

MEDICARE REIMBURSEMENT FOR PHYSICIANS AND HOSPITALS

HEARING

BEFORE A

SUBCOMMITTEE OF THE
COMMITTEE ON APPROPRIATIONS
UNITED STATES SENATE
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MEDICARE REIMBURSEMENT FOR PHYSICIANS AND HOSPITALS

THURSDAY, JANUARY 30, 2003

U.S. SENATE,
SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN
SERVICES, AND EDUCATION, AND RELATED AGENCIES,
COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:30 a.m., in room SD-192, Dirksen Senate Office Building, Hon. Arlen Specter (chairman) presiding.
Present: Senators Specter, Stevens, Cochran, Harkin, Kohl, Murray, and Landrieu.

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Ladies and gentlemen, the hearing of the Appropriations Subcommittee on Labor, Health and Human Services, and Education will now proceed.

This morning's hearing will take up the issue of doctors' reimbursements, hospitals' reimbursements, and the overall grave difficulties which are confronting the delivery of health services in America today. The Balanced Budget Act of 1997 has taken a very heavy toll in many, many directions, and the Congress has moved in a number of ways to try to ameliorate that impact.

Another cut in physicians' payments is scheduled for March 1 of this year, 4.4 percent, and as I have traveled the State of Pennsylvania and elsewhere, I have heard many complaints, which are very justifiable. Therefore, the Appropriations Committee took the lead, and the Senate has now passed an omnibus appropriation bill which will freeze those cuts. Now we have to go through the conference to get the agreement of the House. It is such a controversial issue that we originally scheduled this hearing early, for January 13, but we could not get the Senate reorganized at that time. Nobody knew who the chairman of the subcommittee was, although in the particular case of this subcommittee it does not matter much, because Senator Harkin and I have had what we call a seamless exchange of the gavel on these very, very important public matters. The testimony today from a number of experts will be very important in presenting the case in the conference to try to freeze the current physician payments and to avoid, at least for the time being, the 4.4 percent cut.

We have taken up the issue of rural hospitals, which have been compensated under Medicare at a lower rate than urban hospitals, a 1.6 percent difference, and that has been altered as well. We are raising Medicare reimbursement for rural hospitals to give them

some relief. As I travel the 67 counties of my State, I hear that concern and complaint over and over again.

We are also going to take up the issue of the compensation of doctors for medical malpractice insurance, and that is one strand of a very, very complex issue. Some States have been hit harder than others, and as you know, the Congress is considering legislation on that subject. It is an issue which has quite a number of parts. Reimbursement to doctors for rising malpractice rates is behind the curve. I have a very extensive letter from the Administrator, of the Centers for Medicare and Medicaid Services, Mr. Scully. I wrote him a letter back on November 21 of last year, after I had heard complaints around the State, and I got a very complicated letter dated yesterday, and I——

Mr. SCULLY. Sorry about that.

Senator SPECTER. Excuse me?

Mr. SCULLY. I am sorry about that.

Senator SPECTER. Oh, you have not heard the last of it.

We will come to that, Mr. Scully, when your turn comes to testify, but I started to read the letter as soon as I received it, and I read it right along in the intervening time, but I have not finished it yet. It is that long, and it is that complicated. On a serious note, Mr. Scully, we know how busy you are, and we appreciate what you are doing, and we thank you for your services. It is not the first time that we have received a letter the day before a hearing. In fact, I think it is practically a violation of executive ethics to get it to us any sooner than that.

On the malpractice issue, there are many strands. There are issues involving the insurance industry, which will have to be taken up by appropriate committees. There are the issues of medical errors. We had extensive hearings on the Institute of Medicine some time ago, and we have appropriated funds in the past to try to deal with that, and the issue will be before the Congress as to caps on malpractice claims. I have said publicly that I am prepared to try to avoid the so-called lottery on caps, providing we exclude so-called catastrophic injuries. There are ways to deal with that issue on sanctions under Rule 11, or State rules, if there are frivolous lawsuits brought, and ways of dealing with venue, as it has been dealt with in Pennsylvania. There are ways of dealing with the certification by experts before suit is brought, so that there is a basis in advance of a filing.

We will be taking up a number of these key issues today, and I want to yield to my distinguished colleague, Senator Harkin, who I was pleased to compliment a few moments ago in absentia.

Senator HARKIN. Oh, well, say it again.

Senator SPECTER. I said we could not figure out, Tom, on January 13, when this hearing was originally scheduled, who the chairman was.

Senator HARKIN. That is right.

Senator SPECTER. And I said it did not much matter between you and me because we had a seamless passing of the gavel.

Senator HARKIN. That is true.

Senator SPECTER. But now we are ready to proceed.

Senator HARKIN. It has happened quite a few times. I thank you, Mr. Chairman.

Senator SPECTER. Yes, it has. Senator Harkin.

OPENING STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. Thank you for your leadership, Mr. Chairman, and for bringing us this hearing today.

There are going to be a variety of things discussed today. Two things that I want to focus on. During his State of the Union speech, President Bush announced a new plan to infuse the Medicare program with \$400 billion over the next 10 years to modernize the system. He admitted to a Medicare crisis that must be addressed to save the system for current and future generations.

I think first of all we have to be clear, while many providers are struggling to meet their commitment to beneficiaries, especially in States like Iowa, which lose money providing health care to seniors on Medicare, the solvency of the program is not in crisis. The solvency of the program is not in crisis. In fact, the most recent Medicare actuary report indicates that the Medicare program will be solvent for the next 28 years, the rosier projection since 1970.

That is not to suggest there are not serious problems that need to be addressed, two that I want to point to today, reimbursement equity for health care providers in rural States like Iowa, and the overwhelming need for a prescription drug benefit that is affordable and available to all in every State.

I was greatly encouraged by a couple of words that were in the President's State of the Union message, Mr. Scully, when the President said something about seniors, prescription drugs, and preventative health care. Most important, and I hope that we are going to be focusing on that also.

This is not a new issue about the reimbursement rate for Medicare in rural areas, Mr. Scully. You and I have talked about it many times in the past. Secretary Thompson and I have spoken about it. In fact, Secretary Thompson testified before this committee last year, and he said the existing reimbursement formula for rural areas is nonsensical and unfair, yet, as best as I can tell, the administration has done nothing to reverse the payment gap.

I had a chart, it is on its way here, that would show, for example, in the Medicare program benefits on the reimbursements to beneficiaries, Iowa is dead last. My State is dead last, with a per-beneficiary payment of about \$3,053 per beneficiary. The top State is Louisiana, with \$7,336. Well, again, the discrepancy of two-fold—I can understand there might be discrepancies, that there might be some variance because of labor conditions, high rent, different things like that that might come into play, but to say that there is a 2-to-1 difference is ridiculous.

For example, if you look at our neighbor, Nebraska, from Iowa, they received \$4,856 per beneficiary. What could possibly be the reason that Nebraska, next door to Iowa, should receive 63 percent more per beneficiary than the State of Iowa? Please, someone explain that. If anything, the cost of living and providing services might even be higher in Iowa than it is in Nebraska.

From my perspective, and from the perspective of all the Medicare providers throughout my State, this variation in payments is unjustifiable and unacceptable. As I said, while some differences might be arguable, depending upon where you are—I can under-

stand New York, high cost of living maybe, and other parts of the country, but 2 to 1? Inexcusable.

So we have to get something done about this. Everyone agrees that the reimbursement variance is inappropriate, but what we have today is a result of this flawed system, and is exacerbated by inaction. No one is doing anything. I can tell you, and you might take it from my tone of voice, and I am reflecting what I am hearing in Iowa, it has reached the boiling point in my State. Nurses are going across, out of Iowa, to work in Minnesota, driving, getting buses to go to Minnesota to work, going to Omaha, going across the river. It is like they are just fleeing, like off a sinking ship, and I am telling you, it is getting bad.

Now, people say, well, we are going to fix it. Well, there is something in the omnibus bill. Yeah, a little Band-aid, \$8 million. We have got a billion-dollar problem. \$8 million is laughable, to say that somehow that is going to fix it.

There is that chart I was talking about, Tom. I am sure you have seen it before. You know that chart. As I said, some variance might be acceptable, but you look at the U.S. average, it is \$5,490. There are 30-some States below that national average, Mississippi, North Carolina, South Carolina, Kentucky, and on down the list, Montana, Wyoming, Oregon, New Hampshire, New Mexico, Washington, way down there. Something has got to be done about this, and as I said, in my State, it has reached the boiling point, and a little Band-aid, \$8 million, is not going to do it, that is in the omnibus bill.

So we have got to get this thing changed, Mr. Scully. I know you and I have talked about it. I know I am preaching to the choir, but we have got to get something done about it, and I look forward to this hearing and discussing a little bit more with you on this issue.

I wanted to say a little bit more about prescription drugs, but I have taken much of my time already. Thank you, Mr. Chairman.

Senator SPECTER. Thank you, Senator Harkin.

Senator Cochran, would you care to make an opening statement?

OPENING STATEMENT OF SENATOR THAD COCHRAN

Senator COCHRAN. Thank you very much. I came by the hearing today to compliment Tom Scully and to thank him for taking on this tough job. It is one of the most difficult jobs in this town, in my opinion, but he has shown a willingness to travel around the country. I know he has come to our State and gone to some of the small-town hospitals, and met with officials in our State who are responsible for the Medicaid program, and for trying to make sure that we provide access to health care to the greatest number of people we can in our State at affordable costs.

I am encouraged that the administration is moving forward to modernize Medicare, to make specific recommendations for doing that, to include a prescription drug benefit. I admire the leadership that is being shown in that area.

There are a lot of unmet needs, and there are a lot of other problems to be solved, but I think the administration is on the right track, and if we continue to work together, the Senate and the House and the administration, we can solve these problems and make a difference in the lives of a lot of Americans.

I am pleased, Mr. Chairman, with your leadership in getting the changes in the omnibus appropriations bill that were included, and I hope we can preserve those in conference with the House and can see the effect that they will have in making things better in this area, and I appreciate your holding the hearing, and I appreciate the leadership that you and Senator Harkin are giving to these issues that are under the jurisdiction of this subcommittee.

Senator SPECTER. Thank you very much, Senator Cochran.

In order of arrival, Senator Kohl, would you care to make an opening statement?

OPENING STATEMENT OF SENATOR HERBERT H. KOHL

Senator KOHL. Briefly, Mr. Chairman. We have all heard from doctors, hospitals, nursing homes, and home health agencies in our States about Medicare cuts that they are facing. These cuts have real effects on our seniors and jeopardize our access to care.

I believe we must address these cuts immediately, and I hope the administration will come to the table as a partner in this effort, but while many of us agree that we need to stop these cuts, the reality, as Senator Harkin has said, is that the cuts hit providers in some States much harder. That is because the reimbursement formulas, as we know, that Medicare uses are flawed and outdated. They penalize efficient providers in many States, and my State of Wisconsin is a prime example, by paying them much less than other States, and they penalize Wisconsin seniors by delivering fewer benefits that seniors in other States enjoy.

This system, of course, is indefensible. All of our constituents pay the same Medicare payroll taxes. They suffer from the same illnesses, they need the same treatments, they receive the same types of health providers. Seniors in some States should not be treated like second-class citizens when it comes to health care. They should have the same access to treatments and benefits that seniors in other States receive, but today, too many States lose under Medicare.

For example, Wisconsin Medicare beneficiaries receive on average \$3,800 in Medicare benefits per year, the eighth-lowest, by my calculation, in the country. That is more than 25 percent below the national average of \$5,500. Studies show this costs Wisconsin nearly a billion dollars every year in Medicare dollars lost.

Those costs do not just disappear. Businesses and employees in the private sector pay higher costs to make the Medicare shortfall, so there is simply no logical reason why doctors, hospitals, nursing homes, and ultimately our seniors and the disabled should get less in some States than in others. The formulas Medicare uses are outdated and flawed, and they must be fixed if we are to have true Medicare reform.

I have co-sponsored legislation that would begin to address the inequities in Medicare formulas. I hope the administration will work with me and Senator Harkin and others that have been pushing this issue so that we can once and for all fix this system so that it is fair for all of our seniors, no matter where they live.

Thank you, Mr. Chairman.

Senator SPECTER. Thank you, Senator Kohl.

Senator Murray.

OPENING STATEMENT OF SENATOR PATTY MURRAY

Senator MURRAY. Well, thank you very much, Mr. Chairman, for having this hearing, and I really appreciate Mr. Scully being here, and I guess I will submit my statement for the record and just simply say to Senator Harkin and Senator Kohl, me, too. My constituents are furious about the reimbursement rate and the fact that they pay the same into Medicare, but we rank 42nd on the chart that Senator Harkin put up there. I have introduced legislation, my MediFair Act, to make sure that no State receives below the national average.

But this has reached a crisis point. It is no longer just the fact that our hospitals are screaming about it. It is the fact that we are losing access. Just as Senator Harkin said, our doctors, our nurses, our health care providers are leaving and going to higher reimbursement States. This means that doctors and hospitals are not taking Medicare patients in my State, and they are saying directly as a result of this reimbursing issue they are losing doctors to other States.

We have to deal with this issue. It is an access issue and, as Senator Kohl said, it is not fair that we are rewarding States that encourage inefficiency and high health care cost, and I do not want to see my good friend Mary Landrieu reduce the reimbursement rate to her State, but I think that she can understand in my State when seniors are not getting access because we are 42nd, 42 States behind her in reimbursement. It is not fair to people in our State, either.

PREPARED STATEMENT

We have to deal with this issue, and I will continue to work with my colleagues, and Mr. Scully, I am very interested in what your agency is going to be doing to help us deal with this issue.

[The statement follows:]

PREPARED STATEMENT OF SENATOR PATTY MURRAY

Mr. Chairman, I am very grateful for the Chairman's willingness to schedule this hearing. I recognize that Medicare is not under the jurisdiction of this Subcommittee, however, as many of us know we often have to deal with the reimbursement problems.

Many hospitals come to us for increased funding on the discretionary side or for earmarks to make up for the shortfalls in Medicare reimbursement.

My state faces a particularly difficult situation when it comes to Medicare reimbursement for physicians and hospitals. While all doctors experienced a 5.4 percent reduction in their fee schedule for 2002 and may face additional reductions, doctors in Washington state have been treated unfairly for years.

Doctors and hospitals in my state get far less per beneficiary than most states. In fact, Washington state ranks 42nd in the nation in Medicare payments per beneficiary.

Despite these lower payments, my providers still have to compete in a highly competitive health care arena.

Hospitals in Washington state have the same technology costs as hospitals in Florida or Louisiana, yet they receive significantly less in reimbursements.

I have been working for several years with Senator Harkin to address this inequity. I have introduced the Medifair Act, which would guarantee that no state receives less than the national average per beneficiary cost.

My legislation also includes a mechanism for the Secretary to evaluate outcomes and work with those states that have some of the highest costs. My intent is not to reduce payments for those higher cost states but rather to work to implement healthy, cost-effective practices.

I am pleased that the Senate-passed Omnibus Appropriations bill begins to address the rural/urban inequity. However, much more needs to be done. Seniors in Washington state simply do not have access to the same Medicare program or benefits as seniors in Florida or New York.

It's especially frustrating for my state—because the reason we're at the bottom of the list is because we've done the right things and are highly efficient.

We have lower utilization rates and higher rates of efficiency than other states. Washington's seniors and health care providers have done the right things, yet every year they are penalized.

The incentives are backwards. This has to change. We should not be rewarding and encouraging inefficiency and costly health care decisions.

I will continue to work to eliminate the inequities that are having serious economic and health care impacts in my state.

Hospitals and physicians have little choice but to pass the shortfall in Medicare on to private insurance—driving up the cost for employers and workers.

I can tell you that there is little flexibility remaining to shift costs to private insurance plans. This shift only increases the cost of health insurance pushing more people into the ranks of the uninsured.

Senior citizens in Washington state deserve access to the same Medicare program and benefits as seniors in any other state.

Senator SPECTER. Senator Landrieu.

OPENING STATEMENT OF SENATOR MARY L. LANDRIEU

Senator LANDRIEU. Thank you, Mr. Chairman. I appreciate the opportunity just to make a few brief remarks, and Mr. Scully, thank you for the job that you do. You have a great many challenges before you.

Unfortunately, Mr. Chairman, I am not going to be able to stay. Senator Breaux and I are hosting a major conference of thousands of people from our State that are up here today and tomorrow, so I am going to have to slip out, but I came to make just one brief comment about one of the aspects of the proposed new rule, but before I do, I want to make a comment about the issue being raised by Senator Harkin.

I agree that probably some changes need to be made, and I most certainly appreciate the frustration expressed by the chairman and the other Members about the discrepancy, but there are some good aspects to the formula, and as Louisiana is the highest beneficiary, the current formula is based, in large part, as you know, Mr. Scully, the rate of wages in a State, as well as the frequency of use, both of which give rise to States like Louisiana being on top. The fact is people in Louisiana are paid much less, are poorer, not as healthy, and therefore access the system in greater numbers than a healthier population, so those are some of the contributing factors which I think are very worthy of consideration when trying to provide health care in a Nation as diverse as ours. I would hope to work with the chairman and the ranking member on this issue so that we can reach a solution that serves all of our States.

I wanted to, Mr. Scully, come here for the specific purpose of stating strong objections to one change that you are recommending that has doctors and medical professionals in my State quite concerned, and that is the change in the Medicare pass-through regulations. I have been contacted by several oncology practices in Louisiana specifically expressing a growing concern about the use of functional equivalent standards by CMS. As you know, the standard was introduced in the context of the recently promulgated rules for hospital outpatients, which I am sure you are familiar with.

It is my understanding the new concept was not raised in proposed regulations, not subject to comment from interested parties. Had it been properly introduced, the following stringent objections would have been raised by many practitioners in Louisiana. First, I want to say on the record this is a subjective standard. It is a dangerous precedent which interferes with the physician's ability to prescribe the best care for patients.

Second, the discretionary nature of the standard will stifle innovation, in my opinion, especially among biotechnology firms which lack the resources to roll the dice on whether the new products will be covered, as is the current situation, and I am afraid, Mr. Scully, the effect of the final rule will be to delay faster treatments of highly effective new therapies that we are all very encouraged by, and that are administered less frequently than competing therapies. The result will be dramatically reduced reimbursement rates that make new therapies not a viable option.

Finally, let me just say, in a rural State, which many of us represent, the options of people to have to receive treatment once a week, or twice a week, or three times a week, can have a direct impact on whether they are able to hold down a job or not, having to travel great distances for health care.

So this change, I really want you to look very intently on, and I register my strong objection to the proposed change on behalf of many physicians in Louisiana, and say thank you for your time and attention.

STATEMENT OF THOMAS A. SCULLY, ADMINISTRATOR, CENTERS FOR MEDICARE AND MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Senator SPECTER. Thank you, Senator Landrieu. We now turn to our first witness, Mr. Thomas A. Scully. Since May 2001, he has served as Administrator for the Centers for Medicare and Medicaid Services. Prior to that appointment, he served as president and chief executive officer of the Federation of American Hospitals. He was a partner at Patton, Boggs, and also served as Deputy Assistant to the President and Counselor and Director of the Office of Management and Budget. He has a law degree from Catholic University and a bachelor's degree from the University of Virginia.

Mr. Scully, we are going to ask you to observe our general rule of a 5-minute opening statement. As I said at our initial hearing yesterday, I attended memorial services for Ambassador Annenberg recently, and the speeches were limited to 3 minutes. That applied to former President Gerald Ford, and Secretary of State Colin Powell, and to me, and to the 15 other speakers, so I want you to know that the 5-minute allocation is generous. Please proceed.

Mr. SCULLY. Mr. Chairman, I am going to talk as quickly as I can.

Thank you, Mr. Chairman, Senator Harkin and other Senators for inviting me today. Obviously, there are a lot of complex issues about geographic differences, and I will try to get into those questions, because the primary focus this morning is going to be on the physician payments.

I have worked on physician payments since the first Bush administration. I was very involved in passing the RBRVS reforms in 1989, so I have a strong personal feeling about this, and a great

level of disappointment about how mixed-up our physician payment formula has become.

We paid about \$44 billion for physician services in 2002, and processed about 600 million physician claims for 7,000 different services, but the system for Medicare physician payments has basically imploded. There are some very big flaws in the formula, and I would say that basically, we have had the perfect storm in all these different factors coming together to essentially cause the physician payment formula to just not work. It badly needs to be fixed, and we appreciate the efforts that have been made in both Houses, the House and the Senate—slightly different approaches to fixing this—and we strongly advocate fixing it as fast as we possibly can, and, certainly, hopefully before March 1.

There are a number of reasons that this has happened. The first is that the law, which was rewritten in 1997, is extremely specific, very limiting in the way we are allowed to make changes. The projections, essentially when we did the SGR calculations, the law required us to use projections for actual physician growth, spending growth, and for economic growth in 1998 and 1999, and did not allow us to come back and adjust it for real data later.

After 2000, we could use real numbers, but the law requires us to use projections in 1998 and 1999. That was the first thing that threw off the formula. We are using, by statute, incorrect numbers for 1998 and 1999.

The second is that when the law was changed in 1997, the new measurement for physician payments is directly reflective of the change in GDP, so as the economy has obviously taken turns for the worse, the reduction in GDP growth has had a drastic impact on the physician payment formula. Again, that is set in the statute.

The third is that physician payments have grown pretty rapidly in recent years, and that also is reflected in the downturn in the formula, and one additional factor of that is that we have, as I mentioned, about 7,000 different payments for physicians. In 1998, 1999, and 2000, my agency added a couple of hundred codes, which we do in cooperation with the AMA and physician groups.

We work them all year long to figure out what new things we should pay for, but inadvertently, believe it or not, we added 300 codes and forgot to count them, so we spent \$5 billion in 1998, 1999, and 2000 that we did not know we spent until much later, and the statute is very strict, and requires us to recapture that, and I can explain also, if you like, the actual formula works exactly as it was designed, but there have been a bunch of mistakes made, inadvertent mistakes, that have basically caused it to blow up, which is why we had a negative 5.4 percent reduction for physicians last year in the base fees, and a negative 4.4 percent coming March 1.

We have fixed some of these within my discretion. The original cut was supposed to happen January 1. The administration for a variety of reasons has delayed the rule for 2 months. The original cut would have been negative 5.1 percent. We worked with the physicians in the physician community, and we have buffered it to the limited amount we can under the statute from negative 5.1 to negative 4.4. We certainly don't expect them to be happy about that, but I have probably spent a quarter of my time since I have

been in this job working with the AMA, physician groups, everybody at the highest level of the Justice Department and the White House to try to fix this. Unfortunately the statute is so tightly crafted that there is basically no way for us to do it administratively, or believe me, we would have tried to.

We clearly believe the physician payment formula, while extremely well-intentioned, is broken. The numbers are flawed. The cumulative impact has clearly resulted in physician payments that clearly were never intended, and are not appropriate for physicians.

By February 12, we have discretion to change the way contractors pay physicians. There will be a negative update—or downdate—for doctors on March 1, and the latest that I can actually change that is February 12. I bring that up because I would certainly hope that whatever the process brings, that Congress can fix this before February 12, because that is the date I have to actually send the instructions to our contractors around the country to actually fix this before this thing actually blows up.

Unfortunately, this is not just a short-term problem, it is a long-term problem. The appropriations bill fixes it for 1 year, and this is a top legislative priority for the administration to fix it. We had lots of discussions, which we will get into this morning, about provider give-backs, or different adjustments. There are lots of merits for rural hospitals and other things. We don't believe that this is a give-back. This is a mistake and it needs to be fixed.

Negative 4.4 percent update on top of the negative 5.4 percent update would be comparable for hospitals, for instance, to something like market basket minus 8 percent 2 years in a row. It just is not sustainable, it is not right, and if you want the physicians in this country to be good partners with the Government in providing services, we strongly believe it has to be fixed.

One additional factor that the chairman asked me to get into that causes additional stress for physicians on top of this mistake is the cost of malpractice liability insurance. Obviously, as you know, the President has a strong program that we are pushing aggressively to reform malpractice. We hope to get that through Congress this year, but a factor for most physicians in what they get paid is how Medicare allocates for their costs of malpractice.

Now, there are a number of different ways we measure it, three different ways, which I will try to run through quickly, and basically, malpractice is a very small component, 3.2 percent, of what we pay physicians in Medicare. There are three basic rates that we pay physicians, and malpractice is about 3.2 percent of that. There are three different factors that go into that calculation.

One is the relative value for services, which is the relative payment rates. That is updated, as the chairman pointed out, using 1996 to 1998 data. I am working on trying to find a way to adjust that in real time.

There is an inflation update, which is the only real source of new money into the system every year, which actually is used on 1-year-old data, 2001 and 2002, and that calculation last year was increased by 11 percent, but because it is such a small piece of the Medicare calculation, you can imagine that an 11 percent increase

on a base of 3.2 percent does not have a real big impact for physicians and communities that are affected.

Then finally there is a geographic allocation, so we do allocate differently for different costs. For example, Pennsylvania has had a relative meltdown in malpractice costs this year, and we do allocate differently for different areas. The country is broken up into 89 geographic practice cost areas, and those 89 areas all do get paid quite differently for physicians, which is similar to what I am sure it sounds like we are going to get into on hospitals in a few minutes.

We are working on a policy—I am working on one to try to find a way to get more real time data into the system, but it is extremely complicated to collect, it is difficult to get right. Historically, we have collected it for two of the three categories on basically 5-year-old data, and I think the chairman raised that point in this opening remarks.

I will just wrap up, since it looks like I am through my 5 minutes, by saying that we are working very hard to try to fix this. We are very aware of the issues.

Senator SPECTER. Mr. Scully, we are going to hold the other people to the limits, but you are the Administrator. Take a little more time if you need it.

Mr. SCULLY. Okay. I would just say that in respect to some of the earlier comments about geographic distribution, as Senator Kohl would be aware, my boss, Secretary Thompson, who is also from Wisconsin, is equally concerned about Wisconsin. I spend a lot of time working on rural issues. I believe that in the 2 years we have been there, almost every time we have had the ability in the regulation to try to adjust them—and on the margins it is not always very big—towards helping rural areas, we have done that. We did that this year on the wage index. We have done that across the board. Secretary Thompson is very focused on it. Our ability under the current laws to do that is somewhat limited, but we are very, very focused on it and very aware of that.

There are a lot of reasons, I would say, Iowa may be underpaid, but having gone through a lot of this the last few days, I would also say Iowa has extremely high costs, extremely efficient health care, as does Washington State, by the way. I was out there last year going through the same issue, and to some degree that is a good model. You do get paid about 91 percent on the national average, for instance, in Iowa of your cost, and you get about 71 percent per capita. Part of that is you have a much more efficient, much better quality of care for a lower cost, which is in many ways admirable, and Washington State has the same qualities.

But we are working to make sure that the system is fair. There is a great difference in the way we calculate, historically, physician payments by region versus hospitals, something we can clearly look at, and we are very focused on trying to make sure that these formulas are fair and more equitable State-by-State.

PREPARED STATEMENT

But there is no question, getting back to the primary focus of what I was asked to testify this morning, that we have many flaws in the Medicare program, there are many, many things that obvi-

ously, if I had the power, I would love to fix. We would be happy to work with the committee to fix all of them, but as far as the number 1 clear inequity in the program right now, that clearly is not right or fair for seniors or their physicians, the physician payment system is broken. If there was any way we could fix it administratively, we would have done it already, and we are extremely anxious to work with both the Senate and the House to try and get this resolved before March 1.

Thank you, Mr. Chairman.
[The statement follows:]

PREPARED STATEMENT OF THOMAS A. SCULLY

Chairman Specter, Senator Harkin, distinguished Subcommittee members, thank you for inviting me to discuss how Medicare pays for physicians' services. I have worked on Medicare physician payment issues since 1989 when I was one of the primary people in the previous Bush Administration negotiating the creation of the resource based relative value physician payment system, sometimes referred to as RBRVS. I personally think that, over the years, this has been the most stable payment system in Medicare, and historically there has been far less controversy in physician payments than we have witnessed with other health care providers. In fact, the resource based relative value system has worked reasonably well and often is used by private payers. A number of factors have combined to cause the formula, as set in law, to produce negative updates for 2002 and 2003 as well as projected negative updates for future years.

Over the past 15 months, I personally have devoted about a quarter of my time, working with every group imaginable—lawyers, physicians, and the highest levels of the Administration—to fix the fee schedule administratively. The Agency explored every legal option possible to try to fix the negative update, but unfortunately, the statute is too prescriptive to allow an administrative fix. We, however, were able to modify the methodology used to calculate the Medicare Economic Index (MEI), which measures inflation for the cost of providing physicians' services used in the fee schedule formula. The change we made resulted in a 0.7 percentage point increase in the 2003 MEI update, from 2.3 percent to 3.0 percent, and is expected to increase the MEI in all future years by roughly 0.5 percentage points per year. This change will increase Medicare spending for physicians by about \$15 billion over the next 10 years. While the 2003 update is a negative 4.4 percent, without this technical modification, the update for 2003 would have been negative 5.1 percent. This does not resolve the fee schedule update problems, but it is a step in the right direction. We point out that Medicare expenditures for physicians' services increased by 5 percent in 2002, and are expected to increase by 2 percent in 2003, despite the negative update.

We believe that the physician update formula is broken and can only be corrected by legislation. The physician update has both short-term and long-term problems. The short-term problem is that the negative 4.4 percent update will go into effect on March 1 without a change in law. The long-term problem is that there will be negative updates for future years under current law. No one ever intended that the physician formula have this result. Working with Congress to find a legislative fix is a top legislative priority of the Administration. We believe that fixing the physician update would be a technical correction to a broken system, not a "giveback" that other providers have been seeking. We believe it is important that Congress takes immediate action to prevent the 4.4 percent reduction scheduled to go into effect on March 1. Such an action is the only equitable solution that will stop physicians from experiencing payment reductions that result from this flawed formula.

HISTORY

Let me explain the origins and logistics of the physician fee schedule so that we can all understand how the system works. In 2002, Medicare paid about \$44 billion for physician fee schedule services. Between 1997 and 2002, Medicare physician spending increased from 17.6 percent to 19.8 percent of total Medicare fee-for-service spending. Each year, Medicare processes about 600,000,000 physician claims. The fee schedule reflects the relative value of the resources involved in furnishing each of 7,000 different physicians' services. By law, we actually establish three components of relative values—physician work, practice expenses, and professional liability insurance—for each of these 7,000 services. The actual fee for a particular

service is determined by multiplying the relative values by a dollar-based conversion factor. And the payment for each of the services is adjusted further for geographic cost differences among 89 different payment areas across the nation.

Payment rates for physicians' services are updated annually by a formula specified in law. The annual update is calculated based on inflation in physicians' costs to provide care (the MEI), then adjusted up or down by how "actual" national Medicare spending totals for physicians' services compare to a "target" rate of growth. If spending is less than the target, the physician payment update is increased, and if spending exceeds the target, the update is reduced. The system was designed to constrain the rate of growth in Medicare physician spending and link it to growth in the overall economy, as well as to take into account the physician role in the volume and intensity of services. Until 2000, in large part, the formula has been working as designed.

The law that sets this formula is extremely prescriptive. It does not give the Centers for Medicare & Medicaid Services (CMS) the administrative flexibility to adjust physicians' payments when the formula produces unexpected payment updates, as we witnessed in 2002 and 2003. The size of the negative update for 2002 was a surprise when it first became apparent in September 2001. As we looked at the actual numbers going into the formula, we explored every issue and every alternative that could have produced a different update, but we concluded that we did not have any flexibility. We made sure that every part of the update was accurate and fully in accord with the law.

Several factors lead to the negative updates. First, there were differences between estimates and after-the-fact actual data for components of the fiscal year 1998 and fiscal year 1999 Sustainable Growth Rates (SGRs). As I explain below, this means that the cumulative target was lower than it should have been. Second, there has been a downturn in the economy in recent years, which affected the SGR because it is tied to the growth in the country's Gross Domestic Product. Third, spending for physicians' services has grown very rapidly in recent years. The combination of lower targets and higher expenditures accounts for negative updates. In addition, in 2002, our measure of actual expenditures had to be adjusted to capture spending information on services that were not previously captured in the measurement of actual expenditures. Counting these previously uncounted actual expenses, as required by law, also increased cumulative actual expenditures—driving down the update.

While there are significant differences between the Medicare Volume Performance Standard (or MVPS, the predecessor to the SGR) and SGR, both use the same general concept that expenditures for physicians' services should grow by a limited percentage amount of allowed expenditures each year. One important feature of both the MVPS and the SGRs for fiscal years 1998 and 1999 was that the percentage increase was based on estimates of the four component factors specified in the law, made before the beginning of the year. Under the MVPS and the SGRs for fiscal years 1998 and 1999, the statute did not permit us to revise the estimates used to set the annual percentage increase. Beginning with the fiscal year 2000 SGR, the statute specifically requires us to use actual, after-the-fact data to revise the estimates used to set the SGR. For some of the component factors of both the MVPS and the SGR, there have been differences between the estimates used to set the annual MVPS and SGR and the actual increase based on actual, after-the-fact data. For instance, under both the MVPS and SGR, we are required to account for increases in Medicare beneficiary fee-for-service enrollment. Because it is difficult before the beginning of the year to predict beneficiary enrollment in Medicare + Choice (or Medicare managed care, as they were known under the MVPS) plans, there have been differences between our estimates of the increase in fee-for-service enrollment and the actual increase. Under the MVPS, we generally estimated higher growth in beneficiary fee-for-service enrollment than actually occurred, although the statute has required us to revise our estimates for subsequent years.

