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**WHAT IS HEALTH CARE QUALITY
AND WHO DECIDES?**

HEARING
BEFORE THE
SUBCOMMITTEE ON HEALTH CARE
OF THE
COMMITTEE ON FINANCE
UNITED STATES SENATE
ONE HUNDRED ELEVENTH CONGRESS
FIRST SESSION

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MARCH 18, 2009
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WHAT IS HEALTH CARE QUALITY AND WHO DECIDES?

WEDNESDAY, MARCH 18, 2009

U.S. SENATE,
SUBCOMMITTEE ON HEALTH CARE,
COMMITTEE ON FINANCE,
Washington, DC.

The hearing was convened, pursuant to notice, at 3:35 p.m., in room SD-215, Dirksen Senate Office Building, Hon. John D. Rockefeller IV (chairman of the subcommittee) presiding.

Present: Senators Nelson, Carper, and Hatch.

Also present: Democratic Staff: Jocelyn Moore, Legislative Assistant, Health; and Kate Gross, Legislative Assistant, Health Reform. Republican Staff: Patricia deLoatche, Health Policy Director.

OPENING STATEMENT OF HON. JOHN D. ROCKEFELLER IV, A U.S. SENATOR FROM WEST VIRGINIA, CHAIRMAN, SUB- COMMITTEE ON HEALTH, COMMITTEE ON FINANCE

Senator ROCKEFELLER. All I can say is that it was not my fault that we had about 4½ hours of someone who would cast their 12,000th vote, people giving speeches. I totally apologize. I am totally embarrassed. I probably should resign from the Senate, but I am not going to because I love it.

So I am going to speed this up. Somebody had to catch a plane, or is it already gone? What time is it? Four o'clock? Lots of time. Senator Nelson, welcome. We are all thrilled to be here. I have been wanting to be here now for about an hour and 5 minutes.

Senator Hatch, as I understand it, is not going to be here. He is on his way? All right. Good.

We want to thank you all for your patience. Have you been fed brownies, Coca-Cola, various things?

We have very experienced, knowledgeable witnesses with us today. I am going to ask that my full statement be put in the record. Bill Nelson did not want to hear the whole thing.

[The prepared statement of Senator Rockefeller appears in the appendix.]

Senator ROCKEFELLER. First, we have Dr. Carolyn Clancy, who is Director of the Agency for Healthcare Research and Quality, or AHRQ. I love this. When you add up all the private and the public quality measurement things, I really do not want to get into that. I do not know how they work together. My guess is, they do not. Thank you for being here, Dr. Clancy. Where is Dr. Clancy? Over there.

Second, Dr. Brent James, joining us from Senator Hatch's home State, Salt Lake City, UT, to be exact. Dr. James is chief quality officer and executive director of the Institute for Healthcare Delivery Research at Intermountain Healthcare. Welcome, Dr. James. Thank you for the following 20 minutes.

Last, but not least, we have Dr. Marjorie Kanof. Dr. Kanof is the Managing Director of Health Care at the Government Accountability Office. Thank you for your being here.

You have statements to make, and we have questions to ask. I mean, lots of good questions. This is really good. I am just angry that we had four totally useless votes on the floor of the Senate.

Dr. James has to leave. You should go first.

Dr. JAMES. I will.

STATEMENT OF BRENT C. JAMES, M.D., MStat, CHIEF QUALITY OFFICER AND EXECUTIVE DIRECTOR, INSTITUTE FOR HEALTHCARE DELIVERY RESEARCH, INTERMOUNTAIN HEALTHCARE, SALT LAKE CITY, UT

Dr. JAMES. Well, Mr. Chairman, thanks for the opportunity to share some of the background science, as well as applied experience around the measurement and management of quality and health care delivery.

I am a member of the National Academy of Sciences Institute of Medicine, where I have served on a number of committees addressing health care quality issues. I hold medical informatics and quality-related faculty appointments at a number of universities. But most important, as you mentioned, I serve as the chief quality officer at Intermountain Healthcare, where we have been trying to apply these principles for the last 20 years, at the front line, where the rubber hits the road.

Intermountain is a not-for-profit system of 23 hospitals, more than 100 outpatient clinics, and a health insurance plan. We supply more than half of all care delivered in the State of Utah. We supply tertiary-level services to 7 surrounding States. The short version of our mission statement is—we actually use this internally—the best medical result at the lowest necessary cost.

We have been identified by external evaluators as one of the highest quality, most efficient care delivery organizations in the United States. Frankly, we stack up well against other countries as a system. For example, the Dartmouth Atlas recently asserted that, if the rest of the country delivered the same care that is found at Intermountain, national Medicare costs would fall by more than 30 percent, and clinical outcomes would significantly improve.

We entered on this course in the late 1980s when we encountered the work of Dr. W. Edwards Deming. Dr. Deming called it quality improvement. We were one of the first adopters of clinical quality improvement, though, in the United States and in the world. We had many, many early successes around single projects.

In 1996, though, we launched a major internal strategic initiative to make clinical quality our core business strategy. I believe we were probably the first in the world to try that based off of those industrial models. It was based around Dr. Deming's key teaching. We were able to prove that in most, but not all, circumstances, improvements in quality of clinical outcomes reduced the cost of care

delivery, very significantly, as it turns out. We validated that at a project level, but we had not been able to deploy it broadly. The strategic initiative was to make it core business so we could deploy it broadly.

Now, the center of that strategic transformation was measurement systems. Again, we relied on Deming's model. A careful analysis showed that about 104 key clinical work processes, inpatient and outpatient settings, drawn from more than 1,400—so less than 10 percent—accounted for just under 95 percent of all the care we delivered, concentrated massively. We, therefore, attacked those problems in size order.

Now, in case people miss it, there is a recommendation in that statement: that you go after the big guys first, biggest to smallest, so you achieve the most benefit for the largest number of patients in the least amount of time. For each clinical topic, we applied a rigorous methodology first laid out by the National Quality Forum Strategic Framework Board—truth in advertising: I served on that group—to help generate the science behind it.

It supplied a scientific discipline, a method, for figuring out what measures you would use as opposed to a political consensus approach, which is, frankly, what we have used in most other areas within the country. That is very often based upon available data as opposed to the actual data you need.

As we applied the methodology in size order, we discovered a very interesting fact. Our existing data systems, which were state-of-the-art by any measure, were missing about one-third to one-half of the critical data elements you need to actually manage clinical care and measure its impact and supply accountability at higher levels within the system.

Those existing data systems I am talking about are the same ones that we rely upon as a country. But now today, in essentially any care delivery organization, they are the foundation for most of the measures that we are using across the country at a national level.

Now, we use that data system as we created it to generate reports that compared providers—physicians, care delivery groups, hospitals, regions—within our system. We compared people to their peers, and we found outliers.

However, when we tracked the outlier points back to their root causes, more than half the time the source of those unanticipated defects was in the data system, not in the clinical practice. It turns out that this is a well-established principle and quality theory. It is called “gauge” theory, that the measurement system itself is the source of variability, and it recommends that you build feedback loops in your data systems. So you run them, identify outliers, track them down.

Over a period of time, we use it to clean up the data systems. Unfortunately, that very well-established principle from other industries is not being widely applied in health care today. We assume at some level that the data systems are sufficient and adequate, when in fact they are not.

Well, having built those systems, I can report today that about 80 percent of all the care delivered within Intermountain is documented on our tuned-up measurement system as a complete set of

clinical service, cost process, and outcome measures. We have used that system to drive very significant improvements in clinical outcomes on a broad scale.

I wish I had the time. I have over 100 beautiful examples of fewer deaths.

Senator ROCKEFELLER. Give one.

Dr. JAMES. Pardon me?

Senator ROCKEFELLER. Give one.

Dr. JAMES. One of the more recent ones. We reduced the mortality rate after AMI by about half—acute myocardial infarction, heart attacks—by better delivery and rapid intervention for someone with a blocked artery in the heart. We got better sugar controls in surgery. We were one of the first groups to drop mortality rates in open heart surgery by about half with better sugar control.

Senator ROCKEFELLER. I would say that is pretty dramatic.

Dr. JAMES. So, it is lives saved. One of the ways, as we said, is we measure our successes in lives saved. We think that we have taken about \$100 million out of the cost of operations at Intermountain, and, believe it or not, that is a small down payment on the potential. We just submitted a major article in the research literature.

We estimate that over 50 percent of all health expenditures in health care today, rigorous method, is technically waste. If you use a quality model, it is, in theory, at least, extractable. That \$100 million, for us, is just a down payment on applying those methods, pulling that money back out for more useful purposes.

Now, you need to know that our experience is not unique. Other care delivery groups are driving similar improvements on a broad scale. It does require a team-based approach, a certain amount of intellectual, organizational, and financial capitalization. As a result, it is a phenomenon of organized care. It arises from accountable integrated care delivery systems and group practices, not from solo practice. There is a message in there, too.

My main purpose today, though, is to point out the design principles of quality measurement: they drive success, they are very well understood, and it seems to me they ought to be the foundation for how we proceed with national measurement of quality as well. Those principles are very well understood in other industries. They are just not widely applied in health care, a big opportunity. Frankly, most of our national measurement efforts have missed them along the way.

For those of us working at the front line where the rubber hits the road, we greatly need better information about best care delivery processes. The Agency for Health Care Research and Quality is the primary Federal resource assigned to that task. Carolyn and her people have provided absolutely critical leadership. We need to do a lot more, frankly.

As part of that assignment, we need to move quality measurement much closer to the front line of care. A principle: if I build data systems to manage care at the bedside, I can roll up data and get the accountability measures we need for a country very accurately. When I impose them top-down, the opposite is not true. Nearly always, those measures are not sufficient or properly defined to use for bedside care management, and they actively com-

pete with front-line resources. We now have some good documented examples where those methods have damaged clinical quality at the front line. I see that at Intermountain on a fairly regular basis.

The idea that we design from the bottom up, build a system to improve care, and from that get the accountability and transparency we need as a country—we have the infrastructure. People seated at this table understand how to advance that, but it seems to me to be an opportunity not to be missed as we talk about health care reform in this country.

With that, Mr. Chairman, thank you. Senator Hatch, thanks for inviting me.

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

Senator ROCKEFELLER. And Senator Hatch, you should say something.

Senator HATCH. Well, I would be very happy to. I have to say, I know Dr. James has to catch a plane. But let me just say, I have more confidence in him than any other person in this country, and really worldwide, in being able to handle the matters that he handles every day for Intermountain Healthcare, which is respected worldwide. I just felt like it was very important for us to build a record. You have never disappointed me in being able to talk about what we need to do in these areas, so I am very appreciative of you coming. Hopefully we can get everybody to listen to you.

Senator ROCKEFELLER. What I would like to do, with the permission of the other two witnesses, is to get a few questions to Dr. James. That seems fair, don't you think?

Dr. CLANCY. Absolutely. We are fine.

Senator ROCKEFELLER. It is the good thing to do.

It is absolutely extraordinary to me, if you go through all of the public and then the private quality measurement groups—I mean, there have to be 15 of them. The Institute of Medicine had a particular definition of quality which I like a lot. They said, “The degree to which health services for individuals and populations increase the likelihood of a desired health outcome and are consistent with current professional knowledge.” I like that. Anyway, there are endless numbers of people who work on this. Some were invented by Congress, some invented themselves, some are private. They are all trying to do their best work.

So I guess my first question to you, Dr. James, is, how in heaven's name—and you mentioned that, if you want to start from the top down, the first thing that came into my head was Medicare. You do Medicare, and then almost everybody else is bound to follow at some point.

How do you take all these Federal agencies, Agency for Health Research, the AHRQ, the CDC, CMS, FDA, HRSA, and the VA, which is a huge player in all of this—how do you take these various entities and bring any sense of coordination to them, or is that just something that a government bureaucrat would want to do, but actually is not necessary? I think it is necessary.

Dr. JAMES. It falls into two categories. Some of them, like AHRQ, mostly supply critical information to us about best care. That is their role. They do it very, very well. Frankly, they need to do a lot more, but it is hugely useful when they do. CDC, largely the same. There is another group of entities that imposes measures

upon it. The last count that I did, there are over 1,600 from a list of about 30 different—I am including States—agencies. It is a fairly large effort just to meet the reporting needs. I am a little bit jaded about this, but, so far as I can tell, it produces almost no result. Believe it or not, I regard myself—one of my roles within Inter-mountain is to somehow administratively stand between that and my front-line teams so that they can get to the business of improving health care. Do you see what I mean? There is a growing ground-swell, though, of people who are generating—I think of it as a bottom-up change. In fact, real health reform is happening right now in the hospitals and clinics across this country at a pretty good clip.

The medical profession, the nursing profession, have decided to move to a team-based model of care. It is a sea change. It is the first big change we have had like this in the professions in 100 years, and it is profound, way past the tipping point, good evidence of it. It ties very heavily to our electronic medical records. I believe that this activity should support that effort, or interdigitate with it closely.

Senator ROCKEFELLER. All right. You mentioned—and then I will turn it to Senator Hatch and then Senator Carper—you did not use the word “rogue data,” but you implied, sort of, data outside—

Dr. JAMES. Yes.

Senator ROCKEFELLER. Which messes up what the data really is. What did you mean by that?

Dr. JAMES. The best illustration I have is, some measurement systems happen after the fact. So we are investing a substantial amount of money in reviewing charts after discharge to produce measures for consumption by someone outside of our system. It is not at all clear how it is used. It is mostly pro forma, it is required, so you produce the data.

The data that I generate, you imbed into the actual processes of care. When you design for process management, it is the sort of information that a physician or nurse has to have to deliver best care to this individual patient right this minute. Because you imbed it, it does not feel like a data burden. It is stuff you are using anyway. It's just that you organize it, you automate it, you standardize it to some degree. It is the lifeblood.

Senator ROCKEFELLER. So you are saying, if you try to spread data, based upon an individual case that you are working on, across too large a population, it is going to get skewed?

Dr. JAMES. Well, it is not so much that as where it is collected. If I collect it at the bedside, I get accurate data. I get very timely data. I can roll it up into those national reports. Its direct application is to manage and improve care at the bedside. The trouble is, when they mandate them from top down, it does not match. It does not match what I need to build into that front-line work process. You see what I mean?

Senator ROCKEFELLER. I do. Well, not entirely. But you have to catch your plane, and Senator Hatch and Senator Carper have questions for you.

Senator HATCH. Well, let me just ask you this regarding quality. One point I always raise about Utah is that our State has some of the lowest reimbursement rates in the country for health care, and

yet we have some of the best health care outcomes. Now, can you take a few minutes to discuss Utah's experience, and do you believe that Utah's experience could be replicated on a national level? If so, how do you recommend that we go about achieving it?

Dr. JAMES. Senator Hatch, it is not just that it can be replicated, one level of it is being replicated. We have a number of close partners. It is organized care delivery, it is Mayo Clinic, it is Dartmouth, it is Geisinger Clinic, it is Kaiser, who are a group who are applying these methods on an increasingly broad scale and showing similar results, not just in Utah but across the United States. The principle, I think, is demonstrated at this point and moving ahead fairly vigorously, frankly. It rationalizes electronic medical records in ways we have not seen before.

One of the key principles, Deming's core idea, is that, as you improve quality, it should cause your cost of operations to drop. I think we validated that. It does not happen every time, but it happens a lot. Again, our best estimate is that the size of the opportunity is over 50 percent of the total spent against a \$2.4-trillion budget, frankly, a real up-side to that whole thing. The theory is complex, but not that bad. You see this burgeoning movement that is making it happen.

What I would ask is that we do not suppress that movement. That is where the real reform will come from, right there. It is happening. There are ways that you could really enhance it, by the way. For example, to align payment so that you actually—currently when we make a major improvement, and I can show you many examples, usually we produce windfall savings for a purchaser and are very often financially punished for delivering better care at a lower cost. That would be about three quarters of these projects that fall into that category. We need to fix that so that I align financial incentives to my appropriate professional incentives for best patient care.

Senator HATCH. That is really good. I would like to just move to waste in our health care system. I understand that you believe that over 50 percent of health care expenditures are wasteful. Could you expand on that a little bit?

Dr. JAMES. We had a nice little grant from AHRQ where we tried to build models for using quality tools to estimate total waste in care delivery. I am actually quite proud of the model. I think it is the best that has been developed to date. We could not get estimates in every category, so this is quite conservative.

We first examined care that never should have been delivered, where the risks to the patient outweighed any potential benefit. There is a substantial amount of that in health care today. Perhaps the best group in estimating that is the Dartmouth group. We took a middle level of where you do process management, we took a lower level where we directly measured waste of front-line staff.

We found about 14 percent of all care at that top layer should never have been delivered—over-use. We thought that we should act to eliminate that. The middle layer, we could not come up with a well-organized system for. We have saved it for later. That is why this estimate is conservative. The lower level in the controlled chaos that is care delivery, we found between 20 and 70 percent waste.

At an individual worker level, we think it averaged about 35 percent across the entire care delivery system. We measured it at three major institutions. It would have the net impact, if we could somehow do this for nurses, of roughly increasing nurse staffing by 50 percent without hiring a single additional individual.

When you synthesize those together, that is the beauty of the model, the actual number that we plan to publish is 44 percent. The real numbers suggested 55, but we were being academically conservative. The nice thing about using quality models to do that, Senator Hatch, is it gives you the direct tools to attack it. That is different from other waste models that have been created in the past.

Senator HATCH. That is great. Just one last question. Intermountain has had a series of notable successes in documenting better patient outcomes associated with lower health care delivery costs. Could you tell us what role CMS and JCAHO outcome measures played in that work?

Dr. JAMES. The Joint Commission on Accreditation of Healthcare Organizations is changing its role under the leadership of Dr. Mark Chassin. Dr. Chassin has a new vision that I think is extremely encouraging. He came out of a similar role to mine, and he understands it intimately. Frankly, the current CMS measures have been a major impediment for me. The reason is, they were incomplete. They were missing major measures. You have to understand, for at least three of their measures, much of the research upon which the CMS measures were built came out of our groups—we are a major contributor to it—but they had incomplete data sets and they got the definitions wrong in terms of how you define it at the front line.

I found myself in the difficult position of either downgrading the measures, and I was not willing to do that because it would have damaged our ability to actually deliver high-quality care, or building on an additional expense after the fact to pull those measures out of charts. That is what we did, but it required resources. We saw that demand for resources directly compete against our improvement work back at the bedside. I personally believed that it was a matter of CMS not being careful enough about how they developed the measures.

As Dr. Chassin has so clearly shown, if you develop them correctly, then this discordance need not be. My challenge for CMS was: do it right. Do it so that we can actually manage at the front line and build from that bottom-up, as opposed to a top-down, measurement system. It is not that it is not a good idea. It is. It is just, the competence with which we put the system together.

Senator HATCH. Well, I appreciate it.

Senator ROCKEFELLER. Dr. James, I have a great answer for you for your problem, but that would mean I would have to interrupt Senator Carper, and I cannot do that, and you have to leave in 4 minutes. [Laughter.]

Senator CARPER. Dr. James, welcome. And Dr. Kanof.

Dr. Clancy, great to see you. All of your friends and admirers in Delaware send their best, and our thanks for the great support that you and your colleagues have provided for the Delaware Health Information Network. We are spending up our utility,

thanks in no small part to your help. We have connected a lot of doctors' offices, our hospitals, labs, and so forth.

We are incentivizing the creation of electronic health records in our State, and we think we are among the leading States in this regard, and we are hopeful to be able to harness the money in the stimulus package, health information technology money. But thank you. Were it not for your strong support and that of Tommy Thompson and Mike Leavitt, we would not be where we are. So I just wanted to start by saying a real special thank you.

Dr. James, I was talking recently with a fellow who runs a big utility company out in California, PG&E. They used to make money almost exclusively there by selling more electricity, more natural gas. That was where most utilities made money. If you want to make more money, sell more natural gas, more electricity.

Then they figured out—at least in California now, and then they started doing it in other places—that it is possible to be a utility and to make more money not by selling more gas and electricity, but actually by selling less and empowering your customers to use less. We sort of changed the economic incentives for them and now they are doing wonderful things to help capture that low-hanging fruit to reduce consumption of gas and electricity in California and other places.

It seems to me, with respect to health care, especially with a fee-for-service approach, we pretty much do what we used to do with utilities. We say, in order to make more money, you have to treat more patients, maybe for shorter periods of time. You have to perform more procedures, more tests, and so forth. We have to find a way to incentivize a different kind of behavior.

I think there is actually a pretty good analogy between the utility industry and the provision of health care. Take my example and sort of carry on, if you will, to a more logical conclusion with your experience in Utah.

Dr. JAMES. I could not agree with you more. For example, we just ran a project initially at American Fork Hospital, a little level-5 community hospital with a big birthing service. They get what are technically term infants, 33 weeks gestational age or older, that develop something called Respiratory Distress Syndrome. The way we have traditionally managed them is, you stick them on a mechanical ventilator in an ICU at great expense. It is what you might call "tough love." It is not that easy on the kids, frankly.

