributing to the problem of fiscal sustainability. For example, the Supplementary Medical Insurance Trust Fund (which covers outpatient and physician services, and prescription drugs) is financed automatically with general revenues and beneficiary premiums, but the trustees point out that financing from the federal government's general fund, which is funded primarily through income taxes, would have to increase sharply to match the expected growth in spending. The share of the nation's GDP committed to Medicare is projected to grow to unprecedented levels, squeezing other priorities in the federal budget (see Figure 2).

Figure 2. Medicare faces serious challenges with long-term financing



Note: GDP (gross domestic product), HI (Hospital Insurance). These projections are based on the trustees' intermediate set of assumptions. Tax on benefits refers to a portion of income taxes that higher income individuals pay on Social Security benefits that is designated for Medicare. State transfers (often called the Part D "clawback") refer to payments called for within the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 from the states to Medicare for assuming primary responsibility for prescription drug spending.

Source: 2008 Annual Report of the Boards of Trustees of the Medicare Trust Funds.

In addition, expenditures from the Hospital Insurance (HI) trust fund, which funds inpatient stays and other post-acute care, exceeded its annual income from taxes in 2008. In their most recent report, the Medicare trustees project that, under intermediate assumptions, the assets of the HI trust fund will be exhausted in 2019. Income from payroll taxes collected in that year would cover 78 percent of projected benefit expenditures. Medicare will have no authority to pay the remainder of Part A benefits due.

Rapid growth in Medicare spending has implications for beneficiaries as well as taxpayers. Between 2000 and 2007, Medicare beneficiaries faced average annual increases in the Part B premium of nearly 9.8 percent. Meanwhile, monthly Social Security benefits, grew by about 4 percent annually over the same period. The average cost of SMI premiums and cost sharing for Part B and Part D absorbs about 26 percent of Social Security benefits. In 2006, for 60 percent of the elderly population, those benefits accounted for three-quarters of their income. Growth in Medicare premiums and cost sharing will continue to absorb an increasing share of Social Security income. At the same time, Medicare's lack of a catastrophic cap on cost sharing will continue to represent a financial risk for beneficiaries. Almost 60 percent of beneficiaries (or their former employers) now buy supplemental coverage to help offset this risk and Medicare's cost sharing.

Barriers to achieving value in Medicare

Many of the barriers that prevent Medicare from improving quality and controlling costs—obtaining better value—stem from the incentives in Medicare's payment systems. Medicare's payment systems are primarily fee-for-service (FFS). That is, Medicare pays for each service delivered to a beneficiary by a provider meeting the conditions of participation for the program. FFS payment systems reward providers who increase the volume of services they provide regardless of the benefit of the service. As discussed above, the volume of services per beneficiary varies widely across the country, but areas with higher volume do not have better outcomes. FFS systems are not designed to reward higher quality; payments are not increased if quality improves and in some cases may increase in response to low quality care. For example, some hospital readmissions may be a result of poor quality care and currently those readmissions are fully paid for by Medicare.

In addition to the general incentive of FFS payment systems to reward volume, there are four specific problems that make it difficult for Medicare to achieve its goals; price distortion, lack of accountability, lack of information, and lack of care coordination.

Price distortion. Within Medicare's payment systems, the payment rates for individual products and services may not be accurate. Inaccurate payment rates in Medicare's payment systems can lead to unduly disadvantaging some providers and unintentionally rewarding others. For example, under the physician fee schedule, fees are relatively low for primary care and may be too high for specialty care and procedures. This payment system bias has signaled to physicians that they will be more generously paid for procedural, specialty care, and signals providers to generate more volume. In turn, these signals could influence the supply of providers, resulting in oversupply of specialized services and inadequate numbers of primary care providers. In fact, the share of U.S. medical school graduates entering primary care residency programs has declined in the last decade, and internal medicine residents are increasingly choosing to subspecialize rather than practice as generalists.

Lack of accountability. Providers may provide quality care to uphold professional standards and to have satisfied patients, but Medicare does not hold them accountable for the quality of care they provide. Moreover, providers are not accountable for the full spectrum of care a beneficiary may use; even when they make the referrals that dictate resource use. For example, physicians ordering tests or hospital discharge planners recommending post-acute care do not have to consider the quality outcomes or the financial implications of the care that other providers may furnish. This fragmentation of care puts the quality of care and efficiency at risk.

Lack of information and the tools to use it. The program and its providers lack the information and tools needed to improve quality and use program resources efficiently. For example, Medicare lacks quality data from many settings of care, does not have timely cost or market data to set accurate prices, and does not report resource use or often quality scores back to providers. Individually, providers may have clinical data, but they may not have that data in electronic form, leaving them without an efficient means to process it or an ability to

act on it. Crucial information on clinical effectiveness and standards of care either may not exist or may not have wide acceptance. In this environment, it will be a difficult challenge to determine what health care treatments and procedures are needed, and hence what resource use is appropriate, particularly for Medicare patients, many of whom have multiple comorbidities. In addition, beneficiaries are now being called on to make complex choices among delivery systems, drug plans, and providers. But information for beneficiaries that could help them choose higher quality providers and improve their satisfaction is just beginning to become available.

Lack of care coordination. Growing out of the lack of accountability, there is no incentive for providers to coordinate care. Each provider may treat one aspect of a patient's care without regard to what other providers are doing. There is a focus on procedures and services rather than on the beneficiary's total needs. This becomes a particular problem for beneficiaries with several chronic conditions and for those transitioning between care providers, such as at hospital discharge. Poorly coordinated care may result in patient confusion, over-treatment, duplicative service use, higher spending, and lower quality of care.

While this testimony focuses on changes to Medicare FFS payment systems that would encourage delivery system reform, the payment system for Medicare Advantage (MA) plans also needs reform, as we have previously reported. Many MA plans have not changed the way care is delivered and often function much like the Medicare FFS program. Paying MA plans appropriately would increase pressure on them to compete to find efficiencies in care delivery and improve quality.

Commission recommendations to increase efficiency and improve quality

In previous reports, the Commission has recommended that Medicare adopt tools to surmount barriers to increasing efficiency and improving quality within the current Medicare payment systems. These tools include:

- *Creating pressure for efficiency through payment updates.* Although, the update is a somewhat blunt tool for constraining cost growth (updates are the same for all providers in a sector, both those with high costs and those with low costs), constrained updates will create more pressure on those with higher costs.

- *Improving payment accuracy within Medicare payment systems.* In our 2005 report on specialty hospitals, the Commission made recommendations to improve the accuracy of DRG payments to account for patient severity. Those recommendations corrected distortions in the payment system that among other things, contributed to the formation of hospitals specializing in the treatment of a limited set of profitable DRGs. In another example, the Commission recommended this past June, increasing fee schedule payments for primary care services furnished by clinicians focused on delivering primary care. This budget-neutral adjustment would redistribute Medicare payments toward those primary care services provided by practitioners—physicians, advanced practice nurses, and physician assistants—whose practices focus on primary care. A fee schedule adjustment for primary care would help overcome the undervaluation of primary care services.
- *Linking payment to quality.* In a series of reports, we have recommended that Medicare change payment system incentives by basing a portion of provider payment on the quality of care they provide and recommended that the Congress establish a quality incentive payment policy for physicians, Medicare Advantage plans, dialysis facilities, hospitals, home health agencies and skilled nursing facilities. In March 2005, we recommended setting standards for providers of diagnostic imaging studies to enhance the quality of care and help control Medicare spending.
- *Measuring resource use and providing feedback.* In our March 2008 and 2005 reports to the Congress, we recommended that CMS measure physicians' resource use per episode of care over time and share the results with physicians. Those who used comparatively more resources than their peers could assess their practice styles and modify them as appropriate.
- *Encouraging the use of comparative-effectiveness information and public reporting.* In our June 2007 report, we found that not enough credible, empirically based information is available for health care providers and patients to make informed decisions about alternative services for diagnosing and treating most common clinical conditions and the Commission recommended that the Congress charge an independent entity to sponsor credible research on comparative effectiveness of health care services and disseminate this information to patients, providers, and public and private payers. We have also

recommended public reporting to provide beneficiaries with better information and encourage providers to improve their quality.

The need for more fundamental reform

The recommendations discussed above would make the current Medicare FFS payment systems function better, but they will not fix the problems inherent in those systems for two reasons. First, they cannot overcome the strong incentives inherent in any fee-for-service system to increase volume, thus it will be difficult to make the program sustainable. Second, they cannot switch the focus to the patient rather than the procedure because they cannot directly reward care coordination or joint accountability that cuts across current payment system “silos,” such as the physician fee schedule or the inpatient prospective payment system.

There is evidence that more fundamental reforms could improve the quality of care and potentially lower costs. For example, patient access to high-quality primary care is essential for a well-functioning health care delivery system. Research suggests that reducing reliance on specialty care may improve the efficiency and quality of health care delivery. States with a greater proportion of primary care physicians have better health outcomes and higher scores on performance measures (Baicker and Chandra 2004). Moreover, areas with higher rates of specialty care per person are associated with higher spending but not improved access to care, higher quality, better outcomes, or greater patient satisfaction (Fisher et al. 2003, Kravet et al. 2008, Wennberg 2006). Countries with greater dependence on primary care have lower rates of premature deaths and deaths from treatable conditions, even after accounting for differences in demographics and GDP (Starfield and Shi 2002). Changing the balance in the delivery system between primary and specialist care may have high payoffs for Medicare.

Evidence points to other potential reforms:

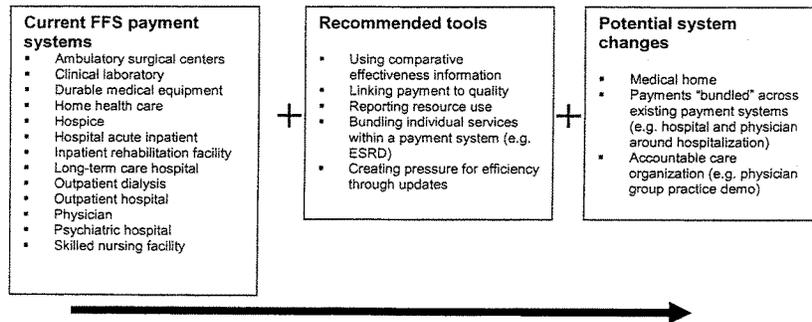
- Evidence shows that care coordination can improve quality. As we discussed in our June 2006 report, studies show self management programs, access to personal health records and transition coaches have resulted in improved care or better outcomes such as reduced readmission for patients with chronic conditions.