Because the physician fee schedule conversion factor has been affected by a comparison of the actual increase in expenditures to the level of allowed expenditures calculated using the MVPS and the SGRs for fiscal years 1998–1999, revision of our estimates would have resulted in different conversion factors than those we actually determined. The 4.4 percent reduction to the physician fee schedule conversion factor is occurring, in part, because of a flawed statute that does not allow us to revise estimates for previous years. Physicians argue that these negative payment updates will hinder their ability to care for beneficiaries, and may result in some physicians not accepting new Medicare patients. We take these statements seriously, and are taking steps to monitor beneficiary access to care to ensure that our nation's most vulnerable citizens continue to receive the care they need. As we consider how to improve the Medicare physician payment formula, I think it's important to under-

stand, from a historical perspective, how and why the formula operates the way it does today. It is, in fact, operating precisely as it was designed in 1997—but we recognize that this has produced some large short-term adjustments.

PHYSICIANS' PAYMENT BEFORE 1997

As the Medicare program has grown and the practice of medicine has changed, Congress and the Administration have worked together in an effort to ensure that Medicare's payments for physicians' services reflect these changes. As a result, the physician payment system has changed significantly in the past two decades. For many years, Medicare paid for physicians' services according to each doctor's actual or customary charge for a service, or the prevailing charge in the physician's area, whichever was less. From 1970 through the 1980's, spending for physicians' services grew at an unaffordable and unsustainable average annual rate of more than 14 percent. And, because the system was based on historical charges, it produced wide discrepancies in payments among different localities, medical specialties, and services. These payment differences did not necessarily reflect actual differences in the cost of furnishing services. As a result, the system was roundly criticized in the 1980's as overvaluing specialty services and undervaluing primary care services.

To address these criticisms, Congress directed the Physician Payment Review Commission, an advisory body established by Congress and one of the predecessor organizations of the Medicare Payment Advisory Commission (MedPAC), to examine different ways of paying physicians while protecting beneficiary access to care, as well as slowing the rate of growth in Medicare physician spending. On a bipartisan basis, and with the support of the first Bush administration, Congress accepted these recommendations and passed these and other reforms in the Omnibus Budget Reconciliation Act (OBRA) of 1989, and the new fee schedule was implemented beginning January 1, 1992. The resource-based work component of the fee schedule was phased in between 1992 and 1996.

Specifically, in its 1989 Annual Report, the Commission recommended a number of ways to change how Medicare pays physicians. The Commission first recommended instituting a fee schedule for physicians' payments based on the resources involved with furnishing each physician's service, rather than on historical charges. The Commission also recommended that the relative value of three separate components of each service—physician work, practice expense and professional liability insurance—be calculated, as discussed above.

Under the Commission's recommendations, once the relative values were established, they were adjusted for cost differences, such as in staff wages and supply costs, based on the area of the country where the service was performed. Then the actual fee for a particular service for a year was determined by multiplying the relative value units by a dollar-based conversion factor. The Relative-Value Update Committee (RUC), a multi-specialty panel of physicians that is supported by the American Medical Association (AMA), plays an important role in making recommendations so that the relative values we assign reflect the resources involved with both new and existing services. We generally accept more than 90 percent of the RUC's recommendations, and our relationship is cooperative and extremely productive. The Physician Payment Review Commission also recommended that HHS provide financial protection to beneficiaries by limiting the amount that a physician could charge beneficiaries for each service.

The Commission's third major recommendation was to establish a target rate of growth for Medicare physician expenditures, called the Medicare Volume Performance Standard (MVPS). The MVPS target growth rate was based on physicians' fees, beneficiary enrollment in Medicare, legal and regulatory changes, and historical measures of the volume and intensity of the services that physicians performed. The MVPS was set by combining these factors and reducing that figure by 2 percentage points, in order to control to growth rate for physicians' services. OBRA 1993 later changed this to minus 4 percentage points. Actual Medicare spending was compared to the MVPS target, which led to an adjustment, up or down, to the MEI to determine the update for a future year. The law provided for a maximum reduction of 3 percentage points, which OBRA 1993 lowered to 5 percentage points.

PHYSICIANS' PAYMENT SINCE 1997

The Balanced Budget Act of 1997 (BBA) further changed the physician payment system based on subsequent Commission recommendations. In BBA, the SGR replaced the MVPS. Like the MVPS, the SGR is calculated based on factors including changes in physicians' fees, beneficiary enrollment, and legal and regulatory changes. However, the BBA did away with using the historical volume and intensity of physicians' services as the factor in the target for growth in the volume and in-

tensity of services. Instead, the real per capita Gross Domestic Product, which measures real economic growth in the overall economy per capita, was instituted as a replacement.

One other important difference between the old and the new growth targets is that the old method compared target and actual expenditures in a single year while the SGR added a cumulative comparison. Under the MVPS, if expenditures exceeded the target in the previous year, the update was adjusted for the amount of the excess in the current year, but there was no recoupment of excess expenditures from the previous year. Under the new SGR, the base period for the growth target was locked in at the 12 months ending March 31, 1997. This is the base period and remains set for all future years. Annual target expenditures for each following year equal the base period expenditures increased by a percentage amount that reflects a formula specified in the law, and they are added to base period expenditures to determine the cumulative target. This process continues year after year, adding a new year of expenditures to the cumulative target. A comparison of actual cumulative expenditures is made to cumulative allowed or target expenditures. Under a cumulative system, if expenditures in a prior year exceed the target, the current year update is adjusted to make annual and target expenditures equal in the current year and to recoup excess expenditures from a prior year. While the BBRA made some further technical changes to allow these adjustments to occur over multiple years, that is the general way the formula was established in law. The SGR is working the way it was designed.

BBA also increased the amount that the update could be reduced in any year if expenditures exceeded the target. The maximum reduction was increased by 2 percentage points, to 7 percentage points. Thus, for example, inflation updates in the range of 2 percent, reduced by the 7 percentage point maximum reduction, would yield a negative update in the range of 5 percent. BBA also established a limit of 3 percentage points on how much the annual inflation update could be increased if spending was less than the target. For example, an inflation update of 2 percent increased by the 3 percentage point maximum increase would yield an update of 5 percent.

Additionally, BBA created a single conversion factor (previously there were three separate ones for different types of services). BBA also required that the practice expense component of the relative value calculation, which reflects a physician's overhead costs, be based on the relative resources involved with performing the service, rather than the physicians' historical charges. This change made the practice expense component of the calculation similar to the physician work component, and reflected actual resources. The change was phased in over four years, and was fully implemented in 2002. BBA further required that the professional liability insurance expense component of the relative value calculation also be resource-based. The law required that the resource-based practice expense and professional liability relative value systems be implemented in a budget-neutral manner. The BBA provisions affecting physicians accounted for about 3 percent of total BBA 10-year Medicare savings. Because physician payment accounts for about 17.6 percent of program payments in 1997, the physician savings in the BBA represented by these changes were relatively modest.

The Balanced Budget Refinement Act of 1999 (BBRA) made further revisions to the SGR in an attempt to help smooth out annual changes to physician payments such as blending cumulative and annual comparisons of target and actual spending. Beginning with the 2000 SGR, the law required us to revise previous SGR estimates based on actual data that became available after the previous estimates. BBRA also required us to make an annual estimate of the expected physician payment update for the succeeding year available to MedPAC and the public. This estimate is due on March 1 of each year, and is very difficult to make, because none of the claims used to determine actual spending are available by the time we are required to make the estimate. In 2001, we estimated that the 2002 update would be around negative 0.1 percent. However, when we determined the actual update, which was published 7 months later—on November 1, 2001, revised figures lowered the Gross Domestic Product figures for 2000 and predicted a slower growing economy for 2001 than was previously estimated. Further, 2001 physician spending was higher than our March estimate.

Additionally, in making updates to the list of codes for specific procedures that are included in the SGR, we discovered that a number of codes for new procedures were inadvertently not included in the measurement of actual expenditures beginning in 1998. Therefore, the previous measurements of actual expenditures for 1998, 1999, and 2000 were lower than they should have been. As a result, the physician fee schedule updates for 2000 and 2001 (5.5 percent and 5.0 percent, respectively) were higher than they should have been had those codes been included. The down-

ward adjustment to the 2002 physician fee schedule was due, in part, to recoup the higher than intended expenditures in 2000 and 2001. The combination of these factors led to the large negative update for 2002.

As you can see, the process for calculating payments for physicians' services is highly complex. It is the result of years of efforts by Congress, previous Administrations, the Physician Payment Review Commission, and MedPAC to ensure that Medicare pays physicians as appropriately as possible. Today, while the underlying fee schedule and relative value system have been successful, we recognize that the update calculation has produced large short-term adjustments and instability in year-to-year updates. I know that you, Mr. Chairman, and others on this Subcommittee and elsewhere in Congress, are involved with legislative efforts to improve the formula. I want to work with you and the physician community to smooth out the yearly adjustments to the fee schedule in a way that is budget-neutral across all providers while ensuring that Medicare beneficiaries continue to get the care they need.

PROFESSIONAL LIABILITY COSTS

We are very disappointed that, despite our best efforts to find an administrative fix, physicians will face a negative 4.4 percent update this year, particularly because we understand the financial pressures that doctors face and want to ensure that Medicare beneficiaries continue to receive the care they need. One contributing factor is the cost of professional liability insurance. CMS' Office of the Actuary (OACT) considers this cost as it develops and maintains input price indexes, or market baskets for the major medical sectors (hospitals, physicians, nursing homes, home health agencies, and the like) that are used to annually update Medicare payments. These market baskets reflect what it would cost in a future period to purchase the same mix of goods and services purchased in a base period. The mix of goods and services that providers purchase include labor (wages and benefits), utilities, pharmaceuticals, food, equipment, capital, and the like. One of these inputs is professional liability insurance, which we want to appropriately reflect in our market baskets.

In fact, Medicare physician payments for malpractice are determined partly by relative value units and partly by other elements of Medicare's physician fee schedule. Payments for each of over 7,000 services under the fee schedule are based upon three factors:

- Relative value units (RVUs) for each service, reflecting the relative amount of physician work effort, practice expenses, and malpractice insurance expenses involved with furnishing each service;
- A dollar conversion factor that translates these RVUs into monetary payment amounts, and;
- Geographic practice cost indexes (GPCIs) for physician work, practice expenses, and malpractice insurance expenses to reflect differences in physician practice costs among geographic areas.

All three of these factors affect the total payment amount for a service. There is a malpractice element in each of these factors.

The first way that malpractice is reflected in the Medicare physician payment system is through a specific component of RVUs for each service for malpractice expenses. Since January 1, 2000, the statute has required that the RVUs for malpractice be based on the resources physicians actually expend to acquire professional liability insurance. We established resource-based malpractice RVUs through notice and comment using a methodology that incorporates actual malpractice premium data and weighting by specialty and frequency of each service. The law requires that we revise the malpractice expense RVUs no less than every 5 years. If malpractice insurance premiums rise for some specialties more than for others, the higher expenses would be reflected in the periodic revisions we make to the malpractice expense RVUs. Subsequently, malpractice expense RVUs for services typically performed by these specialties would increase. We most recently revised these relative values for 2001. By law, we must make these revisions to relative values in a budget neutral manner, which means that if we increase the payment for a service then we are required to reduce the payments for other services. Because malpractice represents 3.2 percent of the average physician fee (physician work is 54.5 percent and practice expenses are 42.3 percent), even relatively large changes in premiums for some specialties would have relatively modest effects on Medicare payments.

The second way that malpractice is reflected in the physician payment system is through the annual update to the fee schedule conversion factor. The statute specifies a formula for the update based on the MEI adjusted by performance under the

SGR system. The MEI is an inflation index measuring year-to-year changes in physician practice costs. One component of the MEI is specifically designed to recognize national year-to-year changes in the costs of malpractice insurance. If malpractice insurance premiums increase nationally, then these higher costs are incorporated into a higher MEI, which subsequently raises all payments under the fee schedule. These calculations are made each year by the Office of the Actuary based on data collected from major insurers. For 2003, the malpractice expense component of the MEI, which represents about 3.2 percent of the total index, was increased by 11.3 percent to reflect the recent liability insurance premium increases that have occurred nationwide. Thus, increases in malpractice insurance costs are reflected in Medicare physician payments relatively quickly.

The third way that malpractice is reflected in the physician payment system is through the geographic adjustment among areas. The statute requires a separate geographic adjustment for the malpractice RVU component to reflect the relative costs of malpractice expenses in different fee schedule geographic areas compared to the national average of such costs. There are 89 physician fee schedule geographic areas. Thirty-four of these areas represent one state apiece, while the other areas represent portions of the remaining 16 states. If malpractice insurance premiums increase more in some geographic areas than others, these higher geographic-level expenses are reflected in the periodic revisions that are made to the geographic practice costs indexes for malpractice expenses. These revisions are made in a budget neutral manner, no less than every three years, as required by law. The next revision will take effect in 2004; these changes will be proposed in the notice of proposed rulemaking for the annual update, which we plan to publish in Spring 2003.

To make these changes, we must gather data from the Insurance Commissioners in each State, which is an involved undertaking that requires the cooperation of 50 State offices. To make adjustments for 89 geographic areas covering the entire country requires much more detailed data than the data used to measure year-to-year national changes in costs for the MEI calculation. I am personally following up to ensure we have the best and most recent data possible for this revision. We have examined whether we should make these updates more frequently in the future. Our experience has been that the changes in the malpractice geographic practice cost indexes from revision to revision have been relatively small, and the effects on physician payments, given only 3.2 percent of these payments are affected by these index values, are also small. For example, a 10 percent increase in malpractice costs in a geographic area would result in only a 0.32 percent increase in Medicare payments in that area, and very small reductions in payments in all other areas. Collecting this data is not trivial and involves time and resources for both Federal and State governments. On balance, given that the annual changes in the Medicare Economic Index capture overall increases in malpractice costs, we do not believe that making revisions in the malpractice geographic practice cost index more often than every 3 years would be an efficient use of resources.

In short, Medicare revises physician payments to reflect changes in malpractice premiums on an annual basis. We do this through changes in the Medicare Economic Index, and thus the update to the physician fee schedule. Changes in malpractice relative value units, which reflect any changes that may have arisen across physician specialties, have been accomplished relatively recently. The malpractice geographic practice cost index in the next update will incorporate the latest available data. While I believe we need to address increases in malpractice premiums forthrightly, I also believe the Medicare physician fee schedule already does a reasonable job in this respect.

HOSPITALS' PAYMENT

I also know that this Subcommittee is concerned about how we update hospital payments. Medicare paid approximately \$100 billion in fiscal year 2003 for Medicare inpatient hospital services. Medicare's approximately 6,000 inpatient hospitals are paid under a prospective payment system (PPS), which is updated annually. This update factor is set in law and determined primarily by the projected increase in the hospital market basket index, which measures the costs of goods and services purchased by hospitals.

CMS has forecasted the fiscal year 2003 market basket to be 3.5 percent. However, the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) established an update of market basket minus 0.55 percentage points for fiscal year 2003. Therefore, the actual fiscal year 2003 hospital market basket update is 3.5 percent minus 0.55, or 2.95 percent. Since the inception of inpatient PPS, hospitals have only once received a full market basket update (fiscal year

2001), and on average, the actual update has been approximately 40 percent lower than the market basket increase.

Despite the difference between the payment update and the market basket increase, inpatient hospital margins have remained very high. In fact, since the early 1990's, there has been a significant drop in the number of hospitals with negative inpatient margins. For example, 61 percent of hospitals had negative inpatient margins in 1991 compared to approximately 25 percent in 1999. Moving forward, we need to continue to ensure that hospitals are paid adequately. In the meantime, we will continue to work hard to do what we can to help physicians and other providers in a variety of ways.

HELPING PROVIDERS OUTSIDE OF PAYMENTS

I worked in the hospital industry for years, and I know how frustrating it can be for physicians and providers to work with Medicare. We know that in order to ensure beneficiaries continue to receive the highest quality care, we must streamline Medicare's requirements, bring openness and responsiveness into the regulatory process, and make certain that regulatory and paperwork changes are sensible and predictable. This effort is a priority for me personally, as well as for Secretary Thompson and President Bush. And we have a lot of activities underway to make Medicare a more physician- and provider-friendly program.

To promote improved responsiveness, we created eleven "Open Door Policy Forums" to interact directly with physicians, as well as beneficiary groups, plans, providers, and suppliers, to strengthen communication and information sharing between stakeholders and the Agency. All of these Open Door Policy Forums facilitate information sharing and enhance communication between the Agency and its partners and beneficiaries. My goal is to make CMS an open agency—one that explains its policies to the beneficiaries and providers who rely on us.

Furthermore, our Physicians' Regulatory Issues Team (PRIT), chaired by an emergency room physician, Dr. Bill Rogers, integrates practicing physicians into our decision making process, allowing us to develop policies that will better serve beneficiaries and physicians. Specifically, PRIT members work within the Agency to serve as catalysts and advisors to policy staff as changes and decisions are discussed. These outreach efforts allow us to hear from physicians and all other Americans who deal with our programs. We are listening and we are learning. I am committed to making lots of common-sense changes and ensuring that the regulations governing our program not only make sense, but also are in plain and understandable language. This will go a long way in alleviating physicians' fears and reducing the amount of paperwork that, in the past, has all too often been an unnecessary burden on physicians.

CONCLUSION

I took this job because I know how important Medicare, Medicaid, and SCHIP are to Americans, and because I want to make a difference in improving our health care system. I am just as frustrated as you and all of the physicians that you hear from when it comes to how confusing and complex these programs are, and I am working hard to improve them. I also am working hard to monitor beneficiary access to care, and ensuring that America's elderly and disabled can receive the high quality care they need and deserve.

The Administration understands that the physician payment system is complex and will continue to work with Congress to smooth out the physician update system. I completely support legislative efforts to fix the short-term and long-term problems with the physician update. We owe it to America's physicians to fix the system so that they can continue to provide Medicare beneficiaries with the vital care they need. Thank you for the opportunity to discuss this important topic with you today. I hope that I have helped to explain the issues, and I look forward to answering your questions.

Senator SPECTER. Thank you very much, Mr. Scully.

We have been joined by the chairman of the full committee, Senator Stevens, and let me say publicly what I have said privately, what an extraordinary job he did last week on the omnibus bill. They said it could not be done, and nobody yet is quite sure how he did it, but it was the manager's amendment which froze the cut in physician payments and increased rural hospitals, and he is the manager.

Mr. Chairman.

OPENING STATEMENT OF SENATOR TED STEVENS

Senator STEVENS. Thank you very much. I am sorry to be late. We had other committee meetings, and I have others to go after this, but I did want to make a short statement, and I do thank you for holding this hearing.

I have great concerns over the effects that continuing to ratchet down Medicare payments to doctors, especially primary care doctors, is having on access to basic health care for our seniors. I find I am one of them. As a matter of fact, my doctor told me to go to see someone else.

It is affecting Alaska even more seriously, because Alaska has no HMO's or managed care plans. Our dispersed and relatively small population is not suitable for those arrangements, so Alaska's seniors must go to solo or group practices to get their medical care or they must overburden hospital emergency rooms at a much greater cost to the system as a whole.

I am told by Alaska family doctors that Medicare pays them only around \$32 for an office visit, compared to around \$75 or \$80 paid by other insurers or health plans. These doctors tell me that the \$32 payment does not cover the cost of seeing the patient, so they lose money every time a Medicare patient walks through the door. Most of our Alaska doctors have felt a commitment to care for Medicare patients, but the low rate of payment means the doctors can afford to only take a limited amount of those patients.

The latest round of cuts in Medicare payments to doctors has been the final straw for some of our doctors, and some have announced that they will no longer see seniors at all. Clearly, this is creating an access problem and, as I said before, seniors in Alaska cannot turn to HMO's as an alternative because we do not have any.

I am also concerned at the lower payment rates to run hospitals, rural hospitals than those located in communities over 1 million people. Alaska does not have one community that fits that urban requirement, so every one of our hospitals gets paid less than those located in the larger cities throughout our country, and I do not understand that discrimination against us at all.

Mr. Chairman, it takes more to provide health care in Alaska and rural areas than it does in the big cities. I do not understand why the payment schedule is turned around. Congress must address this, ensuring fair payment rates to Medicare providers who care for our seniors wherever they are located. As the chairman said, as part of H.J. Res. 2, the omnibus appropriations legislation for fiscal year 2003, the 4.4 percent payment cuts schedule for March 1 will be delayed until September 30 to give the Finance Committee and Ways and Means Committee time to fashion a more permanent solution and suggest it to the Congress.

But Mr. Scully, we want to work with you and other colleagues, including Senators Specter, Grassley, Gregg, and our majority leader, who have been working with us on this problem, to come up with a creative solution to fix these problems for Alaska and other rural areas of the country. I make that commitment to you that we are going to work with you. I hope we have a commitment that you

will work with me and my colleagues from the rural parts of our country to make sure that American seniors have access to first-class health care no matter where they live.

My only question is, and I hope you will answer it after I leave—I must leave, I am sorry—is how did that discrimination take place? Why are we paying more for people who live in big cities than we are paying for people who live in the rural areas, when everyone knows the cost of health care delivery in rural areas costs more? Why did Medicare decide on that type of discrimination, based upon the number of people in the area.

I am sorry I cannot get the answer, but I will certainly read it on the record, and I do sincerely want to know. My people in Alaska want to know.

Thank you very much, Mr. Chairman.

Senator SPECTER. Thank you, Mr. Chairman. Thank you, Senator Stevens.

Senator Harkin has other commitments and has to leave for a time and will return, and has asked leave to ask one question. He has done this on a number of occasions. I have never heard it limited to one question, but he has the floor—

Senator HARKIN. Bifurcating.

Senator SPECTER [continuing]. For however many subparts this one question has.

Senator HARKIN. Mr. Chairman, thank you very much, again, for your indulgence. I appreciate that.

Again, Mr. Scully, I thank you again for being so available to my staff and to me over your tenure here and even before in past administrations.

Mr. SCULLY. Sure.

Senator HARKIN. You know these issues well. You know them better than anyone that I know of that has it all together, and you understand them. You understand our frustration in Iowa on this Medicare reimbursement.

There is one thing I just wanted to add to this. If you took a hospital in Des Moines, and if you assumed the following, same volume of Medicare cases, same Medicare case mix, same staff, same services, assume all of the same, a hospital located in Cincinnati, Ohio, would get \$5.3 million more a year. In Lincoln, Nebraska, they would get \$8.8 million more a year, Denver, Colorado, \$11 million more a year, Ann Arbor, Michigan, \$14.6 million more a year, and these are sort of comparable type of cities to Des Moines, Iowa. And so you can see why our hospitals in Iowa are just at wit's end on this thing.

So again, I am just asking you, will the President's proposed \$400-billion Medicare modernization package include a provision to more fairly reimburse providers in rural States like Iowa, and can you show us any light at the end of the tunnel on this?

Mr. SCULLY. Senator, I cannot tell you—I could quit my job and I can tell you what is in our Medicare plan. I think it might have to wait another week or two until the President's ready to get into details. We are still working on it. I will say one thing, we are not pushing people into HMO's, regardless of what you read in the paper, and I will tell you that I think you are going to find that

some of our proposals will have a significant buffering effect on some of the geographic disparities in the program.

Senator HARKIN. Well, I am glad to hear that, too. I did not mention that, but as you know, we do not have one in Iowa.

Mr. SCULLY. Yes.

Senator HARKIN. Why?

Mr. SCULLY. Well, we will clearly make prescription drugs available to everybody in Iowa through our plan.

Senator HARKIN. Tom, I hope it will be an equivalent. I hope that people who go into HMO's will get more benefit than those who stay in fee-for-service. Do you see what I am saying?

Mr. SCULLY. At the risk of having to quit, I do not want to get too far into this, but I will tell you that I think that we are not pushing people into HMO's. We are going to get prescription drug coverage across the country, certainly in rural areas, and I think you are going to find that some of the geographic disparities that exist in the Medicare—Medicare is a wonderful program, but it is very regulated, very tightly wound, very tight structure, and I think you are going to find some of the impacts will probably help get rid of some of the disparities, but beyond that I probably—unless I want to go back to my law firm, I probably should stop there.

Let me just answer some of the other questions about Iowa, and again, I know the frustration with Iowa, and I know the Iowa Hospital Association, who I have talked to a lot, is testifying after this, so if I could just go through a couple of facts with Iowa.

Iowa should be commended for being very efficient. I went through some of these facts late last night, when I was learning a lot more about Iowa's reimbursement. You get about 92 percent of the national average of cost per service, and you are about 43rd there, and that is about, arguably—this is all about the data, and we do pay—we have a different formula.

We have 89 regions of the country for physicians, and 250 for hospitals, and for example, you get paid 91 percent, or 92 percent of the national average for physicians, and about 88 for hospitals, so clearly there is a difference that has evolved over the years, and it is all legislative. We have very little discretion, but you get paid differently between hospitals and docs.

But you get—even though you get about 92 percent of the costs, on average, you only get 71 percent of the payment, which is 46th, basically, on average, and it depends on how you calculate it. I can explain that.

Your doctors, for instance, are 72 percent of the national average, and they are 40th in the country, but part of it is really, the cost per service is 92 percent, but your health care in Iowa is very high-quality, and very low-utilization, and to some degree, you should be congratulated for that.

I have looked through all the charts, and essentially when you look at who is really doing the best job in the country, it is really North Dakota, Iowa, Oregon, Wisconsin, Wyoming, and a large reason why you are looking at the per capita costs is that your hospitals have shorter lengths of stay, your nursing homes have shorter lengths of stay, your doctors do fewer procedures, and it is not necessarily the payment per procedure, you are doing a lot fewer procedures on average.

For example, your nursing homes spend about 68 percent of the national average on Medicare admissions, \$3,000 versus a national average of \$5,000. Your actual costs per day are 96 percent of the national average, but the average stay in a nursing home in Iowa, for instance, is 14 days, and nationally, it is 22 days, so when you look at the practice behaviors all through Iowa, you do have a geographic disparity, but also, Iowa should be congratulated for having terrifically efficient health care—I mean, it is a model for the rest of the country.

I am not sure it is going to make you feel any better, but I guess one of my arguments, and I got in a little trouble in Washington State for making the same argument out there last year, was, we are certainly concerned about the geographic disparities, and we are working on fixing them, but to some degree Washington State and Iowa are a model for health care for other States, and I know you are worried about the geographic discrepancies, and we are trying to fix them, but I also think it is worthwhile to use them as models for how health care should be practiced as well, because there are a lot of good things that are going on in Iowa and Washington State and some other low-cost States.

So I do not mean to get myself in trouble there. We clearly have a problem with geographic disparity, but to a large degree, a lot of the things that are going on in Iowa and Washington State and Wyoming, Oregon, are very good health care practices and should be a model for other people.

Senator HARKIN. Well, Mr. Scully, commendations are nice, but it does not put bread and butter on the table.

Mr. SCULLY. I understand.

Senator HARKIN. And it does not help the hospitals.

Now, you are getting into a chicken-and-egg argument here. You are pointing out the efficiency of the hospitals, their shortness of stays. Kirk Norris is here, who is the head of our hospital association, who will be testifying. You know why that is happening, because they cannot afford to keep them there any longer, because the reimbursement rates are so low they have got to get them out, and so now, you look at that and say, that is a wonderful thing.

It is not wonderful when you are forced to do things against the best interest of your patients, and it is not a good thing when these hospitals cannot afford to keep doctors and nurses on board because the reimbursement rates are so low. So you may look at that as efficiency. We look upon it as a penalty, and it keeps getting worse, because as we ratchet down, as we become more efficient, you say, oh, wonderful, we can cut you even more, so it is a never-ending spiral that we are on, and you know that.

Mr. SCULLY. I agree with you. It is just, unfortunately, for me it is a statutory spiral, and I would urge you—I mean, we are happy to work on the formulas, but they have been there for years. There are historical reasons for—the people that wrote them 15 years ago generally were not from rural States, and that is just the way they work.

Now, I am just pointing out that I think that the cost per service in Iowa, which is on average about 91 percent, does arguably reflect some of the costs, but there are reasons why it is lower. I agree with you, and I spent a lot of time in Iowa this year, as you

know. I drove 2 days through most of at least the eastern half of the State earlier this year. I went to seven different hospitals, and I think the fact is, once you get into the spiral of wage indexes for hospitals, if you have a lower wage index, you get reimbursed less, your nurses get less, and it is a death spiral, but it is a statutory death spiral—

Senator HARKIN. Exactly.

Mr. SCULLY [continuing]. And I agree with you that there are inequities in the system, and we are anxious to fix them.

Senator HARKIN. Again, you cannot—I mean, you might be able to explain an Iowa compared to New York City. I can understand that, or a Miami, Florida, maybe, or different high-cost areas. You cannot explain it with regard to Lincoln, Nebraska. You just cannot explain it. \$8 million more to the same hospital, same mix of cases and everything, for Lincoln, Nebraska compared to a hospital in Des Moines. There is no explanation for that, other than, well, that is the historical way we have done things.

Well, I just—okay, let us change it. We have got to change it, and with all respect, Mr. Scully, you are a great friend of mine, I have a great deal of respect for you professionally and personally, we need some help from the administration to start moving and changing these formulas and helping us out here and getting something done, and a little bit, a couple of million here, a couple of million there is not going to do it.

I know we cannot do it overnight. I do not think there is any hospital, any health provider in my State that would say, we have got to change it tomorrow. We know we cannot do that. But for crying out loud, to get us on a path that over, say, 4 or 5 or 6 years would get us to a more equitable system, people could live with that if they knew there was, as I said, that light at the end of the tunnel, not 20 years from now but 4, 5 or 6 years we could get on that pathway, we could do it.

Mr. SCULLY. Well, sir, to be honest, as you know, Medicare is growing rather rapidly, and hospital reimbursement is still growing at a rather healthy rate. Nationally, we spent \$100 billion for inpatient hospital services this year, and this is a big geographic issue. When I was in the hospital business, AHA did a very good job of representing everybody, getting the rurals and the urbans into the room trying to work this out over a very long period of time, but obviously, unless you add more money in, which you know, we are already growing at 7 or 8 percent a year, that is a redistribution from urbans to rurals, and even in your own State that probably causes some sensitivity, and I am sure in Pennsylvania, which is my home State, I know it does.

So as you level these inequities out, you are taking money from some of the higher-cost, traditionally, reimbursed urban areas and putting them out in the rural areas. Then—I used to work in the Washington State delegation—whether it is, you know, Seattle too—it is very painful and difficult. But we are all for you. We will help you.

Senator HARKIN. No one wants to take money away, but the rate of growth, if you could just say to those really high reimbursed States that over the next 4 or 5 years your rate of growth will be

less than the States who are at the bottom, you could pull those together.

Mr. SCULLY. I think we would be happy to discuss that, but they are legislative formulas, and I think we have said repeatedly that we think if you are looking at a place in Medicare this year, and we have been hesitant outside of physicians to look at other provider give-backs, we have pretty much said that we think the place where there is the most—beyond fixing the docs—the second best most equitable argument is probably rural hospitals.

Senator HARKIN. I would reverse them, but that is all right, the order of priority.

Mr. SCULLY. Yes, I think the docs should get fixed first—thank you.

Senator HARKIN. Thank you very much, Mr. Scully. I will be back. I just have to leave. Thank you very much, Mr. Chairman, I appreciate that.

Senator SPECTER. Thank you for your question, Senator Harkin.

Mr. Scully, when you were talking about the reimbursement on malpractice rates, I believe you referred to some 1996 to 1998 data. Would you amplify that, please?

Mr. SCULLY. Mr. Chairman, there is basically three different components that we use to account for malpractice costs.

Senator SPECTER. I recall the three components. Could you focus on 1996 to 1998?

Mr. SCULLY. Yes. When we figure in the relative values for what we pay a doctor, let us say an internist in Philadelphia, roughly 42 percent of that is their practice expenses, about 54 percent is their work, and—

Senator SPECTER. I noted that part. How about 1996 and 1998?

Mr. SCULLY. The data we have used for payments in 2001–2003 has been based on 1996 to 1998 data that we collect across the country in a survey every 5 years from large malpractice insurers.

Senator SPECTER. Well, when the rates go up substantially, isn't data from 1996 very badly outdated?

Mr. SCULLY. It probably is.

Senator SPECTER. What do you mean, probably? Any chance that it is not?

Mr. SCULLY. Well, the last—if we actually looked at it, the impact, even if you put, for instance, in Philadelphia the 40 percent increase in malpractice premiums, even if you put that into the formula it would have a very small impact on the results.

Senator SPECTER. Well, you emphasized the small impact in your letter repeatedly, but no impact is too small if you are a doctor paying the rates.

Mr. SCULLY. I totally agree with you, Senator, and I am trying to fix this. We do—the major development that adds money—

Senator SPECTER. Why do you use 1996 statistics?

Mr. SCULLY. Senator, to be honest with you, it is difficult to collect. We use 2001 and 2002 statistics for the more variable component, which is the MEI, the inflation—

Senator SPECTER. I know you have some statistics from 2001, and 2002, but I go back to 1996 statistics, and I am asking you if there is any, any conceivable justification for that.