We had a team who came up with a bright idea. It is called Nasal Continuous Positive Airway Pressure, or Nasal CPAP. You know those machines we use for sleep apnea that you plug into someone's nose? It turns out that, if you use one in a neonate, you can keep their lungs inflated, which is the key factor: a little oxygen, something called surfactant.

We went from 78 percent of those infants being transferred to the ICU to 18 percent being transferred. They were all going to live anyway, but we still saw it as a major improvement in care. Well, I tracked the exact financials. The income to the hospital went up by about \$550,000 to our little American Fork Hospital. The trouble is, the income to our newborn ICU—we own that, too—fell by about \$950,000 with this shift.

We came out, when you added it all up, about \$330,000 in the red. It was reducing the volume of care. The way to say it, you realize, I get paid to harm my patients. You understand that? In the current system, I am actively financially encouraged to harm my patients, and I am financially penalized when I stop doing harm by figuring out a clever way.

Well, Intermountain, that mission statement I talked about, we really mean it. We are deploying it system-wide. We know that we are taking a tens of millions of dollars' hit. Frankly, a lot of this is commercial insurance, not much labor and delivery and Medicare, needless to say. It means that we are out with our commercial purchasers, saying, we saved you. We lost \$330,000, but our billings to you dropped by about \$1 million, just American Fork Hospital, just the one. We need part of that money. Make us whole, help us with the project, we all come out ahead. I need somebody at CMS who will negotiate the same way, who will see it in the same way.

Senator CARPER. I see.

Senator ROCKEFELLER. I am going to have a much better solution for you, but you are going to be on your way to the airport. [Laughter.]

Dr. JAMES. Promises, promises.

Senator ROCKEFELLER. But you really should go. I mean, I do not know what time your plane is, but they said you had to leave at 4. It is after 4.

Dr. JAMES. 5:10.

Senator ROCKEFELLER. 5:10?

Dr. JAMES. Yes.

Senator ROCKEFELLER. This is a bad traffic time.

Dr. JAMES. Yes, I know. So, can I say thank you very much?

Senator ROCKEFELLER. Yes, you can. And will somebody make sure that he gets out all right? All right.

Now, going back to the regular order. That would be Dr. Carolyn Clancy. She has already been praised, so I will not bother to do that again.

Dr. CLANCY. Thank you.

Senator ROCKEFELLER. Please. We would welcome your testimony.

STATEMENT OF CAROLYN CLANCY, M.D., DIRECTOR, AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, DEPARTMENT OF HEALTH AND HUMAN SERVICES, ROCKVILLE, MD

Dr. CLANCY. Mr. Chairman, thanks for the opportunity to address the subcommittee on the very timely and important issue of health care quality. I have asked for my full statement to be part of the record.

Senator ROCKEFELLER. Absolutely.

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

Dr. CLANCY. As one of 12 independent agencies in HHS, the mission of the Agency for Healthcare Research and Quality, or AHRQ, is to improve the quality, safety, efficiency, and effectiveness of health care for all Americans. So the title of this hearing is, "What is Quality?" I love the IOM definition too, but the sort of common-

sense definition I use all the time is, it is the right care, for the right patient, at the right time, every time.

Unfortunately for our health care system right now, that is a stretch goal. This is borne out and shown every year in data from AHRQ's annual National Healthcare Quality Report. What we have seen is that the quality of health care overall has improved by 1.5 percent per year.

Now, in some areas—and I disagree with Dr. James a little bit here—where public reporting has been required, or certainly encouraged by CMS, we have seen some bigger improvements. So care overall for patients with heart attacks has improved about 15 percent, but in most cases the pace is pretty glacial.

We have also seen some progress in reducing disparities in care—for example, reduced disparities in childhood vaccinations—but we also have a Disparities Report that is a companion to the Quality Report, and it shows that most disparities in health care quality and access are either staying the same or actually getting worse.

So one of your Senate colleagues asked me once why the hospitals in his State were not doing better, which I thought was a very basic and pretty profound question. So what I told him at the time, I thought, was that they do not know how, nobody is making them, and the incentives are not steep enough to make a difference.

So I think it is fair to say, building on what Senator Carper said a moment ago, that we are still in an environment where many CEOs lie awake at night worrying about their financial bottom line, but not the quality bottom line. For them, there is not yet an established link between the two. We very much need to establish and reinforce that link so that quality becomes the guiding principle for all of health care.

Now, I do think there is good news. There are many, many organizations, but they are starting to work together much more effectively, so we are not starting from scratch. The foundation we have now is strong public/private partnerships and collaboration. It includes an increasing amount of good information on quality that consumers, clinicians, and others can use to make informed health care decisions. This includes information on individuals' experiences as they navigate the health care system.

CMS Hospital Compare is a good example. It helps people pick a hospital based on some information about clinical performance, as well as patient perspectives on their experience. That comes out of an AHRQ survey.

We also have seen very recently a huge surge in enthusiasm from physicians, nurses, hospitals, and others, trying to improve health care quality, and, tapping into that, I think the potential is almost limitless. They are coming together, both within organizations and within communities. AHRQ has helped set up a number of community quality collaboratives in a whole variety of States, including Massachusetts, Oregon, New York, Utah, Maine, Kansas, and Nevada. They have not gotten to West Virginia yet, but we are open for their application.

Now, the less good news in all of this is that we do not always do what we know. We could greatly improve quality by imple-

menting the research findings, tools, and best practices that we already know. So I think they actually need to shift from asking, what is quality, to asking the question, how do we make it better, how do we improve quality? I do not want to imply that people are not doing anything.

In fact, doctors, nurses, hospitals, et cetera are working very, very hard. But we still have a system that makes implementing that not so easy. Brent James and Intermountain are way, way ahead of the curve and we can learn a lot from them, but most other organizations are not quite so far along. Our infrastructure is pretty fragile. The processes are laborious and often not as effective as they should be. In short, we do not make it easy to do the right thing.

So I am really pleased that the American Recovery and Reinvestment Act includes significant investments in health IT, comparative effectiveness research, and prevention, all of which have incredible potential to improve the infrastructure, capacity, and quality of our health care system. The Recovery Act will provide a huge boost for our efforts because it will help us expand that foundation and our knowledge base.

What I would like to do is just close on what I think are three near-term high opportunities for improving quality of care where we can, and should, see dramatic improvements. One is improving care for people with chronic illnesses. Because of all our successes in biomedical science, we now have increased—dramatically increased—life expectancy because we have effective treatment for diseases that were previously lethal, and we have seen a corresponding increase in the proportion of Americans with chronic illnesses.

If you look at the 20 percent of people who incur about 72 percent of the expenditures, addressing their needs, most of those people have multiple chronic illnesses. The quality reporting you have heard about has been very effective at publicizing and motivating improvements in those processes that are under the direct control of a clinician or health care organization, so it reminds me to order the tests to check diabetes, cardiac risk factors, and so forth.

Where we have not seen improvements is in the outcomes. Part of that is because the real improvement takes place after the patient leaves the office, so we have to figure out how to make more effective partnerships between clinical care and community resources and partners.

The second big opportunity is improving care for America's children. As you know, the recent reauthorization of CHIP provides a terrific high-impact opportunity. We think the provisions and resources in that act for quality are very important because many low-income children move frequently between Medicaid, CHIP, private coverage, and then no coverage, and because a focus on children has not been a part of all these organizations you have been reading about. So we are really excited about working closely with CMS, States, and all stakeholders on these initiatives to assure that all children receive the highest possible quality care.

The third issue is reducing disparities. Every report on quality has two major findings; it does not matter what the condition or where it was done. The first finding is a substantial gap between

best possible care and actual care. The second finding is a larger gap for people who are members of racial or ethnic minority groups, who are poor, who have limited education, or who live in remote or rural areas.

The tools and data needed to improve quality can be used simultaneously to close those gaps. In some instances, a focused approach to quality improvement overall has closed the gaps. In other areas, we are going to need to figure out how to close those gaps more effectively for those population subgroups. But I think the bottom line is, in looking at improvements in health care, we can be equal and excellent, too.

So we have begun to make progress. We know a lot of what to do, and we now have to work together to put it into action. Thank you.

Senator ROCKEFELLER. Thank you. Right on time.

Dr. Kanof?

STATEMENT OF MARJORIE KANOF, M.D., MPH, MANAGING DIRECTOR, HEALTH CARE, GOVERNMENT ACCOUNTABILITY OFFICE, WASHINGTON, DC

Dr. KANOF. Mr. Chairman, Mr. Hatch, I am pleased to be here today, too, as you discuss health care quality. I actually was going to begin my opening remarks with the IOM definition, so I will take it one step further.

Senator ROCKEFELLER. But you agree that hers was better?

Dr. KANOF. I like hers. I think, actually, Dr. Clancy's is the right one when you are sitting and taking care of a patient, so maybe it could be the new Hippocratic Oath.

But the IOM also identified six dimensions of quality that I think are also important for us to focus on. They include safe, effective, patient-centered, timely, efficient, and equitable health care.

My remarks today are actually going to focus on healthcare-associated infections, HAIs, which I think illustrate all of these dimensions. According to the CDC, HAIs are infections that patients acquire while receiving treatment for other conditions, and are estimated to be one of the top 10 causes of death in the United States. The most common HAIs are urinary tract infections, surgical site infections, ventilator-associated pneumonias, and bloodstream infections.

Our March 2008 report found that the Federal Government had undertaken a number of activities to address the problems of HAIs. My comments today are going to focus on three of these activities.

We reported that CDC issued 13 guidelines for hospitals on infection control and prevention that contained approximately 1,200 recommended practices; 500 of these were strongly recommended. Although most of the practices were sorted on the basis of the strength of the scientific evidence, other factors that actually AHRQ had noted, such as cost or organizational obstacles, were not taken into account. In addition, activities across HHS to promote implementation of these practices were not guided by a department-level prioritization.

We also found that CMS required infection control standards for hospitals that described the fundamental components of an infection control program, but generally did not require hospitals to

implement the recommended practices and CDC guidelines, such as practices for hand-washing. We did acknowledge that it was difficult to require recommended practices of over 500 without prioritization.

Lastly, we reported that HHS programs have databases for HAIs, but they are very limited in the scope of the information collected, and more importantly, there is lack of integration across the programs' databases, which was impeding combining the information to better understand the extent of HAIs and to measure progress in reducing HAIs. For example, there is no linkage between one database on surgical processes which would tell you when antibiotics were given and another on surgical infection rates, even though they cover some of the same patients.

We concluded that HHS leadership was not effectively leveraging their resources to reduce HAIs, and that no one within the Office of the Secretary was responsible for coordinating infection control activities across HHS.

We made two recommendations that, if implemented, could help HHS be more effective in reducing HAIs. First, we recommended that the Secretary identify priorities among the CDC's recommended practices and determine ways to promote their implementation, such as by incorporating the practices into CMS's Conditions of Participation for Hospitals. In comments on our draft, CMS said that it welcomed the chance to work with CDC on this matter.

Second, we recommended that the Secretary establish greater consistency and compatibility of the data across HHS to increase the information available, including reliable national estimates of the major types of HAIs. Such estimates could help benchmark the individual hospitals to gauge their performance and design targeted interventions. HHS, in comments on our draft report, agreed with this recommendation.

After our report was published, HHS actually established a steering committee for the prevention of healthcare-associated infections that included senior-level representatives of HHS to develop their action plan. This plan consists of several strategies, including identification of priorities from among the 1,200 recommended practices and plans to coordinate data across HHS.

The plan was released in early January of 2009 for public comment, and it has still remained open for public comment. Today it remains uncertain, however, when, or if, the new administration will choose to implement this plan to reduce the serious problem of HAIs. We urge the Department to remain committed to this important effort that will improve the quality of care.

Mr. Chairman, Mr. Hatch, this concludes my remarks.

Senator ROCKEFELLER. Thank you very much. Thank you very, very much.

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

Senator ROCKEFELLER. Everybody is all enthused about HIT, that it is the solution to everything. Just get the information. What I think I have heard from all three of you is that it can be misleading and that, as you said, a patient treated for something overlaps with a patient being treated for something else, and those two things are merged and it becomes health information technology,

and it is not necessarily useful. Data is a magic word in this country because we are sort of all pseudo-engineers, and anything that is data, we go by.

Now, my question is about establishing benchmarks. You have a lot of entities that are seemingly tasked with establishing quality benchmarks—the National Committee on Hospital Insurance, National Quality Forum. I mentioned new ones—the Hospital Quality Alliance, the Joint Commission, the Physicians Consortium for Performance Improvement. All of these groups are trying to move towards better delivery of health care.

My question is, between the private, where the government may not have, obviously, responsibility, and all the government agencies working on this, nothing ultimately works in this country. We discovered this, Senator Hatch and I, in intelligence. Our intelligence collection was stove-piped. I mean, there were 18 folks, different agencies out there who were all collecting intelligence, and they refused to share it with each other for all kinds of various reasons, or less excusable than I would imagine among hospitals, but maybe pretty dangerous, too.

So we created something called the Director of National Intelligence. Everyone said, oh, that is just an easy answer to a complicated problem. Well, it was for the first 4 years, but now that person is establishing himself, in this case, and is forcing people to collaborate and to share, forcing them to, thus taking people out of their comfort zones into discomfort zones, where they could be embarrassed by what somebody else, collecting on the same subject, might say, which to me is the way the world ought to work.

So my question basically is, whose responsibility is it to generate the necessary information to establish benchmarks of care and whose responsibility is it to measure and report an individual physician's performance on such benchmarks, if there is an answer to that?

Dr. CLANCY. Right now, what we have seen is it is very easy to make measures. What is much harder is to put them into practice, as you say, in a way that works for the front lines of care, as we have said. There are a number of groups that do create measures now, and the National Quality Forum sort of certifies, if you will, that they are valid and scientific by bringing together all stakeholders, both technical experts as well as patients, to say, is this what we care about and think is important? Of all the things we could measure, are these the most important items, and so forth?

They also look at, how easy is it to put it into care? In our health care system, the Federal Government has a very important leadership and coordination role, but obviously delivery for the most part is handled by the private sector, not altogether, but for large parts of what gets delivered in health care. It is, indeed, the private sector, so you have to have a way for the public and private sectors to work together.

In the past few years, the reason we could have Hospital Compare was because hospitals and other stakeholders, including doctors, nurses, patients, and so forth, came together to say, we think this is important. We cannot do the whole ball of wax all at once, but we are going to start with 10 and we are going to keep on building that out. I think it is a very good model.

I think what we have to figure out how to do is to create an organic connection between those measures and what needs to get done in everyday care. The danger that you heard from Dr. James is that, if the data collection is too slow, and too laborious, and too far away, most people do not see that as connected to their day jobs.

In his system, what you have heard about is a system where, indeed, the measures are built from people's day jobs. I think that we can get there with measures, but it is, by definition, a multi-sector challenge.

Senator ROCKEFELLER. Just a bit impinging on Senator Hatch's time, I am not sure that can be an excuse. In other words, Dr. James's is a self-enclosed system, sort of a perfect system, as Senator Hatch explained to me. But that is not the country.

Dr. CLANCY. Absolutely.

Senator ROCKEFELLER. And we have to deal with the country. So you have to go to the taking care of the individual patient, to the next step up. How is it going to affect other departments within that same enclosed hospital system? I saw this at Johns Hopkins, when they were going crazy because the accreditation teams were all arriving and everybody was stopping doing everything they were doing, and doctors and nurses were scrubbing floors and windows and everything. I said, wait a second. This is the best hospital in the world, I think—I hope, because I was there—and why are they doing this? So, it is very complicated. But at the root, there has to be somebody who says, not an organic connection, but this is what you have to do.

Dr. CLANCY. Yes.

Senator ROCKEFELLER. And maybe it is not perfect at first, just like the DNI solution was not perfect at first. But it began to push. And it is not perfect yet, but it is still pushing, and people are beginning to cooperate, even the FBI is beginning to cooperate. They could not even talk to the CIA until we passed a law after 9/11. It was quite embarrassing for us.

But somebody, some agency, somebody—I am not trying to take turf away from anybody, except that I really am—has to be responsible for this. I have a solution for it, but I do not want to put it out quite yet. I would like to have your response.

Dr. CLANCY. I think that the Federal Government has to insist on quality of care, period. They pay for more than half of the care that is provided in this country. I think they can also provide leadership to bring the private sector along.

Senator ROCKEFELLER. Who in the Federal Government?

Dr. CLANCY. HHS. The Secretary of Health and Human Services has that responsibility.

Senator ROCKEFELLER. But he has all those 15 groups underneath him.

Dr. CLANCY. CMS, clearly, has a huge role. But you want CMS, or any payer, to be using measures that the profession believes are valid and consistent with science, as the Institute of Medicine has said, and that the people whom we are serving think are important. So you do want that input from all stakeholders. Otherwise we would just have accountants tell us what was important in

health care quality. I do not think any of us would want that for ourselves.

So, clearly, the payment function has to be tightly linked to quality, but you also want the scientific functions of HHS to be brought to bear—the newest knowledge from NIH, AHRQ, CDC, and so forth—so that the measures and tools are kept as up-to-date as possible.

Dr. KANOF. And I just want to add that, while the importance of the specific quality measures is valid—but going back to what Dr. James talked about, our own report, and the Dartmouth—there is a lot of important information that we get on a fairly regular real-time basis from CMS claims information that can be used to do hospital profiling, physician profiling, and can give real-time feedback loops to both providers and hospitals in terms of a comparison. That is just an important factor that one should not forget about in terms of, do we have the data and can we use the data.

Senator ROCKEFELLER. I am way over my time.

Doctor—Senator Hatch? I said “Dr. Hatch.” [Laughter.]

Senator HATCH. Well, thank you, Mr. Chairman.

I know that Senator Rockefeller has touched on this already, but let me just ask a question. As I reviewed the material for the hearing, I too was puzzled by the apparent lack of coordination among Federal agencies responsible for quality.

Do you both agree with that assessment?

Dr. KANOF. I think that is actually one of our major findings in our March report.

Senator HATCH. In addition, it appears that these Federal agencies do not collaborate with the private entities responsible for developing and reviewing quality standards.

Dr. CLANCY. That I would disagree with. Actually, we work very closely with those who develop the quality standards and the Quality Forum, and so forth. In fact, the Quality Forum is now doing a lot of their work under a contract from HHS.

Senator HATCH. All right. Can we improve that situation? Because we have another impression on that.

Dr. CLANCY. Sure. We would be happy to provide additional information

Senator HATCH. Sure. I was also surprised to learn that there is not a Federal entity responsible for collecting quality standards across the country. Or is there?

Dr. CLANCY. We have a clearinghouse of quality measures on the web, the National Quality Measures Clearinghouse. What it does is collect measures that have been certified as valid in reflecting current science so that you can choose. It does not say, these are the ones that you need to use. In essence, CMS has done that through the success of incentive programs that they have implemented.

Dr. KANOF. But to get to Dr. James’s point, there are many different systems out there in the Federal Government, asking for different information.

Senator HATCH. Do you believe that such a national entity that I have just suggested could be, or should be, created? Is it even necessary, since quality standards may vary across geographic areas?

Dr. CLANCY. My own view is that you want a common set of goals for the Nation. How you are going to get there? As Senator Rockefeller talked about, the whole country is going to look a whole lot different at Intermountain than it is going to look in parts of West Virginia, or southern Florida, or pick your community. I do not think you want anyone prescribing how to improve, but I think a clear set of national goals for where we are investing in health care nationally makes a lot of sense.

Senator HATCH. All right.

Are there ways to improve or leverage existing national studies, data sets, or registries to gather information that would allow us to draw conclusions about the comparative effectiveness of the treatments for various diseases, conditions, or disorders?

Dr. KANOF. We actually think that the CMS database can be mined for that, and the Dartmouth research group has clearly demonstrated that in their work, now almost 2 years ago, where they looked at the cardiac and some surgical outcomes, comparing Minnesota versus Florida. Using the CMS data, the risk adjustment was the same, the outcomes were the same, but yet in Minnesota the beneficiaries received fewer services than in Florida. So, we believe the data are there.

Dr. CLANCY. Well, I guess I would, with due respect, say that those billing claims can be used to ask very important questions, and the Dartmouth group does really terrific work, makes us say, what is going on here? What it does not tell you is how to change what is happening in one community to look like a better community. For that, you need more clinical detail. A lot of the work of what AHRQ does is exactly taking advantage of those existing data sources, including claims, but also including the kinds of data that doctors get together and collect themselves.

The Society for Thoracic Surgeons, for example, has been doing this for about 20 years, and they have learned a whole lot. Probably the best project that we ever funded was connected to Dartmouth, where they actually got all the cardiac surgeons in northern New England, three States, had them work together, initially on bypass surgery, but then they started looking at other procedures.

What they were able to do was dramatically reduce mortality and improve their processes through a process of learning. When the project was over—this was really good—the hospital started paying dues to actually keep this going. Since that time, it has only grown. So the people know now about the benefits of alternative intervention: should I have bypass surgery, should I have a stent, what will happen to me if I go one way or another? That is the comparative effectiveness that you talked about, Senator Hatch. We are going to have a huge opportunity to do a lot more of that with the Recovery Act.