- Savings from preventing readmissions could be considerable. About 18 percent of Medicare hospital admissions result in readmissions with 30 days of discharge, accounting for \$15 billion in spending. The Commission found that Medicare spends about \$12 billion on potentially preventable readmissions, some portion of which should be avoidable.
- The Medicare Participating Heart Bypass Center demonstration of the 1990s found that bundling of hospital DRG payments and inpatient physician payments could increase providers' efficiency and reduce Medicare's costs. Most of the participating sites found that, under a bundled payment, hospitals and physicians reduced laboratory, pharmacy, and ICU spending. Spending on consulting physicians also decreased as did spending for post discharge care. Quality remained high.

A direction for payment and delivery system reform

To increase value for the Medicare program, its beneficiaries, and the taxpayers, we are looking at payment policies that go beyond the current FFS payment system boundaries of scope and time. This new direction would pay for care that spans across provider types and time and would hold providers jointly accountable for the quality of that care and the resources used to provide it. It would create payment systems that reward value and encourage closer provider integration—delivery system reform. For example, if Medicare held physicians and hospitals jointly responsible for outcomes and resource use, new efficiencies such as programs to avoid readmissions and standardization of operating room supplies could be pursued. In the longer term, joint responsibility could lead to closer integration and development of a more coordinated health care delivery system.

This direction is illustrated in Figure 3. The potential payment system changes shown are not the end point for reform and further reforms could move the payment systems farther away from FFS and toward systems of providers who accept some level of risk, driving further delivery system reform.

Figure 3. Direction for payment and delivery system reform

History has shown that providers will respond to financial incentives. For example, the advent of the inpatient prospective payment system in 1983 led to shorter inpatient lengths of stay and increasing use of post acute care services, physician services have increased as payments have been restrained by volume control mechanisms, and a greater proportion of patients in skilled nursing facilities (SNFs) were given therapy, and more of it, in response to the SNF prospective payment system incentives. Financial incentives can also result in structural changes in the health care delivery system. In the 1990s, the rise of HMO and the prospect of capitation led doctors and hospitals to form physician-hospital organizations whose primary purpose was to allocate capitated payments. Paying differently will motivate providers to interact differently with each other, and, if reforms are carefully designed for joint accountability, to pay more attention to outcomes and costs. (An additional consideration is whether the current benefit design and cost sharing need to be reformed to modify the demand for services. This could reinforce the provider-oriented reforms we discuss here.)

Recommended system changes

We discuss three recommendations in our June report that might move Medicare in the direction of better coordination and more accountable care: a medical home pilot program, changing payments for hospital readmissions, and bundling of payments for services around a hospital admission.

Medical home

A medical home is a clinical setting that serves as a central resource for a patient's ongoing care. The Commission considers medical homes to be a promising concept to explore. Accordingly, it recommends that Medicare establish a medical home pilot program for beneficiaries with chronic conditions to assess whether beneficiaries with medical homes receive higher quality, more coordinated care, without incurring higher Medicare spending. Qualifying medical homes could be primary care practices, multispecialty practices, or specialty practices that focus on care for certain chronic conditions, such as endocrinology for people with diabetes. Geriatric practices would be ideal candidates for Medicare medical homes.

In addition to receiving payments for fee-schedule services, qualifying medical homes would receive monthly, per beneficiary payments that could be used to support infrastructure and activities that promote ongoing comprehensive care management. To be eligible for these monthly payments, medical homes would be required to meet stringent criteria including:

- furnish primary care (including coordinating appropriate preventive, maintenance, and acute health services);
- use of a team to conduct care management;
- use health information technology (IT) for active clinical decision support;
- have a formal quality improvement program;
- maintain 24-hour patient communication and rapid access;
- keep up-to-date records of beneficiaries' advance directives; and
- maintain a written understanding with each beneficiary designating the provider as a medical home.

These stringent criteria are necessary to ensure that the pilot evaluates outcomes for the kind of coordinated, timely, high-quality care that has the highest probability to improve cost, quality, and access. The pilot must assess a true intervention rather than care that is essentially business as usual.

In rural areas, the pilot could test the ability for medical homes to provide high-quality, efficient care with somewhat modified structural requirements.

Beneficiaries with multiple chronic conditions would be eligible to participate because they are most in need of improved care coordination. About 60 percent of FFS beneficiaries have two or more chronic conditions. Beneficiaries would not incur any additional cost sharing for the medical home fees. As a basic principle, medical home practitioners would discuss with beneficiaries the importance of seeking guidance from the medical home before obtaining specialty services. Participating beneficiaries would, however, retain their ability to see specialists and other practitioners of their choice. Under the pilot, Medicare should also provide medical homes with timely data on patients' Medicare-covered utilization outside the medical home, including services under Part A, Part B and drugs under Part D.

A medical home pilot provides an excellent opportunity to implement and test physician P4P with payment incentives based on quality and efficiency. Under the pilot project, the Commission envisions that the P4P incentives would allow for rewards and penalties based on performance. Efficiency measures should be calculated from spending on Part A, Part B and Part D, and efficiency incentives could take the form of shared savings models similar to those under Medicare's ongoing physician group practice demonstration. Bonuses for efficiency should be available only to medical homes that have first met quality goals and that have a sufficient number of patients to permit reliable spending comparisons. Medical homes that are consistently unable to meet minimum quality requirements would become ineligible to continue participation.

It is imperative that the medical home pilot be on a large enough scale to provide statistically reliable results with a relatively short testing cycle. Additionally, the pilot must have clear and explicit results-based thresholds for determining whether it should be expanded into the full Medicare program or discontinued entirely. Focusing on beneficiaries with multiple chronic conditions and medical homes meeting stringent criteria should provide a good test of the medical home concept.

Readmissions and bundled payments around a hospitalization

Evidence suggests there is an enormous opportunity to improve care and address the lack of coordination at hospital discharge. Discharge from the hospital is a very vulnerable time for patients, and in particular for Medicare beneficiaries, who often cope with multiple chronic conditions. Often they are expected to assume a self-management role in recovery with little support or preparation. They may not understand their discharge instructions on what medications to take, know whom to call with questions, and know what signs indicate the need for immediate follow-up care. Often they do not receive timely follow-up care and communication between their hospital providers and post-acute care providers is uneven.

The variation in spending around hospitalization episodes suggests lower spending is possible. For example, spending on readmissions for chronic obstructive pulmonary disease is 65 percent higher than the average in high resource use hospitals, and spending on post acute care 78 percent higher. Often it is these and other hospitalized patients that are among the most costly beneficiaries to Medicare. Greater coordination of care is needed for this population, and changing incentives around their hospital care could be the catalyst.

How can Medicare policy change the way care is provided? First, the Commission recommends that the Secretary confidentially report to hospitals and physicians information about readmission rates and resource use around hospitalization episodes (e.g., 30 days postdischarge) for select conditions. This information would allow a given hospital and the physicians who practice in it to compare their risk-adjusted performance relative to other hospitals, physicians, and post-acute care providers. Once equipped with this information, providers may consider ways to adjust their practice styles and coordinate care to reduce service use. After two years of confidential disclosure to providers, this information should be publicly available.

Information alone, however, will not likely inspire the degree of change needed. Payment incentives are needed. We have two recommendations—one to change payment for readmissions and one to bundle payments across a hospitalization episode. (A bundled payment creates a single prospective payment for all services provided around a

hospitalization episode rather than a series of individual payments for each service provided.) Either policy could be pursued independently, but the Commission views them as complementary. A change in readmissions payment policy could be a critical step in creating an environment of joint accountability among providers that would, in turn, enable more providers to be ready for bundled payment.

Readmissions

The Commission recommends changing payment to hold providers financially accountable for service use around a hospitalization episode. Specifically, it would reduce payment to hospitals with relatively high readmission rates for select conditions. The Commission recommends that this payment change be made in tandem with a previously recommended change in law (often referred to as gainsharing or shared accountability) to allow hospitals and physicians to share in the savings that result from reengineering inefficient care processes during the episode of care. Conditions with high volume and high readmissions rates may be good candidates for selection.

Currently, Medicare pays for all admissions based on the patient's diagnosis regardless of whether it is an initial stay or a readmission for the same or a related condition. This is a concern because we know that some readmissions are avoidable and in fact are a sign of poor care or a missed opportunity to better coordinate care.

Penalizing high rates of readmissions encourages providers to do the kinds of things that lead to good care, but are not reliably done now. For example, the kinds of strategies that appear to reduce avoidable readmissions include preventing adverse events during the admission, reviewing each patient's medications at discharge for appropriateness, and communicating more clearly with beneficiaries about their self-care at discharge. In addition, hospitals, working with physicians, can better communicate with providers caring for patients after discharge and help facilitate patient's follow-up care.

Spending on readmissions is considerable. We have found that Medicare spends \$15 billion on all-cause readmissions and \$12 billion if we exclude certain readmissions, for example,

those that were planned or for situations such as unrelated traumatic events occurring after discharge. Of this \$12 billion, some is spent on readmissions that were avoidable and some on readmissions that were not. To target policy to avoidable readmissions, Medicare could compare hospitals' rates of potentially preventable readmissions and penalize those with high rates. The savings from this policy would be determined by where the benchmark that defines a high rate is set, the size of the penalty, the number and type of conditions selected, and the responsiveness of providers.

The Commission recognizes that hospitals need physician cooperation in making practice changes that lead to a lower readmission rate. Therefore, hospitals should be permitted to financially reward physicians for helping to reduce readmission rates. Sharing in the financial rewards or cost savings associated with reengineering clinical care in the hospital is called gainsharing or, shared accountability. Allowing hospitals this flexibility in aligning incentives could help them make the goal of reducing unnecessary readmissions a joint one between hospitals and physicians. As discussed in a 2005 MedPAC report to the Congress, shared accountability arrangements should be subject to safeguards to minimize the undesirable incentives potentially associated with these arrangements. For example, physicians who participate should not be rewarded for increasing referrals, stinting on care, or reducing quality.