Mr. SCULLY. Well, to be honest I spent a large part of yesterday, and that is because I anticipated this might come up—

Senator SPECTER. I am sorry, I cannot understand you. You have to start off to be honest with me. We are going to assume everything you say is honest. Just tell us why you are using 1996 statistics.

Mr. SCULLY. Because it is very difficult to collect this data. It is extremely expensive, and we basically do not have the staff resources to do it more regularly.

I believe, and I pushed my staff for the last week to essentially factor in a more informal polling which we do in other places through our contractors on an annual basis, to supplement the massive data collection we do every 5 years, with the more informal polling of our 23 contractors around the country that pay doctors' claims to see if our data that we collect every 5 years actually reflects things like the 40 percent increases in malpractice premiums in Philadelphia, which it obviously does not, when it is 5 years old.

Senator SPECTER. Well, we are going to put a direction in our conference report, Mr. Scully, not to use 1996 statistics, to update the statistics.

You refer repeatedly, and I know this is a matter of statute, that wherever you make the decisions on increases, they have to be in a budget-neutral manner, so if you take away a little from Peter, you deduct it from Paul. Is there some reasonable likelihood that the administration will come up with a proposal to use some of the \$400 million that the President talked about in his State of the Union Tuesday so that we add in some here instead of making them all budget-neutral?

Mr. SCULLY. Well, again Mr. Chairman, at the risk of involuntarily returning to the private sector, I will not get into the details of the plan, but I will say our plan is going to be much more reflective of what is going on in the real world, and that if you have high malpractice costs in Philadelphia or Pittsburgh or any place in your State they will be much more directly and much more quickly reflected in the Medicare program. So I think yes, I think the Medicare program is a wonderful program, but it is very restrictive in the way it reacts to changes in the markets as you have right now in malpractice in Pennsylvania.

Senator SPECTER. I take that to be a yes.

Mr. SCULLY. I think that is a yes.

Senator SPECTER. Okay. The MSA's are very, very problematic, especially in some areas of Pennsylvania in the northeast, in the Scranton area, Wilkes-Barre, where the surrounding areas have preferential costing factors, medical personnel moves. What can be done about that, Mr. Scully, so that we do not have that inequity continued?

Mr. SCULLY. Mr. Chairman, I think the whole Scranton, Wilkes-Barre MSA, as I am sure you are aware, has a real geographic equity problem, and I have spent a lot of time working with them, and it is a legitimate issue.

The problem they have, essentially, though, is that—I have their wage indexes here somewhere, but roughly their wage index I believe is about .85 off the wage index.

Senator SPECTER. Most of the counties in Pennsylvania have the same problem.

Mr. SCULLY. Yes.

Senator SPECTER. And there are other areas across the country which do. What can be done about that?

Mr. SCULLY. Well, I believe that their wage index actually roughly approximates their actual cost. The problem you have in Scranton is that legislatively the northern counties in New York, west of New York, a 2-hour drive west of New York, have been legislated in New York City, so they actually have a wage index of like 1.2, and Philadelphia has been legislated so far north of Philadelphia over the years their index is 1.1, so Scranton, for instance, is stuck in a little pocket.

Senator SPECTER. You are articulating the problem expertly. What is the answer?

Mr. SCULLY. Well, my own personal view, Senator, would be, the answer would be to get rid of all the previous legislative adjustments and go back and rebase the system more accurately, because what has happened over the years is some of these counties that had their neighbors legislatively increased are now surrounded, where they are actually getting paid 30, 40 percent less than the surrounding counties and they cannot recruit nurses. I think to raise them—

Senator SPECTER. Could your Department come up with a proposal on that to submit to this subcommittee?

Mr. SCULLY. Sure. We would be absolutely happy to.

Senator SPECTER. My red light went on, so I want to observe the time limits, since we have so many witnesses.

On Senator Stevens' time, I think you ought to answer his question so he will not miss it in the record as to why the rural reimbursements are so much lower than the urban reimbursements.

Mr. SCULLY. In Alaska, actually, the issue in Alaska is actually Alaska's—for the doctors, which their reimbursement per service is actually rather high. It is actually, their weighted average across the country is about 1.115, the average being 1 percent, and that actually does reflect the higher cost of practicing medicine in Alaska. I think the issue in Alaska is that again their volume of services is lower, their behavior is better, and per capita they get paid less, but per service, I believe they are actually one of the higher cost areas in the country, and that is reflected.

On the hospitals, it is probably not reflected as well, and again I would argue that the hospital formula is probably more flawed in many ways than the physician formula, and I think that is something arguably Congress should look into, is making sure that the physician practice geographic adjustments and the hospital practice geographic adjustments are more parallel. They have grown over the years very independently, and completely disconnected from each other, so I think that, I would guess that in Alaska they probably have more problems with the hospital index than the physician index.

Senator SPECTER. Senator Murray.

Senator MURRAY. Thank you, Mr. Chairman, and before I ask you a question I just wanted to follow up on what Senator Landrieu spoke to you about on the outpatient prospective payment

pass-through, and really urge you to strike the functional equivalent standard from the final rule, and I agree with what she said and hope we hear from you on that soon.

On the whole issue that Senator Harkin has raised in terms of the Medicare reimbursement, I know we have talked about this many times. I just think it is grossly inadequate to say you are really efficient, therefore, you know, we are just going to leave you where you are, because this is affecting access in our States. It is affecting our ability to provide health care.

It is not fair to our seniors, who pay the same as seniors in other States, to not get the same kind of health care. Our hospitals have the same costs, and Senator Harkin is correct, the reason we are becoming more efficient is because we are having to put people out on the streets before they should be, and we should not be penalizing people for that.

I would just really urge you—I know you keep saying this is a legislative fix. That is fine, but it would be extremely helpful if you would come to us with a proposal, and I think you would find bipartisan support to help move that through, but with your agency just keeping a hands-off approach it is very difficult for us to move something through Congress, so I hope we can get that commitment from you.

I did want to ask you about the changes in Medicare that you are going to be proposing, and I know you do not want to lose your job, but I am going to make some points anyway, because I think we all understand that the intent is to save money and to integrate market forces into Medicare, and that is where the administration is coming, and we have not seen the specifics, but I just want to share with you that I am very concerned about what I am hearing, and that is because seniors in my home State of Washington have seen what happens when market forces come into play. They end up with less access to benefits and less access to doctors.

Because of the inequities in Medicare reimbursement there is no open Medicare plus choice plan in Washington State that provides prescription drug coverage today, and many seniors are seeing increased premiums and copayments in Medicare plus choice plans for prescription drugs. Seniors in my State do not even have that option.

We do have a limited number of Medicare plus choice plans that provide additional benefits for our seniors, but most of those plans are closed, or have seen dramatic increases in premiums, and frankly, I am not sure that these plans are going to remain open very much longer in my State. That is what we are hearing, so I am concerned that the administration is planning on building on this inequitable formula and designing a program that provides vastly different levels of benefits to seniors depending on where they live, and I wondered if you would comment on that.

Senator SPECTER. Senator, Murray, if I could, just a moment. I have to go to another committee very, very briefly, so would you continue your questioning, and when you conclude we will be in a very, very brief recess. I shall return momentarily. Pardon the interruption.

Mr. SCULLY. Well, Senator, my wife probably wants me to totally answer the question so that I could quit and go get a job again.

I will try to answer it as thoroughly as I can. I will just say that, as you may know, I worked in the Washington State delegation for 5 years. I am very familiar with Washington State health care.

We are clearly not building a reform package on the Medicare plus choice program. I cannot tell you all the details, but I can tell you that, you know, there are a lot of great things about Medicare plus choice.

I happen to be a very big defender of it, because I think for especially low-income seniors and minority seniors who are disproportionately signed up for those managed care plans, they do it because they cannot afford Medigap premiums, which are frequently \$150 to \$300 a month, and the only way for them to get drugs in many cases, even though it is now limited is to sign up for Medicare plus—

Senator MURRAY. Very limited.

Mr. SCULLY. Well, very limited, but the fact is it is frequently the only place to get any drugs, and to cover your extremely high deductibles in Medicare, so most—you know, the disproportionate number of people that sign up for Medicare+Choice across the country, even as the reimbursement has dropped and plans have dropped out, it is disproportionately minorities and low-income people, and they do it because they cannot afford Medigap and it is the best coverage that they can get.

So I am a big defender of the Medicare+Choice program, despite the fact that it has many flaws, and we are interested in fixing that as well, but that is not what our proposal is built on. We have zero desire to push people into HMO's. That is not what the proposal is.

I think you will find when it comes out that while there is absolutely no doubt that many people will criticize it, I hope that you will be open-minded and let me come explain it to you and at least help your discussion with us, because I think the President, who is very involved in this, has really committed to making the Medicare program work better, and I hope that, while I have no doubt that you will have some concerns, I hope you will spend the time to at least give us a chance to talk about it.

I was stunned, actually, to read the Washington Post this morning. I would say that their editorial reflects kind of where I hope you will think we are when we come out with this plan, and not that I always love everything the Washington Post writes, but that was the most constructive editorial I have seen in a long time. So I hope—I think you will find it is not based on the Medicare+Choice program.

Senator MURRAY. Well, I look forward to having that conversation with you, because we have some real concerns about that, and I want to make sure—

Mr. SCULLY. Just to be clear, we still have a little work to do. Whether it is 1 week or 2 weeks, it is extremely complicated stuff that is very sensitive, and my guess is that we are not going to be rolling it out until we are sure everything is final.

Senator MURRAY. Well, knowing that, I hope you take my comments into consideration as you work through the final details on this.

Mr. SCULLY. Sure. Thank you.

Senator MURRAY. One other question, and that has to do with the administration not supporting increasing provider payments beyond fixing the physician fee schedule. I think you know hospitals in my State are in really tough shape, as I assume they are Nationwide.

There are a lot of reasons, the historically low Medicare, Medicaid reimbursements, it is the increasing cost of technology, it is the health care professional shortage, we have bioterrorism procedures that they are asking to be limited, there are more and more people uninsured—the financial outlook is pretty grim right now, so I was surprised by the recent recommendations from MedPAC that proposed no new payment increases for hospitals or other health care providers like home health and skilled nursing care, and wanted to find out from you today if the administration is going to accept those recommendations from MedPAC.

Mr. SCULLY. Well, the budget, Senator, comes out Monday, so once again I cannot tell you what is in there on hospitals. I will tell you, I used to have a lot of friends in the hospital business, since I ran a hospital for 6 years. I am not sure I do anymore, but my view as a regulator is that we have to identify the trouble spots.

The number one trouble spot for us is the financing mechanism for doctors, which is broken. We have not supported other—we have talked a little more favorably about rural hospitals. We think there are some hospitals that have problems, but we have a big, global Medicare program that pays roughly, we fix the same rate for virtually all hospitals, or the same payments. Some are doing better than others. In some spots we think there are problems, and when you look at, on average, the Medicare margins on average for hospitals are almost exactly at their historical average for 35 years.

If you looked at the average Medicare reimbursement since 1992, it would be market basket minus 1.4. If you look back at the average of what Congress has done since 1992, it would be market basket minus 1.4. MedPAC has recommended market basket minus .4, which would make it probably the third best reimbursement year hospitals have had since the beginning of the program, so I understand because I used to argue as a hospital lobbyist that that is a cut.

From the hospital's point of view it is relatively better than they have done in almost any other year, and I cannot tell you whether we are going to support it or not, but I think MedPAC's recommendation was responsible.

There are always going to be—in 1991 61 percent of the hospitals in the country had negative margins. Right now, we are looking at about 32 percent of the hospitals. That is about the historical average. Is it good that 32 percent of the hospitals are losing money? I would say no.

Many of the hospitals have got mad at me for saying this, but generally when you have 40 percent of the hospitals losing money you have a problem, and when you have 25 percent of hospitals losing money, you have historically high averages for margins which we had in 1996. The reason Congress whacked hospitals, and I would argue far too hard, in 1997, was because margins were very

high, and even in that year we had 25 percent of hospitals losing money.

So there are clearly trouble spots that we need to focus on. I would say rural hospitals is probably one, but overall, my argument to my former friends and, I hope, current friends in the hospital sector is that when things are going relatively well, you should—you know, if Congress gives too much money back, they are going to come back and take it away in a couple of years, and you are going to get these big roller coasters.

My personal view right now is, hospitals are about where they should be on a national average, and there are clearly trouble spots, and the best thing we can do in Congress is keep them on the existing glide path without big cuts or big add-backs, and I would say that if you look at the historical trends, the MedPAC recommendations are extremely responsible.

That does not mean that I know or could say what is in the budget next Monday.

Senator MURRAY. Well, we will be looking at the budget, and I am sure hospitals will have a lot to say about that as well, but I know my time is up, and the committee will take a short recess until the chairman returns.

Mr. SCULLY. Thank you.

Senator SPECTER. Mr. Scully, thank you very much. We are going to move on to panel 2. You are on panel 3. I hope you will be able to stay and hear what our witnesses on panel 2 have to say about this very important issue.

We will now proceed with Dr. Roth, Dr. Desai, Mr. Anderson, Mr. Norris, Dr. Kleiman, Dr. Blomain, and Mr. D'Alberto.

I might give you just a little insight for the very brief interruption. The schedules here are very involved. I was committed to introduce a distinguished Pennsylvanian, Paul McHale, who is having a hearing before Armed Services, and I abbreviated my lengthy introduction to 4 minutes under the 5-minute rule to make it as brief as possible. I am due in the Judiciary Committee for the Estrada vote briefly, but that is part of my problems, not yours. You have your own problems, and I thank all of you for coming to present testimony on this very important subject.

STATEMENT OF LOREN H. ROTH, M.D., M.P.H., SENIOR VICE PRESIDENT, MEDICAL SERVICES, UPMC HEALTH SYSTEM, ASSOCIATE SENIOR VICE CHANCELLOR, SCHOOLS OF THE HEALTH SCIENCES, UNIVERSITY OF PITTSBURGH

Senator SPECTER. Our first witness will be Dr. Loren Roth, senior vice president for medical services at the University of Pittsburgh Medical Center Health Systems, also serves as associate senior vice chancellor for health sciences and professor of medicine at the University of Pittsburgh, a B.A. from Cornell, an M.D. from Harvard, and a master's in public health of the Harvard School of Public Health.

Thank you for joining us, Dr. Roth, and the red light goes on at zero, you have a green for 4 minutes, and a yellow to sum up at 1 minute. Thank you for joining us, and on a personal note, may I say that I have known Loren Roth for a couple of decades, really an outstanding physician and public servant. Dr. Roth.

Dr. ROTH. Thank you very much, Senator, and thank you for having this hearing. These are critical issues. In my role as the chief medical officer of the UPMC, I represent the medical interests and concerns of the more than 4,500 physicians who are affiliates or employees of our largest health care system. The UPMC today has 20 hospitals. We employ more than 25 percent of the physicians in Allegheny County.

As you are hearing today, there is a crisis in health care delivery in Pennsylvania and nationally. I recommend for your review and have given you the paper from the New England Journal of Medicine, which echoes what you are hearing today.

The paper is entitled, "Homeostasis without Reserves, the Risk of Health System Collapse." Dr. Sandy notes three deep forces at work, steady increases in real health care costs, unabated demand for health care services, and dispirited providers, in part on the basis of malpractice and their decreasing reimbursement.

Medical school applications have decreased 15 percent over the last 4 years. Although, Senators, you have heard a good deal about physicians moving from State to State, I would suggest that these statistics may predict a future in which not only that physicians go from State to State, but that we have less physicians, or less competent competitive physicians. This is truly a crisis.

Furthermore, I have emphasized the UPMC employs physicians. A large number of physicians today are not in private practice, but are employed by organizations such as hospitals and what-have-you. The interests of physicians and hospitals today largely run together. What is economic damage to one is economic damage to the other. Therefore, even though we are focusing mainly on physician reimbursement, which is a real problem, as you heard from Mr. Scully, this effect spreads throughout the entire health care system.

Given my time limits I will not review the malpractice crisis in Pennsylvania, with which you are very aware. I will add that malpractice is only one of the several costs of business that physicians and hospitals are coping with as our operating costs rise, as you have heard from the various other Senators. New technology, pharmaceutical costs, workforce issues, securing payments, all the money we spend with denials from insurance companies, managed care companies, regulatory requirements, HIPAA, bioterrorism. The hospitals are called upon to spend a tremendous amount of money, et cetera, et cetera.

I have been involved with the UPMC for about 10 years, helping to build our network. Overhead costs have risen from 45 percent to 60 percent. These are serious matters, and we and the hospitals are not being reimbursed for them.

You are aware, of course, of the Code Blue emergency in Pennsylvania. I will not comment in depth on that. However, I will note from 1999 to 2003 the cost of malpractice premiums paid by our University of Pittsburgh academic clinical physicians escalated from more than \$5 million to \$23 million a year, an increase of 200 percent per faculty member. In no way is that represented, as you have heard, in the calculation of the malpractice costs that go into the Medicare formula.

However, Senators, this malpractice crisis and, I would say paradoxically, physician Medicare reimbursement cuts have the very same effect. No one to date has noted the extent to which these problems of decreased reimbursement and rising costs fundamentally affect the practice and pattern of how medicine is delivered.

If physicians must meet their costs in the office and they are receiving less reimbursement, how can they stay in business unless, one, they see more patients, and I think this is actually the experience of many consumers and patients, so they attempt to see more patients, possibly, or in the Medicare example, because they cannot afford it, see less of those and more of others, but when you go into a doctor's office, you want that physician to have sufficient time to be able to take a clinical history and not simply to order a lab test or a very fancy test.

This is a most complex economic problem of the relationship between resource utilization and what-have-you, versus what really should be done, and the patterns of medicine are being negatively affected by the patterns that I am saying here.

I will not review in depth data, then. In my written testimony there is extensive discussion of the same issues that Mr. Scully discussed about the problems in the malpractice calculations, which simply do not keep up with the costs that the physicians and hospitals are experiencing, and so I will just refer you to my written testimony there.

Senator SPECTER. All of the written testimony will be made a part of the record, so we would appreciate it if you would stay within the time limits of the oral presentation.

Dr. ROTH. Okay. How much time do I have left?

Senator SPECTER. You are now almost a minute over. The timing is right before you. The red light is on.

Dr. ROTH. Oh, I am sorry. I will summarize, then, with your indulgence, with too major points.

Senator SPECTER. Thank you.

Dr. ROTH. You have heard that the formula is inaccurate. It is extremely frustrating to physicians to know that there is a known inaccuracy which cannot seemingly be fixed by the legislative process, with all of the decrements coming.

My second major point, and for you, Senator, I think this is of particular interest, you have been a wonderful supporter of the NIH and research. We are talking here not only about physician decrements in reimbursement. We are talking about complete impact on the academic medical center.

PREPARED STATEMENT

Every amount of money that must be paid to a greater extent for malpractice, 90 percent of our clinical doctors survive in good part by their clinical income. When their clinical income goes down, there is less time for research, there is less time for education, so what I am trying to do is give you a holistic picture that this is a generic problem, and the tradeoffs here, as you have heard previously, when one takes from the other, is that you and we want to preserve the academic mission, and this is directly impacting in a negative way upon it.

Thank you for asking me to testify.

[The statement follows:]

PREPARED STATEMENT OF DR. LOREN H. ROTH

Greetings to the Subcommittee. Thank you for giving me the opportunity to testify before you today on the need to address problems with Medicare's reimbursement and its negative impact on physicians and academic medical centers such as ours.

I am Dr. Loren H. Roth, Senior Vice President, Medical Services and Chief Medical Officer of the University of Pittsburgh Medical Center (UPMC). I am also the Associate Senior Vice Chancellor, Health Sciences, of the University of Pittsburgh and Professor of Health Policy and Management at the University.

The University of Pittsburgh Medical Center and the University of Pittsburgh School of Medicine are each nationally highly ranked institutions. They are recognized for their role in supporting and performing medical research, education of medical students and residents, and for their delivery of innovative tertiary/quaternary and community-based care. The UPMC is committed to system wide quality improvement efforts, patient safety, and the elimination of medical errors. We have well-established programs in all these areas of critical importance for patient well-being and the practice of medicine.

In my role as Chief Medical Officer of the UPMC, I represent the medical interests and concerns of more than 4,500 physicians who are affiliates or employed physicians of one of the largest academic health care systems in the nation. The UPMC today includes 20 hospitals, a large number of University of Pittsburgh full time clinical faculty physicians (more than 1,300), a large number of community-based physicians (350 employed by the System) as well as other community-based private practice physicians who are members of UPMC hospitals' medical staffs.

Almost one in every two people in Allegheny County and one of every four people in the region who need hospital care obtain it in a UPMC hospital. The University of Pittsburgh Medical Center employs more than 25 percent of the physicians in Allegheny County, Pennsylvania. The important issues that this hearing addresses affect many parties and institutions, academic and community-based physicians, our School of Medicine, its academic mission, many hospitals, and our patients.

Western Pennsylvania has a comparative national overrepresentation of Medicare eligible citizens, who number 19 percent of our population base. "On average, hospitals in this region receive nearly half of their patient revenue from Medicare, while nationwide the average is about 38 percent."¹ Community and teaching hospitals are particularly dependent upon Medicare reimbursement. With the exception of South Florida, Western Pennsylvania has the highest percentage of elderly population in the country. Medicare policies, payments, and procedures greatly affect the healthcare status of our community.

The issues we confront today are critical to the survival and well being of Southwestern Pennsylvania physicians and patients, as well to the educational/research mission of the University of Pittsburgh and the UPMC.

Senators, I regret to inform you that there is a crisis in healthcare delivery in Southwestern Pennsylvania and nationally. I recommend for your review a recent *New England Journal of Medicine* article by Dr. Lewis G. Sandy entitled "Homeostasis without Reserve—the Risk of Health System Collapse,"—I have brought several copies for you.²

See also the recent statement of the National Academy of Sciences, Institute of Medicine, "The health care delivery system is incapable of meeting the present, let alone the future needs of the American Public—For the first time in nearly 20 years—the United States is facing a broad-based crisis in the availability and affordability of malpractice liability insurance for physicians, hospitals, and other health care providers."³

To substantiate his case, Dr. Sandy (from the Robert Wood Johnson Foundation) notes three "deep" forces at work: (1) Steady Increases in Real Healthcare Costs; (2) Unabated Demand for Healthcare Services; and (3) Dispirited Providers. Dr. Sandy notes that "Dissatisfaction is widespread among physicians and medical school applications have decreased 15 percent over the past 4 years."⁴ These are but some of the facts and trends that relate to this hearing.

¹ Gaynor, P., *Pittsburgh Post Gazette*, page E-2, January 5, 2003.

² Sandy, L.G., *New England Journal of Medicine*, Volume 347, pp 1971-75, December 12, 2002.

³ Pear R., "Panel Citing Healthcare Crisis, Presses Bush to Act", *New York Times*, November 21, 2002.

⁴ Sandy, *ibid*.

Let me turn then to the subject of “dispirited providers” and specifically the impact that recent trends in escalating medical malpractice costs, as well as repetitive, severe reductions in Medicare and other reimbursements are having on both physicians and hospitals. Recall that a great number of physicians are presently employed by hospitals and healthcare systems. The subject for today is vital to the health of the entire provider community and the patients it serves.

LIABILITY CRISIS AND CONCERNS

Senator Specter, you are well acquainted with the current malpractice crisis in Pennsylvania and the negative impact it is having on hospitals, physicians, and patients with respect to the provision of and access to specialty and other care. The total cost of medical professional liability insurance coverage for Pennsylvania’s hospitals increased 86 percent over the past 12 months.⁵ Meanwhile hospital and physician operating costs continue to rise as a result of new technology, pharmaceutical costs, work force issues, securing payments due them from insurance and managed care companies, regulatory requirements (such as HIPAA implementation), and other administrative costs. In the last several years office overhead for most physicians has risen from 40/45 percent to 60/65 percent.

The cost of malpractice insurance for physicians has escalated dramatically, placing physicians in impossible dilemmas with respect to obtaining and paying for adequate malpractice coverage from either private insurers or the state.

Pennsylvania is not alone. We are one of 12 states identified by the AMA as now in a liability (cost/availability) crisis. The similar crisis and its impact upon physicians in West Virginia have made the national news. More than two dozen surgeons who operate at four West Virginia hospitals have recently taken leaves of absence and pledged that they won’t return until the government and legislators address the malpractice problem.

As noted by the Hospital Association of Pennsylvania in a recent survey of 150 Pennsylvania hospitals and health systems, “Nearly two thirds of hospitals report that some physicians are retiring early, curtailing practices, or relocating as a result of increasing liability costs.⁶ In the last three years, nine insurance companies have stopped writing medical malpractice policies in Pennsylvania.⁷

Because of progressive loss of specialists in rural and urban areas, increasing costs of coverage for high risk specialists such as neurosurgeons, orthopedists and obstetricians, and the shutting or threatened shutting of vital services such as trauma centers, this fall the Pennsylvania Medical Society declared a “Code-Blue Emergency”. This could have culminated in physicians electively declining to pay state mandated surcharges to the State Catastrophic Fund (CAT Fund—now called MCare Fund) thereby taking a vacation from their vital professional work beginning January 1, 2003. Only last minute action by Pennsylvania Governor Elect Rendell prevented such a negative outcome. “We have to go back to the drawing board to keep all these physicians from leaving the state.”⁸

The proposed Pennsylvania plan is by no means certain to occur because of opposition from private insurance companies. The plan is for these companies to “foot the bill” (\$220 million additional) for the necessary CAT Fund dollar infusion. This would waive certain high-risk specialty physicians from this surcharge and provide a 50 percent discount for other physician specialists in CY 2003. The outcome for the physicians and their patients is still uncertain. The problem is far from solved because this plan is a “quick fix” and does not resolve the underlying problems faced by Pennsylvania physicians and hospitals.

These issues have very negatively impacted our medical center, its physicians and the academic mission. For example, between fiscal years 1999 and 2003 the cost of malpractice premiums paid by our University of Pittsburgh academic clinical physicians escalated from more than \$5 million to more than \$23 million per year, an increase of more than 200 percent per faculty member. The increase for fiscal year 2003 alone is 23 percent. At the University of Pittsburgh Medical Center (UPMC) our cost for “excess coverage” for physicians (beyond state requirements and desirable because of the proliferation of very large verdicts, especially in the eastern part of the state) has increased 500 percent from 2000 to 2002. As a result, we are having progressive difficulty in retaining graduating residents in certain specialties to remain in Pennsylvania. A recent HAP survey found that nearly two-thirds of med-

⁵ HAP Update, “HAP survey shows continuing liability crisis”, page 1, November 15, 2002.

⁶ HAP Healthcare Outlook, page 1, November 2002.

⁷ Bull, J., *Pittsburgh Post Gazette*, page D2, December 25, 2002.

⁸ HAP Update, page 3, December 13, 2002.

ical teaching programs in Pennsylvania report that their medical residents are choosing to continue their practices outside of Pennsylvania.⁹

The impact on other Pennsylvania physicians, some faced with individual malpractice payments in the hundreds of thousands of dollars, has been even more dramatic. For example, three obstetricians in Uniontown, Pennsylvania “stopped delivering babies this fall because the physicians, all in their thirties, couldn’t afford the insurance, \$400,000 this year compared with \$150,000 last year.”¹⁰

The announcement of dramatic and extremely high malpractice awards has a very negative effect on physicians, provokes defensive medicine, poor patterns of healthcare delivery, excess resource utilization, and escalating healthcare costs. For example, announcement of a recent very large malpractice verdict immediately raised the bar on malpractice settlements throughout Southwestern Pennsylvania. This significantly drives up premiums and decreases our academic health center’s ability to invest in new technology, quality improvement programs, recruit and maintain physician talent, and invest in biomedical research.

Our experience parallels that summarized by U.S. Government experts. See, for example, the Report from the U.S. Department of Health and Human Services, “Confronting the New Healthcare Crisis: Improving Healthcare Quality and Lowering Costs by Fixing our Medical Liability System”, July 24, 2002. The report estimates that limiting unreasonable awards for non-economic damages (caps on pain and suffering) could reduce healthcare costs by 5–9 percent without adversely affecting quality of care.

For the purposes of today’s hearing we must relate the above facts and problems that I have thus far highlighted, to the formulas used by CMS, and mandated by Congress, to reimburse physicians. There is a great deal of technical complexity here. However, it is my belief supported by the following observations that the present approach to Medicare physician reimbursement is deficient in this respect. The formulas by no means keep up with the current costly malpractice premium and settlement expense trends discussed above.

For example, there is an opportunity in the RBRVS system (Resource Based Relative Value Scale), which computes the number of RVU’s (Relative Value Units) to be paid for a specific piece of physician work (CPT Codes, levels) to take malpractice costs into account. The total number of RVU’s awarded include “Work RVU’s”; “Practice expense RVU’s” and “Malpractice RVU’s”. However, in CY 2002, and despite the trends above, “Malpractice RVU’s” did not change significantly in the Federal calculation of physician resources involved in a particular piece of medical work.

Another opportunity for including malpractice expenses in determining physician Medicare fees comes in the calculation of the *Conversion Factor*, which changes administratively on an annual basis as set forth by the Balanced Budget Act, BBA, of 1997. Presently for 2003, physicians must (we hope not) once again endure an additional reduction of 4.4 percent in the *Conversion Factor*, which when multiplied times geographically corrected RVU’s for a particular piece of work results in a specific payment. The *Conversion Factor* is determined by factors related to the Medicare Economic Index (MEI), Medicare Sustainable Growth Rate (SGR) and by the Statutory Adjustment Factor. As you are aware, during 2002, the reduction was 5.4 percent.

Again this is a very complex matter. In fact, this approach to physician Medicare reimbursement has been repetitively criticized by the American Medical Association, the Association of American Medical Colleges (AAMC)—representing academic interests, the Medical Group Management Association (MGMA), as well as by highly regarded independent commissions such as MedPAC (Medicare Payment Advisory Commission). The present approach needs to have an immediate overhaul. It is misleading and not structured to reflect true increases in practice costs. (See below)

For our purposes today, however, the relevant fact is that the recently released data concerning the federal computation of the *Conversion Factor* for CY 2003 reflects only an 11.3 percent increase (2002 to 2003) in the Professional Liability Insurance Factor (as relates to the calculation of the MEI). This is inadequate from any realistic account of what is actually happening to physicians and hospitals “in the field” (see above). The 2002 MEI PLI factor of only 3 percent increase was also clearly inadequate. Furthermore, the MEI/SGR systems approach to Medicare physician payments does not yield an actual 11 percent increase in payments.

The conclusion is that physicians and hospitals are not paid sufficiently by Medicare in light of these malpractice costs trends and computations. This requires immediate correction.

⁹ HAP Healthcare Outlook, page 1, November 2002.

¹⁰ Albert T., “Pennsylvania Faces Liability Meltdown,” AMA News, page 4, December 9, 2002.

From our perspective in the field (both academic and community), an important first step to halting the dramatic increases in liability premiums would be for the Senate to immediately consider, pass and adopt the approach of the House HEALTH Act, H.R. 4600 (*Help Efficient, Accessible, Low-Cost, Timely Health Care Act*) passed in 2002. This approach would offer a more definitive solution for physicians, hospitals, and their patients to the national liability crisis discussed above.

MEDICARE CY 2003 PHYSICIAN REIMBURSEMENT

The above discussion of escalating liability insurance costs is but one blow to physicians and hospitals. The next blow, likely to occur unless you and your fellow Senators act immediately, is the CY 2003 physician fee schedule and the 4.4 percent reduction in the *Conversion Factor*. This blow cannot be sustained by American medicine and its patients. As previously mentioned, this will be the second year of such reductions.

This reduction is particularly aggravating to physicians and hospitals. Responsible government officials such as Mr. Thomas A. Scully, the Medicare Administrator who has just testified, has himself recently indicated that the concepts and facts propelling this "mandated" reduction are not accurate. In fact, the inaccuracy is 6 percent, to the present detriment of physicians and the hospitals that employ them.

According to Mr. Scully, the correct *Conversion Factor* for CY 2003 should be a 1.6 percent increase, not a 4.4 percent decrease in physician reimbursement. As noted by Mr. Scully and reported in *The BNA Health Care Daily Report* dated December 18, 2002, "If you go back to 1992 and take all of the errors up and down and fix the fee schedule the way it should be fixed, that's our calculation." Mr. Scully also notes in a CMS Public Affairs announcement dated December 20, 2002, that "The reduction in physician fee schedule rates results from a formula specified in the Medicare law and we believe that formula is flawed and must be fixed."

The reasons for these inaccuracies and unfairness are well known. Here I quote from a recent public plea directed by more than 4,500 University of Pittsburgh Medical Center physicians to the Pennsylvania Congressional delegation: "The current update formula ignores erroneous past projected targets of gross domestic product growth and (Medicare) fee-for-service enrollment, fails to reflect the actual cost of providing physician services, and contributes to payment volatility. If such flaws are ignored (more cuts are coming) in just three years, Medicare physician payment rates are expected to fall below 1991 levels, despite an estimated 40 percent increase in medical practice costs over the same period." There are other reasons for this inaccuracy, such as the growth of medical technology.

