U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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TOWN HALL MEETING

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THURSDAY,
NOVEMBER 3, 2005

The Public Meeting was held in the Lower Level Conference Room of the Washington Court Hotel, 425 New Jersey Avenue N.W., Washington, D.C., at 10:00 a.m., Carol Simon, moderating.

PANELISTS:

CAROL SIMON, Moderator

CHRISTOPHER CONOVER
TED FRECH
MARK HALL
RICHARD LAWLOR
MICHAEL MORRISEY
DAN MULHOLLAND

SPEAKERS PRESENTING COMMENTS:

RENE CABRAL-DANIELS
TOBY EDELMAN
SANDRA FITZLER
WALTON FRANCIS
FRANCIS KIRLEY
LAURENCE LANE
JANET WELLS
MARY ST. PIERRE
TERRY MAGGIO

A-G-E-N-D-A

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

10:03 a.m.

DR. SIMON: I think we're going to get started now. I want to welcome everybody to our first meeting on the Economic Impact of Health Care Regulations at our first town hall. My name is Carol Simon with Abt Associates. I'm going to be moderator today and general timekeeper and public traffic cop for the proceedings.

I want to thank you all for coming and particularly on this gorgeous autumn day in Washington. We have an important agenda that as you are going to be hearing from the commentators, from our panelists, and from our representatives from HHS is that this is a kickoff of a important process in which HHS in conjunction with OMB are collaborating to take a good solid look at the economic costs of health care regulation.

The purpose of today's meeting is to hear from you, the stars of today's meeting and the important information that is coming from the floor.

This is a public forum for us to receive commentary, receive evidence.

We have assembled a panel of experts who are going to be here to assist me and to assist our staff in helping put some of the comments in perspective, to ask potentially clarifying questions, and in general to make our day go in what we hope is actually an informative and somewhat delightful process.

Without further ado, what I would like to do is turn over the podium for some opening remarks to Marty McGeein. Marty is Acting Deputy Assistant Secretary for Planning and Evaluation or ASPE.

Marty, thank you very much.

MS. McGEEIN: Thank you, Carol. I will be followed by a representative from OMB. Thanks for taking part in our initial town hall meeting. It's sort of like a dinner party with a lot of preparation and now we are about to eat.

As Carol said, I'm Marty McGeein with the Secretary's Office for Planning and Evaluation, or ASPE as we are more commonly known. Many things have

changed over the last decade in health care. The one thing that never seems to change, however, is regulation.

The chief complaint, using the language of my clinical background, is about how Government regulates and whether it does or does not distort practice. Would you be doing what you are doing with or without the regulation.

Oh, you can't hear me? How unusual. When ASPE accepted the assignment to examine the economic impact of regulations on the health care sector of our country, we made some very important decisions.

First was while this examination could be an academic exercise in that we could look to the literature for answers, we quickly decided that the literature that we needed to hear or to examine were the reports on the charts of the people who live these regulations every minute of every single day. You, the providers of health care, and the representatives are those people.

Our second decision was to ask you what you think, to ask you basically what the symptoms are.

That led to the Federal Register notice which some of you read and commented on seeking comment on the quantification of this issue, the town hall meeting, this first one, the three that will follow in Chicago, Oklahoma, and San Francisco, plus numerous, numerous conversations with what we know as the Washington health community. These efforts are what I will call the preliminary lab results. So far the patient isn't dead.

Our third decision was to make some house calls. We plan to do a series of case studies in the field to help us dig really deep into this issue to find out exactly what is going on on the ground. Abt Associates will be helping us with that effort as well as some of the analytical work.

I'm anxious to get started to hear what you have to say. You are serving as part of our data gathering process. But I'm also anxious to let you know what we're doing. I believe that one of our panelists, Rich Lawlor, will be sharing some of the exciting and creative initiatives that Dr. McClellan and Dr. Lawlor are implementing at CMS.

I would like to say let's begin but before we do, let's have a few words from OMB.

MR. SAADE: Good morning. I just want to say that we at OMB are very pleased to be part of this process. We have been linked at the hip, I believe, with the folks at CMS and we are really pleased to be part of that process. I'm definitely looking forward to listening from the community here today and report back to my office. Thank you.

DR. SIMON: Okay. Before we get started with introductions on the panel and then the important public commentary, let me go through a little bit of the logistics.

For those of you who have signed up to present comments today. What we are going to be doing is I'm going to be operating from the public sign-up list form which means that in the order in which you arrived today is the order in which I'm going to be taking for public comment. What I will be doing is calling you to the microphone, giving a brief introduction, allowing you to more fully introduce yourself, and then allowing between five to seven

minutes for presentation of public comment.

At the close of the five to seven minutes, and I think we have the luxury today of perhaps a little bit more time so I'm not going to be too strict of a guardian on the time frame but within the constraints we want to make sure everybody has a chance to get their due.

At the close of the public comments I'm going to be asking our panel if they have any questions and the questions are meant to be clarifying extensions, commentary, not an engagement in extended academic debate. Right, guys? You hear me. Just remember we control the microphones at this end.

As we said, the important part here is to hear from the public. The important logistics, there's water to the side of the room and the converse restrooms at the back. We are going to be running until about noon today at which time we are going to take about a 45-minute lunch break to allow folks to sort of re-energize themselves and then continuing on after that.

I'm going to try to let you know where we

stand so if, indeed, you have signed up in advance or signed up today to present public comment, please make sure that your name is on this public comment sign-in list. This is essentially the dance card I'm going to be pulling from. I'm going to try to let us know in terms of where we stand so that you can make your own personal arrangements as to when you need to be here.

