TOWN HALL MEETING ON "ECONOMIC IMPACT OF HEALTH CARE REGULATIONS"

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MEETING

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Thursday,
December 8, 2005

Millennium Knickerbocker Hotel Chicago
163 East Walton Place at North Michigan Ave.
Chicago, Illinois

The above-entitled matter commenced

at the hour of 10:05 a.m.

MODERATOR:
CAROL SIMON, PhD, MODERATOR

I-N-D-E-X

P-R-O-C-E-E-D-I-N-G-S

(10:05 a.m.)

DR. SIMON: Good morning, my name is Carol Simon. And on behalf of HHS and OMB and Abt Associates and Triple S, I welcome you to the Second Town Hall Meeting.

This meeting is part of a series that we're holding throughout the country, number two of four, which is designed to gain public commentary on the economic burden and costs of healthcare regulations. So I appreciate your attendance today and your participation. This is part of a larger study per Congressional appropriation that is examining ways that we may be able to streamline, simplify, reduce the burden on healthcare compliance, while at the same time continuing to protect patient rights and the quality of healthcare.

We've brought together today a panel of experts who are in many ways, with no criticism intended, secondary to the comments in the room.

Just to put you in your place.

The focus today is to hear from the public, from the providers. But these distinguished gentlemen are here to assist me in terms of putting some of the comments in perspective. And so their role is to ask

clarifying questions, to help us drill down in terms of what some of the economic costs are, some of the resource costs, and to help us to, in many ways, frame the commentary that we're going to hear today.

I understand there's a snowstorm coming, so we want to move through the agenda as quickly as possible. So what I'm going to do is introduce some of the key folks who are important to this process, and then come back and give you the ground rules as official moderator and traffic cop for the process.

May I introduce Marty McGeein, from ASPE. Marty, are you going to make some introductory comments for us?

MS. McGEEIN: I have about three pages of remarks, but Doug's back there whispering, “Six inches of snow, six inches of snow, six inches of snow.” You're the only one that's going to get out of here alive tonight.

So I'm just going to welcome you and thank you for coming. I'm Marty McGeein. I'm Deputy Assistant Secretary in the Office of Planning and Evaluation at the Department of Health and Human Services.

We are delighted that you are here. I want to thank Doug O'Brien for the help that he gave us in

pulling this meeting together. It would not be nearly as successful without him.

As Carol told you, this is a Congressionally mandated study. And during the Bush Administration, this is the second go-around at looking at regulation. The first one was a Secretary's Advisory Committee on Regulatory Reform that produced a report in 2003. That report contained 255 recommendations for changes and improvements to regulations. Of that 255, 84 percent have been implemented. So we've got a really good track record. I'm taking these public comments seriously.

We are here to listen to you. Unlike the usual thing, I'm from the federal government and I'm here to help, I'm from the federal government and you are here to help me. So I really appreciate you being here and look forward to your comments, and I would like to suggest that Doug may have a comment or two.

MR. O'BRIEN: Thanks, Marty.

My name's Doug O'Brien. I'm the Regional Director of the U.S. Department of Health and Human Services here in Region Five in Chicago.

For those of you who have come in from out of town, welcome and enjoy your layover.

Great restaurants. The hotels are wonderful.

We planned this. It's one of our great tourism techniques. We schedule snowstorms when people come into town.

For those of you who are from the Midwest and the Chicago area, this is a great opportunity. Prior to this position, having spent time out in Washington working as Chief of Staff for a member of the Appropriations Committee, it's one of the lesser known ways that Congress does its work is commissioning research and studies just like this.

When you go out to Washington and you testify before a Congressional committee and all the lights and the fanciness is going on, a lot of that just sort of fades off into the ether, but studies like this provide the basis for important legislative initiatives. This is the research, this is the data, this is the thought process that goes into major initiatives. And as you all know, the appropriators tend to get a lot done, and they put a lot of meat on the bone when they pass their appropriations bills every year.

So this really is an important process. And it's important to bring diverse voices here today. We have people who could tell you chapter and verse about regulation. And we have people who have no idea how regulations work or come to pass, but they know the

impact that they have on their particular business. So having the diversity of views brought to bear, being given to a distinguished panel of experts, is going to result in an outstanding piece of work that is going to have an impact on public policy.

So, again, thank you all for coming and taking time to participate and enjoy the rest of the day. Thanks.

DR. SIMON: Thank you.

Okay. Let me go over a little bit of housekeeping chores. Excuse me. I teach my children to share and they give me a cold.

For those of you who are intending to present testimony, we are going to be going according to the sign-in sheet. If you have any special accommodations that are necessary, please see me. We will try to work this in, but with a sense of equitability, in terms of still moving, in terms of first come, first served.

Let me bring to your attention a couple of important things in your packet. And I think that, you know, around the lunch break, when we all sort of need to get up and stand, I'll remind you of them, as well.

The packet has a bunch of information about the process and about the study itself. There are two important things that will make our job more effective

and will make your comments resonate more clearly in the final report.

First of all, there's a website for those presenting testimony, for those not presenting testimony, who may be sparked to tell us something after this meeting is over. There is a web address in which we are asking you to submit copies of your testimony, in particular any additional documentation, any studies that your organization has done, that will help us crystallize some of the costs and some of the impact of healthcare regulation. That is the grist that is going to make our report, you know, come alive.

The second thing is there's a website for folks who could not attend. And I've had conversations with many of you this morning about organizations or individuals who wished they could be here but couldn't. Encourage them and your colleagues to also submit commentary to this web address. This is going to be open through the middle of February. And, again, this is a direct portal into evidence that is going to be incorporated in the study.

And if you have any questions, please come see me during the break, and I'll be happy to address those.

Now for the most important part about this,

the time. We have a reasonably full agenda this morning, and I'm very happy about that. So that what we're going to be doing is staying to a reasonably strict schedule. I'm going to ask you the comment. I'm going to call the commentators up here one at a time. I'm going to ask you to introduce yourselves, ask you to introduce the organization that you're representing. We'll give you roughly four minutes for your remarks. I don't pull the plug, but, you know.

And then what we're going to do is open to the panel, who I'll be introducing in a moment, that you ask clarifying questions. And, again, I'm going to be giving the panel another roughly four minutes, with a little bit of spillover allowed. Hopefully this will allow us to get all of you in today in a timely fashion.

At the close of the afternoon, we're going to reserve a little bit of time for the panelists to discuss amongst themselves some of the key themes that have come up here and also open a little bit to the floor for additional Q and A.

So, without further ado, I'd like to introduce a very distinguished panel and ask them to make a couple of remarks about why they're here and some of their particular interests so that we can start

the process going. We'll start with Dr. Conover.

DR. CONOVER: My name is Chris Conover. I'm a research professor at Duke University in the Center for Health Policy, the Terry Sanford Institute of Public Policy.

I've done work on certificate of need regulation. I've looked at hospital conversion regulation, regulation of conversion of health insurance plans, such as Blue Cross and Blue Shield, but most importantly, I've spent the last three years doing an analysis of the cost of health services regulation for ASPE. And if you look in your packets, there's a little monograph that sort of summarizes the preliminary estimates that we've come up with.

We've calculated that the cost of health services regulation is measured in hundreds of billions of dollars. It's clearly a sizable burden. So I'm looking forward to hearing commentary today so we can understand the nature of this burden and what we can do about it. Thank you.

DR. DRANOVE: My name is David Dranove. I'm a Walter McNerney Distinguished Professor of Health Industry Management at the Kellogg School of Management at Northwestern University.

And I've been an active researcher in health

services research for over 20 years, mostly focusing on provider markets and hospitals, including issues involving regulations of hospitals. I also do a lot of work on cost benefit analysis, and I've written extensively on how to measure the cost of providing healthcare.

DR. HELMS: My name is Bob Helms. I'm with the American Enterprise Institute.

I'm here because of a fellow named Sam Peltzman. Sam Peltzman is a professor here at the University of Chicago. He's had a career of writing a lot of theoretical things and empirical work about the cost of regulation and theories about the effects of regulation.

I happened to be his student when he was at UCLA. I wrote my dissertation for him. So, people incorrectly assumed that I knew something about regulation. Anyway, I did write a dissertation having to do with the effects of regulation, but it was in the natural gas area.

But when I went over to the Reagan Administration, one of the first tasks I had was to chair a group that was going to try to deregulate what was called the Hospital Conditions of Participation. And so I learned a lot about the effects of those

regulations and so on, and I remember we tried to eliminate a lot of the rules and go from a system of sort of rules and regulations to specifying what outcomes we wanted.

And in the process we greatly reduced the number of requirements having to do with such things as dietary nurses and, you know, so on, requirements, and also eliminated a little requirement in there that specified that a rural hospital had to have a library. And that's when I learned that there was an association of hospital librarians who came in to see me.

And, anyway, I had seen in my small hometown, I had actually looked at the hospital library, which was two bookshelves in the corner of the staff nursing station, you know, where they went for coffee and so on. And I asked the people there, did anybody ever use it, and they said no, not that they were aware of.

I didn't think it cost a lot, you know, to get rid of those, but getting rid of something like that doesn't mean that the hospital, if they wanted a library, couldn't do it. I mean it's just, I didn't think it had to be in the Conditions of Participation.

I have another interest in this area now. I'm serving on HHS Medicaid Commission. It's supposed

to come up in the next year with a plan on how to reform Medicaid and the regulatory impact of that. I've always felt there are way too many rules and regulations in Medicaid and there should be a better way to do that. So I have that interest, also. Thanks.

DR. SIMON: Thank you. Mike Morrisey of UAB.

DR. MORRISEY: Good morning.

I'm Mike Morrisey. I'm a professor of Health Economics and Health Insurance in the School of Public Health at the University of Alabama at Birmingham.

Like David, I've spent 20 years or so looking at issues of hospital economics, of employer sponsored health insurance and looking at regulation. In that area, most of my work has looked at things like certificate of need, any willing provider laws, insurance mandates, and, most recently, looking at malpractice tort reforms.

DR. SIMON: Great. Thank you, Mike.

Dan Mulholland?

MR. MULHOLLAND: Hi. Dan Mulholland. I'm a practicing attorney with Horty, Springer & Mattern in Pittsburgh. Our firm represents hospitals, healthcare systems, and their physician and board leaders exclusively. We're in the trenches day in and day out

dealing with the regulatory system, either in terms of advising people or representing them in litigation that spins out as a result of regulatory initiatives.

So I guess that helps me understand how this affects people on a daily basis, and it probably makes me part of the cost, as well. So I'd be very interested in hearing your comments today. Thank you.

DR. SIMON: Very good.

And, finally, Kevin Schulman.

DR. SCHULMAN: Good morning.

I'm a physician at Duke University, professor of medicine. I also am professor of business administration and run the Health Sector Management Program at the Fuqua School of Business at Duke.

And my interest, I've had a career in health services research, economic evaluation of new drugs and new technologies, but my specific interest in regulation is actually more recent, looking at the opportunity cost of regulation as a barrier to entry. Looking at why we have these escalating healthcare costs compared to other industries that seem to have a different trajectory in terms of the use of technology.

DR. SIMON: All right. Thank you very much.

I've been reminded that there are a couple of other issues and logistics in the packet.

For those of you who are presenting testimony, there is a sample regulation, a sample submission, that is included in your packet, which has been drawn up to give you an idea of the sort of level of detail in some of the information that may be of use to us in preparing the report. If you have additional information that you'd like to submit and are wondering is this really what they're looking for, the idea here is to give you a little bit of guidance on form, format, and content but not to oversubscribe in any respect.

The second announcement is we do have coffee and tea in the hallway and, subsequently, restrooms further down the hallway, which, my mother reminded me last night in a telephone call that she had designed the ladies' powder room at the Knickerbocker Hotel when she worked for Crane Company 51 years ago. So I guess if you have any comments about that, I would be happy to hear that, as well.

So, without further ado, I'd like to introduce our first speaker, Dr. Peter Eupierre, President-Elect of the Illinois State Medical Society.

Dr. Eupierre.

DR. EUPIERRE: Thank you. Good morning. Let me see if I can get this back in there.

DR. SIMON: Need some help?

DR. EUPIERRE: My name is Peter Eupierre. I am a partner in an internal medicine practice in Melrose Park, Illinois. I am also the President-Elect of the Illinois State Medical Society. Thank you for the opportunity to testify today on behalf of Illinois physicians. We are grateful for you hosting this town hall meeting on the economic impact of healthcare regulation.

My statements this morning will focus on Medicare and the impact that Medicare regulations have on physicians. As a practicing physician, I currently see a large number of Medicare patients and have been a Medicare participating physician for a number of years.

When I talk to my colleagues about the current healthcare market, one of the reoccurring topics that inevitably comes up is the time the physicians and their staff spend complying with numerous Medicare regulations. This, of course, detracts from time that could be better-spent delivering healthcare.

Physicians are facing a very challenging practice environment, and the combination of Medicare regulations and low payment rates do not instill enthusiasm in Medicare programs. The sheer quantity of

Medicare regulations is so hefty that it's almost impossible for physicians to monitor. I hope that your work will involve an analysis of the volume of regulations that are issued that affect physicians, as well as a process for disseminating this information to physicians.

It sometimes feels like a full-time job trying to keep up with the various types of Medicare regulations and policies. There are notices of proposed rules, the final rules, correction notices, as well as local coverage determinations. Tracking and complying with Medicare regulations is a time-consuming process.

For example, physicians face hours and hours of paperwork completing claim forms, advance beneficiary notices, certifying medical necessity, filing enrollment forms, and complying with coding documentation guidelines. All of these regulatory activities require a physician’s time. Ideally, doctors should spend as much time as possible with our Medicare patients, to assure the best possible treatment. Our obligations to bureaucracy and paperwork have the potential to detract from our ability to maintain these important patient interactions.

I would like to highlight just a few regulatory burdens placed on physicians. The first has to do with a regulation concerning power mobility devices, such as electric wheelchairs and scooters. CMS has been examining this issue for the past several years, in an effort to ensure that beneficiaries who need mobility assistance have access to these devices and that Medicare pays appropriately. CMS has focused on curbing fraud and abuse by certain unscrupulous suppliers, but now the burden is placed on physicians and their patients instead of the suppliers who initiated the problem.

For example, if a patient of mine qualifies for use of one of these devices because they're immobile, I must now require my patient to come into the office for an exam in order for the patient to receive the device. If this were a new patient who I had never met before, this would be perfectly appropriate.

But for patients I know, it is an unnecessary burden. This is especially concerning for patients in rural areas that must travel great distances for an office visit. In my practice, an established patient's medical record is already full of documentation justifying the need for a device, and a separate office

visit, at an additional expense to CMS I might add, is not needed.

Beginning this year, Medicare for the first time allowed new Medicare beneficiaries an initial preventative physical exam. This is referred to as the "Welcome to Medicare Visit." Such coverage was long overdue, since up until now Medicare did not pay for any routine physical exams, but when Medicare first issued regulations on this new benefit, the regulations were unnecessarily complex, involving strong criticism from a number of physician organizations.

The CMS revised these regulations, but there are still lengthy requirements, so much so that I wonder if any of these visits are being provided. I personally have never provided one of these visits, and I'm not even familiar with all the requirements.

In preparation for this presentation, I found a description of the preventative physical examinations on the CMS website. This includes a description of seven components for the exam, including billing information. The guide is ten pages long describing this service, ten pages instructing a physician how to perform a comprehensive examination, as well as education and counseling.

My medical practice is dedicated to

preventive health, but CMS regulations now dictate how I am to perform preventive care. Since physicians must follow these detailed requirements, one would think that the reimbursement would be taking these factors into consideration, but CMS has linked payment to a mid-level office visit. Clearly a comprehensive physical examination with detailed documentation requirements should be reimbursed at a higher rate.

But the real issue here is why the need to go to such regulatory detail rather than to just leave it to the physician as to what is appropriate for an initial comprehensive evaluation. While I also applaud your efforts to identify loss in regulations that impose more costs than benefits, this issue on the effect on healthcare fails in comparison to the looming Medicare payment cuts and the effect the payment reduction will have on physician access. Unless Congress acts to stop these cuts, physicians will face a 4.4 percent payment reduction next year. And that's 26 percent reduction.

DR. SIMON: Excuse me, Dr. Eupierre, if you could wrap up in the next couple seconds.

DR. EUPIERRE: Any strategy in reducing the regulatory burdens on physicians must include an examination of the Medicare physician payment

methodology. The cuts in Medicare reimbursement will dramatically affect physicians' ability to serve Medicare beneficiaries. Thank you.

DR. SIMON: Thank you very much.

We'll start with our panelist, Dr. Conover.

DR. CONOVER: I understand the three specific examples you gave, but you started by talking about the burden of dealing with Medicare patients sort of in general. And my question is, are the documentation requirements and that sort of thing for dealing with Medicare patients substantially different than for your private paid patients, and can you be a little bit more specific about the nature of those differences and the burden it entails?

DR. EUPIERRE: Let's say, for example, if I have a patient that needs enteral feedings, there is a form there I must fill out. Now, frequently these patients will be in a nursing home so we write the order. There is usually a nutritionist that would help us with the formula we have to prescribe, the type of pump, how long to give it.

Three, four, six months down the line, I will get a form from the supplier asking me to fill out the form, put in exactly the diagnosis for this patient who is now offsite, not even in my office, and I don't even

have a record on this patient, to put in the formula, the amount of formula per hour, what type of pump that patient needs.

And I would say on the average, I would do about five to ten of these forms a week because there is so many weeks or months you have to refile another one of these forms. And like this or many examples, of course, now for the motility devices, there will be a new form.

DR. CONOVER: And the private payers aren't asking you to fill out forms of this sort?

DR. EUPIERRE: I have never filled one out for a private payer, as far as the enteral feedings. Now, most of these patients are older under Medicare, or they're disabled on Medicare, but I have never seen this from a private payer, no.