Because of Medicare cuts already made in 2002 (5.4 percent) and cuts reflecting other pay factors in the *Conversion Factor*, the percent change in average payments by Medicare Specialty Physician Fee Schedule for CY 2002 and 2003 reflects a 10 percent average decrement for all physicians.

There is also variation for CY 2002 and 2003 by specialty, from a total cut of 4 percent (OB/GYN) to higher cuts for Cardiac Surgery (16 percent), neurosurgery (14 percent), Orthopedic Surgery (13 percent), and Family Practice (8 percent).

I note with great concern the differential negative effect of the already discussed liability insurance increases and these Medicare payment cuts upon specialties such as neurosurgery and orthopedics. These are the very specialties needed in advanced trauma centers, essential for producing "best patient" treatment outcomes in tertiary medical centers such as ours in Pittsburgh.

Can such cuts and continuing problems in the unaffordable costs of liability insurance be accomplished without negative consequences for patients? I doubt it and so does CMS.

As noted in the CMS Public Affairs Office Announcement on December 20, 2002: "Almost 90 percent of physicians accept Medicare assignment today and as yet CMS has not seen access problems. However, CMS expects that may change after these rules take effect." There is much to suggest that this is so. For example, the American Medical Association reported on September 16, 2002 that the American Academy of Family Physicians has released survey data showing that nearly 22 percent of family physicians are no longer taking new Medicare patients, a significant increase from the same survey data one year earlier.¹¹ More than 40 percent of physi-

¹¹Maves, M., MD, MBA, "AMA Letter to Entire U.S. Senate Urging Medicare Payment Update Increase of 3 percent," September 16, 2002.

cians surveyed in a recent AMA poll said they wouldn't sign Medicare participation agreements if pay cuts continued.¹²

A similar concern has been expressed by John C. Rother, Policy Director of AARP and a well-known advocate for senior citizens. He notes with respect to the Medicare payment formula that "Congress should correct it as soon as possible. . . . We are getting complaints that it is becoming difficult for Medicare beneficiaries to find a doctor willing to accept them in some parts of the country. We don't want that problem to spread."¹³

IMPACT OF MEDICARE PHYSICIAN CUTS UPON THE ACADEMIC MEDICAL CENTERS AND ITS PATIENTS/STUDENTS

What do these clearly unwarranted cuts mean for academic healthcare centers such as the University of Pittsburgh Medical Center? Some local statistics are of interest:

Medicare physician fee cuts from fiscal year 2002, compounded with those to occur in fiscal year 2003, have or will result in a loss of \$6.4 million to our University of Pittsburgh Medical Center academic clinical faculty physicians. Medicare cuts have or will result in an additional loss of \$2.3 million for UPMC community based physicians over this same time period.

Medicare payments are the "standard" upon which other insurance payers base their payments. A drop in Medicare payments will mean a commensurate drop in physician reimbursement for both academic clinical faculty and community physicians, damaging their ability to provide care for both Medicare beneficiaries and their other patients.

These cuts in physician reimbursement can "only possibly and very painfully" be restored by the University of Pittsburgh Medical Center which will then have many less dollars to spend for support of academic medicine, research and investment in young, promising physician/scientists or otherwise we risk losing key faculty clinical and community based physicians. This is a Hobson's choice.

Academic success and vitality are dependent upon physician earned clinical income and the economic well being of the parent teaching hospital. For example, at the University of Pittsburgh Medical Center, more than 90 percent of clinical faculty salaries are paid by their clinical earnings or by the hospital. At academic healthcare centers, clinical faculty provide innovative expert care. They teach and perform research and clinical trials. They require financial support. If we are to retain clinical faculty and profit from their experience and longstanding "value commitments"; then these unwarranted Medicare cuts in physician reimbursement must stop.

The same is true for the University of Pittsburgh Medical Center physicians who practice in the community. Patient access to their outstanding care is vital to Southwestern Pennsylvania.

Clinical faculty and University of Pittsburgh Medical Center community based physicians also do much for which they are not paid at all or paid very poorly. Society is dependent upon them for clinical care that is otherwise not available to disadvantaged persons. There is a crisis in American medicine. This crisis includes how best to provide care for the uninsured and disadvantaged. Presently, almost 42 million Americans have no health insurance. The AAMC's member teaching hospitals, which are 6 percent of all hospitals, provide nearly 50 percent of all hospital charity care.

As recently noted by Senator Bill Frist (R-Tennessee), "We need to focus on the uninsured and those who suffer from healthcare disparities that we so inadequately addressed in the past, but which I saw every day working at a hospital for eight or nine years just several blocks from here."¹⁴ Unless the formula is fixed and Medicare reimbursement can be stabilized, many problems will be coming for medical innovation, teaching, and patient care. As noted by the AAMC, "Medical schools finance up to 46 percent of their operating budgets from income generated by their clinical faculty and relationships with teaching hospitals."¹⁵ Such clinical income also affects medical student support and scholarships. In today's economic climate,

¹² Albert, A., "Delegates rally to knock out cuts in Medicare payments", *AMA News*, page 2, January 6, 2003.

¹³ *New York Times*, page A14, December 21, 2002.

¹⁴ "Republicans Pick Frist as Senate Leader; He vows to 'Heal Wounds of Division'", *New York Times*, page A18, December 24, 2002.

¹⁵ Cohen, J., "AAMC Letter to Congress on Fixing the Sustainable Growth Rate", AAMC, 1999.

85 percent of medical students presently graduate with debts averaging about \$125,000 per student. This debt compounds during their residency and later.

MEDICARE HOSPITAL REIMBURSEMENTS

To fully understand the impact of Medicare physician reimbursement cuts on the academic healthcare center, we must also keep in mind cuts that have and are occurring with Medicare hospital reimbursements.

Hospital operating margins in Western Pennsylvania are at the lowest they have been in decades. In the last five years, Pittsburgh has experienced two major hospital system de facto bankruptcies and one of these systems, St. Francis Medical Center, has recently closed. Given declines in investment income secondary to the poor economy, hospital total operating income is barely positive and not positive at all for many hospitals.

In the case of the University of Pittsburgh Medical Center, as a consequence of the 1997 BBA, we have experienced Medicare related reductions in reimbursements compounding the economic and academic effects noted above. Mandated market basket reductions over the last five years have totaled \$52.7 million to our medical center's bottom line.

Additionally, IME reductions (Indirect Medical Education payments) consequent to the BBA of 1997 (Balanced Budget Act) and BIPA of 2000 (Benefits Improvement and Protection Act) for the medical center have totaled \$55.9 million over the last five years. In fact, the last phase of the IME reductions—a 15 percent cut—were effective on October 1, 2002.

These combined hospital and Medicare-related reductions now constitute a continuing reduction to medical center income of about \$30.1 million per year, with attendant negative consequences for the academic and clinical mission as discussed above.

I urge you to work towards maintaining the IME at fiscal year 2002 levels as well as ensuring full inflation or market basket updates to hospital inpatient and outpatient rates.

CONCLUSION

(1) The Senate should consider and pass legislation to address the current malpractice crisis. The HEALTH Act, H.R. 4600 endorsed last year (2002) by the House, is model legislation for this purpose. That approach deserves your support.

Just 2 weeks ago, President Bush (January 16, 2003 speech at the University of Scranton, Pennsylvania on the national malpractice crisis) appealed for medical liability reform along these lines.

(2) As documented above, multiple negative consequences to physicians, hospitals, nursing homes, academic health care centers, medical schools, and patients will ensue if CY 2003 Medicare physician payment reductions are implemented. Patient access to medical care will be jeopardized and innovative medical research and education will be compromised.

The physician community, and the hospitals that help support them, cannot sustain unwarranted cuts of 18 percent of physician pay over a four year period combined with increased medical liability burdens, escalating regulatory and insurance based administrative practice costs, and other escalating operating costs that are impacting all U.S. businesses.

A mistake has been made. It has been clearly acknowledged by those most expert in this field. It is time to fix the mistake. I urge this committee and the full Senate to immediately debate and bring an end to this plan.

(3) The Senate fiscal year 2003 omnibus appropriations bill includes a temporary freeze in the CY 2003 cut to physician payments and I support this temporary fix. However, a long term solution to the reductions and the overall false Medicare formula must be addressed. Last year, over three-quarters of the Senate cosponsored legislation (the "Medicare Physician Payment Fairness Act," S. 1707) that would halt the scheduled reductions and call for a more equitable alternative to the current payment methodology. Despite the indicated of strong bipartisan support, no action has been taken.¹⁶

(4) Halt the current IME reductions and maintain IME payments at 6.5 percent (fiscal year 2002 levels);

(5) My experience and reading convince me that the Congress should also initiate and debate how better to pay for the future medical treatment of Medicare patients.

¹⁶Letter on Medicare Physician Payment Relief Signed by (106) Medical School Deans, Sent to Senate Finance Committee and Full Senate," *AAMC Government Affairs and Advocacy*, September 19, 2002.

We need to devise a much better system for assessing justified physician and hospital payment that will take into account escalating health care costs from every quarter.

Senator SPECTER. Thank you, Dr. Roth.

Gentlemen, we are going to have to observe the time limits. We have another panel. I have to get to the Judiciary Committee, and there is floor action coming up this afternoon, so take a look at the timer, and please observe the time limits.

STATEMENT OF JITENDRA DESAI, M.D., PRESIDENT-ELECT, PENNSYLVANIA MEDICAL SOCIETY

ACCOMPANIED BY DENIS OLMSTEAD, ECONOMIST, PENNSYLVANIA MEDICAL SOCIETY

Senator SPECTER. Dr. Jitendra Desai is president of the Allegheny County Medical Society, senior attending physician at Allegheny General Hospital. He is accompanied by Mr. Denis Olmstead, senior economist and vice president of the Division of Representation for the Pennsylvania Medical Society. Thank you for joining us, Dr. Desai, and the floor is yours.

Dr. DESAI. Good morning, Senator, and members of the Appropriations Committee. I am Jitendra Desai. I am president-elect also of the Pennsylvania Medical Society, a solo practicing urologist from Allegheny General Hospital, a low income, medically underserved community near Pittsburgh. With me is Denis Olmstead. We are here on behalf of Pennsylvania physicians and their patients to comment on the current Medicare payment system and professional liability system and their increasingly adverse effect on the availability of quality health care for our citizens.

Let me start by reinforcing what you already know, that the current formula used by Medicare physician reimbursement is dangerously flawed. This fact has been openly recognized by the administration and must be fixed legislatively by the U.S. Congress. Pennsylvania physicians, the backbone of Pennsylvania's health care delivery system, cannot afford any additional payment cuts. Without a doubt, the latest scheduled Medicare cuts could not have come at a worse time. Pennsylvania physicians are caught in a vise. We have a very low health insurance reimbursement, national commercial insurance payments 40 to 50 percent higher than Pennsylvania's commercial insurance payment levels. We also have extremely high physician practicing cost, driven in large part by runaway professional liability premiums.

With such low commercial health, Medicaid and Medicare plus choice payments, reduced Medicare fee for service payments may be the last straw.

In addition to the reduction in Medicare conversion factors, other important elements of the formula work against Pennsylvania physicians. As mandated by Congress, the Medicare payment formula is resource-based. In other words, relative other units for work costs, practice costs, and professional liability costs ought to deflect physicians' true expense of delivering service to the Medicare beneficiary. This is not what is happening. The payment formula does not account for the actual cost of delivering care. For example, from January 1997 to September 2001, the major professional liability

carriers in Pennsylvania increased their liability insurance rates between 80 percent to 147 percent.

Even before the horrible terrorist attacks on September 11, rates were already climbing at a significant rate. Since then, medical liability insurance rates have increased further. In 2002, major carriers increased rates between 40 to 50 percent, followed by similar increases in 2003.

The Medicare payment formula, on the other hand, has not kept up. Professional liability relative value units and its associated geographic adjuster designated to differentiate costs to practice of medicine in a defined geographic locality are based on data collected from the period 1996 to 1998, as you mentioned.

Our present liability cost increases will not work their way into the formula until 2007 and 2009. It is just inconceivable that in the age of computers data reflecting the current cost of liability insurance is not being used to determine current payment rates, so you can see not only does the current formula short-change physicians from the professional liability perspective, but also continue to short-change physicians for many years.

To exacerbate this situation further for many clinical physicians, the current payment formula would have you believe that the cost of professional liability insurance and other practice costs are less than the national average costs incurred by physicians in other Medicare carrier payment jurisdictions. If one is the national average geographic adjuster, most of Pennsylvania falls under the average. That is, .989 for the work relative value units, .929 for the practice value units, and .774 for the professional liability values.

Again, this is the ultimate outcome of further reducing Medicare payments in Pennsylvania.

In addition to the Medicare payment formula problem, Pennsylvania physicians are also faced with other specific circumstances which act to dissuade physicians from participating in Medicare. First, our State does not allow for balance billing of Medicare beneficiaries. We are one of the only few States that do not permit Medicare nonparticipating physicians to balance bill the patients. This limits the choices physicians can make regarding the billing of Medicare beneficiaries with higher income.

Second, because of the dual eligible exclusion in Pennsylvania, Pennsylvania Medicaid has opted not to pay for Medicare beneficiary deductibles and coinsurances. Dual eligibles are the poorest and the sickest Medicare beneficiaries, and there are many in my poor community where I work.

Senator SPECTER. Dr. Desai, your time has expired. Your full statement will be in the record.

PREPARED STATEMENT

Dr. DESAI. Thank you very much. All I want to stress at this point is that the professional liability insurance has been a problem with us, and unless it is corrected something will happen.

Thank you very much.
[The statement follows:]

PREPARED STATEMENT OF DR. JITENDRA M. DESAI

Chairman Specter and members of the U.S. Senate Appropriations Committee's Subcommittee on Labor, Health & Human Services: Good morning and thank you for hosting this important hearing to further address the serious physician Medicare payment and professional liability problems facing our country and Pennsylvania.

I am Jitendra M. Desai, MD, President Elect of the Pennsylvania Medical Society and a urologist from Pittsburgh. With me is Dennis Olmstead, chief economist for the Pennsylvania Medical Society. We are here on behalf of Pennsylvania physicians and their patients to comment on the current Medicare payment system and professional liability system and their increasingly adverse effect on the availability of quality healthcare for our citizens.

Let me start by reinforcing what you already know, that the current formula used for Medicare physician reimbursement is dangerously flawed. This fact has been openly recognized by the Administration and must be fixed legislatively by the U.S. Congress.

Pennsylvania physicians, the backbone of Pennsylvania's health care delivery system cannot afford any additional payment cuts. Without a doubt, the latest scheduled Medicare reimbursement cuts couldn't have come at a worse time.

Pennsylvania physicians are caught in a vice. We have very low health insurance reimbursement. National commercial insurance payment norms are 40 percent to 50 percent higher than Pennsylvania's commercial insurance payment levels. We also have extremely high physician practice costs driven in large part by runaway professional liability premiums. With such low commercial health, Medicaid and Medicare + Choice payments, reduced Medicare fee-for-service payments may be the last straw.

The latest round of payment cuts will make Pennsylvania's Medicare practice climate untenable. With 17 percent of its population eligible for Medicare one of the highest in the nation, Pennsylvania's physicians have already suffered a \$128.6 million hit, or \$4,074 per physician, as a result of the 2002 Medicare payment reduction. If not corrected, the flawed formula will cost Pennsylvania physicians another \$553 million or \$17,396 per physician for the period 2003–2005. They simply cannot afford these payment cuts.

In addition to the reduction in the Medicare conversion factor other important elements of the formula work against Pennsylvania physicians. As mandated by Congress, the Medicare payment formula is resource based. In other words relative value units for work costs, practice costs and professional liability costs are to reflect the physician's true expense of delivering a service to a Medicare beneficiary. This is not what is happening. The payment formula does not account for the actual costs of delivering care.

For example, from January 1997 to September 2001, major professional liability carriers in Pennsylvania increased their liability insurance rates between 80.7 percent and 147.8 percent. Even before the horrible terrorist attacks on September 11, rates were already climbing at a significant rate. Since then, medical liability insurance rates have increased further. In 2002 major carriers increased rates between 40 and 50 percent, followed by similar increases for 2003.

The Medicare payment formula on the other hand has not kept pace. Professional liability relative value units and its associated geographic adjuster (which is designed to differentiate costs to practice medicine in a defined geographic locality) are based on data collected for the period 1996 through 1998. In 2004 when relative value units and the geographic adjusters are to be updated as mandated by Congress, the data collection period will run from 1999 through 2001. Our present liability cost increases will not work their way into the formula until 2007 and 2009. It is just inconceivable that in an age of computers, data reflecting the current cost of liability insurance is not being used to determine current payment rates. So as you can see not only does the current formula short change physicians from a professional liability perspective, but also will continue to short change physicians for many years. Additionally, for the 2001–2003-payment period the weight of the geographic adjuster as a percent of the total geographic adjuster weight has been reduced from 5.6 percent to 3.2 percent. As professional liability costs continue drive practice costs this trend should be going the other way.

To exacerbate this situation further for many Pennsylvania physicians, the current payment formula would have you believe that the costs of professional liability insurance and other practice costs are less than the national average costs incurred by physicians in other Medicare carrier payment jurisdictions. If one is the national average geographic adjuster, most of Pennsylvania falls under the average i.e. .989 for work relative value units, .929 for practice relative value units, and .774 for pro-

fessional liability relative value units. Again, this has the ultimate outcome of further reducing Medicare payment in Pennsylvania.

In addition to the Medicare payment formula problems, Pennsylvania physicians are also faced with other specific circumstances that act to dissuade physicians from participating in Medicare.

First, our state does not allow for balance billing of Medicare beneficiaries. We are one of only a few states that do not permit Medicare non-participating physicians to balance bill patients. This limits the choices physicians can make regarding the billing of Medicare beneficiaries with higher incomes.

Second, because of a dual eligible exclusion in Pennsylvania, Pennsylvania Medicaid has opted not to pay for Medicare beneficiary deductibles and co-insurance. Dual eligibles are the poorest and sickest Medicare beneficiaries. This creates several problems including non-payment to the physician community for the 20 percent co-insurance and the \$100 deductible as well as increasing the number of dual eligibles who seek care in the hospital emergency room rather than through a physician's office.

And third, the rates paid by a number of commercial payers (including automobile insurance) in Pennsylvania are tied either directly or indirectly to the payment rates paid by Medicare. If Medicare fees are decreased these other insurers will follow suit, exacerbating even more the health care reimbursement crisis in Pennsylvania and the resulting exodus of even more physicians from the Commonwealth. Pennsylvania already has 729 boroughs and townships designated by the federal government as "medically underserved." Exodus of additional physicians will serve to create more medically underserved areas in the Commonwealth.

But, the Medicare cuts alone did not create such a disastrous situation that nearly shut down health care in numerous pockets of Pennsylvania. Instead, the litigious climate in Pennsylvania has made our great Commonwealth the second worst in the country in terms of medical liability insurance payouts. According to the National Practitioner Databank, Pennsylvania's total payout for medical liability claims in 2000 was more than \$352 million. That's nearly 10 percent of the national total, yet our state's population makes up less than five percent of the national population.

In Philadelphia alone, the median jury verdict from January 1994 through August 2001 was \$972,909. Excluding Philadelphia statistics, the median jury verdict for the rest of the state was \$410,000.

Chairman Specter, while I understand that the liability insurance crisis is complex, in order to preserve the fragile doctor-patient relationship, we must evaluate the need for reasonable tort reforms much like California adopted in the 1970s.

California's landmark medical liability law, known as the Medical Injury Compensation Reform Act (MICRA) of 1975, proved that fair and equitable compensation for those negligently injured, within reasonable limits, could stabilize the insurance marketplace while maintaining access to quality health care.

After more than a quarter of a century, MICRA has proven itself as an effective tool for limiting runaway litigation costs while maintaining access to health care for all. It also has enabled health care professionals to focus on providing high quality care without engaging in costly defensive medicine.

In 2001, when the Pennsylvania Medical Society commissioned a study comparing the cost of liability insurance in California's highest rated area compared to Pennsylvania's highest rated area, it was clear that MICRA was working. At that time, a Pennsylvania orthopedic surgeon could expect to pay on average \$96,199, while the same doctor in California could expect to pay \$36,310. A neurosurgeon in Pennsylvania at that time would have expected to pay \$111,296, while the same neurosurgeon in California would have spent \$58,164 for coverage. Similar results could be shown for other specialties.

The time has come to adopt the California MICRA model on a national level. We must find a way to adopt a reasonable ceiling on non-economic damage awards and a sliding scale on attorney fees to bring a degree of certainty and predictability to the insurance market, as well as to ultimately preserve the fundamental doctor-patient relationship.

Chairman Specter, I commend you for your continued interest in addressing the flawed Medicare formula at a time when health care can scarcely afford cuts anywhere. As you investigate this further, I would hope that you would also play a significant role in fixing the liability insurance crisis as well.

Thank you for your time. I would be happy to answer any question you might have.

STATEMENT OF RICH ANDERSON, CHIEF EXECUTIVE OFFICER, ST. LUKE'S HOSPITAL

Senator SPECTER. Thank you very much. We turn now to Mr. Rick Anderson with St. Luke's Hospital and Health Network. He has been there for 17 years, has been president and CEO since 1986. He has a master of public health from the University of Pittsburgh, and an undergraduate degree from the University of Illinois.

Mr. Anderson, thank you for joining us, and we look forward to your testimony.

Mr. ANDERSON. Good morning, Senator. Good morning members of the committee. I appreciate the opportunity to be here. Just a brief background about St. Luke's. We are a nationally recognized organization. In the past 5 years we have received 11 national awards. We have five hospitals, soon to be six. We are in eight counties in Pennsylvania, one in New Jersey.

We have been recognized in U.S. News and World Report for consecutive times for our open heart surgery program. We have strategic partnerships at the University of Pennsylvania Health System, programs in trauma and medical education and cancer. We are certainly a major teaching hospital, over 110 residents. We have had growth in market share over the last 15 years, consecutive years, and significantly for us, our cost structure is over 95 percent, so by any measure, what I am trying to establish for you and your committee is that we are a very successful organization.

Yet despite the success that we are having right now, we are struggling hard to maintain margins, and we certainly need these margins for investments and other essential services and labor issues that we are facing.

In 2001, 40 percent of our patient revenues came from Medicare, and that certainly is a significant number, and when you consider the fact that in our State of Pennsylvania, populationwise we are the second oldest State, that puts the hospitals, all the hospitals in a very difficult position when you consider the reimbursement issues.

In our State, it is a matter of fact, it is a matter of record that physicians are leaving our State because of our high Medicare population to practice in other States where there is a more favorable payer mix, and that is an issue that certainly needs to be addressed, and respectfully to Mr. Scully's testimony about the \$1½ billion that was raised at the hospitals, I do not know the exact context, probably a billion of that money that he speaks about was lost in inappropriate outlier payments, and certainly that is an issue that needs to be addressed.

The average margin in our State of Pennsylvania is minus 3 percent. Seven out of 10 hospitals have negative patient care margins, so I do not know what the country's averages are, but in our State, we are hurting. St. Luke's margins, despite our success, we have about a 3.68 percent plus margin, so that puts us in a nice position.

So imagine, if we are doing what we are doing and we are doing it very well, what are some of these other hospitals, not only in our State but in our country, facing? What I am afraid—I mean, this is our health care world. It is not meant to be whining, but the financial plight of our Nation's hospitals is real, and it is serious,

and I am afraid in the next few years we are going to have a sign, and this is hospital jargon, put on our doctors' offices, our hospitals, DNR, do not resuscitate.

We need to get this fixed. I am certain this is going to occur, but nonetheless, it needs to happen quickly. We had a certain significant issue with the Balanced Budget Act, I will not dwell on that, and we got some relief through the Refinement Act, but it was not enough. It was only a 25 percent relief.

If I do not communicate one other issue today to this committee, I think it is essential that you understand that with the reimbursement the way it is, and the way it is going, despite all the ratios and how we hide behind formulas and what the general numbers are, and the extremely high expenses—I mean, we are in the midst, and it was used earlier, of a perfect storm. We are out there on the ocean. We do not see it coming, but it is happening, and it is coming, and we need to fix it.

The extraordinary expenses that we have, for example—I have got 1 minute—medical liability costs. I will not go into that. We all know what it is, but we all want to be number 1 in everything we do, and we want Pennsylvania to be number 1. Well, we are number 1. We are the worst State in the Union for the malpractice situation that we are in, and that has to be fixed.

President Bush has spoken about it. He is on target. I applaud him. We have labor shortages, nurses. We have a gap between what we are paid for Medicare and what we receive in terms of—what we have to pay our nurses. We have drug costs, and we all understand about the pharmaceutical business and the industry.

PREPARED STATEMENT

I want to summarize by saying that in the last year—I am sorry, 13 years, we have only received one full market basket increase in 13 years. That is not fair. That needs to be fixed, and it needs to be fixed as soon as we are able to talk through the issues.

Thank you, Senator. I appreciate the opportunity to come here. I am honored.

[The statement follows:]

PREPARED STATEMENT OF RICHARD A. ANDERSON

Mr. Chairman and Members of the Subcommittee: I am pleased and honored to be here today to discuss various aspects of Medicare reimbursement. My name is Richard A. Anderson and for almost 18 years I have served as President and Chief Executive Officer of St. Luke's Hospital & Health Network. To begin my remarks, and to provide you with background that will help you to understand my perspective, I would like to take a few moments to describe our organization.

St. Luke's Hospital & Health Network is a fully integrated, nationally recognized, health care network based in Bethlehem, Pennsylvania. In the next few weeks, we expect to sign an agreement with a neighboring hospital that will make us the largest health care network in the Greater Lehigh Valley. Our Network is presently comprised of five, soon to be six, acute care, non-profit hospitals. The Network encompasses more than 1,400 physicians, 1,020 licensed beds, more than 6,200 employees and 40,000 annual patient admissions and is the second largest employer in Lehigh County. Offering 72 medical specialties, the Network also includes a home health agency, an ambulatory surgery center, numerous outpatient facilities and various other related health organizations. St. Luke's provides direct services in Lehigh, Northampton, Carbon, Schuylkill, upper Bucks, eastern Berks, upper Montgomery and Monroe counties in Pennsylvania and Warren County in New Jersey. St. Luke's Hospital—Bethlehem Campus is the Network's tertiary hub and has been recognized in 1997 and 2001 in the highly coveted *100 Top Hospitals: Benchmarks*

for *Success* studies. These studies objectively measure, among other criteria, quality care and efficient management.

Areas of special expertise available in the Network include: trauma, open-heart surgery, high-risk pregnancy, oncology, interventional radiology, robotic surgery, geriatrics and community health. Our open-heart surgery program has been recognized four consecutive times, beginning in 1999, in U.S. News & World Report's annual America's Best Hospitals rankings and recently four times by the *100 Top Cardiovascular Hospitals: Benchmarks for Success* studies. In addition, our Intensive Care Unit has also received national recognition for superior care.

St. Luke's developed the first, and only, strategic partnership in the Greater Lehigh Valley with the University of Pennsylvania Health System (UPHS). St. Luke's and UPHS have successful cooperative agreements in trauma, cancer and medical education. Pediatric specialists from St. Christopher's Hospital for Children in Philadelphia also work in cooperation with St. Luke's specialists to provide a full range of specialty pediatric services in Bethlehem. Both UPHS and St. Christopher's have also been recognized in U.S. News & World Report's annual listings of America's Best Hospitals.

St. Luke's is a major teaching institution and offers 10 fully accredited residencies in multiple specialties. St. Luke's has both allopathic and osteopathic residencies in family practice, emergency medicine and obstetrics and gynecology. We also have residencies in general surgery, internal medicine and podiatry; plus a transitional year and an osteopathic internship.

St. Luke's is one of only 400 members of the prestigious Council of Teaching Hospitals and Health Systems. Residents who complete their training at St. Luke's routinely achieve a 100 percent pass rate on post-residency national board examinations.

By all accounts, St. Luke's is a very successful organization. We have experienced growth in market share for more than 15 consecutive years and, by independent measure, our cost structure nationally ranks well above the 95th percentile. Simply stated, we are an efficient, cost-effective health care network that provides our patients and the citizens of the Greater Lehigh Valley with excellent medical outcomes. Yet, we are struggling to maintain a sufficient margin to enable us to make investments required to remain a nationally recognized health care provider.

In 2001, 46 percent of St. Luke's net patient revenue came from the Medicare program. This is not surprising, since Pennsylvania has the nation's second oldest population. When Medicare reimbursement is inadequate physicians leave states with high Medicare populations to practice in states with a more favorable payer mix. Currently, we are seeing an increasing number of physicians in our region moving to other states. The strength and security of the Medicare program is not only essential to the beneficiaries in our region, but to the hospitals and physicians providing care.

Let me now further address the issue of Medicare reimbursement. It probably has not escaped your notice that hospitals throughout Pennsylvania are continuing to experience severe financial pressures. According to 2001 data collected by the Pennsylvania Health Care Cost Containment Council (PHC4), the average patient care margin in the state stands at a negative 3 percent. Seven in ten Pennsylvania hospitals—or 192 of the state's 274 hospitals—have a negative patient care margin.

Thankfully, St. Luke's, due to its extremely low cost structure, is more fortunate. Our margin for the 2001 fiscal year, as published in this report, was 2.83 and averaged 3.68 for the three-year period covered in the document. While this certainly is better than experiencing a loss, one can readily see that these margins, from a business perspective, are razor thin. Most of us, if given the choice to invest in a business venture with these slim margins, would politely decline the opportunity. Nonetheless, this is the health care world in which St. Luke's and other health care systems must function. At a minimum, we must have even these slim margins to buy new equipment, upgrade our facilities, bring new and advanced technology to our community—investments that are so important if St. Luke's and others in the not-for-profit world are to meet its communities' health care needs.

The financial plight of our nation's hospitals is real. We are not crying wolf. The wolf is no longer at the door, he is in our living room and he is eating our dinner. Will we be his next meal?

The Balanced Budget Act of 1997 cut Medicare payments to our nation's hospitals by nearly \$4 billion over the past five years. St. Luke's reduction was projected at \$16.5 million through fiscal year 2000 and \$33.8 million through fiscal year 2002. Fortunately, as I previously mentioned, St. Luke's operates well above the 95th percentile for efficiency. If one of the nation's most efficient hospitals is so drastically and so negatively impacted by this legislation, what then are other hospitals experiencing?

The subsequent Balanced Budget Refinement Act of 1999 and the Benefits Improvement and Protection Act of 2000 thankfully restored 25 percent of the cuts across the nation. At St. Luke's, after this legislative relief, we saw our reimbursement reduced by \$13.6 million, rather than \$16.5 million, through fiscal year 2000. Through fiscal year 2002, St. Luke's BBA-related reduction totaled \$24.6 million, down from \$33.8 million. One can conclude that these are still rather substantial reimbursement losses for St. Luke's, which was previously noted as operating on a razor-thin margin.

Medicare reimbursement reductions, extraordinary expense pressures and other significant factors are converging to threaten our nation's hospitals. I cannot overemphasize the significance of these issues as they relate to St. Luke's and other health systems' futures.

These issues include:

Medical Liability Costs

Professional medical liability costs at St. Luke's have risen 133 percent, or more than \$4 million, in just two years, bringing the total annual premium to \$8 million.

As I speak, 14 of our 22 active, private practice obstetricians are telling us they have to either leave Pennsylvania or seek financial security through hospital employment. We can not afford to employ them due to the previous factors I have been discussing.

Anesthesiologists' medical professional liability insurance rates are rising faster than those of any other physician group. Not only are anesthesiologists impacted by a 46 percent increase in malpractice premiums, their plight is further compounded by the exodus of other physician specialists from Pennsylvania due to the drastic reduction in Medicare reimbursement rates. Fewer physicians result in fewer procedures for anesthesiologists. In the last two years, anesthesiologists' Medicare reimbursement rates have also been reduced by 6 percent, while their expenses continue to escalate at a unreasonable rate.

Pennsylvania's horrific malpractice insurance climate has effectively eliminated the ability of hospitals and physicians to recruit new physicians. Eighty-five percent of the graduate orthopedic surgery residents who completed training programs last year in Pennsylvania hospitals would not even consider applying for a permanent position in our state.

Most recently, general practitioners and pediatricians say professional medical liability insurance is getting more difficult to obtain while premium costs are increasing 25 to 50 percent per year on average. This rate of increase is also consistent with what St. Luke's has experienced.

The largest pediatric group in a community near St. Luke's Quakertown Hospital has spent more than a year trying to recruit new doctors without success. Last summer the practice stopped accepting new patients even though it is located in an area with significant population growth. Several weeks ago, the practice informed parents it would no longer be able to schedule well-baby visits for children over the age of 2 since the doctors needed to devote full time to caring for sick children and administering immunizations for children under the age of 2.

Yet another financial ramification of the medical liability and Medicare reimbursement crisis, and what is generally an unspoken consequence, is that individual hospitals are being forced to subsidize certain hospital-based specialists to the tune of millions of dollars a year. This is also a fact of life for St. Luke's. Radiologists, pathologists, emergency room physicians and anesthesiologists, specialists our patients depend on, can no longer afford to practice in Pennsylvania because of the combination of financial pressures of Medicare reimbursement and medical malpractice premiums.