Bundled payments for care over a hospitalization episode

Under bundled payment, Medicare would pay a single provider entity an amount intended to cover the costs of providing the full range of care needed over the hospitalization episode. Because we are concerned about care transitions and creating incentives for coordination at this juncture, the hospitalization episode should include time post-discharge (e.g., 30 days). With the bundle extending across providers, providers would not only be motivated to contain their own costs but also have a financial incentive to choose new partners or collaborate with current partners to improve their collective performance. Providers involved in the episode could develop new ways to allocate this payment among themselves. Ideally, this flexibility gives providers a greater incentive to work together and to be mindful of the impact their service use has on the overall quality of care, the volume of services provided,

and the cost of providing each service. In the early 1990s, Medicare conducted a successful demonstration of a combined physician–hospital payment for coronary artery bypass graft admissions, showing that costs per admission could be reduced without lowering quality.

The Commission recommends that CMS conduct a voluntary pilot program to test bundled payment for all services around a hospitalization for select conditions. Candidate conditions might be those with high costs and high volumes. This pilot program would be concurrent with information dissemination and a change in payment for high rates of readmissions.

Bundled payment raises a wide set of implementation issues. It requires not only that Medicare create a new payment rate for a bundle of services but also that providers decide how they will share the payment and what behavior they will reward. A pilot allows CMS to resolve the attendant design and implementation issues, while giving providers who are ready the chance to start receiving a bundled payment.

The objective of the pilot should be to determine whether bundled payment for all covered services under Part A and Part B associated with a hospitalization episode (e.g., the stay plus 30 days) improves coordination of care, reduces the incentive for providers to furnish services of low value, improves providers' efficiency, and reduces Medicare spending while not otherwise adversely affecting the quality of care. The pilot should begin applying payment changes to only a selected set of medical conditions.

Conclusion

The process of reform should begin as soon as possible—reform will take many years and Medicare's financial sustainability is deteriorating. That deterioration can be traced in part to the dysfunctional delivery system that the current payment systems have helped to create. Those payment systems must be fundamentally reformed, and the recommendations we have made are a first step on that path. I thank the Committee for its attention, and look forward to working with you to reform Medicare's payment systems and help bring the health care delivery system into the 21st century.

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Testimony of
Glenn D. Steele Jr., MD, PhD
President and Chief Executive Officer
Geisinger Health System

Before the
Senate Finance Committee
US Senate
September 16, 2008

Thank you for the invitation to testify today at your hearing on reforming the nation's healthcare system.

I am Glenn Steele, the CEO and President of the Geisinger Healthcare System. To give you some background, I spent 20 years as an active cancer surgeon at both the Brigham and Women's Hospital and the Deaconess Hospital in Boston, the latter at which I served as Chairman of the Department of Surgery. After my service in Boston, I became Vice President for Medical Affairs and the Dean of the Division of Biological Sciences and the Pritzker School of Medicine at the University of Chicago with more than 700 physicians in our practice group at the University of Chicago Hospitals. This has given me firsthand experience with patients, their access to care, issues affecting physicians and other caregivers, medical education and research, and healthcare reimbursement.

In 2001, I accepted the role of President and CEO of Geisinger Health System. I was excited about this opportunity because Geisinger offered the potential as an integrated healthcare system of developing cutting-edge approaches to increasing efficiency and quality in healthcare. And I believed that, if we could achieve this at Geisinger, which serves a rural population that is older, sicker, and poorer than national averages, we might make some contribution to the nation's search for a more effective healthcare system.

BACKGROUND

Geisinger is an integrated healthcare system. That means we are a healthcare system that includes physicians, hospitals, various outpatient healthcare facilities and programs, as well as a healthcare plan. Our organizational structure is relatively flat with less bureaucracy than is inherent in most academic medical environments. We can make changes faster¹.

We serve a population of 2.6 million located in central and northeastern Pennsylvania. And we have an electronic health record (EHR) that was implemented more than 13 years ago with now more than 3 million individual health records. And we have been named as “Most Wired” by *Healthcare’s Most Wired* magazine six times. We also lead our area’s regional electronic health information sharing among both Geisinger and non-Geisinger healthcare providers, called the Keystone Health Information Exchange. We have a fully-integrated electronic health record with direct patient access. This secure, patient-approved sharing of information means that our doctors (and non-Geisinger doctors who share care of patients with us) can access patient information 24/7 from anywhere they are – a remote two-doctor primary care office, a multispecialty clinic, an operating room, or at 3 am from their home when their patient has been admitted to the Emergency Department.

Our patients can also access their electronic health record – which means they can see lab results, radiology results, request prescription refills, and email their doctors and nurses with questions and schedule appointments. Some of our elderly patients, who have family living outside of our area, give their children access to their own records. That way, family members can check on their

parents' care, view their medication list and health maintenance reminders, and encourage them to be sure to make that upcoming doctor's visit.

Geisinger employs more than 740 physicians who see patients in more than 50 clinical practice sites, 40 of which are primary care sites in local communities. As clinically appropriate, physicians in these clinical sites admit their patients to local community hospitals - ensuring that patients receive most of their care in their local communities and helping to keep rural community hospitals vital. We invest in quality and pay accordingly. Doctors who have better clinical outcomes are rewarded (financially and by recognition) and we constantly measure our outcomes against our peers both within Geisinger and nationally.

Our system provides all adult and pediatric primary and specialty care and includes three hospitals, multiple specialty hospitals (heart, cancer, and an alcohol and chemical dependency treatment center) and ambulatory surgery campuses. We also have dedicated personnel who are devoted to addressing post-traumatic stress disorder -- a disorder that is more prevalent in rural areas where diagnosis and treatment for returning veterans, their spouses, and their children are especially problematic. We have taken on as a special responsibility working with the Veteran's Administration to care for our men and women returning from Iraq, Afghanistan, and other fields of combat who are suffering from these medical problems.

Geisinger has a 220,000 member health plan -- Geisinger Health Plan (GHP) -- that has been instrumental in designing and incenting new models of healthcare delivery. This is because we have both clinical and financial responsibility for these patients. When our innovation tests are

successful, we can then implement them across our system. Geisinger providers actively serve both Geisinger Health Plan enrollees and non-GHP patients who are covered under Medicare, Medicaid, and private insurers.

As I mentioned, Geisinger serves a population that is poorer, older, and sicker than national averages. Most of our patients have multiple chronic diseases, such as diabetes, high blood pressure, and lung disease. Geisinger has committed significant resources and has been working aggressively to use its unique strengths to bring value to healthcare using innovations that redesign how and when these patients navigate through a complex healthcare system. As we have learned from others, I firmly believe that the nation can take advantage of our experiences and make similar changes to improve health care value.

PROBLEMS IN THE HEALTHCARE SYSTEM

It is widely acknowledged that our healthcare system is struggling against what appears to be intractable problems: incomplete and unequal access to care; perverse payment incentives that fail to reward good outcomes; fragmented, uncoordinated and highly variable care that results in safety risks and waste; a disconnect between quality and price; rising costs; consumer dissatisfaction; and the absence of productivity and efficiency gains that are common in other industries. Healthcare value (that is, clinical outcomes relative to costs) simply must increase to achieve these goals.

GEISINGER'S ACUTE EPISODIC CARE PROGRAM (THE "WARRANTY")^{2,3}

ProvenCareSM

A great paradox in healthcare is that we get paid for making more mistakes. It doesn't mean that we

intentionally make mistakes, but we are frequently rewarded financially when an outcome is not beneficial to the patient. For example, with few exceptions, if a patient develops a post-operative complication that might have been avoided by proper care, we may receive more reimbursement for that case than for a comparable case without a complication. This does not happen in other industries. Purchase of a car, a computer or even a home typically includes a warranty. Why should healthcare services be an exception?

In 2006, we started transforming care by testing and rewarding how we provide elective cardiac surgical care – what is known as coronary artery bypass grafts (or CABG). CABG is known as an episodic acute event – an event with a determined time frame from diagnosis through rehabilitation and recovery (unlike chronic disease, which stays with you for life). Led by Dr. Alfred Casale, our cardiology service line reviewed the American Heart Association and the American College of Cardiology guidelines for cardiac surgery and translated them into 40 verifiable process steps that we could implement with each patient undergoing this surgery. We embedded these behaviors into our electronic health record so that we would be prompted (or forced) to meet each identified step – or document the specific reason for an exception.

We then established a packaged price (based on historical data) that included costs of the first physician visit that determined surgery was necessary, all hospital costs for the surgery, and for related care for 90-days after surgery, including cardiac rehabilitation. We named this program “ProvenCare”, since it is based on evidence of best practices or (at least) consensus of best practice by our cardiology experts. As long as the pre-operative, post-operative and rehabilitation are part of the expected care for that surgery and received at Geisinger, we have only one charge. And we do

not charge for mistakes. In other words, we take the financial responsibility for any associated complications and their treatment.

While our cardiac surgery outcome was already above the national average, upon initiation of this program only 59% of patients received all 40 best practice steps. Three months into the study, 86% were receiving best care. We raised that to 100% and, with few exceptions, have kept it at that high rate.

So, we knew we were onto something. We knew our patient care was better – using comparative, standardized data from the Society of Thoracic Surgery. We had a reduction in complications of 21%, sternal infections were down 25%, and re-admissions fell by 44%. Costs for treatment fell, too. Our average length of hospital stay decreased by half a day, and our net revenue increased by nearly 8%.

For many of our high volume, hospital-based treatments, we have considered every step in the patient's care flow. For instance, in orthopedic surgery, why should one doctor use one set of surgical instruments and another insist on a different design for the same procedure? That type of demand – if there is no medical justification for variation – results in unnecessary costs that are passed off to third party payors, such as Medicare.