DR. SIMON: Okay. Thank you.

I'm going to go to Dan, and then to David.

MR. MULHOLLAND: Doctor, are you seeing that doctors are dropping out of Medicare as a result of the complexity of the regulations and the costs associated with billing?

DR. EUPIERRE: Definitely. We are seeing that of course more in rural areas than in the Chicago area, but we are seeing more and more doctors planning

not to accept Medicare patients. That is a grave concern for the Illinois Medical Society at this point.

DR. CONOVER: Dr. Eupierre, you mentioned how physicians are taking time doing activities such as billing and record keeping that's taking away from patient care. Are these activities that doctors, say, in larger groups might be able to assign to staff who can take care of those activities, and therefore free up your time?

DR. EUPIERRE: No. The physician must put down the encounter code. If I see a patient, I have to code that patient. I have what is called an encounter form, and I have to say this is a 99313 or 99214. Then I have to put down the diagnosis for the patient, all these things, and then that goes to the person who does the billing. But it is my responsibility on each encounter to code the diagnosis code and the encounter code.

MR. MULHOLLAND: Just following up from what Dr. Conover mentioned, that's something that every insurer has required for the past 30 or 40 years, isn't it?

DR. EUPIERRE: That is correct. That is every patient that I see, not only Medicare patients.

DR. SIMON: Okay. You guys are all in gray

suits, so it's going to be really hard to figure out whose hand is up there. We should always remind you to dress a little differently.

Bob, and then we'll see who's over there.

DR. HELMS: This is not to justify, but of course, just my remembering what went on in HHS, you know, and now what is now CMS. As you well know, what's behind a lot of these requirements is sort of past examples of people that have abused these kinds of things.

There is a term in the government, you know, when people try to estimate the cost of a program, they refer to the woodwork affect. In other words, you know, you can put up a rule and then, say, and you're going to have certain benefit, and there's an estimate, you know, a few thousand people will come. And then there's a woodwork affect and people come out of the woodwork, and it ends up costing a lot more. But there are also in this example, you know, sort of cases which have been investigated by fraud and abuse, as fraud and abuse, in the past.

Now, you mentioned something in there, something about there should be a way to put requirements on the suppliers rather than the physicians. I wonder if you could just elaborate a

little bit on that.

DR. EUPIERRE: Definitely. Those forms we fill out, let's say for enteral feedings or the forms that we have to fill out now for the devices, it would be much easier if the supplier would say, “I have a prescription here from a doctor and filled out the form.” They know how to fill out the form. Every time I get a form that is different, I have to work, try to fill them in. And then I might get it sent back because I did not fill it correctly because not every one of those forms are exact copies of each other, and one may have one thing that the other doesn't have.

If they have the requirement to file with Medicare, I believe a prescription from a licensed physician would probably be enough to do that instead of my sitting down and filling out five, ten questions for if anybody needs just about any kind of dear old medical equipment.

DR. HELMS: Can I do one other follow up question?

DR. SIMON: No. In a word. Dr. Eupierre, thank you very much.

DR. EUPIERRE: Thank you.

DR. SIMON: I appreciate -- I see that you've submitted a written copy of your testimony. If you

have any additional information that you'd like to submit to the panel for consideration, I'd encourage you to use our website or to send it to us directly. Thank you very much.

Our second speaker is Pat Comstock from the Illinois Healthcare Association. Ms. Comstock?

MS. COMSTOCK: Good morning.

My name is Pat Comstock, and I am the director of Legislation and Communication for the Illinois Healthcare Association, which is the largest and oldest long-term care association in Illinois. We represent not only traditional skilled nursing facilities but also facilities for the developmentally disabled and assisted living facilities.

My comments this morning, though, are going to be related to skilled nursing facilities. My colleague Mike Bibo, who is also signed up to speak this morning, will talk about the ICFMR-DD population.

Also, our national organization, the American Healthcare Association, is working with us to gather data nationwide, and it's my understanding that they'll be submitting some more comments to you in writing. I've submitted comments in writing so I'm just going to quickly go over a few highlights this morning, since you have my written comments in front of you.

Before I proceed, I want to make sure that you all understand that we see regulations as a very important part of resident and patient safety. However, we think that regulations should be reasonable, fairly interpreted, and consistently enforced. And those are some of the things I want to share with you this morning. Those are where some of the problems lie.

Specifically to highlight, regulations have caused us to create new staffing categories. For example, the federal regulations with respect to MDS and filling out the Minimum Data Set on every resident has created a new category in our facilities of MDS coordinator. And it's not just the fact that this individual, this new staffing category, is required at a fairly high salary level in comparison to other facility employees, it is also a problem that in Illinois our reimbursement rates have not kept up with our additional staffing requirements.

For example, our rates are based upon 1999 costs, and for salaries they have been inflated to 2001. Still five years behind. And it's difficult for us to continue to be competitive to compete with other healthcare entities for the high skilled staff that we need since our resident population grows ever sicker as

the less complex residents are going to other service areas. So, it kind of is a circular thing and one thing relates to the other.

The second area of staffing that we think will be impacted is as a result of the new Medicare Part D regulations. Our legal counsel is advising us that every facility may indeed, as this thing moves forward, be in a position of having to have a full-time staff member at a salary of $40 to $50,000 just to manage the Medicare Part D issues in our facility. But, again, the jury is totally out on that as we're just at the beginning of rolling that out.

An interesting byproduct occurs in Illinois that sometimes one regulation or something that happened causes other things to occur. And in Illinois we have two new pieces of legislation this year that will affect facilities as a result of the federal abuse tags being changed, and that is that we will be required to do criminal background checks on every employee that we have without funding strength to support that.

And, secondly, we are now required to do criminal background checks on all of our new residents. So any new resident being admitted to a facility in Illinois will undergo the formal criminal background

check process. And that came out of a need to sort out how many sex offenders and other felons that we have in nursing homes, which has been a problem in other states, but in Illinois we have about 110 residents across the state that fit into that category. And if you count not only Medicaid, Medicare and private pay, we're serving nearly 100,000 residents. So, it's a small part of a bigger pie.

The last thing I wanted to highlight -- my red light's going off. To close, going to the inconsistently applied regulations, I just want to share one story. In Illinois, we have a problem with the way regulations are applied in the area of elopements. As you know, facilities are required to have their doors alarmed so that if a resident tries to leave, the alarm goes off and a staff member can respond and retrieve them before the elopement occurs.

In Illinois, we're getting cited for immediate jeopardy if the system works. In other words, the alarm goes off, the person is retrieved, and no harm is done, we're getting cited for immediate jeopardy. So that's a problem because in those cases, the system has worked.

I apologize. I thought I was going to be shorter, but you know, you put me up here, I get

talking and I just can't stop. Thanks.

DR. SIMON: It is not a unique problem, actually, as we've seen on all sides of the podium.

So, with that, I'm going to open this up. And I'll start with Mike, since I cut you off before.

DR. MORRISEY: In testimony that we heard in Washington, there was concern that the quality in skilled nursing facilities had declined over the last few years. And I was curious your sense of -- there's certainly been increased competition in the skilled nursing market, as occupancy rates have fallen a bit. And do you have a sense in any data of the nature of whether there's been an increase or a degradation or no change at all in the quality of care delivered?

MS. COMSTOCK: I can get you the actual data because we do monitor that with our folks, but I can tell you that in Illinois we've actually seen an increase in quality as we have tried to focus on increasing staffing. And we've been, our facilities have been moving more toward resident-centered care in the area of the pioneer practices, you know, buffet dining and allowing residents the flexibility to choose during the day when they want to eat, when they want to do various activities, in comparison to in the past when that was all, you know, fairly regimented, more in

a medical sort of model.

So we've seen really a lot of strong moves in that direction. But we have more to do. There's no question, but I'll get that information onto the website for you.

DR. SIMON: Very good.

Chris?

DR. CONOVER: On the MDS coordinators, it wasn't clear from your testimony. Do you think those individuals are needed at all, or the issue is just how much they're compensated and how much you're paid to, you know, be able to cover their cost?

MS. COMSTOCK: That individual is critical to our facility operation, particularly as it relates back to the area of quality. So it's not that we don't need that person, it's the other factors that come into play, and, frankly, for us, it's not just one regulation. It's all the regulations that get piled on top of each other, and we seem to be at the end of the food chain. And there's always this presumption that we're bad first and good later, and that makes it difficult.

DR. CONOVER: Okay. So on a related point, on the criminal background checks, again, is that something that you view as necessary or it's just

you're spending way too much for much too little yield? And please differentiate between the background checks for the staff versus the patients.

MS. COMSTOCK: Okay. And that is an important distinction.

With respect to the criminal background checks for the staff, we think that that's very important to protect the safety of every resident and the other employees. Previously, though, in Illinois, we were able to get a waiver for offenses that had occurred 20 years ago, that people had done their time and were now trying to reintroduce themselves into society.

This new legislation eliminates that waiver so we have people that have previous offenses that have been working for years in our homes without incident that we are now not going to be able to utilize. So that becomes a problem. And, of course, then, being asked to do that without any corresponding compensation.

The criminal background checks for our residents is a bit more controversial piece of legislation for us, particularly as I think about admitting my grandmother into a nursing home and what that means she would be subjected to. However, it is

the only way to ensure that we don't have convicted felons in our facilities. So, again, it's a double-edged sword.

We're required to check two active websites in Illinois, which will enable us to find most of the people, but it's not going to help us find all of them, and we're concerned that the cost benefit of that is not, is probably not appropriate. But, again, something that we're working very closely with the Attorney General's Office on, and hopefully we'll be able to work out the bugs in that pretty soon.

DR. SIMON: David, did you have a quick question?

It would help us by distinguishing any regulations that are specifically Illinois from those which are, also have Federal mandates attached to them. That will also be extraordinarily helpful.

MS. COMSTOCK: Okay. Thank you.

DR. SIMON: Thank you very much. And a comment for everybody on that.

Mike Bibo, from RFMS. I guess we're going to stay on a theme at this point.

MR. BIBO: Good morning.

My name is Mike Bibo and I'm the government relations director for RFMS, Inc., and the first vice-

president for MRDD, which is Mentally Retarded Developmental Disabilities, for Illinois Healthcare Association. I'm speaking here today on behalf of all MRDD residents in Illinois, and I would like to address several significant ways that regulations impact facility operations.

This population is often overlooked when regulatory impact is being considered. Much in the same way skilled nursing facilities are over regulated, intermediate care facilities, ICFMR's, for the mentally retarded, which serve individuals with developmental disabilities and mental retardation, are subject to some of the most extreme regulatory oversight in the nation.

ICFMR's are Medicaid funded programs. And for an individual to reside in an ICFMR, an individual has been determined by a pre-assessment screening agent that they need 24 hour supervision and supports. In fact, throughout the United States approximately 67 percent of all individuals living in ICFMR's function at a severe or profound level.

Every regulation requires extensive paperwork to remain in compliance, and these administrative requirements take well-qualified care givers away from their primary role of providing quality care to persons

with severe disabilities. The original intent of the ICFMR survey and enforcement system was to be a person-centered, outcome-oriented system of oversight, which bears little resemblance to the very subjective, process-oriented, and punishment-driven system that has evolved.

To alter the system to one that recognizes, seeks to improve, and rewards quality care would foster an environment of partnership dedicated to providing such care and result in significant improvements in the lives of the individuals receiving services. A coordination, or the very least clarification, between state and federal regulations could help facilitate a single set of regulations, as opposed to the current system that at times have regulations in direct opposition to one another. This type of approach to a survey and enforcement system would reduce the confusion over which regulations is the most appropriate.

A concrete example of how opposing regulations can create problems can be seen in the Illinois regulations regarding elopement, which require alarms on all exterior doors to protect individuals and also to prevent individuals from wandering away from their residence. This is an Illinois requirement. But

CMS with federal regulations considers that to be a rights violation, and they don't want doors.

Other examples of similar problems have to do with, in Illinois, we have a regulation that says all chemicals will be locked and kept away from the individuals we serve. CMS sees that as a civil rights violation, that we're keeping it away from individuals. Yet if an individual ever gets involved or accesses that inappropriately, you know, maybe ingests a chemical, the facility would be cited for an immediate jeopardy. And we have these conflicts in regulations.

And, again, I want to remind you, 67 percent of the people we serve have been determined by an independent agent as needing 24-hour supports -- well, or 67 percent function at a severe or profound level, and everyone has been determined by an independent agent to need supports and supervision.

The federal regulators, however, interprets these same protections, as defined by the state, as violations of individual civil rights. The facility must take time and resources away from their primary role of providing care to the very vulnerable population to determine which of these regulations is more stringent and thus, which one should be followed.

The ICFMR federal regulations, which became

effective October 3, 1988, have not changed in nearly two decades. However, the interpretational changes have changed significantly.

Thank you for the opportunity to share a few. I'll be glad to answer any questions.

DR. SIMON: Thank you, Mr. Bibo.

Kevin?

DR. SCHULMAN: I have two questions. Chris brought up the issue before about the regulations of private payers put on basically the healthcare system compared to the government. And one of the interesting things about the government is the government also has regulations that violations of those regs are criminal statutes, not civil.

So how much of what you're -- when you're trying to interpret these regs, how much of these differences actually have criminal prosecution potential for people that work in your facilities. Where if you make a small error on the civil side, it would just be a fine or something like that.

MR. BIBO: Assuming it can, if it's determined that the administrator, well, if it's determined that there was a significant care or service, the administrator becomes liable in long term care, including in the ICFMR's. And there's been

significant amounts of criminal prosecution against the administrators of facilities where you have these conflicts. The exact numbers, I'm not certain.

DR. SCHULMAN: The -- and this is also in the way of anecdote. We wanted to go to an electronic billing system and the CMS regional office actually decided that by going on an electronic billing system and documentation system in one area of our hospital, we were out of compliance with their documentation standards because we weren't creating unique records for each individual patient.

So when you get into these conflicts, how much have you observed that the conflicts are due to regional interpretations of statutes, and how much do you understand that there might be in, you know, in Iowa or somewhere else an entirely different interpretation of what the national standards are.

MR. BIBO: Again, addressing solely the ICFMR facilities, that is tremendous. In my conversations with Diane Smith from Baltimore, who's in charge of ICFMR's in the country, she tells me that she doesn't control what goes on in regions such as Region Five here out of Chicago. And that there's a lot of things that get interpreted in the region here that Baltimore hasn't necessarily sanctioned.

Also, formerly, up until recently, I was the vice-president for American Healthcare Association for MRDD, and so I have lots of national knowledge of what goes on with ICFMR's in the country. And we would talk with my other members across the United States and find that things we're seeing here in this region would not be what they're seeing maybe in California or Oklahoma or Washington, D.C., or, you know. And it would all vary and there would be variations, and yet we all follow the same exact set of regulations.

DR. SIMON: David?

DR. DRANOVE You've described a couple of irreconcilable conflicts with elopement and the locking up of meds. To help the team trying to write new rules, would you be able to, one, just identify how often these conflicts actually turn up in reality and possibly do some kind of 20/80 kind of rule where you can identify the 20 percent of the conflicts that constitute 80 percent of your problems?

MR. BIBO: I think we could. I think we've been looking at that. And I've met with Tom Hamilton and discussed some of this with him at CMS, and yes, I think we could.

DR. SIMON: Great. That would be very helpful. Thank you, David.

Additional questions?

Mr. Bibo, thank you very much.

MR. BIBO: All right. Well, thank you.

DR. SIMON: Mr. Doug Whitley, from the Illinois Chamber of Commerce.

MR. WHITLEY: Good morning.

The Illinois Chamber of Commerce is an organization of many members, small business and large corporations alike. And I'm here in part because I would like to express to you how important healthcare has become as a theme and as a message and an issue for our organization. I've seen it go from a committee, where almost no one showed up, to now being a very aggressive and active council and I would have to say perhaps the second most important issue that the Illinois Chamber's dealing with on a routine basis.

Our council, which has been working on many aspects of healthcare now for the last several months, we've got 65 very active people involved in it. And I think one of the things that makes it special is we have the insurance companies, we have the hospitals, we have the doctors, we have the employers, all convening at the same time, sharing ideas and trying to come to some consensus about some of the issues that we have to deal with.

I've been directed today to simply offer to you the council's policy statement that we've been working on, and I'm prepared -- it's a couple of pages -- I'm prepared to read it to you, or I'm prepared to leave it with you, whatever would be your pleasure. Perhaps I could just touch upon a couple of the high points.

DR. SIMON: Actually I would encourage you to do that and also to leave us a copy.

MR. WHITLEY: Okay.

Today virtually every employer plan -- an employee must share in the cost of their health plan in the form of co-payments, coinsurance, and deductibles. Consequently, cost increases are impacting patients as well as purchasers.

And then I have a series of points here. Fundamentally healthcare costs are out of control as a result of several reasons. Our healthcare system until now has not focused on or rewarded quality and efficiency. Patients have had little information or incentive to consider quality or efficiency when making healthcare decisions. The healthcare delivery system is years behind other disciplines and institutions in implementation of health information technology. Prescription drug costs have accelerated without

sufficient control. Our population is aging with an increased percentage of our citizens moving into higher health cost years.

Our strategy for the future, re-engineering our healthcare system, these are broad based principles. One, implement measurement transparency and disclosure of provider and health plan performance, using nationally accepted standards. Two, move in larger rather than incremental steps towards consumerism. Three, introduce payment of providers based on performance, focus on healthy people, use health information technology to help drive savings, and collaborate with government to implement strategies in public and private programs. And in every one of those, I've got some material to be of assistance, hopefully to you.

We strongly support protections offered employees -- employers under ERISA plans. The council strongly believes that efforts to mandate a specific coverage or attempts to dictate policy provisions within an employer's healthcare plan reduces employer health benefit plan flexibility and innovation, and it increases the cost of health insurance to employers and employees.