The past year, three of six neurosurgeons serving our hospital left to practice in other states. The three remaining neurosurgeons who practice at our hospital and our trauma center came to us and requested that we either employ them or they would be forced to leave the state. They simply could not cover their expenses in Pennsylvania because of insufficient Medicare reimbursement and escalating malpractice coverage costs. We employed them in order to keep our trauma center open. This last event was the most recent untoward event not anticipated in our budget and the financial consequences of this are yet to be realized.

Lest you not fully comprehend the gravity of the exodus of neurosurgeons, there are only seven neurosurgeons to serve our region's 1.5 million citizens. Limited access to care is escalating for many people, and is increasing as a real threat to our citizens' health.

Our President's recent speech in Scranton, Pennsylvania on January 16 was right on target relative to the major issues I have just discussed. He pointed out that, "There are too many lawsuits in America, and there are too many lawsuits filed

against doctors and hospitals without merit.” He went on to caution the American people that they must understand that, even though many lawsuits are, in his words, “junk lawsuits” and “they have no basis,” they are still expensive to our health care system.

President Bush further observed that, “The direct cost of malpractice insurance and the indirect cost from defensive medicine raises the federal government’s health care cost by at least \$28 billion a year.” He also warned that, “When a physician can not pay insurance premiums and, therefore, can not practice, somebody is going without health care.” Mr. President, I could not agree with you more.

Labor Shortages

In the current Medicare reimbursement climate, escalating salary expenses are especially onerous. Labor shortages are forcing hospitals to raise salaries to retain existing workers and to attract new employees. For example, St. Luke’s average hourly wage increased 9.4 percent in the last two years. During this same period, the actual payment rate increase received from Medicare was only 5.7 percent. This 3.7 percent gap translates into a \$4,300,000 annual shortfall for St. Luke’s.

In 2000, the supply of RNs in Pennsylvania was estimated at 104,000 nurses while the demand was for nearly 110,000 nurses. This reflects a 5 percent shortage that is anticipated to grow to 30 percent by 2020. With this shortage comes increased upward pressure on nursing salary expenses, while factors such as compressed Medicare reimbursement continue to strain our resources.

Thankfully, St. Luke’s has been able to maintain a low vacancy rate because of our competitive salaries and because we run a cost-effective hospital. St. Luke’s 8 percent vacancy rate for registered nurses is well below the 13 percent national average reported by the American Hospital Association.

Our low vacancy rate can also be attributed to our ability to recruit nurses from St. Luke’s School of Nursing, the nation’s oldest, hospital-based, continuously operating, fully accredited diploma program. In addition, St. Luke’s School of Nursing at Moravian College in Bethlehem offers a baccalaureate degree in nursing. More than 800 students have made inquiries about our nursing education programs in the last few months.

Pharmaceutical Costs

St. Luke’s and other hospitals have experienced significant increases in pharmaceutical costs—while trying to recover from the reductions of the Balanced Budget Act and inadequate Medicare reimbursement. The increase in pharmaceutical expenses has cost Pennsylvania hospitals nearly \$400 million over the past four years. St. Luke’s has experienced a 38 percent increase in pharmaceutical costs during this period, increasing expenses from \$9.5 million to \$13 million a year.

Medical Technology

It is no secret that health care is, in large part, driven by technology. We all expect hospitals to have the latest medical technology. Patients at St. Luke’s are no exception. In the last five years, St. Luke’s has invested more than \$121 million in capital projects across our Network. This represents 10 percent of our Network operating budget.

Bioterrorism Readiness

In the wake of September 11, every hospital in the country is assessing its ability to care for patients in the aftermath of a bioterrorism attack. Our world has certainly changed since that ghastly September day. While it is painful and creates a sense of frustration to even contemplate a bioterrorism attack, as responsible health care providers we must be prepared for this eventuality. This preparation further strains hospital budgets already at a breaking point. Please, I implore you to consider allowing hospitals to play a responsible role through the private sector in assisting our government in this endeavor. It is essential, therefore, that adequate funding be provided for this effort.

Insufficient Medicare reimbursement and the lack of recognition of additional expenses I have just listed, force providers to shift the burden of increasing Medicare shortfalls to non-governmental payers. Inadequate Medicare reimbursement is really nothing more than a hidden tax.

Now, let us cover the issue of how Medicare reimbursement is calculated. On October 1, 2002, at the start of the current federal fiscal year, providers saw additional reductions in the inpatient market basket. The inpatient market basket is intended to measure the various cost components of goods and services related to the health care industry.

We have only received one full market basket update in the last 13 years. Further compounding the problem is the simple fact that the market basket does not reflect

true increases in health care costs. It is absolutely essential, given these factors, that Medicare provide hospitals with Medicare increases equal to the true market basket.

Medical inflation, as measured by the Medicare market basket during the last five years, was 16.3 percent on a compound basis. The Medicare increase during the same five-year period was only 11 percent, resulting in a compound deficit of 5.3 percent. Had St. Luke's received a full market basket increase during this period, Medicare reimbursement in just the current year would have increased by \$4,000,000.

Our hospitals are in financial crisis.—We simply can not continue to survive, to offer full access to care, to provide a full continuum of services in this oppressive financial environment. We need to strengthen the bridge between Medicare reimbursement and hospitals' actual expenses before it collapses and our nation's hospitals are swept away in a raging current of financial chaos. To restate the obvious, insufficient Medicare reimbursement results in a hidden tax.

Certainly, long-term solutions to achieve equitable Medicare reimbursement and to address the medical liability crisis will require ongoing discussions. There is no easy fix. Meaningful reform will take time, patience, understanding and continuing education. In our country, consequential change takes place not by revolution, but by evolution. However, in the interim, we must stop the hemorrhaging occurring in our American health care system caused by the convergence of the professional liability crisis, the expense pressures that I have outlined and insufficient Medicare reimbursement.

While I understand this subcommittee does not directly deal with medical malpractice insurance rates, it is imperative that you understand how the current premium crisis exacerbates the effects of insufficient Medicare reimbursement. Let me further address the medical malpractice crisis, an issue that invokes great passion for me with very good cause. Anyone who reads a newspaper is aware that Pennsylvania has the nation's worst malpractice insurance climate. Having a malpractice case tried in the Philadelphia court system is often akin to the lawyers and plaintiffs winning the lottery or, worse yet, an economic death sentence for hospitals and physicians. Runaway jury verdicts and multi-million dollar awards have become the norm. We desperately need reform to balance the rights of those who have legitimately been harmed with the rights of those who are unfairly, excessively and frivolously sued.

I speak with authority on this subject. In October 2000, a Philadelphia jury returned a verdict in the amount of \$100 million against multiple defendants including St. Luke's Hospital. Previous to this time St. Luke's had an exemplary track record in malpractice actions. Our hospital was a part of this suit only because of alleged "ostensible agency." A patient's mother perceived that one of the private-practice physicians who treated her infant was employed by the hospital.

The patient had been cared for in our Neonatal Intensive Care Unit for 90 days and none of this care was faulted in any respect. Although we would have preferred to challenge this award in the court system, our insurance carrier took the matter from our hands and settled the claim for a far lesser, but substantial, amount. In Pennsylvania, 53 cents of every malpractice settlement goes to the lawyers and to pay administrative costs. Other than the attorney, I have no idea how the remainder of the settlement was dispersed. The child's biological mother, who had no contact with the child, did not bring the suit and who did not receive any payment from the settlement, is incarcerated for drug-related offenses. The adoptive parents of the minor plaintiff were also not part of the legal action and wanted no part of the settlement.

It is no exaggeration to say that if we had been required to pay the full award, our 130-year-old hospital would have ceased to exist. We would have been bankrupt. This misplaced attempt at social reengineering is corrupt and utterly wrong. It allows for an excessive redistribution of resources from the medical care system to a few individuals. If this system is allowed to continue, access to quality health care will become very limited for thousands and thousands of our citizens.

The fallout from this travesty of justice continues to haunt our organization in that we have been unable to secure affordable excess malpractice insurance. We were also forced to establish our own captive insurance company in order to obtain primary liability coverage. Prior to the jury's \$100 million award, St. Luke's annually paid \$280,000 for a \$25 million excess coverage policy. At present, St. Luke's pays its captive insurance company \$3 million for a \$3 million excess policy. In the current climate, no insurance company will provide St. Luke's with excess coverage.

The medical liability crisis is not just a financial issue, it is also a moral and ethical issue that we must address. We must ask ourselves, it is right to take \$100

million out of the health care system and give it to one family—after the lawyers receive their 40 or more percent?

This social injustice and inequity in the system must be changed. This system, if allowed to continue unchallenged, is creating all of the elements of the “perfect storm” which our American health system may not survive.

In closing, I am asking Congress to reverse the inpatient market basket cuts that went into place on October 1, 2002 and to provide adequate reimbursement to hospitals. There is the need for full market basket updates that accurately reflect the current costs hospitals are facing. It is my understanding that The Hospital and Health System Association of Pennsylvania has written to the Centers for Medicare and Medicaid (CMS) asking for changes to the current market basket methodology. I am pleased that CMS implemented the recommendation to use a re-based market basket, updating from 1992 data to 1997 data and revising the calculation by replacing some of the proxies that are used to measure cost changes. While the new market basket is an improvement, I am still concerned that the market basket does not reflect the true increases in costs for technology, recruitment, professional liability and other items.

I would urge CMS to reconsider the proxy used for professional liability insurance cost growth. As I mentioned earlier, hospitals, particularly those in Pennsylvania, have experienced significant increases in the cost of medical malpractice insurance. It is my understanding that CMS has contracted with the economic information firm, DRI-WEFA to collect malpractice insurance premium data from a sample of hospitals and plans to combine this information with their current proxy source once the data is collected. This potentially flawed methodology could be catastrophic for American health care. It has been recommended by The Hospital and Health System Association of Pennsylvania that DRI-WEFA collect data from Pennsylvania hospitals including those with trauma centers. These numbers will be far higher than those selected at random across the United States. I support this recommendation. Premium increases for hospitals in Pennsylvania with trauma centers have skyrocketed and it is essential these numbers be reflected in the data.

It is important to note that, according to a 2001 study by the Pennsylvania Legislative Budget and Finance Committee, Pennsylvania’s acute care hospitals are the second most cost-efficient in the nation based on Medicare inpatient costs per discharge. The fat is out of the Pennsylvania health care system. We are now experiencing cuts to muscle and bone and it hurts, it really hurts. Something has got to give and we need your help. We are trying hard to contain costs but, many of these expenses are out of our control.

My final comments would be to ask the members of the subcommittee to consider enacting legislation that would result in the following outcomes:

- More timely increases in Medicare reimbursement
- especially those related to the introduction of new technology. Presently, Medicare’s long delays in adding new technology to its reimbursement formulas “punishes” hospitals that are financially able to provide patients with leading-edge technology to improve outcomes.
- Full Medicare reimbursement for true health care inflation.
- Timely increases in Medicare payments that reflect increases in the costs of malpractice insurance
- these costs should be geographically adjusted and state specific.

I appreciate the subcommittee’s focus on issues affecting our nation’s hospitals. In particular, I’d like to thank Senator Specter for his years of understanding and support for the Medicare program and the beneficiaries who rely so heavily on the Medicare program.

It is only through further cooperation in an atmosphere of mutual respect, that our hospitals and our elected officials can work together to solve the challenges before us. Thank you.

Senator SPECTER. Thank you, Mr. Anderson. Thank you very much.

STATEMENT OF KIRK NORRIS, PRESIDENT, IOWA HOSPITAL ASSOCIATION

Senator SPECTER. We now turn to Mr. Kirk Norris, president and CEO of the Iowa Hospital Association. Mr. Norris served as a director of the Southeast Full Community School District, 1979 graduate of Simpson College, and a 1984 graduate of the Drake University School of Law.

Thank you for joining us, Mr. Norris, and we look forward to your testimony.

Mr. NORRIS. Good morning, Mr. Chairman, and also I want to give my thanks and appreciation for your invitation and for Senator Harkin's invitation to speak here today on the critical subject of Medicare payment policy.

In various professional positions for the past 16 years at the Iowa Hospital Association it has been my privilege to represent 116—

Senator SPECTER. I am sorry, but I am going to have to interrupt you. We will start the clock again. They are about to go to a vote on Miguel Estrada, and I am going to have to excuse myself for a few minutes. I will be back as soon as I can. I am sorry for the interruption, but I just have to do that. We will stand in recess for a few minutes.

We will resume the hearing. Again, my regrets, but in the interim Senator Harkin has joined us, so he will be in a position to hear your testimony, Mr. Norris.

Mr. NORRIS. Thank you.

Senator SPECTER. You were in mid-sentence. Can you pick it right up there?

Mr. NORRIS. That is why it is written down.

Thanks again for starting the clock over, and thanks for the invitation of both you and Senator Harkin to come today and speak.

In various professional positions for the past 16 years with the Iowa Hospital Association, it has been my privilege to represent 116 private nonprofit and publicly governed community institutions in a variety of legislative, judicial, and other public forums. It is my pleasure to come before you this morning to address the impending health care crisis in Iowa that is being driven by payment policy for the Medicare program.

The premise of my presentation today is that no policy difference exists between the necessary Medicare payment corrections for physicians and the necessary payment corrections for hospitals. In consideration of the time limitations for presenting this morning, I am focusing on the fact that bad payment policy is just that, bad payment policy, regardless of the recipient of the policy.

In the circumstance at hand, the primary recipients of this bad policy are the hospitals and physicians of Iowa. Ultimately, the impact of any payment policy decision in Medicare is borne by Iowa's 475,000 Medicare beneficiaries. It impacts Iowa seniors every time a hospital is unable to staff a physician at a rural clinic, when 32 out of 36 hospital school nursing graduates choose to leave the State for better starting salaries, and every time a clinic or hospital fails to recruit a needed physician specialist to replace a retiring physician as medical recruits examine Medicare payments in Iowa and determine that Iowa is not a place they want to practice when 50 percent of all revenues come from Medicare.

These issues are not new or without previous discussion in various Medicare payment policy forums, as was recognized in previous comments today. In fact, the details of these issues have all been discussed in a series of Medicare Payment Advisory Commission reports to Congress since 1999.

I am also aware that Congress, and particularly the U.S. Senate, understands these issues. Evidence of this fact is found in the fiscal year 2003 omnibus budget bill currently headed to conference committee. Both the hospital and physician payment corrections inserted in the fiscal year 2003 omnibus bill by Senate finance chair Grassley and supported by Senator Harkin and the rest of the U.S. Senate are an acknowledgement that these payment policy issues coexist and need further discussion and address in the 108th Congress. The Iowa Hospital Association supports Senator Grassley's and Senator Harkin's approach to these issues.

MedPAC and the Director of CMS have evaluated the need and called for change in the methodology for physician payment. MedPAC has also considered the need for change in the methodology for hospital payment and recognizes its potential for positive impact in States like Iowa.

The predominant policy issue affecting hospital payment in Iowa and other similar states is the wage index. As you know, the wage index is the major determinant for the amount of payment a hospital receives for its services. Policy corrections for the wage index are apparent, and should be acted on by Congress. Medicare reform should encompass payment policy reform to assure that high quality, efficient care is not jeopardized but, rather, is rewarded.

Iowa's efficient health care system, which also ranks in the top 10 in quality, is in serious jeopardy of sustaining itself without correction of Medicare payment policy for both physicians and hospitals. Iowa hospitals currently subsidize the Medicare program in excess of \$80 million per year. This number is growing, and will leap in disproportionate amounts as payment shortfalls mount for skilled nursing services, home help, and outpatient care.

As with the payment methodology for inpatient care, Congress has moved these other services to fixed payments, and only the time-limited payment safety measures of the Benefit Improvement and Protection Act are preventing the geometric accumulation of losses for certain services in specific sizes of hospitals. For other hospitals with these same services, significant losses are mounting.

The action of Congress in these other areas reinforces the need to immediately address policy mistakes in mature patient methodologies like inpatient care. These payment flaws are apparent and have long been identified, but CMS needs direction from Congress on the appropriate solutions, otherwise immediate potential for significant curtailment of access to services for Medicare beneficiaries exists in Iowa and many other States. This potential for seniors exists at a time when Iowa has the fifth highest percentage of citizens over age 65, and the highest percentage of population over 85 in the country.

PREPARED STATEMENT

The Iowa Hospital Association appreciates the additional focus that this subcommittee brings to the topic of necessary payment corrections in the Medicare fee for service system for the inter-related services provided by hospitals and physicians. I am pleased to provide background information for any testimony I have given today, and answer any questions related to the same.

Thank you for the committee's time, Mr. Chairman.

[The statement follows:]

PREPARED STATEMENT OF J. KIRK NORRIS

Good Morning Mr. Chairman, Ranking member Mr. Harkin and members of the committee and thank you for providing me an opportunity to speak on the critical subject of Medicare payment policy.

In various professional positions for the past sixteen years at the Iowa Hospital Association, it has been my privilege to represent 116 private non-profit and publicly governed community institutions in a variety of legislative, judicial and other public forums. It is my pleasure to come before you this morning to address the impending healthcare crisis in Iowa that is being driven by payment policy for the Medicare Program. The premise of my presentation today is that no policy difference exists between the necessary Medicare payment corrections for physicians and the necessary payment corrections for hospitals.

In consideration of the time limitations for presenting this morning, I am focusing on the fact that bad payment policy is just that, bad payment policy, regardless of the recipient of the policy. In the circumstance at hand, the primary recipients of this bad policy are the hospitals and physicians of Iowa. Ultimately, the impact of any payment policy decision in Medicare is borne by Iowa's 475,000 Medicare beneficiaries. It impacts Iowa seniors every time a hospital is unable to staff a physician at a rural clinic, when 32 of 36 hospital school nursing graduates choose to leave the state for better starting salaries and every time a clinic or hospital fails to recruit a needed physician specialist to replace a retiring physician as medical recruits examine Medicare payments in Iowa and determine that Iowa is not a place they want to practice when 50 percent of all revenues come from Medicare.¹ These issues are not new or without previous discussion in various Medicare payment policy forums. In fact, the details of these issues have all been discussed in a series of Medicare Payment Advisory Commission Reports to Congress since 1999. I am also aware that Congress and particularly, the United States Senate, understands these issues.

Evidence of this fact is found in the fiscal year 2003 omnibus budget bill currently headed to conference committee. Both the hospital and physician payment corrections inserted in the fiscal year 2003 omnibus bill by Senate Finance Chair Grassley and supported by Senator Harkin and the rest of the U.S. Senate, are an acknowledgement that these payment policy issues co-exist and need further discussion and address in the context of the 108th Congress. The Iowa Hospital Association supports Senator Grassley's and Senator Harkin's approach to these issues.

Med PAC and the Director of CMS have evaluated the need and called for change in the methodology for physician payment. Med PAC has also considered the need for change in the methodology for hospital payment and recognizes its potential for positive impact in states like Iowa.² The predominant policy issue affecting hospital payment in Iowa and other similar states is the wage index. As you know, the wage index is the major determinant for the amount of payment a hospital receives for its services. Policy corrections for the wage index are apparent and should be acted on by Congress. Medicare reform should encompass payment policy reform to assure that high quality, efficient care is not jeopardized, but rather is rewarded.³

Iowa's efficient healthcare system,⁴ which also ranks in the top ten in quality, is in serious jeopardy of sustaining itself without correction of Medicare payment policy for both physicians and hospitals. Iowa hospitals currently subsidize the Medicare program in excess of eighty million dollars per year.⁵ This number is growing and will leap in disproportionate amounts as payment shortfalls mount for skilled nursing services, home health and outpatient care.⁶ As with the payment methodology for inpatient care, Congress has moved these other services to fixed payments and only the time-limited payment safety measures of the Benefits Improvement and Protection Act are preventing the geometric accumulation of losses for certain services in specific sizes of hospitals. For other hospitals with the same services, significant losses are mounting. The action of Congress in these other areas reinforces the need to immediately address policy mistakes in mature payment methodologies like inpatient care. These payment flaws are apparent and have long been identified, but CMS needs direction from Congress on the appropriate solutions. Other-

¹ Iowa Hospital Association Profiles/Databank Program, August 2002.

² Med PAC Report to Congress, March 2002.

³ Med PAC Reports to Congress, March 1999, 2000, 2001, 2002.

⁴ Healthcare Financial Management Association, Iowa Chapter, October 2002.

⁵ Med PAC Report to Congress, March 2001.

⁶ Audited Cost Report Data Files, CMS, 1998-2000.

wise, immediate potential for significant curtailment of access to services for Medicare beneficiaries exists in Iowa and many other states. This potential for seniors exists at a time when Iowa has the 5th highest percentage of citizens over age 65 and the highest percentage of population over 85 in the country.⁷ The Iowa Hospital Association appreciates the additional focus that this subcommittee brings to the topic of necessary payment corrections in the Medicare fee for service system for the inter-related services provided by hospitals and physicians. I'm pleased to provide back-up information for any of the testimony I've given today and answer any question related to the same. Thank you for the committee's time Mr. Chair.

Senator SPECTER. Thank you very much, Mr. Norris, for your testimony, and for yielding back 17 seconds.

STATEMENT OF JAY KLEIMAN, M.D., M.P.A., FELLOW, AMERICAN COLLEGE OF CARDIOLOGY, CLINICAL ASSISTANT PROFESSOR OF MEDICINE, NORTHWESTERN UNIVERSITY MEDICAL SCHOOL

Senator SPECTER. Our next witness is Dr. Jay Kleiman, M.D., M.P.A., clinical assistant professor of medicine at Northwestern University Medical School, medical director for cardiovascular research and development for Pharmacia Corporation, and a Fellow at the American College of Cardiology.

He holds a master's degree in public administration from Harvard University's Kennedy School of Government, received his M.D. from the University of Michigan, did his post-graduate medical training at the University of Chicago, National Institutes of Health, and Georgetown University, and he has achieved this spectacular resume notwithstanding the disadvantage of being my first cousin.

He and I are sons of sisters, and I can tell you, he is an extraordinary doctor and an extraordinary man. Dr. Kleiman, we are deducting that introduction from your time.

Thank you for coming, Jay, and the floor is yours.

Dr. KLEIMAN. Thank you, Senator Specter, Senator Harkin, members of the subcommittee. I am Dr. Jay Kleiman, a cardiovascular specialist, research scientist, and member of the American College of Cardiology. I am honored to testify today on behalf of the American College of Cardiology, and on behalf of the Alliance of Specialty Medicine, an organization representing more than 160,000 specialty care physicians.

Mr. Chairman, members of the subcommittee, we have reached a critical juncture in the evolution of our health care system. At a time when life-saving scientific advances are being made in every area of medical care, basic access to quality care is in jeopardy. This situation has been precipitated by several factors, one of the most important of which is cuts in Medicare reimbursement to physicians.

These cuts in reimbursement threaten access to care and access to quality for our senior citizens, but the impact goes well beyond Medicare. Most private payers link their fee to the Medicare fee schedule. When Medicare cuts, so do nearly all forms of reimbursement, yet the costs of running a practice continue to increase faster than the rate of general inflation. As the Medicare population becomes a larger portion of a practice, the viability of the practice is itself threatened.

⁷U.S. Bureau of Census.

As you are aware, last year physicians and other health care professionals received a 5.4 percent across-the-board cut in Medicare reimbursement. On March 1, a second cut of 4.4 percent is scheduled. The American College of Cardiology and Alliance of Specialty Medicine greatly appreciate the language passed by the Senate last week as part of the fiscal year 2003 appropriations bill which will stave off further cuts for at least 7 months. We hope the House will act swiftly, before the additional cut takes place on March 1. This is an important step toward the solution we seek.

You are well aware of the flaws in the Medicare schedule. I will not reiterate them here, in the interests of time, but even if Congress stops the 4.4 percent decrease from taking effect this year, steep cuts are in store for 2004–2005. By midway through this decade, Medicare reimbursement could be at 1991 levels and, although today's hearing is focused on Medicare reimbursement, it is impossible to separate this issue from the precipitous nationwide increase in medical liability insurance premiums.

Skyrocketing premiums have created a crisis that is evidenced by reduced access to orthopaedic surgeons, neurosurgeons, and trauma centers, by the exodus of physicians from Pennsylvania, Mississippi, West Virginia, and Iowa, by increased reliance on already strained emergency departments.

Steep reductions in Medicare and third-party payments, coupled with the spiraling cost of medical liability insurance, are coalescing towards a catastrophe that threatens our health care system. The ultimate victims of this brewing calamity will be patients.

Many practices are reaching the breaking point. According to a recent survey of physician practices, more than half will limit the number of Medicare patients they treat in 2003. Approximately two-thirds postpone investments in new technology, and two-thirds will limit practice services or expansion.

For example, in Chicago, a large cardiology practice severely limited hours at a free clinic that counsels patients on managing high cholesterol and lipids, and at a second clinic that helps patients manage their blood-thinning Coumadin doses.

In Kansas City, cardiology practice delayed a new program to treat patients with heart rhythm disorders like the one that afflicted Vice President Cheney last year. Orthopaedic surgery is in jeopardy in a growing number of States. Fifty-five percent of orthopaedic surgeons have reduced the scope of operative procedures due to liability exposure, and 39 percent avoid performing spinal surgery.

Pennsylvania, as you know, has been particularly hard hit. Bedford County's only orthopaedic surgeon left the State last year, and Huntingdon County has just one orthopaedic surgeon to take trauma calls at two hospitals. In the case of neurosurgery, an alarming 10 percent of the neurosurgeons in the United States retired in 2001.

There is impact, too, on the pipeline of physicians. Applications for medical schools have decreased for 6 years running, threatening the future supply of physicians.

The American College of Cardiology and Alliance of Specialty Medicine are heartened that short-term relief from further Medicare cuts may be on the horizon, but fixing the flaws in Medicare

reimbursement will require an act of Congress. If CMS does not have the authority to change the payment formula, then only Congress can solve this issue for the long term. The Congress must recognize the unacceptable costs to the health care system if it does not do so. Above all, quality of care must be protected, and access to care must be assured for Medicare beneficiaries and for all patients as well.

PREPARED STATEMENT

Mr. Chairman, your leadership in health care is widely recognized within the physician community. I greatly appreciate and thank you for the opportunity to speak before this subcommittee today.

[The statement follows:]

PREPARED STATEMENT OF DR. JAY KLEIMAN

Mr. Chairman and members of the subcommittee, I am Jay Kleiman, a cardiovascular specialist from Evanston, Illinois, and a member of the American College of Cardiology. As a practicing cardiologist for 25 years and now a full-time clinical research scientist, I am honored to testify today on behalf of the Alliance of Specialty Medicine, an organization of 13 national medical societies representing more than 160,000 specialty care physicians.

We have reached a very important juncture in the evolution of the U.S. health care system. At a time when lifesaving scientific advances are being made in nearly every area of health care, patients are facing a situation in which basic access to quality health care is in serious jeopardy. This situation has been brought about by several factors, one of the most important of which we are here to discuss today: cuts in Medicare reimbursement for physicians.

BACKGROUND

As you are aware, last year, physicians, as well as nonphysician health care professionals, received a 5.4 percent across-the-board cut in their Medicare reimbursement. On March 1, physicians are scheduled to receive an additional 4.4 percent cut.

The American College of Cardiology as well as the Alliance of Specialty Medicine greatly appreciates the language passed by the Senate last week as part of the fiscal year 2003 omnibus appropriations bill that would stave off another round of cuts in physicians' Medicare reimbursement for at least seven months. It is our hope that the House will act swiftly and send legislation to the president's desk before the 4.4 percent cut takes effect on March 1. This is an important step toward the solution we seek.

The primary cause of these cuts are errors made by Medicare in calculating the 1998 and 1999 expenditure targets, including underestimates of the gross domestic product and failure to account for the enrollment of one million beneficiaries in Medicare fee-for-service. The formula used to determine annual physician payment updates is inappropriately tied to the gross domestic product (GDP). Linking physician payments to the GDP causes volatile swings in payment updates from year-to-year and fails to accurately measure the costs of providing medical services to Medicare beneficiaries. This formula penalizes physicians when there is a decline in the nation's economy, even as Medicare utilization and practice costs continue to increase. The current formula also ignores the expense of new technology—from new, cutting-edge devices to electronic medical records—which physician practices must absorb. Finally, the cost of outpatient drugs has been inappropriately included in the physician expenditure target.

Even if Congress stops the 4.4 percent cut from taking effect this year, physicians still face steep cuts in 2004 and 2005. If this does in fact happen, by midway through this decade, physicians' Medicare reimbursement will be at 1991 levels.

These reductions in Medicare reimbursement are extremely troublesome because they threaten access to care and quality of care for our senior citizens. The impact of these cuts, however, goes well beyond Medicare. Most private payers—including the large managed care plans—link their fee schedules to the Medicare fee schedule, as does the military Tricare system. So when Medicare reimbursement is reduced, so are nearly all other forms of reimbursement.

In short, physicians have been experiencing significant decreases in reimbursement from nearly all payers, while the costs of running a practice and caring for patients continue to increase faster than the rate of general inflation. As the Medicare population becomes a larger portion of the patients a practice serves, the viability of the practice itself is threatened.

Although today's hearing is focused on Medicare reimbursement, it is impossible to separate this issue from the precipitous nationwide increase in physicians' medical liability insurance premiums. Many have rightfully called the medical liability situation a "crisis," and its impact has become visible all across the country. This crisis is evidenced:

- by reduced access to orthopaedic surgeons, neurosurgeons, and trauma centers;
- by the exodus of physicians from states like Pennsylvania, Mississippi, and West Virginia;
- by increased reliance on already strained emergency departments; and
- in the growing practice of defensive medicine, which drives up the cost of care and further strains an already fragile health care budget.

Yet this is just the beginning. The expected steep reductions in Medicare and third-party payer reimbursement over the next several years and the spiraling costs of medical liability insurance are coalescing toward a "perfect storm" that threatens to dismantle our health care system.

CONSEQUENCES

This leads me to the most important point of my testimony today. The ultimate victims of mistakes in the Medicare reimbursement system and a medical liability system that is out of control are patients. Many practices are reaching the breaking point. Both quality and access to care now suffer from the combined burden of Medicare miscalculations and the liability crisis.

A worst-case scenario for Medicare patients is developing. It is starting to cost physicians more to treat Medicare patients than the physician is reimbursed. According to a survey of physician practices released by the Medical Group Management Association last week, for example, more than half of the practices surveyed will be forced to limit the number of Medicare beneficiaries they treat in 2003. Sixty-eight percent of respondents said they will postpone investments in new technology and 62 percent said that they would limit expansion of their practice.

Examples of these kinds of alterations in practice abound.

A large cardiology practice in Chicago has had to severely limit hours at two clinics that provided free services to Medicare patients: one clinic counsels patients on managing lipid disorders such as elevated cholesterol, and the other assists patients in managing their blood thinning Coumadin doses.

A small cardiology practice in Kansas City, Missouri, recently postponed the launch of a new program to treat the growing number of patients with heart rhythm disorders like the one that afflicted Vice President Cheney last year.

Likewise, orthopaedic care is in jeopardy in a growing number of states. A recent survey by the American Association of Orthopaedic Surgeons found that 55 percent of orthopaedic surgeons have reduced the range of operative procedures they perform. Thirty-nine percent avoid performing spine surgery and 48 percent limited other surgical procedures. Pennsylvania has been particularly hard hit. Bedford County's only orthopaedic surgeon left the state last year, and Huntingdon County has just one orthopaedic surgeon to take trauma calls at two hospitals.

In the case of neurosurgery, in 2001 alone, 327 neurosurgeons retired, representing an alarming 10 percent of the neurosurgical workforce in the United States. This, coupled with the fact that it takes seven years to complete a neurosurgical residency training program, will create a supply pool that is simply inadequate to meet the growing aging population and its corresponding health care needs.

Likewise, the Society of Thoracic Surgeons announced this past summer that the number of applicants for the 7–8 year postgraduate cardiothoracic surgery residency programs dropped to only 145 in 2002, and that 21 of the 144 available positions went unfilled.

This climate has also had a noticeable impact on the pipeline of physicians. Applications for medical school have decreased six years in a row. The best and brightest are beginning to eschew medical school—which requires 12 years of rigorous schooling and training. The medical trainees I teach each week tell me they will enter practice with between \$75,000 and \$200,000 in educational loan debt. Simply put, the population is aging, baby boomers are approaching Medicare eligibility, and there are serious questions about whether the supply of physicians will be adequate to meet the demand.

ACTION

The American College of Cardiology and the Alliance of Specialty Medicine are heartened that short-term relief from further Medicare reimbursement reductions appears to be on the horizon. But we know that the biggest challenge is yet to come.

It is clear, however, that fixing the flaws in the Medicare reimbursement formula will require an act of Congress. The Centers for Medicare and Medicaid Services has steadfastly maintained that it does not have the authority under current law to make changes to the payment formula. While there is the continuing debate about the cost of passing legislation to permanently fix the problems with this formula, the question before Congress right now should not be whether we can afford to address this issue for the longer term, but the cost to the health care system if Congress fails to act?

The answer is clear: quality of care must be protected for all patients. Access to care must be assured—not just for Medicare beneficiaries, but for all patients.

Mr. Chairman, your leadership in health care is widely recognized within the physician community. I greatly appreciate and thank you for the opportunity to speak before the subcommittee today. Thank you.