I think we can run this pretty not informally but a little less rigorously than if we had 100 people in the room so there should be ample time for good discussion and a little bit of question and answer.

Without further ado, what I would like to do is introduce our panel and let them introduce themselves a little bit quickly and then we'll move to the public commentary.

Our first panelist here is Professor Chris Conover from Duke University. Chris is with the Center for Health Policy as well as with the School of Public Policy at Duke. Chris has an impressive background in doing regulatory studies on the impact of health care. Without any further ado, Chris.

DR. CONOVER: Good morning. It's a pleasure to be here. I have done work for various states on certificate of need regulation, hospital conversion regulation, and regulation of conversion of Blue Cross and Blue Shield plans before profit status.

Most importantly, I spent the last three years under a contract with the Department of Health and Human Services working on a global estimate of the cost and benefits of health services regulation. Preliminary findings from our work are contained in your handout.

We wanted to know in this study how much of the phenomenally high cost of medical care in the U.S. can be attributed to health services regulation. A related question of interest to me is how many uninsured might be covered where we could reduce this sizable regulatory burden.

We examined the literature for nearly 50 different kinds of federal and state health services regulations including regulation of health facilities, health professionals, health insurance, FDA regulation, and the medical tort system. These various regulations

covered the gamut from mandated health benefits to state certificate of need requirements for hospitals and nursing homes.

We systematically tallied the benefits and cost associated with such regulations and found that the expected cost of regulation in the United States amounted to $339 billion in 2002. Our estimated benefits was $170 billion leaving a net cost of $169 billion.

We found that the states and Federal Government both have roles to play in order to reduce this regulatory excess. It was not the purpose of our study to make recommendations on specific regulatory reforms to be pursued. Instead, we were trying to provide something that has never before been achieved previously, a big picture view of the overall impact of health services regulation with the intent of identifying areas where regulation might be excessive.

For all of the areas so identified one would have to rely on further study or experts to sort through the best approach to reforming that aspect of regulation. In all likelihood only in some of these

cases would experts conclude that we should dispense entirely with regulation.

How do these figures relate to the uninsured? Our figures imply that the net cost of regulation imposed directly on the health industry is 8.9 percent meaning that health expenditures and health insurance premiums are at least that much higher as a result of regulation.

Based on consensus estimates about the impact of higher prices on how many might drop health insurance, this increased cost translates into 6.8 million additional uninsured whose plight might be attributed to excess regulatory cost, or roughly one in six of the uninsured.

There is a different way of looking at the burden as well. Although our estimates are still preliminary and we are engaged in a careful process of updating them and ensuring that they are accurate, it seems unlikely that the adjustments yet to come would alter this central conclusion.

The overall excess cost of regulation in the U.S. exceeds by several orders of magnitude the

amount that would be required to cover all of this nation's uninsured. In the context of the Institute of Medicine finding that 18,000 uninsured die every year due to lack of coverage, is maintaining our current regime of health regulation worth letting that continue?

I think this is a question worthy of serious consideration as we consider how to strike the proper balance between the benefits and cost of regulation. I welcome this opportunity to hear first hand from you how to do regulation better.

DR. SIMON: Great. Thank you very much, Chris.

Our second panelist is Ted Frech. Ted is a Professor of Economics at the University of California, Santa Barbara. Ted.

DR. FRECH: Thank you. A lot of my research over the years has been in health economic issues, way more than half, especially competition and regulation issues. I have published over 120 books and articles. Perhaps the most notable one in this context is Competition and Regulation of Medical Care. It's

AEI Press 1996.

I've also worked as a consultant and expert witness in health care competition and regulatory matters at various levels. I've testified in the Senate, the Massachusetts legislature, Massachusetts Insurance Commissioner, the FTC and Department of Justice. The topics I've worked on include health insurance, hospitals, physicians, malpractice, and probably some others I haven't thought of.

DR. SIMON: Thank you, Ted.

Our third panelist and, if you haven't noticed, we are going alphabetically, not in any other order, Mark Hall. Mark is a professor of law and public health. He comes to us today from Wake Forest University School of Law and also School of Medicine.

Mark.

MR. HALL: I think I have two areas of activity that are relevant to the focus today. One is that I have spent several years studying insurance regulation, initially in the states but also as those models of regulation have been adopted in federal laws

as well. That is one field. The second is I have worked with Chris Conover in doing some pilot case studies, field interviews with hospital administrators and senior executives about the burden of regulation attempting to determine to what extent we can document the burden of regulation through in-depth interviews.

DR. SIMON: Thank you very much. I'll be technologically savvy by the time this is done.

Our fourth panelist comes to us from CMS, Rich Lawlor. Rich is the Director of Outreach and advisor to the administrator at CMS and also runs the popular Open Door program.

Rich, you want to tell us a little bit about that?

DR. LAWLOR: Thanks. Yes. I'm probably the least published of any panelist up here today. I can count all those publications on less than one elbow. I do work within obviously an agency that has to deal with updating and renewing and improving regulations on a daily basis at a very rapid pace, in particular since the Medicare Modernization Act was passed less than two years ago.

The Open Door forums are an outreach program so as far as considering this a mini-laboratory, as was mentioned earlier, for input, we do that on an almost daily basis doing almost 200 forums a year with all the types of providers that we regulate. I think what I bring here is sort of a tempered ear to a lot of these concerns that are raised. I hope that this panel can help address some of your ideas and point out some of the ways that we can expand the perspective around any individual concern to make sure that we are looking at this as holistically as possible.