We knew we needed to extrapolate our experience with heart surgery to other episodic and frequent healthcare events. That included hip replacement, cataract surgery, obesity surgery, care for babies from conception to birth, and heart catheterization. To-date, I am pleased to say are showing success

in each area. We have improved outcomes and, in most cases, we have reduced costs. This is because we have systematically researched how best to deliver care, embedded the evidence into our electronic health record to prompt us on what best practices are and removed unjustified variation in the way we deliver care.

ProvenCare – Chronic Disease

But it wasn't enough to simply address episodic care. A large part of healthcare is preventing and treating chronic diseases. So we identified the most common chronic diseases – diabetes, coronary artery disease, congestive heart failure, kidney disease – and defined the best steps needed to limit disease progression. We call this “bundled” care, since we put each of these steps into a bundle of care and strive to achieve as close to 100% adoption as medically appropriate and feasible. In the case of diabetes, we began to track how we performed in meeting 100% of the expected levels of care for diabetic patients. Our primary caregivers receive more compensation as more of our 25,000 diabetic patients reach higher levels in the practice “bundle”.

Preventing disease also became an obvious priority and we developed an adult prevention bundle that includes cancer screening, heart care, prevention of infectious diseases (such as pneumonia), encouragement of proper nutritional care, and reduction of substance abuse. Each of these are measured as needed by sex, age, and recommended screening time frames. Doctors and their support staff have compensation tied to meeting these quality goals.

ProvenTransitions

To move patients through the healthcare system and make care consistent in each step of care, Geisinger has worked diligently to make “hand-offs” in care transparent. When a patient is scheduled for admission, we start the discharge process before they arrive. As much as possible, the patient is made aware of what they need to do to prepare for discharge, the length of time they should expect to be in the hospital, how they will be cared for after leaving, the medications they will be on, when they will need to see the doctor again (and how they can access transportation to that visit), and what financial and social assistance may be available. Geisinger’s patient-centered medical home initiative (titled ProvenHealth Navigator) combines traditional medical home models with patient engagement and is designed to deliver value by improving patient care coordination and optimizing health status for every individual.

ProvenHealth Navigator

As I’ve said, if we are to achieve the diverse healthcare goals of the United States, healthcare value must increase. We understand that navigating through the complexities of any healthcare system is not easy, so we have invested in programs and staff to help support each patient’s journey, placing dedicated nurses in each targeted outpatient clinic. There, they get to know the patients and their families, follow their care, help them get access to specialists and social services, follow them when they are admitted to a hospital, contact them to confirm that they are taking the appropriate medication dosages, and are available for advice 24 hours a day.

Importantly, we didn’t just ask our clinicians to “try harder” we actually resourced them so that they could get the job done via extra payments from our health plan. In our initial pilot program, using

this method of care, we have significantly reduced admissions of our sickest chronic disease patients. We lowered readmissions by 18.5%. The payback on the resource investments for the health plan occurred within the first year. The benefit to patients avoiding multiple hospital admissions and emergency department visits was priceless!

Let me give you an example – which, I assure you, is not unusual. Patient “A” is a 75-year old widowed female whose two children are now married and living in other states. She owns her house and lives independently. She has diabetes, high blood pressure, congestive heart failure, and depression and must remember to take 15 pills each day. One day she falls, breaks her hip and must be hospitalized. When she leaves the hospital, who picks her up to take her home? Who makes sure she is not disoriented? Who understands that she may need help at home? Who makes sure she is able to see a doctor when she should and anytime she should? Who coordinates her prescriptions, gets her pills, and sees to it that she takes those pills at the right times?

That is what our ProvenHealth Navigator nurse does. And it works – for the patient and for healthcare costs.

Summary

In summary, our ProvenCare programs focus on delivering value through a system of care that can be easily and reliably updated as clinical evidence changes. We are not rigidly wedded to any current piece of evidence, but rather to the ability to apply new evidence and learning to care. With our electronic health record, we are able to “hardwire” reminders and prompts into the system in real-time. Information technology is necessary, but not sufficient. It enables the re-engineering of

care. That is the key. We have established metrics to measure how well we perform and hold ourselves accountable for providing the best clinical care. We are fortunate to have a health insurance company that we can partner with to test new models of reimbursement and care delivery. We include and encourage the patient to be part of the decision-making for their care and to let us know how they prefer their care to be given (will they take two pills a day or do they prefer only one? Different dosages of varying medications may be ordered). And we try to “close the loop” with our ProvenTransitions and ProvenHealth Navigator nurses.

As noted earlier, Geisinger has unique attributes that lend itself the ability to test and apply new methods of healthcare. But what we are doing is not unique. Application of best practices can be shared and used by others.

What we need to do is reward good clinical practice and not reward bad practice. Paying for readmitting a patient for an infection that should have been prevented is unacceptable. National policies that address these reimbursement issues (particularly for Medicare patients) should be changed. Programs like Medical Home need to be recognized for their value and reimbursed appropriately. Those changes will result in creating a practice environment for physicians that is rewarding, will increase interest in our young caregivers entering the field of primary care – where prevention of disease is centered – and move toward making the cost of healthcare more affordable for our nation.

As we all struggle together with adopting the right healthcare reform plan to make our nation’s healthcare system the best, we would welcome the opportunity to support your efforts in any way

that we can. We also extend an open invitation to each of you to visit Geisinger and see some of what I have talked about firsthand.

Thank you again for the opportunity to testify today and I look forward to your questions.

References

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- 2 – Casale A, Paulus R, Steele G, et al ProvenCareSM. *A Provider-Driven Pay-for-Performance Program for Acute Episodic Cardiac Surgical Care*, Annals of Surgery. Vol. 246, Number 4, Oct. 2007
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President and
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GEISINGER
HEALTH SYSTEM

January 6, 2009

Honorable Jay Rockefeller
Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510

Via: email to Andrew Hu - Andrew.Hu@finance-dem.senate.gov

Senator Rockefeller,

Thank you for the opportunity to provide additional information regarding the testimony that I gave to the Senate Finance Committee on September 16, 2008. Our healthcare coverage area is similar to the same challenges you are facing in West Virginia: shortage of specialists, decreasing numbers of medical students going into primary care because of lack of incentives, and an aging population with multiple chronic diseases.

At Geisinger, we are committed to moving forward to address the issues that strongly affect our citizens – sufficient care for children, preventative medicine, access to affordable healthcare, chronic disease management, and providing comfort (and dignity) for patients living with disease and those that are facing death. We believe that the actions we describe below in response to your questions reflect this commitment.

Our responses are in the order of your questions, which touch on the provider shortage in rural areas, the role of health information technology and telemedicine, improving end-of-life care, and how to address the disparity of resources throughout our healthcare delivery system in order to improve care coordination and clinical outcomes.

The following is a compilation and summary of ideas provided by Geisinger leaders. The responses are in the order of your questions. Bulleted items precede the full text; that text provides you with background information.

1. In the face of crippling rural provider shortages – in both primary care and specialty areas – what steps can we take in rural parts of the country to create a much more integrated healthcare delivery system that better coordinates care and focuses on outcomes? What is the role of health information technology and telemedicine?

- Restructure the payment system to better reward primary care physicians. This should encourage entry into this field.
- Electronic health records (EHRs) are vital to patient quality, assessment of care given, and innovating healthcare delivery. In rural areas, EHRs are essential in providing consistent care across large geographic areas.

W W W . G E I S I N G E R . O R G

Senator Rockefeller ltr
Page 2

- Telemedicine offers one of the best solutions for addressing the shortage of physicians in rural areas. Adequate reimbursement for distance diagnosis and treatment is essential.
- The Medical Home model should be adapted and expanded in its use with incentives built that reward quality, efficiency, and decrease unnecessary admissions and readmissions.
- Specialists should be attracted to centers of excellence. A “hub and spoke” design – one with a centrally located hub that offers state-of-the-art care – is needed in rural areas to allow innovative care and innovative patient payment models with quality of life advantages for patients and their doctors.
- Primary care providers living close to their patients must be connected to centrally-located specialists by shared EHRs with broadband-enabled telemedicine. Together, they can provide the best advice as necessary, in real-time.

The declining number of physicians pursuing non-procedural based medicine (both specialty and primary care) in the face of the surge of elderly patients in this country is worrisome – and in rural areas extreme. Our current payment systems discourage most graduating medical students from pursuing careers in primary care with starting compensation low and limited future earning potential. Faced with an average graduating debt of \$160,000, other medical career options are more attractive. In addition, women entering the field of medicine over the past several decades juggle medical careers with family time. Both men and women now entering medicine no longer accept the tradition of prioritizing careers over their families – and certain specialties are now much more attractive to graduating medical students because more money can be made with shorter working hours.

So, what can be done? Restructure the payment system to better reward primary care; use informatics that brings support to the primary care physician’s ability to make complex decisions; advance telemedicine that supports distance diagnosis and treatment; and change how primary care is delivered – developing the primary care physician as a leader of a team of providers (e.g., midlevel extenders, nurses) – based on the concepts in the patient-centered Medical Home model. At Geisinger, we use an advanced version of this model (titled ProvenHealth Navigator). Financial incentives (by payors and/or systems) are based on provision of high quality medical services over a patient’s continuum of care. Payment based on better clinical outcomes (such as decreased hospitalization and decreased rehospitalization rates, along with increased patient and family satisfaction) is moving even small practices towards more integrated care.

Implementation of the electronic health record (EHR) across a large geographic area is essential. At Geisinger, we share access to our EHR (free of charge) with more than 1,500 non-Geisinger physicians and their staff. This access is HIPPA-compliant, at the approval of the patient, but is “read-only”. This means that entering patient data by non-Geisinger physicians is not allowed. Mitigation of Stark regulations prohibiting this type of patient-care sharing of information would improve our ability to provide access to care, particularly in our more rural areas.

Telemedicine should have a much larger role in addressing some of the subspecialty work force issues. One area that is immediately evident is in the provision of critical care/ICU services. The gap in the work force will continue to widen over the ensuing years. The ability to provide critical care in a rural geography will be dependent upon nontraditional modes of care. Remote monitoring is an area that is of considerable interest in a rural setting. The demonstration of its effectiveness and viability as a model is evolving. But it is one example of a technology that has the potential to improve and impact patient care in the near-term – and it deserves financial support. Remote diagnosis and treatment of PTSD is another key example of dissemination of specialty health expertise from our centrally located psychiatrists to rural community practice sites at Geisinger.