STATEMENT OF ERIC W. BLOMAIN, M.D., PAST PRESIDENT, PENNSYLVANIA PLASTIC SURGEONS SOCIETY

Senator SPECTER. Your timing was perfect, Dr. Kleiman. Our next witness is Dr. Eric Blomain, past president of the Pennsylvania Plastic Surgeons Society, chief of plastic surgery at Community Medical Center, staff member at Moses, Taylor, and Mercy Hospitals, all located in Scranton. He received his A.B. from Cornell and his M.D. from Thomas Jefferson University.

Thank you for joining us, Dr. Blomain, and we look forward to your testimony.

Dr. BLOMAIN. Thank you, Senator. Senator Specter, members of the committee, and members of the audience, I would like to thank you for the opportunity to testify before you. I am Eric Blomain, past president of Pennsylvania Plastic Surgeons Society, and a practicing plastic surgeon in Northeastern Pennsylvania.

It is with deep humility that I speak on behalf of the patients and physicians of Northeastern Pennsylvania. I come to express my opposition to the proposed Medicare cuts, since they will curtail the care rendered to Medicare recipients. I am not speaking as a Medicare expert, but as a practicing physician observing a failing system.

Medicare is a good institution, but it must be brought into the 21st Century. Medicare reimburses physicians with rules designed in the mid-1960s. These rules were flawed. Reimbursement differs from region to region, and is based upon a complex formula which is supposed to accurately represent costs and the effort in providing care. A number of assumptions are wrong, causing the process to be inaccurate.

For instance, it is assumed that the cost of providing medical care in a low wage or rural area is considerably cheaper than in an affluent area. Costs in low wage areas can equal or exceed those in affluent areas. Malpractice costs and other expenses can be higher in low wage areas, as is evident in my region in northeastern Pennsylvania.

Physician costs continue to escalate. Malpractice insurance, supplies, equipment, wages, rents, management fees continue to increase. Compounding the problem, the Federal Government increases costs by implementing new rules such as compliance guide-

lines, HIPAA guidelines, and OSHA regulations. Complying with these needed and important regulations is expensive.

In Pennsylvania, there is a crisis in the availability of affordable malpractice insurance. Philadelphia pays out more in malpractice payments than the entire State of California. In the fifties, a family physician paid \$19 for malpractice insurance. In the sixties, that same physician paid \$49. Here, a typical family physician in Pennsylvania with no malpractice claims may pay in excess of \$10,000.

The cost of malpractice insurance in Pennsylvania compared to other States with documented effective tort reform are considerably higher for all types of physicians, causing many doctors to leave the State. The real solution is to implement the system started in California 25 years ago, which has a proven track record.

Declining reimbursement is a reality. Cardiologists in Northeastern Pennsylvania are paid approximately \$164 for cardiac catheterization. Compare this to Roto Rooter charging \$150 to fix a blocked drainage pipe. Cardiologists who do catheterizations are then charged an additional \$10,000 in malpractice.

Medicare cuts greatly affect Pennsylvania physicians, since approximately 17 percent of the population is covered by Medicare. Additionally, other insurances such as Workman's Comp, automobile insurance and most managed care plans are linked to the Medicare fee schedule. Because of this fee linkage, Medicare costs automatically lower the reimbursement for physicians, involving as much as 60 percent of the marketplace in Northeastern Pennsylvania.

The declining reimbursement caused by previous Medicare cuts, the flawed reimbursement formula, and the catastrophic rise in medical malpractice premiums have created a perfect storm, where some physicians cannot practice because their expenses exceed their income. Recently, in Northeastern Pennsylvania more than 40 surgeons faced this dilemma, causing them to make the painful decision to close their practices. This was a devastating blow to our region, threatening to reduce the availability of care to the community, particularly the elderly, the poor, and the disabled, who find it difficult to travel to alternative sources of care.

Pennsylvania medical schools turn out numerous specialists. Last year, only 14 percent of surgical specialists trained in Pennsylvania stayed in Pennsylvania because of the situation of rising malpractice costs and declining reimbursement. These two adverse facts create a hostile practice environment and make it impossible to offer fair and competitive salaries to recruit new graduates, many of whom are carrying large educational debts.

Recently, a disturbing trend has emerged where some attorneys and accountants and practice management specialists are advising physicians to avoid treating Medicare recipients because of low reimbursement. Thankfully, this advice is generally ignored.

PREPARED STATEMENT

In conclusion, the current Medicare reimbursement formulas are flawed and are hurting low wage areas. The proposed cuts may cause low wage areas to be unable to attract new physicians, get adequate support staff, buy new equipment, and make capital improvements. This system will eventually implode, where the quality

and availability of care will decrease. The elderly, the poor, and the disabled will be the first to experience this phenomenon. This phenomenon could spread to other parts of the Nation. I would humbly ask this committee to prevent further Medicare cuts, revise the flawed formulas, increase Medicare funding, and to resolve the medical liability crisis.

Thank you for your concern, and for the privilege of being allowed to address you.

[The statement follows:]

PREPARED STATEMENT OF DR. ERIC W. BLOMAIN

Senator Specter, members of the Committee and members of the audience: I would like to thank you for the opportunity to testify before you. I am Eric Blomain, M.D., Past President of the Pennsylvania Plastic Surgical Society and a practicing plastic surgeon in Northeastern Pennsylvania.

It is with deep humility I speak on behalf of the patients and physicians in Northeastern Pennsylvania. I come to express my opposition to the proposed Medicare and Medicaid recipients. I am not speaking as a Medicare reimbursement expert with detailed fact and figures, but as a practicing physician observing a failing system.

Medicare is a good institution, but it must be brought into the 21st Century. Medicare reimburses physicians with rules designed in the mid 1960's. These rules were flawed then and have had severe unforeseen adverse consequences. Reimbursement differs from region to region and is based upon a complex formula which is supposed to accurately represent the cost of overhead, the cost of malpractice, the cost of living, the cost of rendering the care and the effort expended in providing the care. A number of assumptions are wrong, causing the process to be inaccurate. For instance, it is assumed that the cost of providing Medicare care in a low wage or rural area is considerably cheaper than in an affluent area. Costs in low wage areas can equal or exceed those in affluent areas. Malpractice costs can be higher in low wage areas, as is evident in my region of Northeastern Pennsylvania and it is frequently not accurately represented in the Medicare reimbursement formula. The costs of surgical equipment and supplies purchased from national vendors can be the same or higher because of inability of small practices to get substantial discounts.

Physician costs continue to escalate. Malpractice insurance, supplies, equipment, wages, rents and management fees continue to increase. Compounding the problem, the Federal Government increases costs by implementing new rules as a Compliance Guidelines, Evaluation and Management Guidelines, HIPPA guidelines and new OSHA regulations. Complying with these needed and important regulations is expensive. Declining reimbursement and rising expenses are beginning to threaten the ability of many physicians to practice.

In Pennsylvania there is a crisis of availability of affordable malpractice insurance. Philadelphia pays out more in malpractice payments than the entire state of California. In the 1950's a family physician paid \$19.00 for malpractice insurance. In the 1960's \$49.00. This year's typical family physician with no malpractice suits may be in excess of \$10,000. The costs of malpractice insurance in Pennsylvania compared to other states with documented effective tort reform are considerably higher for all types of physicians. The real solution is to implement the system started in California 25 years ago, which has an established and proven track record of reducing costs and being fair to all parties.

Declining reimbursement is a reality. Cardiologists in Northeastern Pennsylvania are paid approximately \$164 for a cardiac catheterization. Compare this to Roto Rooter charging \$150 to fix a blocked drain pipe. Cardiologists who do catheterizations are charged an additional \$10,000 in malpractice surcharges. The average cardiologist does 75 cardiac catheterizations a year. Forty of these catheterizations are used to pay for this one single practice expense of malpractice insurance surcharge. Orthopedic surgeons, neurosurgeons, general surgeons, vascular surgeons, radiologists and most medical and surgical subspecialties have experienced rising malpractice premiums and practice overhead costs with declining reimbursement. Family doctors in the past few years have seen their reimbursement fall, causing them to see more patients and to spend less time with patients to maintain practice expenses. Some family physicians are beginning to leave the state, particularly in the under served areas.

Medicare cuts greatly affect Pennsylvania physicians, since approximately 17 percent of the population is covered by Medicare. Additionally, other insurances such as Workmen's comp, auto insurance and most of the managed surgical care plans are linked to Medicare fee schedules. Medicare cuts automatically lower reimbursement for physicians involving as much as 60 percent of the market in Northeastern Pennsylvania.

The declining reimbursement caused by previous Medicare cuts, the flawed reimbursement formula and the catastrophic rise in medical malpractice premiums have created a "perfect storm" where some physicians cannot practice because their expenses exceed their income. Recently in Northeastern Pennsylvania more than 40 surgeons faced this dilemma. They made the painful decision to close their practices. This was a devastating blow to our entire region threatening to reduce the availability of care to the community, particularly the elderly, the poor and the disabled, who found it difficult to travel to alternative sources of care. This catastrophe has been temporarily averted, but the situation remains critical. Medicare has historically underestimated the impact of malpractice problems and practice costs in Pennsylvania, as is evidenced by testimony of other members of this panel. Because of all of these problems, the recruitment of physicians has suffered with most surgical subspecialties reporting problems. Pennsylvania has a number of fine medical schools which turns out numerous specialists. Last year approximately 14 percent of the surgical specialists trained in Pennsylvania stayed in Pennsylvania because of the situation of rising malpractice costs and declining reimbursement. These two adverse facts create a hostile practice environment and make it impossible to offer fair and competitive salaries to new graduates, many of whom are carrying large educational debts. In my home county in Pennsylvania (Lackawanna County) the number of general surgeons, vascular surgeons and neurosurgeons has declined in the last five years. New surgeons are not replacing those who die, retire or leave the area.

Recently a disturbing trend has emerged where some attorneys, accountants and practice management specialists are advising physicians to avoid treating Medicare and Medicaid recipients because of the low reimbursement. Thankfully this advice in general is not heeded in Pennsylvania and throughout the nation.

In conclusion, the current Medicare reimbursement formulas are flawed and are hurting low wage areas. They must be revised. The proposed 4.4 percent additional cuts may cause low wage areas to be unable to attract new physicians, get adequate support staff, buy new equipment and make capital improvements. This system will eventually implode, where the quality and availability of care will decrease. The elderly, the poor, the disabled and the under served in low wage areas will be the first to experience this and be further deprived. This phenomenon can spread to other areas of the nation. I would humbly ask the Committee to prevent further Medicare cuts, revise the flawed reimbursement formulas so that they would be more fair, to increase Medicare funding if possible and to resolve the medical liability crisis facing the nation.

Thank you for your concern and for the privilege granted to me to address you.

**STATEMENT OF RICHARD E. D'ALBERTO, CHIEF EXECUTIVE OFFICER,
J.C. BLAIR MEMORIAL HOSPITAL**

Senator SPECTER. Thank you very much for your testimony, Dr. Blomain. Our final witness from this panel is Mr. Richard D'Alberto, president and CEO of J.C. Blair Memorial Hospital in Huntingdon, Pennsylvania, bachelor's degree in health services administration from the Russell State College in Troy, New York. Thank you for joining us today, Mr. D'Alberto. We look forward to your testimony.

Mr. D'ALBERTO. Good morning, Mr. Chairman, and members of the subcommittee. I thank you for the opportunity to come before you today to talk about Medicare.

Let me tell you about J.C. Blair Memorial Hospital first. We are a 104-bed full-service community hospital. We recently celebrated our 92nd year. We are located in Huntingdon County. Huntingdon County is an 800 square mile area with 46,000 population. We are 45 minutes to 1 hour away from any other hospital in all direc-

tions, sometimes over treacherous roads and over mountainous terrain.

Our county has the second highest unemployment rate in Pennsylvania, leading to a high number of underinsured and uninsured individuals, and leads to \$1.4 million worth of uncompensated care at our hospital. In addition, 75 percent of our patients' revenue is from Medicare and Medicaid.

Senators, we are in the County of Huntingdon, Pennsylvania.

I will discuss three major points for your information today. First, I know it is a popular opinion in Washington for people to think that hospitals are inefficient. The fact of the matter is, we have worked over the last 5 years at our hospital to adjust our cost structure to become one of the most efficient hospitals in Pennsylvania, and yet we continue to lose in operations over \$1 million in each of the last 3 years.

Simply put, our costs have risen significantly faster than reimbursement. Some examples of the costs are recent increases of 10 percent for salaries for RN's. Our drug budget has doubled in 5 years, from \$500,000 to \$1 million a year. There are regulatory requirements, disaster planning, malpractice, and medical technology that often contribute to the rising costs. There are no more areas for us to cut our costs. The only thing left is to attack some of our programs.

Second, there have been a number of well-intentioned programs implemented to assist small and rural hospitals over the past few years, sole community hospital, Medicare dependency, critical access are some examples. All of these programs have arbitrary cut-offs for qualification. For various reasons we have come very close to qualifying, and yet we are not qualified.

Like most of our small hospital colleagues in Pennsylvania, we have the same problems, but with significant more population to serve than those hospitals that have benefitted from these programs. For us, the life preserver is only at arm's length. We still cannot seem to reach it.

Third, the medical malpractice issue. We were able to avoid a four times increase in our malpractice insurance in the past year by forming a risk retention group with 31 other hospitals, so for the time being, the issue for us is not cost, the issue for us is access to care.

Let me share a story with regard to our pathologists, one of the finest group of pathologists in the State of Pennsylvania, in practice for 17 years. They were dropped by their insurance carrier at the end of June, and at the eleventh hour, literally on a Friday night at 11 p.m., that I heard from them that they were picked up by the joint underwriters. Without a pathologist, you cannot run a laboratory, you cannot run an ER. Without a pathologist, you cannot run a laboratory, you cannot do OR surgery. We were on the verge of closing our hospital unless those pathologists got their insurance, and that occurred less than 1 hour before midnight.

In closing, financial relief for us is what was recently included in the fiscal year 2003 omnibus appropriations, and that is an increase in the Medicare standard amount to the urban classification for all hospitals. In addition, a full market basket update, and I

emphasize what was said earlier, that there has not been a full market basket adjustment in the past 13 years.

Our biggest concern is that the Medicare reform package of 2004 will further cut hospitals' reimbursements in order to pay for other programs. Senators, please do not cut hospitals again and, in particular, small and rural.

PREPARED STATEMENT

We sincerely appreciate the committee's concern about the pressures rural hospitals are facing and your willingness to learn more, and we also thank you, Senator Specter, for your longstanding support for the Medicare program in your hospitals in Pennsylvania.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF RICHARD E. D'ALBERTO

Mr. Chairman and Members of the Subcommittee: I thank you for the opportunity to come before you today to discuss the Medicare Program. Allow me to first tell you about my hospital. J.C. Blair Memorial Hospital is a full service community hospital of 104 beds serving as the only hospital in a county of 46,000 population spanning 800 square miles. Huntingdon County has the unfortunate distinction of having the second highest unemployment rate in the state, which has resulted in the hospital serving a significant number of underinsured and uninsured leading to \$1.4 million worth of bad debt and charity care. Our operating revenue of \$28 million consists of 75 percent Medicare and Medicaid. The remainder is from Blue Cross, HMOs, PPOs and approximately \$1.4 million self pay. Since the full impact of the Balanced Budget Act of 1997, J.C. Blair has suffered deficits of \$1.4 million in 2000, \$1.5 million in 2001, \$1.7 million in 2002, and we are heading for another sizable loss in this fiscal year. Medicare reimbursement has simply not kept up with the continuing cost of providing service to our community.

Over the last 5 years we have adjusted our cost structure and become one of the most efficient hospitals in Pennsylvania. We are managed by Quorum Health Resources. As a result, we consistently compare our operating indicators to several like hospitals in Pennsylvania and across the country. Let me share some of those indicators with you.

Indicator	Standard	J.C. Blair
Man hours per adjusted admission	90	84
Full Time Equivalents per Adjusted Occupied Bed	4.6	3.2
Supply Expense as a percent of Net Revenue	16.5	16.1
Salaries as a percent of Net Revenue ¹	40	43

¹ This number is higher because we have to pay competitive wages while our reimbursement is shrinking.

There have been a number of other cost drivers contributing to this situation:

- Shortages of nurses and other key personnel have driven up our salary costs—10 percent for RN's alone this past year.
- Our drug budget in 1996 was \$500,000. This year it is \$1,000,000
- Blood and blood products increased in price 50 percent this past year.
- Regulatory burdens such as HIPAA, EMTALA, and compliance have increased our costs of doing business.
- Disaster planning and smallpox vaccination will cost us tens of thousands more over the next year.
- The rising cost of malpractice insurance is crippling us in many ways. We escaped a four times increase by joining a captive.
- New medical technology, if we ever have a positive operating margin, will continue to drain our capital reserves.

Over the past several years there have been specific programs implemented to assist small and rural hospitals with their financial crisis in managing the Medicare population. Some of them are: Sole Community Hospital status, Medicare Dependency status, and Critical Access Hospital status. All of these programs have arbitrary cut-offs for qualification. These programs have been designed to give relief to some small and rural hospitals, but many, like ours, "fall through the cracks." We

have tested our qualification for all of them and we fall short in every case, yet we are a small and rural hospital like many others across the mid-west and west that have benefited. We, like most of our small hospital colleagues in Pennsylvania, have the same problems, but with significantly more population to serve. Pennsylvania has the third highest rural population and second highest elderly population—this translates into small, rural hospitals that need to be larger to effectively serve their communities than the cut-offs that have been established for the rural relief programs, but are no less vital to their communities and no less in need of financial relief than their smaller counterparts in other states.

Probably the most significant inequity is the Medicare Wage Index Factor, which is .84 for J.C. Blair Memorial Hospital. In order to remain competitive regarding wages we must pay the same or more for professional staff as the urban areas. Equalizing our rate with other areas would bring us at least an additional \$600,000 of Medicare reimbursement next year.

Just yesterday morning, I had to recommend to the hospital's Finance Committee that we begin serious deliberations regarding the elimination of basic and vital services. We are at the point where we have no other choice. Decreasing these vital services would result in many of our patients in most need traveling 35 or more miles away, with mountainous terrain in all directions and treacherous roads during the winter months, to receive care. We also have no public transportation system.

Over the years we have formed very successful relationships with other providers in our region to keep many specialty services in our service area. Those relationships will be seriously jeopardized.

In my mind we are a "Sole Community Provider" and our county would be devastated if we provide any less than full service to our community. The following statistics show that we are a vital service to this community:

- 380 deliveries per year 18,500 patient days per year of which 11,000 are Medicare days and 2681 are Medicaid days
- 4,100 admissions per year of which 1,850 are Medicare and 750 are Medicaid
- 93,000 out patient visits per year
- 13,800 emergency department visits per year

We are asking Congress to reverse the cuts that went into effect on October 1, 2002, expand upon rural hospital provisions, provide more flexibility in qualifying for special designations, equalize the Wage Index across the board, lessen the regulatory burdens, and provide full market basket updates that accurately reflect the current cost pressures hospitals are facing.

We sincerely appreciate the Committee's concern about the pressures rural hospitals are facing, and your willingness to learn more. We also thank you, Senator Specter, for your longstanding support of the Medicare Program and your hospitals in Pennsylvania. One size does not fit all. Please do what you can to keep more of us from "falling through the cracks."

Senator SPECTER. Thank you very much, Mr. D'Alberto.

The testimony has been very, very impressive, and especially since we have had a partially captive audience in Mr. Scully.

In light of the time, I am not going to ask for any oral responses, but I would ask two questions. Mr. Anderson raised the issue of more problems caused by the Balanced Budget Act, and I would appreciate it if you gentlemen would respond in writing to what changes you think ought to be made in that act. We would like to have your inputs as to what ought to be done.

The other question which I would like in writing, to save time, relates to whether the Federal restriction on hospitals covering doctors who practice at the hospitals—Mr. Scully, will you confirm that under existing regulations—what are the regulations with respect to hospitals including doctors who practice there in their malpractice coverage?

Well, I believe the answer to that is that hospitals are precluded at the present time from covering doctors who practice there. I am not sure about the employee status, or those that just have practicing rights. If a change were made in the Federal restrictions it would lower malpractice rates for the doctors who would be in a pool basis. It would not impose—I am not suggesting imposing an

obligation on the hospitals to cover the doctors, but I am suggesting a change which would eliminate the prohibition against hospitals covering the doctors.

In conversations I have had informally, I have had a negative response from hospitals on the ground that if the prohibition is removed there would be pressure to include the doctors, but in light of the very severe problems on medical malpractice, I would like your answers in writing.

I wish we had time to do a great deal more. This is already an exceptionally long hearing for this subcommittee, and now I am going to yield to my colleague, Senator Harkin.

Senator HARKIN. Well, again, thank you, Mr. Chairman, for holding this hearing and bringing all of these very intelligent and well-informed witnesses before us, and I have appreciated it. I did not hear all of the testimony. I have been sitting here reading them and catching up, but it is vital to our deliberations, what we are going to be doing here.

Again, I just—you will excuse me if I want to just get back to the idea of the Medicare reimbursements to our providers, to our hospitals. You have heard a lot of talk today about the wage index, and how that wage index works and everything. I just ask Kirk Norris from Iowa, who I know very well, if you would just sort of—specifically, what is the payment flaw in the wage index, and can you give us some idea of how you think Congress ought to correct it?

Mr. NORRIS. Specifically, the flaw in the wage index is the portion which is attributed to labor, which are your salaries and benefits costs. For hospitals in Iowa, salaries and benefits account for 50 percent of all of their expenses.

The wage index has a proxy that says 71 percent of hospital expenses are salaries and benefits. That discriminates against States like Iowa, where you have lower wage expenses. That does not necessarily—as I think Mr. Scully indicated, that was an issue that was addressed, we thought wrongly, in the proposed rules last year, and he did as well, by taking that percentage upward.

We would say it needs to go downward, but to move it downward, Congress would have to provide money so that there was not a reallocation of dollars within that framework, because once you—for example, if the policy was—let us say the sound policy is to attribute that percentage to what actually are the salary and benefits expenses in that particular region, or State. That is good policy.

To do that, if you did it today in a budget-neutral context, you are going to reallocate money between hospitals, which is a problem, at least, it is a problem politically. So what Congress would need to do is get the policy changed so that States like Iowa were no longer discriminated against, and that is a rule that Mr. Scully can promulgate. The money would have to be there to fund that differential, because there would be additional moneys that would have to go to those low wage States.

Senator HARKIN. So the Medicare reimbursement rate based on 71 percent of these costs you say is wrong, and we have good data in our State that can show that it is really 50 percent rather than—

Mr. NORRIS. We have excellent data. CMS has excellent data.

Senator HARKIN. CMS has that data?

Mr. NORRIS. Yes. We do as well.

Senator HARKIN. I guess my question, Mr. Scully, if I might just ask you, why would not CMS then just look at each State and say, rather than 71 percent, if it is 50 percent in Iowa, then use that as a factor, or if it is—what is it in Pennsylvania? Does anyone know what it is in Pennsylvania?

Mr. SCULLY. It is around 72 percent, pretty close to the national average, almost 72 percent.

Senator HARKIN. In Pennsylvania. But Iowa seems to be much lower than that, so why can we just not take each State separately and say, okay, if that is what the proportion is of your costs, then that is what we are going to reimburse on?

Mr. SCULLY. Do you want me to answer?

Senator HARKIN. Yes, please, Mr. Scully, if you could.

Mr. SCULLY. I would just say that something that we have looked at, as Kirk mentioned. The traditional way we have measured this, it was supposed to go up from 71 to 72 percent last year. The Secretary decided to freeze it at 71 percent, and we looked at doing exactly what you describe. The issue is, it would cause very big redistributions, for example, out of Pennsylvania and into Iowa, out of New York and into Kansas.

Senator HARKIN. But if it is honest, I mean, if our proportion is only 50 percent, why are we getting penalized by having it put at 71 percent?

Mr. SCULLY. Well, we have looked at that and discussed it at great length with the AHA and others. It has always been a national blended rate, going backwards 30 years, where we took the national average of what wages are. In some States, wages are 80 percent of costs, in some States—Iowa I believe may be the lowest—it is in the low 50s as a percentage of the real costs, and there are many, many variations of how to do it, county by county, MSA by MSA, State-by-State, and we would be happy to look at all of them, but as he accurately mentioned, it causes fairly significant redistributions, and not always—sometimes it is actually out of rural areas.

It is very specific to each State and each county. Actually, in some cases, rural hospitals actually lose. As a general matter, urbans generally lose and rurals win, but it is not always the case. I have looked at it a lot, and it has hugely different impacts around the country, but we are certainly happy to get into the weeds with you if you like and go through it.

Senator HARKIN. It was Dr. Blomain, I think—I think it was, that testified about how—maybe it was you. I have heard so much testimony here—about how hospitals in small and rural areas actually pay higher costs. I forget who it was that was talking about that.

Dr. BLOMAIN. Yes.

Senator HARKIN. Because they cannot buy in volume, but sometimes they have to actually pay higher wages to get someone to come to a rural area because, let us face it, they maybe do not want to go there, so to entice them there they have to actually pay more than what they would pay in an urban area.

Dr. BLOMAIN. That is true, Senator.

Senator HARKIN. That is why this thing has got to be—we have got to address this, because it is hurting rural areas I am sure in Pennsylvania, as well as it is in Iowa.

Now, God bless Philadelphia and Pittsburgh, but how about the rural areas of Pennsylvania and other States out there that are getting hurt by this, that is my only point, is that we have got to make some changes in this thing.

Well, my time is up. Thank you very much, Mr. Chairman.

Senator SPECTER. Thank you, Senator Harkin.

Thank you very, very much, gentlemen. I think it has been very informative, and I predict it will have an impact. Thank you.

STATEMENT OF RICHARD F. POPS, CHIEF EXECUTIVE OFFICER, ALKERMES, INC.

Senator SPECTER. Our final panel, finally, is Mr. Richard Pops and Thomas Scully. Mr. Pops is the chief executive officer of Alkermes, Inc., located in Cambridge, Massachusetts, and he is on the board of directors of Biotechnology Industry Organization.

The issue which we are taking up here involves the newly created concept of functional equivalence. Under this standard, different drugs and biologicals could be reimbursed based on the lowest applicable rate if CMS chooses to designate them as functional equivalents. This modifies the heretofore traditional practice of CMS utilizing the pass-through payments.

Thank you very much for joining us, gentlemen. I hope the differences between the witnesses are not as extreme as the distances between the chairs, and we will start with you, Mr. Pops.

Mr. POPS. Thank you very much. It is a pleasure to be here, and thanks for allowing us to address this committee.

As you said, I am the CEO of a biotechnology company called Alkermes. I am also the vice chairman of BIO, and BIO, as you may know, is the largest trade organization in the world for biotechnology companies, and it represents over 1,000 biotechnology companies.

Senator SPECTER. Pull the microphone up, Mr. Pops.

Mr. POPS. Can you hear better now?

Senator SPECTER. Yes. Go ahead.

Mr. POPS. I was saying that BIO represents about 1,000 biotechnology companies, academic institutions, and state biotechnology centers and, as such, it spans 50 States and actually across the globe, so I am here both as the CEO of Alkermes and as a representative of BIO.

It is interesting, our company, like most of these biotechnology companies, is dedicated to developing important new drugs, and this is, as some would say, an inherently optimistic strategy for a couple of reasons; number one, how long it takes to do so, generally measured on the order of 10 plus years to develop a new medicine, and also the cost. In the 12 years that I have been the CEO of Alkermes, we have raised now just on the threshold of \$1 billion, and we are not alone in this process.

Senator SPECTER. You say \$1 billion for what?

Mr. POPS. \$1 billion that we have raised from investors in order to fund the expensive R&D and prior development that we do to

develop our first drugs, so it is a daunting economic prospect, and some would say—

Senator SPECTER. So you are saying that it takes \$1 billion to develop a new drug?

Mr. POPS. I think the data from Tufts and other places show that a new drug costs on the order of \$200 to \$400 million to develop, and about 5 to 10 years.

Senator SPECTER. What was the \$1 billion figure?

Mr. POPS. That is what we spent to build our company, build our buildings, build our manufacturing plants, pay our employees, and stay in business for the last 12 years.

Senator SPECTER. Okay.

Mr. POPS. These companies are fueled essentially by two things. Number one is by a culture within these companies which is based on a strong intellectual commitment to developing new drugs based on new science, applying new science to develop drugs that the large pharmaceutical companies either choose not to develop because they are for orphan indications, or indications they are not particularly economically interested in, or they do not have the technology to do, because we tend to employ the youngest, brightest, cutting edge technologies that are available in the medical sciences.

The second thing that fuels these companies is capital, as we were just saying, tremendous amounts of capital, and that capital is raised from venture capitalists and also from the public equity markets. We have done both. We have been a public company for about 11 years now, and most of our money is raised through the public equity markets.

So for this reason you can think of the biotech industry as essentially being almost an early warning alarm for policies or legislation that has the impact or the potential impact of restricting the flow of new medicines into the marketplace. Faced with the prospect of reduced access to important medicines, our investors very quickly shift funds into other sectors, and your investment dollars—without the investment dollars, the expected outcome occurs.

So today's hearing essentially addresses, as you said in the preamble, one of these potential situations. On January 1, a new and what we think is a flawed payment scheme went into effect for medicines covered under Medicare's hospital outpatient prospective payment system, or OPSP. This covers innovative medicines used in hospital outpatient centers such as cancer chemotherapies, kidney failure drugs, and medicines for autoimmune diseases. Often, many of these drugs are developed by biotechnology companies.

Senator SPECTER. Mr. Pops, your voice drops off when you move away from the microphone. Would you please speak into the microphone?

Mr. POPS. I will try to do that.

Senator SPECTER. We are missing a fair amount of what you are saying.

Mr. POPS. All right. Can you hear now?

Senator SPECTER. Yes.

Mr. POPS. Okay. These are critical medicines for the Nation's senior citizens and the disabled population, who are covered under Medicare. Unfortunately, CMS has now slashed the reimbursement

by an average of about 35 percent to below what the drugs cost hospitals, and has introduced a series of precedents that we do not think should be allowed to stand, such as arbitrarily deciding that drugs known as radiopharmaceuticals are not drugs, choosing to exclude only four orphan drugs from the OPPS, and creating out of whole cloth the concept of functional equivalence.

Let me start by sharing with you just a simple data that show the OPPS methodology.

Senator SPECTER. How do you define a functional equivalent, Mr. Pops?

Mr. POPS. Well, I think it is essentially an arbitrary standard, and that is the problem. Beauty is in the eye of the beholder, so at the moment, it is currently limited to two particular drugs, but our concern is that it may be expanded to interpretations of functional equivalence between all kinds of different classes of drugs, and therein lies the risk, because for us to develop medicines over a decade and several hundred million dollars and then, post hoc, to have it determined to be functionally equivalent by some type of a bureaucratic determination is inherently not in the best interest of the public health, and also I think it will have the unintended effect of stopping this innovation from occurring.

Senator SPECTER. How does this definition compare with the so-called pass-through payments?

Mr. POPS. Well, the pass-through payments, and I am far from an expert on these specific issues, but generally the pass-through payments were put in place by Congress to allow certain drugs like chemotherapy and radiopharmaceuticals and orphan drugs to bypass this process of arbitrarily determining their price and allowing them to flow into the community and to allow patients access to these drugs on a more unimpeded basis.

What has happened now is that these drugs are being folded back into this method that I can describe, and that the chart describes to some extent, showing how these relatively expensive drugs, these innovative drugs for smaller patient populations often get affected in the same way that a common aspirin would be affected in the way it is reimbursed.

If you want to look at the chart, it will show you that to reflect overhead costs—and this is in your package as well—the hospital may charge \$10 for a 10-cent aspirin, an increase of 10,000 percent, while charging \$1,000 for an \$800 biological, or biotech product, an increase of only 25 percent.

In 2001, the average hospital pharmacy cost-to-charge ratio was about .3. In the end, according to CMS, the aspirin would end up costing \$3, and the biological would end up costing \$300. This is a dramatic underreimbursement, and it provides a clear incentive, we feel, for hospitals to stop providing higher cost, innovative drugs and biologicals in their outpatient departments. Unless CMS recalculates OPPS rates for these products, we fear that patients will be denied access to these types of medicines, so that is one important issue that we are worried about.

Second, we believe that the agency's arbitrary determination that FDA-approved radiopharmaceutical products are not drugs or biologicals and therefore not eligible for pass-through status con-

tradicts the clear intention of Congress to protect Medicare patients' access to these types of drugs.

Third, CMS decided to reimburse only four orphan drugs at actual hospital cost, leaving dozens of other products for orphan conditions inadequately reimbursed.

Fourth, in the final rule establishing hospital outpatient department rates for 2003, CMS completed this entirely new concept of functional equivalence in order to avoid covering a new drug under the traditional pass-through payment system, so we are troubled by that as well.

In part, we are troubled by the disregard in our view of due process. CMS implemented this new functional equivalent standard without any mention of it at all within the proposed rule, and interested parties like BIO and my company and others had no notice and no opportunity to voice our opposition to that standard.

Second, we believe that the functional equivalent standard is bad policy in a country that values medical innovation. Manufacturers simply will not devote years of clinical development and hundreds of millions of dollars of research toward improving current therapies or developing brand new therapies if that at the end of the day could be seen as, quote-unquote, functionally equivalent to another product, and I think that has real potential ramifications for patients.