Senator HATCH. All right.

Dr. Clancy, does AHRQ interact with the National Quality Forum? Does it collaborate with the National Quality Forum, and are there any joint projects that AHRQ and the National Quality Forum work together on?

Dr. CLANCY. We work very closely with the National Quality Forum. Probably the most specific example of one of many projects that we are working on with them is trying to make sure that elec-

tronic health records and health IT—everyone is excited about health IT—can support assessing and improving quality of care in the way that all of you are very interested in.

Senator HATCH. Dr. Kanof, with regard to GAO findings on hospital-acquired infections, how do we know how to prioritize recommended practices, especially when the Centers for Disease Control and Prevention have almost, if I recall it correctly, 1,200 recommended practices?

Dr. KANOF. Well, actually, there has been some movement along that line. We had recommended that HHS take the lead, and, as I mentioned, HHS actually has, in the Office of the Secretary, brought together representatives from all of the disciplines within organizations within HHS. They have actually done a prioritization of identifying what should be some preventive guidelines that should be implemented. The logic goes—as, again, Dr. James said—to prioritize what are the most common. So they have at least taken the initiative to say, what are the most common causes of HAIs, and let us work on those.

Senator HATCH. Thank you.

Dr. CLANCY. I just would add, just for the record, that the 2008 report from GAO did prompt a lot of serious internal collaboration at HHS, and we are continuing to move forward. So I think Dr. Kanof had some potential doubts about whether we had lost our steam. From my colleagues and others across the Department, I can assure you that this remains a very high priority.

Senator HATCH. Thank you.

Senator ROCKEFELLER. Thoracic surgeons, lower back pain, Resource-Based Relative Value Scale. Who made the most noise to try to derail that? It was the lower back pain doctors. Why do I say that? Because there has been tremendous emphasis from all three of you actually, but you two in particular, on CMS. I have not heard the word “MedPAC” once.

Now, my theory, which the late Dr. James never got to hear, is that one of our problems around here is that we let lobbyists, doctors’ groups, Congressman, political pressure—lower back pain being the best example of that—it basically virtually derailed something. We let them make too many decisions. There is something called expertise. Expertise can be very quickly turned into highly sophisticated data if the political process is not involved, either medical or congressional.

My approach would be to take MedPAC, which now has terrific people—and has over the years—give them a whole lot of money for research, and give them power, of which they have none whatsoever. CMS, which is the complaint—if you had to ask me, who would I choose to complain about, it would be CMS. I consider them the disbursers of payments, not the judges of quality.

You take a MedPAC and you give them the money and the time to go from the nuance of the valleys of Utah—you have valleys?

Senator HATCH. Yes.

Senator ROCKEFELLER. You have valleys; to the mountains, to Dr. James’s system. Go all around the country, and they can dissect health care.

Now, they have something at their disposal which others do not, and that is, they have the ability to reimburse physicians and hos-

pitals, particularly, obviously, related to Medicare-type things. But I have always believed—no one will ever talk me out of it—what happens in Medicare eventually happens elsewhere in medicine because it is so huge.

I like this idea very much. I like it because it takes doctor groups. I mean, at the end of the Clinton health care, and I was very heavily involved in that, there were 14,000 lobbyists in Washington, DC. Obviously the thoracic surgeons had them.

Do you remember the fight between the psychiatrists and the psychologists that went on for 10 years? The psychiatrists were saying that the psychologists should not be reimbursed by Medicare, absent 1 year post-college work, and could not prescribe medicine. There are so many examples of that, where people are paid, and now they are much more sophisticated, much better educated, as are members of Congress, because their staffs are so much more educated in health care.

So to me, one of the things you do is you remove false potential for data from the system and you leave it up—I would not call it a BRAC commission because I do not want a military comparison, but you leave it up to experts. You give experts the money, the time, and the freedom to go county by county, hospital by hospital, to whatever minutiae you want, and they have the power of reimbursement. It is just that nobody pays any attention. Reimbursement, if you talk about incentivizing medicine, is about the most powerful incentive I can think of.

Now, you cannot equate reimbursement directly to quality because there are some children or adults who will go to a properly reimbursed physician and will not accept the quality or will not follow through on the quality in their own personal lives, so-called personal responsibility-type things. But I honestly believe, and I would just ask your reaction to this; you both have observed Washington for a long time. This place just is overwhelmed with lobbyists. I think there are something like 20,000 now. They each represent durable medical equipment, oxygen tanks, or whatever it is. But boy, do they push for their product!

Now, how can you possibly talk to me about a system of quality when you have that kind of activity? It ought to be professionalized. So then how do you professionalize? I cannot come up with a perfect answer. That is the best I can do so far. But you take it out of the hands of Congress. I do not say out of the hands of Senator Hatch or myself, because we are clean and mean and lean.

Senator HATCH. Especially him. [Laughter.]

Senator ROCKEFELLER. But that is not the way it works in the rest of it. I have seen the deals that were cut. I actually moderated that psychiatrists/psychologists thing. But it is not pretty. It is not quality. It is not American medicine the way it ought to be.

Just respond to the fact of removal of politics and Congress and the power of reimbursement based upon a set of criteria which does not yet properly include, in my own definition, quality, but which might be the first step to that, other than what Dr. James is doing.

Dr. CLANCY. Well, there are a couple of points that you have made that I think are incredibly important. One is a focus on science and expertise. Medicine is a highly technical business, and you would like to know that people providing care have access to

the best information so that all patients, no matter where you live, get terrifically good care. So I think that is a very, very important theme.

You have also talked about making this a congressional commission. I will note that in the early 1970s this idea came up. As I recall the history, it was a little bit derailed by Watergate. I learned this just a couple of years ago. Congress went home, and that was the end of that idea. But it was around the time of the HMO Act.

I think the idea of having that independent source of expertise has a lot to do with the mission of AHRQ. I do not know that I think there is such a place as a politically insulated place that can never, ever be pressured, because people care a lot about health care quality.

Senator ROCKEFELLER. It is pretty hard to push Gail Wilensky around, and she is a Republican, and I think she is terrific, and so is Senator Hatch.

Dr. CLANCY. I would agree with you in that assessment.

Senator ROCKEFELLER. And it is pretty hard to push Stuart Altman around, and he is a Democrat.

I mean, look. I do not know exactly who all the folks are on it now, because I have looked at the list and there are not enough familiar names. But you get a group which is completely dedicated to proper levels of reimbursement, which is the best incentive thing you have going. I still cannot make the direct connection between that and quality. And that is a failing on my part, but I am working on it. I just think, in medicine, with public dollars, you have to do that.

Dr. CLANCY. Well, you and Senator Carper, I think, both pointed out that, right now, we pay for volume.

Senator ROCKEFELLER. Correct.

Dr. CLANCY. If you do more stuff, we pay more money.

Senator ROCKEFELLER. Yes.

Dr. CLANCY. As opposed to quality or value.

Senator ROCKEFELLER. Everybody has to have an MRI.

Dr. CLANCY. So clearly, reimbursement is a huge part of getting us to the other place. But I would hate us to lose the professional incentives where doctors' board certification is linked to how they are improving quality, which we have started to see in the past few years, or other regulations.

I mean, there are some things that are not about how much you are paying for services, but you want very specific features of facilities and so forth, to know that there are enough nurses. I think the other question really is, how do you put a system in place so that you know that in every corner of West Virginia there is the capacity to improve quality?

I cannot quite get my head around a Washington, DC-based organization literally going around and providing that kind of technical assistance. The QIOs do some of that. Clearly, I think we probably need more technical assistance. I think this answer of "they do not know how" is actually important.

Senator ROCKEFELLER. But they could reach into those groups.

Dr. CLANCY. Yes.

Senator ROCKEFELLER. You see, it is the question of who has the authority. I am looking for something. And I apologize to the good

Senator. I have talked for 12 minutes, for heaven's sake. I am looking for somebody who can lead this effort. I do not think it is going to happen haphazardly. I will guarantee you, intelligence sharing will not happen haphazardly. I will never forget when Dick Darman, who was Reagan's OMB guy, came before the Senate Finance Committee. He disappeared for a week, and his assignment was to talk about, what is the effect of the cost of health care—you will remember this—

Senator HATCH. I do.

Senator ROCKEFELLER [continuing]. The cost of health care on the GDP. He said, by X year—we probably have already passed it—it is going to be 36 percent. He was ashen white during his presentation. Or maybe he just had not slept for a week, I do not know. But, I mean, it told me a great deal, that here was an OMB director who could not make the system work.

Dr. KANOF. Well, Senator Rockefeller, I am very glad you think so highly of MedPAC, since it is GAO that has the role of appointing the commissioners.

Senator ROCKEFELLER. Now, no turf here. No turf.

Dr. KANOF. Right. No. I think, though, that there is a lot that MedPAC can do, and has done. It is more a question of, how do you take what they have recommended and get that implemented? So they have studied and made recommendations about quality, and they are very concerned about the lack of—

Senator ROCKEFELLER. They do not have the money to do that.

Dr. KANOF. Right. There is a lack of linkage between quality and payment. But they have made recommendations to Congress and to CMS in terms of stepping back and thinking how to restructure payment reform so that you are not in a fee-for-service world and you are not paying the physicians and hospitals separately.

Senator ROCKEFELLER. It could be the end of fee-for-service medicine. I do not doubt that. But I am saying, give them the money. I cannot complete my sentence entirely to connect it to quality. But it strikes me that, if you do not want people turning away Medicare patients because they say they are not getting reimbursed properly, which could be, in many cases, phony and just a reason to complain or not to see people, or it could be real depending upon where you are, which doctors you are talking about.

And I am not just talking about doctors and hospitals. I am talking about systems of people. I am talking about the entire health care system. I am looking for—I do not want to say a general, but I am looking for somebody who could be over the top of this and make sure that all of these various agencies somehow come together, that the best parts of them are taken out and given to something like MedPAC, which is greatly expanded in authority, power, research, money, et cetera, et cetera, give them some time. To me, they are a lot better deal than having Congress do it, and having politics do it. I have not answered the quality question. I am working on that. We will do that at our next meeting.

Dr. KANOF. I think you will make headway on the quality when we reform payment so that there is a better link between the quality and payment, just like Dr. James explained to you.

Senator ROCKEFELLER. I think I have certainly taken up my time here.

Senator HATCH. Well, we have brought Dr. James back a number of times, and almost everybody recognizes him as one of the real authorities. Too bad he wants to only live in Utah, because he would make a great deal of difference back here. I want to express my personal gratitude to both of you. I thought this has been a very interesting hearing, and you are both very enlightening people.

I want to thank the chairman for holding this hearing.

Senator ROCKEFELLER. He is ending the hearing.

Senator HATCH. The chairman takes a very great interest in health care. We have worked together on a lot of things, and I expect that we will be working together, if we can come together on, really, health care for everybody. Hopefully we can do that. But it is one of the most difficult things in the world if we do not find some way of containing costs, and yet upping quality. I do not think they are inconsistent, those two goals.

Dr. CLANCY. They are not.

Senator HATCH. I think we can do it. I think we can do it with your help, and the help of others. So I just want to personally tell you I have enjoyed listening to you and appreciate having both of you here.

Senator ROCKEFELLER. We have a whole separate subcommittee hearing coming up on cost containment.

Dr. CLANCY. Great.

Senator ROCKEFELLER. I mean, this is just quality. Then we have others coming up, and we have full committee hearings on subjects. Then we have White House meetings, and we have something called the Board of Directors, which strikes me as an anomaly. It is actually the Gang of Nine that Senator Hatch and I are on that is trying to figure out what to do with health care reform. We have a President who has said, here is \$634 billion, and that is more than you ever had for health care in your entire life. Let me see what you can do with it. If it is not particularly good, I have some ideas of my own. I happen to agree with many of his ideas.

So, having said that, the hearing is adjourned, with great thanks to both of you.

[Whereupon, at 4:48 p.m., the hearing was concluded.]

APPENDIX

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD



Statement Before the

**Subcommittee on Health Care
Committee on Finance
United States Senate**

**What is Health Care Quality and Who
Decides?**

Statement of

Carolyn M. Clancy, M.D.

Director

Agency for Healthcare Research and Quality

U.S. Department of Health and Human Services



For Release on Delivery
Expected at 2:30 p.m.
on Wednesday, March 18, 2009

Mr. Chairman, thank you for giving me the opportunity to address the Subcommittee on the very timely and important issue of health care quality. I ask that my full statement be made part of the official record.

The mission of the Agency for Healthcare Research and Quality (AHRQ), an agency of the U.S. Department of Health and Human Services (HHS), is to improve the quality, safety, efficiency, and effectiveness of health care for all Americans. The Agency fulfills this mission by developing evidence and working with the health care system to utilize information that:

- Reduces the risk of harm from health care services by using evidence-based research and technology to promote the delivery of the best possible care;
- Transforms the practice of health care to achieve wider access to effective services and reduce unnecessary health care costs; and
- Improves health care outcomes by encouraging providers, consumers, and patients to use evidence-based information to make informed treatment decisions.

Ultimately, AHRQ's goal is to improve the quality and safety of health care. It achieves this goal by developing evidence about which interventions are most effective, developing quality measures, working with frontline clinicians, health care organizations, and health care leaders, and through close collaborations with the Centers for Medicare and Medicaid Services (CMS) and other HHS operating divisions. AHRQ provides clinicians, patients, and other stakeholders with evidence-based "best practices" and quality measures through its support of the National Guideline Clearinghouse and National Quality Measures Clearinghouse.

What is Quality?

Simply put, health care quality is getting the right care to the right patient at the right time – every time.

There are three basic dimensions to this: structure, process, and outcome. Structure represents the basic characteristics of physicians, hospitals, other professionals, and other facilities. It describes whether there are well-educated health professionals, appropriate hospitals, nursing homes, and clinics, as well as well-maintained medical records and good mechanisms for communication between clinicians. For example: Is the mammography equipment up to date and maintained properly? Are the cardiologists well-trained and board certified?

If the structure is solid, we can concern ourselves with the process of medical care. Concern for process suggests that quality is determined not just by having the right people and facilities available, but also by having the right things get

done in the right way. Process includes questions like: Was the mammogram done for a woman at risk for breast cancer? Was the heart attack treated in the most up-to-date manner?

The third dimension, outcome, reflects the end result of care. Did people get better? What was the risk-adjusted mortality rate? Was disease or disability reduced or prevented? Was it reduced as much as it could have been, given what we know is scientifically possible? We need to be able to measure the outcomes of care so that we know which types of care really help patients and so that we can look to instances of poor outcome for opportunities for improvement.

Together, these components are the foundation of providing care that is consistently safe, timely, effective, efficient, equitable, and patient-centered. (IOM 2001)

Quality Today

The U.S. leads the world in biomedical advances and innovation. However, we do far less well in getting the right care to the right patient at the right time consistently. Moreover, the U.S. spends far more than any other nation, yet numerous studies have found that there is no relationship between high spending and care quality.

This is borne out by AHRQ data.

AHRQ is required to report to the Congress annually on the state of quality in the nation. Last year, according to statistics from AHRQ's 2007 *National Healthcare Quality Report (NHQR)*, the U.S. health care system continues to face challenges in improving the safety and quality of health care, ensuring access to care, increasing value for health care, and reducing disparities associated with patients' race, ethnicity, income, education, or place of residence.

The *National Healthcare Quality Report* tracks the health care system through quality measures, such as what proportion of heart attack patients received recommended care when they reached the hospital, or what percentage of children received recommended vaccinations. The Report is based on a framework established by the Institute of Medicine and is developed working with an interagency working group within HHS. It includes more than 100 measures culled from a wide-range of existing public- and private-sector data collection effort.

Overall, the quality of health care as measured by the quality indicators in our report improved by an average of 1.5 percent per year between the years 2000 and 2005, although this represents a decline when compared with the 2.3 percent average annual rate between 1994 and 2005. Quality indicators in some

areas have improved, such as the percentage of patients who are counseled to quit smoking. For example, the percentage of patients receiving recommended care after a heart attack has increased more than 15 percent between 2002 and 2006. However, measures of patient safety, such as appropriate timing of antibiotics received by adult patients having surgery and inappropriate medication use by the elderly, showed an average annual improvement of 1 percent. In addition, the report reflects larger improvements associated with public reporting by providers of performance.

There has been some progress in reducing care disparities. For example, the disparity between the rates of black and white hemodialysis patients who receive adequate dialysis has been eliminated, and disparities in childhood vaccinations rates for different racial groups have been reduced. However, the most recent National Healthcare Disparities Report (NHDR), AHRQ's companion report to the NHQR, shows that most disparities in health care quality *and* access are either staying the same or actually getting worse. The NHDR showed that more than 60 percent of disparities in measures of quality have stayed the same or worsened for Blacks, Asians, and poor populations. Also, nearly 60 percent of disparities have stayed the same or worsened for Hispanics.

Quality problems have implications beyond health. A July 2008 AHRQ study found that potentially preventable medical errors that occur during or after surgery may cost employers nearly \$1.5 billion a year ("Impact of Medical Errors on 90-Day Costs and Outcomes: An Examination of Surgical Patients," in the July 2008 issue of *Health Services Research*). Care for surgery patients who experienced acute respiratory failure or post-operative infections increased the cost of their care by 100 percent! The authors also concluded that studies which focus only on medical errors that occur during the initial hospital stay may underestimate the financial impact of patient safety events by up to 30 percent.

Measures of health care quality averaged over the U.S. population are not a substitute for the daily reality faced by every health care provider and patient in clinics and hospitals. At the same time, statistics reflect the aggregated everyday experiences of patients and their doctors and nurses across the Nation. It makes a difference in people's lives when breast cancer is diagnosed early with timely mammography; when a patient suffering from a heart attack is given the correct lifesaving treatment in a timely fashion; when medications are correctly administered; and when doctors listen to their patients and their families, show them respect, and answer their questions.

Yet reports do not improve quality by themselves. Findings need to be disseminated and awareness raised. Providers need to be trained. Community partnerships that bring together all the stakeholders that can make or break a quality improvement initiative need to be created and maintained. Building on information contained in the AHRQ quality and disparities reports, HHS

organizations are implementing an exciting range of programs that address health care quality nationwide.

There is good news. Today, we have a window of opportunity made possible by all of the attention that is being paid to changing the health care system. We need to be more engaged and aggressive and completely committed to transforming the health care system, because what we are doing clearly is still not good enough.

The President has taken advantage of this opportunity by emphasizing quality as a key element of health reform. His budget blueprint names improving patient safety and quality as one of the eight principles to guide the development of a health reform plan. Its proposals include building quality into Medicare payment systems. And the American Recovery and Reinvestment Act of 2009 (ARRA), Pub. L. 111-5, includes significant investments in health information technology (health IT), comparative effectiveness research, and prevention – all of which have enormous potential to improve the structure, process, and outcomes of our health system.

Accelerating Improvement

As attention has shifted from documenting that health care organizations and clinicians have the right equipment and training to deliver excellent care (structure), to assessing whether that competence is reflected in day-to-day care (process and outcomes), it has become clear that performance is often less than ideal. That is because we have not yet designed systems to make the right thing the easy thing to do. For example, a landmark study from RAND in 2003 found that Americans receive recommended care 55 percent of the time.

In the past decade, we have made enormous strides in developing and implementing scientifically based measures of quality that reflect current science as well as patients' experiences. The National Quality Forum, a private voluntary consensus organization, now endorses quality measures through a transparent process involving clinicians, hospitals, health plans, employers, and patients. Private and public sector purchasers increasingly require use of these measures in their contracts and are linking performance to financial rewards. Health care professional organizations have developed strategies to link engagement in quality improvement initiatives with continuing education and specialty certification, rather than assuming that superb knowledge automatically results in excellent care. Accrediting bodies have also incorporated these measures into their programs.

As a result of focusing on actual performance and transparency, we can now see clearly where improvements are needed. While biomedical innovations mean that health care is often far better than it was 10 years ago, we also need innovations in care delivery to accelerate the pace of improvement. Translating

scientific advances into better care for all requires the capacity for making that information available to clinicians and patients when care is delivered, and incentives and infrastructure to make this achievable.

Accelerating improvements is essential to sustainable health care reform. Effective partnerships between the public and private sectors that engage the commitment and energy of clinicians, patients, health care leaders, and payers are indispensable. Most economists believe that payment reforms that reward quality and value rather than volume are also essential. Today I want to focus on specific infrastructure components that form the essential foundation for consistently excellent care: widespread effective use of health IT; uniformity of measurement approaches across payers; focus on high-impact opportunities; and a commitment to linking quality improvements with eliminating disparities.