Medical Home models should be encouraged as we provide the necessary infrastructure to support patient care needs. Connectivity among specialists, primary care providers, and family caregivers is vital to long-term success. At Geisinger, ProvenHealth Navigator (our advanced Medical Home model) has significantly reduced admissions and readmissions of our sickest, multiple chronic disease patients (Paulus R, Davis K, Steele G. Continuous Innovations in Health Care: Implications of the Geisinger Experience. *Health Affairs* 27, no.5 (2008), 1235-1245). This does, however, stress small community hospitals with which we work. If our physicians who admit to numerous community hospitals decrease unnecessary admissions to these hospitals, what will be the future role and structure of the local hospital?

2. How does your integrated system deal with end-of-life care issues, particularly provider payment and coordination? When are advanced directives discussed with patients and how are patient wishes disseminated throughout your integrated system? Do you have any specific suggestions for how we can change Medicare reimbursement to better respond to the needs of patients at the end-of-life?

- We engage patients and their families so that they are knowledgeable and able to participate in decisions regarding their care (and their death).
- We have initiated our own PACE program in rural central and northeastern Pennsylvania. And we are assigning primary care providers specific nursing home patient care responsibilities. This extends our geographic footprint in caring for the sickest and oldest patients.
- We formally encourage the use of palliative specialists in our hubs, providing expert direction in comfort measures and a smooth transition to hospice care.
- Advanced Directives are offered to anyone scheduled for inpatient treatment (if they are above 18 years of age). In the out-patient setting, physicians (or other caregivers) make that determination based on disease and risk status.
- We believe the six-month prognosis rule for Medicare Hospice Benefits should be extended to one year, allowing for non-curative (but life-extending or comfort measures) to be enacted and reimbursed.

Senator Rockefeller Itr
Page 4

Across all of healthcare, we need to do a better job of engaging patients to consider their options, including end-of-life care as early as possible in the care continuum. There is no question that both palliative medicine specialty services and hospice should be offered further upstream.

Once again, a major problem is that reimbursement systems reward procedures, not communicating with patients. Managing patients at the end-of-life (including while they are in hospice) does not get adequately reimbursed and there is little payment recognition of care, in the absence of face-to-face visits (making remote meetings in the rural setting more difficult).

At Geisinger, we have two innovative examples of managing care for our elders. One program, titled Life Geisinger, is the same as the national PACE program (Program for All-inclusive Care for the Elderly). We offer all care needed in a well-equipped and professionally staffed "day care" facility. Our clients receive overall (and individualized) care including travel to and from the center, diagnosis, treatment, and comfort means in one place – with their friends and caregivers at their center. This also gives spouses, children, and other family caregivers respite from having to provide 24/7 care themselves. There is a great deal of respect for the wishes of the centers' clients – about their choices on treatment (or no treatment) and their wishes concerning their last days.

In 1999, Geisinger's main "hub" (Geisinger Medical Center) was one of the first hospitals/healthcare systems in the nation to institute a full-time, physician-led, comprehensive inpatient and outpatient Palliative Medicine Service (comfort services, particularly for terminal patients). The staff is board-certified in palliative medicine. All of our internal medicine resident trainees (and many other residents, fellows, medical students, and advanced practice nursing students) rotate on the Palliative Medicine Service. This has led to a culture change throughout our system. An assessment tool was developed so that various other clinical services can evaluate the appropriateness of a consultation by Palliative Medicine specialists. Palliative Medicine offers continuing medical education conferences, including day-long courses, bimonthly resident lectures and interdepartmental conferences pertaining to Palliative Medicine and end-of-life issues. Community education is also ongoing, with forums at nursing homes, adult education programs, high school student intergenerational activities, and undergraduate university courses in aging and end-of-life issues.

Advanced Directives are part of the pre-inpatient registration process at Geisinger. Patients 18 years of age or older are given information about Advanced Directives and the opportunity to pick options regarding their directive choices. This information is entered into our EHR and is clearly flagged as identifiable by all caregivers. A simple "click" will provide the patient's detailed directives. As part of our Transitions of Care Program, code status chosen during hospitalization is relayed to the patient's primary care physician at time of discharge and documented in the discharge synopsis provided to the primary care team. Advanced Directives need to include documentation of understanding from the patient and their family – and be readdressed on several occasions. At present, none of this is reimbursed by any payor. We do it at Geisinger because it is the right thing to do. Formal reimbursement for counseling and management of this kind should be a mandatory part of every insurance coverage plan.

The six-month prognosis requirement of the Medicare Hospice Benefit should be extended to one year and allow for non-curative (but life-extending) treatments that are primarily directed at comfort and dignity.

Hospice care should not have the stigma of “giving up”. To counteract this, incorporating Palliative Medicine delivery and involvement of Palliative Medicine and hospice specialists (along with appropriate reimbursement) earlier in the terminal disease trajectory is key. For Palliative Medicine, referring patients with a life-limiting illness and a prognosis of death within two years or less is our goal at Geisinger. Medicare should lead efforts to reform access, payment, delivery, and efficiency of high quality care at the end of life, including incentives to appropriately transition patients from acute care to hospice, along with more comprehensive data collection to evaluate end-of-life quality and value provided.

3. How can we address the disparity of resources throughout our healthcare delivery system and provide incentives for both large and small healthcare systems – as well as integrated and non-integrated providers – to improve care coordination and clinical outcomes?

- Integrated systems (or virtually integrated systems) will be needed to meet regulatory and reporting standards for continuum of care quality and value. We should create incentives to evolve towards these structures as soon as possible.
- Telemedicine and an EHR are crucial, particularly in rural areas. Access to care - in the absence of sufficient caregivers – can benefit by linkage to family caregivers and midlevel providers and other community-based professional staff whose scope of practice is expanded with adequate supervision by centrally-located specialists and primary care physicians.
- Healthcare organizations must be made accountable for patient experience, quality, and efficiency – with payment based on episodes of acute hospital care, and based upon outcomes measured over time for patients with multiple chronic diseases.

Integrated delivery systems will continue to evolve and grow. The need for infrastructure and response to increasing continuum of care requirements will limit the growth of providers that are not part of a more structured system of care. The increasing need for capital to support technology and enable innovative care changes will drive this integrated provider model. Hospital and physician goals in caring for patients will need to be aligned. Geisinger’s ProvenCare® is an example of moving away from a traditional to an alternative financial incentive model that guarantees care using best practice and enables the hospitals and providers to take financial risk together for achieving optimal outcome across the entire episode of care (Casale A, Paulus R, Selna M, Doll M, et al. “ProvenCareSM” A Provider-Driven Pay-for-Performance Program for Acute Episodic Cardiac Surgical Care. *Annals of Surgery* 246, no.4 (2007), 613-623).

Currently, large and small provider groups within a region compete with each other. We have challenged this by opening our system up to non-Geisinger practices and non-

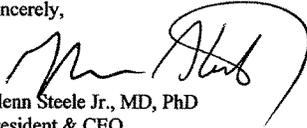
Senator Rockefeller ltr
Page 6

Geisinger hospitals. Geisinger recognizes that patients prefer to be treated locally but, when expertise is needed and not available in the local community, access to specialists and state-of-the-art services should be seamless. We ensure this concept through our EHR – where a specialist and a community physician (Geisinger or non-Geisinger) can manage a patient together and determine if a transfer of care is needed.

In summary, “Accountable Health Organizations” should be paid according to outcomes in patient experience, quality, and efficiency. Integrated systems or virtually integrated systems of independent practitioners working closely together will be necessary to achieve most of what is prescribed above. Incenting the development of these entities, means paying for demonstrated improved outcomes, instead of our present payment for units of work performed – regardless of benefit to patients.

I appreciate the opportunity to respond to your questions and welcome further inquiries.

Sincerely,

A handwritten signature in black ink, appearing to read "Glenn Steele Jr.", enclosed within a large, hand-drawn oval.

Glenn Steele Jr., MD, PhD
President & CEO
Geisinger Health System

cc: Max S. Baucus
Chairman, United States Finance Committee

Senator Charles E. Grassley
Ranking Member, Senate Finance Committee

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UNITED STATES SENATE COMMITTEE ON FINANCE
ALIGNING INCENTIVE: THE CASE FOR DELIVERY SYSTEM REFORM
SEPTEMBER 16, 2008

STATEMENT FOR THE RECORD:
The ADVANCED MEDICAL TECHNOLOGY ASSOCIATION (AdvaMed)
701 PENNSYLVANIA AVENUE NW, Suite 800
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Bringing innovation to patient care worldwide

The Advanced Medical Technology Association (AdvaMed)

AdvaMed represents over 1,600 of the world's leading medical technology innovators and manufacturers of medical devices, diagnostic products and medical information systems. Over 70% of our member companies are relatively small companies with sales of less than \$30 million per year. Our members are devoted to the development of new technologies that allow patients to lead longer, healthier, and more productive lives. Together, our members manufacture nearly 90 percent of the \$86 billion in life-enhancing health care technology products purchased annually in the United States, and nearly 50 percent of the \$220 billion in medical technology products purchased globally.

The medical technology industry is a critical component of the U.S. health sector and is fueled by intense competition and the innovative energy of small companies – firms that drive very rapid innovation cycles among products, in many cases leading to new product iterations every 18 months. Constant innovation by our member companies leads to the introduction of new technologies that prevent illness, allow earlier detection of diseases, and treat patients as effectively and efficiently as possible.

AdvaMed is pleased that today's Senate Finance Committee hearing will explore the issue of delivery system reform, including the role physicians play in determining which services are provided to patients. As the Committee considers this issue, it is critical to have a full discussion of the relationships that exist between physicians and industry in the innovation and delivery of medical technology.

Physicians play a vital role in medical technology innovation, and their contribution, which leads to improved patient care, should be valued and understood. AdvaMed supports appropriate disclosure of relationships between the medical technology industry and physicians. We recognize that strong ethical standards are critical to ensuring the valuable collaboration between our industry and health care professionals that fuels the world's most advanced medical technologies. We have been pleased to work with Senator Grassley and Senator Kohl, and their staff, on the revised Physician Payment Sunshine Act, which lays out a framework for the appropriate disclosure of financial relationships between physician innovators and the companies that make their vision a reality.