In Illinois, and I know it's true for many

other states, mandates continue to come year after year. We believe a smorgasbord approach is much more favorable to trying to help control cost.

Our council will work to preserve the ability of employers to contract with healthcare insurers and providers in an environment that is not burdened with government intervention. The council will support efforts to reform Medicaid to improve quality and efficiency, and incentivize provider performance, reduce inappropriate bureaucracy placed upon healthcare providers, and install reimbursement structures that reflect what the actual cost of delivering healthcare services as paid by private employers.

With a fundamental belief that private enterprise initiatives result in maximum quality and efficiency, the Illinois Chamber Council will work with Illinois policymakers to identify private sector, rather than government controlled or mandated opportunities, to cover the uninsured in a manner that does not shift cost disproportionately to employers already providing coverage.

Six, with a focus on quality and efficiency, the council will assist regulators in the implementation of recently enacted legislation.

Seven, the council believes efforts to expand

healthcare liability for employers, referred to as enterprise liability, merely shifts liability to an enterprise like an employer or health plans allegedly connected with the cause of action. These proposals increase litigation, increase healthcare cost, and are counterproductive in achieving a more efficient and effective healthcare system.

And, finally, the council supports tax incentives that encourage employers to maintain and provide healthcare benefits to their employees and dependents.

I appreciate the opportunity to talk to you on behalf of employers in Illinois who have spent a great deal of time in this subject matter. And I realize that I've given you a broad brush review, but I assure you there's a lot of effort that's gone on behind this statement.

DR. SIMON: Thank you, Mr. Whitley.

We'll go to our panelists. Mike, and then Kevin.

DR. MORRISEY: Two-part question.

You talked a bit about consumerism in health insurance. Currently what would be your best guess as to proportion of employees amongst your members who have access to consumer directed health plans, and what

sort of proportion would you expect, say, in three years?

MR. WHITLEY: I can't give you a specific answer to, you know, a percentage answer because I don't know, but I'd be willing to try to find that out for you following up the meeting.

But I believe that the focus with our employers that we interact with, increasingly it's going to be consumer-focused, the sharing of the cost. But also trying to get the individual employees to pay attention, number one, to their lifestyle and their quality of life choices. Secondly, what those cost choices are. And I see more and more employers trying to encourage their employees to make wise decisions. I think there's going to be, for example, more focus towards individual accounts.

DR. MORRISEY: Well, and then the follow up question is, if consumers are to be empowered in that fashion, that implies some good information on price, quality, and related sorts of things.

Can the private sector do that, or is there a necessity for federal or perhaps state efforts to direct those activities?

MR. WHITLEY: What we've done in Illinois is we've passed legislation that requires, first of all,

hospitals, but now medical clinics and others, to begin providing that quality data that will be able to be retrieved online. And I believe individual employers will also begin providing more and more of that information to their employees, so they'll make choices.

But we have moved towards the point where the healthcare providers must provide their information about cost and their quality measures so that anyone can retrieve it.

DR. SIMON: Kevin?

DR. SCHULMAN: You know, the theme of today is on regulation. And as a Chamber of Commerce, you're acutely aware of regulation's impact on business.

How do you view the impact of regulation on the rising cost of healthcare? Is regulation a barrier to new firms coming in to serve your members with higher quality at lower price points?

MR. WHITLEY: I think it is. I mean, fundamentally, the Chamber is in favor of less regulation.

And I would even argue that one of the issues that we deal with in the United States, not just healthcare but in all aspects, is we've gotten too sophisticated for our own good. We want to regulate

and we want to litigate every possible turn in one's life. And I'm afraid that that's counter to an entrepreneurial spirit and a capitalist society that in fact encourages innovation. And we try to find, in this country I think increasingly we are trying to find ways not to do things, as opposed to trying to find ways to do things.

So, generally speaking, our organization is not in favor of regulation.

DR. SIMON: Dan?

DR. MORRISEY: Mr. Whitley, has the Chamber attempted to quantify the additional costs imposed by the mandated -- that you mentioned earlier. And whether you have or not, in your opinion, is that a factor in a lot of small businesses deciding to either terminate coverage for their employees or significantly restrict it?

MR. WHITLEY: Yes. Specifically in the case of mandated healthcare coverage, we've tried for the last three years to pass legislation in the Illinois General Assembly that we call mandate light, which will allow more options. In Illinois, I think we have 26 required mandates in insurance coverage.

We've followed and have paid close attention to the Texas experience. Texas passed some legislation

that was mandate light, to use a loose term on it. They had a significant increase in the number of people who started buying healthcare insurance for themselves after that new legislation passed down there. Most of those people who were buying that healthcare were people who were previously uninsured. So we think the cost factor is a key point towards trying to reach the uninsured, and we'd like to see that legislation passed in this state.

Now, how much savings? The estimates have run from four to 10 percent, depending on how much flexibility you give to the buyer. But we think any savings in that area's going to be a plus.

DR. SIMON: Very good. Mr. Whitley, I want to thank you very much and encourage you to leave a copy of your testimony with one of the ladies outside, submit additional information to our website.

And, again following up on a theme that I think was brought up earlier is that, to the extent that any of your membership, particularly who have experience outside of Illinois, can help us identify Illinois versus federal regulations that have an impact, we would be appreciative.

MR. WHITLEY: I'll take that question back. As I said, this has become a very active area within

our membership and so I've got good access to people who may have experiences to share.

DR. SIMON: Very good.

MR. WHITLEY: Thank you.

DR. SIMON: Thank you.

I'd like to call to the microphone Mr. Howard Peters from the Illinois Hospital Association.

MR. PETERS: Good morning, and thank you.

And I'm joined by my colleague Tom Jendro, who is a lot smarter on these issues than I am. He'll be here to answer any tough questions that you have.

I'm Howard Peters, on behalf of the Illinois Hospital Association and our more than 200 hospital members.

The burden of regulation is real and it has a real consequence on healthcare delivery. Typically, for every one hour of patient care, it now requires an hour of paperwork for services provided to Medicaid patients in the emergency department and 30 minutes of paperwork for every hour of skilled care provided.

And while the volume of regulation is relevant, how regulation is implemented is also relevant and provides a burden and a cost. And I actually want to in the time that we have here, and we will be providing expanded written testimony, speak to

several areas of implementation of regulations and how that affects healthcare delivery and specifically hospitals.

HIPAA, for example, in its design, was intended to generate cost savings by reduced administrative burden. But the fact of the matter is the cost of the administrative burden has actually increased with the implementation of HIPAA, particularly because of a lack of widespread adoption of electronic eligibility, enrollment and remittance systems that are called for by HIPAA.

For example, there are 2,400 pages of technical specifications to build an electronic claims format. And because of that complexity, many hospitals have had to pay third party clearing houses to process billing data and files to be sent to health plans, which adds cost.

Similarly, HIPAA requires that health plans are required to maintain current eligibility files in electronic forms, and to update them in a timely fashion. However, there's no definition of what current means, and therefore, many plans do not update their files and do not have electronic eligibility files that exist at all. And that causes a number of problems for healthcare providers.

There are many struggles that go on when employees or patients show up at hospitals, get care. And because the files might show that they are current employees and therefore eligible, but later we determine that they've left their employer and they're no longer eligible. And so all of the fights that take place and the cost related to that, and hospitals often have to eat the cost.

So we would urge HHS to assess the compliance by health plans for the requirement of adopting electronic eligibility enrollment and remittance systems, and to enforce that requirement. Because there are consequences to the healthcare delivery system for their not doing so.

Pay for performance is another area. The entire healthcare delivery system could benefit from pay for performance. However, there needs to be better coordination within the Center for Medicare and Medicaid Services to implement a variety of measures which are the foundation of pay for performance.

For example, the expansion of diagnostic and procedural codes used by HIPAA transactions for Medicaid payment claims now more accurately reflect the patient's condition and the complexity of care provided, and more closely matches Medicare's various

performance measures. The number of diagnostic codes expanded from nine to 25. The number of procedure codes expanded from six to 25.

Such an expansion is critical for the measuring of performance, but it should also be equally important to determining payments to providers. However, CMS uses the inadequate and flawed software, DRG Grouper Software, that will only process the first nine diagnostic codes and the first six procedural codes submitted. But many patients with co-morbidity problems might need many more than nine diagnostic codes to describe their condition, such as a diabetic patient who also has a heart condition from many years of smoking.

But then CMS pays based on the limited number of codes, even if a claim has many more codes. And even though they are required by federal regulations to submit all of the appropriate codes. As a result, many hospitals and providers are underpaid, and we would urge that this problem also be addressed.

There's also a lack of advanced notice about regulations. Again, the pay for performance measures is -- obviously a critical part of pay for performance is the performance measures. However, CMS needs to do a better job of informing providers well in advance

about what measures are being planned and what the required release date is.

An example is that CMS, along with the American Hospital Association and other leading organizations, are in the process of partnering an exciting new national hospital based quality improvement program called the Surgical Care Improvement Project. This is designed to reduce four common surgical complications by 25 percent by 2010. However, no information has been released yet on the specific measures for this project, which is scheduled to take effect January 1, less than a month from now. And we'd actually recommend that such measures be released a year in advance to allow implementation in a more orderly fashion.

The final comment I would make, Mr. Chairman, is this: Three years ago, the U.S. Health and Human Services Secretary Tommy Thompson's Advisory Committee on Regulatory Reform issued a report. And included in it was some 225 regulatory reforms that were viewed as critical to improving and reducing regulatory burdens on healthcare deliverers, healthcare providers.

However, to date, there's been very little public accountability with regard to whether any of those, or how many of those, reform regulations

suggestions were implemented. And we would urge this effort to go back to that report and indeed assess to what extent the 225 regulatory reforms have been implemented as a measure of to what extent burden on providers has been indeed reduced.

Again, we thank you for this opportunity and we will be submitting an expanded report to you.

DR. SCHULMAN: One interesting paradigm shift that seems to be occurring on the regulatory front is from this idea of accreditation through JCAHO where, as a condition of participation, the federal government has asked this independent regulatory group to come up with a whole set of independent regs, which keeps expanding, and the idea of pay for performance.

I mean, to some extent, if we have pay for performance and we know the performance measures actually impact patient care, what's the role of the enormous amount of work that goes into accreditation, where we've never actually documented that any of those activities improve performance or benefit patients.

MR. JENDRO: Good morning.

We hope that one of the benefits of pay for performance studies, and actually we're seeing the JCAHO and we're seeing some of these other accreditation agencies looking at disease management

and other types of programs, would be ultimately to streamline and composite these into one uniform program. Because, again, it contributes to hospitals having to deal with, you know, different sets of criteria for different accreditations, different performance evaluations.

Sometimes the differences aren't very great, but they're great enough to require staff and other people at hospitals to look at things and evaluate things a little bit differently. So hopefully, as pay for performance gets streamlined and gets perfected, which will probably take a few years at least, that we could see more commonality among the agencies, whether it's CMS or JCAHO, to go towards the same goals.

I'm sorry. I'm Tom Jendro. I'm a senior director of finance at Illinois Hospital Association.

DR. DRANOVE: A common theme between your presentation and the Chamber of Commerce, I think, actually is about, you know, pay for performance and report cards and just information that we can obtain from hospitals.

In 1974, the National Health Planning and Resources Development Act set as one of its objectives to have uniform billing and medical information records in all hospitals, and that has remained an objective to

this day. I think one reason we have not met that objective is because, as you discussed initially, instead of the federal government saying here's what you're going to use, it says here's 1,000 rules that you have to comply with.

How would your members feel if the federal government, as it's been suggested, developed the information systems and said to all of your members this is what you're going to use, rather than allow each one the freedom to have potentially conflicting and inconsistent technologies?

MR. PETERS: I think that the process of how they come to that conclusion is important. But as long as there is sufficient interaction with the field in developing that one way of doing things, I think the field would welcome that as a result. Because it also impacts on how we interface with patients and whether patients can even begin to understand the bills that they're receiving and so forth.

So we think that's the right way to go, as long as it involves the right kind of process.

MR. MULHOLLAND: Have you polled your members or could you get information about the cost that they incur in maintaining corporate compliance programs in maintaining staff to handle JCAHO or Medicare survey

issues, EMTALA? I mean those kind of specific data could be very useful in terms of analyzing what the incremental costs of compliance would be with all these different rules and regulations.

MR. PETERS: The answer to the question of "Can we gather such information?"; the answer is yes. I don't believe we have in our possession the information that you're requesting, but I do agree that that would be very revealing in terms of the cost of all of these various processes.

MR. MULHOLLAND: Yes. And you don't want to add additional costs by sending out another survey form if you can avoid it.

(Laughter.)

MR. MULHOLLAND: But just even knowing the compliance budgets of each one of your hospitals would be a helpful thing.

MR. JENDRO: And I would like to add to that. I know that working with many of the members in Illinois, within their administrative departments, there are some departments that are literally created only for the purpose of monitoring Medicare and Medicaid regulations, reporting to the government, dealing with auditors. So you've got people working at providers that are 100 percent regulatory.

And I would agree with Mr. Peters, we could get that information. It's not something that we have routinely gathered, but we could I think certainly put that together.

DR. SIMON: To the extent that that is routinely gathered that speaks to that or can even point one to other public documents that may provide some quantified evidence on that, that would be extraordinarily useful to the actions here.

Additional questions?

Mr. Peters, thank you very much.

MS. McGEEIN: I'm sorry. I stepped out of the room and I didn't hear your comment. You had a question about the Secretary's Advisory Committee on Regulatory Reform?

MR. PETERS: Yes. I really didn't have a question, as much as a point. And that is that there were 225 regulatory reforms suggested.

MS. McGEEIN: Recommendations.

MR. PETERS: Recommendations.

MS. McGEEIN: Right.

MR. PETERS: However, there's not been any kind of public accountability or public report on to what extent those 225 recommendations were implemented, and we think that's important. And if they haven't

been implemented, since a lot of work went into developing them, we think it's important to implement them and to report back to the field that they have been implemented. Or indeed, if they aren't, if they're not, as a measure of the extent to which this burden of regulation is being addressed.

MS. McGEEIN: There are 255 recommendations and, as I said in my opening remarks, 84 percent of them have been implemented. The remaining really cannot be implemented for all sorts of reasons.

I would suggest that you have a sit down with Paul Hughes. If you'll raise your hand, Paul. He knew I was going to do this. We are willing to walk through the ones that we've implemented, identify where we've made a difference. CMS has gone overboard; their open doors, their physician panels. They've done a variety of things trying to address the very things that you're talking about.

But I certainly will take back to Secretary Leavitt that you would like a public accounting of the recommendations.

MR. PETERS: Thank you very much.

DR. SIMON: Thank you.

Ms. Bonnie Lubin, from Hektoen Institute.

MS. LUBIN: Hektoen Institute for Medical

Research.

DR. SIMON: Thank you.

MS. LUBIN: This is an entire change of pace. I'm interested in the effect on healthcare grants administration on the development and management of projects in the discretionary budgets.

Obviously we are a very small piece of the pie you're interested in. I think our problems are similar to those of our larger colleagues, in that we're talking about poor communication, poor administration, duplicative efforts, over-regulation and over-reporting.

One of the things that concerns me about this problem is that in creating vastly onerous regulatory environments for the development of grants and new projects, the federal government is eating its young. That is, that the idea of innovative projects, as they are developed, is becoming so difficult that people are simply declining to develop new ideas, to write grants, to demonstrate new ideas, and then to implement them as possible.

So there could be, you know, the next Shakespeare of the healthcare field, could be out there thinking I don't want to spend the required 400 hours to write this grant and then the other 2,000 hours to

administer it. I'm going to wait. Somebody else will do it.

So, let me just give you an example. And I thought maybe I would entertain you with some of the more absurd examples. We have a grant, just for discussion sake, we have a grant from HRSA for Ryan White CARE Act. As you know, there are five titles for the Ryan White CARE Act; four of them deal with direct services to people who are impacted, whose lives are affected by HIV. And these are the safety net programs that we're talking about.

This grant's for a million dollars. Our allowable indirect is $100,000. Those indirects are spent on allowable reporting requirements, and those are paid for by the federal government. Another $200,000 is spent on reporting requirements that are not allowable, not paid for, and which are nevertheless required by the federal government. Those costs are stolen, eked, pressed, defined, somewhere out of the healthcare services of that particular project. And they're also, by the way, paid for from charitable dollars, which if you've ever tried to raise charitable dollars, are harder than money from the federal government.

Much of these costs are related to

duplicative reporting. For instance, HRSA does not have one patient database for people with HIV. There are five. Those databases have different definitions of ethnicities. All of those projects have different timeframes. In our five major HRSA grants, we have five different timeframes. Many of the patients are seen by more than one of these projects. They can't be managed seamlessly. They must be managed discreetly. Each one has a different timeframe. Those patients and their accompanying ethnicities, their accompanying healthcare costs, et cetera, et cetera, are sliced and diced five times. Needless to say, it's cheaper to slice and dice once than five. Obviously, things also get lost in the margins.

So we think that there are problems that you can fix and you can fix easily. First of all, there's disconnects between fiscal and management reporting. Even though grants administration is defined by carefully and well articulated principles in OMB circulars, those circulars aren't apparently read by many members of the programmatic staff of the agencies administering them.

Just to give you an example, and this ought to cause a chuckle, at least I hope it does, in Ryan White Title One, it is not allowable to provide condoms

to patients. Now, as you know, condoms are a major help, in fact, one of the few helps we have, for secondary prevention of HIV. Ryan White Title One is the largest service of the titles, except for the drugs, but that's another story. Therefore, it's our opinion that the federal government is an engine of the epidemic, not the source of help that it ought to be.