One funny thing that I would like to point out is that I don't know how they choose these conference rooms but they've got pictures of monuments all around us and maybe modes of transportation, but this one looks like there's a blimp about to hit a building. This one over here is a federal monument with no head.

It's really hard to say what's going on here, but CMS is very grateful to be at the table with these excellent economists to do this discussion with

you under really the charge at the Health and Human Services Department.

We do work with all the other agencies within HHS when it comes to developing these regulations so maybe my perspective of having listened to you and sort of interacted with all the different stakeholders that we have can be useful and I'll try my best.

DR. SIMON: Rich, we are very happy to have you and CMS here today represented.

Our fifth panelist comes to us from the University of Alabama at Birmingham. We seem to have the south very well represented here today. Mike Morrisey is a professor at the School of Public Health and an economist as well by training.

DR. MORRISEY: Yes, indeed. Health economist focusing on issues of hospitals and employer-sponsored health insurance markets.

With respect to regulation most of my work has looked at the effects of state regulation focusing on certificate of need, any willing provider laws, health insurance mandated benefits, small group reform.

I am currently looking at malpractice reform issues. In a broader context very interested and have worked on issues of competition and hospital cost shifting.

DR. SIMON: Very good. Thank you.

Our final panelist, Dan Mulholland, is a practicing attorney with Horty, Springer & Mattern in Pittsburgh.

Dan.

MR. MULHOLLAND: Thank you. Hello, everybody. Our firm does nothing except represent hospitals, health systems, and their medical staff leadership around the country. I have the pressure, or the curse, of having to deal with the regulatory system day in and day out on the receiving end.

I'm particularly interested in some of the non-economic cost of health care regulation, specifically how regulation can change behavior to the point of preventing efficiencies from being achieved and delivery and access to health care services.

Two brief examples. We represent a hospital in Pennsylvania in a small county adjacent to Allegheny County where Pittsburgh is located. This

hospital was able to build a cardiac surgery program over the last five years primarily because Pennsylvania got rid of its certificate of need program in 1996.

In that county there has been a reduction in cardiac related deaths, avoidable deaths according to the criteria in the Dartmouth Health Atlas, from 111 in 2000 to 38 this year. Dramatic decrease in deaths simply because that hospital was able to put in a heart program.

Whereas in Georgia where we represent a similar hospital in a similar-sized county, that hospital was struggling to be one of a few who might be approved for this C-PORT program which would allow invasive cardiology without a cardiac surgery program simply because Georgia has an active certificate of need program and it would be beyond a realm of comprehension for a community that size to have a heart program.

Another issue that we faced in the non-economic cost of health care regulation has to do with the confusion and sometimes the contempt that people who are regulated can have for the law. Brief example

here has to do with the EMTALA statute, the Emergency Medical Treatment and Active Labor Act.

In the last month I've had two different clients ask me if it was okay to reserve psychiatric beds for anticipated admissions from some source other than the chaotic first come first serve that is mandated by EMTALA. This was not just to get maximization of reimbursement.

One hospital wanted to have an arrangement with the community mental health provider to provide for better transition for people who needed to be admitted. The other wanted to reserve beds for people coming out of the emergency room knowing that on a regular basis the police would bring a lot of people there.

Neither hospital was able to come to the conclusion that it could safely do it without risking legal sanctions simply because they had an obligation not only to take all comers out of the ER, but also anyone who would be transferred. As a result, those hospitals are stymied in terms of what might be a better way to provide psychiatric service to an

endangered population.

In my practice I often hear clients throw up their hands and basically say that they have no respect for the regulations because no one can understand them and no matter what they do at some point they could be called to task. To the extent anyone has any observations on these non-economic costs, I would be very interested in hearing them. Thank you.

DR. SIMON: All right. Thank you very much. I seemed to be glued to the floor.

What we would like to do now is begin the public commentary portion. What I'm going to do is, as I said, be operating off of the sign-in sheet that you may have completed on your way in. I remind you if you would like to present public commentary, please sign up on the sheets outside. This is going to be our vehicle for calling people to the microphone and for identifying you.

We have two microphones set up. Please use the one that is most convenient. I would ask you to identify yourself, identify the organization that

you are with or speaking on behalf of, and then I will leave the floor to you.

We have a timer here that is going to go for roughly five to seven minutes. I'm going to be a little generous around that this morning because I don't want to cut off anybody who has important things to tell the audience. If you are still going after 10 minutes strong, then I'm going to get a little bit more forceful in my role up here just so that we can make sure everybody has their due. Everybody fine? Very good.

Toby Edelman.

MS. EDELMAN: Good morning. My name is Toby Edelman. I'm a Senior Policy Attorney with the Center for Medicare Advocacy, which is a public interest law firm that represents Medicare beneficiaries nationwide. I have quite a different perspective from members of the panel. For at least the past 25 years, we have heard from one task force and committee after another complaining about the regulatory burden. Advocates for beneficiaries have a different perspective. Many of us believe that federal

laws and their implementing regulations can serve the critical function of protecting beneficiaries of federal health programs.

We also know that to be effective laws and regulations must be specific and enforced. In the absence of strong standards that are enforced poor care often results. Government is then forced to spend money to try to repair the damage that could have been avoided and health care providers may be forced to repay the Government for their reimbursement and then may be forced to repay beneficiaries for the harm they caused.

While de-regulatory task forces always focus on the cost of regulations, from my perspective they fail to look at the benefits of the regulations or the burdens on the public in general or on program beneficiaries in particular of failing to regulate adequately.