Health IT Health IT is the foundation that supports quality measurement and improvement, care coordination, and provides clinicians and patients the information necessary to optimize care. Data collection to assess quality has traditionally been based largely on chart reviews, use of billing claims with insufficient clinical detail, and patient surveys. This infrastructure is laborious and incapable of supporting timely feedback to clinicians providing care. Moreover, quality improvement and assessment initiatives have been almost exclusively setting-specific, thereby bypassing important opportunities to improve care, such as care transitions between settings. Widespread adoption of electronic health records, personal health records, and other health IT applications could reduce the burden of data collection and provide a platform for providing the right care to the right patient at the right time – every time. The “right care” includes performance measures as well as information that helps clinicians coordinate care effectively. Moreover, enhanced efficiency of data retrieval and collection can serve multiple purposes, including assessment of adverse drug events, evaluation of the comparative effectiveness of alternative treatments, and monitoring for public health emergencies.

Uniform Measures We understand and appreciate that the health care system faces a data burden imposed by both the public and private sectors. Today physicians and hospitals face multiple demands for quality information from payers, accrediting bodies, States, and purchasers. Disparate requirements too often add administrative burdens and disrupt workflow without enhancing patient care. In addition, physicians have expressed concern that some measures may have the unintended consequence of discouraging physicians from seeing sicker patients, as well as worsening disparities.

Since 2004 a multi-stakeholder, collaborative approach to measure development and consistency in their use has resulted in nearly all U.S. hospitals now reporting on the same measures to Hospital Compare, a Web site created by CMS and the Hospital Quality Alliance to give consumers the information necessary to compare their local hospitals on dozens of quality measures,

procedures, and the patients' perspectives on their care. This cooperation helps set the stage for value-based purchasing by both public and private sector purchasers. Similar efforts have been established for nursing home, home health, and dialysis facility performance. These efforts provide a foundation for rapid progress toward providing meaningful information that patients can use to make decisions and that clinicians can use to improve care. In short, the goal should not be only additional measures – but better information.

Collaboration among Federal Government agencies is also important to achieve uniformity in measurement and quality. We work together closely to ensure that the health care services that we provide and purchase are safe and of high quality, and that Americans have science-based information to make informed health care decisions.

The bottom line is that improving health care quality is not the sole responsibility of government or of the private sector. Public-private partnerships to develop and use measures that guide progress toward high-quality, affordable care are essential. Because quality is ultimately very personal, these partnerships have included and must continue to include all perspectives, especially those of consumers and patients. Patients and families see problems from a personal perspective and may observe deficiencies that busy providers do not or cannot notice. They are uniquely situated to detect flaws during transitions of care and to experience the effects of inadequate care coordination.

High-impact Opportunities

Focus on Chronic Illness Increased longevity and advances in effective treatment of previously lethal diseases have resulted in steady increases in the proportion of Americans suffering from chronic illnesses. These illnesses are rarely isolated; for example, AHRQ data show that just under 10 percent of adults with diabetes have only that condition – the majority have one or more additional conditions. Individuals with multiple chronic illnesses comprise most of the 20 percent of adults whose needs account for over 70 percent of spending. Quality reporting efforts have resulted in important improvements; for example, the proportion of people with diabetes who receive appropriate testing for control of their disease and associated risk factors has increased significantly. Those process improvements, however, have not yet resulted in significant improvements in near-term outcomes, in part because changing outcomes requires a sustained effort beyond the clinical care.

Within the past 2 years, based on findings from the 2006 *National Healthcare Disparities Report*, HHS agencies (AHRQ, CMS, the Administration on Aging, and the Centers for Disease Control and Prevention) collaborated to reduce disparities for Hispanic elders in 8 metropolitan communities, with a focus on diabetes and preventive care. The combination of data to identify the patients at highest need and effective collaboration with community partners to assist

individuals with managing their conditions enabled communities to maximize the impact of chronic disease self-management programs. The enhanced approach to patient self-management is now being adapted in Medicare reimbursement for diabetes education.

Quality Care for America's Children The reauthorization of the Children's Health Insurance Program (CHIP) is the most recent example of a high-impact opportunity to advance care quality. The law (Pub. L. 111-3) provides \$45 million in each of 5 years to carry out several quality improvement provisions. These provisions are particularly important because many low-income children move frequently between Medicaid, CHIP, and private sector coverage, and because a focus on children has not been a substantial part of recent quality efforts. We look forward to working closely with CMS, States and all stakeholders on these initiatives to assure that all children receive high quality care.

Inequality in Quality Studies or reports on quality share two common findings, irrespective of focus or location: (1) a substantial gap between best possible and actual care; and (2) an even larger gap for members of racial and ethnic minority groups, the poor, those with limited education, and those in remote areas. The tools and data to improve care quality can be used simultaneously to improve care and reduce disparities. In some instances, a focused approach to quality improvement has resulted in improvements for all, such as those with end-stage renal disease. In other areas, we urgently need to learn how to close the gaps effectively for subgroups at the highest risk of poor quality. The Commonwealth of Massachusetts will require reporting on quality and disparities in 2010, and other States are exploring similar approaches. The Institute of Medicine will make recommendations regarding a voluntary standard approach for combined reporting of quality and disparities later this year.

Future Directions

Lessons from quality improvement initiatives in other sectors, such as manufacturing and transportation, are reminders that there is no quick fix or easy overall remedy. Instead, it seems clear that quality improvement in health care, as in other sectors, requires a coordinated, deliberate, consistent, and sustained approach. It is important to recognize that health care quality is improving, but this improvement is happening slowly. Resources provided by ARRA for health IT, comparative effectiveness research, and prevention should accelerate the achievement of consistently high quality care.

Addressing health care issues involving people with chronic illnesses can take us a long way in our efforts to change the system. Consumer engagement and the involvement of patients and their families in health care are critical. Recognition of the importance of comparative effectiveness in evaluating various drugs, devices, and treatments; publicizing which work best and at what cost; and

making that information useful and relevant for patients, caregivers, and clinicians will be enormously important.

Improved quality and value need not cost more. Studies from Dartmouth have consistently found that areas with the highest Medicare spending are often associated with inferior, rather than better quality, care. We need to ensure that we are basing our quality improvement efforts on good science, the best data, and effective collaboration. High quality and affordable care can, and should be, one and the same. For this reason, quality is central to the President's health reform effort.

Mr. Chairman, we have begun to make progress toward creating a high-quality, safe health care system. The ultimate answer to the question "Who Decides?" will be provided by patients and all stakeholders in health care. The Federal Government can convene stakeholders and provide leadership and guidance, but this has to be a collaborative effort to succeed. Don Berwick, a nationally renowned quality expert, once observed that "In the end, only those who provide care can improve that care." Accelerating the pace of improvement can and must be guided at all times by the needs of clinicians and patients. With the recent comparative effectiveness funding in ARRA, a critical investment was made to determine what care works best for which patients. We must strive to capitalize on this investment and share the results, so all stakeholders in health care can decide how best to use the information. Finally, we must increasingly focus on measuring the value of results achieved in health care and how to enable and reward the delivery of evidence-based care. We know much of what to do to improve health care, we now must work together to put it into action. Thank you.

Statement of Michael B. Enzi
Committee on Finance, Subcommittee on Health Hearing
“What is Healthcare Quality and Who Decides?”
March 18, 2009

I have been working to improve access to high-quality, affordable health care in this nation. One way to ensure that we are getting valuable care for our health care dollars is by incorporating quality and performance measures that ensure the best patient outcomes. Quality care not only leads to better health outcomes, but often reduces the cost of care. We must incorporate better quality measures to reduce the runaway increases in health-related costs so that we don't leave mountains of debt for our children and grandchildren. As stewards of the public trust, we must assure the future strength of this nation and fashion a health system that provides quality care to all Americans that is sustainable over the long-term.

STATEMENT OF THE
HONORABLE ORRIN G. HATCH
SENATE FINANCE
SUBCOMMITTEE ON HEALTH CARE
WHAT IS HEALTH CARE QUALITY AND WHO DECIDES?

MARCH 18, 2009

Thank you Mr. Chairman. Before I begin, I want to thank all three witnesses for taking time out of their busy schedules to join us this afternoon, especially Dr. Brent James, who is one of my constituents and a national leader in health care quality. He made several adjustments to his schedule to join us this afternoon. Dr. James, please know how much both Chairman Rockefeller and I appreciate your being here.

Mr. Chairman, I commend you for holding this afternoon's hearing on health care quality. I want to remind you that we have a record of working together on health care quality. As you may recall, we worked together in 2007 on a provision in the new State Children's Health Insurance Program (CHIP) law that requires the development of pediatric quality standards.

I noted that Dr. Clancy's testimony that she defines health care quality as *getting the right care to the right patient at the right time – every time*. I would like to revise that statement to say that quality could be defined as providing *the right care for the right patient at the right time in the right place*. Understanding health care quality is critical, especially as the Senate grapples with both improving our nation's health care system and reining in health care costs and other expenses that threaten our economy during these troubling times.

The definition of quality varies depending upon whom you ask. For my constituents in Utah, quality means having access to care from a health care provider who knows you, is concerned about your wellbeing and has the tools at his or her disposal to assist you when providing health care services. Those quality tools may be state of the art diagnostic equipment. They may be the opportunity to be treated in a hospital that has a good track record on hospital acquired infections.

Quality preventive care could mean a referral to a wellness program that may help you stop smoking. Quality also means maintaining your health for as long as possible and receiving timely and appropriate therapy should you have the misfortune of falling ill. Quality means supporting research efforts that may yield tomorrow's breakthroughs and better treatments for diseases that defeat our best efforts today.

Perhaps some of our biggest challenges regarding quality measurement are how these measurements are developed and which providers are included in the development and implementation of these quality measures. For example, rural providers may lack the capacity to participate in these discussions due to size or geographic barriers. As a result, the needs of rural providers and their patients may not be reflected in the quality measures adopted. Since I represent a state that has many rural areas, this issue is important to me.

Another issue is once the quality measures are completed, how will they be disseminated and who will be able to use them? Currently, quality measurements are useful for clinicians who are evaluating other clinicians. Quality measures are also helpful to federal and state agencies that purchase health care services. So, how would health care consumers gain access to this information so they may make wise health care decisions? Shouldn't information on quality variations be made not only to providers but to the public as well so it is both user and consumer friendly?

Today, with the help of our distinguished witnesses, we will discover some tangible ways that quality may be measured. We also will discuss some best practices that may be applied broadly to our health care delivery system. We will explore which scientific and medical evidence is worthy of duplicating in physicians' offices, hospitals and community health clinics across the country. We also will consider which types of care we should reward through provider incentives.

Let me make one point clear. It is not my intent to tie the hands of our health providers, who have a wealth of knowledge and experience and who are steadfast in their desire to practice the art of medicine while adhering to commonly accepted standards of care. We should not, under any circumstance, let our concern with runaway health expenditures cause us to limit treatment options to those that are lowest in cost. It is my hope that we continue in the tradition of offering the very best health care of the very highest quality. Americans deserve quality health care and it is our responsibility to ensure that we do not interfere with that goal.

As we will learn from our witnesses today, the federal government and the private sector have both done a lot of work on quality. Unfortunately, there appears to be limited coordination among the federal agencies and private entities responsible for overseeing health care quality. However, at the present time, there is not an entity responsible for coordinating quality measures on a national level. I am interested in hearing the perspective of witnesses regarding the need for such an entity since quality is different from region to region. What works for Utah may not work for New York. Additionally, I believe that there needs to be a stronger public-private partnership when it comes to developing quality measurement standards. It is my hope that this public-private partnership will result in patients receiving quality health care at affordable prices.

My home state of Utah is a leader in this area – we have some of the lowest reimbursement rates in the country for health care services and the best health care outcomes in the country. And that is due, in most part, to Dr. Brent James' leadership in this area.

So I want to thank the witnesses again for coming today and I look forward to having this dialogue with you as together we engage in this important work.

Testimony to

**The United States Senate Committee on Finance
Subcommittee on Health**

A hearing addressing:

What Is Health Care Quality, and Who Decides?

**Wednesday, 18 March 2009, 2:30p
Dirksen Senate Office Building, Room 215**

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**Quality Measurement and Improvement:
A Tale of Two Projects**

Project 1

In December, 2004, the Institute for Healthcare Improvement launched its 100,000 Lives Campaign. The Campaign targeted 6 clinical areas: central venous IV line infections, ventilator-associated pneumonias, rapid response teams, surgical site infections, acute myocardial infarction (heart attack) care, and medication reconciliation. For each target, IHI developed “bundles” that described implementable best care processes at the bedside. Each bundle included embedded process and outcome measures. IHI sponsored teleconferences, web sites, and meetings in which hospitals shared barriers, lessons learned, and successes. More than 3,100 U.S. hospitals, representing more than 80 percent of all U.S. hospital admissions, voluntarily participated. They were motivated by professional values – better patient care – without direct financial incentives or regulatory mandates.

IHI estimated that the 100K Lives Campaign saved over 120,000 lives. While the overall IHI evaluation method was somewhat controversial – the IHI Campaign approach lacked the structure necessary for careful observational research – a large number of individual hospital-level instances of improvement from within the Campaign are compelling. For example, a Johns Hopkins University Hospital team helped the Michigan Hospital Association implement the central venous line infection bundle in 108 ICUs (Pronovost et al., NEJM, 2006). Historically, about 80,000 such infections occurred in U.S. hospitals each year, accounting for more than 28,000 deaths and increasing health care costs (marginal resource consumption to treat the infections) by more than \$2.3 billion. The Hopkins team supported the local clinicians with embedded measurement and implementation advice. Central line infection rates fell from 7.7 to 1.4 per thousand catheter days. Mortality rates fell by more than 1,700 deaths per year in Michigan alone.

Project 2

In 2004, the DHHS Centers for Medicare and Medicaid Services (CMS), acting under Section 501(b) of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA), reduced Medicare payments to hospitals for certain diagnoses by 0.8 percent. Hospitals could recover the payment by reporting 10 “quality performance measures.” Over time, CMS has added additional measures. The core set now addresses 5 areas: Acute myocardial infarction (heart attack) (7 measures); heart failure (4 measures); community-acquired pneumonia (7 measures); infection, hyperglycemia, and venous thromboembolism prophylaxis in surgery (7 measures); and asthma care in children (2 measures).

Subsequent external evaluations showed that while hospitals’ performance scores on the CMS process measures changed significantly, final outcomes did not (Werner & Bradlow, JAMA, 2006; Fonarow et al., JAMA, 2007; Managlat, Smith, & Butler, J Card Fail, 2008).

Why the difference? How is it that a privately launched, voluntary effort produced massive improvements in quality, while a parallel governmental effort produced, at best, a very minor impact?

Background information

Quality measurement has improved significantly over the past 3 decades:

- W. Edwards Deming linked quality to underlying work processes. He suggested that every process produces 3 parallel classes of outcomes: quality, cost, and service. This provided a robust structure for quality measurement, in context.
- Health services researchers (Nelson, James) further broke medical quality into 4 major subdivisions, which greatly simplified measurement within much more consistent categories. Those 4 major subdivisions are:
 1. appropriateness (indications)
 2. complications
 3. therapeutic goals (biologic performance as seen by a health professional)
 4. patient functional status (biologic performance as seen by a patient)
- These advances have led to validated quality measures within well-defined patient populations.

Despite those advances, quality measurement still has major limitations:

- There are widespread problems with incomplete science, incomplete assessment, incomplete documentation, and incomplete data extraction from fragmented, dispersed medical records.
- “Availability bias”
- Problems with attribution (most care is delivered by teams)

Any quality measurement system itself contains variability, which can obscure the underlying care delivery performance:

- there is a clear need for feedback and follow up on the data system itself, using well-established methods found in industrial quality control theory (gauge theory)
- no national groups currently employ this critical element
- example of how it works: condition-specific measurement within Intermountain Healthcare

As a result, it is currently impossible for quality measures to accurately rank providers in most circumstances:

- a very robust scientific literature supports this conclusion (will supply on request)
- good quality accountability therefore needs to use approaches that do not rely on ranking – these approaches do exist, primarily derived from quality improvement theory

Provider quality performance is highly condition specific:

- 3 decades of investigation have found no reliable general quality indicators (the fact that a provider does well or poorly on one condition does not imply that the same provider will do well or poorly on other conditions)
- however, care delivery concentrates massively. About 10% of clinical conditions account for over 90% of all care delivery
- therefore, build in measures by condition, in size order, to address the most good for the most patients

Poorly-constructed quality measurement systems often lead to “data gaming”

(principle: it is easier to look good than to be good):

- There are 3 ways to get a better number (Deming):
 1. improve the underlying process
 2. shift resources to the area under the measurement spotlight, at the expense of areas not under the measurement spotlight (very often, the peripheral damage outweighs the focused gain)
 3. game the number
- “as one attaches greater rewards or punishments to achieving a number, one gets increasing proportions of (2) and (3)”
- extrinsic rewards tend to destroy intrinsic motivation
- it is very clear that type (2) and (3) activities are becoming common among U.S. hospitals, relative to the CMS measures

Transparency is not the same as accountability:

- high-quality care delivery usually involves a series of decisions around sequential care delivery choices
- patients usually make those decisions in the context of a caring relationship, with a physician or nurse advisor
- “transparency” means that all participants – the clinician advisors as well as the patients – have sufficiently accurate, detailed information to make wise choices at each step in the chain
- Accountability measures, that reduce the problem to a single patient choice of a hospital or a physician, can directly undermine the true transparency that is essential to high quality care.

There are 2 primary approaches to quality - (1) measurement for selection (accountability) versus (2) measurement for improvement:

- measurement for improvement contains measurement for selection / accountability – the opposite is not true (measures for accountability, mandated from above, do not create capacity for actual quality management and improvement at the front line)
- measurement systems designed for accountability often consume limited front-line resources and actively damage quality of care (Localio, NEJM, 1999; Wachter et al. Ann Int Med, 2008)
- there are rigorous methodologies for generating reliable front-line, embedded data systems that minimize burden and maximize data quality (NQF SFB report). These

methods stand in contrast to the political methods currently used by most national reporting groups.

Two national groups are showing strong approaches to quality measurement:

- NCQA methodology has historically been strong
- The new Joint Commission initiative holds very great promise

The CMS and Joint Commission ORYX measures currently face significant technical challenges:

The CMS measures operate in parallel with other quality measures required by The Joint Commission (the ORYX system). A hospital can submit its measures directly to CMS through a web-based interface (the CART system). However, The Joint Commission requires data submission through tested and certified Performance Measurement System Vendors (Vendors). As most Vendors offer parallel support for both CMS and The Joint Commission ORYX system, most hospitals combine the two activities into a single effort, using the services of a certified vendor. Once CMS has received a hospital's quality measures, either through direct submission (CART) or a Vendor, CMS performs computerized integrity checks on the submitted data.

Over time, the CMS measures have become operationally complex. For example, Heart Failure is arguably the simplest of the CMS quality areas. It includes 4 main measures, along with patient demographic data. Evaluating the 4 main measures requires evaluation of almost 20 data subelements. Each of the subelements has complex descriptions – inclusion and exclusion criteria – that run from 1 to 6 pages per in length.

Both CMS and The Joint Commission have used the National Quality Forum (NQF) to select appropriate measures for quality reporting. NQF has established committee structures that represent major constituencies, including health insurance groups, patient advocates, system vendors, health and hospital professional organizations, and care providers. The measure selection process usually starts with a review of available medical evidence, then uses a political consensus approach that draws upon the various constituencies.

When constructing its quality measures, CMS faced a major dilemma: While “quality” innately implies final outcomes that are important to patients – for example, mortality following a heart attack – it is very difficult to account for underlying differences in patients (severity of illness or risk adjustment) when interpreting final outcomes. CMS therefore chose instead to track process measures (also known as intermediate outcomes) – the factors that current best medical science suggest should drive final outcomes. This had the effect of greatly increasing effective sample sizes, and of shortening measurement timelines. CMS relied upon process measures that showed a strong association with final outcomes in the medical literature (evidence-based medicine). The key to using process measures is the strength of the linkages between the intermediate outcomes used for performance assessment, and the final patient outcomes that the intermediate measures are believed to predict. Unfortunately, those linkages are highly sensitive to small changes in the underlying data systems. As the complexity of the

underlying data definitions increases, opportunities to change measured performance by purposefully or inadvertently manipulating the underlying data system multiply.

As result of the foregoing, both the CMS measures and The Joint Commission measures are designed for “after the fact” chart abstraction (as opposed to being embedded into the clinical work flow); they rely on a subset of measures based upon what can be found in a typical hospital chart or existing electronic financial data systems (called “availability bias”), and focus on process measures rather than final outcomes measures. Subsequent external evaluation suggests that the process-outcomes linkages upon which the CMS measures rely are weak.