I could give you more examples very similar to those, but just another one. The federal government does not allow expenditures for food for patients when they come in for care. That's fine, except that when you have patients who are HIV positive, who can't take their meds, who come in for care, and who are then -- it is impossible for them to take their meds that morning. They're fasting because of, let's say, a blood glucose test or whatever, we can't provide them with care. Our patients have a two-hour bus ride back to their homes. That seems to be, to us, to be utterly absurd. We ought to be able to, on our grants, provide them with food for the interim period. We're not talking about feeding their families. We're talking about food as a necessary component of healthcare. Spending it, the federal government for any grants, and the academics among you, I know you must've received grants. Multi-year projects. Grants are usually given

on three or five year bases. These monies are allocated. They're specifically given in a Notice of Grant Award.

For healthcare grants, it is very rare for you to be able to have carry forward from one year to the next. That is, if you put in a budget, a very specific line item budget, for let's say $1,450,000, and you spend $1,438,000, the remaining amount must be managed by you down to zero on that year's grant, or else you run the risk of losing it. Now, if you've ever managed a project, you can't run it to zero ordinarily because, of course, that would be fiscally irresponsible. You run the risk of overspending the grant.

But, at the year end, you can't carry it forward, which it might support the projects for the next year. You have to spend it down. And in spending it down, you may, in fact, spend it down in ways that you don't necessarily want, or don't necessarily, in the most efficient way, contribute to the project.

DR. SIMON: If I could just ask you to sum up, please.

MS. LUBIN: Sure.

DR. SIMON: Thank you.

MS. LUBIN: We think that those communication

issues with the grantees could be best solved by having an intergovernmental grantee to government conference of some sort that might, in fact, affect the regulations grant. And, as our colleagues with the larger problems have said, we're in a private sector. We're doing the work. You need to trust us at least a little bit more, in order so that that work can be accomplished in a reasonable timeframe.

I thank you very much.

DR. SIMON: Thank you very much.

Could you just spend maybe about 15 seconds telling us a little bit about the Hektoen Institute.

MS. LUBIN: Hektoen Institute is a private non-profit that is affiliated with the Cook County Bureau of Health Services. We administer grants for the Cook County Bureau. The Cook County Bureau is an agency of county government, and we are the public safety net for the citizens of Cook without other alternative healthcare.

DR. SIMON: Great. Thank you very much.

Actually, I can guarantee you that you have a sympathetic ear from researchers on the panel who frequently don't use the words research administration and kind words in the same sentence. But with that in mind, I had a whole bunch of hands, you all went down.

So, I'll start with Chris.

DR. CONOVER: I was interested by your remarks. Two questions. One is, from where you sit, if everything were done the right way, do you have some estimate of, you know, in percentage terms, roughly how much you would --

MS. LUBIN: In my back of the envelope calculation, I think we could save about a third of research administration costs.

DR. CONOVER: And --

MS. LUBIN: -- in the healthcare program administration.

DR. CONOVER: And the second has to do with, so, who exactly needs to change their behavior. It wasn't clear whether these are arising from OMB, they're arising from subagencies within DHHS, or whether there's some, you know, something at the secretary level that could fix all this. Do you know?

MS. LUBIN: I think it's both the secretary level and the subagencies. I think, for instance, if we have a uniform grants administration application process. If we had one application with, for instance, the allowable cost clearly delineated. I mean, after all, OMB-circular-whatever-whatever exists, and it ought to be pretty clear to apply that to a particular

project. So, that's one aspect of it.

DR. SIMON: Dan?

MR. MULHOLLAND: You may want to talk to Ms. McGeein. Her office is in charge of the Ryan White program, so she'll solve all your problems today.

MS. LUBIN: Great. I'm happy to do that. Thanks.

DR. SIMON: Additional questions?

(No response.)

Very good. Thank you very much.

Mr. John Blum?

MR. BLUM: Good morning. Thank you for this opportunity.

I'm John Blum. I'm a law professor at Loyola University, Chicago. I'm here on behalf of myself only, having worked in this area for many years on a variety of regulatory programs.

First of all, Dr. Conover, thank you for your work. I've stolen from it liberally, giving you credit, of course.

(Laughter.)

MR. BLUM: What I'd like to do is make a couple of generic comments that reflect upon what's already been said.

My first point is, it's my perspective that

what we need in this area, it's obvious, but is harmonization. There is frequently duplication between state and federal regulation, which in some ways may be unavoidable because of politics. But we add to that the fact that there's also private regulation, and that makes this area particularly challenging. I know that's an obvious point, but I'm thinking about it in the context of work that I've done recently on patient safety.

If you look at the responses to patient safety issues, a dramatic problem, we see JCAHO has a private sector response. Over 20 to 25 states now have legislation, some of which is pretty elaborate, dealing with patient safety programs. And now, we've got federal legislation that's about to create patient safety organizations. I'm not suggesting that's bad. But I'm suggesting that, realizing that we need harmonization, we have to reflect upon the behavior of all these levels of regulators in terms of what they're doing, and who they look to when they do these particular, or engage, rather, in these particular projects.

My second point is also an obvious point, but one that I see is problematic, and that is post implementation review of regulation. There is not, in

some instances, a lot of post implementation, consistent methodological processes, done by the regulators about the impacts of regulation. Rather, what we tend to see is regulations dangle for years, and eventually they disappear because they're not used. And I can give you a number of examples, but one that I go back to, which is a while ago, is the regulation dealing with utilization review, which comes out of the original Medicare statute. That had been on the books for many years. At the same time, we see a whole initiative called PSRO, now PRO, now QIO, which has been out there. And it took years before UR was actually abolished because UR comes out of the different -- or came out of a different agency. That's one of many examples.

We don't have the concept of sunset in regulation, but I would like to urge that that concept be thought about. We have the concept of sunset, particularly at the state level and state legislation. Perhaps we ought to have a similar concept in terms of federal regulations. At some point, they should sunset.

My other point that I'd like to make is somewhat broader and more generic, and it deals with how we regulate, and the models we look at. There is

an international movement referred to as new governance. New governance covers a wide range of regulatory formats. They're formats that have been used widely in Europe and in Australia. As a matter of fact, new governance has its birth in Australia in the work of an academic named John Braithwaite.

The theory behind new governance is that regulation, the regulatory process, needs to be more collaborative, more fluid, and more tailored to individual situations. We have, within the context of models, there is one model in particular, which has received considerable attention, and it's referred to as management-based regulation.

Management-based regulation has been promoted by a couple of academics at the Kennedy School at Harvard. Cary Coglianese and David Lazer have been the primary motivators, or primary people, rather, who have promoted the notion of management-based regulation, which is a planning model of regulation. We see it in other industries, and not yet, although there is one example in healthcare. But we see it in the environmental area. We see it in the occupational area, and in the food safety area. And basically what it is, is it's a model that looks at and charges the regulated industry with coming up with a planning model to

address a particular problem in collaboration with the regulatory industry. It is particularly helpful in situations where we have very technically challenging issues. Issues like patient safety would fall right into that context.

I'm encouraged by CMS, actually, because there is one CMS example: The Quality Assessment Performance Improvement Program, which is now part of the conditions of participation, that looks at a planning model. And to my knowledge, it's the first time where a more fluid model has been adopted.

Part of the problem is that, when we regulate, we think about command and control, which is a term widely used. But we think about the Administrative Procedures Act as a statute which has fairly rigid dictates. I would argue that, in point of fact, the Administrative Procedures Act is not as rigid as it's been interpreted but allows for a variety of models and a variety of approaches. And I would hope that this committee would consider a variety of additional or alternative regulatory strategies in your deliberations.

One of the areas that I also want to comment on, which really touches on a lot of what's been said, is private sector regulation. And here, of course, we

do see different models, and in some instances, more fluid models. I would like to argue that what we need to think about is opening the door beyond JCAHO, and letting other groups come in to provide regulatory structure for various sectors of the healthcare industry.

I'm aware of the fact that the American Osteopathic Association has a program which is being used by some hospitals. But the model I want to focus on in my remarks this morning is the ISO 9000 model, which is an international industry model which has been used by industries of varying sorts around the globe. We are now seeing, there's one hospital here in Chicago, actually, which has dropped JCAHO, and now uses ISO 9000, or ISO 9001/2000, as its model.

The ISO model is a very fluid model. It's a planning-based model, and it's a model which allows the regulated party to generate a lot of self-assessment. It is an organization-wide program, and in the remarks that I will submit, I'll describe it in a bit more detail for those of you who aren't familiar with it.

I'd like to sum up by saying, I think we need to be creative in this area, and we need to move away from tradition. Part of the problem, however, is that there is a culture of regulation, which exists on the

part of state and federal regulators. I've had numerous conversations with people in the regulatory community. They all agree. Yes, we need alternatives. But the one conclusion that many of them come to is, we have a very legalistic regulatory culture. Inevitably, we fall back on tradition. And I would like to argue, maybe it's impossible, but some of that tradition and culture be changed.

I appreciate the opportunity.

DR. SIMON: Thank you.

MR. BLUM: Thank you very much.

DR. SIMON: All right. Mike?

DR. MORRISEY: I'd like to follow up on your sunset arguments.

Regulations don't necessarily sort of come out of government but arise from efforts on the part of providers in one direction or another, and I'm struck by the certificate of need legislation, that the federal impetus for which disappeared but yet, you know, 36 states continue to have certificate of need legislation, and many have argued because it protects existing providers. How would you see a sunset process sort of working in that kind of setting?

MR. BLUM: Well, I think that's a good example because I think you're absolutely right. I

mean, frankly, my perception of CON law, now, is it's really an industry protection.

And if you look at the current dialogue, we've had actually a certain amount of debate about this in Illinois, recently, whether or not CON should continue. And it's quite interesting because if you talk privately to hospital administrators, none of them like it. But in point of fact, because of specialty hospitals, and the potential threat from specialty hospitals, there is a perception that we need CON to protect the playing field and protect our market.

Now, whether or not that's right or wrong, I don't know. But I think the fact of the matter is, is that that's a piece of legislation whose time, in many ways, has come and gone. It's still there. I mean, maybe it has a purpose, but, by sunset, what I'm suggesting is that there ought to be a period of time where we have a, maybe not a drop dead date but certainly a point at which there is a mandated re-examination of major regulatory programs. Some of that's ongoing. Some of that happens in the courts. But it doesn't happen within the context of the regulatory system as a matter of course.

DR. SIMON: David?

DR. DRANOVE: One of the themes this morning

has been that a lot of what's going on in the government sector is being repeated in the private sector.

How does the government distinguish between a regulation, and simply a contractual term that would be part of any supplier/buyer relationship, such as, for example, requiring some kind of accreditation or certification before you'll do business with a supplier?

MR. BLUM: I'm not sure there is a major distinction you can make, but I'm also encouraged by the possibility of using a contract-based process as an alternative to regulation. I mean, maybe there's some things that we're doing that could come within the context of a condition of participation.

We think very rigidly about a lot of these issues because they're regulatorily-based. But the actual negotiation between hospital A and CMS might be based on a more fluid model, which in point of fact becomes contractually-based.

DR. DRANOVE: I guess what I'm asking is, how do we -- we call it a regulation because Medicare has written it, but why shouldn't we just think of it as a contractual term because regulation has this connotation that if the private sector did it, it

wouldn't happen?

MR. BLUM: Well, we could. I mean, I don't see any reason why we couldn't think of it in those terms. I mean, I tend to think of regulation as a very formal process. You know, something you picked up, you pick up the federal register and, you know, there it is. And it really is something that flows out of the Administrative Procedures Act, whereas a contractual provision may or may not have that genesis. It probably has its origin in a legal relationship which has a regulatory base, but I think you can do a lot by contract. And, in point of fact, we do.

DR. SIMON: Okay.

Kevin?

DR. SCHULMAN: One of the questions you're kind of raising is the difference in terms of interpretation of the regulatory structures across the different branches of government.

And one of the things that's really potentially very striking is the culture within HHS and the General Counsel's Office in HHS, in terms of their interpretation, compared to commerce or somewhere else in the federal government. And part of that is, if you think about the types of industries they're trying to regulate, and the structures we have in place to do

that,those industries are much more fluid. And those regulatory structures are much more fluid.

To some extent, the regulatory structures in healthcare are growing out of -- we're celebrating the 75th anniversary at Duke this year. You know, there's no telecom company that's been around for 75 years, although AT&T just came back.

But to some extent, one of the arguments you might want to make is that we need to force the regulators to go and examine the different regulatory paradigms within our own federal government, to adopt best practices and share them across. And maybe it might even be more at the General Counsel level that they have to understand some of the flexibility and interpretation that labor or commerce figured out, that HHS has never figured out.

MR. BLUM: I would concur with that. I mean, I think there are a lot of different approaches to regulation within the context of both federal agencies, as well as state agencies, but I don't see a lot of that interagency dialogue. I mean, obviously CMS and HHS is an enormous entity, and so, even to have that dialogue within the agency is challenging. To have it cut across agencies, I think, is even more challenging.

But I would argue that, you know, even though

some of these other industries may be newer, there are things like -- food safety is a good example of an area where there is a fairly fluid base of regulation. That that kind of fluidity, at least in certain segments of healthcare, ought to be introduced. I mean, something I, again I mention patient safety, which is an area I'm sure, as a physician, you're very familiar with this national movement.

We haven't really figured out a lot of answers here. And I think at the point where an issue is in flux, this is an ideal point for the regulators to say, let's treat this in a looser fashion. Not that we're not concerned, but let's see what bubbles up from the industry itself in terms of approaches to this problem.

DR. SIMON: Okay. Dr. Helms---Oh, did you have a quick question?

DR. HELMS: Yes. I'll try to make it quick.

First of all, I'm glad to have an academic here who thinks about the theory of regulation, so I guess this -- kind of one thing I want to ask you about this -- If you look at sort of the classic economic theories of regulation and so on, there was all this notion of sort of regulatory capture. That regulation in, historically and so on, was alleged to sort of

facilitate collusive behavior, which is not in the public interest and so on.

As I understand your testimony, when you talk about harmonization or other models of forming things, you seem to be saying, you know, that there's room for improvement for letting the private sector parties of this be more involved in the process of determining the regulations and so on. And I think you mean well by this, but how do you counter the argument that you just open this up for them as a way to sort of benefit themselves?

MR. BLUM: Well, I think that's a very real concern, but I think that we're at the point where we have created -- and we haven't talked about this today -- somewhat of a combative relationship between the regulator and the regulated. It's fine to talk about rulemaking, which sounds fairly benign. But one of the realities is that underpinning rulemaking as part of the strategy, is there is a legal strategy that underpins all of this, that, if the process degenerates, if the regulated industry is unhappy, inevitably, it leads to a lawsuit.

I'm not suggesting that we scrap our entire regulatory process. But what I am suggesting, is that in areas that are very technical, and there are many

technical areas in healthcare, that's where we really can benefit from industry input and in more of a collaborative process. I think there's always a risk of capture, but I think that we've gone significantly in the other direction, and there is an alienation that exists.

And a lot, frankly, of this whole business deals with, how does the regulated industry strategize itself to minimize the impact of the regulation, and move onto the next level? And, frankly, there's always a next level, because if you look at healthcare regulation, it's just been wave after wave, particularly in the 1990's. So, we have a fairly combative regime.

And then, I know several of you mentioned, at least indirectly, the Medicare fraud and abuse issues. Well, that's always an overlay, now, on everything that healthcare institutions do. And there's always that hammer, you know, if you're really creative, and if you're a little too creative, you know, that might be a violation of STARK, or it might be a violation of the other two big laws in this area. So, I think that I'd be willing to take somewhat of a risk here, recognizing that capture is always a problem if you're going to go to a more fluid, looser model.

DR. SIMON: I thank you.

You've clearly written a lot on this, and what would be particularly useful for us in our exercise is, first of all, send me your resume or your CV on the publications, but particularly any work that uses case studies or examples that highlights how existing structures may be posing particular burdens, either in compliance and information generation, in duplicative mandates, that we can then use to extract some quantifiable evidence on this end.

MR. BLUM: You know, as you asked the questions of the gentlemen from the Illinois Hospital Association, I'm going to try to track it down, but IHA did do a study in the late nineties about the burden of regulation on hospitals, and it was done more in terms of the volume of agencies that the average hospital deals with.

My memory may be a little fuzzy, but it was somewhere in the 200 plus range of local, state, and federal agencies that the average hospital here faces with. If I can find that, I'll send it along.

DR. SIMON: That would be very useful.

MR. BLUM: Thank you very much.

DR. SIMON: Thank you very much.

Well, we've had a productive morning. I have

on my list an additional five individuals who have signed up for this afternoon. I think now is a good time to take a lunch break so we can also rejuvenate a bit.

If you are interested in knowing your order of presentation for this afternoon, and I know that we have additional folks signed up, as well, please come see me. If you have any particular constraints, we'll try to work around them to the best that we can.

Lunch is on your own. We will reconvene here at one o'clock, and I thank you very much for your attention and contribution this morning.

(Whereupon, the meeting was recessed to reconvene this same day, Thursday, December 8, 2005, at 1:00 p.m.)

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A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

(1:05 p.m.)

DR. SIMON: Welcome everybody back to our afternoon session. We're going to pick up where we left off on the public commentary.

I will just remind anybody who was not in the room at the beginning that we have two websites that are established for collecting additional information, and I encourage both you, your organizations, and your colleagues who have studies, reports, analyses, particularly for folks who weren't able to come today or who have additional information that they weren't able to present in our generous allotment of five minutes, to submit your written commentary and supporting information to one of the websites, and those are listed in your packet of information.

The same house rules apply as before. We have another half a dozen individuals slated to prepare testimony. Our panelists stand ready with questions, and at the close, we're going to give them a little bit of time, too, I think, is it talk amongst yourselves, and help us bring out some of the major themes, and perhaps also open to the floor for additional questions.