I just offer one example this morning, nurse staffing standards for nursing homes. The Federal Nursing Home Reform Law that was enacted in 1987 called for nurse staffing that was "sufficient to

meet the needs of residents." Nearly a decade after that law went into effect the Department of Health and Human Services reported that more than 92 percent of facilities did not have sufficient staff to meet the standards of the law. The vague statutory and regulatory language was insufficient to compel good practice and it was, of course, very difficult to enforce.

At about the same time that HHS was reporting that staffing was inadequate, Congress responded to the nursing home industry's complaints about changes to the Medicare reimbursement system and increased reimbursement for skilled nursing facilities.

One increase was specifically focused on nurse staffing and the nurse staffing component of the prospective reimbursement system. Despite increased reimbursement for staffing the Government Accountability Office found that staffing remained stagnate. In fact, the numbers of registered nurses declined after Congress increased reimbursement for nurse staffing.

The GAO reported that nurse staffing

increased primarily in the handful of states that mandated specific staffing ratios. The federal standard was too vague to compel facilities to have sufficient staff. In other words, Congress and HHS told nursing homes to hire enough staff and then paid extra to employ more staff but neither approach was successful to assure adequate staffing.

What are the consequences of inadequate staffing? There is universal recognition that staffing is highly correlated with good care. When staffing is insufficient residents suffer harm they should never have suffered. The Government pays for poor resident outcomes when residents are hospitalized with bad outcomes. So significant is this cost that the Government's pay-for-performance demonstration program for nursing homes is focused on reducing hospitalizations as a major component.

As for facilities they are sued by the Government and by resident's families. One example, last month the United States and the State of Missouri settled a false claims act case with management in three of its facilities. The company and facilities

were required to pay $1.25 million in civil penalties.

They are subject to separate litigation to collect back the money that they received for reimbursement for care that they did not provide and the possibility of criminal prosecution is still there. What did they do wrong? They basically failed to employ sufficient staff to meet their residents.

This is how the settlement describes the problems that resulted from poor staffing. "The facilities failed to provide the required services to certain residents as evidenced by dehydration and malnutrition of residents, elopements of residents, residents contracting preventable pressure sores, residents being found soaking in their own urine and feces, residents going for extended periods of time without cleaning or bathing, insect infestation, resident abuse, and general lack of quality care." The management company in all three facilities are now permanently barred from getting Medicare and Medicaid reimbursement.

The U.S. Attorney's press release was even more specific in describing some of the gross practices

and situations in the nursing home. She describes elopements, a resident being found covered with ants, and a resident found to have been physically abused by a staff member.

From my perspective and the perspective of many beneficiaries' representatives, health care law and regulations serve a very important purpose in ensuring good care for beneficiaries. Thank you.

DR. SIMON: Thank you, Ms. Edelman. I think this is an important comment for us to remember, to keep a clear eye open from the intent of the regulation as well as an important discourse on the policy. May I open this to any of the panelists?

DR. CONOVER: Well, one observation I would like to make is that when we did some of this case study work and went out in the field and actually talked to nursing home operators, the picture that got painted was that too often regulation is overly prescriptive in terms of how to achieve an objective and their claim was that if they had less regulation, they actually would keep the same staffing levels but be able to provide better quality care. That's a

little bit different perspective. I think the key is right. Carol is right. We have to look at what's the objective of regulation and what's the best way to achieve that objective.

DR. SIMON: Other comments?

MR. MULHOLLAND: Just one brief comment. I heard from my cousin who runs an -- she is an administrator for a nursing home in New Jersey that it takes her two FTE nurses in administration simply to comply with all the regulatory requirements they have.

I think you raised a good point, Ms. Edelman, about nurse staffing being critical to good patient care but if regulations are too prescriptive, on the other hand, you could be sapping a lot of talent that could be delivering care to people and instead handling the paperwork and other requirements that come with the regulations that these nursing homes have to comply with.

I think you raise a good point that if you are going to try to provide care to people, let the providers provide care rather than have to spend a lot of time handling paperwork and other matters that could

be the by-product of regulation that is overly prescriptive.

DR. SIMON: Thank you very much.

Ms. Edelman, just a reminder to make sure that we have a copy of your testimony at the front or submit it through the web for other folks who may also want to either submit comments at today's meeting or subsequent to the meeting. There is also a website available to make it easy for you to send in electronic comments.

I and my colleagues who are helping HHS and ASPE in terms of assimilating the information and analyzing it rely very heavily on receiving your public commentary. In particular commentary which, as we have just heard, is specific about the nature of the impact and offers constructive recommendations and helps us to get a good handle on both the cost side, the benefit side, and the barriers. I think the barriers may be described as barriers to good quality care as well as barriers that raise explicit costs so I thank you very much.

MR. HALL: I had a question.

DR. SIMON: I'm sorry, Mark.

MR. HALL: Yeah, sorry. I guess it is my understanding that the panel can ask questions. Is that okay?

DR. SIMON: You betcha. That's the game plan.

MR. HALL: I think the nurse staffing is a good example so I thought I would spend just a minute or two thinking about that example. One question is viewing that as a successful regulation whose benefits outweighs cost and, therefore, good regulation. Do you think there is a case to be made that it could be even more beneficial, that it could be even more cost effective, and it could continue to achieve 99 percent of its benefits by reducing some of its cost or is it at the right level of sort of benefit --

MS. EDELMAN: Are you talking about the Nursing Home Reform Law in general?