Recommendations

1. **Build balanced measurement** (clinical intermediate and final outcomes, cost outcomes, and service outcomes) **for specific clinical conditions, in priority order.** Prioritize on the basis of careful analysis addressing (1) the number of patients affected, (2) risk to the patient (= intensity of care = cost per case), (3) internal variability (coefficient of variation in care intensity, within a condition), and (4) social equity (underserved populations).
2. **Build the measures from the bottom up** – create a measurement set that can embed in care delivery at the bedside, and that directly supports the ability of clinical teams to deliver care, manage care processes, and systematically improve. **“Roll up” selected front-line measures into system, State, and national reporting.**
 - this approach minimizes burden on front-line teams
 - it is the best way to insure accurate, complete, and timely data (by centering around data that are actually used at the point of patient contact)
 - it provides true transparency – it will inform all involved in the chain of clinical decision making (patients, physicians, nurses, etc.)
3. **Examine outlier cases to find root causes, then use the resulting knowledge to systematically clean up and improve the data system itself** (gauge theory). For example:
 - Intermountain Healthcare currently has a full set of intermediate and final, clinical, cost, and service outcomes measures available to patients, clinicians, and managers, for almost 80% of all of our care delivery.
 - Those data systems were specifically created for true transparency. Rather than rely on existing measures derived primarily from financial systems, we applied the NQF SFB methodology to identify the full necessary measurement set, then began to collect missing measures (about 30 – 50% of the required measures were missing from “state of the art” existing data systems available at the start of the effort).

- About half of all outliers (cases, physicians, hospitals, etc.) initially identified through this clinically-based, purpose-specific measurement system traced back to the data system – not the underlying clinical care.
 - We used those outlier cases to systematically identify failures in the measurement system, then corrected them. Over time, this led to a very robust quality measurement system.
4. **Don't target the entire care delivery system at the start. Instead, provide financial incentives (shared savings) to care delivery groups who can build and implement such measurement systems**, then build out from that foundation. Let the financial incentives drive positive change over time, based upon successful models generated by early participants. Don't be trapped by the "lowest common denominator," in terms of data readily available within the existing system. This method will allow progress even though it is very difficult to accurately rank providers.
 5. **As specific clinical topics mature, move from voluntary to mandatory participation.**

References

Hospital Compare website; Information for Professionals; Hospital Process of Care Measures, accessed 16Mar09 at http://www.hospitalcompare.hhs.gov/Hospital/Static/InformationforProfessionals_tabset.asp?activeTab=1&Language=English&version=&subTab=7#POC3

United States Government Accountability Office

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Testimony
Before the Subcommittee on Health Care,
Committee on Finance, U.S. Senate

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**HEALTH-CARE-
ASSOCIATED INFECTIONS
IN HOSPITALS**

**Continuing Leadership
Needed from HHS to
Prioritize Prevention
Practices and Improve Data
on These Infections**

Statement of Dr. Marjorie Kanof, Managing Director
Health Care



GAO-09-516T

March 18, 2009

GAO
Accountability-Integrity-Reliability
Highlights

Highlights of GAO-09-516T, a testimony before the Subcommittee on Health Care, Committee on Finance, U.S. Senate

Why GAO Did This Study

According to the Centers for Disease Control and Prevention (CDC), health-care-associated infections (HAI)—infections that patients acquire while receiving treatment for other conditions—are estimated to be 1 of the top 10 causes of death in the nation. The statement GAO is issuing today summarizes a March 2008 report, *Health-Care-Associated Infections in Hospitals: Leadership Needed from HHS to Prioritize Prevention Practices and Improve Data on These Infections* (GAO-08-283). In this report, GAO examined (1) CDC's guidelines for hospitals to reduce or prevent HAIs and what HHS does to promote their implementation, (2) Centers for Medicare & Medicaid Services' (CMS) and hospital accrediting organizations' required standards for hospitals to reduce or prevent HAIs, and (3) HHS programs that collect data related to HAIs and integration of the data across HHS. To conduct the work, GAO reviewed documents and interviewed HHS and accrediting organization officials. To update certain information for this statement, GAO reviewed relevant HHS documents released after GAO's March 2008 report.

What GAO Recommends

In its report, GAO recommended that the Secretary of HHS identify priorities among the recommended practices in CDC's guidelines and establish greater consistency and compatibility of the data collected across HHS on HAIs. HHS generally agreed with GAO's recommendations.

View GAO-09-516T or key components. For more information, contact Marjorie Kanoff at (202) 512-7114 or kanoffm@gao.gov.

HEALTH-CARE-ASSOCIATED INFECTIONS IN HOSPITALS

Continuing Leadership Needed from HHS to Prioritize Prevention Practices and Improve Data on These Infections

What GAO Found

In its March 2008 report, which is summarized in this statement, GAO found the following:

- CDC has 13 guidelines for hospitals on infection control and prevention, which contain almost 1,200 recommended practices, but activities across HHS to promote implementation of these practices are not guided by a prioritization of the practices. Although most of the practices have been sorted into categories primarily on the basis of the strength of the scientific evidence for the practice, other factors to consider in prioritizing, such as costs or organizational obstacles, have not been taken into account.
- While CDC's guidelines describe specific clinical practices recommended to reduce HAIs, the infection control standards that CMS and the accrediting organizations require describe the fundamental components of a hospital's infection control program. The standards are far fewer in number than CDC's recommended practices and generally do not require that hospitals implement all recommended practices in CDC's guidelines.
- Multiple HHS programs have databases that collect data on HAIs, but limitations in the scope of information collected and a lack of integration across the databases constrain the utility of the data.

GAO concluded that the lack of department-level prioritization of CDC's large number of recommended practices had hindered efforts to promote their implementation. GAO noted that a few of CDC's strongly recommended practices were required by CMS or the accrediting organizations but that it was not reasonable to expect CMS or the accrediting organizations to require additional practices without prioritization. GAO also concluded that HHS had not effectively used the HAI-related data it had collected through multiple databases across the department to provide a complete picture of the extent of the problem.

Subsequent to GAO's report, HHS established a steering committee, with senior-level representation of HHS offices and operating divisions, to develop the *HHS Action Plan to Prevent Healthcare-Associated Infections*. This plan includes strategies that are intended to address some of the reasons for the lack of effective actions to control HAIs, including some identification of priorities from among the 1,200 recommended practices, and plans to coordinate HAI-related data collection activities across HHS. HHS released the Action Plan for comment in early January 2009, with the intent of revising it based on the public input it received. Following the transition to the new presidential administration, HHS has continued to solicit public comments. Consequently, it remains uncertain when or if the new administration will choose to implement this plan, and if so, with what modifications, to address GAO's recommendations and reduce the serious problem of HAIs.

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to discuss our work on federal government efforts to address the problem of health-care-associated infections (HAI) in hospitals and to provide a summary of our March 2008 report entitled *Health-Care-Associated Infections in Hospitals: Leadership Needed from HHS to Prioritize Prevention Practices and Improve Data on These Infections*.¹ According to the Centers for Disease Control and Prevention (CDC), HAIs are infections that patients acquire while receiving treatment for other conditions² and are estimated to be 1 of the top 10 causes of death in the United States. HAIs can be acquired in several ways, such as from bacteria on a needle or tube used to deliver medicine, fluids, or blood to a patient. According to CDC, the most common HAIs are urinary tract infections, surgical site infections, pneumonia, and bloodstream infections. A reduction in the prevalence of HAIs through implementation of practices that are based on the best available scientific evidence would represent a substantial improvement in health care quality.

HAIs can be expensive. In 2005 the average payment for a hospitalization in Pennsylvania was over six times higher for patients who contracted a hospital-acquired infection than for patients who did not acquire infections.³ A 2007 study of 1.69 million patients who were discharged from 77 hospitals found that the additional cost of treating a patient with an HAI averaged \$8,832.⁴ The costs of HAIs are borne not only by the patients who suffer infections, but also by those who pay for care, such as the Centers for Medicare & Medicaid Services (CMS). According to the

¹GAO, *Health-Care-Associated Infections in Hospitals: Leadership Needed from HHS to Prioritize Prevention Practices and Improve Data on These Infections*, GAO-08-283 (Washington, D.C.: Mar. 31, 2008).

²In general, HAIs are distinct from community-acquired infections, that is, infections that patients may have acquired before entering the hospital.

³See Pennsylvania Health Care Cost Containment Council, *Hospital-Acquired Infections in Pennsylvania* (Harrisburg, Pa., November 2006).

⁴See D. Murphy et al., *Dispelling the Myths: The True Cost of Healthcare-Associated Infections* (Washington, D.C.: Association for Professionals in Infection Control and Epidemiology, February 2007).

American Hospital Association, Medicare paid for over one-third of all hospital costs in 2007.⁵

Although not all HAIs are preventable, the federal government and private organizations have established standards and other activities aimed at controlling and preventing them. CMS has established health and safety standards—known as conditions of participation (COP)—with which hospitals must comply in order to be eligible for payment by Medicare and Medicaid and which include the COP for infection control.⁶ Hospitals may choose one of two ways to show that they have met these or equivalent standards: they may be certified by a state agency under agreement with CMS to survey the hospital's compliance with the COPs or they may be accredited by a CMS-approved private organization, including the Joint Commission or the Healthcare Facilities Accreditation Program of the American Osteopathic Association (AOA).⁷ Most hospitals are accredited by the Joint Commission.⁸ Other activities within the Department of Health and Human Services (HHS) aimed at addressing the problem of HAIs in hospitals include CDC's development of guidelines, which contain recommended practices that hospitals may adopt, and the management of several databases in different parts of HHS that contain information about HAIs in hospitals. According to the Institute of Medicine, prevention of HAIs through implementation of evidence-based guidelines can lead to improvements in quality of care.⁹ Furthermore, the collection of national data on these infections can provide a benchmark for individual hospitals to gauge their performance and design targeted interventions. In addition to these activities, in January 2009 HHS released for public comment the

⁵Medicare is a federal health insurance program that serves over 42 million elderly and certain disabled beneficiaries and pays for health care needs, such as inpatient hospital stays and physician visits.

⁶See 42 C.F.R. § 482.1 (2007).

⁷Section 1865(b)(1) of the Social Security Act also provides that any other national accreditation body that meets certain requirements as determined by the Department of Health and Human Services may accredit hospitals. CMS approved Det Norske Veritas Healthcare as a hospital accrediting organization in September 2008.

⁸In fiscal year 2008, 81 percent of hospitals were accredited by the Joint Commission, state survey agencies certified approximately 16 percent of hospitals, less than 2 percent were accredited by AOA, and 1 percent of hospitals were accredited by both the Joint Commission and AOA.

⁹See K. Adams et al., *Priority Areas for National Action: Transforming Health Care Quality*, Institute of Medicine of the National Academies (Washington, D.C.: The National Academies Press, 2003).

*Action Plan to Prevent Healthcare-Associated Infections.*¹⁰ This document is designed as a road map for how the department plans to address HAIs.

Federal and state lawmakers are also concerned about HAIs and have taken action to reduce them. With the passage of the Deficit Reduction Act of 2005 (DRA),¹¹ the Congress took steps to revise the way Medicare pays hospitals so that beginning on October 1, 2008, they would not receive higher payments for patients who acquire certain preventable conditions (including any of three HAIs) during their hospital stays.¹² The HAI-related preventable conditions that CMS identified under subsection 5001(c) of the DRA were urinary tract infections caused by catheters, infections caused by vascular catheters, and surgical site infections following selected types of surgery.¹³ In addition, 23 states were designing or had implemented state-mandated public reporting of hospital HAI rates or HAI-related information as of February 2008.¹⁴

My statement today is based largely on our March 2008 report, and includes some updated information from the HHS Action Plan.¹⁵ In the March 2008 report, we examined (1) CDC's guidelines for hospitals to

¹⁰See Department of Health and Human Services, *HHS Action Plan to Prevent Healthcare-Associated Infections*, <http://www.hhs.gov/ophis/initiatives/hai/index.html> (accessed Mar. 14, 2009).

¹¹Pub. L. No. 109-171, § 5001(c), 120 Stat. 4, 30.

¹²Under Medicare, hospitals generally receive fixed payments for inpatient stays based on diagnosis-related groups (DRG), a system that classifies stays by patient diagnoses and procedures. Some DRGs take account of certain comorbidities or complications associated with a diagnosis or procedure and pay at a higher rate than would otherwise be paid for the diagnosis or procedure. In a final regulation implementing section 5001(c) of the DRA, CMS identified certain preventable conditions that it would not consider as a comorbidity or complication that would lead to the higher payment. See 72 Fed. Reg. 47130, 47200-217 (Aug. 22, 2007). The DRA also requires hospitals to indicate the diagnoses that were present in patients at the time of admission in order for CMS to determine if a preventable condition developed during a patient's hospital stay.

¹³The selected surgeries are certain orthopedic procedures, bariatric surgery for obesity, and coronary artery bypass graft. Additional preventable conditions that will no longer result in higher payments to hospitals include hospital-acquired injuries, such as fractures, pressure ulcers, objects left in the body during surgery, air embolisms, and blood incompatibility. See 73 Fed. Reg. 48434, 48477-79; 72 Fed. Reg. at 47200-217.

¹⁴See GAO, *Health-Care-Associated Infections in Hospitals: An Overview of State Reporting Programs and Individual Hospital Initiatives to Reduce Certain Infections*, GAO-08-808 (Washington, D.C.: Sept. 5, 2008).

¹⁵GAO-08-283.

reduce or prevent HAIs, and what HHS does to promote their implementation; (2) CMS's and the accrediting organizations' required standards for hospitals to reduce or prevent HAIs, and how compliance is assessed; and (3) HHS programs that collect data related to HAIs in hospitals, and the extent to which the data are integrated across HHS.

In carrying out this work for our March 2008 report, we interviewed officials from CDC, CMS, the Agency for Healthcare Research and Quality (AHRQ), the Food and Drug Administration, the Joint Commission, and AOA. We also interviewed selected experts in the field of infection control. In addition, we reviewed and analyzed CDC's infection control and prevention guidelines issued from 1981 through 2007; minutes of HHS's Healthcare Infection Control Practices Advisory Committee (HICPAC); the World Health Organization's guideline on hand hygiene;¹⁶ CMS's COPs for hospitals and interpretive guidelines,¹⁷ which describe the COPs and provide survey procedures used to determine compliance with them; the Joint Commission's 2008 standards for hospitals and its hospital standards manual; and AOA's 2005 standards for hospitals and its hospital standards manual. We refer to the guidance that CMS provides about its COPs in the interpretive guidelines, and that the Joint Commission and AOA provide about their standards in their respective manuals, as "standards interpretations."¹⁸ We also reviewed manuals and other documents that explain the HHS programs that collect HAI-related data, and related publications and data analyses conducted by the agencies based on the data collected. We conducted the performance audit for the March 2008

¹⁶See World Health Organization, *WHO Guidelines on Hand Hygiene in Healthcare (Advanced Draft): Global Patient Safety Challenge 2005-2006: Clean Care Is Safer Care* (Geneva, Switzerland, 2006).

¹⁷In addition to reviewing CMS's interpretive guidelines that can be found in CMS's *State Operations Manual*, we reviewed CMS's revised interpretive guidelines for the infection control COP, which were published in November 2007. Throughout this report, where we refer to the interpretive guidelines for infection control we are referring to the November 2007 revision.

¹⁸Standards interpretations are given by CMS primarily in its *State Operations Manual*, which is arranged by COP (Appendix A of the *State Operations Manual* contains the COPs for hospitals); by the Joint Commission in its *Comprehensive Accreditation Manual for Hospitals: The Official Handbook*, which identifies rationales and performance expectations that are used to measure each standard and is organized into 11 chapters of safety and quality standards, such as "Medication Management" and "Leadership"; and by AOA's standards manual, *Accreditation Requirements for Healthcare Facilities*, which provides explanations for surveyors and the scoring procedures along with its standards and is organized into 32 chapters.

report from January 2007 to March 2008, and updated certain information from the report for this testimony in March 2009 by reviewing the HHS Action Plan and other relevant HHS documents, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives. A detailed explanation of our methodology is included in our March 2008 report.

In brief, we found that federal authorities and private organizations had undertaken a number of activities to address the problem of HAIs. We reported that CDC had 13 guidelines for hospitals on infection control and prevention, which contained almost 1,200 recommended practices. However, activities across HHS to promote implementation of these practices were not guided by a prioritization of the practices. Although most of the practices have been sorted into categories primarily on the basis of the strength of the scientific evidence for the practice, there were other factors to consider in prioritizing, such as costs or organizational obstacles. We concluded that a lack of department-level prioritization of CDC's large number of recommended practices had hindered efforts to promote their implementation. While CDC's guidelines describe specific clinical practices recommended to reduce HAIs, the infection control standards that CMS and the accrediting organizations require of hospitals describe the fundamental components of a hospital's infection control program. We found that the standards were far fewer in number than CDC's recommended practices and generally did not require that hospitals implement all recommended practices in CDC's guidelines. We noted that a few of CDC's strongly recommended practices were required by CMS or the accrediting organizations but that it was not reasonable to expect CMS or the accrediting organizations to require additional practices without prioritization. Other HAI-related federal efforts included multiple HHS programs that collect data on HAIs, but we found that limitations in the scope of information collected and a lack of integration across the programs' databases constrained the utility of the data. We concluded that HHS had not effectively used the HAI-related data it had collected through multiple databases across the department to provide a complete picture of the extent of the problem and make progress in reducing HAIs.

In order to help reduce HAIs in hospitals, we recommended that the Secretary of HHS take the following two actions: (1) identify priorities among CDC's recommended practices and determine how to promote implementation of the prioritized practices, including whether to incorporate selected practices into CMS's conditions of participation (COP) for hospitals, and (2) establish greater consistency and compatibility of the data collected across HHS on HAIs to increase information available about HAIs, including reliable national estimates of the major types of HAIs. In commenting on a draft of our report, HHS generally agreed with our recommendations. HHS's Action Plan includes a number of strategies, some of which are intended to address our recommendations. HHS released the Action Plan for comment in early January 2009, with the intent of revising it based on the public input it received. Following the transition to the new presidential administration, HHS has continued to solicit public comments on the plan with no designated deadline for submissions. Consequently, it remains uncertain when or if the new administration will choose to implement this plan, and if so, with what modifications.

CDC Had 13 Infection Control and Prevention Guidelines Containing Almost 1,200 Recommended Practices, and HHS's Action Plan Includes Some Prioritized Practices to Promote Implementation

In March 2008, we reported that CDC had 13 guidelines for hospitals on infection control and prevention, and in these guidelines CDC recommended almost 1,200 practices for implementation to prevent HAIs and related adverse events.¹⁹ (See table 1.) CDC's infection control and prevention guidelines set forth recommended practices, summarize the applicable scientific evidence and research, and contain contextual information and citations for relevant studies and literature. Most of CDC's infection control and prevention guidelines are developed in conjunction with HICPAC, an advisory body created in 1992 by the Secretary of HHS. CDC publishes the final guidelines in its *Morbidity and Mortality Weekly Report*, on its Web site, or through a professional journal.

¹⁹This total does not include the practices recommended in CDC's *Guideline for Disinfection and Sterilization in Healthcare Facilities*, which was issued in November 2008.

Table 1: CDC's Infection Control and Prevention Guidelines, with Number of Recommended Practices, Issued between 1981 and 2007

	Guideline (Issue date)	Total number of recommended practices
1	Guideline for Prevention of Catheter-associated Urinary Tract Infections (1981)	24
2	Guideline for Infection Control in Health Care Personnel (1998)	183
3	Guideline for Prevention of Surgical Site Infection (1999)	63
4	Guidelines for Preventing Opportunistic Infections among Hematopoietic Stem Cell Transplant Recipients (2000)	^a
5	Guidelines for the Prevention of Intravascular Catheter-Related Infections (2002)	111
6	Guideline for Hand Hygiene in Health-Care Settings (2002)	42
7	Recommendations for Using Smallpox Vaccine in a Pre-Event Vaccination Program (2003)	^b
8	Guidelines for Environmental Infection Control in Health-Care Facilities (2003)	329
9	Guidelines for Preventing Health-Care-Associated Pneumonia (2003)	208
10	Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health-Care Settings (2005)	^b
11	Influenza Vaccination of Health-Care Personnel (2006)	6
12	Management of Multidrug-Resistant Organisms in Healthcare Settings (2006)	80
13	Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings (2007)	152
	Total	1,198

Source: GAO-09-293.

^aFor the purpose of this table, we do not include a count of the recommended practices in this guideline because the guideline is targeted to a specific patient population that not all hospitals treat. However, for the hospitals that do treat such patients, this guideline provides at least another 164 recommended practices.

^bThe practices in these guidelines are not organized in a way that supports counting the total number of practices.

We found that CDC's guidelines covered such topics as prevention of catheter-associated urinary tract infections, prevention of surgical site infections, and hand hygiene. An example of a recommended practice in the hand hygiene guideline is the recommendation that health care workers decontaminate their hands before having direct contact with patients. Most of the practices were sorted into five categories—from strongly recommended for implementation to not recommended—primarily on the basis of the strength of the scientific evidence for each practice. Over 500 practices were strongly recommended.