Okay. Linda Kloss, from the American Health

Information Management Association. Ms. Kloss?

MS. KLOSS: Good afternoon.

I'm Linda Kloss, and I'm the chief executive officer of the American Health Information Management Association. We're headquartered here in Chicago, but we're a national professional association of 50,000 members who work in the weeds. We oversee all of the medical record management functions in provider organizations, and that includes coding and the transition to electronic health records. So, our members are some of those folks that work in compliance.

I'd like to describe three projects that we're involved in and the lessons relating to this issue of economic impact of regulations, specifically in the area of medical documentation, and then bring out three examples and move through those quite rapidly.

We are one of the sponsoring organizations of a new private entity called the Certification Commission for Health IT that has a government contract, and its purpose is to do private sector certification of electronic health records. I think that the work of the Certification Commission for Health IT, as a way of driving market forces toward

adoption of health IT, may provide an innovative model going forward for how to move change in this complex health environment. And I know there's been quite a lot written about the plan for the Office of the National Coordinator, but this is one of the key contracts that is going to bring about some much needed market force changes in medical documentation.

We also, as an organization, just completed some very interesting work on the impact, or the potential impact on fraud and abuse for the adoption -- if there were a national health information network in place -- and the opportunities. And we did include in that research economic modeling on what the potential impact of an improved health information network would be on fraud prevention.

Thirdly, there is a lot going on in the private sector, and I think that relates to our comments this morning about private sector initiatives. We're working, for example, with a medical group management association, The American Academy of Family Physicians and 10 other organizations in a coalition on administrative simplification because some of the research done by MGMA has shown that just simple mundane tasks like insurance verification, or telephone calls to and from pharmacies or processing

credentialing applications cost the average 10 Physician Plan something like $250,000 a year in those three mundane tasks. So we are advocating, for example, for all organizations, including CMS, to use a single national credentialing service sponsored by the council for affordable quality healthcare, and our mission is to try to get private plans and public plans using those systems that were set up for just that very purpose.

With respect to some examples of problematic areas, our organization has been, for the last 15 years, advocating for certain quite simple changes to the conditions of participation as it relates to medical documentation. And we've seen those as barriers, using people resources to do checking work that is tied and tethered to the paper world, rather than enabling our systems to be moving to electronic world.

So one of the messages is, please look at those regulations that are holding us back in a paper-based healthcare world, when at the same time this administration has shown unique leadership in trying to get us moving in an electronic direction.

A second example of that is the fact that for the past, also, 15 years, we've been advocating for

adoption of ICD-10 PCS. Now, I won't get that far into the weeds. I'll just say that this is the modern version of the coding system. That for all diagnoses and procedures, we're now using a 30-year-old disease and procedure classification system, and we're going to use that for these modern quality reporting systems that are coming out. And I think that no one's paying enough attention to the data quality problems of these new systems. So, 15 years.

So, that leads me to my final theme, that, with simple conditions of participation, ICD-9 to ICD-10 transitions. We're in 2005. We've been advocating, as other organizations have been, for needed changes, and they're not on the horizon. So whatever is done with the regulatory process, I think we need to look at how it can expedite change rather than impede it.

We are laboring under many, many regulations that are very tethered, as I said, to the paper world. At the same time, we're trying very hard to transition our healthcare environment to a health IT-based system that will drive all the change that we're looking for.

HIPAA regulations, particularly, they really were designed to be a very crippling process. There is no way that any change under HIPAA can be made in less than four to six years. And the conditions of

participation that I mentioned, while we commented on some drafts this year, it was just announced that the earliest we're going to see any update in those is 2008.

So, I urge you to look at medical documentation, moving that forward, eliminating those things that are impeding and finding a way for this regulatory process to move change along more quickly. Thank you.

DR. SIMON: Thank you very much.

Kevin, then Chris, then David.

DR. SCHULMAN: One of the themes of this idea of government regulation is the relationship between the industry and the regulatory process. So, when industry says the regulatory process isn't responsive, is it because other aspects of the industry are fighting to maintain the status quo? Or, is it because the bureaucracy itself has some inertia that's preventing this change from occurring?

MS. KLOSS: I'll use the transition to ICD-10 as an example, and I think it's a combination. Advisory bodies to the Secretary have recommended the change, the modernization of these code sets. But there are some industry interests that either don't thoroughly understand the implications of staying with

what we have or are dealing with the very real burden of implementing other regulations.

And so, you know, no matter what the benefit is, or what Rand cites as the cost benefit, positive cost benefit relationship, they're occupied with other things. And I don't think there's a robust way to adjudicate these and come to some consensus. I think, if there were a consensus process that was better, we've looked for years at trying to bring groups together, trying to find a way to advance the discussion. But, you know, there just needs to be a better process for adjudicating those differences of opinion and coming to some conclusion, just laying out a road map. And I do believe, as some of the commentators said this morning, that the industry would, frankly, be happy with that leadership.

DR. SIMON: Okay. Chris?

DR. CONOVER: I don't know if you were here this morning to hear the fellow from the hospital industry.

MS. KLOSS: I was.

DR. CONOVER: Okay. So I'm just curious if you would react to his comment because the impression he left was that the hospitals are sort of doing their part on HIPAA, and the carriers aren't implementing

these standards fast enough. So what we need is more enforcement. And I'm just curious how you view HIPAA. I mean, I assume we're not, we shouldn't junk HIPAA.

MS. KLOSS: We should finish it and put it behind us as an interesting era.

I think where we're at right now is we're stuck in the middle of it. We don't have enough enforcement to complete it. And I just think we need to look at what's left to be done, get it done, and move into, you know, do those things that move us forward in the health IT arena.

An example, for example, this is a good one. One of the provisions of HIPAA is that there be electronic claims attachment. Well, the electronic claims attachment standards are really very rudimentary, and they have to be kind of that way as a compromise. And they won't really do all that much substantively to benefit where we're at. We'd be better putting that energy, or redirecting that energy into some network interchange that are more robust and for the future, rather than tying us up for another five years to implement what will not satisfy anybody. So I think there needs to be a process for assessing what's left to be done, and then moving at it and moving beyond it.

DR. DRANOVE: I just wanted to also repeat a theme from this morning. You just brought up network interchange. There have been technologies in many industries for a long time which have had this kind of interchange property: Rail gauges in the nineteenth century, or the TCPIP protocol for the Internet in the twentieth century where, if it were not for centralized decisions kind of supervised by the government, we would not have seen these industries advance, and we'd still, on the railroads, the railcars would have to stop at the end of one state, just the way health data has to stop from one provider before it goes to another. Is this a case where the U.S. government really can nationally create a benefit through more regulation, rather than leave the market free?

MS. KLOSS: I do think there is absolutely a role for the central. We've been in favor of a better national standard for privacy. We are fully supportive of the current work from the Office of the National Coordinator to create a standards harmonization mechanism. And I think this is a great example of where national leadership will be absolutely vital.

DR. SIMON: Dan?

MR. MULHOLLAND: If you could just comment on one criticism I've heard about moving to ICD-10.

That's primarily from clinicians, who say it's putting the cart before the horse. It's coming up with, perhaps, a more elegant system to process information for quality tracking payment purposes, but one that's going to be more complicated for the person who's actually providing the care. They say it's putting the cart before the horse, letting the needs of the system drive what clinicians will do.

The other criticism I've heard from hospitals, as well as physicians, is that this would be unduly complex. There would be a lot of transition costs associated with it, and a fear that there would be more potential liability under the False Claims Act for people making inadvertent mistakes while they're getting used to the new system. And you could account for that with, you know, maybe a relaxed enforcement scheme for a while. But I just wondered if your organization has addressed those issues.

MS. KLOSS: We do have an implementation study that I'll make available. And I would refer you to the work that Rand did, to look at the cost benefit. I think that, also, you need to look at ICD-10 in the context of the electronic health information world, where I envision, not very far into the future, where physicians will have electronic health record systems,

and an ICD-10 will enable use of computer-based coding, where ICD-9 won't be robust enough to take full benefit of the technology.

So, certainly we see modern classifications in the context of an electronic environment.

DR. SIMON: Bob?

DR. HELMS: I'll try to make this a question. But basically, David brought up about, sort of the nineteenth century, standardizing the rails, and so on. But I was a student of a transportation historian economist, named George Hilton, who pointed out that then, they may have standardized the rails, but then they had a series of regulations that basically determined how the cars were built. In other words, they had to be interchangeable.

But his point was that they prevented an existing technology, which we now see in the Metros where you have electric motors on the wheels. They couldn't adopt that technology, and, as a result, railroads were sort of relegated to carrying bulk items, and they never could compete with the trucks on the high value shipment. And he always presented this as a major cost of sort of ICC regulation.

So you'd translate that story into this present thing. Sure, CMS could be the 800 pound

gorilla, and sort of, as I guess, push this system onto people. But how do you do that while maintaining the flexibility for the innovators out there, and that you could get some new models or some, you know, people have better ideas over time?

MS. KLOSS: I would refer the panel to perhaps a little more study in what's being done with the Certification Commission for Health IT. I think it's actually quite an interesting model where there's consensus among stakeholders, including the federal government, as to what the basic functionality requirements of this electronic health records system is, but then plenty of room for vendors to innovate. But some baseline as to, it needs to be able to process a medication order and do this and do that, and provide notification where there is medication incongruities but still plenty of room for the market to innovate.

I think it's a market-based model that is cross sector collaborative to try to drive change and to speed adoption.

DR. SIMON: Additional questions?

(No response.)

DR. SIMON: Ms. Kloss, thank you very much for your comments, and we look forward to getting many of your documents through the e-mail.

Marjorie Maurer?

MS. MAURER: Good afternoon.

My name is Marjorie Maurer. I am the chief nurse executive and vice-president of operations at Advocate Good Samaritan Hospital, in Downers Grove, Illinois. I'm here testifying today on behalf of Good Samaritan's parent company, Advocate Healthcare, which is the largest healthcare provider in the state.

Before I begin my comments, I'd like to thank the panel for taking the time today to consider the impact of regulation in the healthcare industry. Today, I will focus my comments on how government regulation limits the time nurses can spend caring for patients. The nursing shortage is a challenge faced by healthcare providers across the country. Metropolitan Chicago Healthcare Council recently reported a demand for nurses as currently at approximately 2,500 full-time equivalents. That shortage could grow to nearly tenfold in the next 15 years.

We believe that government regulation has the potential to exacerbate this shortage by pulling nurses further away from direct patient care. Ask any nurse how she spends her time, and you will soon learn that nurses do significant amounts of paperwork and that this burden is increasing. The paperwork is often

required by the varying entities that regulate hospital industry, such as Medicare, Medicaid, the Joint Commission, as well as state licensing departments. Of these regulations, often they're duplicative or, in worse case scenario, are in conflict with each other.

The bottom line, however, is that the policymakers must recognize that these increasing regulatory obligations have a cost in terms of nurse time and productivity. The less productive nurse workforce means that we'll need more nurses to care for the same number of patients.

Nursing researchers studying how nurses spend their time have collected data regarding this regulatory burden. For example, over the past three years, Advocate has been in partnership with the U of I College of Nursing through a nursing retention grant. And we've been working most specifically with Judy Storfjell, associate dean, on studying the work activities, processes of acute care nurses in the Chicago area, using an activity-based costing methodology as a part of our effort to further understand and improve nurse retention.

This study has yielded some fascinating results about how nurses spend their time, and these findings are important when considering the economic

burden of healthcare regulation. I'd like to take a moment to share some of these findings with you.

Using a combination of nurse focus group testimony, manager validation, surveys, and actual observations regarding practice activities, the time and cost of nursing activities were analyzed. As the project progressed, a number of trends became apparent that persisted, regardless of the facility type or the unit. These included low RN time spent providing direct patient care, limited RN time spent teaching patients and providing psycho social support to patients and families, and high RN time and cost for support activities, including managing clinical records and coordination of care, and a high amount of non-productive work time which included some rework and delays.

This prompted a more in depth analysis of the 11 medical surgical units that we used in our study, for which activity and wage cost data had been collected in the three participating hospitals with an Advocate. Particularly important is the finding that nurses in these medical surgical units had limited time available to provide direct patient care. Out of their entire shift, only 42 percent of that time was regarding direct patient care.

The majority of nurses' time, over 58 percent, is spent doing support activities, including management of clinical records. Management of clinical records includes time spent documenting care as required by the accreditation and regulation requirements. This is significant, since there are over 70 research studies that have shown that as nurse-patient time increases, patient mortality, adverse events, and complications will decrease. Nurse job satisfaction increases, as well as hospital financial performance.

RN wages make up more than 60 percent of total medical surgical unit wages. Of that amount, 24 percent is used in managing clinical records. This includes documenting care required by the accreditation and regulation, locating charts, paperwork, and 32 percent is used in coordination of care. And while we talk about this as how the nurse is coordinating information between other care givers and other care providers. It ends up being that less than five percent of an RN time is spent teaching or providing direct psychosocial support to patients and families.

We further took that and took the average wage midpoint of salaries at the time of this study. Annualized wage costs for managing clinical records

averaged $732,000 per medical surgical unit, and nearly one million in wages is spent annually coordinating patient care on a single medical surgical unit.

For the purposes of conversation today, these findings indicate that a vicious cycle could be at work. The more regulations on healthcare providers, the more time nurses must spend away from patients, the more nurses in our society will be necessary to require giving care for the same number of patients. The impact on the cost for healthcare could be considerable.

I would be remiss today if I tell you or leave you with the impression that all healthcare regulation that takes nurses away from the bedside is bad. Certainly regulations that have improved patient safety and outcomes can be of great benefit to patients and care givers.

However, we at Advocate do think that the government needs to study carefully what documentation nurses must perform, whether such documentation is necessary or duplicative. Certainly the federal government should partner with accreditation bodies, such as the Joint Commission, as well as state and local health departments to ensure that regulations are consistent and minimize costs whenever possible.

Additionally, the government must recognize that the hospital community, whose costs are generally not covered by Medicare and Medicaid programs today, cannot continue to absorb the unfunded mandates that many regulations have become. I appreciate your time and attention to this matter.

DR. SIMON: Thank you very much, Ms. Maurer.

Kevin, then Chris.

DR. SCHULMAN: It's interesting a lot of the documentation requirements that you were talking about actually are JCAHO requirements, right?

MS. MAURER: Yes.

DR. SCHULMAN: Not all Medicare requirements.

MS. MAURER: Yes.

DR. SCHULMAN: We talked about this earlier today because JCAHO's actually not a body of the federal government. The federal government seats the regulatory authority in this space for accreditation to JCAHO. JCAHO's sole, you know, in terms of where we're at in terms of modern quality, the kinds of standards that JCAHO are using and continue to promulgate aren't really what you see in the literature, in terms of performance measures.

Could you talk a little bit about the types of things that JCAHO requires you to do, because it's

just as, you know -- For example, in the literature we know that volume is an important predictor of mortality. But JCAHO certifies the high volume hospitals just as well as the low volume hospitals, so how does accreditation actually help the patients choose the better provider?

MS. MAURER: Wow, that's quite a question.

First of all, Medicare requires that in order to be a participant, you must be accredited by the Joint Commission. So hospitals need to be able to comply with both Joint Commission standards, as well as the Medicare conditions for participation, as well as Illinois licensing standards. And there are some duplications between the conditions of participation for Medicare and what you're seeing in Joint Commission. Sometimes it feels like you're being caught in a meat grinder between all these different agencies when you're a direct provider.

An example of some of the most recent regulations or standards that Joint Commission's come out with is around patient safety. What they want to see hospitals implementing effective January 1st, for example, is medication reconciliation. Are you familiar with that?

This is where patients come into a hospital

and you must validate all the medications that they've been on at home. And what Joint Commission is saying is it's not enough anymore for the patient to be the person to say, "Here's my pills. This is what I was taking." You now must call pharmacies. You may even have to call physicians to verify the whole profile of medications that a patient's been on prior to being admitted into the hospital.

That goes on to the beginning of a database. It gets given to the attending physician to say, "Okay, this is what we want to continue for in-hospital stay," or, "This is not." It takes a lot of time. And what we have found -- we piloted this process in our emergency room -- it can take anywhere from 20 minutes to over two hours to do medication reconciliation on patients.

As a patient goes through the continuum of care in the hospital setting, every time they transition between care, they have to again go through medication reconciliation and then, of course at the point of discharge before they leave.

So while it makes sense and I understand the issue in terms of medical error reduction, it has added a lot of work time on care givers, both nursing as well as pharmacists, to meet the requirements that are being

laid out. That's just one example.

DR. SCHULMAN: Is there any literature that supports that actually reconciliation is either a problem that contributes to patient death or that actually this reconciliation process would reduce these errors?

MS. MAURER: Yes. I have not -- I can't cite them for you. I understand that Joint Commission and Don Burwick's 100,000 Lives Campaign and all of that, with all of this work with reduction of medical errors, have shown that patients sometimes themselves are their worst historians. They don't know what the medication is, and you have to try to reconcile that so that you're not further, either overdosing patients or giving them medications that, you know, don't work together with each other.

So yes. That was one of the things that they established.

DR. SIMON: Chris?

DR. CONOVER: I'm confused why you can't delegate some of these activities to lower cost or lower skilled individuals. I mean, in particular, the example of the medication reconciliation. Surely an RN doesn't have to be the one to be calling pharmacies and things like that, do they?

MS. MAURER: Yes. Either the RN or the pharmacist and here's why: They have the critical thinking skills, the education, and the background to be able to ask the questions. Someone that didn't have that kind of theory or education base really wouldn't be able to make some of the critical decision-making as far as like what to ask the patient, what to ask the pharmacist, and that type of thing. Or to recognize if there's some problems in terms of different medications that really shouldn't be used together.