MR. HALL: Yes.

MS. EDELMAN: Well, I think the Nursing Home Reform Law has had some beneficial effects.

MR. HALL: Sure.

MS. EDELMAN: The reduction of restraints in this country is an enormous change which also has saved money. There is considerable amount of research that indicates that using restraints for people is more expensive than not using restraints. But that practice, that good practice of reducing restraints came about because it was required by law.

I participated in the Commonwealth Fund meeting when they looked at the restraint reduction program that they had funded in some facilities and the question was raised is it worthwhile to have a program like this when the law already requires restraint reduction.

The research itself indicated that providers said they participated in the demonstration to learn how to reduce restraints because they knew they were going to be required to reduce restraints from the law. I think the law was an important motivating factor for those facilities. I think the law could be more effectively enforced. That is probably one of the major shortcomings of the law.

I would just say that the Nursing Home

Reform Law is somewhat unusual as a piece of legislation because it was based on an Institute of Medicine Committee Report, numerous hearings, and what was called the Campaign for Quality Care which was a coalition organized by the National Citizen's Coalition for Nursing Home Reform to bring together all the interested parties, the health care professionals, the industry, the advocates.

We sat for a year talking about what should be required by the law and basically the standards of care which you won't hear nursing homes generally complain about. The standards are good practices that were generalized to the whole country. I think that has been a successful law except for the enforcement which has been repeatedly criticized by the GAO. I'm not an academic but I did put a lot of footnotes for each of the statements I made in my paper and I will e-mail that do you as well.

DR. SIMON: We appreciate that.

DR. CONOVER: I have a related follow-up question.

DR. SIMON: Actually, Rich has a question

first.

DR. CONOVER: Oh, I'm sorry.

DR. SIMON: Then we'll circle back to you, Chris.

DR. CONOVER: Okay.

DR. LAWLOR: Thank you. I don't mind any order at all but thanks. First thing, of course, thanks for that example as well as a lot of the comments that you made going into it. Sort of our charge today is maybe to consider how regulations work. It seems to me that your example sort of begs the question what are the requirements or, more broadly, the devices in a regulation that can be improved.

I think without a doubt my eyes were opened five years ago when I entered into federal service that the purpose of a regulation is always altruistic and admirable. I've never seen one that's not. Getting rid of a regulation versus tweaking is really sort of the primary question a lot of us have going in at the agency level, too.

You talked about that particular regulation being insufficient to compel good practice.

Then went on to talk about some of the ramifications and litigation charges and sort of coming back again to maybe there is a need for enforcement in between those two sets of ideas.

Then also you brought up the pay-for-performance demonstration for nursing homes which I appreciate. That happens to be one of the particular discussions we had a separate forum on with the nursing home community. I think you were listening in on that recently. Marty McGeein pointed out that I would try to bring up a couple of things that our agency within HHS is trying to do as well.

I just want to point out that, No. 1, the questions that we need to sort of come back from these examples are in terms of -- and using examples is good -- what are the things within the regulation, the devices that sort of provide the checks and balances for how people react. You pointed out that the funds were given out and then somebody's investigation said that it never really -- there was no rubber on the tires in the end.

The pay-for-performance demonstrations

always start with generally a consensus building process to figure out what the metrics are that are going to lead to those payment incentives to make it improve the health care outcomes of the patients and their experience, or the residents in this case.

If you have any input as to do you think that demonstration project right now has an opportunity to address these staffing requirements or do you think that we need to look at a regulation now or do we wait on a demonstration?

MS. EDELMAN: I think HHS, from my perspective, has sufficient information from the huge study that it did itself with Abt and other people in the late '90s and beginning of the 2000s showing that 92 percent of the staff was the simulated part of the staffing but the facilities didn't have enough staffing to meet the needs so I think you have sufficient authority now or sufficient support for putting in staffing ratios.

The law says sufficient staff and that really is the way it should be done. Facilities should have the appropriate staff to meet the needs but it

hasn't worked. If it worked, we wouldn't have 92 percent of facilities not staffing appropriately. I think the demonstration is considering staffing as one of the components and that would be important but I have some other concerns about the pay-for-performance.

Chiefly I think this Missouri case shows that we already pay for performance. That's what we're paying for. Why should we pay extra money when we have already paid for the service. I think what a number of the states have done, and the U.S. Attorneys in these False Claims Act and other cases are saying, "You, the facility, did such an incredibly bad job, the care was so egregious, that we want our money back. You didn't perform at all. It's the opposite of paying for performance. You get paid for performing. If you do a terrible job we are going to take back our money. Why would we pay extra for doing what they are already required to do and paid to do doesn't make sense."

Then the part of the demonstration that talks about the lowest tier paid for improving. There was a lot of concern at that open door forum about paying for facilities that improved but if they are

still way below the standard, does that make sense.

We want to encourage improvement but why would you pay facilities more when they are still doing an inadequate job whereas other facilities are already doing a better job and they are not going to get the benefit of a pay-for-performance demonstration. I think pay-for-performance is very complicated. It sounds appealing. We should pay for what we want to see happen but there are a lot of difficulties with this.

DR. LAWLOR: The only thing I was just trying to point out, and I want to ask anybody else to include in their remarks, is parallel tracks on demonstrations versus regulations that are either not in effect now or haven't been invented yet. Do we just rebuild and repair regulations or do you consider running a demonstration and then an all or none approach on the regulation side?

DR. SIMON: Chris and then we'll go to Ted.