We also found that CDC and AHRQ had conducted some activities to promote implementation of recommended practices, such as disseminating the guidelines and providing research funds. However, these steps were not guided by a prioritization of recommended practices. Our March 2008 report noted that one factor to consider in prioritization is strength of evidence, as CDC had done. In addition to strength of evidence, an AHRQ study identified other factors to consider in prioritizing recommended practices, such as costs and organizational obstacles. Furthermore, the efforts of the two agencies had not been coordinated. For example, we found that CDC and AHRQ independently examined various aspects of the evidence related to improving hand hygiene compliance, such as the selection of hand hygiene products and health care worker education. This could have been an opportunity for coordination. We found that no one in the HHS Office of the Secretary was responsible for coordinating infection control activities across HHS. The department subsequently established the Steering Committee for the Prevention of Healthcare-Associated Infections, with senior-level representation of HHS offices and operating divisions, to develop the HHS Action Plan. To facilitate implementation of recommended practices among health care organizations, the plan prioritized some recommended practices to address four of its six targeted HAIs.²⁹

²⁹The Action Plan identified six targeted HAIs: central-line-associated bloodstream infections, catheter-associated urinary tract infections, surgical site infections, ventilator-associated pneumonia, *Clostridium difficile* infections, and methicillin-resistant *Staphylococcus aureus* infections. It identified prioritized recommended practices for all but *Clostridium difficile* infections and methicillin-resistant *Staphylococcus aureus* infections.

**CMS's and
Accrediting
Organizations'
Required Hospital
Standards Described
Components of
Infection Control
Programs, and
Compliance with
These Standards Was
Assessed through On-
Site Surveys**

In March 2008, we reported that while CDC's infection control guidelines described specific clinical practices recommended to reduce HAIs, the infection control standards that CMS and accrediting organizations require as part of the hospital certification and accreditation processes described the fundamental components of a hospital's infection control program. These components included the active prevention, control, and investigation of infections. Examples of standards and corresponding standards interpretations that hospitals must follow included educating hospital personnel about infection control and having infection control policies in place. The standards were far fewer in number than the recommended practices in CDC's guidelines—for example, CMS's infection control COP contained two standards.

We also found that as a whole, the CMS, Joint Commission, and AOA standards and their interpretations described similar required elements of hospital infection programs. For example, all required that the hospital designate a person or persons to be responsible for the infection control program. However, there were differences, including the extent to which the standards and their interpretations required implementation of practices recommended in CDC's infection control guidelines. Although CMS and the accrediting organizations generally did not require that hospitals implement all recommended practices in CDC's infection control and prevention guidelines, we reported that the Joint Commission and AOA had standards that required the implementation of certain practices recommended in CDC's infection control guidelines. For example, we reported that the Joint Commission and AOA required hospitals to annually offer influenza vaccinations to health care workers, whereas CMS's interpretive guidelines, or standards interpretations, were more general, stating that hospitals should adopt policies and procedures based as much as possible on national guidelines that address hospital-staff-related issues, such as evaluating hospital staff immunization status for designated infectious diseases. In our March 2008 report, we proposed that HHS determine how to promote implementation of prioritized practices, including whether to incorporate selected practices into CMS's hospital standards. In its Action Plan, HHS indicates its preference not to include specific infection control practices in its hospital standards in order to keep its standards flexible and broad.

In our March 2008 report, we also discussed how compliance with hospital standards is assessed. CMS, the Joint Commission, and AOA assessed compliance with their infection control standards during on-site surveys through direct observation of hospital activities and review of hospital policy documents. Among the surveys conducted in the first quarter of

2007, 12.6 percent of CMS-surveyed hospitals, 17.6 percent of Joint Commission-surveyed hospitals, and 22.2 percent of AOA-surveyed hospitals were cited as noncompliant with one of the respective organizations' standards on infection control.

Multiple HHS Programs Collected Data on HAIs, but Lack of Integration of Available Data and Other Problems Limited Utility of the Data

In March 2008, we reported that multiple HHS programs collected data on HAIs but that limitations in the scope of information they collected and the lack of integration across the databases maintained by these separate programs constrained the utility of the data. Three agencies within HHS—CDC, CMS, and AHRQ—collect HAI-related data for a variety of purposes in databases maintained by four separate programs: CDC's National Healthcare Safety Network (NHSN) program, CMS's Medicare Patient Safety Monitoring System (MPSMS), CMS's Annual Payment Update (APU) program, and AHRQ's Healthcare Cost and Utilization Project (HCUP). (See table 2.) We found that the most detailed source of information on HAIs in HHS was the NHSN database. It began as a voluntary program in the 1970s to assist hospitals that wanted to monitor their HAI rates. CDC has drawn on these data to publicly report aggregate trends in selected HAIs, and we found that it was working with a number of states that were implementing mandatory programs for hospitals to submit HAI-related data through NHSN. We reported that the MPSMS database provided CMS with information on national trends in the incidence of selected adverse events among hospitalized Medicare beneficiaries, including a number of different types of HAIs. These data were collected from medical records selected for annual random samples of approximately 25,000 Medicare inpatients. We also reported that the APU program implemented a financial incentive for hospitals to submit to CMS data that were used to calculate hospital performance on measures of quality of care. The program received quality-related data quarterly for a range of medical conditions, including data on three surgical infection prevention measures. We noted that CMS reported the results of its analyses of these data on its Hospital Compare Web site. Finally, we reported that AHRQ sponsored the development of the HCUP databases to create a national information resource of patient-level health care data. Two of the 20 Patient Safety Indicators that AHRQ derived from these data were related to HAIs, one involving infections caused by intravenous lines and catheters, and the other postoperative sepsis.

Table 2: Selected Characteristics of HHS Databases That Contain HAI-Related Information, 2008

Responsible agency and database	HAI-related data collected	Population for which data are collected
CDC's National Healthcare Safety Network (NHSN)	Infection types <ul style="list-style-type: none"> • central-line-associated BSI • catheter-associated UTI • VAP • postprocedure pneumonia • SSI • MDRO^a • other^b 	Most hospitals report on patients in selected critical care units and those undergoing selected procedures such as coronary bypass surgery and colon surgery.
CMS's Medicare Patient Safety Monitoring System (MPSMS)	Infection types ^c <ul style="list-style-type: none"> • central-line-associated BSI • catheter-associated UTI • postoperative pneumonia • antibiotic-associated <i>C. difficile</i> • MRSA • VRE 	National sample of hospitalized Medicare patients.
CMS's Annual Payment Update (APU) database	Practices to prevent or reduce SSIs <ul style="list-style-type: none"> • providing antibiotics within 1 hour of surgery • selecting appropriate antibiotics to prevent surgical infections • stopping the administration of the antibiotics within 24 hours of end of surgery 	National inpatient population for selected surgical procedures. ^d
AHRQ's Healthcare Cost and Utilization Project (HCUP) database, Nationwide Inpatient Sample	Infection types <ul style="list-style-type: none"> • postoperative sepsis^e • "infection due to medical care" (focused on intravenous and catheter infections) 	A sample of inpatients in hospitals in 37 states.

Source: GAO-08-283.

Notes: BSI is bloodstream infection; *C. difficile* is *Clostridium difficile*; MDRO is multidrug-resistant organism; MRSA is methicillin-resistant *Staphylococcus aureus*; SSI is surgical site infection; UTI is urinary tract infection; VAP is ventilator-associated pneumonia; and VRE is vancomycin-resistant enterococci.

^aFor patients whose infections are laboratory-confirmed, NHSN collects data on the pathogens identified, and for specified pathogens (including those responsible for MRSA and VRE), the result of any testing of their resistance to specific antibiotics. Participating hospitals have the option to report separately the number of times in a given month that they tested specimens of any of eight specified organisms for resistance to selected antibiotics, as well as the results of those tests. From these data, NHSN produces rates of antimicrobial resistance relative to the number of nonduplicative specimens tested (i.e., excluding multiple tests for the same organism in the same patient). This part of NHSN does not distinguish between MDRO infections acquired in the hospital and community-acquired infections present at admission.

^bHospitals can choose to submit to NHSN data on other types of HAIs, such as skin and soft tissue infections, cardiovascular system infections, and gastrointestinal system infections. CDC does not provide data collection protocols for these types of infections, but they can be entered into NHSN as "custom events" using definitions provided separately by CDC.

¹In 2007, CMS added catheter-associated UTIs, VAP, MRSA, and VRE to MPSMS and dropped insertion-site infections associated with central vascular catheters, BSIs, and postoperative-associated UTIs.

²The three practice measures are assessed for certain categories of surgeries: coronary artery bypass graft; other cardiac surgery; colon surgery; hip arthroplasty; knee arthroplasty; abdominal hysterectomy; vaginal hysterectomy; and vascular surgery.

³The rate of postoperative sepsis is computed only for patients undergoing elective surgeries.

We found that each of these databases presented only a partial view of the extent of the HAI problem because each focused its data collection on selected types of HAIs and collected data from a different subset of hospital patients across the country. Although two databases—NHSN and MPSMS—addressed many of the same types of HAIs, the former provided information only from selected units of hospitals that participated in the NHSN program (which did not represent hospitals nationwide), while the latter provided information only on a representative sample of Medicare inpatients (i.e., MPSMS did not provide information on non-Medicare patients). In addition, the data collection methods employed by the NHSN, MPSMS, and HCUP databases ranged from concurrent review of patient care as patients were being treated in the hospital, to retrospective review of patient medical records after patients had been discharged, to analyses of diagnostic codes recorded electronically in patient billing data.

Although we noted that officials from the various HHS agencies discussed HAI data collection with each other, we found that the agencies were not taking steps to integrate any of the existing data from the four databases. This integration could involve creating linkages across the databases by, for example, creating common patient identifiers so that data from the same individuals in multiple databases could be pulled together. Creating linkages across the HAI-related databases could enhance the availability of information to better understand where and how HAIs occur. For example, data on surgical infection rates and data on surgical processes of care were collected for some of the same patients in two different databases that were not linked. In our March 2008 report, we concluded that, as a consequence, the potential benefit of using the existing data to monitor the extent to which compliance with the recommended surgical care processes led to actual improvements in surgical infection rates had not been realized. In its January 2009 Action Plan, HHS proposes remedying this situation by undertaking a series of short- and longer-term initiatives to coordinate and align its various HAI-related data collection activities, under the guidance of a new interagency working group.

In our March 2008 report, we reported concerns with the use of HAI data for providing a national picture of HAIs. Although none of the databases collected data on the incidence of HAIs for a nationally representative sample of hospital patients, CDC officials had produced national estimates of HAIs. However, those estimates derived from assumptions and extrapolations that raised questions about the reliability of those estimates. In its Action Plan, HHS proposes to draw on some of the same data sources—primarily NHSN—to track progress in reducing the incidence of five of its six targeted HAIs.

Concluding Observations

HAIs in hospitals can cause needless suffering and death. Federal authorities and private organizations have undertaken a number of activities to address this serious problem; however, to date, these activities have not gained sufficient traction to be effective.

In our March 2008 report, we identified two possible reasons for the lack of effective actions to control HAIs. First, although CDC's guidelines are an important source for its recommended practices on how to reduce HAIs, the large number of recommended practices and lack of department-level prioritization hinder efforts to promote their implementation. The guidelines we reviewed contain almost 1,200 recommended practices for hospitals, including over 500 that are strongly recommended—a large number for a hospital trying to implement them. A few of these are required by CMS's or accrediting organizations' standards or their standards interpretations, but it is not reasonable to expect CMS or accrediting organizations to require additional practices without prioritization. Although CDC has categorized the practices on the basis of the strength of the scientific evidence, there are other factors to consider in developing priorities. For example, work by AHRQ suggests factors such as costs or organizational obstacles that could be considered. The lack of coordinated prioritization may have resulted in duplication of effort by CDC and AHRQ in their reviews of scientific evidence on HAI-related practices.

Second, we reported that HHS had not effectively used the HAI-related data it had collected through multiple databases across the department to provide a complete picture of the extent of the problem. Limitations in the databases, such as nonrepresentative samples, hinder HHS's ability to produce reliable national estimates on the frequency of different types of HAIs. In addition, data collected on HAIs are not being combined to maximize their utility. HHS has made efforts to use the currently collected data to understand the extent of the problem of HAIs, but the lack of

linkages across the various databases results in a lost opportunity to gain a better grasp of the problem of HAIs.

HHS has multiple methods to influence hospitals to take more aggressive action to control or prevent HAIs, including issuing guidelines with recommended practices, requiring hospitals to comply with certain standards, releasing data to the public to expand information about the nature of the problem, and using hospital payment methods to encourage the reduction of HAIs. Prioritization of CDC's many recommended practices can help guide their implementation, and better use of currently collected data on HAIs could help HHS—and hospitals themselves—monitor efforts to reduce HAIs. In our March 2008 report, we concluded that leadership from the Secretary of HHS was lacking to do this and that without such leadership, the department would not be able to effectively leverage its various methods to have a significant effect on the suffering and death caused by HAIs.

The recently released HHS Action Plan identifies strategies that are intended to address some of the reasons for the lack of effective actions to control HAIs, including some identification of priorities from among the 1,200 recommended practices, and plans to coordinate HAI-related data collection activities across HHS. HHS released the Action Plan for comment in early January 2009, with the intent of revising it based on the public input it received. Following the transition to the new presidential administration, HHS has continued to solicit public comments on the plan with no designated deadline for submissions. Consequently, it remains uncertain when or if the new administration will choose to implement this plan, and if so, with what modifications, to address our recommendations and reduce the serious problem of HAIs.

Mr. Chairman, this completes my prepared remarks. I would be happy to respond to any questions you or other members of the subcommittee may have at this time.

**Contacts and
Acknowledgments**

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News From
Senate Finance Subcommittee on
Health Care

For immediate release: March 18, 2009
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CHAIRMAN ROCKEFELLER
OPENING STATEMENT
"QUALITY HEARING: WHAT IS HEALTH CARE
QUALITY AND WHO DECIDES?"

Good afternoon. I am thrilled to be here today with my friend and colleague, Senator Hatch, as we commence the first of many Subcommittee hearings on health care reform. I would also like to thank each of our witnesses for being here today, and I will introduce each of them shortly.

I have been working on health care policy for more than 25 years, and I have never been more hopeful about the prospect of reform – or more convinced about the overwhelming need for reform – than I am now.

We are on the brink of bringing real change to working families and it's about time. Will it be easy to do? No.

But nothing worth doing is ever easy.

Right now, we have an overwhelming opportunity before us to make sweeping changes to our health care system – and one of the most important changes is improving the quality of care delivered.

Too often, we hear stories of loved ones and strangers who have contracted infections or suffered greater injury than necessary because the care they received was not of the best quality.

This could be anything from a central line infection in a hospital to improper diagnosis and treatment for heart disease.

Creating a delivery system that rewards quality care and improves health outcomes is an absolutely essential part of health reform.

According to the Department of Health and Human Services, the United States will spend nearly \$8,160 per person on health care this year, more than any other country in the world.

Yet, more of our children die and we live shorter lives than almost any other developed country.

This is simply unacceptable.

Right now, we pay health care providers for quantity – the number of services delivered – instead of quality – whether or not the services provided actually improve patient health.

This must change. Now.

I believe we must significantly alter federal provider payment policy so that we only pay providers for achieving good health outcomes for patients.

In order to transform our system into one that promotes greater quality and improves patient health, we first need a solid understanding of the landscape of quality today.

We must know how the federal government defines health care quality for federal health programs.

We must also understand how the Department of Health and Human Services uses established definitions of quality to implement quality improvement activities in federal programs, like Medicare.

Finally, it is important to understand how all the public and private entities that deal with health care quality coordinate their efforts – and if there is room for improvement.

In the end, our goal is to improve health care quality in a way that is coordinated, meaningful, and reasonable for both providers and their patients.

We must get this right if we are to successfully reform health care.

We have three very experienced and knowledgeable witnesses with us today:

- First, we have **Dr. Carolyn Clancy**. Dr. Clancy is the Director of the Agency for Healthcare Research and Quality (or AHRQ). Thank you for being here, Dr. Clancy.
- Next, we have **Dr. Brent C. James** joining us from Senator Hatch's state - Salt Lake City, UT to be exact. Dr. James is Chief Quality Officer and Executive Director of the Institute for Healthcare Delivery Research at Intermountain Healthcare. Welcome, Dr. James and thanks for traveling to join us.
- Last, but certainly not least, we have **Dr. Marjorie Kanof** with us this afternoon. Dr. Kanof is Managing Director of Health Care at the Government Accountability Office. Thank you for being here.

Our witnesses will help us gain a better understanding of the quality landscape today.

I look forward to their thoughtful testimony and now would like to turn it over to Senator Hatch for his opening statement.

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COMMUNICATIONS

STATEMENT
Of



For the
U.S. Senate
Subcommittee on Health Care of the Committee on Finance

Hearing on
“What is Health Care Quality and Who Decides?”

March 18, 2009

The American Health Care Association and National Center for Assisted Living (AHCA/NCAL), which represent nearly 11,000 dedicated long term care providers, commend Chairman Jay Rockefeller and Ranking Member Orrin Hatch and the members of this committee for holding this hearing and for asking a fundamental question, “What is Health Care Quality and Who Decides?” For long term care providers, the answer to that question must come from the health care consumer and accompany the answer to yet another key question—how is quality measured and who decides what measures are not only valid, but meaningful to the health care consumer?

Consumer-Defined Quality

As the majority of Americans will require long term care services at some point in their lives, this Committee’s effort to address these critical questions now is especially important as we look toward much-needed, national health care reform—reform that AHCA/NCAL believes must include and address Americans’ long term care needs.

To begin, we must understand—from the viewpoint of the health care consumer—what consumers want, need, and expect when it comes to long term care and other health care services. “Quality” will surely be at the top of a consumer’s list, and not just quality of care, but quality of life. Perhaps the best way to answer the question, “What is Health Care Quality and Who Decides?” is to ask consumers – actual health care consumers and not just those who claim to represent the consumer voice – to define quality. Once consumers have defined quality and have articulated what care and services they want and need, then providers can adapt to meet consumers’ expectations.

Reforming Oversight Around Consumer Expectations

As we consider health care from the consumer's perspective, we cannot ignore the impact that regulatory reform could have on quality long term care. Today's regulatory and oversight system for nursing homes does little to recognize or reward quality outcomes – in fact, it defines “success” and quality in a context that is often measured by the level of fines levied and the violations tallied – not by the quality of care, or quality of life.

While it may be a fine point, it is important to note in the context of health care reform that the Quality Measures (QMs) now used by the Centers for Medicare & Medicaid Services (CMS) to evaluate nursing home care were developed as a means for measuring quality improvement – not care quality. For example, a QM that looks at the prevalence of a particular patient condition tells us more about the patient population being treated in long term care than it does about whether that condition is related to the care received. In other words, QMs can provide valuable information if the goal is quality improvement; however, these QMs are limited in terms of being meaningful to anyone interested in evaluating the quality of care that patients and residents are receiving.

With CMS presiding “over 150 regulatory standards¹ that nursing homes must meet at all times,” it is little wonder that consumers would seek a simple way to assess quality nursing home care. Unfortunately, CMS' answer to the consumer – its Five Star Quality Rating System – fails to help consumers make sound, health care decisions.

Based on a flawed survey system that was never designed to measure quality, but rather compliance with federal regulations, the Five Star system includes inaccurate and out-of-date information, while predetermining that 20 percent of all facilities would achieve a status of only 1 star. At best, this system merely adds to the confusion around how we define and reward quality care. At worst, this system ignores the laws of logic as CMS purports to use Five Star as a means of encouraging providers to improve care, while in fact, it restricts the 5 star category to only 10 percent of all facilities. Moreover, to say that consumers are not going to see a Zagat-like rating guide as a measure of poor, average, and best nursing homes is to ignore human nature.

Just as every one of our nation's nursing home residents deserves the highest quality nursing home care, consumers deserve accurate, consistent and comparable data when choosing a nursing facility for a loved one. Satisfaction of patients, residents, and family members is a critical measure of quality, which is why AHCA/NCAL has encouraged our membership to survey resident, family, and employee satisfaction. In May 2008, My InnerView, Inc. (MIV), which offers Web-based quality management systems, released its independent, annual report on patient and family satisfaction for the care and services provided in nursing facilities. The report's findings indicate that the vast majority of consumers (82 percent) nationwide are very satisfied with the care provided at our nation's nursing homes, and 88 percent of respondents would rate care as either good or excellent.”

A January 2006 GAO report on nursing home oversight indicates that the nation's Survey and Enforcement System for nursing homes is consistently inconsistent, with significant

variations from state to state. AHCA and our members have long maintained that a one-dimensional punitive approach does not get to the overall goal of achieving quality care.

In looking at our survey and enforcement system, what most people have not considered is how the survey process impacts caregivers in nursing homes. The system focuses solely on operational shortcomings with rare positive acknowledgement for the quality of services provided. Certainly, surveys must first protect the health and safety of residents, and also be fair, accurate, and consistent. But, if we are to improve care, we must also begin to recognize our most valuable resource—the human capital that work within our facilities and within our profession.