Your other point that I'm glad that you brought up is the fact that as we look at in acute care and the workforce, we are looking at what must a registered nurse be doing that cannot be delegated away. And much of the documentation has to be done by the registered nurse. So what's ending up being delegated to the direct patient carer, to the unlicensed personnel, are the things where they're seeing these unlicensed people at the bedside because the nurse is doing these other things that by license are required to do.

DR. CONOVER: Okay. In the study you've done, that 58 percent figure, you acknowledge that not all regulation should be going away. So the question is, is there any way of telling from that study how

much of that 58 percent is really, you know, really time wasted, duplication, or things like that?

MS. MAURER: Yes. In fact, that's going to be the next wave of this study, and we're also going to expand it to other medical surgical sites. We just did this within three hospitals at Advocate Healthcare; one big medical center and two community hospitals.

When I talk about duplication, there's duplication that's within the site. For example, when patients come in, often times they have several co-morbidities. They have more than one physician on the case. And it ends up being the nurse that's kind of the coordinator or having to call all the docs and, you know, get things all together. And that's time on the nurse to be doing that because often times the docs aren't talking directly to each other. They talk either via the medical record or through the nurse to do that.

So we are looking at how to improve processes. One of the things Advocate Healthcare did, we've invested over $60 million in capital on the electronic medical record, hoping that it would improve some of the efficiencies. What we're finding -- the good news with that -- is that there's more accuracy in documentation, better legibility. However, it's really

not improving time.

And what we're seeing particularly with our physicians is it can take them 10 seconds to write an order in the chart. In the electronic medical record, it takes them a little bit longer because there's all these alerts and, you know, that type of thing. They don't want to do it so they'll call the nurse and give them an order over the phone, and then the nurse has to input it into the electronic medical record.

So we're still looking at, there are some things that we need to be doing, and clearly we understand that. But we do look at often times that Medicare, Joint Commission, our own state licensing regs, will come up with similar regulations. We go with what's the most restrictive, and we know we will satisfy the other two agencies. But sometimes it kind of makes you wonder, aren't these people talking to each other.

DR. SIMON: Mike?

DR. MORRISEY: Just a real quick follow-up question on Chris's.

You indicated that with respect to documentation, that nurses had to do that, is that because it's required in the regulation or is that another example of background knowledge necessary to

comply?

MS. MAURER: Well, it's both. Because of the Practice Act, especially in our state of Illinois, but I am also familiar with practice acts across the country, there are only certain things that a licensed individual can do.

Now, in terms of medications, pharmacists are also able to accept orders from physicians, but they cannot administer drugs. Respiratory therapists can administer drugs; they can't take orders from physicians. It's only a registered nurse. So there are some things by virtue of their Practice Act that they're able to do within their scope of practice. And that cannot be delegated away to other individuals.

Some of the documentation, the flow sheets, doing some of the more critical vital signs -- blood pressures can be delegated to an unlicensed personnel. But when you're doing intercranial monitoring and some of that, that needs to be a nurse. And you would want it to be a nurse.

DR. SIMON: Additional questions from the panel?

(No response.)

DR. SIMON: Ms. Maurer, thank you very much.

MS. MAURER: Thank you.

DR. SIMON: Will you be submitting written testimony, as well?

MS. MAURER: I did. I gave some copies to someone.

DR. SIMON: Excellent. And if you have additional studies that you could send us, particularly the one that you cited from the Illinois School of Nursing and any portions of your own internal study, we would very much appreciate it.

Ms. Wendy Meltzer, from the Illinois Citizens for Better Care.

MS. MELTZER: My name is Wendy Meltzer. I'm with Illinois Citizens for Better Care. We're a nursing home residents' advocacy and civil rights organization. We've been in Illinois since about 1978.

I thought it would be helpful today to talk some about the economic impact of the failure to enforce nursing home regulations on families, on residents, on the Medicare trust fund and other payers, and, if I've got time, on the nursing home front line staff.

You've heard from the National Citizens Coalition for Nursing Home Reform in Washington. They're our national organization, and we join in much of what they said.

I'd like to give you the Illinois data about violation histories. I think, for instance, that you'd find that the number of G violations in Illinois, double G's, and in some case triple G's, has actually increased in the last few years. But Illinois has actually cut off our access to that information, so I can get it for you, but it's going to take awhile.

I can tell you that in 2004, for instance, the Department of Public Health found 14 confirmed complaints of sexual assault on nursing home residents. Those weren't individual instances of assault. Virtually all of them were multiple assaults involving multiple victims, in which the facility knew about the assaults and did nothing to report it or prevent it, in some cases for a year or more.

We just recently had a very well-publicized case of the mother of one of two twin profoundly developmentally disabled young women being told by her nursing home that her daughter was six months pregnant. The grandmother is now raising her infant granddaughter and waiting to see if the baby has her mother's and aunt's profound developmental disability. I don't know -- I don't know how to quantify the cost to the mother or to society of that child and raising that child. But I think that it's a significant one.

We have in the past, again, before we were cut off, reviewed instances, literally hundreds of instances of multiple sexual assault and other physical assaults on nursing home residents. Exactly one of those where there was a failure to report, and in all these multiple instances, pretty much by definition, there was a failure to report on the part of the people who were theoretically mandatory abuse neglect reporters. In only one of them was there any professional discipline against any individual who was a mandatory reporter.

In that case it was for a facility called Chateau Center in Willowbrook. There were more than a dozen sexual assaults in 16 months against a number of women in a dementia unit in the facility, the director of nursing. And we know about that because the staff wrote it down. In that case, the director of nursing had her license suspended for one month, and the administrator received a letter of discipline, of reprimand.

There have been no other instances that we can find under the Department of Professional Regulation website indicating that there's been ever any professional liability or consequence for failure to report. Or if you go to the Department of Public

Health website for CNA's or other individuals who have a comparable duty to report.

We have also, as best we can tell, never had a prosecution in Illinois against any individual employed in a nursing home or employed elsewhere who's a mandatory reporter, for failing to report abuse and neglect.

Second, the financial impact on families. I asked four people that I've been working with pretty closely, some are members and some are just people I've been working with pretty closely in the last few months if they could come today. One of them is a realtor and she said, "Look, I can't miss any more work." One of them is a high school secretary and one of them is a kindergarten teacher. They said, "Can't miss any more work. If I miss any more work, I'm going to get fired."

And then I had this really sweet 86-year old lady. She's retired so she's not working, and she said, "I have to be with Henry." Henry is her husband. Henry has Alzheimer's. She goes to be with Henry at 10:00 in the morning, and she stays with him until 8:00 at night. Why does she do that? First of all, because Henry will not initiate going to activities in the nursing home. They're happy to have him go, but the

staff just can't be bothered or doesn't remember most of time to get him there.

Second, most important, Henry, unless he sits at the corner at the table of the nursing home, tends to take food from other residents. And sometimes he gets hit. Sometimes he gets hit really hard. So she needs to be there because the staff doesn't remember that Henry needs to sit in a particular place. And she's tired, and she's sad about Henry winding up with bruises on his face or his arm because the other residents hit him.

She's also there because sometimes the staff doesn't change him when he needs to be changed. He can't say that, and because he's a very quiet person, a very calm person, he doesn't protest. He just stays there and sits in his own waste for hours unless she reminds the staff that he needs to be changed.

So the financial impact of poor care on families includes the loss of work, missing days or sometimes quitting work in order to be with their relatives because that's the only way they can make sure that they're going to get appropriate care. Limited or no recreational choices for retired people and for families because they're spending all their time there.

In some cases hiring what -- I don't know if they call this nationally, but in Illinois we call them sitters. People essentially with CNA skills or sometimes really no training at all, to stay with residents and either call the staff or perform basic care functions that the staff isn't performing.

Sometimes quitting work or paying for home healthcare and actually taking the resident home because they just can't trust the facility to do it anymore.

Third, when the license recertification agency finds abuse or neglect, poor infection control leading to iatrogenic illness, one of my favorite terms, even that which results in hospitalization, the Medicare trust funds, the Medicaid, private insurers absolutely never recoup their costs. The nursing home is never required to refund the cost of hospitalization or ancillary care to Medicare or other insurers.

Now, we understand there may be issues with doing that and, honestly, the unexpected or unintended consequence can be that if the nursing home has to pay for the cost of hospitalization, they may be less likely to send very sick people to the hospital. And so I'm not sure that that's the answer. But I think that you need to at least consider the possibility that

there are significant costs, essentially cost shifting to poor care.

Fourth, the injury to the staff, especially lifting injuries and from poor infection control. We're talking about pretty much by definition low income, overwhelmingly women, overwhelmingly women who are black and Hispanic and probably in other areas, other minorities. If you look, I believe you will find that I think OSHA still shows that CNA's have the highest injury rate of any occupancy group in the country. And for the most part, there is no regulation, no protection. There's not appropriate training for things like how to lift or appropriate equipment in many facilities to help them lift.

We don't think that regulation with economic penalties is the only way to get good care. Actually I'd love to say I agree with the guy from the Chamber of Commerce. It's like a wonderful thing to be able to say, that transparency and family involvement really improve care.

But we need to improve and strengthen current regulation which strengthen the abilities of families, to create family councils which both empower them to inform facilities, administrators, and staff about problems from the resident's and the family's

perspective before they get really bad, to work cooperatively to solve them, to keep them from getting worse. We need to see nursing homes more open to the public because, honestly, you're not going to have really bad stuff happening when there are a lot of people there to see it.

As part of that transparency, though, you need to make sure that families know about violations when they happen. Right now the surveys are supposed to be posted in the facility, but those are done anonymously. Essentially, R-1 wasn't changed. R-6 wasn't fed. R-3, -4, and -5 were sexually assaulted. But unless you actually know and there's enough physical description that you can say, "Hey, maybe my mother is that 84-year old woman living on the third floor and she only has one leg, and I guess there isn't anyone else like that," you're not going to know that.

If you inform families about what's actually going on with respect to their particular family members before it gets really, really bad, there's likely to be that kind of pressure to improve it.

And families also need to be informed more about what the rules currently are about care planning and their involvement in care planning. That doesn't have to be done by regulation of nursing homes. It

could be done with cooperation of the state agencies so that they know going in what the system is, and it's not just the Wild West out there and nursing homes can do whatever they want to do.

I'm done.

DR. SIMON: Thank you.

David?

DR. DRANOVE: We know that there's a major ongoing effort to try to document and disseminate hospital quality. And we know about a lot of the issues in terms of trying to identify meaningful outcome measures, standardized data, do risk adjustment, prevent hospitals from self-selecting patients to make themselves look better.

Do you think the same effort for nursing homes would be easier or more difficult?

MS. MELTZER: I think it would be more difficult, but I think it's doable.

It's more difficult because the outcomes are harder to know. Okay? I mean in a sense we have regulation now that looks at outcomes because it really only looks at the bad stuff, you know, how many people developed pressure sores.

Some of the quality control stuff that you have now is counterproductive, honestly. I mean if you

look at a facility where you say it's a bad thing for people to be reporting pain for a significant amount of time, then what you're really doing is punishing the facilities that recognize that people are in pain and doing something about it. And that's just a terrible, terrible thing to do.

It's possible to do it. I think you need, you need a vast amount of information which honestly, right now, in most states, we don't even know who dies in nursing homes in Illinois. And I believe that that is true nationally. I think Arkansas, they now know who's dead. In Illinois, we don't even know who dies. And so, and until you have that basic information, and then you can start saying, "Well, here's the co-morbidity data for that," you know.

It's possible to do it. It's possible to do it more easily for the short-term rehab people because then there really are measures, and some of those are very good. You look, for instance, at who comes in not walking and then they're walking. I mean that -- that's great. I mean, that's great. Who couldn't feed themselves, and now they're feeding themselves. Now, maybe it's because of what the nursing home did and maybe not, but I'm happy for them, you know. And you can do that.

But the harder quality of life issues and the, you know, who gets changed and, well, they didn't actually, you know. It's not only did they get it, but is the facility reporting it. You know, that's very, very much harder to do. I think it's doable, but it's really hard.

DR. SIMON: Chris, and then Dan.

DR. CONOVER: I believe CMS now has a Nursing Home Compare website or something, and could you just comment on that?

I'm just curious whether you ever see a world in which we could rely on that sort of quality information in giving better information to consumers as a way of displacing sort of process oriented regulation.

MS. MELTZER: The CMS website is a very general sort of website. In the Nursing Home Compare, for instance, it has a general description of what, you know. It has the name of the violation, but it doesn't tell you what actually happens. And honestly, the graphicness of it is what really matters to people, you know. I mean the details of the violation. That's what we used to be able to provide in Illinois and, as I said, we've been cut off. We can't do that anymore.

The more general stuff, the quality measures

they said, some of them are very good, like who's walking, who wasn't, how many people are walking. But for a lot of people when they're going in, say, for dementia care, that's just not an issue for them. And I don't think anybody -- I don't see the CMS website as doing that.

I think that for the most part -- because nursing home choices are made under such time pressures. The majority of people going to a nursing home from the hospital, and some of those are readmits and nobody's really -- I haven't been able to find any data which shows whether that's really -- that the people who go from the nursing home to the hospital and back to that nursing home or a different one. And that may, I think that actually lowers their percentage. But I think it's pretty clear the majority now are going in from a hospital.

The time pressures are enormous. The amount of information that you can get that you need to make a choice about quality, as well as the fact that many people, for many families, quality means not necessarily quality of care. It may mean the distance. It may mean the religious affiliation of the facility. You know, it may be because your brother-in-law works there. I mean there are a lot of things that affect

it.

And you also have a significant number of residents who really have no involved family members, or the family members are so far distant. You know, mom's in Florida and you're here, or you're here and your daughter's -- your mom's here and the daughter's in Minnesota or something.

That substituting family -- or everybody's dead. You know, I mean we get some of those, where we're dealing with the public guardian or their guardian because there's nobody there. And you can't expect that degree of responsibility, I think, or information to substitute for real involvement and oversight. It helps.

DR. SIMON: Dan?

MR. MULHOLLAND: Just two brief questions, please.

One, could you comment on what you would view to be the cost benefit analysis of mandated criminal background checks that one of the previous speakers talked about, both in terms of residents and employees? And then just briefly comment on whether the kind of detailed reporting that you were mentioning ought to be privileged from discovery so it couldn't be used against the providers in the subsequent malpractice

case.

MS. MELTZER: I don't do malpractice so I have no stake, you know, I don't have a horse in that race. I'm perfectly happy to have anybody tell everybody anything. I mean I just, I don't care, you know.

I mean I used to see malpractice cases as being a real shove towards better care, and I think that happens sometimes. I mean there's some people who just -- that's the only reason that they get better is because they get sued, and then they go out of business, or they sell it to somebody else. And that's so -- but I think that the greater impact of information is, so personally I'm fine with that.

And the criminal background checks, we're not actually requiring that for everybody. They're requiring it when there's a question. I mean they're not actually -- I think that with the criminal background check stuff does, as far as cost-benefit analysis, is I don't know how you say what the financial benefit of preventing sexual assaults or physical attacks on people is. And we've seen that, you know. So I don't know.

I mean, if it were your mother, would you say like, "Well, she'll take a check and let her get

raped?" I mean that's just, that's horrible! You can't do that. I mean, that's not what this is about. I mean, how much would make her feel okay about that? Or how much would make you feel okay about that? That's just, I think that that's not the world, the nursing home world that we really live in. Is that fair?

DR. SIMON: Thank you very much.

MS. MELTZER: Thank you.

DR. SIMON: Mr. Jim Knutson from the Aircraft Gear Corporation.

MR. KNUTSON: Thank you.

DR. SIMON: Thank you.

MR. KNUTSON: I haven't looked outside lately, but I was reminded driving in this morning by a local radio disc jockey that the area meteorologists have predicted 10 of the last three blizzards in the Chicago area so so much for --

(Laughter.)

MR. KNUTSON: -- predictive modeling.

I'm Jim Knutson and --

DR. SIMON: And with that note, one of our Southern panelists is making his way to the airport.

(Laughter.)

DR. SIMON: We'll see you there, Kevin.

MR. KNUTSON: Jim Knutson, director of human resources and risk management at Aircraft Gear Corporation. We are a closely held manufacturer of driveline assemblies and gearboxes for the automotive and the aviation industry. We have about 85 employees. We're headquartered in Rockford, Illinois. And we've been providing healthcare benefits to our employees and their dependents for about 50 years so we've been in the game for quite awhile.

And I'd like to address two issues of regulation this afternoon. One is with respect to COBRA, and the second -- and the timing was pretty good. I didn't realize this before, but the facts sheet about coverage criteria is the second area that I'd like to speak to a little bit. So, and if I could borrow about one minute from the question and answers session, there were three items that came up in Doug Whitley's presentation this morning that I thought I'd like to comment on.

One was the extent to which consumer-driven health plans are penetrating the market or not. And the sense that we get from work that we do through the National Business Group on Health and the Midwest Business Group on Health is that currently there's about 10 percent of the employer market has gone to

consumer-directed healthcare. Surprisingly, it's larger employers. When we looked at it initially four or five years ago, we thought the small employer market would take that up more quickly.

The second was in the area of mandates, and the extent or the cost of state insurance department mandates to healthcare plans. And from studies that we did about five or six years ago, we think that mandates add about 20 percent to the cost. And we estimated that by comparing the cost of our self-funded health plan with the cost of going with a fully insured plan at the time and matching up some of the different coverage elements to it. So not statistically probably real compliant but close enough.

And then the third area was the interaction of state regulations and the federal rules. And there, our own personal experience with something called Kid Care and All Kids Coverage in Illinois is that it's pretty messy. The criteria for rebates and reimbursement under the state insurance rules don't mesh, for example, in our plan we don't charge a premium for coverage. And in order to benefit under the All Kids program, parents -- participants have to pay a premium because they get that premium rebated. So they don't always align very well.