Finally, we believe that this functionally equivalent standard will harm Medicare beneficiaries' access to advanced new therapies. Advancements such as less frequent dosing, fewer side effects, recombinant DNA production methods, or more convenient modes of administration often improve safety and in many cases increase compliance and tolerance of these medications for patients, and therefore they increase the odds that the therapy will succeed.

My company's products, for example, are heavily oriented towards this notion. For example, we have a drug that we are developing that replaces the need for schizophrenic patients to take their oral medication every day. It replaces that with a single injection that lasts 2 weeks, so the patient, the caregiver, the families do not have to worry about compliance, because these medications often are only as good as the compliance regimen that supports them.

PREPARED STATEMENT

So because the exact benefits of our advances vary patient by patient, we really firmly believe that the physicians, not CMS, should determine on a patient-by-patient basis whether one drug is a suitable substitute for another one.

So I will stop there. We really appreciate the opportunity to address you, and I would be happy to answer any questions.

[The statement follows:]

PREPARED STATEMENT OF RICHARD F. POPS

The Biotechnology Industry Organization ("BIO") sincerely appreciates this opportunity to express our deep concerns about the Medicare hospital outpatient department prospective payment system ("OPPS") and 2003 payment rates. My name is Richard Pops, and I am the CEO of Alkermes, Inc. and Vice-Chairman of the Board of BIO. My company is a leader in the development of products based on sophisticated drug delivery technologies and a member of BIO. BIO is the largest trade or-

ganization to serve and represent the biotechnology industry in the United States and around the globe. BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in all 50 states. BIO members are involved in the research and development of health-care, agricultural, industrial and environmental biotechnology products.

Representing an industry that is devoted to discovering new cures and ensuring patient access to them, BIO consistently has expressed concerns that the OPPS could create substantial access and quality of care issues for Medicare beneficiaries. Our concerns fall into four categories:

1. CMS' creation of a new "functionally equivalent" standard;
2. The agency's determination that FDA-approved radiopharmaceuticals are not drugs or biologicals and therefore are not eligible for pass-through status;
3. CMS' decision to exclude only four orphan drugs from the OPPS, leaving dozens of other products for orphan conditions inadequately reimbursed; and
4. CMS' use of a fundamentally flawed rate-setting methodology for higher cost drug and biological therapies.

CMS' NEW "FUNCTIONALLY EQUIVALENT" STANDARD

CMS has for the first time in the final rule developed the concept of "functional equivalence" in making payment determinations for erythropoietic products.¹ The use of the term "functionally equivalent" as a concept raises numerous concerns for our industry. Had BIO been notified of the use of such a standard, we would have presented our comments and vigorous objections. A practice that allows CMS to arbitrarily set standards such as "functionally equivalent" creates uncertainty in the industry. In addition, it has substantial legal implications and, as a policy matter, clearly discourages innovation—the foundation of the biotechnology industry. The decision to remove pass-through payments for a new drug also is beyond the scope of authority granted to CMS under the statute. At a minimum, it is inappropriate for CMS to impose this dramatic departure from prior policy for the first time in a final rule without notice and, therefore, without the opportunity for the public to respond. BIO fears that the application of CMS' new "functionally equivalent" standard will deny patients access to innovative therapies on the horizon that offer them fewer side effects, more convenient dosing and modes of administration, and even new hope for survival.

BIO's first concern is CMS' clear failure to heed the Administrative Procedure Act's ("APA") requirements for rulemaking. CMS implemented its new "functionally equivalent" standard without any mention whatsoever in the proposed rule. Interested parties, such as BIO, had no notice and opportunity to comment on this deeply troubling new policy. Had it been discussed in the proposed rule, we would have vigorously voiced our opposition. CMS' implementation of this brand new standard in the final rule sets a dangerous precedent and makes a mockery of the notice and comment process.

Second, BIO fears that this new "functionally equivalent" standard will harm the future development of new drugs and biologicals by creating uncertainty in the industry. Without the assurance of adequate payment rates, innovation—the foundation of the biotechnology industry—will be stifled. CMS has sent the message that even if a company develops an improved drug and even if the improvement saves money elsewhere in the healthcare system, the drug nonetheless may be reimbursed based on the agency's calculation of a comparable dose of another drug. Changing the rules after a company has invested hundreds of millions of dollars in a new product will make the next company think twice about making a similar investment. Manufacturers simply will not devote precious resources toward improving current therapies or in developing new therapies that could be seen as "functionally equivalent" to another product. This will have unfortunate long-term ramifications for all patients who truly could benefit from improvements to existing therapies.

Finally, and most important, we believe that the "functionally equivalent" standard will harm Medicare beneficiaries' access to advanced, new therapies. In creating this standard, CMS ignores the incremental nature of many pharmaceutical and biological developments. Many advancements in drugs and biologicals improve existing therapies, rather than create entirely new treatments. Existing therapies have been improved to require less frequent dosing, cause fewer side effects, offer recombinant versions, or more convenient modes of administration. Advancements such as these often increase compliance and allow patients to tolerate the most effective treatment available, especially when patients are elderly or live in rural areas without convenient access to hospital outpatient departments. For example, therapies

¹67 Fed. Reg. 66718, 66757–59 (Nov. 1, 2002).

with fewer side effects increase the probability that patients can tolerate the full dosage of chemotherapeutic regimens. Cures and longer remissions are more likely as a result of this increased compliance. Likewise, the development of a recombinant version of a drug may make it safer and enable more patients to tolerate it.

Moreover, a drug or biological that is only incrementally beneficial to one patient could be significantly beneficial to another. This is why physicians should be the only ones to make the decision of whether one drug is a suitable substitute for another. This point was raised in President Bush's State of the Union Address when he said, "Instead of bureaucrats . . . , we must put doctors and nurses and patients back in charge of American medicine." This determination should only be made on an individual patient basis, rather than for the entire Medicare population.

Medicine is constantly evolving. When a new drug or biological is approved, it often is difficult to predict who will benefit from it and how it should most effectively be therapeutically utilized. This is precisely why Congress created the transitional pass-through system. Through this system, CMS can collect data on new therapies as clinical experts actually use them for a few years before establishing payment rates. Unfortunately, darbepoetin alfa and any other new drug to which CMS decides to apply its "functionally equivalent" standard will be illegally deprived of this critical data collection period.

Congress already has attempted to protect Medicare beneficiaries' access to modern therapies. Now we ask that you ensure that CMS adheres to those statutory protections and abolish the agency's "functionally equivalent" standard immediately.

CMS' FAILURE TO RECOGNIZE RADIOPHARMACEUTICALS AS DRUGS OR BIOLOGICALS FOR PURPOSES OF PASS-THROUGH STATUS

In addition to the new "functionally equivalent" standard, CMS announced a new policy in the final rule regarding diagnostic and therapeutic radiopharmaceuticals. In a decision that prevents current, as well as future FDA approved radiopharmaceuticals, from qualifying for pass-through payments, CMS also has determined for the first time in the final rule that diagnostic or therapeutic radiopharmaceuticals are not "drugs" or "biologicals."² Specifically, the agency stated that Zevalin—, that has been approved by the FDA as a biological and is listed as such in the USPDI, is not a drug or biological for purposes of Medicare.³ Accordingly, this therapy—as well as other radiopharmaceuticals in the future—no longer will be eligible for pass-through payments, even though Congress clearly intended to include them in this system. CMS' redefinition of these longstanding terms is outrageous and clearly contradicts the statute as well as FDA policy. This substantial change in reimbursement policy for radiopharmaceuticals also was not mentioned at all in the proposed rule. Once again, CMS has blatantly ignored the notice and comment rulemaking requirements of the APA.⁴ BIO asks Congress to work with us to reverse this troubling policy and continue pass-through payments for new radiopharmaceuticals as Congress intended, ensuring patient access to these important therapies.

Section 1833(t)(6)(A)(iv) of the Social Security Act ("SSA") establishes pass-through payments for new medical devices, drugs, and biologicals for which payment as a outpatient hospital service was not being made as of December 31, 1996, and for which cost is not insignificant in relation to the outpatient department fee schedule amount. In addition to current orphan and cancer therapy drugs and biologicals, the statute also specifies that pass-through payments would be made for "current radiopharmaceutical drugs and biological products," defined as a "radiopharmaceutical drug or biological product used in diagnostic, monitoring, and therapeutic nuclear medicine procedures."⁵ Obviously, Congress considered radiopharmaceuticals to be "drug or biological products" and intended patient access to them to be protected through the transitional pass-through system. It is inconceivable that Congress meant to exclude these therapies from the definition of drugs and biologicals under section 1833(t)(6)(A)(iv) of the SSA, and no theory of statutory construction would support CMS' interpretation on this point.

The treatment of radiopharmaceuticals as "drugs or biologicals" also is consistent with other provisions of the SSA as well as longstanding CMS policy. Section 1861(t)(1) of the SSA defines the terms "drugs" and "biologicals" for Medicare purposes to include only such drugs or biologicals as are included (or approved for inclusion) in the United States Pharmacopoeia, the National Formulary, or the United States Homeopathic Pharmacopoeia, or in New Drugs or Accepted Dental Remedies,

² 67 Fed. Reg. at 66757.

³ Id.

⁴ 5 U.S.C. § 553.

⁵ 42 U.S.C. § 1395l(t)(6)(A)(iii).

or as are approved by a hospital pharmacy and drug therapeutics committee (or equivalent committee). Historically, CMS has considered a product approved by the FDA as a drug or biologic and that is included or approved for inclusion in one of the listed compendia to be a “drug” or “biological” for Medicare purposes. In July 1997, the Health Care Financing Administration issued a transmittal that instructed hospitals to use revenue code 636—drugs requiring detailed coding—for radiopharmaceuticals.⁶ Clearly, the agency has characterized radiopharmaceuticals as drugs in the past and should not be permitted to arbitrarily change that classification now.

In any event, such a dramatic departure from the plain language of the statute as well as CMS policy should not have occurred for the first time in a final rule. Section 553(b)(3) of the APA requires an agency proposing a new rule to include in the notice of proposed rulemaking “either the terms or the substance of the proposed rule or a description of the subjects and issues involved.” CMS gave no indication in its proposed rule that it intended to reclassify radiopharmaceuticals. In fact, the proposed rule indicates that CMS fully intended to continue pass-through payments for both Y-90 Zevalin and IN111-Zevalin in calendar year 2003 by publishing anticipated pass-through payments for 2003.⁷ Because CMS published rates for Zevalin . . . , it is incomprehensible that interested parties could have concluded that CMS intended to reclassify radiopharmaceuticals and discontinue the existing policy of providing pass-through payments for them.

Zevalin became the first radioimmunotherapy approved by the FDA in February of 2002. It consists of monoclonal antibodies that are chemically bonded with a radionuclide. Manufacturers increasingly are using biological agents such as monoclonal antibodies, which are disease-fighting proteins that seek out and bind with specific tissues or cells. Radioimmunotherapies are made by linking monoclonal antibodies—engineered in a laboratory to recognize and attach to substances on the surface of certain cells—to radioactive isotopes. When the drug is administered to the patient through infusion, “radiation-carrying antibodies circulate in the body until they locate and bind to the surface of specific cells, and then deliver their cytotoxic radiation directly to malignant cells.”⁸

Radioimmunotherapies provide new hope for patients battling cancer. It is essential that these radiopharmaceuticals be treated as what they are and always have been—drugs and biologicals. Congress clearly intended for Medicare beneficiaries to continue to have access to these important radiopharmaceuticals by including them in the pass-through system. Congress now must ensure that therapies approved by the FDA as “drugs” and “biologicals” and listed as such in the USPDI as drugs and biologicals are eligible for pass-through payments. Not only is this treatment consistent with the plain language and intent of the statute, but it also protects patient access to these critical medicines.

EXCLUSION OF ALL ORPHAN DRUGS USED FOR ORPHAN INDICATIONS

BIO applauds CMS for recognizing that certain orphan drugs are generally expensive and, by definition, rarely used, and as a result, should not be included in the OPPS.⁹ Rather than carving out all drugs and biologicals designated by the FDA as orphan and used for their orphan indications, however, CMS instead has decided to exclude only those that the current USPDI shows have neither an approved use for other than an orphan condition nor an off-label use for conditions other than the orphan condition. As a result, only four orphan products are excluded. The agency’s approach fails to do what is necessary to ensure that patients suffering from rare diseases continue to have access to the treatments they need. Instead, BIO believes that all drugs and biologicals designated as orphan by the FDA and used for their orphan indications should be excluded from the OPPS.

In the August 9, 2002, proposed rule, CMS created two categories of “orphan drugs:” orphan drugs used solely for orphan conditions and orphan drugs that are used for other conditions. CMS “recognize [d] that orphan drugs that are used solely for an orphan indication or conditions are generally expensive, and by definition, are rarely used.”¹⁰ Rather than packaging the costs of these drugs into procedure APCs, which might not be sufficient to compensate a hospital for the costs of the drug, CMS proposed to “establish separate APCs to pay for those orphan drugs that are used solely for orphan conditions.”¹¹ Payment for all other orphan drugs would be

⁶ Medicare Intermediary Manual, Part 3 (CMS-Pub. 13-3), Transmittal No. 1717, July 1, 1997.

⁷ 67 Fed. Reg. 52092, 52119 (Aug. 9, 2002).

⁸ <http://www.idcpharm.com/site/science/zevalin.htm>

⁹ 67 Fed. Reg. at 66772.

¹⁰ 67 Fed. Reg. at 52124.

¹¹ Id.

packaged into the procedure or service for which the drug is integral and directly related, unless they were considered to be “higher cost drugs.”

CMS proposed new criteria for identifying orphan drugs that would be paid separately under the OPPS. First, the drug must be “designated as an orphan drug by FDA and approved by FDA for the orphan indication.” Second, the entry for the drug in the USPDI must show that the drug has neither an approved use nor an off-label use for a condition other than the orphan condition.¹² Thus, separate payment would be provided only for orphan drugs that are used only by patients suffering from rare diseases. Using these criteria, CMS identified only three orphan drugs that are eligible for separate payment under the OPPS: alglucerase injection (J0205), alpha 1 proteinase inhibitor (J0256), and gemtuzumab ozogamicin (J9300).¹³ In a recent program memorandum, CMS added injection imiglucerase (J1785) to this carve-out.¹⁴

When CMS adopted the proposed criteria for identifying orphan drugs in the November 1, 2002, final rule, however, it also announced an entirely new payment policy for orphan products. Instead of placing orphan drugs into separate APCs, CMS excluded them entirely from the OPPS.¹⁵ These products now will be paid on a reasonable cost basis. Thus, CMS introduced a new payment policy in the final rule that had not been discussed in the proposed rule. The parties affected by this policy change did not have notice that such a change would be made and therefore may not have commented on it. In particular, some of the manufacturers of orphan drugs that CMS failed to recognize in the proposed rule may not have identified their products to CMS as orphan products because the payment rates for their products would have been the same under either the orphan drug or higher cost drug criteria in the proposed rule. These organizations may have commented about other orphan products that met CMS’ criteria had they known about the final rule’s new payment policy for these orphan drugs and biologicals.

In addition to failing to give notice of a change in the payment policy, CMS failed to identify all the drugs and biologicals that met its criteria. In the final rule, CMS recognized only the same three drugs identified in the proposed rule as meeting its criteria for orphan status.¹⁶ As some organizations discussed in their comments to CMS, however, these three products are not the only drugs that meet CMS’ standard. We know of several other products that meet CMS’ orphan criteria: amphotericin B lipid complex (J0286), oprelvekin (J2355), thyrotropin alfa (J3240), daclizumab (J7513), aldesleukin (J9015), denileukin difitox (J9160), interferon gamma 1-b (J9216), rituximab (J9310), coagulation factor VIIa (Q0187), and basiliximab (Q2019). At least one other product, interferon beta 1-a (J1825), meets the spirit of CMS’ criteria, but the USPDI includes one off-label use that is extremely rarely used. In fact, in examining the 1,691 claims in Medicare database, the company knows of no claims for the off-label indication. Similarly, other drugs and biologicals essentially meet CMS’ new standard by having FDA-approved uses and USPDI accepted uses that nearly all are recognized as rare diseases by the National Institutes of Health. Botulinum toxin type A (J0585) is an example of an orphan biological that fits under this “essentially meets” standard.

Although we appreciate CMS’ attempt to exclude certain orphan products from the OPPS entirely, we are concerned that CMS’ eligibility criteria were too rigid and the agency failed to recognize many true orphan drugs and biologicals as a result. The CMS criteria attempt to distinguish rarely used orphan drugs from drugs with an orphan indication that are frequently used for other conditions. As CMS explained in the final rule, drugs meeting its criteria can be distinguished from other drugs “because of their low volume of patient use and their lack of other indications, which means that they can rely on no other source of payment.”¹⁷ The agency recognized that treating these products like most other drugs under the OPPS could produce payment levels that would be “insufficient to compensate a hospital for the typically high cost of this special type of drug.”¹⁸

Simply having alternate indications in the USPDI does not mean that the drug has other, sufficient sources of payment, however. Many orphan products are rarely used, even though they have approved or off-label non-orphan indications. These products have “low volume of patient use” and very few, if any, other sources of pay-

¹²Id.

¹³Id.

¹⁴ Medicare Program Memorandum to Intermediaries, Transmittal No. A-02-129, January 3, 2003.

¹⁵ 67 Fed. Reg. at 66772.

¹⁶Id.

¹⁷Id.

¹⁸Id.

ment. Including them in the OPSS system is just as likely to produce insufficient payment levels as including the drugs that meet CMS' limited criteria. We believe that nearly all orphan-designated drugs are low volume drugs and biologicals used for chronic diseases and generally are provided by specialists who may be available only in the hospital outpatient department setting. Low-volume drugs and biologicals with payment rates below hospital costs are unlikely to be stocked by hospitals—regardless of whether they have non-orphan uses or not. Congress needs to ensure patient access to all low-volume orphan-designated products is protected by excluding them from the OPSS.

Although BIO recognizes that CMS may be hesitant to use the FDA's orphan drug designation as the sole determinant for drugs and biologicals to be excluded from the OPSS, we firmly believe that CMS' standard is too narrow and does not go far enough to protect patient access. A true orphan product, under the Orphan Drug Act, is used to treat a small population or has no reasonable expectation of recovering the costs of research and development.¹⁹ BIO strongly believes Congress should expand the orphan drug exclusion criteria to include all FDA-designated orphan drugs when they are used for their orphan indications. This solution will further the same policy goals as the Orphan Drug Act itself by encouraging manufacturers to engage in the research and development necessary to obtain FDA approval for orphan indications, even when the drug or biological has other more widely-used indications.

Ideally, CMS would be able to determine when an FDA-designated orphan drug is used for an orphan condition and reimburse hospitals for the drug or biological accordingly. We realize, though, that CMS' current system is not set up to make these distinctions and that this solution may take some time to implement. Alternatively, CMS could use the number of claims submitted for a drug to determine whether it is a true orphan product. By looking at the number of claims filed for a product, CMS should be able to distinguish the rarely used orphans from the products with common non-orphan indications. CMS' current narrow criteria clearly will deny adequate payment for many deserving orphan drugs, threatening their availability for patients without any other treatment options. Broadening CMS' orphan exclusion criteria to include other worthy orphan drugs and biologicals will help to ensure that these therapies remain available for patients who suffer from rare diseases. At a minimum, Congress should ensure that the 10 additional drugs and biologicals BIO has identified as meeting the agency's restrictive criteria are excluded from the OPSS.

CMS' FUNDAMENTALLY FLAWED METHODOLOGY FOR RATE-SETTING

Finally, BIO is deeply concerned that CMS is using a fundamentally flawed methodology for setting payment rates that are biased against higher cost drugs and biologicals. Unless this methodology is revamped immediately, patient access to critical drug and biological therapies in hospital outpatient departments will be compromised substantially.

Specifically, CMS has used a single ratio to derive all pharmacy costs within a hospital, without regard for hospitals' actual practices in setting charges for drugs. When hospitals set their charge levels to reflect overhead costs, they raise the charge levels much less for higher cost drugs than they do for low-cost products. As shown in the diagram below, an aspirin, for example, may have a cost-to-charge ratio of .01 (charging \$10 for a \$0.10 pill), while a higher cost biological could have a cost-to-charge ratio of .80 (charging \$1,000 for an \$800 injection). The outpatient methodology ignores this difference and uses a single cost-to-charge ratio for all products in a hospital's pharmacy department. This produces substantial over-reimbursement for low-cost products and substantial under-reimbursement for higher cost products. Using the 2001 average cost-to-charge ratio of .30 produces a \$3.00 payment for the aspirin and a \$300 payment for the biological—less than half of its acquisition cost. This methodological bias results in payment rates that provide a clear incentive for hospitals to stop providing higher cost drug and biological therapies.

CMS attempted to defend its methodology in the final rule by saying that, in the inpatient setting, its assumption that cost-to-charge ratios are constant across all services has worked for almost 20 years.²⁰ CMS asserted that, in the inpatient setting, "any deviations [between costs and charges] should largely cancel out."²¹ At the same time, CMS admitted that if hospitals do not mark-up costs uniformly, the

¹⁹ See 21 U.S.C. § 360ee.

²⁰ 67 Fed. Reg. at 66752.

²¹ *Id.*

payment rates resulting from CMS' methodology "would create incentives for hospitals to avoid (or favor) particular services."²² Yet, CMS claimed that it had neither enough information nor enough time to revise the methodology for 2003.

In the final rule, CMS applied a "dampening option" to "lessen the impact of the dramatic reduction in the proposed payment rates for many of the drugs and biologicals from 2002 to 2003."²³ Although well-intentioned, the dampening option does not go far enough to address the most egregious under-reimbursements for higher cost drugs. In fact, the dampening option actually produced lower payment rates for all APCs because of the budget neutrality adjustments required to compensate for its cost.

Once again, we believe that CMS must correct this fundamentally flawed methodology before it produces grave consequences for patients. Unlike the inpatient PPS, where CMS believes that over and under-reimbursements will be cancelled out, the OPPS bundles few items and services together. Often the only service the hospital provides to the patient is administration of the drug or biological. In these cases, the hospital does not provide other services with over-reimbursements that can average out the under-reimbursements for higher cost therapies. In a cancer center, for example, the \$2.90 over-reimbursement in our hypothetical example for each aspirin cannot compensate for oncology drug reimbursements that fall hundreds of dollars below their costs. Unless CMS calculates OPPS rates to acknowledge that this charge compression occurs, its methodology and payment rates will discourage hospitals from providing the most appropriate care for patients.

Although we understand that CMS needs time to study problems associated with charge compression and to determine how best to respond, BIO does not believe that patients should suffer during this time. Therefore, we believe Congress should adopt an interim solution to ensure that hospitals are adequately reimbursed during the period before a permanent correction can be achieved. This solution should be adopted immediately. It should encompass not only hospital acquisition costs, but also pharmacy service and other hospital overhead and handling costs involved in delivering safe and appropriate pharmacy therapy.

CONCLUSION

BIO is deeply concerned that patient access to critical drug and biological therapies in hospital outpatient departments will be impeded substantially after January 1, 2003 as a result of the final rule. We believe that Congress must act quickly to revamp this fundamentally flawed rate-setting methodology and to adopt an interim solution in the meantime. We also believe that Congress should exclude all FDA-designated orphan drugs from the OPPS when they are used for their orphan indications. Finally, we believe Congress should act now to require CMS to abandon its new policies with respect to radiopharmaceuticals and the "functionally equivalent" standard. BIO appreciates this opportunity to testify and looks forward to working with you to ensure that patients continue to have access to critical therapies in hospital outpatient departments—both now and in the future.

Senator SPECTER. Thank you very much, Mr. Pops.

Mr. Scully.

Mr. SCULLY. I was asked to respond, so I was trying to—so I am not prepared to testify. I will just respond to the BIO testimony.

Let me digress for one second on the malpractice issue. You mentioned Pennsylvania. Just for your future interest, physicians are allowed to be on a hospital's malpractice plan if they are employees, and it is an antikickback rule that comes through the Inspector General, Janet Rehnquist. She did give an exemption for that, and a temporary waiver for a while, and we are working on that, but the bottom line is, your point about trying to save money for physicians by folding them into the malpractice for the hospital is a legitimate one, and we are working on it, but traditionally that has been looked at as a kickback from the hospital to the doctor and it violated the Stark antikickback rules.

Senator SPECTER. Where was the kickback?

²² Id.

²³ 67 Fed. Reg. at 66769.

Mr. SCULLY. Well, the argument is, if the hospital goes in and subsidizes the doctor's insurance premium, that that is, you know—there is a long legislative history about inappropriate incentives for—

Senator SPECTER. If you have the doctor on your insurance policy so he gets a group rate, that that is a kickback to the doctor?

Mr. SCULLY. There is long case law that is involved—it is Justice Department and Inspector General, not CMS, where theoretically—

Senator SPECTER. You say there is case law on that?

Mr. SCULLY. Oh, there are many, many, many cases in the Justice Department about if hospitals inappropriately subsidize physicians' office rents or anything else, that that is an inappropriate incentive for them to refer doctors to their hospitals, and subsidizing malpractice premiums have been part of—

Senator SPECTER. These are doctors who practice at the hospital? If a doctor is an employee of the hospital, is there any problem in being covered?

Mr. SCULLY. No. If they are an employee, they can be on the plan.

Senator SPECTER. If a doctor practices at the hospital, you are saying that that would be regarded as a kickback?

Mr. SCULLY. In the past, it has been by the Inspector General under these antikickback statutes, and I believe they have given a waiver while they try to work out some exclusions to this.

Senator SPECTER. They have given a waiver, you say?

Mr. SCULLY. I was just informed by some hospital folks that there is a temporary waiver while they look at adjusting that rule for this purpose, but your point—I just brought it up to say that you are very much on point. If you are an employee, you can be an employee doctor, which is very rare. Most doctors are not employees of hospitals. You can be in a pooled malpractice plan.

Generically, you cannot, if you are not an employee, be pooled into the hospital's malpractice plan because it is perceived to be an inappropriate kickback. That has nothing to do with CMS. That is a longstanding Inspector General rule that I believe Janet Rehnquist has given some temporary exemptions to.

Senator SPECTER. Curious rule. I used to deal in kickbacks all the time as a district attorney. It does not sound like a kickback to me.

Mr. SCULLY. Well, generally those are left to Justice and the IG. I was just—you were interested, so I thought I would pass along the most I knew about it.

Senator SPECTER. Now, Mr. Scully, you are the administrator. You have got to deal with what they recommend to you and make an evaluation, and I would ask you to take a look at that. That does not make any sense.

Mr. SCULLY. Well, I have been working with Janet Rehnquist and the Inspector General on a lot of areas of the antikickback rule to make it more realistic, and I think this is certainly one of them.

Senator SPECTER. Okay. On to functional equivalence.

Mr. SCULLY. I have spent hundreds of hours on this issue, and Secretary Thompson I can tell you has spent probably many dozens.

Senator SPECTER. Try to summarize.

Mr. SCULLY. It is just a very complicated issue, but I would say that we did not create a new functional equivalence rule. We have always had the authority. I will just give you a quick summary.

We pay for outpatient drugs in two settings. We have the outpatient prospective payment rule, which brought this up, arguably one of the more complex reimbursement tools of the Medicare program. We are capped at \$19 billion a year in spending this year on outpatient PPS. That pays for all outpatient payments, including hospital payments. We pay for drugs, outpatient drugs in that setting and in the physician setting.

The way this issue came up is, the most expensive pair of drugs in the Medicare program are two drugs that are similar called Aranesp and Procrit. Procrit has been around for many years, a great drug for cancer patients, also used very heavily for dialysis. In the cancer area we spend a couple of million dollars—billion dollars a year, excuse me, on both.

The way this new payment mechanism came up 2 years ago, Congress created a new outpatient payment mechanism, and for 2 years existing cancer and certain other drugs were put on there and were paid at 95 percent of average wholesale price, which by all accounts, including every congressional committee, is a ridiculously overpaid price. But temporarily in 2000 for certain drugs and for new drugs that come out—for patients to have access to them—they are paid at that price.

Senator SPECTER. That is a ridiculous overpayment that Congress has authorized?

Mr. SCULLY. I have testified before the Finance Committee, the Ways & Means Committee, and the Commerce Committee in the last year, and on a bipartisan basis I would say there is extremely strong support for fixing it, and that by all accounts we are overpaying by about \$1 billion a year due to an existing formula.

Senator SPECTER. So there is a strong reason, you say, for having Congress make a modification of that?

Mr. SCULLY. Yes, but there are two pots that are going on here. One is the 20 percent of the payments in the outpatient—

Senator SPECTER. If it is so clearcut, why hasn't the Finance Committee acted on it?

Mr. SCULLY. The Finance Committee has acted, as has the Commerce Committee, as has the Ways & Means Committee. They just happen to have three different fixes, and they have not quite worked it out, but I would say if you talk to Chairman Grassley or Senator Baucus you would find they have very strong feelings about fixing this, as does Chairman Tauzin and Mr. Dingell and Chairman Thomas and Mr. Stark, and the administration has not acted, and we said we would, largely to allow Congress to act so that hopefully they can get—

Senator SPECTER. But at the present time there is this pass-through rule.

Mr. SCULLY. There is a pass-through rule.

Senator SPECTER. And would you define what that pass-through rule is?

Mr. SCULLY. The pass-through rule says that new drugs for 2 years after they are determined to be new drugs, that we should pay them at 95 percent of average wholesale price.

Senator SPECTER. 95 percent of average wholesale price?

Mr. SCULLY. Of average wholesale price, which is an industry-listed book, but my agency has the discretion to—

Senator SPECTER. And the average wholesale price you think is exorbitant?

Mr. SCULLY. Is clearly exorbitant in most cases, not all. Some companies list legitimate prices. It is an industry—by reference, CMS has adopted an industry document called the Red book. Some companies report accurately, some do not. We have the discretion to use anything we like under the law.

Also, because it is capped at \$19 billion, this pot, the Secretary also has clear discretion under the law to make equitable adjustments in payment. So the standard we came up with, that functionally equivalent, is not a new standard. It was an explanation of a longstanding legal authority that we clearly have to adjust payments in either one of the two methods, either to say—

Senator SPECTER. When you say the average wholesale price is absurdly high, that really touches on a much broader issue.

Mr. SCULLY. Yes.

Senator SPECTER. That is pricing of pharmaceuticals. Average wholesale price. On its face you would think that a wholesale price would be low.

Mr. SCULLY. Well, average wholesale price is reported by the companies, and by virtually all accounts they report exceptionally high ones, and by tradition, and we are looking at changing it, my agency has paid 95 percent of whatever the price is the company makes up. I will give you an example.

Senator SPECTER. What does wholesale mean? Wholesale means, before you get to retail.

Mr. SCULLY. But it is not—we are required under the Medicaid statute, for Medicaid remits to collect what is called average manufacturer price, which is the real price that people actually pay.

Senator SPECTER. What is that definition again?

Mr. SCULLY. Average manufacturer price.

Senator SPECTER. Average manufacturing price?

Mr. SCULLY. Which is substantially lower, we collect for Medicaid, but by statute we are not allowed to use that.

Senator SPECTER. How do you determine an average manufacturing price? Does that include the research costs?

Mr. SCULLY. The average manufacturer's price for Medicaid, which we are not allowed to use for Medicare, manufacturers actually have to report the average manufacturer's price that they charge all customers. It is an audited number. It is also secret, only for use in Medicaid, believe it or not. Half of my agency can use it, the other half cannot.

Senator SPECTER. You can use it for Medicaid, but not for Medicare? Why that distinction?

Mr. SCULLY. That is what the statute reads. We have proposed changing it in the last two budgets, and I would suggest it may well be in the Monday budget.

The average wholesale price, on the other hand, is just whatever the manufacturer wants to report to this industry book, called the Red book, and that is usually much, much, much higher.

I will give you an example of how this came up.

Senator SPECTER. When you define an average manufacturing price, is that what it costs to manufacture the last pill?

Mr. SCULLY. It is an average of all the prices you charge, and we have not advocated that is what we should pay in Medicare, but it arguably does not create enough margin for oncologists and others to acquire the drug. It factors in sales to large hospitals, large buyers. We would not argue that is appropriate for Medicare, but it is clearly a much lower price than average wholesale price, which is essentially whatever the manufacturer wants to report, and it is obviously to their incentive to make up the highest price that they can credibly put in the book.

But I can give you the functional way this works, which I think will show you the problem we have, and why this has become controversial, if you would like. In the average wholesale price for the 80 percent of the market that is physicians, we currently, including right now, pay about \$1,422 every 2 weeks for Aranesp, and we pay about \$1,200 for Procrit. Procrit got paid that in the outpatient setting for 2 years.

Senator SPECTER. How much are those again?

Mr. SCULLY. For Procrit it is about \$1,200, and for Aranesp, similar drug, with slightly different chemical makeup, about \$1,422, and in the outpatient setting for 2 years—

Senator SPECTER. \$1,422 for one?

Mr. SCULLY. Every 2 weeks for one patient.

Senator SPECTER. And \$400 for the other?

Mr. SCULLY. \$1,200 for the other.

Senator SPECTER. \$1,200.