DR. CONOVER: I wanted to go back to Mark Hall's question and maybe ask it a little more

pointedly. From your point of view are there any aspects of nursing home regulation where regulation has gone too far and is overly prescriptive or anything like that?

MS. EDELMAN: Anything specifically in the Nursing Home Reform Law, those regulations?

DR. CONOVER: Yes.

MS. EDELMAN: You know, I really haven't heard even from the providers that there are problems with the substantive requirements in the reform law. Most of the complaints are with the enforcement system. They don't complain about the substantive requirements. I don't think they really are at fault.

In fact, there are areas where the law itself says states can go further. Talking about quality of life, requiring staff training of nurse aides, you know, at the time the law was passed half the states didn't require any training. Now we require training. I don't think that's anything we object to. Doing a uniform assessment.

I mean, I think these things are all very reasonable. They were based on good practices. Maybe

this is an unusual law because it really was based on the good provider practices that were going on. I don't think parts of the substantive requirements need to be changed.

DR. SIMON: Ted.

DR. FRECH: I want to kind of broaden or raise our level of abstraction, I guess. Seems that the ultimate goal here is to encourage higher quality care, particularly at the very lowest levels to get those up to a reasonable level.

It seems like this interacts with other regulations that we haven't talked about, particularly state certificate of need which is, in some states, very restrictive so it restricts the amount of competition among nursing homes and makes it even hard to get into nursing homes.

I wonder if you have a view of relaxing that would put less pressure on these regulations and lead to more competition and more availability of nursing home space.

MS. EDELMAN: Well, actually, most of -- I don't know how wide spread certificate of need is

anymore. At this point because nursing homes do have competition from other sources, other places, a lot of people are living in assisted living. Some of those people would have been in nursing homes. A lot of people are getting care at home that never did before.

Occupancy rates are extremely low. I mean, they can be in the 80s now. In certain places they are still high, in the high 90s but overall occupancy rates are very low because of competition from other choices for people so I don't know if certificate of need would help in that situation, reducing or eliminating certificate of need.

DR. SIMON: I think we are going to have to move on. Thank you very much, Ms. Edelman.

Our next commentor is Walton Francis.

Walt.

MR. FRANCIS: This is live, right? Hi. I'm Walt Francis. I'm an independent consultant and author. I specialize in consumer advice, particularly on health insurance, but I'm also allegedly a regulatory expert and worked for decades as sort of the regulatory czar in HHS to ensure compliance with all

the requirements for keeping regulatory burden minimal.

I have a whole bunch of points I want to make almost stiletto fashion about how I think this exercise should be approached and the kinds of things you should look at. I'll also follow up a little bit on our nursing home example because I think it's a really good illustration of some of the opportunities you have to do a great job.

We start with Chris' paper which is a wonderful paper. It is far and away the best job ever done on totalling up the cost of health care regulation despite the flaws I'll mention. But I want to urge you -- it's a score card. Okay? I don't think your exercise should wind up with a score card.

I think you need to look for targets of real opportunity for making a difference that matters. Areas that are big gains possibly in economic wealth because you can prove the benefits regulations or reduce their cost, or come up with regulatory alternatives that will be superior to existing approaches.

There is also a temptation to focus on

minutiae rather than policy in these kinds of exercises. I'm a veteran at many of them. I noticed that you had an estimate of the cost of federal regulation of organ transplant as $1.815 billion and the benefits are $1.807 billion.

Leaving aside the fact I couldn't figure out what -- I'm even an expert in that area and I don't even know what they are supposed to be but let's skip over that. The point is that in and of itself, and I'm not criticizing you for having that estimate but it's not a helpful kind of thing as a result so I don't want you to be producing results like that.

The cost estimate and the benefit estimate in and of themselves tell us absolutely nothing about whether or not there's a problem, whether there's an alternative that can improve things or not.

Another general point. It's easy to blame the bureaucrats for bad regulations. The reality is far more complex but the most important part of that reality is that all Government regulations come from law. It's the Congress and you ought to be careful in the work you do to distinguish reforms that can be made

by bureaucrats through the code of federal regulations as opposed to legislative changes that in many areas are vital and it's silly even to talk about what the bureaucracy could do differently without changes in law.

There's also a tendency, and I'm sure you'll avoid it particularly if this distinguished group continues with you at other meetings and other work that's being done, for each new reform effort to figure we'll review the world and discover the bad actors. Hey, the bad actors, I submit to you, have already been discovered. There has been an awful lot of work on reviewing oversight of federal health care regulations.

I won't go through the history but just recently former Secretary Thompson had a massive review involving providers telling them where they wanted things fixed and a lot of recommendations were made and a lot of changes were made. I'm not saying there is no more gold to be found but in a lot of areas there's probably not much.

I also think that there are some problems

in dealing with benefits that need to be sort of frontfully addressed. I noticed in the whole area of providing regulation Chris' paper estimates some benefits for nursing home regulation and no benefits at all from hospital or any of the other categories.

I assume that's because you couldn't find any credible studies that produced benefit estimates but there are benefits, okay? There is sort of a danger here in assuming that the benefits are nonexistent or much lower than expected.

The other problem, and I have no idea to what extent you were prey to it, not because of mistakes you would have made but because it's easy to make that mistake, there's a lot of federal regulations that simply ratify best practice, particularly in a broader area.

One of my favorite examples is we require hospitals to keep patient charts, the chart at the foot of the bed. OMB scores -- that's a paperwork burden, by the way, and it's huge. I mean, there's a lot of hospital patients. There's a lot of charts.