And now, back on the original, back on my quota time. COBRA, first, we support the extension of coverage, healthcare coverage, in the event of the termination of employment. What we object to are some of the unnecessarily complicated rules, regulations, regarding the coverage. And in that area, for example, I would point out there are three different coverage periods of 18 months, 29 months, and 36 months, depending on whether you're an employee, a disabled employee at the time of the qualifying event, or a dependent who would qualify under certain circumstances. And we think we could simplify rules like that without causing any damage or doing any harm.

The second area under COBRA that I think is more significant to us is the impact of, or the concept of, adverse selection and risk pool destruction that comes about when you have voluntarily coverage, which COBRA is. What we see a lot of times is the people who are going to use the plan, people who are sicker, taking it up and those who are healthy or who don't have a sense that they're going to use it decline the coverage.

And we have estimated that that can add anywhere from 15 to 20 percent to the cost of our healthcare plan in any given year. And if you're in a

cyclical industry like we are, we are sensitive to the fact that we could be at the bottom of our business cycle and at the time that we are at the height of our healthcare cost cycle, and that doesn't always converge real well either.

The third area, really quickly, is concern about uncoordinated timeframes. For example, you have a provision, which in effect gives a terminated employee about 90 days to elect COBRA coverage. And if you have a pending claim, high cost claim, where you may be a part of a PPO network that has a prompt pay provision for a discount, you may find yourself having to, faced with a choice of either having to pay a claim for someone who may not elect coverage or lose what could be a significant discount. So that can be a real dilemma.

What we'd like to see, like considered in that area, is some sort of a voucher system that would employ some of the consumer-driven healthcare principles like our account-based plans. So that people who would otherwise maybe decline coverage would have some economic stake or motivation in continuing coverage and preserving a better balanced risk pool.

The second area, quickly, is with respect to developing standards for coverage criteria. Most plans

continue to use a coverage clause based on the concept of medical necessity, which was a term designed to be a placeholder in old indemnity insurance contracts from the forties and fifties, designed to reimburse hospitals and doctors for costs of care and, as Linda Kloss pointed out, with respect to the coding system, a coverage clause that's 50 or 60 years old was born in a different time and worked in a different time. But healthcare has gotten to be a lot more complex today. We know that quality and utilization of healthcare services varies. We've studied the work of Wennberg with the Dartmouth Atlas, the Institute of Medicine Report, and the Rand Corporation study that said that people get effective care maybe only about 50 percent of the time. So we know there's a high degree of variation out there.

We think that a coverage clause that's based, that employs some of the work of government agencies like AHRQ, the Agency for Health Research and Quality, and other evidence-based medicine standards, would go a long way towards restoring value to the healthcare equation.

We participated in a study done by the Midwest Business Group on Health about five years ago, that indicated that probably 30 to 35 percent of

healthcare costs could be attributable to poor quality, specifically areas of under use, misuse and over use. And we think that if we redefine coverage criteria to pay for effective care, we could take some of those dollars, improve access and cover the uninsured. Thanks.

DR. SIMON: Thank you.

Mike?

DR. MORRISEY: Two questions. One with respect to your adverse selection comment, about 15 to 20 percent additional plan costs. You mean for an individual who accepts COBRA coverage relative to an average worker or do you mean overall plan costs?

MR. KNUTSON: I mean the impact of that large claim. Again, we're a small group of 80 employees. So if we have a 75 or $80,000 claim, the impact of that claim on our average cost could be as much as 15 to 20 percent.

DR. MORRISEY: And the second question had to do with your concept of a voucher system. So the idea would be if I was terminated from employment with you, I would be granted a voucher by you that I could use to buy health insurance in the market, not necessarily your plan?

MR. KNUTSON: Yes. Right.

DR. SIMON: Other questions? David?

DR. DRANOVE: It's obvious you're very active with the Midwest Business Group on Health. I heard you talk about consumer directed health plans, and I don't want to speak for the panel. But at least the majority of health economists that I've spoken with, not necessarily on this panel, believe that there are two critical problems with consumer directed health plans as a cost containment device.

The first is the 15/85 rule: That 15 percent of patients consume 85 percent of costs, and therefore 85 percent of costs are based on decisions made when you have full coverage. And the second is that the majority of expenditures when you are using the deductible are preventive in nature, and therefore that's the wrong kind of thing you want to make people price sensitive to.

I'm curious to know if the business community, as you've heard it, really thinks that consumer directed healthcare is anything more than a way of, one, exploiting the tax exemption for employer sponsored health insurance and, two, a way of shifting more costs onto employees rather than a way of reducing healthcare costs.

MR. KNUDSON: We're skeptical. We feel that

the real issue goes with utilization of high cost services. That if the risk stops at $1,000 or even $3,000, the incentive to control the multiple six-figure claim isn't really there.

And those plans do a lot to talk about healthcare finance, but healthcare and the low levels of healthcare literacy are not adequately addressed by consumer directed plans.

DR. SIMON: All right.

Anything else?

(No response.)

DR. SIMON: Thank you very much. And to follow up on the comment on the Midwest Business Group on Health. You cited a number of studies that had been done by the group. And if you can forward those to us, I'm sure they'd be very beneficial.

MR. KNUTSON: Be glad to. Yes.

DR. SIMON: Thank you very much.

Okay. This is at exactly the right time of the day where we have a change in the mode of presentation. Our next speaker is Linda Diamond Shapiro, from Access Community Health Network.

MS. SHAPIRO: Thank you. And -- is running technology for us. It's a pleasure to be here.

And, Dr. Dranove, I am a former student.

DR. DRANOVE: Yes. I recognize you.

MS. SHAPIRO: You do not! A mere 25 -- it's just a couple of years.

DR. SIMON: Have her write an exam for you, David, and it'll all come back. But actually the shoe's on the other foot right now, so.

MS. SHAPIRO: Back to my foot.

I'm here to talk about the healthcare safety net from the perspective of a community health center organization. And just to contextualize what I'm going to say a little bit, I'm vice president of planning and strategy at Access, which is the largest federally qualified health center network in the country. And I've put together a little bit about what an FQHC is, and I can go into that in the questions. Are there questions about, you know, who we are, how we fit in the safety net. Let's go to the next one, next slide.

In our particular organization, we take care, you skipped one. We take care of 200,000 unduplicated patients, so we do have some health sector muscle. About 600,000 annual encounters. All of our patients are under 200 percent of poverty. We're -- so primarily a racial and ethnic minority population. One in three of our patients are completely uninsured, and they pay about $15 for a visit. Medicaid is our

strongest payer, as you can see from that profile. We're a no margin business.

We are scaled to Chicagoland. And if you can see on the slides, the way other mapmakers portray Alaska and Hawaii, we're way out into DuPage and up in the Northwest suburbs and the South suburbs as well. So we cover a large jurisdiction. And we've pretty much, by mission and design, followed the diaspora of poverty over the last 10-

15 years as we've sought expansion. Next slide.

I want to highlight our role in the safety net and the role that community health centers play on the safety net. In our particular instance we have had considerable success in collaborating with emergency rooms to solve issues, such as overcrowding and too many general medicine admissions in the case of University of Chicago hospitals. And we find that we retain about one in five patients referred through this mechanism. And there are a lot of other confounding factors, including historical, cultural patterns of using the ER for primary care. In the case of UC hospitals, they have very strong brand equity, compared to mine, which is negligible, et cetera.

We have the role in our own network, and it's something I think is highly replicable. We have

federal approval within our scope of service to include specialty care, and that does a lot to secure our role in the safety net. Because, again, when people can get specialty care access in their neighborhoods, that changes how they use other health sector entities.

And, finally, I think we are extremely well organized with regard to providing screening and preventive interventions. Strong emphasis, led by the Bureau of Primary Healthcare, but also by our own physician leaders, on chronic disease management. We can do things like address substance use, mental health issues, which really end up being confounding and frustrating to emergency room professionals. We can create management scenarios.

And something I'd just like to reference, if you're interested for other purposes, we have a provider compensation system that compensates our physicians who are either employed or contractually engaged with us. We compensate them for the preventive screenings, the way other systems compensate for procedures. That's our own system. You know, we get a Medicaid encounter rate, so we just used our own mechanism to transfer that to our providers.

I want to, again, talk about the safety net and how a strong safety net affects the health sector

as a whole. I touched on emergency room overcrowding in our own regions. Certainly on the South side of Chicago there's been a regional bypass crisis where ER's go on bypass because of the overcrowding. And if you look at admissions, ER, and even admissions from the ER for ambulatory sensitive conditions, you can see how that crisis can be relieved.

Certainly on the academic medical center side the general medicine admissions definitely destabilize their academic medical center and their teaching research admissions. And Dean Madera from U of Chicago just put an editorial in JAMA I think about three weeks ago, talking about their side of the equation.

And then, finally, we can prevent some of the high intensity and high cost services that occur in emergency rooms in a hospital setting by offering prudent management on an ambulatory basis in our system. So an example would be diabetes care, asthma care, where the related costs have been studied and are available.

The next slide I want to start going into some of the remedies we'd like to talk about. We get a single enhanced encounter rate. But as we begin to offer specialty care and office-based procedures, we would like an enhancement for the reimbursement we

receive for some of those other procedures. Why? A specialist costs us more, therefore we'd like to reimburse them appropriately.

We get the same Medicaid rate for everybody, and it was based on a primary care scenario. And our examples would be, you know, colposcopy and dermatology, both really are dealing with precancerous conditions. And, again, dealing with that in a clinical community center works well for our patients, works well for the local economies.

The next slide, we cannot bill for all that we feel we can provide to the community. A couple of examples, group visits have been well shown as a very good methodology for improving self-management for chronic conditions. Diabetes is a good case in point. Podiatry, chiropractic, optometry. These are services that are all included, quote, unquote, in our enhanced rate but, again, are very costly to us and prohibitively costly so that we can't get them to all of our patients with the encounter rate we have and the payer mix we have.

We are only allowed one medical bill per day. So if we want to do, if we want to create a one-stop ambulatory model for seniors, for example, who, you know, may want to see a psychiatrist, they need to see

a dentist, and really would benefit from a one-stop, we can't do that. We can't do that, well, with the current payment arrangements. Next slide.

We have expanded greatly. When I started at Access a decade ago, we had nine centers. We now have 44. And we have expanded to address unmet need for primary healthcare. Now, we have also expanded prudently, where we have good partnerships, primarily hospital partnerships, where we can assure that our patients will have access to specialty and diagnostic services.

When we want to expand, the Bureau of Primary Healthcare, a HRSA entity, is thinking, gee, they're not going to allow us new expansion opportunities within a one mile radius of an existing health center. That really doesn't take into consideration some of the demography of urban poverty, and that would hinder us greatly.

When we apply for new 330 funding, 330 is, again, the Bureau of Primary Healthcare language for our authorization to bill at an enhanced rate, and then to get a small grant to address, in small part, the uninsured burden, they tell us, well, tell us what you're going to do in this community with regard to uninsured care. What I'd like them to do is look at

the uninsured burden in our whole organization because we run the organization to cross-subsidize as a whole, not in terms of individuals centers. And that's part of the source of strength. I've got one center with a 90 percent uninsured rate. I've got to have a couple centers with some Medicaid paying patients.

And then finally I'd like to point to incentives that encourage community health centers to collaborate with hospitals, seating specialty care at a neighborhood level and offering a continual care for under-served populations.

Going to the next slide, I would like us to look at the DSH mechanism in particular. It could be through an enhancement of DSH or even a regulatory requirement that says the quid quo pro would be evidence of hospital collaboration with CHC's in exchange for a DSH. Another way to look at this is using the DSH mechanism to promote hospital specialty diagnostic screening treatment center services for other patients we see.

And then, finally, I know there are many who've come to the mike with health information technology issues. Ours is simply as we look at the health sector as a whole and health information technology to include community health centers in those

policy and funding initiatives, again to look at partnerships that can be established electronically.

And then, I would like to highlight tele-medicine, which all the funding that we seem to be able to put our fingers on now really points to rural populations. And the use of tele-medicine in an urban settings, the uses are many and they're well documented. Certainly remote access for dermatology for specialty consultation would be very valuable for our seniors, again. Very valuable for people who aren't going to go out and Medicaid indeed is silent on the reimbursement issue. Medicare has reimbursed us for that.

And thank you. And I'd welcome the opportunity to talk to you further.

DR. SIMON: Thank you.

Let's start with Dan.

MR. MULHOLLAND: Thank you.

That's a very good presentation. I wonder if you could follow up on this issue of hospital FQHC collaboration.

MS. SHAPIRO: Yes.

MR. MULHOLLAND: Because in my practice, a few times our hospital clients have found some regulatory barriers to full cooperation. One is that

there's some federal regulations in the FQHC regs which strictly limit the degree of participation a hospital can have in a governance of the FQHC.

MS. SHAPIRO: Yes.

MR. MULHOLLAND: And the second is the anti-kickback statute.

MS. SHAPIRO: Yes.

MR. MULHOLLAND: There's always a concern if a hospital is going to subsidize an FQHC, which makes perfect sense for the reasons you outlined, that that could be viewed by the government as an inducement to refer to that particular hospital. And I just wondered what your views were on those two points.

MS. SHAPIRO: Yes. So I'll sleep with those issues under my pillow. And just to go back historically, the Bureau of Primary Healthcare, which has been our oxygen since the beginning, really had an anti-institutional bias in the old days. And, you know, it's a different animal now.

But this is an old OEO program that was oriented toward community-based control of a little bit of federal money. And I think nobody expected it to survive as a healthy mechanism into a modern integrated scenario that we were talking about today.

Initially the anti-institutional bias was so

strong. There was a feeling that if community health centers had a relationship with hospitals, they'd be swallowed up and they wouldn't have that local autonomy. So you'll see evidences of that.

Now, most recently both our professional association, the National Association of Community Health Centers and Jackie Leifer, who's an attorney who has been engaged by them and also by me and several other community health centers that want these hospital relationships, have been working to secure some safe harbors. And those are in place, both with regard to the anti-kickback and with regard to the ability of hospitals to partner with us.

Now, some of that's still on the OIG desk. I get, you know, good updates every six months, and the last two updates were: “it's coming,” “it's coming.” What I usually do is I talk to Jackie Leifer and the OIG together, and I fully believe we're well protected. I probably wouldn't do anything personally without that kind of scrutiny from those two entities at this point, because it's such new turf. But it seems like this is an area in which regulation has been moving in a good direction from our perspective.

So that's the testimony on behalf of not the burden but the opportunity. Now, I don't know how much

that's rippled through the community health center world. And, you know, I'm in a position where size really matters. I can affect the health sector because of the volume we see, and so there are organizations that are interested in partnering with us. That scenario probably isn't equal across the entire country. There are quite a few very small community health center entities.

DR. SIMON: Chris?

DR. CONOVER: On this you said vote down the proposed one mile radius rule. Am I to understand that your current network, like if you strictly enforced that rule, that some of your centers would be in violation? I'm curious how many. And does the proposed rule grandfather them in any way?

MS. SHAPIRO: Yes. I would assume we'd be grandfathered, and I'm not so worried about that.

What I guess I'm more concerned about is the opportunity to open new centers. And, again, in an urban geography, you know, we have some pretty homogenous neighborhoods in Chicago, and the racial and economic lines in Chicago are pretty strict. It's not like New York where you can achieve pair mix on every corner. And there are real boundaries.

You know, I was driving today down Wood

Avenue and again was just -- it's staggering. You go under the tracks, and you're in a different world. You could be on a different planet.

And so for our patients we have, you know, a majority of Latino population patients. People in many of these families don't speak English. All our Latino sites, if you will, bilingual, bicultural sites, everybody from the front desk to the physicians, we pay our physicians a bonus for bilingual capability in the language their patients speak. So, again, the other side of the tracks could be within a mile.

What I would say, also, is I have an ability to contract with some hospitals and to create some business with hospitals that a small entity down the street may not. I don't want to put them out of business. I don't want to overwhelm them. They are good -- it's good for them to be there. If they weren't there in this other entity, they might be in my doors. They might be in the hospital's doors. And, again, you have the destabilization. But, you know, that's my only opportunity.

My other option really is to try to put them out of business so that I'm not, you know, I could do some relocation. I don't think that's healthy. I don't think this is that costly a program that we'd

have to go that way.

DR. CONOVER: And the other question had to do with urban tele-medicine. I'm from North Carolina so we know tele-medicine for rural counties obviously. I'm just curious whether there are, you said Medicaid is silent on the issue, and I presume this is a state Medicaid decision about whether to allow reimbursement, or is this a federal decision?

MS. SHAPIRO: You know, I'm really talking about two things at once. And yes, when I mentioned Medicaid is silent, it's our state system.

I don't have the luxury right now to test the billing because we don't have the access to capital, and then seeding the practice to start these telemedicine initiatives. We'd like to do this.

I guess my comment is there's such a strong feeling that telemedicine is a rural healthcare solution that there aren't opportunities for me to compete. Now, I should say we raise, you know, one in every $5 we get are through competitive federal, competitive grants, either, you know, smaller philanthropical grants.

But we raise about $20 million a year through these federal competitions, and so if I don't have access to those competitions, you know. I don't mind

losing a little fair deal, but I do want to be in there saying, you know, I could create a good argument for why this would be good for our seniors or why -- I can't afford a dermatologist in every site, but dermatology is one of those areas it's very well documented to be effective for telemedicine. And if I've got a site in Blue Island and I've got a physician downtown, why not use that capacity.

DR. CONOVER: Can I ask one more or are we done?

DR. SIMON: I think we are running short on time. If it's a short one. Can you do it in 30 seconds?

DR. CONOVER: Is it only a reimbursement issue with telemedicine, or are there other regulatory barriers that you're aware of in that?