Mr. SCULLY. Procrit is made by Johnson & Johnson, Aranesp is made by Amgen, and believe me, Secretary Thompson and I spent many hundreds of hours on this. For nearly 2 years, when this new system was created, Procrit was the only drug on the market for oncology. We paid them at about \$1,200 every 2 weeks. At the end of the 2 years, we basically, within this finite pot of \$19 billion, we used 90 million hospital claims, which is what some of the dispute is about, is how we set the price, to figure out what the appropriate price is. It is not AWP.

We determined, and I do not believe that J&J argued with this, that the appropriate price for Procrit was about \$700 every 2 weeks, so we lowered their price from about \$1,200 to about \$720 every 2 weeks in the 20 percent of the market that is hospital outpatient. We are still paying them \$1,200 every 2 weeks on the physician side, okay.

The argument for Aranesp is, it is a new drug, and it came on the market. Were we to pay Aranesp \$1,422, we would have spent a couple of hundred million dollars a year, which would have required me, in that finite pot of money, to cut mammographies, colonoscopies, pro rata cut all other drugs, because it is a finite pot of money. We only have a finite pool of money to spend on the outpatient side.

This 20 percent that Congress created is capped, and so if I were to say that Aranesp and Procrit were different drugs, and that Aranesp was, in fact, a new drug, we would have paid it double the rate of Procrit, and we would have paid a few hundred million dollars a year in extra payments.

The Secretary has the ability to make sure he does not have to cut other services under the current statute to make equitable adjustments. We have determined the AWP is a different price, so when they make the argument that, under the rule, this is a new concept, all this was is an explanation of two statutory authorities which we have always had, which is on the outpatient side to adjust the payment. We made the decision that these drugs, and believe me, I have—this has been a very unpleasant experience.

I have people that I have worked with at both companies for a long time. I hired—in fact, Secretary Thompson was very involved in this—I hired the most credible, well-known doctor in this area that I know, who has had years of experience with both drugs, asked him to write a study, and Secretary Thompson and I followed his guidance, and he said that these drugs were functionally the same. The impact of paying Aranesp at twice as much, on the other drugs would be, we would have had to cut many other drugs and devices, and we would have had to cut mammographies, emergency room visits, and everything else in this \$19 billion pot to pay more for it. We made the decision in that 20 percent pot to pay the two drugs the same because we believe they are functionally equivalent, but we clearly had the statutory authority to do that.

Senator SPECTER. Mr. Pops, do you disagree that they are functional equivalents?

Mr. POPS. I completely disagree with the whole notion that Mr. Scully and his consultant can make that determination.

Mr. SCULLY. Well, there is no question we have the legal authority to do that.

Mr. POPS. Oh, I am not questioning—I am not a lawyer, so I do not know whether you had the legal standing to do it—

Mr. SCULLY. I would point out, on the other 80 percent, which is the much bigger pot of money, \$4 billion, which should be their much bigger concern, where we have not done this—because in the \$19 billion pot that exists, had we paid the one drug more and not made this determination we would have cut emergency room visits, colonoscopies, mammographies, and other drugs.

On the other pot, which is much bigger, the 80 percent on the physicians side, we have not made the determination yet until we get more information, because we are still paying the one drug at \$1,400 every 2 weeks, and Procrit at \$1,200 every 2 weeks, arguably maybe the taxpayer is overpaying, but until we get more information, we made the decision not to do that.

The Secretary and many other people thought that we should have lowered both prices, which we have the authority to do as well, down to \$700 every 2 weeks. We have not yet done that, subject to doing some studies with the National Cancer Institute and others, but we clearly—we did not create a new standard with functional equivalence. We basically explained why we did it under existing legal authority, which we believe protected many, many other patient payments in the outpatient setting.

Senator SPECTER. Let us give Mr. Pops an opportunity to comment here. I had asked him as to whether he thought these two items were functional equivalents, and your response was that you challenge their entire system, but dealing with the narrower question of functional equivalency, are they functional equivalents?

Mr. POPS. These two particular drugs?

Senator SPECTER. Yes.

Mr. POPS. I think it is very difficult to make that determination. There are literally millions of pages of data from extensive clinical trials and clinical use of these two drugs. I am not an expert on both of them. I know them both generally. They are administered under different regimens. They have different molecular compositions. They have different patents covering them. They are very different things.

Senator SPECTER. So your point is, they are different drugs. Well, do they function differently, or can a patient take either one and get the same result?

Mr. POPS. I think a physician should make that determination. I do not think either I should or Mr. Scully should make that determination.

Mr. SCULLY. Well, my understanding—

Senator SPECTER. Wait just a minute. Wait just a minute, Mr. Scully. Let me pursue this with Mr. Pops.

You think it is a matter that each individual prescribing physician should evaluate these two drugs and make that decision?

Mr. POPS. I think the answer to that is yes. Again, I want to try to make sure that I am clear that I really do not have a particular point of view with respect to Procrit versus Aranesp. What I am worried about is the general principle of somebody making that determination based on a single consultant or 10 consultants in a closed room.

Senator SPECTER. On this issue of the average wholesale price, do you disagree with Mr. Scully's comment that it is exorbitant?

Mr. POPS. Our drugs right now, we have one approved drug that is sold through our partners at Genentech, so they make that determination. Our next drug will be sold through a major pharmaceutical company, so we will not make that—I do not have personal direct experience with that.

Senator SPECTER. You are not able to comment on the average wholesale price.

Mr. POPS. I cannot comment, but what I do sense, though, is this—

Senator SPECTER. Are you able to comment on his statement—

Mr. POPS. No. No.

Senator SPECTER [continuing]. That the average wholesale price is exorbitant?

Mr. POPS. No, because I have no direct experience myself on that. We can get that data for you, though, through BIO and through our member companies. We would be happy to respond to that.

Senator SPECTER. I would be interested to have a written response from your company.

Mr. POPS. We would be happy to do that.

Senator SPECTER. Anything you want to add, Mr. Pops?

Mr. POPS. No.

Senator SPECTER. Mr. Scully.

Mr. SCULLY. I would just like to add, I would clearly defer to doctors on this. I am a lawyer, not a doctor. I have a large staff of doctors. I did not have one that was particularly expert in this area. I hired the former head of policy at HHS, who is a physician and has long experience in this area. He was the head of it in the Reagan administration. He had absolutely no interest in this. In fact, he did it as a favor to me. He had no desire to get into this quagmire.

I believe, and Secretary Thompson strongly believes after many hours of working on this we made the right decision on a scientific basis, and the issue, I believe, if you look—this is a very tense issue involving billions of dollars for two very large companies. It was on the front page of the Wall Street Journal yesterday, and it is very difficult. It has a big impact on people, and we believe we have done absolutely the right thing scientifically.

Mr. POPS. A final comment I would make, Senator, is that—

Senator SPECTER. Go ahead, Mr. Pops.

Mr. POPS. I would just be worried of detecting a certain inherent bias toward drugs being expensive, and sometimes drugs nominally are expensive, but sometimes they deliver tremendous amounts of economic and medical value to people, and when one views the world through the prism of cost, which is a legitimate way to view the world, particularly when you are facing the pressures that Mr. Scully is facing—I completely understand the logic—at the end of the day I do not want to lose sight of the fact that we are talking about patients' lives and their well-being, and I think that the dollar denomination is only one of the many variables that should be considered.

Mr. SCULLY. May I make one more comment?

Senator SPECTER. Sure.

Mr. SCULLY. Drugs cost a lot. Gleevec, a drug that was also mentioned yesterday, is a wonderful new leukemia drug that cost \$50,000 a year. It is a great drug. We pay for several drugs, and there are other examples in their testimony. They brought up one called Zevalin, that I was also involved in for hundreds of hours.

The Congresswoman, Democratic Congresswoman from California called me up and said, could you check on this drug's approval, and I called over my staff and they said, yes, we are about to give it a new code. I said, well, just out of curiosity, what does it cost? \$28,000 a dose, and the tradition on these programs was, nobody asked any questions, and they were about to just give it a new code.

We looked at it in great detail. It is an interesting drug, a very good drug. It is not another issue that is—it is an add-on to an existing drug. The VA pays \$12,000. \$28,000 is a price they made up. After significant involvement with the company, who is very cooperative, we worked out a price which, not through the pass-through, of \$21,000. It is going to be available to patients. It is a great drug.

But the tradition in these programs is, whatever the companies come in and say the number is in their Red book, the Government pays, and in the use of taxpayer dollars, we are determined to give patients the right drugs, access to the right drugs and pay a rea-

sonable price, but we should not just say, well, list the price and we will write you a check. It is crazy.

Senator SPECTER. Well, it is obviously a very complicated approach here. Where you talk about average wholesale price being exorbitant, and you talk about an average manufacturing price, I am going to pursue that further to see how you make that determination, and some of these prices apply for Medicare, there is a difference in application for Medicare and Medicaid, which I am going to pursue to see what the rationality is of that basis.

We face this on the Veterans Committee, which buys in enormous bulk, we face it on HHS, we are now facing it on Homeland Security, and this subcommittee and the Veterans Committee are going to be pursuing this question as to how pharmaceuticals are priced, because it is very, very hard to figure out exactly what is going on here.

We appreciate your testimony. Anything either of you wishes to add?

Mr. POPS. No.

Mr. SCULLY. Thank you, Mr. Chairman.

PREPARED STATEMENTS AND ADDITIONAL COMMITTEE QUESTIONS

Senator SPECTER. We have received the statements of the American Association for Geriatric Psychiatry and the American College of Physicians—American Society of Internal Medicine. They will be made part of the record at this time, along with other statements we receive. Senator Landrieu's question for the record will also be included at this point.

[The information follows:]

PREPARED STATEMENT OF THE AMERICAN ASSOCIATION FOR GERIATRIC PSYCHIATRY

Mr. Chairman, the American Association for Geriatric Psychiatry (AAGP) appreciates the opportunity to share our concerns, with the Members of the Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, on the problems facing physicians who treat older Americans enrolled in Medicare. AAGP is a professional membership organization dedicated to promoting the mental health and well-being of older people and improving the care of those with late-life mental disorders. Our membership consists of more than 2,000 geriatric psychiatrists as well as other health care professionals who focus on the mental health problems faced by senior citizens.

Physicians who treat Medicare beneficiaries, as Medicare providers, accept a fee schedule that is, at baseline, often significantly lower than their "usual and customary" fee schedule for providing services to their self-paying patients. As you are aware, these physicians now face a second consecutive year of across-the-board reductions in the fees paid by the program. Unlike many other payment "cuts" in Washington, these reductions are not simply reductions in a rate of increase, but are absolute reductions in fee levels. In 2002, fees were cut by 5.4 percent below 2001 levels. Unless the 108th Congress acts early in the new year to prevent it, fees for 2003 are scheduled to be reduced by another 4.4 percent below 2002 levels on March 1. Moreover, Medicare actuaries project that—without any further changes in law—annual fee reductions of a similar magnitude are likely to continue at least through 2005. At this rate, the conversion factor—the dollar multiplier used to compute Medicare physician fees—will fall in 2005 to a level that is close to its level in 1993.

This issue is most important because of the effect it will have on access to care for Medicare beneficiaries, especially for the vulnerable among them—those elderly and disabled persons who have multiple, complex medical conditions and limited financial resources.

As a result of the recent reductions, many physicians are having to reevaluate their willingness to treat Medicare patients, as well as their willingness to be "participating physicians" who accept Medicare payment as payment-in-full for their

services. Consequently, many Medicare patients are already having trouble finding physicians to treat them. A recent survey by the American Medical Association found that because of the recent cuts (5.4 percent in 2002) in Medicare payments, 24 percent of physicians have either placed limits on the number of Medicare patients they treat or plan to institute limits soon. In the case of geriatric psychiatrists—most of whose patients are enrolled in Medicare—the impact of these reductions is particularly severe and is causing at least some in our profession to consider leaving clinical practice altogether to enter other fields where their experience and expertise are valued more appropriately.

The impact on geriatric psychiatrists—and their patients—is compounded by the discriminatory reimbursement policies Medicare already imposes on consumers of mental health services. Under current law, Medicare requires beneficiaries to pay a 20 percent copayment for Part B services with the single exception of a requirement of a 50 percent copayment for outpatient mental health services. The lack of parity for mental health treatment is unconscionable—and of great consequence to older adults who feel more stigmatized by psychiatric illness than any other group. Despite widespread need, many seniors decline, delay, or drop out of treatment because of the high copayment. In addition, current law discriminates against the non-elderly disabled Medicare population, many of whom have severe mental disorders.

The result of these factors—declining reimbursement rates, existing discriminatory reimbursement for mental health care, and stigma—will undoubtedly compound the existing serious access problems for Medicare beneficiaries in need of mental health treatment—either in finding a physician to treat them or in “balance billing” charges by physicians who previously accepted assignment.¹ Shifting costs to beneficiaries—many of whom are low income—can make essential mental health care unaffordable.

The fee reductions that are forcing these choices stem from the mechanism for automatic annual fee “updates” that is currently part of the Medicare statute. For most types of providers, Medicare law incorporates a mechanism by which payment rates are automatically updated annually for inflation, in much the same way that Social Security and other Federal cash benefits are automatically increased by the cost of living adjustment (COLA) each year.

However, since the inception of Medicare physician payment reform in the early 1990s, updating physician fees has been handled somewhat differently from those of other providers. The payment reform law established a mechanism under which the annual inflation update for physicians’ services is automatically adjusted—above or below the rate of inflation—based on how actual Medicare spending for physicians’ services compares to an annual spending target computed by the Centers for Medicare and Medicaid Services (CMS) based on a formula set out in the law.

Until recently, this mechanism resulted in some relatively modest reductions below full inflation—as well as some “bonuses” above inflation. However, changes made in the “Balanced Budget Act of 1997” (BBA) tightened the annual spending targets, making it substantially more difficult for physicians to meet them.

Before the BBA, the annual spending target was based on a formula that included a reasonable allowance for spending increases due to changes in technology and other related factors affecting the “volume and intensity” of services provided by physicians. The BBA replaced this allowance with a much less generous proxy—the estimated increase in the gross domestic product (GDP)—which bears no relationship to the factors affecting volume and intensity of services provided. The impact of this change can be demonstrated quite simply. Where the volume and intensity allowances for 1992 and 1993 were 6.8 percent and 6.0 percent, respectively, the corresponding GDP allowances for 1999 and 2000 were 1.3 percent and 2.7 percent.

Furthermore, because the BBA made the new targets cumulative—so that a breach in one year’s target would have to be fully offset by corresponding expenditure reductions in later years—inaccurate CMS estimates of several components of the formula used to compute the spending targets for 1998 and 1999 have been carried forward, producing inappropriately low targets in each subsequent year.

For example, actual growth in the GDP for 1998 and 1999 was greater than the estimates on which CMS based its targets. Growth in the beneficiary population is another component of the target. CMS overestimated beneficiary migration from

¹ Although “balance billing” may provide a short-term safety valve that allows some physicians to continue treating Medicare patients, the additional 9.25 percent that Medicare permits physicians to collect from beneficiaries under its balance billing limits will not fully offset the cumulative reductions in program payments for 2002 and 2003. Moreover, some States prohibit balance billing Medicare beneficiaries as a condition of licensure in the State, which leaves those physicians without this option.

traditional Medicare into managed care plans during 1998, which had the effect of understating beneficiary enrollment growth in the traditional program.

All of these forecasting errors resulted in lower targets than would have occurred if better data had been available. Correction of them would eliminate the fee reductions scheduled for 2003 and significantly improve the outlook for future years as well.

Unfortunately, CMS interprets the law as precluding it from correcting these errors. Although AAGP takes no position on this arcane legal issue, we do think that it is fundamentally unfair to make physicians—and Medicare beneficiaries—pay for estimates that everyone agrees in hindsight were wrong.

Physicians want to serve all Americans. However, they simply cannot afford to accept an unlimited number of Medicare patients into their practices when they are facing continued payment reductions. These drastic cuts must be stopped before they devastate Medicare beneficiaries' access to health care.

We commend the Senate for its recent action on legislation to avert the impending 4.4 percent reduction in Medicare physician fees and urge it to work out its differences with the House of Representatives at the earliest possible date.

We note, however, that neither the legislation recently passed by the Senate nor that passed by the House of Representatives in the 107th Congress on the issue addresses the fundamental defects in the formula for setting annual Medicare spending targets for physicians' services. We urge Congress to revisit this issue in the near future and—at a minimum—to replace the GDP component of the formula with a more realistic proxy for changes technology and other factors affecting the volume and intensity of the services furnished to Medicare beneficiaries.

Thank you again for the opportunity to share our views on this important issue. We look forward to working with you as you craft a correction to the Medicare physician payment formula.

PREPARED STATEMENT OF THE AMERICAN COLLEGE OF PHYSICIANS—AMERICAN SOCIETY OF INTERNAL MEDICINE

The American College of Physicians-American Society of Internal Medicine (ACP-ASIM)—representing 115,000 physicians and medical students—is the largest medical specialty society and the second largest medical organization in the United States. Internists provide care for more Medicare patients than any other medical specialty. We congratulate the Appropriations Subcommittee on Labor, Health and Human Services, and Education for holding this important hearing. Of the College's top priorities for 2003, addressing the inadequacies of physician payment by the Medicare program is the most critical to our members. ACP-ASIM thanks Senator Arlen Specter, chair of the Subcommittee, and Senator Tom Harkin, ranking member of the Subcommittee, and other members, for their commitment to a strong and stable Medicare program. We also want to extend special appreciation to Senator Specter for his extensive efforts to improve health care for all Americans, including his leadership on biomedical and health services research and patient safety.

In spite of efforts in both the House and Senate in the last Congress, Medicare payments were cut by 5.4 percent on January 1, 2002. Unless Congress acts immediately, Medicare payments will be cut by another 4.4 percent on March 1, 2003 under a final rule promulgated by the Center for Medicare and Medicaid Services (CMS) in December 2002. The effect of the cut was felt immediately in physician offices across the country, prompting difficult decisions about the level of services that could be provided and concerns about the future.

The Omnibus Appropriations Bill recently passed by the Senate includes language to halt the 4.4 percent cut. A bill has been introduced in the House of Representatives (H. Con. Res. 3) that would halt implementation of the final rule, including the 4.4 percent cut, through the authority given to Congress under the Congressional Review Act. As the conference committee begins the difficult work of resolving differences between the House and Senate versions, ACP-ASIM urges Congress to enact legislation to halt the 4.4 percent cut as a necessary first step toward developing a long-term solution.

Whatever approach is taken, the House and Senate must agree on a bill that the President will sign before the cut goes into effect on March 1. By freezing payments until September 30, the Senate appropriations provisions create a reprieve that will allow the Congress to address a long-term solution to physician reimbursement problems. Congress will have to immediately find a way to guarantee adequate and predictable payments that will keep pace with increases in the costs of providing services.

BACKGROUND

The Centers for Medicare and Medicaid Services (CMS) has projected that Medicare payments will decline by a grand total of 17 percent from 2002–2005. This is an absolute reduction in payments; it does not take into account the impact of inflation in the costs of providing services. Using a very conservative inflation assumption of 3 percent per year, Medicare payments per service in constant dollars will be cut by 28.1 percent over the 2002–2005 period.

This is not a problem that was created overnight. Congress adopted the current physician payment methodology (known as the Sustainable Growth Rate or SGR) in the Balanced Budget Act of 1997. Even then, ACP–ASIM recognized the serious flaws inherent in the SGR payment system and voiced our concern. Congress attempted to make corrections to the payment formula in 1999 with the Balanced Budget Refinement Act, however, it was not sufficient to correct the intrinsic problems. The recent economic downturn the country is now facing has only exacerbated the problem.

Recognizing the unfairness of the SGR methodology and the tremendous hardship it has placed on physicians across the country, a super-majority of members of the 107th Congress cosponsored legislation, (the Medicare Physician Payment Fairness Act of 2001, H.R. 3351 and S. 1707) which would have reduced the magnitude of the 5.4 percent cut. Unfortunately, Congress failed to act prior to adjournment and physicians suffered the effects of the across-the-board reduction in their medical practices throughout 2002. A delay in the implementation of the Medicare Fee Schedule Regulation has provided a window of opportunity to stop the scheduled 4.4 percent decrease from going into effect

FLAWED DATA USED IN FORMULA

The 5.4 percent across-the-board reduction in Medicare payment is primarily due to the flawed SGR system that governs the annual payment for physician services. The SGR system errantly ties physician payment to the Gross Domestic Product (GDP). There is no other segment of the health care industry that uses such a methodology to update payment. What is most unfortunate is that this method of tying physician payment to the health of the overall economy bears absolutely no relation to the cost of providing actual physician services. In the years where the economy is facing a downturn, such as has been the case in the recent past, a reduction in physician payment is significant.

SGR system may even cause payments to deviate from physician costs because it does not fully account for factors affecting the actual cost of providing services. Specifically, while the current SGR payment system accounts for input price inflation and productivity growth, it provides no opportunity to account for other factors, such as an increase in the regulatory burden of the Medicare program.

In addition to the flawed SGR payment system, physicians have repeatedly been penalized for inaccurate estimates in the past. Since the SGR payment formula was first utilized in 1998 and 1999, Medicare officials have consistently relied upon flawed data for the annual update. Because the SGR formula is cumulative (i.e., it relies on previous years' estimates), these errors that were never corrected are compounded, further exacerbating the problem year after year. Due to these successive errors, the spending target is about \$15 billion lower than it actually should be.

EFFECT ON PHYSICIANS AND THEIR PATIENTS

As physician compensation falls below costs, fewer doctors are willing to see new Medicare patients, at least in part due to Medicare payment cuts. The percentage of physicians saying they accept all new Medicare fee-for-service patients declined by 7.2 percent from 1999 to 2002, according to a preliminary survey by the Medicare Payment Advisory Commission released in September, 2002. Surveys by ACP–ASIM, the American Medical Association, the American Academy of Family Physicians, and other medical organizations show an even more pronounced deterioration in access since the 5.4 percent payment cut went into effect on January 1, 2002. Large numbers of physicians are reporting that it will be necessary for them to further restrict the number of Medicare patients they will see if they are subjected to another scheduled cut of 4.4 percent on March 1, 2003.

Research by the Center for the Study of Health System Change attributes Medicare-beneficiary access problems to a number of factors, including Medicare cuts. According to the Center's director, Paul Ginsburg, PhD, "Additional Medicare cuts of the magnitude expected over the next few years are likely to increase beneficiaries' access problems, especially in markets where private insurers pay significantly more than Medicare for physician services." Availability of care for Medicare patients has

already deteriorated over the past four years. Dr. Ginsburg reports that the percentage of Medicare patients who did not receive or delayed needed care increased from 9.27 percent in 1997 to 11.1 percent in 2001. The percentage of primary care physicians accepting all new Medicare patients declined steadily over the 1997–2001 period before the 5.4 percent cut went into effect.

Members of ACP–ASIM who responded to a recent online questionnaire received by January 10, 2003 reported major changes in their ability to provide services to Medicare patients as continued cuts in reimbursement take effect:

- The number of physicians who will no longer accept new Medicare patients in 2003 increased by 78 percent over the previous year.
- Less than two-thirds of participating physicians have decided to renew their Medicare contracts for 2003.
- Of those physicians who currently accept all new Medicare patients, only one in five will continue to do so.
- Only one-third of physicians plan to maintain their current policy towards accepting new Medicare patients.
- Of those implementing or undecided on changes, 88 percent plan to limit the number of new Medicare patients, close their practices to new Medicare patients, or close their practice to all Medicare patients. 38 percent will completely close their practice to new Medicare patients.
- Of those implementing or undecided on changes, only 12 percent report that they will accept all new Medicare patients.
- Nearly 50 percent of physicians report considering early retirement or a career change. Of those physicians, 80 percent report being concerned that their patients would be unable to find another participating Medicare provider.
- More than 70 percent of physicians have already taken cost cutting measures to absorb previous cuts including reducing their staff, putting off the purchase of new medical equipment and technology, or postponing raises and decreasing staff salaries.

Reductions in Medicare reimbursement are exacerbated by increases in medical liability insurance premiums and the expense of complying with government regulations. Rising medical liability insurance premiums are forcing many doctors to limit services, relocate their practices, or retire early. The adverse results for patients who are unable to find the care they need are unacceptable. In addition, physician concerns about the billing paperwork and administration required by Medicare are leading many to limit their acceptance of Medicare patients. According to a recent MedPac survey of physicians, almost 75 percent were concerned about this “hassle factor” and 16 percent said that they had limited their acceptance of Medicare patients because of this factor.

These financial burdens—cuts in reimbursement, increases in liability premiums and unfunded mandates—are converging to stress the health care system to the breaking point. The impact is being felt now but will also affect generations to come. Without health care providers little health care can be provided. Compensation for providers must be adequate if the system is to remain viable and open to a broad range of patients. Inadequate compensation undermines the foundation of the current system and severely handicaps its capacity to meet future needs. Even the most altruistic students will think twice before choosing medicine as a career.

Physicians have a strong sense of commitment to their Medicare patients. They will do everything within reason to continue to provide their Medicare patients with high quality, accessible health care, even in the face of rising costs and declining reimbursement. However, there is a point where the economics of running a practice will force physicians to institute changes to limit the damage from continued Medicare payment cuts. Like any small business, revenue must exceed the costs of providing services in order for a practice to remain financially viable. For practices that are heavily dependent on Medicare revenue, such as a typical internal medicine practice, the reduction of 5.4 percent in 2002 and the additional reductions that are planned through 2005 force primary care providers to take preventive steps to cut their losses from seeing large numbers of Medicare patients.

Physicians will have essentially only four options available to them to offset the losses from declining Medicare payments and rising costs. They can reduce their reliance on Medicare revenue by decreasing the share of practice revenue that comes from Medicare while increasing the share that comes from more reliable (non-Medicare) payers. This would be accomplished by putting limits on how many Medicare patients will be seen while marketing the practice to non-Medicare populations. They can cut costs—eliminating beneficial services and technology. They can do both: cut beneficial services and reduce their reliance on Medicare. Or they can go out of business, by closing their practices entirely.

We believe that it is very likely that physicians will be forced to limit the number of Medicare patients in their practice; lay off staff that help Medicare patients with appointments or medications; relocate to areas with a younger, non-Medicare eligible patients; spend less time with Medicare patients; discontinue participation in the Medicare program; limit or discontinue investment in new technology; limit or discontinue charitable care; or in some cases, retire or close their practices. Physicians will make such changes reluctantly, but the laws of economics will leave them no choice but to do so.

The effects of the most recent and projected cuts in reimbursement will most likely be hardest felt in rural and other areas that are already underserved. The problems that we see today will certainly only get worse unless the severely flawed methodology utilized by Medicare to compute physician payments is immediately addressed.

Physicians' efforts to reduce their reliance on an unstable and unreliable Medicare payment system will make it even more difficult for patients to gain access to an increasingly under-funded health care system, particularly as the number of Medicare patients increases from 34 million today, to 40 million in 2010, to 60 million in 2030. More Medicare beneficiaries will be seeking care, yet fewer and fewer physicians will be able and willing to provide care to Medicare patients. As Medicare is increasingly viewed as an unreliable payer whose reimbursement does not cover the costs of providing services, young physicians will be disinclined to go into specialties that are viewed as being heavily dependent on Medicare—particularly internal medicine and geriatrics—at the time when those specialties should be most in demand to provide care to an aging population.

CONCLUSION

ACP-ASIM urges members of the Subcommittee to help retain in the final conference report the Senate provisions in the Omnibus Appropriations bill to halt the 4.4 percent decrease in Medicare reimbursement. Our organization stands ready to work with Congress to make constructive and lasting improvements to the Medicare program.

AMGEN ARANESP® DATA SUBMISSIONS TO CMS

In July of 2002 the FDA granted approval to Aranesp® (darbepoetin alfa) when used for the treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitantly administered chemotherapy.¹ The label recognized 2.25 mcg/kg/week as the starting dose for this indication, and the clinical studies section of the label recognized the minimum effective starting dose as 1.5 mcg/kg/week. The label also states that “Due to the longer serum half-life, Aranesp® should be dosed less frequently than Epoetin alfa.” In addition, the USP-DI updated the monograph for Aranesp® at this same time to indicate that the 1.5 mcg/week to 3.0 mcg/kg every other week (Q2W) is an effective dosing paradigm.

Based upon the newly approved label for Aranesp® for the treatment of chemotherapy induced anemia (CIA), and the fact that Amgen learned that CMS had questions regarding the cost of Aranesp as compared to Epoetin alfa, Amgen initiated a series of meetings with CMS.

The information provided to CMS as part of these meetings refutes specific sections of Tom Scully's testimony provided to Senator Specter during the Medicare hearing on January 30. Specifically, Amgen provided data substantiating that Aranesp® dosed at 200 mcg Q2W is less expensive than Epoetin alfa and represents a cost savings to the Medicare program.

Aranesp® Dosed at 200 mcg Q2W is less expensive than Epoetin Alfa at 40,000 units weekly.—At the hearing on January 30, Tom Scully stated that CMS pays more for Aranesp® than it does for Epoetin alfa in the physician office setting. The quote is as follows: “We [CMS] right now pay about \$1422 every two weeks for Aranesp® and we pay about \$1,200 every two weeks for Procrit®.” Amgen disagrees with this statement.

From September of 2002 through and including February of 2003, Amgen has provided consistent data to CMS supporting the fact that the dose of Aranesp® most commonly used for the treatment of CIA is 200 mcg Q2W, and that this dosing paradigm is cost effective as compared to Epoetin alfa. The wealth of evidence sup-

¹This indication is in addition to the indication of chronic renal failure, including patients on dialysis and patient not on dialysis, which was the indication Aranesp® was originally approved for in 2001.

porting the fact that Aranesp® is a cost effective alternative to Epoetin alfa has increased significantly each month and has been supplied to CMS.

The data supplied to CMS includes:

- USP–DI monograph supporting 1.5 mcg/kg/week–3.0 mcg/kg Q2W.
- SDI claims data² demonstrating that in a review of over 6,000 claims, 89 percent of providers dose Aranesp® in CIA at 200 mcg Q2W.
- Clinical trial data for Aranesp® demonstrating that the 200 mcg Q2W dose of Aranesp® is efficacious as compared to 40,000 units of Epoetin alfa.³
- Clinical data invited to be presented at ASH 2002 demonstrating that Aranesp® 3.0 mcg/kg (200 mcg) administered Q2W is cost-effective compared to Epoetin alfa administered weekly (40,000U/week). The authors conclude that Aranesp® is 11–13 percent less expensive than Epoetin alfa while providing similar efficacy.⁴

	Physician Office	Hospital outpatient department
Aranesp®:		
Reimbursement	\$4.74	\$2.37
Common Dose (mcg Q2W)	200	200
Weekly Reimbursement	\$948/2=\$474	\$474/2=\$237
Epoetin alfa:		
Reimbursement	\$12.69	\$9.10
Common dose (units QW)	40,000	40,000
Weekly Reimbursement	\$507.60	\$364
Savings (percent)	7	35

QUESTIONS SUBMITTED BY SENATOR MARY L. LANDRIEU

Question. Was the term “functional equivalence” introduced in the proposed rule-making? If so, would you please highlight the appropriate reference from the notice of proposed rulemaking?

Answer. Functional equivalence is a term CMS developed as a result of comments received during the comment period on the notice of proposed rulemaking on the 2003 update for Medicare’s outpatient prospective payment system to describe the relationship between Aranesp and Procrit. As we explain in the final rule, it became apparent that darbepoetin alfa, while not structurally identical to epoetin alfa, uses the same biological mechanism to create the same clinical effect in the body. To encapsulate this phenomenon, we used the term “functional equivalence.”

Question. What, if any, opportunity did interested parties have to comment of the new standard?

Answer. First, we would note that the term “functional equivalence” is not a standard, but a descriptive term used to capture a relationship between two drugs. As you may know, the comment period is a vital part of the process we use to issue every regulation. We place high value on all comments we received from interested parties. In fact, it was through comments received during the comment period on the proposed rule regarding the relationship between Aranesp and Procrit that led us to employ the term “functional equivalence.”

Question. Do you believe the “functional equivalence” standard requires any consideration of “quality-of-life” issues such as frequency of administration?

Answer. We would remain open to the possibility that quality-of-life issues may affect how we address payments for similar drugs in the future. However, as to these two drugs and the circumstances in which they are administered, we believe there is not a significant impact with regard to quality of life. As we noted in the final rule, the relationship between darbepoetin alfa and epoetin alfa is unusual in the strong similarity of the two drugs.

Question. What assurances can you give biotechnology firms that the ill-defined “functional equivalence” standard won’t be used to deny “pass-through” status for their new product?

Answer. We consider the situation of darbepoetin alfa and epoetin alfa to be unusual. In the final rule we note that the situation related to darbepoetin alfa and epoetin alfa is distinguished by the very strong similarity of the two products and by the potential effects on the Medicare program. Thus, if a similar situation arises

² Surveillance Data Inc. (SDI) claims consist of claims from U.S. physician offices.

³ Mirtching et al, Oncology 2002.

⁴ Blood 2002 (Supplement), abstract #3447.

in the future, we might consider whether to determine two drugs to be functionally equivalent, but we do not anticipate such a situation would be at all common.

CONCLUSION OF HEARING

Senator SPECTER. Thank you all very much for being here. That concludes our hearing.

[Whereupon, at 12:21 p.m., Thursday, January 30, the hearing was concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]

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