OMB scores the cost of that regulatory

requirement as zero. Zero in paperwork terms, in dollars for that matter. The reason for that is they don't count as regulatory burdens things that people are going to do anyway. Those charts are going to be there whether or not our regulation requires it.

I talked a little bit about fruitful targets. I have some large and small examples. A very small one but I think it's just ironic and wonderful. The very same House committee, the Appropriations Subcommittee, that is mandating this study also is about to mandate that Medicare advantage and Medicaid prescription drug plans use Federal Government contracting procedures designed to encourage small businesses, set-asides for small and disadvantaged businesses.

This is the bane of life of places like the Defense Department and so on. A great deal of money is spent on complying with set-aside requirements. I think in the real world in which we live health plans will, if they survive the appropriations process, and it is expected to, CMS and health plans will find ways to live with that at

minimal cost.

Nonetheless, it is on its face ludicrous and meaningless and unjustified regulatory requirement. It's sort of if we use the food stamp program to require the grocery stores because they took food stamps and agreed to participate in the program would have to engage in federal contracting practices. Just bizarre.

DR. SIMON: I see you have a lot of stuff here. Can I ask you to focus on the big picture items?

MR. FRANCIS: Yeah, I am. I'm sorry. I think that one of the things you ought to be looking at are regulatory reforms underway that are likely to pay big dividends and there are a number of them that are very important. You have to decide which items you are going to pick but the health savings accounts and high-deductible health plans have major implications and major potential effects on health care in this country.

You could argue that what the Congress did in enacting that section of the Medicare Modernization

Act, which isn't about Medicare at all, was to level the playing field in terms of tax preferences. I won't go into detail on that but that's a major reform.

Another major reform underway is the new Medicare Advantage Program. Very substantially restructured. Huge incentives to health plans to both attract customers and keep cost down. How that plays out remains to be seen but it is a radical departure from traditional Medicare. We pay for whatever is delivered whether it was needed or not.

A few other examples. We have some regulations on the protection of human subject to research which I believe have been applied or interpreted, and I won't get into the details of that, by some concern as impeding the ability of health care institutions to initiate reforms within the institution because the argument is if you say the hospital tries to institute a new nosocomial control program to see if it can improve its results.

If they measure those results in terms of lives saved, they must be engaging in research on human subjects and why these regulations require that every

single person provide voluntary informed consent, an impossible requirement to meet if you are making a systemic change for a large population.

There are lots of regulations that have no victims that know they are victims and are sort of hidden. A recent example, I have not researched it but it's my understanding, and there is actually something in the CMS website that says an employer may not provide a voucher to his employees as part of their compensation to go buy their own health insurance plan.

We ban that. We ban it because that health plan the employee buys won't meet HIPAA and COBRA requirements which only could be met by large group plans. Therefore, the employer can't do it. In effect, we are directly denying the small employers the ability to give people a tax preferred benefit that would enable them to buy insurance. Extraordinary.

DR. SIMON: Walt, can I ask you to take maybe one more minute?

MR. FRANCIS: Yeah, I'll just name the two arguments and I won't go into them because they are

well known to almost everyone here. Two huge reform areas that are worthy of serious attention are the tax preference for health insurance that exist in the current income tax laws. The President's commission just recommended having that tax preference for policies of roughly $5,000 for individuals and $11,000 for families.

I think that has huge implications. That is not the first time such a proposal has been made. I think of it as regulatory reform of the tax laws, of you will, with huge implications for the cost of medical care in this country if you look down the road at behavioral changes.

My final example is the whole question of why states are, in effect, allowed to burden interstate commerce by regulating health insurance to the degree they do. It is illegal for a health policy sold in 49 states to be sold in the 50th state if that 50th state says, "Nope, you don't meet our requirements, whatever they may be."

It is literally illegal to sell a policy. I think that is extraordinary. It's an example, I

think, largely written for a vacuum in the sense that the Federal Government has not in any way, shape, or form preempted that field so maybe there is an area where more regulation is needed.

I'll simply stop with one last point about nursing homes. Sorry about that but I just want to comment there is a whole set of alternative strategies for regulation of institutions. Pay-for-performance is one example. There are many other ways to pay for performance than is currently being used.

Information that empowers consumers to make their own choices. There are ways to get adequate staffing, I would argue, in nursing homes without specifying a staff ratio. Thank you very much.

DR. SIMON: Great. Thank you. I hope we will be able to engage you in more specifics that I know you have enumerated here in some of the Q&A. Just, again, so we keep our focus here is that while I know Walt has commented in a couple areas about specific state regulation, I would ask us first to deal with federal regulation issues and then state regulations as they impact federal boundaries.

Mike, since I cut you off last time you get property rights first.

DR. MORRISEY: Walt, the discussion of federal and state laws just ratifying existing practice, clearly there's been a lot of research that finds that regulation is ineffective, largely I think because those regulations do just ratify existing practice.

So what do we do about that? Does that mean that these are regulations that we ignore or these are regulations that should be repealed?

MR. FRANCIS: I think you have to look at -- I hate to say this but you really need to look at the particular regulatory area of what is going on. I'll take a fairly silly example of patient charges in hospitals. Every now and then there are things that -- there are hospitals that are bad actors just like there are plenty of nursing homes that are bad actors so sometimes you want to close them down. If you don't have a requirement, it's hard to cite them.

There is a whole question here of how do you actually enforce standards. If you don't have a

standard, do you have anything to enforce? I think the whole issue of are we as clever as we can be in devising standards and then enforcing them through the survey process is ripe for review but I don't think you're going to find easy solutions. Just get rid of all the regs? I don't think that solves anything.