Human Capital – Addressing the Workforce Shortage

A common theme echoed by presenters at a recent Institute of Medicine (IOM) symposium focusing on the IOM report, *Retooling for an Aging America: Building the Health Care Workforce*, was the need for more health care professionals who are trained in geriatric care, including: nurses, oral health workers, pharmacists, physician assistants, physicians, and social workers. AHCA/NCAL agrees—a well-trained nursing staff is essential to quality long term care, which is why the current healthcare workforce and nurse educator shortage requires immediate attention.

AHCA's *Vacancy & Turnover Survey* released in late 2008 indicates that there are more than 110,000 vacant nursing positions nationwide. More than two-thirds of nursing schools have vacant faculty positions, many lack the resources to fill or create new positions. In 2005, the National League of Nursing estimated that more than 147,000 qualified applicants were denied admission to nursing schools because the schools did not have enough nurse educators. With the projected need for long term care workers equal to 800,000 new jobs in this decade, we cannot afford any more delay in addressing today's workforce shortage. Retaining this workforce is also a challenge—again, one that is made more difficult by a survey and enforcement system that foregoes acknowledging the quality of services provided in favor of focusing solely on operational shortcomings.

Realigning Priorities to Reflect Our Society's Values

The investments we make now will affect the quality of long term care in the future. With a financing system that pays for the care consumers expect; an oversight system that is fair, consistent, and rewards quality; and a workforce that meets the growing needs of our nation, we have the components for a system that encourages transparency, accountability, and continued improvement in quality care.

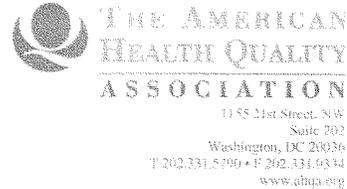
None of us would have wished for the economic upheaval our country is experiencing. Yet, we welcome the opportunity to do as President Obama has said—to respond to this economic upheaval with big ideas and bold action that will realign our nation's budgetary priorities with our society's values.

The fact is healthcare reform has been delayed – and long term care has been left on the sidelines—for far too long. Now is the time to change that fact. In the coming weeks, Avalere Health will be releasing an update to last year’s *Long Term and Post-Acute Care Financing Reform Proposal* for reforming both financing and delivery of long term and post-acute care. We understand from Avalere Health, which has worked with AHCA/NCAL and the Alliance for Quality Nursing Home Care on this proposal, that the update will include conservative cost-estimates that illustrate how the comprehensive reform plan will provide budgetary savings over time. We look forward to sharing this proposal and its recommendations for maximizing patient preferences and program value by ensuring that patients are cared for in the most clinically appropriate, high quality setting.

As caregivers, we know that patients and families are the ultimate arbiters of the quality we provide. The American Health Care Association and National Center for Assisted Living stand ready to work with Chairman Rockefeller, Ranking Member Hatch, and all who have a stake in reforming our nation’s health care system to achieve person-centered, cost-effective, quality health care for all Americans.

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ⁱ Source: “About Nursing Home Inspections,” see <http://www.medicare.gov/Nursing/AboutInspections.asp>.



**U.S. Senate, Committee on Finance
Subcommittee on Health
Statement of the American Health Quality Association
David G. Schulke, Executive Vice President
March 18, 2009**

This statement is submitted to the Finance Subcommittee on Health for its hearing, “What Is Health Care Quality and Who Decides?” The American Health Quality Association (AHQA) represents the national network of state-based Quality Improvement Organizations (QIOs). QIOs serve as contractors to the Centers for Medicare and Medicaid Services (CMS) and other public and private payers, purchasers, and providers seeking to improve outcomes across the continuum of health care delivery settings.

The Importance of Health Care Quality Improvement

Health care in the United States is often justly criticized for its high cost and suboptimal performance in reliably delivering evidence-based recommended care. Dramatic improvements in quality and efficiency are needed within daily health care operations if we are to ensure that patients are consistently provided services that medical research finds effective and efficient. The change must take place at the ground level, where care is delivered. Health care reform must emphasize and support improvements in the quality and efficiency of care delivered across the range of settings, as well as transitions between those settings. Payment reform provides motivation and capital to encourage greater quality and efficiency among providers. However, payment reform alone cannot speed the pace of learning and implementation of best practices among competing providers. We believe the promise of health care reform will not be fully realized without a field force working with providers to accelerate the pace of learning and improvement in care.

The QIOs are that field force of change management expeditors. The national network of QIOs is a valuable public infrastructure, trusted by key stakeholders, experienced in responding to federal direction, and effective in quality performance measurement, public education, and improvement.

Overview: QIO Contributions to Reforming the Health Care Delivery System

We propose five ways this field force of QIOs can speed the pace of improvement in the health care delivery system. The Medicare scope of work for the QIO program, and the Medicaid program’s quality oversight system, should be expanded to satisfy the following aims:

- (1) Ensure payment incentives do not unintentionally widen the quality gap between “have” and “have not” providers and practitioners.
- (2) Assist health professionals in planning for, purchasing, and using health IT in daily practice to promote wellness, timely preventive care, and manage patients’ chronic care needs.

- (3) Support providers' incorporation of evidence-based comparative effectiveness findings into daily care practices.
- (4) Link hospitals and providers of ambulatory care in community-based initiatives to improve the safety and reliability of transitions between care settings, reducing costly hospital readmissions.
- (5) Analyze, report and explain how to use data on providers' quality performance to providers, practitioners, purchasers, and the public.

Safeguard Against Inequitable Outcomes Resulting from Payment Incentives

Payment reforms have been widely discussed as a method to encourage providers to self-assess and publicly report quality performance. These are useful tools for bringing about awareness of clinical shortcomings and stimulating improvement. Providers serving patient populations that are well-insured, healthier, better-educated, or from a higher socioeconomic stratum are well-positioned to hire consultants or draw on shared corporate resources to respond to financial incentives for reporting and improvement. However, many providers are less able to compete for lucrative partnerships, academic affiliations, or attract better educated, well-insured customers seeking elective procedures. These providers include safety net providers, providers disproportionately serving vulnerable patient populations, small community hospitals and rural providers.

These providers are likely to struggle to hire and retain the experienced staff and commercial consultants needed to lead implementation of cutting-edge, high-performance practices. Without special assistance, incentive payments are likely to widen the quality gap between the "have" and "have not" health care providers¹. This problem will worsen if Congress finds it is necessary to enact budget-neutral incentive programs in which the cost of payments to those who qualify for incentives are offset by reductions in payment to those who do not.

Recommendation: Special assistance should be offered to these providers by focusing Medicare QIO assistance on meeting their needs. In the area of public reporting, QIOs have been successfully providing assistance to Critical Access Hospitals (CAHs) for several years, resulting in steady growth in the number of CAHs reporting quality performance even in the absence of payment incentives offered to PPS hospitals. A number of studies strongly suggest that QIOs have effectively assisted providers in improving care (see appended summary of studies).

While AHQA recommends making substantial QIO assistance available to those providers and practitioners least able to qualify for incentive payments because of their size, funding, or service to vulnerable populations, we caution against unduly restricting QIO assistance so that it is available *only* to these providers. Both to improve equity and to permit effective learning techniques, it is important to permit QIOs to recruit significant numbers of high-performing providers to participate in quality improvement initiatives. This will ensure QIOs can engage both higher performing and lower-performing hospitals in learning collaboratives to share improvement strategies. This method aims to accomplish *community-based* quality improvement in which a large number of health care providers work together to offer patients the best possible care, raising the quality of care across the board in a community. This approach minimizes the likelihood that a consumer will choose or be referred to a low quality provider.

Implementing Health Information Technology and Health Information Exchange

Public policy debate about health information technology (HIT) has focused on the slow pace of adoption in the United States; a positive impact on the quality of care is generally assumed. While HIT been shown in several studies to improve processes of care where it is in place and used by clinicians², some studies have not confirmed this finding.³ Others note that while care processes may improve with use of HIT, there is still little evidence that HIT improves patient outcomes (other than in the care of end stage renal disease patients).⁴ In their recent study, Linder and colleagues found no association between ambulatory care quality and possession of EHR technology, cautioning that “as EHR use broadens, one should not assume an automatic diffusion of improved quality of care. . . Policy makers should consider steps to increase the likelihood that further diffusion of EHR has the desired effect of improving quality of care.”

The slow pace of HIT adoption is unquestionably a problem that calls for action. The American Recovery and Reinvestment Act (ARRA) took an important step in assisting providers afford the cost of EHR adoption. But physicians and health professionals lack training and experience in the process of evaluating their current care processes, conceiving a better way to organize their care teams, and retraining themselves to take advantage of the capabilities of new information systems. There is evidence many providers and office practices have purchased inadequate clinical decision support software (CDSS), or are not using their CDSS to improve care management despite having purchased a fully functional system⁵.

While the ARRA does contain technical assistance provisions for small physician offices, it will be vital for that technical assistance to be competent to aid physicians and medical practice staff through the entire change management process. Using the full capability of EHRs, including care management and improved health outcomes, requires a redesign of a practice’s entire clinical workflow. There has been little in the way of technical assistance for small physician practices. Commercial consultancy firms have had little interest in serving typical office practices and small providers, even if those practices and providers could afford to hire them. This is unfortunate, because the majority of ambulatory care physicians work in practices of three or fewer physicians. Health care reform must ensure not only that EHRs are being purchased by small physician practices, but that their full implementation and use is being used to transform the quality and efficiency of care provided by the practice.

QIOs worked with hundreds of hospitals and 3,600 physician offices from August 2005-July 2008, assisting them in re-designing their clinical workflow to incorporate HIT into daily practice. The QIO-assisted practices exceeded expectations in using their EHRs for care management, and the QIO program influenced HIT vendors to make significant changes in their programming to enable physicians to generate care management reports. Demand was so strong that QIOs had to turn providers away. An independent evaluation found three-quarters of practices were satisfied with the QIOs’ knowledge of technology options, their ability to appropriately assess the practice’s technology needs, and their assistance in improving the quality and efficiency of care.^{6,7}

Recommendation: Medicare should build on the success of the QIO program helping providers and practices plan for adoption of HIT, select software and hardware, and modify daily clinical workflow to incorporate technology into their caregiving. QIOs also help providers report their performance, supporting public accountability. QIO assistance should not be limited only to practices that already possess EHRs, as it is today, but should once again be made available to speed the pace of adoption and reduce the number of providers that fail in their implementation efforts.

Ensuring Implementation of Comparative Effectiveness Research Findings

The Congressional Budget Office has reported that “hard evidence is often unavailable about which treatments work best for which patients and whether the added benefits of more effective but more expensive services are sufficient to warrant their added costs” and suggested that “generating additional information comparing treatments would tend to reduce federal health spending somewhat in the near term,” though perhaps not enough to offset the costs of research in the short term.⁸ The Medicare Payment Advisory Commission (MedPAC) concluded that “the Congress should establish an independent entity whose sole mission is to produce and provide information about the comparative effectiveness of health care services.”⁹

However, most studies trace the poor performance of the current system to failures by health care organizations, providers, practitioners and even patients to routinely implement, day-in and day-out, what is already known. The nation’s continuing challenge is to move new research findings from the bookshelf to the bedside. Dissemination of comparative effectiveness research, too, is likely to languish on the bookshelf without a sustained national effort at incorporating that knowledge into the local, day-to-day clinical workflow.

QIOs are perfectly situated to accomplish this mission. Fostering integration of evidence-based medicine in everyday clinical care has been a primary purpose of the QIOs ever since the multi-state Cooperative Cardiovascular Project demonstrated in 1995 that QIOs improved use of evidence-based heart attack treatments and reduced mortality. Studies document that QIOs combine clinical expertise with change management to speed adoption of evidence-based medicine (see Appendix A).

Recommendation: The Medicare program should task QIOs to help physicians implement Comparative Effectiveness findings that the Secretary determines would yield clinically significant improvements in the safety or effectiveness of health care. The Secretary would be required to evaluate QIO work using measures that have been endorsed by the National Quality Forum.

Improving Transitions of Care and Reducing Readmissions

MedPAC reported to Congress in 2007 that unsafe and poor quality care occurs with disturbing frequency as patients transition between care settings. One result is that about 18% of Medicare patients discharged from a hospital are readmitted within 30 days; MedPAC estimated three-quarters of those readmissions are preventable, adding \$12 billion to Medicare costs¹⁰. A similar proportion of patients discharged from a hospital experience an adverse event within 3 weeks of discharge from a hospital, with two-thirds of the problems being adverse drug events—most of them preventable.¹¹

Systems to follow up hospitalizations and assure that patients receive safe and effective care after being sent home or to a nursing home are generally lacking. Following up with these patients after discharge is currently no one’s job; patients and families must manage these transitions for themselves. The skilled health professionals working in hospitals, nursing homes, home health agencies and in physician offices are isolated from one another in care “silos” and often don’t understand what the “downstream” providers need in the way of information and follow up. “Bundling” payments to providers and practitioners could encourage a shared financial as well as professional interest in better linkage of care between settings. However, bundling methodologies are not yet ready; when they are, providers will implement them faster with assistance.

For many years, QIO initiatives have focused on the hospital discharge component of care transitions. QIOs have helped hospitals more reliably give patients written discharge medication

orders after hospitalization for heart attack, heart failure and community acquired pneumonia—to reduce the risk for readmission due to missing needed long-term drug therapy. Quality measures for these important hospital functions have steadily improved during this period. However, little has been done by QIOs or others to ensure that caregivers in the community have the information they need and are working together to provide timely follow up after a patient transitions from a hospital.

In 2008, CMS launched 14 QIO pilots to improve critical aspects of care transitions. These projects include discharge instructions for hospital patients; follow up “coaching” phone calls after discharge; and convening of community-based workgroups of hospital, physician, and post-acute care provider staff who have informal referral relationships that result in them often treating the same patients. The QIOs introduce practices to ensure the timely flow of information between the providers and practitioners, and trigger timely follow-up, such as physician visits within a few days of discharge. Results from the initial pilot suggest dramatic reductions in rehospitalizations are being achieved. These initial results bode well for saving Medicare money through safer and better quality care.

Recommendation: Medicare should expand the current 14-state QIO project nationally to improve coordination and follow up of patient care as patients transition from one care setting to another.

Publicize and Promote Reliance on Quality and Cost Performance Data

Currently, QIOs are founding members of twenty out of twenty-four chartered value exchanges (CVEs), entities designated by HHS Secretary Leavitt as community based partnerships to promote transparency in health care cost and quality. In several cases, QIOs are co-convenors of their local CVE organization.

QIOs currently have extensive access to Medicare claims data, but operate under strong confidentiality requirements that prohibit the release of that data to the public or to other providers. The restrictions in current law exceed those governing private third party payers, which commonly share clinical data with physicians and others when needed to improve care or hold providers accountable. The QIO statute should be amended to allow QIOs to release aggregated de-identified quality and cost data for hospitals, nursing homes, home health agencies and physician practices. Standards must set limits on this authority to ensure that only valid and reliable data is published.

Likewise, transparency data that is not explained or provided in a user-friendly manner will have little influence on patient decision-making. QIOs can analyze and explain complex data to the public in a format tailored to their communities, while respecting the limitations of the data. QIOs should also ensure that providers have an opportunity to review their data first in order to validate it and learn from QIOs how to interpret and appropriately respond to quality performance feedback reports.

Recommendation: Include in the Medicare QIO contracts the responsibility to conduct claims data analysis on cost and quality performance, educate the public (working with CVEs and local partners) about what the findings mean, and work directly with providers and purchasers to improve care.

Studies of the Effectiveness of the QIOs in

Promoting Population-based Quality Improvement:

An Annotated Bibliography

In addition to targeted, case-based quality improvement, since the launch of the Cooperative Cardiovascular Project in the mid-1990s, QIOs have implemented community-wide and statewide improvement initiatives to reduce the gap between scientific evidence and daily clinical care. Although the IOM could not find national studies published by late 2005 that proved QIO effectiveness to a scientific certainty, a number of state and multi-state studies published before and after the IOM review strongly suggest that QIO technical assistance to providers is valuable in improving the quality of care.

- 89% of respondents reported in a survey of 462 hospitals weighted to be representative that QIOs' influence on their quality improvement activities were "very positive" (59%) or "somewhat positive" (30%). (Medical Care and Review, June 2008)
- Nationwide, physicians, nursing homes, and home health agencies working intensively with QIOs achieved greater improvement on 18 of 20 clinical quality measures than providers that did not work intensively with a QIO. (Annals of Internal Medicine, September 2006)
- 33 hospitals reduced patient heart attack mortality by 21% to 26% working with the American College of Cardiology, the Michigan QIO, and supported by a local business coalition. (Journal of the American College of Cardiology, October 2005)
- A national QIO project reduced hospital post-surgical infections by 27%. The publication's editor called the outcome "a critical accomplishment in the surgical world, showing measurable and consistent improvement in performance." (American Journal of Surgery, June 2005)
- A QIO intervention improved the quality of cardiovascular care for patients in 24 Massachusetts hospitals, leading to "enhanced adherence to prevention guidelines" associated with better patient outcomes. (Archives of Internal Medicine, January 2004)
- QIO assistance to small rural hospitals substantially improved pneumonia care in 20 rural Oklahoma hospitals compared to a control group of 16 similar hospitals. Midway through the project, the QIO brought their intervention to the control hospitals, which improved to a similar degree. (Archives of Internal Medicine, February 2003)
- QIO interventions improved quality of bypass surgery in 20 Alabama hospitals over a two-year period, compared to control hospitals. (JAMA, June 2001)
- QIO quality measurement and assistance to hospitals improved adherence to evidence-based practice guidelines, significantly reducing heart attack mortality in four states compared to hospitals without QIO support. (JAMA, May 1998)

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**Statement
of the
American Medical Association
For the Record
Senate Committee on Finance
Subcommittee on Health Care**

Re: What is Health Care Quality and Who Decides?

March 18, 2009

The American Medical Association (AMA) appreciates the opportunity to provide our views regarding health care quality. As we move forward in the new millennium, health care quality is and will continue to be a key factor in the delivery, payment, and coverage of health care across the country. The AMA has long been at the forefront of quality efforts and we continue to be committed to the development of quality improvement initiatives that increase the quality of care provided to patients.

Commitment of the Physician Community to Quality Improvement

As leaders in the profession of medicine, the AMA shares with Congress, the Administration, and other stakeholders a sense of urgency and responsibility to meet the challenges that we face in creating a sustainable 21st Century health care system. We are committed to creating a cultural transformation that better supports delivery of the highest quality care for individual patients and communities and which, among other strategies, will allow for a more appropriate allocation of finite resources. These two elements are extremely important, and we hold ourselves accountable to achieve them.

The Role of the Physician Consortium for Performance Improvement

The AMA has long advocated for initiatives that advance the delivery of quality health care to patients. In 2000, the AMA convened the Physician Consortium for Performance Improvement (PCPI) to develop clinical performance measures that are patient-focused and that can be implemented to improve patient outcomes. It is critical that physicians develop the quality measures used in any quality reporting or other quality improvement program. This ensures that the measures are accurate and clinically relevant to patients. Without this tenet, a quality program cannot achieve its quality improvement goals.

The PCPI actively engages all stakeholders, including payers, patient advocates, and organizations that are committed to high quality care. The PCPI is comprised of over 100 national medical specialty and state medical societies, the Council of Medical Specialty Societies, American Board of Medical Specialties and its member-boards, experts in methodology and data collection, the Agency for Healthcare Research and Quality, and the Centers for Medicare and Medicaid Services (CMS). In addition, in January 2009, the PCPI extended invitations to the American Optometric Association, American Physical Therapy Association, and American Dental Association to join the PCPI as voting members. This expansion will increase the ability of the PCPI to achieve consensus on its measures and their implementation across the health care continuum.

The PCPI operates through a transparent, cross-specialty, consensus-based process for developing physician-level measures that are evidence-based and include enhanced relevance to clinical practice. The PCPI has worked aggressively in developing to date 266 physician performance measures and specifications covering 42 clinical topics and conditions. These measures are available for implementation and many have been adopted by CMS for use in quality improvement demonstration projects and Medicare's Physician Quality Reporting Initiative (PQRI). Currently, 77 percent of the 2008 PQRI measures were developed by the PCPI.

In addition, the PCPI ensures that its measures, through their translation into Current Procedural Terminology (CPT) II codes, capture clinically relevant information about variations in care, such as whether there are medical or patient reasons for not providing a treatment or service. This practice level information lends itself to identifying variation in local health care delivery systems and across geographic boundaries. To date, this information has not been readily available or captured at the point of care. Currently, institutions such as academic medical centers, federally qualified health clinics, and local physician practices are using this data on variation to improve the care at the practice level. Discussions are also underway to have PCPI measures embedded in registries and electronic health record systems (EHRS).

Finally, the AMA-PCPI has developed PQRI participation tools to help improve the ease of participation in the program. Many specialties societies have utilized these tools in educating their members about PQRI participation, and before this year CMS contracted with the AMA-PCPI to develop these tools for its website. Although CMS completed its contract with the AMA-PCPI, the PCPI has continued to develop and update these tools for the 2009 PQRI.