Medical Device Company-Physician Collaboration is Essential to Safe and Effective Patient Care

Continued innovation in healthcare is driven by the ability of America's medical technology manufacturers to interact and work closely with physicians and other care providers. Medical device companies develop on-going relationships with physicians and other health care professionals. These relationships are an essential ingredient in developing new treatments and cures and assuring that medical technology products are used safely and effectively.

Physicians are often themselves inventors of new technologies; skilled advisors to improve existing devices; researchers; trainers of other health care professionals on the appropriate use of advanced medical technology, and trainees themselves by companies who have developed breakthrough or sophisticated devices requiring skilled preparation, deployment and use. Of course, physicians are also customers or otherwise influential in a health care provider's acquisition of medical technology. In short, physicians play a central role in our health care delivery system, and wear many hats in their interactions with medical device companies.

AdvaMed's Code of Ethics

AdvaMed believes that close and ongoing collaboration is necessary to develop new technologies and ensure the safe and effective use of those technologies. At the same time, we respect the need for health care professionals to make independent decisions regarding product selection. That is why AdvaMed developed a Code of Ethics and is in the process of updating and strengthening it, to distinguish interactions that contribute to the advancement of medical technology, from interactions that may be perceived to influence medical decision-making inappropriately.

The medical device industry's commitment does not stop with the Code. We have taken aggressive steps to educate the health care industry about the Code, ethical interactions and compliance. We sometimes present along side enforcement agencies to underscore that adherence to the Code of Ethics is beneficial to all stakeholders. Recently, our industry adopted a Code Logo program, under which companies certify that they meet eight requirements, derived from the OIG's compliance effectiveness guidance, in order to display the Logo. Compliance is an ongoing process and a priority for our companies.

Key Features of the Revised Physician Payment Sunshine Act

AdvaMed is pleased to support Senator Grassley and Senator Kohl's revised legislation. It will create a strong framework to ensure that patients receive meaningful information about industry relationships with physicians in a manner that preserves future innovation. We especially appreciate three key improvements that will ensure that the information being disclosed is useful, meaningful and put in full context.

First, the revised legislation now expressly preempts State laws requiring disclosure of relationships with physicians. Our industry supports one comprehensive Federal standard for disclosure so that patients have clear information on reportable payments. A patchwork of 50 State laws – all with different standards of what types of payments must be disclosed, different details and context provided, all published in different formats and for different time periods – would be confusing for patients to interpret and burdensome for companies to comply with. Expressly preempting state disclosure laws will ensure consistency in application and patient understanding.

A second provision requires compliance by physician-owned manufacturers, distributors and group purchasing organizations (GPOs). These are entities in which physicians both have an equity ownership interest and generate a substantial portion of the companies' revenues through ordering (or influencing orders for) devices sold or manufactured by the company, or through improperly influencing such orders or purchases in some other way. AdvaMed is concerned that at least some of these entities for which physicians generate substantial revenues have the potential to create conflicts of interest between physicians' responsibility to provide the best care and physicians' equity interests which may compromise (or appear to compromise) the physician-patient relationship and could further serve to restrict patient access to the most appropriate advanced medical technologies. The Office of the Inspector General last year stated in correspondence to AdvaMed that these arrangements should be closely scrutinized under the fraud and abuse laws. AdvaMed supports the updated disclosure program proposed in the revised Grassley-Kohl legislation that applies to these physician owned entities regardless of their size.

Finally, the updated legislation allows disclosure information to be displayed in a meaningful and easily understood format that provides the appropriate context for patient education. It creates a public database giving companies the opportunity to provide the context of those payments to

physicians. The database will go a long way to making “sunshine” work. Physicians wear many hats in their interactions with medical device companies, and patients deserve to know if a physician is listed because he or she worked with a company to invent or improve a device, or because he or she received training to use a device safely and effectively. The absence of context could be misconstrued and would be a disservice to our physician partners who take very seriously their role to bring new technologies to patients. AdvaMed supports the updated design of the disclosure program to provide appropriate context for patients.

While we are pleased with the direction of the revised bill, we remain concerned that many smaller medical device companies may lack the resources to meet the administrative requirements set forth in the bill. We appreciate the willingness of Senators Grassley and Kohl to consider our concerns on the original threshold based on annual revenues, however, we continue to seek an alternative approach that would exempt companies that make payments to physicians of less than \$250,000 annually. We look forward to continuing to work with the sponsors on this important issue.

Conclusion

AdvaMed and our member companies support appropriate disclosure of relationships between medical technology companies and physicians. As the Finance Committee continues to explore the important issue of health care reform in general and delivery system reform in particular, we want to reiterate our support for the revised Physician Payments Sunshine Act (S. 2029). This legislation will help provide information to patients about important relationships between industry and physicians, and do so in a manner that preserves innovation and access to medical technology. We greatly appreciate Senator Grassley’s and Senator Kohl’s willingness to work with our industry on this important legislation, and we encourage its swift enactment. Preserving our member companies’ ability to interact with physicians in a collaborative, transparent and ethical manner is essential.



American Academy of Pediatrics



Statement for the Record

**on behalf of the
AMERICAN ACADEMY OF PEDIATRICS**

**before the
Senate Finance Committee**

For

Aligning Incentives: The Case for Delivery System Reform

September 16th, 2008

Department of Federal Affairs
The Homer Building
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This statement on children's health care access and quality is submitted on behalf of the American Academy of Pediatrics (the Academy), which represents more than 60,000 primary care pediatricians as well as pediatric medical and surgical subspecialists. The Academy and its members are dedicated to the health, safety, and well-being of children from infancy through young adulthood. With health reform a major concern for many families, the time is right to make the health and well being of America's children a national priority and to fix the broken system under which they receive health care.

Medicaid Payment

Medicaid, established in 1965, has grown to be incredibly important to the health of children in the United States. Currently, over 28 million children are enrolled in Medicaid. SCHIP, which targets low-income uninsured children who do not qualify for Medicaid, covers 6 million additional children. Together, Medicaid and the State Children's Health Insurance Program (SCHIP) provide health coverage for one in four of our nation's children. The gains in Medicaid and SCHIP coverage have outpaced the erosion of employer-sponsored coverage, resulting in the percentage of low-income children who were uninsured declining by one-third over the last decade.

When Medicaid was established in 1965, most health professionals were delighted because they would be paid something for seeing patients who most often were unable to pay for health services, and therefore many providers chose to participate in Medicaid. Providers did not know what would happen with reimbursement decisions at the state level, but were willing to be patient to allow the system to mature as states implemented their Medicaid programs.

State Medicaid administrators were permitted to reimburse providers up to the Medicare rate for the state. In the beginning, providers accepted these fees and "cost shifted" by increasing the fees charged to private-pay patients in order to include Medicaid patients in their practices and remain in business. There were very few insurance plans that paid for office-based health services in 1965, so physicians' private sector fees were not capped by managed care contracts. Over time, fewer and fewer states have approached Medicare payment rates under their Medicaid systems, and when the economy declines, states have historically slashed Medicaid payment rates.

Very few states have ever reached the Medicare rate and the average reimbursement paid in Medicaid today, according to Academy surveys of Medicaid fee for service programs, is 69% of Medicare rates for the fifty state Medicaid programs. For example, the usual office visit fee paid by Medicare in New Jersey is \$65.65, while the Medicaid fee for the same service is \$20.60 (42% of the Medicare rate).

There is evidence to show that Medicaid payment rates are directly proportional to provider participation in Medicaid and to patients' access to primary care and specialty care from physicians. The Equal Access Clause of the 1989 OBRA statutes was designed to guarantee Medicaid patients access to care by requiring states to pay providers providing medical care for Medicaid patients at the same level that private patients are paying for health services. Most all states are failing to meet the OBRA guidelines; the

courts are not enforcing the OBRA guidelines; and Congress has not stepped in to require the states or the courts to abide by the OBRA guidelines. Children will not have optimal pediatric care until incentives to provide care to children in Medicaid are rational. This is because pediatricians, like other physicians, also run businesses and must often limit the number of Medicaid patients they see to keep their doors open.

The Medical Home

The Academy introduced the medical home concept in 1967, initially referring to a central location for archiving a child's medical record. In its 2002 policy statement, the Academy expanded the medical home concept to include the following operational characteristics: accessible, continuous, comprehensive, family-centered, coordinated, compassionate, and culturally effective care.

Joining with the American Academy of Family Physicians, the American College of Physicians, and the American Osteopathic Association, the Academy jointly published a set of patient-centered medical home principles. These principles call for care that is led by a personal physician involving a team of professionals at the practice level. Also recommended is care that is coordinated and integrated through information technology and registries, care that actively involves and supports children and families, care that is guided by evidence-based medicine and clinical decision support tools, and care with expanded hours and open access.

Major delivery and financing reforms are needed in public and private health insurance to support advances in the provision of comprehensive care for infants, children, and adolescents. Referred to as a "Family- or Patient-Centered Medical Home," this evolving model of care incorporates expanded access and communication, improved coordination and integration of care, changes in administrative processes and quality oversight, active patient and family involvement, and linkages with community-based services.

Although the American Academy of Pediatrics (AAP) pioneered the medical home concept and has long supported the medical home model of care, pediatric practices have not had the financial support of public and private payers to organize their practices to fully implement this model of care. Pediatric practices, for example, provide telephone and email communication with patients and families, team care, extended time to manage the care of children with chronic and complex conditions, consultation and coordination with specialists and other services providers, as well as patient and family education and support. These efforts also require the implementation and maintenance of new health information technology and quality improvement programs. Compensation mechanisms for all of these services need to be addressed to enable pediatric practices to provide and sustain the level of care called for in the medical home model.