MS. SHAPIRO: It's the reimbursement and the access to federal funds to get this seeded. You know, and again, in a low margin business, anything I do that's creative, I've got to have a little bit, something to play with.

DR. SIMON: It was a good question for 30 seconds. Thank you very much.

Should we exit you guys here? Okay.

And Esther, and I'm going to butcher your

name, Sciammarella. Thank you very much.

MS. SCIAMMARELLA: Thank you for the opportunity to testify on behalf of the Chicago --

DR. SIMON: Wait. We need, is the mike on? Are we good to go? Thank you.

MS. SCIAMMARELLA: My name is Esther Sciammarella. I'm the Executive Director of the Chicago Hispanic Health Coalition. Previously, before I retired, I was the assistant commissioner for the Chicago Department of Public Health, for the Hispanic Affairs Office. And I wanted to really commend Region Five for Dr. Nasda. In the past week I have been working with Dr. Susan Nasda on dealing with diabetes, Hispanic diabetic patients in Illinois.

And I want to commend Dr. McClellan for the tremendous work that he is doing, and CMS just came from Washington to deal with Part D and try to enroll Hispanics for Medicare Part D. So I have been -- we have been working with seniors to get their flu shots, influenza pneumococcal vaccine. And I'm not only working in Illinois, but all over the country about the need of the minority community, particularly in the Hispanic community.

I think I challenge everybody here because it's interesting that -- I'm very concerned about

regulation and how much cost regulation can effect -- It's something that nobody has been discussing here but against regulating the implementation of translator for medical services and institutions.

I don't want to enter into details of the documentation of overcoming the language barrier in healthcare; the cost benefits of interpreter service who has been published in the American Journal of Public Health, May 2004.

I'm a member of the National Alliance of Hispanic Health, and I think Dr. Jane Delgado has been advocating in discussion in many forums about the language, the limited English proficiency issues in healthcare. The panel of economists -- I've been traveling all over Latin America and Europe, and in this global economy, depending what variables you use, you can have certain results.

In the psychological impact on the service because, and I hear colleagues talking about nurses and their coalition has been working with binational, with Mexico and United States, with a shortage of nurses and the difficulties and barriers of not having cultural competent nurses. They can deal with medication. I hear about how much they need to pay attention, how much medication, and I want to wondering for many

institutions, how many bilingual nurses we have.

I agree, I think the issue with the new models, that I think it to serving more than 46 million people who don't speak English, what kind of model we can use that the coalition has been allocated. And we were able to implement in the city of Chicago the outreach, a community health worker who can work with a doctor and nurses and work on the time the nurse is spending with a patient about communication of medication.

And sometimes we use, I don't want to repeat myself with things that you maybe know, but that violation of having no adequate system for people costs the system much more money -- it maybe costs $300 to address later for a patient to add to those needs.

I think if – I'll be a planner in dealing with the economy - we need to shift the way we deal with different groups. I mean Chicago has 87 different ethnic groups, and I have personal experience doing that outreach; the follow up with a doctor in diabetes clinic, chronic asthma, name it. When you have a team with outreach workers who know the culture and the language, and different cultures, Korean, Chinese, Hispanic, the system works better, and we save money through prevention in healthcare.

So it's interesting to say that I don't think one group, the private sector or the public sector, can do independently good things. I think what Dr. Blum mentioned, I don't want to elaborate, but I think he made excellent points that we need to work on different ways to approach the systems. And evidently systems -- the planning system in public health is not working with the shift of the population that we have.

So I challenge the panel, the group, and again I'm very confident from the years that I have been working, probably 20 years in advocacy, on the consumer in general. And Dr. McClellan is really doing an excellent job because to have a portable laptop going to different communities, the church, whatever, and be sure that we communicate with Social Security and see through the card how we can help people to change medication. It's like the electronic system is working.

I think that we cannot protect ourselves for fears. I don't think we can avoid changes in technology because we are scared. And sometimes we move into this to benefit our institution, our system, because we fear change. So that's my comment to the panel. Thank you for the opportunity.

DR. SIMON: Thank you very much.

First Chris, then Dan.

DR. CONOVER: I don't know a lot about this area. I'm just curious from your perspective, in terms of how the regulations about having translators, et cetera, are done today, is there any room for improvement in those? Any ways in which we could do that less expensively?

MS. SCIAMMARELLA: I don't think -- this is again how we evaluate how expensive a system is -- it's expensive when we need to serve a consumer, or is not expensive when I need to protect that system. What is important? And I think sometimes we are not driving for the needs of the consumer.

I was part of the first reg. in FDA. I'm a breast cancer survivor. And I was, I formed part of, as a consumer, their reg. for FDA for a standard of care for mammogram, and sometime people in an institution or organization missing the point and what is needed there. And I think it's very valuable that sometimes hospitals I mean, I wanted to say, there are things that I leave out every day. I don't know. Sometimes we want to promote what we are doing. And we think we're doing well and we are not doing well.

When CMS returns money to the hospital, the money that goes to the hospital is, if you are a

member, if you are not member you maybe are uncompensated for the uninsured people who cover the hospital in that community. So I'm really telling you that studies demonstrated that it's not costly. But because nobody wants to hire interpreters -- they think it's, we have, it's a lawsuit because of these things. And again, it's because doctors think that it is too -- so we practice a defensive medicine here.

So it's easy to get a janitor or something in the family to translate. There are many cases that I don't want to enter into, where people misuse medication. Don’t you think people say yes, yet they have no clue how many pills to take. They take three every one hour, every two hours, or they take three together. There are many cases.

So when you compare this to hiring a translator, or then consider the lawsuit because some person misuses the medication or has an operation that they don't need to be performed, or they don't follow a treatment. Think how costly that.

DR. CONOVER: When you get down to the individual patient level and a patient needs care, and the issue is do you have a translator or not. I mean I understand what you're saying. You know, it's smarter to have the translator there.

The concern I have is, you said there's 87 different ethnic groups just in Chicago. So I'm trying to imagine a provider having the capability to provide translation 87 different ways. In theory, just because at any given time they don't know if a patient is going to show up.

MS. SCIAMMARELLA: You can use AT&T or other companies, they can do translations. The issue is to guarantee that institutions - I don't believe that people who can serve, maybe I'm wrong, they need to clarify to me, that we have a good ratio of nurses and doctor who can cover the services that we need.

And I say, when I say translator, I don't ask you to have bilingual-bicultural doctors, but we need to have services. We need to see that aspect and I don't hear -- it's just negative impact to have solution for people who don't speak English not to provide a service. I mean I have other documentation, California for the one point, California has the same problem. In Texas the majority people and California. In Chicago we are 30 percent of the population who are bilingual. And I tell you that half of those may, when they go for service, they need translators.

So again, what I'm saying to CMS and to the system in general is that we need, the different

offices need to collaborate to be sure that no one of the regulators are really implemented or take their time to analyze the cost to see that we are violating the healthcare system because we cannot offer adequate service because there is not an adequate system to translate the service patients need.

DR. SIMON: Dan?

MR. MULHOLLAND: Just a brief follow-up on that. In my experience, a lot of hospitals aren't even aware that there are rules about limited English proficiency. And they literally require, when you get into them, that you have access to about 187 linguistic groups. And the only way you could do that is through a professional translator.

But one of the problems is that they're really not rules. They're interpretive guidelines from the Office of Civil Rights. And I just wondered if you would comment on the need for perhaps more clarity and definition about what the rules are. And then flexibility, too, in terms of family members, because that's often the most readily available source of translation.

I understand now, they're beginning to push back on that. Some suspect it's the professional translators who want more business and don't want

family members in the way.

MS. SCIAMMARELLA: Well they are -- husband working with the Office of Civil Right. The issue when you go and analyze the whole thing is minimal; the one percent of the population. The need depends on the quantity of patient they serve. So if I need to go to a hospital and I see they are one percent, less than one percent, no. But Vietnamese, they need to have somebody who speaks Vietnamese. I mean it's not only the Hispanic community. There are many systems.

The issue is, they don't pay attention to this, when you compare the problem that you have serving people who have no -- we will have more disparity here than ever because if you cannot tell people what system or what you need to take care, I mean I cannot speak to understand it. We don't communicate it. I mean I don't want to do that, but that's, it's a big issue.

And I think when the institution or the system in this case, I again repeat to Dr. McClellan who was very sensitive in the FDA and here, that when you have interest or have a vision, not because it's a personal interest, but you see what is happen in the country about the serving minority population. You need to be prepared, and CMS is translating materials.

The problem is the institutions providing those services don't enforce, or don't pay attention to that.

I mean we, the organization, we are literally fighting about what kind of system we need to have with nurses. We have a bilateral, we discussed this to have nurses to come -- it's easy to come from Canada to here through the bilateral agreement to provide service. Social worker, nurses, from Mexico, to come and get training and go back to Mexico. And then we're talking about the burden that people cross the border and come here to New Mexico or Texas.

The issues again, we need to be more global, since we have a more global economy. We've got different people. They will not stop coming here from all over the world, or vice versa. But to have certain systems that are more sociable to the population that they service. It's a recommendation to review this system. Okay. Thank you very much.

DR. SIMON: Thank you.

And I want to thank the audience and the presenters for, excuse me, for your comments this afternoon.

We have about 15 minutes and, as I promised the panelists the last time, those of you who weren't here the last time and are now obligated to the

recommendations of the prior generation, is that we take a little bit of time at the end to ask you to -- all right, who did that –- to wrap up a little bit in your own sense, discuss, debate with each other.

And so what I'm going to do is I'm going to ask sort of each of you to sort of expand on a theme that came up in the last few hours, make some overarching comments. All those things that you've just been dying to get off your chest, and I cut you off before. Now is your opportunity, so don't blow it.

MR. MULHOLLAND: Just two comments that I thought I saw as themes coming through today's testimony, which are kind of troubling and I don't know how you quantify them.

One is that there's a lot of different regulations that have an adverse impact on access. You heard the gentleman from the Illinois State Medical Society talking about how doctors were dropping out of Medicare because of the complexity and costs of the payment system. The LEP, Limited English Proficiency regulations, or lack thereof or confusion about it or another, where that could actually hamper people getting emergency care. You know, the list goes on and on.

The other theme that I thought was

particularly troubling was that a tremendous amount of time is being diverted from direct patient care to comply with a lot of confusing and arguably unnecessary regulations. I don't know how you would quantify that from an economic standpoint, but that's the theme we hear again and again from our clients, is that the regulatory system is tying both hands behind their back and one foot, in terms of letting them provide care to people in the way that would best address the healthcare needs of the people they serve.

So I thought that came across, you know, loud and clear in a lot of the discussion today.

DR. MORRISEY: Two themes that emerged from my perspective.

One has to do with a sense that there are regulatory issues out there, when in fact what we're seeing is contractual arrangements by other names. If it's done in the private sector, it's a contractual arrangement. If it's done out of government auspices, it's regulation.

And while clearly there are rule making differences and all of that, at base there's not necessarily a lot of difference between the two of those. And one shouldn't expect that if the government is doing what largely the private sector is doing as

well, there's probably not a lot of cost savings to be achieved by changing those regulations.

The second point that I would raise is that it's fascinating to sort of listen to the discussion of the extent to how my particular group's world would be a whole lot better if some other group incurred additional regulatory costs. Physicians with respect to suppliers bearing the costs of filling out forms, employers with providers bearing the costs of providing price and quality data, to give just two examples.

DR. DRANOVE: There's a lot of different things that came out. Let me try to take a couple of the most salient. Bob Helms would probably be embracing the capture theory one more time. But I think even the most cynical opponent of regulation probably will find that for every regulation there was at least one credible reason for it. And there are a lot of regulations that actually make sense.

People have been calling for certain changes in regulation for a long, long time. I mentioned the National Health Planning and Resources Development Act in 1974. Anybody would be well served to go back and look at what people were saying about the problems of the healthcare system at that time.

And the big one, we heard this time and time

again today, was information systems, problems with communication from one provider to another, from one provider to a patient and another. And when I hear the same complaints being raised, and I'm embarrassed to be old enough now to actually have heard these raised more than one generation apart, one has to ask has something fundamentally changed in the world that makes us think that we can solve this problem better today than we could 20 or 30 years ago. And if so, then we'd better use that as our solution.

And the problem that I hear, for example, consumer driven health plans and big deductible health plans, there's nothing different about that today. Somebody's just reinventing an old wheel. That's not going to solve anybody's problems.

But information technology today is quite a bit different from information technology 20 or 30 years ago. And I'm a real firm believer that if we can unlock the key to standardization, then lots and lots of good things will follow. And I'd like to see a lot of effort put in that direction.

DR. SIMON: All right.

Chris?

DR. CONOVER: Well, let me echo on some of these comments. If we start from the premise that

every regulation had a reason or a defender, or something like that, it seems like we've drawn a continuum. And some of the low hanging fruit are things like someone said, well, we could have simple changes to COP's to move away from paper. Hopefully that would be relatively easy to do. There's not a whole lot of vested interest in that.

But moving up the tree, things like eliminating duplication and conflicts between levels of regulation, federal versus state, that might be harder to achieve because, you know, some people may have more vested interests in those. But it would be hard to defend those things, you know, saying, well, we ought to just keep it this way because people don't want to change. So I guess it would be a good idea to try to change some of those things.

Interestingly we've had some, more than one person's come up to say we need greater enforcement of existing regulation. So the problem isn't too much regulation, maybe it's too little regulation in terms of enforcement.

And I also was surprised to hear people actually advocating for the federal government to come in and basically set the standard to, you know, as opposed to relying on the market to work some of those

things out. And that strikes me as being maybe there is a lot of promise to it, but it also strikes me as being a harder thing to achieve.

So the most promising thing I heard today was trying to come up with better methods for reaching consensus and doing regulation less rigidly. So the first four of those things are sort of treatment of the existing problem, and the last step is sort of maybe we can avoid having this conversation 20 years down the road and spare David another panel.

MR. MULHOLLAND: If I could just make a comment to respond to something Mike said about the difference between a regulation and something that's essentially contractual. I think there's a very fundamental difference between the government contract and a private contract for two reasons.

Number one, government contracts are not really contracts. They're the result of a government program. You could choose to participate in it or not. Beyond that there's no negotiation. The government sets the rules. Plus the penalties are 100 times more severe if you violate government regulations or government, quote, unquote, contracts like the conditions of participation. You can have liability under the False Claims Act. At some point you may even

have criminal liability. Whereas, if you breach a private contract or allegedly breach it, somebody sues you. And that's not the end of the world. In fact, that's kind of a good thing when you're a lawyer.

But the real concern is that when government starts setting these rules, more often than not what I've seen, especially in payment policy, is that the private payers follow the government rather than vice versa. So I'm not sure that the same rules would be applied by the private sector, unless the government has set certain standards that may or may not be economically efficient. And then they're either aped or followed voluntarily by the private sector.

So I think we need to distinguish between the affect of a government contract and what two parties at arm's length in the private sector would agree upon.

DR. SIMON: Actually I've been the traffic cop all day, and I want to get behind one of the race cars right now.

I also found that analogy to be very interesting because in many ways you might think of the government in many ways a monopolist in this respect. And there isn't competition around those contractual terms, like you'll see in the marketplace.

And so if I write a stupid contract and,

unless I've got a great lawyer like Dan to defend me, it's going to affect my bottom line in business, the marketplace. Competitors will write a better contract and put me out of business. And those same sort of forces don't exist in the regulatory arena.

And so I think there's some very important distinctions in terms of what the margins for change are when there are errors, in both the regulatory realm as opposed to the private contracting realm.

MS. SCIAMMARELLA: It's interesting to hear the Chamber of Commerce. Two years ago, I think, the government call in Washington for discussing the uninsured, particularly in this case with Hispanic about the small businesses to try to get an insurance for the uninsured. There was another issue. Nothing. And I'm still, we're still discussing this.

The people come buy insurance and try to work out something to depleted the burden of uninsured people. And I never hear a general statement without knowing that they are not in response to only the private sector, to respond to see how we can buy insurance for the business people. That these people don't burn the system, not the private sector, not the public sector.

And the other thing is we talking about money

and economic free trade between Mexico and United States. There is room to get certain quantities of money to support uninsured people, to pay hospital institutions. It's nothing has been done for that. And they need to discuss with the Department of Labor about how we can use better pull between government and private sector to have more incentive for people who are more uninsured than insured.

DR. SIMON: All right. Thank you.

All right. David.

DR. DRANOVE: I think your example of trying to pool small businesses into an insurance pool actually makes our point and supports Mike's argument very clearly.

Insurance companies, private insurance companies, are voluntary pools of employers. So, too, are all of the state proposals and the federally sponsored state proposals to create such pools. The fact that so many small employers do not participate in the private sector should've been a very strong indication of what was going to happen when the federal government tried to replicate a private sector type program.

I think, on the other hand, it's absolutely true if you look at some of the major reforms in

payments from payers in the private sector, they follow on the heels of what the government has done. You know, when you rank right down with tobacco companies in terms of how the American public views you, you're not going to be very innovative. You're going to be very gun shy.

And in fact, there's one thing to remember, anything innovative that the federal government does in terms of payments is likely to be followed by the private sector. Having said that, if the private sector and the government are both doing something at the same time, that's probably a good indication that it's not such a bad thing after all.

DR. MORRISEY: Which was indeed my point to begin with.

(Laughter.)

DR. SIMON: And that may be the best place to stop right now.

I want to thank you all for your time, for your attention. And oh my God! We are right on schedule. I don't know. They closed the doors so we can't see if the snowflakes are falling, but I wish you a -- is it already? It's snowing. Well, it's Chicago.

I wish you all safe journeys home. And that particularly for the participants in the audience, I

encourage you to contact us. My contact information is on the participant list. The websites are up 24/7. And thank you so much for your participation and your time. Thank you.

(Whereupon, at 3 p.m., the meeting was concluded).