Physician Consortium for Performance Improvement Activities to Advance Quality Efforts into the Future

The PCPI recognizes and seeks to promote quality improvement programs and measures that apply to patients across the continuum of care and can be used by physicians across a variety of practice settings. The PCPI, therefore, is advancing its work to incorporate the concepts of grouping or bundling measures and moving beyond individual level measurement. Specifically, the PCPI is developing measures in overuse, care coordination for transitions between certain care settings, and other high-impact areas identified by the NQF National Priorities Partnership. Each of these types of measures will provide a more comprehensive picture of all aspects of care and identify where the greatest impact for quality improvement

can occur. In addition, the PCPI will develop these measures for specific clinical conditions to fit within episodes of care, as applicable.

Further, PCPI efforts are underway to better communicate and document why a measure was developed and, if it is a process measure, what is the link to a patient outcome. As a part of the development process, a rationale behind a measure's construction and the reasons it may or may not be used at the individual or group level will be provided. In addition, whether a gap in care or variations in care exist will be explicitly discussed, and any efforts to harmonize with existing measurement sets will be outlined.

Vision for Achieving Significant Progress in Quality Improvement and Delivering Health Care

The AMA is collaborating with health care professionals, consumer groups, public and private payers, quality organizations, and employers to advance policy decisions concerning quality by broadening discussions to include a framework for creating a "patient-centered culture" throughout the health care system, which we believe is integral to achieving both high quality and high efficiency healthcare delivery. To promote this transformation, we envision moving from a focus of data aggregation and reporting at the national level to a focus that includes "real time" data availability for decision making, timely review of measurement results to identify leverage points, best practices to improve the quality of care, and incorporation of a broader set of evaluation tools.

The critical components to achieving this new patient-centered focus are as follows:

- There is **shared decision making** among each patient, caregiver, and the accountable team of physicians and health care professionals in understanding treatment options, selecting treatment plans, and the desired outcomes.
- There is **shared understanding of quality**, along with the ability to practice in a 21st Century system.
- The team of healthcare professionals: (i) has **timely access to patient records** to avoid redundancy and patient risk; (ii) has **access to comparative-effectiveness research** information to assist in value-based decision-making at the point of care, (iii) is **implementing a set of performance measures** (based on clinical evidence and supported by their profession and other stakeholders) which encompass processes, outcomes, and appropriateness of care; (iv) **enters patient data into EHRS once**, and the EHRS provides decision support, performance measurement results, and the ability to export data to other entities overseeing professional accountability, data aggregation, and public reporting; (v) **reviews performance reports** routinely to identify areas for improvement—these reports would include risk-adjusted information on variations in care, particularly across patient co-morbidities as well as patient race, ethnicity, primary language, and other relevant demographic characteristics; and (vi) **implements best practices** from participation in a Quality Improvement (QI) collaborative—partnership among local and state entities that provide resources, tools, technical assistance, and training on quality improvement techniques.

- The profession of medicine collaborates to: **consistently set targets; evaluate its progress on improving patient outcomes and effectively managing resources; determine which improvement methodologies have the greatest impact in practice; monitor unintended consequences; and practice transparency and accountability by reporting findings broadly.**

The foundation for this cultural transformation exists today, and the AMA in collaboration with other stakeholders is moving forward on these fronts. There remains, however, tremendous work to accomplish the foregoing. In addition, efforts are ongoing to develop: (i) clinical guidelines by medical specialty societies that translate the evidence (including experience from practice) into recommendations, with regular updates; (ii) training for medical students and residents that includes quality and safety strategies and requirements to demonstrate competence in these areas; (iii) maintenance of board certification requirements that include self-evaluation of practice using measurements for quality and efficiency as well as a broader set of evaluation tools that assess patient experience and physician characteristics critical at the point of care, such as diagnostic acumen, clinical judgment, and medical knowledge; (iv) condition-specific data registries for timely feedback to physicians and external reporting; (v) best practices in integrating performance measures into EHRs, using the data at the point of care, and exporting data from EHRs to a data warehouse for external analysis; (vi) coding methodology for tracking variation in care and a schema for providing measure specifications to EHRs vendors; and (vii) best practices that work in complex practice environments. Further, as discussed above, the PCPI is developing sets of clinical performance measures that will include not only process measures—including measures of overuse—but also measures of outcomes and measures for teams of health care professionals.

The AMA is dedicated to working collaboratively with others to improve quality, and our physicians are committed to delivering high quality care for patients while increasing efficiencies in health care. The physician community is in a unique position to advance a patient-centered culture and, therefore, must be an integral partner in all national efforts to transform our health care system.

The Development of Effective Physician Quality Improvement Initiatives

Experience with the PQRI

In moving toward the vision discussed above, the development of effective quality improvement initiatives is critical. These programs must be thoughtfully developed in order to avoid unintentional adverse consequences such as patient de-selection, unwarranted penalties for physicians, conflicting and potentially erroneous information for patients and physicians, lack of participation in the program, and inequitable payment and coverage decisions.

The AMA has been working aggressively with the physician community, Congress, and the Administration to advance the use of and improve the development of effective quality improvement initiatives. For example, we have been working with CMS to address significant issues with the PQRI. Many of these problems were outlined by CMS in its December 2008 report detailing its experience with the 2007 PQRI. According to CMS data,

about 16 percent of physicians attempted to report on measures in the 2007 PQRI, but only half received bonuses. Feedback reports and bonuses were not disseminated until 7 months after the reporting period ended, well after this information could be used by physicians to correct reporting procedures for either 2007 or 2008. Physicians' reported to the AMA that initial experiences with the PQRI program were extremely discouraging, and thus the AMA has provided CMS with several important recommendations for changes to the PQRI calling for: (i) early education and outreach for physicians and carriers; (ii) timely confidential interim and final feedback reports; and (iii) easier access to feedback reports. We also urge Congress to provide an appeals process for physicians who participate in the PQRI. Because of measure algorithms applied to the 2007 PQRI, some physicians may have been inaccurately deemed unsuccessful participants. This underscores the need for physicians to have appeal rights under the PQRI. Finally, CMS should work more closely with its contractors to ensure physicians have access to information regarding PQRI program changes, as well as information about participation, bonus payments, and feedback reports. Posting information on the CMS PQRI website and conducting national provider calls are not enough.

The AMA is encouraged that CMS discussed in its 2007 PQRI report opportunities to work with medical specialties to improve successful participation in the program, including quarterly aggregate feedback reports by measure for the 2008 PQRI reporting period. These first feedback reports were posted at the beginning of March, and provide aggregate reporting information for January–September 2008. CMS is also considering ways to improve the feedback report process without compromising data security, and has conducted focus groups to evaluate the content of feedback reports to make them more useful for PQRI participants. Finally, CMS has also undertaken modifications to the PQRI program's analytics and algorithms to address problems with PQRI claims processing issues. These efforts will be applied to 2007 and 2008 quality data submissions. As a result, the agency anticipates that these new analyses and any associated incentive payments for both 2007 and 2008 will be completed and paid by the fall of 2009.

We are pleased with CMS' foregoing efforts to improve the PQRI. It will not be clear whether these efforts are successful, however, until October 2009, when CMS issues the 2008 bonus payments, along with 2007 bonus payments for those physicians found successful as a result of correcting their analytics. In the meantime, the AMA will continue to work with CMS regarding the outstanding PQRI concerns discussed above.

Value-Based Purchasing Programs

Section 131(d) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) required CMS to develop a plan for the transition to a value-based purchasing (VBP) program for physicians and other professional services. Under a VBP program, there are incentives for meeting quality and/or efficiency benchmarks, including patient satisfaction measures, or for other actions or behaviors, such as the adoption and effective use of HIT. VBP programs, if developed effectively, have the ability to: (i) improve physician performance on selected measures; (ii) improve value-based decision-making at the point of care; (iii) increase patient access to shared decision making aids (e.g., with respect to discretionary surgery) or reduce unexplained geographic variation in Medicare per-beneficiary expenditures; and (iv) encourage investment in health information technology and EHRs and the development of an interoperable health information technology network.

In developing the MIPPA-required plan, last December, CMS held a listening session and released an “Issues Paper” outlining four major components of its plan for transitioning to VBP: (1) measures; (2) data infrastructure and reporting; (3) incentive methodology; and (4) public reporting. The AMA provided extensive comments to CMS addressing each of these components.

In summary, we advised CMS that in order for any quality physician program to be effective and meaningful to patients, it is vital that certain elements be integral to the program, including such factors as: (i) physician development of quality measures; (ii) appropriate use of quality data; (iii) effective educational efforts to help ensure that physicians can easily and properly report data under the program; (iv) the ability for physicians to verify the data that is used in developing a physician rating under a quality program; physician appeal rights with regard to various aspects of the program; and (v) a stable physician payment structure. Further, we note that Medicare does not have the statutory authority to publicly report physician level quality data, and therefore CMS does not have the authority to implement a physician public reporting program. Nevertheless, significant barriers in the public reporting process must be addressed for effective reporting. If not, patient de-selection can occur for individuals at higher-risk for illness due to age, diagnosis, severity of illness, multiple comorbidities, or economic and cultural characteristics that make them less adherent to established protocols. Further, health literacy may not be adequate to comprehend basic medical information.

Programs must be designed so that appropriate information is available to patients to enable them to make educated decisions about their health care needs. If done correctly, public reporting has the potential to help provide such appropriate information to patients. **There remain, however, several critical issues that CMS must ensure are resolved before public reporting provisions can be implemented. First, Congress and CMS should devote resources to develop improved risk adjustment methodologies.** Without properly adjusting for risk, quality information will be skewed, and patients and physicians will be unfairly penalized and misinformed. **Further, Congress and CMS must ensure that any publicly reported information is correctly attributed to those involved in the care and is accurate, user-friendly, meaningful, and helpful to the consumer/patient.**

Thorough consideration must also be given to the development of any cost of care, or “efficiency,” measures. These measures must be evidence-based, and must seek quality improvement in patient care, not simply monetary savings as a primary goal. “Efficiency” ratings attempt to measure the cost for specific episodes of care.

Because of the foregoing concerns, it is critical that physicians and other providers involved in the treatment of a patient have the opportunity for prior review and comment and the right to appeal with regard to any data that is part of the public review process. Any such comments should also be included with any publicly reported data. This is necessary to give an accurate and complete picture of what is otherwise only a snapshot, and possibly skewed, view of the patient care provided by physicians and other professionals or providers involved in the patient’s care.

MIPPA requires the Secretary of the Department of Health and Human Services to submit a report to Congress by May 1, 2020, containing the plan to transition to VBP, along with recommendations for legislation and administrative action. As CMS moves forward with developing its plan to transition to VBP, it is important that Congress and CMS work closely with the AMA so that physicians' concerns will be adequately addressed.

The AMA appreciates the opportunity to provide our views to the Subcommittee on these critical matters. We look forward to working with the Subcommittee and Congress to effectively utilize and advance quality improvement programs and goals to assure the continued delivery of high quality, cost-effective care to patients.

Statement for the Hearing Record
The Society of Thoracic Surgeons
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Senate Finance Subcommittee on Health Care
“What is Health Care Quality and Who Decides?”
March 18, 2009

Chairman Rockefeller, Ranking Member Hatch, and members of the Senate Finance Subcommittee on Health Care, The Society of Thoracic Surgeons (STS) appreciates your dedication to health care reform and your recognition that there must be an increased focus on quality of care. STS respectfully requests this statement be included as part of the hearing record.

STS is a not-for-profit organization representing surgeons, researchers, and allied health professionals worldwide who are dedicated to ensuring the best possible surgical care for patients with diseases of the heart, lung, esophagus, and other organs in the chest. Founded in 1964, the mission of STS is to enhance the ability of cardiothoracic surgeons to provide the highest quality patient care through education, research and advocacy.

STS believes that in order to achieve health reform goals, there must be a system in place that recognizes and rewards physicians who fulfill their responsibilities to society and to their patients by improving the quality and value of care. This effort requires the acquisition and use of reliable outcomes and effectiveness data, including cost effectiveness, and developing a reimbursement system that rewards physicians for improved outcomes.

Measuring Health Care Quality

There is a critical need to improve the value of health care provided and to ensure higher quality care. We believe that physicians in collaboration with their professional societies are best and most appropriately positioned to define what constitutes high quality care. Since 1989, STS has fostered data-driven approaches to quality measurement, improvement, and reporting through the National Cardiac Database (NCD). Today, the NCD contains more than 3.6 million surgical records and is the largest clinical cardiac surgery database in the world. Through this database, we have demonstrated that the collection of clinical data and the feedback of that data to physicians can improve outcomes and have demonstrated that collaborative efforts by surgeons and hospitals that are based on merging clinical data with hospital cost data can result in cost savings.

Building true continuous quality improvement systems is dependent upon the collection of risk-adjusted clinical outcomes data rather than simply relying on administrative claims data. Clinical data can then be linked with administrative data to track clinical outcomes and provide an assessment of cost effectiveness, including the cost effectiveness of reduction in complications and potentially the use of new technologies and devices.

Increased Transparency

Patients should ultimately be empowered with information that allows them to make educated decisions about treatments and their providers. STS supports creating greater transparency and accountability among physicians but suggests proceeding with caution in the area of public reporting. STS believes that the best results from data reporting, particularly in “high-risk” procedural specialties where outcomes depend both on individual physician performance and the complex hospital care system in which they work, will therefore occur at the institutional/practice level, given potential sample size issues at the individual practitioner level. We suggest that the appropriate end point for any quality improvement initiative is improved outcomes, and we suggest that public reporting be reserved for those situations in which improved outcomes have not been achieved. This approach would actually provide an incentive for physicians to act as members of a profession with the responsibility to society to self-regulate, to share knowledge, and to improve patient outcomes. Any reporting must be based upon clinical data – with outcomes data being appropriately risk adjusted – and should encompass multiple years of data to examine consistency of outcomes. If public reporting is done at the individual physician level, it must be limited to the reporting of measures over which the physician has control.

STS opposes the use of quality data for the purpose of physician profiling, which will serve to exacerbate gaps in quality and access through risk avoidance. STS acknowledges the need to reduce variation in care across the country. Rather than profiling, STS has shown that through the use of the STS clinical database and its active educational and research efforts, outcomes can be improved, while simultaneously reducing variation among providers.

We wish to remind you that feedback and profiling are two distinct concepts and will achieve vastly different results. This distinction is one that will be critical for all to understand. Feedback is the use of data designed to improve physician practice, while profiling is use of data designed to discriminate among physicians and steer patients – without affecting the practice behavior of the provider. Physicians who may have had patients steered away from them, but do not receive constructive feedback, will continue to treat patients in the same way to neither the benefit of patients nor the system. The quality improvement driven by clinical data collection and risk-adjusted feedback promotes system-wide quality improvement and is not focused on the care of a single patient.

Refocusing Payment Incentives toward Quality

Existing payment systems reward providers for delivering more care rather than better care. Moving to a quality-based payment system must start with redesign of the unstable and unsustainable Medicare physician payment formula. The current Sustainable Growth Rate (SGR) formula is fatally flawed and must be replaced. STS recommends repealing the current SGR formula in favor of a system that encourages, through financial incentives, professional responsibility. We believe that this professional responsibility to American society includes both the effective allocation of societal health care resources and effective self-regulation by physicians. Toward this end, STS supports a physician payment system that will allow multiple payment methodologies to exist and will include multiple conversion factors. Our experience and

those of other specialties demonstrate that outcomes data effectively motivates physicians to change their practice. We believe that outcomes focused clinical registries provide the tool with which physicians can effectively self-regulate and improve their practice, and we suggest that there needs to be a movement towards more granular conversion factors that provide incentives for specialties to self-regulate. Adoption of such a system should not preclude physicians from entering into other organizational arrangements, such as bundled physician and hospital payments for episodes of care or for elective surgical procedures, where appropriate. However, since the vast majority of physicians are in practices of five or less and may be unable or unwilling to enter into other organizational structures for payment purposes, we suggest that a revised specialty-based RBRVS may be necessary as a “default” position for these physicians.

Promoting Provider Collaboration and Accountability

Health care delivery system reform should also encourage providers to collaborate and provide patient-centered care that improves quality and results in cost savings. STS believes that patient-centered systems of care should be encouraged in order to reform and reorganize the delivery of at least certain types of health care. Care must be refocused around the needs of patients, and systems of delivery and should allow and encourage collaboration across organizational boundaries and disciplines. We believe that enabling and facilitating the exchange of information among the various physicians and other care-givers is an essential step in improving coordination of care by various providers. This information exchange will likely require changes in both privacy and anti-trust laws. Moreover, to lower costs and improve quality, restructuring of payment systems must also allow and promote integrated delivery systems that focus on specific patient needs. We urge Congress to consider modify and enhance current payment systems to encourage — rather than discourage — collaboration and accountability among health care providers across treatment settings and sites of care, wherever these collaborations will contribute to improved outcomes and increased value. Bundled hospital and physician payments for defined episodes of care or elective surgical procedures and quality-sharing are two mechanisms that seem likely to encourage collaboration among physicians and hospitals in certain situations by aligning incentives.

STS supports the concept of quality-sharing between hospitals and physicians, but we believe that this quality-sharing should not be based solely on cost, but should also include increases in *value* (quality divided by cost). Quality-sharing refers to the sharing of Medicare Part A savings that accrue from improvements in the quality and value of care. We believe that quality-sharing can appropriately align incentives between physicians, hospitals, and payers to improve the quality of care for Medicare beneficiaries and other patients leading to reductions in costly complications, the creation of quality guided resource utilization, and the achievement of sustained savings. Quality-sharing will, however, require the development of payment programs that allow physicians to participate in the sharing of savings generated by these quality improvement efforts.

STS believes that bundling of payments can be an appropriate reimbursement methodology for hospital-based services for defined episodes of care, including elective surgical procedures. We believe that bundling will likely serve to align incentives for better quality and more appropriate care. To align payment with quality and efficiency, care delivery must be focused on patient

need, organized around the disease or condition of the patient. When possible, payment for treatment should be made on the basis of a period or episode for treating each condition. While this transition will take time, there are areas of Medicare where bundling is working well to control spending growth and encourage only the most appropriate care. In cardiothoracic surgery, as well as nearly all major surgical procedures under Medicare, physicians are paid one fixed fee (in a 90-day bundle) for almost all of the care they provide related to that procedure. They do not, however, participate in any of the bundled DRG payments to hospitals for the same procedures (Part A).

A bundled (Part A and Part B) payment for treatment of many surgical services under Medicare would shift the incentives from the current system that pays “a la carte” for each service or test to a system that rewards for reducing post-operative complications and for using only the most appropriate and helpful tests or procedures. This bundled payment model could be developed for the care of beneficiaries with defined conditions over a defined period of time, particularly for those with the most costly diseases and chronic conditions.

We envision a system that enables professionals to regulate themselves based upon what is most effective and most appropriate for the patient. However, a bundled payment without a measure of patient outcomes (or results) could reward underutilization. The coupling of outcome measures with bundled payment would align incentives, prevent underutilization, and encourage efficiency and innovation. However, protections and rewards must exist for both the hospitals and the physicians who become partners under a bundled payment scheme.

Improving the Health Care Infrastructure

Health care delivery system reform cannot succeed without taking additional steps to modernize our system. Modernization should include investing in new information technology and more outcomes focused research. STS applauds the inclusion of funds in the American Recovery and Reinvestment Act for both health information technology (HIT) and comparative effectiveness research. It is vital to establish an infrastructure for comparative effectiveness research that would provide systematic, unbiased information about what treatments, technologies, and procedures work best. This information would be utilized to educate both patients and physicians on the appropriateness, risks, and benefits of care. However, cost alone should not be the sole factor in limiting decisions made by physicians regarding the appropriate care for patients, as such a system carries the potential for placing physicians in the ethically untenable position of choosing between what they believe is best treatment for an individual patient and the cost associated with such treatment. The best metric is value (cost/quality) and not simply cost alone. We believe, and there are data to support, that better quality care is frequently less costly, particularly if post-operative complications are reduced. The acquisition of longitudinal follow-up clinical and cost information will be essential to the determination of the *value* of all medical and surgical therapies.

An investment in HIT would facilitate having comparative effectiveness research and other clinical decision-support information more readily available to providers, thereby improving the delivery of care across settings and helping providers to better coordinate patient care.

Moreover, an investment in HIT can also facilitate initiatives to improve quality performance and data collection. The creation of HIT standards will allow physicians to upgrade systems with confidence of continuing interoperability. HIT systems must be clinically based and interoperable with all other systems. We wish to re-emphasize the value of outcomes focus clinical registries in making assessments of effectiveness and altering physician practice. Comparative effectiveness research initiatives should encourage and facilitate the development and expansion of new and existing outcomes-focused clinical registries. Finally, the important role of an information technology infrastructure to solving the problems of care coordination and collaboration cannot be underestimated, as outlined previously in this testimony.

As the Finance Committee continues hearings and discussions related to health care reform in the 111th Congress, STS offers members and staff as a resource, particularly in the areas of workforce development, comparative effectiveness research, quality improvement and delivery of specialized surgical care.