Joining with the American Academy of Family Physicians, the American College of Physicians, and the American Osteopathic Association, the AAP jointly published a set of patient-centered medical home principles. These principles call for care that is led by a personal physician involving a team of professionals at the practice level. Also recommended is care that is coordinated and integrated through information technology

and registries, care that actively involves and supports children and families, care that is guided by evidence-based medicine and clinical decision support tools, and care with expanded hours and open access. Further, the principles call for a new payment structure that promotes the value of primary care and recognizes the additional physician and non-physician staff time required to implement the medical home model, along with the infrastructure support necessary to ensure its start-up and sustainability.

Payment Strategies to Support the Medical Home in Pediatrics

Payment to support medical home innovations should include up-front start-up funding for practices that are not part of larger organized systems and that do not have the necessary infrastructure to implement NCQA's medical home standards. Practices will incur additional significant infrastructure and staffing costs associated with practice management information and electronic health record systems, expanded physician and non-physician time for care coordination, and marked changes associated with the loss of income due to less acute care and more chronic care. There also will be a need to provide training to accelerate familiarity and adoption of the model. Provision of an up-front structural practice payment or other investment strategies in the form of subsidies, favorable loans, grants, or other financial incentives will enable pediatric practices to participate in providing a family- and patient-centered medical home.

The medical home payment method should have three components:

1. A *contact or visit-based fee* component that recognizes and values evaluative/cognitive services and also preventive counseling, telephone and email communication, consultation, and team care, as defined by CPT or HCPCS codes and paid on a fee-for-service or capitated basis.
2. A *care management fee* to cover physician and non-physician clinical and administrative staff work linked to the delivery of medical home services and paid as a per member per month fee.
3. A *performance or pay-for-performance fee* for evidence-based process, structure, or outcome measures and paid as a bonus, either on a per member per month basis or as a fee schedule increase.

Importantly, as of 2008, most medical home services can now be reported with CPT codes that reflect physician and non-physician work. However, payment policies by public and private payers to support these codes continue to be an ongoing challenge. Overall, the fee-for-service system is a necessary but not sufficient source of funding for the medical home. Other sources of payment will be needed to supplement the costs of implementing the medical home model and to ensure its financial and organizational success. Continued efforts to obtain fair payment for medical home services will be essential.

Recommendations

The American Academy of Pediatrics calls for a partnership among private and public payers, employers, clinicians, and families and patients to ensure that medical homes for

the pediatric population are implemented in a way that assures quality, financial sustainability, and equity among payers.

1. New payment and delivery reforms should be based on the medical home principles adopted jointly by the AAP, AAFP, AOA, and ACP.
2. All private and public payers should adopt a comprehensive set of payment reforms to support the family- and patient-centered medical home for children. The payment structure should encompass recognition of relevant CPT and HCPS codes, expanded care management responsibilities, new quality improvement activities, and up-front investments and support for infrastructure support.
3. Congress should enact legislation to direct the Secretary of the Department of Health and Human Services to implement and evaluate large-scale Medicaid medical home pilot projects for children. It should also support an all-payer pilot project of the medical home model of children.
4. The Centers for Medicare and Medicaid Services should update RBRVS to take into account the value of the complex and comprehensive nature of cognitive care and practice expenses associated with the medical home model of care, provide health information technology support, and create incentives for continuous quality improvement.

Conclusion

The AAP believes that the family- and patient-centered medical home will achieve marked improvements in access and continuity, family-centered and culturally competent care, integration and coordination of care, quality of care, family and patient satisfaction, and cost effectiveness. Implementing these payment reforms is critically important for pediatric practices to offer a comprehensive medical home for all children in the United States.

**Statement for the Record of
Patricia Volland, MSW, MBA
Senior Vice President and Director, Social Work Leadership Institute
New York Academy of Medicine
for the United States Senate Committee on Finance on
“Aligning Incentives: The Case for Delivery System Reform”
Hearing - 9/16/08**

Submitted by:

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Chairman Baucus, Senator Grassley, and Members of the Committee:

On behalf of the New York Academy of Medicine’s Social Work Leadership Institute (SWLI), I would like to commend you for your attention to the urgent need for health care reform and support for initiatives that realize savings and efficiency through care coordination. We applaud your examination of how the “medical home” model can improve health care delivery.

The purpose of my statement is:

- To urge you to be aware of and promote the importance of the “care team” in the medical home model to ensure that older adults receive care coordination services which are comprehensive;
- To emphasize the essential elements of any model of care coordination identified by our research; and
- To affirm the need for health care financing reform as noted by hearing witnesses.

As you know, the need for effective care coordination solutions is urgent. The costs of health care and long-term care are escalating. Overall health care spending is projected to increase 25% by 2030, largely due to the aging population.¹ In addition to the aging of the baby boom generation and increased longevity for Americans generally, a major factor in increased health care spending is improvements in health care: development of medical technology² and new drugs for the diagnosis, care and treatment of disease. Americans now live with multiple chronic conditions that in the past would have been fatal. Twenty percent of Medicare beneficiaries suffer from five or more chronic conditions and therefore account for almost 70%

¹ Healthy Aging: Preserving Function and Improving Quality of Life Among Older Americans (2/12/08)
<http://www.cdc.gov/nccdphp/publications/aag/aging.htm>.

² Bach, P. Paying Doctors to Ignore Patients. (July 24, 2008). *New York Times*.
<http://www.nytimes.com/2008/07/24/opinion/24bach.html?ex=1217563200&en=c252c0b0ee917294&ei=5070&emc=eta1>.

of all Medicare spending.³ Another factor in escalating costs is duplicative, unnecessary, or avoidable treatments and services. Appropriate care coordination can help reduce these costs.

The New York Academy of Medicine formed the Social Work Leadership Institute (SWLI) in 1999 to address the need for more and better-trained geriatric social workers to care for the burgeoning numbers of older Americans. Since that time, SWLI has developed a focus on promoting policy to ensure that older adults have access to care coordination services offered by skilled professionals. As part of this focus, SWLI conducted a national survey on the challenges faced by family caregivers of aging parents. SWLI has also conducted research on effective care coordination models at the state level.

Based on our research on comprehensive care coordination, SWLI recommends the following policy approaches to care coordination as a remedy for some of the challenges faced by the nation's health care system:

- 1) Require the use of an interdisciplinary team (including social workers) approach among the criteria to be used in the medical home demonstration;
- 2) Require comprehensive approaches (including social and long-term care services) in any care coordination models which receive federal support; and
- 3) Include non-medical care coordination in any bundled payment for coordinated care.

The Importance of the “Care Team” in the Medical Home Model

As was noted in Chairman Baucus' opening remarks and echoed by the witnesses, the fragmentation and complexity of our health care system are detrimental to the quality and efficiency of health care delivery. The nature of these challenges, the suitability of social work skills to meet these challenges, and the critical shortage of primary care physicians, particularly with geriatric training, noted by Dr. Berenson, accentuate the need to recognize and support the vital role that social workers can and do play in comprehensive care coordination.

Social workers are essential members of the interdisciplinary care coordination teams designed to serve the needs of older adults. They are skilled in guiding older adults in navigating the health care and social service systems, and connecting them with the health care services they need. Although the hearing witnesses did not refer specifically to social workers, each of them alluded to the important role of professionals, in addition to physicians, in care coordination. Dr. Steele noted the “health care teams” that work with Geisinger patients, including “dedicated nurses” that work as “proven health navigators.” Dr. Berenson recommended a “team-based approach” and changing payment to reward preventing problems such as avoidable readmissions. Dr. Miller recommended criteria for studying of medical homes, including use of “care management teams.” Best practices in state-level model programs prove that social workers are key members of these care coordination teams.

Several of the witnesses recommended that the initial focus of federally-funded care coordination be on patients with chronic illness who account for a large percentage of all Medicare spending. Comprehensive, interdisciplinary care coordination, which addresses coordinated health, social and long term care services, is essential to efficiently and cost-effectively meeting the needs of patients with chronic illness. In the effort to remain in the community, independent older individuals often need assistance with the activities of daily living

³Partnership for Solutions National Program Office (2004). *Chronic Conditions: Making the Case of Ongoing Care: September 2004 Update*. Baltimore, MD: Johns Hopkins University.

(ADLs) and instrumental activities of daily living (IADLs). They also need direct and indirect financial support, help maintaining a home, social services and support, transportation, financial planning, legal services and other forms of assistance. Although some social services are paid by Medicare in the contexts of hospice, discharge planning and brief periods of skilled nursing care in a facility or at home, they are not paid for in the primary care provider's office or any other setting which is not focused on an acute episode of health care.

As you know, the options or lack of options available to those in need of social and long term care services are mind-boggling to a person without professional training or expertise in navigating the system. Connecting a patient with adequate and appropriate support services can be the key to heading off an expensive hospital nursing home admission. The models of comprehensive care coordination SWLI has studied resulted in positive outcomes such as improved functional status among older adults, fewer hospital admissions and fewer nursing home stays. For example, the New Jersey Easy Access Single Entry (NJEASE) program has resulted in a 10 percent reduction in Medicaid-supported nursing home residents in the state. Comprehensive care coordination, including both health and long term care services and delivered by an interdisciplinary care team, is essential to improve care of the aging and lighten the load on family caregivers.

Essential Elements for a Comprehensive Approach to Care Coordination

The coordination of care must be carried out by many professionals in many ways and occur continuously between acute episodes. SWLI's research analyzes existing models of care coordination at the state level and reports results of interviews with care coordination professionals. The research identifies six essential elements of care coordination. All care coordination models should:

- *Be Assessment Driven:* services delivered or recommended should be based on a comprehensive, current assessment of the client's medical and psychosocial needs, including evaluation of their caregiver supports;
- *Develop a Comprehensive Care Plan:* assessment of the client and her/his supports should inform development of a plan which outlines coordination within and between health, mental health and social service systems;
- *Conduct Ongoing Evaluation:* Care coordination is an ongoing process, which requires a continuing relationship between the client and coordinator who follows the client through all settings;
- *Include a Qualified Care Coordinator as part of an interdisciplinary team;*
- *Be Client Centered:* Quality care coordination must always start by listening to and respecting clients' goals, desires, and preferences in decisions and choices about care;
- *Be Accessible:* To maximize the transformative potential of care coordination, care coordination should be available to clients regardless of insurance coverage.

Constraints on Care Coordination by Fee-For-Service Incentives in Health Care Financing

As several hearing witnesses noted, the current system of health care financing rewards acute care, hospital admissions, and sometimes unnecessary tests and treatments. The "current system of payment essentially segments the population by the provider whose services the patient is using at the moment—for example a nursing home population, a hospitalized

population, a home care population, or an office-based care population. The results are dehumanizing and produce discontinuous, wasteful and unreliable care.”⁴ Within this provider-based payment scheme, the reimbursement incentives are generally geared to specific, episodic patient services. What should be paid for is the coordination of continuous care, carried out by many professionals in many ways, that occurs around and sometimes including acute episodes. This coordination is required to effectively manage multiple chronic conditions and reduce reliance on acute interventions. As the April, 2008, IOM report “Retooling for an Aging America” notes:

One major problem is that brief visits are a poor way of managing chronic conditions even though care for chronic conditions is the most common reason that Medicare patients seek physician care. Furthermore, under the [fee-for-service] system more visits lead to higher physician and hospital revenues regardless of the quality or the efficacy of the services being delivered. Payment is directed to physicians and emphasizes treatment for inpatient care, which serves as a barrier to care coordination. This disincentive is significant since most Medicare patients seek care from multiple providers. Furthermore, such a payment mechanism provides no financial incentive for health care providers to deliver services that extend beyond the typical office visit, such as ongoing patient education to teach older adults how to better manage their chronic conditions between visits.⁵

Examples of the Value of Care Coordination

SWLI’s research has also identified programs that demonstrate the value, in terms of both quality and cost savings, of care coordination models that include the essential elements listed above. Examples of care coordination programs which show positive outcomes are:

(a) University of Colorado Health Sciences Center Care Transitions

Based at the University of Colorado Health Sciences Center, Eric Coleman, MD has developed a model to address the uncoordinated care problems, including medication errors, around the period of hospitalization—on admission, during hospital treatment, and discharge to home or to a nursing home. The model has four main elements: a patient-centered record (Personal Health Record) to facilitate productive interdisciplinary communication during the transition period; a structured checklist of critical activities to empower the patient, before discharge; an education session in the hospital for the patient and family with a transition coach/geriatric nurse practitioner; and follow-up visits by the transition coach in the new environment. A consistent theme in the program is empowerment of the patient or, as the case may be, informal caregiver who uses the personal Health Record, has a medication management system, schedules follow-up

⁴ Lynn, J. et. al. (2007). Using Population Segmentation to Provide Better Health Care for All: The ‘Bridges to Health’ Model. *The Milbank Quarterly* 85(2): 185-208.

⁵ Institute of Medicine (2008). *Retooling for an Aging America: Building the Health Care Workforce* (prepublication copy; uncorrected proofs): 3-17 Washington, DC: Institute of Medicine of the National Academy of Science. [hereinafter, *IOM Report*]

visits, and is aware of red flags that a condition may be worsening as well as possible side-effects of medications.⁶

(b) Rush University Medical Center Enhanced Discharge Planning Pilot Program (EDPP)

At Rush University Medical Center, EDPP was a recent demonstration project, a collaboration of the Case Management Department and Older Adult Programs. It focused on facilitating through telephone follow-up access to community services for high risk older adults being discharged to their homes. Within 2 days of discharge, social workers phoned patients and families to make sure that planned services were being provided, to assist communication between care providers and to make additional referrals as needed. The duration of the telephone intervention depended on specific patient needs.

Social workers made 3.8 calls, on average, to each EDPP participant; among those needing 2 or more calls, the mean intervention duration was 6.9 days. Close to 40% of participants were getting community based services, following through with discharge plans, and coping with care demands; of those who were not able to follow through, 50% cited a need for patient or caregiver support. Analysis of outcomes is pending.

(c) IMPACT (Improving Mood Promoting Access to Collaborative Treatment)

This care coordination model, developed at the University of Washington Department of Psychiatry and Behavioral Sciences, is intended for clinically depressed older adults. Its 'cornerstone' is collaboration between the individual's primary care provider and a depression care manager, who may be a nurse, social worker or psychologist. The two work together to develop and implement a treatment plan (medications and/or brief, evidence-based psychotherapy). The care manager measures depressive symptoms at the beginning of the intervention and the goal is 50% reduction in symptoms in 10-12 weeks. If this goal is not met, the designated team psychiatrist consults with the PCP and care manager on changes in treatment plan. When an individual has improved, a relapse prevention program is worked out between the patient and the care manager.⁷ The IMPACT model of depression care more than doubles the usual rate of recovery from depression; at 12 months, about half of the patients receiving IMPACT care reported at least a 50 percent reduction in depressive symptoms, compared with only 19 percent of those in other care.⁸

Thank you again for your consideration of these comments and recommendations. Please do not hesitate to call on me and the Academy as a resource as you continue to tackle the issue of health care reform.

⁶ Bodenheimer, T. (2008). Coordinating Care—A Perilous Journey Through the Health Care System. *NEJM* 358:10. See also the Care Transitions website, www.caretransitions.org, and another hospital transition care model developed by the Society of Hospital Medicine, http://www.hospitalmedicine.org/ResourceRoomRedesign/RR_CareTransitions/CT_Home.cfm.

⁷ <http://impact-uw.org/about/key.html>.

⁸ <http://impact-uw.org/about/research.html>.



**Statement for the Record
Zimmer Holdings, Inc.**

**United States Senate Committee on Finance
Hearing on "Aligning Incentives: The Case for Delivery System Reform"**

September 16, 2008

Zimmer Holdings, Inc. ("Zimmer") thanks the Committee for holding this important hearing on possible ways to reform the health care delivery system. As a leading manufacturer of medical technologies that improve quality of care, help reduce cost and increase value, we support efforts to explore ways to improve the efficiency of the health care system.

Founded in 1927, Zimmer is a global leader in the design, development, manufacture and marketing of joint reconstruction and spinal implants, trauma and related orthopaedic surgical products. These products help restore joint-related function lost because of disease or trauma. Zimmer is continually achieving technological advancements that make a difference in patients' lives for each of the medical markets we serve. A key interest is ensuring that patients continue to receive appropriate access to high quality, effective healthcare solutions including new and innovative orthopaedic technologies that improve quality of life.

Comments on Disclosure of Industry Financial Arrangements with Physicians

Zimmer joins the Advanced Medical Technology Association (AdvaMed) and other stakeholders in supporting the appropriate disclosure of relationships between medical technology companies and physicians. Zimmer has expressed this position publicly in the recent past, including through formal testimony to the Senate Special Committee on Aging this past February, and is pleased to hear that this issue will be addressed in the Committee's hearing today.

Zimmer has, in fact, already undertaken efforts at transparency of financial arrangements between the company and physicians, including those who serve as consultants to develop or train on the safe and effective use of Zimmer's products. These efforts include, but are not limited to, public disclosure of our financial arrangements with physicians, a thorough review of existing consulting arrangements with physicians, a ban on all gifts to and entertainment of physicians, and the use of independent third parties when making donations or funding medical fellowships, residencies and educational programs.

These efforts represent the underpinnings of a robust, corporate compliance program that align the company's collaboration with physicians strictly with necessity and will aggressively reduce the risk of actual, potential or perceived conflicts of interest that may result from such collaboration. Moreover, Zimmer's compliance program gives patients what they deserve: Full disclosure and transparency of their physicians' financial arrangements with industry.

Zimmer believes its corporate compliance program allows the company to continue to deliver industry-leading products of the highest quality backed by business practices that inspire confidence and trust. Ultimately, the company seeks to ensure that patients benefit from innovations focused on their needs and that everyone with a stake in quality health care can trust that physicians choose products based on what they believe is best

for patients. For this reason, Zimmer will continue to guard against even the appearance of impropriety in any of its collaborations with physicians and other health care providers.

Importance of Continued Collaboration between Industry and Physicians

The medical device industry has transformed patients' lives through a rare combination of clinical knowledge and engineering, bringing the insights of highly-skilled physicians who work directly with patients together with the technical knowledge of engineers who design and build safe and effective devices. Collaboration with physicians will always be important to clinically meaningful innovation in medical technology.

This collaboration has been and must continue to be the heart of a product development model that identifies and addresses profound unmet patient needs. Because physician skill level is a key driver of successful patient outcomes, physician training on the safe and effective use of today's complex products and procedures has also been central to the significant benefit patients have experienced with medical devices. We appreciate that the federal government recognizes the importance of collaboration in the medical device industry and is focusing its efforts not on eliminating collaboration, but rather on determining models for appropriate and necessary collaboration.

Comments on Existing Legislation

Zimmer supports legislative efforts at the federal level to increase the level of transparency of industry financial arrangements with physicians. The Physician Payments Sunshine Act (S. 2029) is legislation that Zimmer continues to support because it is particularly strong in a number of important areas, including the following:

- **Federal preemption:** S. 2029 expressly preempts state laws requiring the tracking and public reporting of industry's financial relationships with physicians. The prospect of multiple reporting systems and formats will confuse the very patients that the legislation is attempting to aid. A single reporting system is of paramount importance.
- **No sales revenue reporting exemptions:** S. 2029 pertains to all companies regardless of sales revenue. This is important because patients deserve to have full disclosure and transparency of the financial arrangements between all companies and physicians, and because small, medium and large device companies are all involved in collaborative arrangements with physicians.
- **Physician-owned companies:** The legislation, rightly, requires that physician-owned medical device companies, distributors or group purchasing organizations comply with the requirements of the legislation. Zimmer believes that a patient has a right to know when his or her physician intends to use a medical device that

is made or distributed by a company in which that physician stands to profit as a result of his or her equity ownership stake in that company.

Conclusion

Again, Zimmer thanks the Committee for holding this hearing today on reforming the health care delivery system. As the Committee considers legislation, particularly in the area of appropriate disclosure of financial arrangements between industry and physicians, Zimmer respectfully urges the Committee to consider these comments. It is important that any legislative activity in this area address any real, potential or perceived conflict of interest that may result from such arrangements while also protecting the important collaborations between industry and physicians, which yield technological advances for patients. Zimmer looks forward to working with the Committee on this important issue.