DR. SIMON: Mark and then Dan and then Rich.

MR. HALL: Go ahead, Dan.

MR. MULHOLLAND: Thanks. Mr. Francis, you mentioned survey and cert and that's an interesting area in terms of how regulations are actually enforced. Hospitals, for instance, have to comply with Medicare conditions of participation, they have to comply with their state licensure requirements, and they have to comply with informal but very important accreditation requirements, say the joint commission.

They have three different agencies enforcing different regulations all aimed at the same thing, improving the quality of care, but adding layer after layer of regulatory cost on. I would like to

know what kind of reforms you think might be appropriate to avoid some of the duplication and some of the inconsistent enforcement in that area.

MR. FRANCIS: Let me say first I disagree with the premise of the question, in part, at least. In that particular case we deemed joint commission standards so HHS does not directly enforce its hospital standards on a hospital for participation in joint commission process. CMS relies extensively on deeming approaches to avoid the very problem you're talking about.

Having said that, yes, of course, there are plenty of institutions that are subject to lots of regulations. Minimum wage laws, don't hire illegal alien laws, voting laws.

MR. MULHOLLAND: Not to argue but in terms of deemed status, deemed status is virtually meaningless now because if someone complains, for instance, about an improper restraint or an EMTALA violation, state surveyors acting on behalf of CMS will come in and survey for compliance with all the conditions of participation, notwithstanding the fact

that the hospital's joint commission accredited.

Once that happens the joint commission has to be notified. They come in and do a resurvey. After that the inspector general comes in and surveys to see if the joint commission is doing what it is supposed to be doing relative to deemed status.

We've had several clients that had a regulatory pile-on, if you will, as a result of just one alleged infraction. That has created a lot of chaos. You basically have to pull your management team off of whatever they are doing to answer all the questions, come up with a plan of correction.

There are often times things that need to be corrected. But when you have to answer to not one, not two, but three or four masters and you have somebody else watching all of them in the background, it becomes a very daunting task and begins to sap a lot of needed talent away from actually delivering care.

MR. FRANCIS: Let's assume your example is correct, and I have no reason to challenge it. I'm not an expert in the actual practice of survey and cert but, yes, I could easily imagine such a sequence

occurring.

It seems to me you have identified a wonderful example of sort of mend it as an approach. If you can identify the realities of real world administration of survey and cert as a big problem for health care institutions, I think that's great. If you come up with some possible solutions, wonderful.

DR. SIMON: Mark.

MR. HALL: You gave two examples at the, insurance issues. One was the employer vouchers to buy individual insurance. I just want to clarify to what extent these examples relate to federal law just so that's clear on the record. The inability of employers to give individual vouchers is due to federal law, right? HIPAA and --

MR. FRANCIS: Yes. Now, let me also say --

MR. HALL: I understand the example.

MR. FRANCIS: I have not nailed down precisely is that in the law, is it in the regs, or was it just some excess of the regulatory zeal on the part of some bureaucrats or something. I don't know. I'm

sure the purpose is to grant employers from using a loophole to get out of HIPAA.

MR. HALL: If it's employer sponsored, it has to meet --

MR. FRANCIS: This is federal, strictly federal.

MR. HALL: Okay. The second example was, as you phrased it, burdens on interstate commerce to the sale of insurance plans. Each state can impose its own requirements so anybody who wants to sell a plan nationwide over the Internet or something like that has this heavy state regulatory burden.

My understanding is that is connected with federal law to the extent that it results from the McCarran-Ferguson Act which --

MR. FRANCIS: Oh, yeah. I wanted to just take a slight exception here. In a whole lot of health care regulatory areas the states and the feds have overlapping, which is often a problem, responsibilities or maybe they have set some boundaries and one is one side and one is on the other.

In a lot of these areas the Federal

Government is the actor who is ultimately able to set the boundaries. I mean, in my written testimony I gave the example of the recent Supreme Court decision on the interstate sales of wines even in an area where the constitution provides some very special language related to the sale of alcoholic beverages, I don't want to argue the point strongly but I think the Federal Government has deliberately left a regulatory vacuum which I would argue -- I know it's in Chris' paper -- very expensive adverse effects.

MR. HALL: Okay. So in this particular case the source of that would be the McCarran-Ferguson Act.

MR. FRANCIS: Yeah. The McCarran-Ferguson Act is actually a policy statement. It's not a statute that sort of -- I think it basically says we think the field of insurance should basically be regulated by the states and we'll stay out of it as much as we can. It doesn't specifically provide a statutory framework for state regulation of insurance is my understanding.

DR. SIMON: Rich.

DR. LAWLOR: Okay. Thanks. First of all,

I know this is the first of four town halls they are doing so maybe we are all sort of just warming up looking towards maybe more quantification at times. This is all very useful, of course, though.

One thing you did way, and I'm not sure you meant it the way I'm hearing it, but something like not much change can be made in certain things that we've already got written in regulations. I think I definitely disagree with that. I think a lot of improvement is available for creative regulatory changes within HHS.

I say that with a grain of salt. Be careful what you ask for. We all know that once you start tinkering with the regulation the trickle into other regulations has to be recognized to the best of your ability. I think that is when we started hearing the same thing with state and federal crossing into the same whelms.

Obviously we live in a dynamic state of regulations now and how we got here isn't as important as what we have and what we can do to make changes. At least to my particular favor, and this is what I really

wanted to bring up, CMS and our other agencies in HHS are partnering with consensus-building organizations on measures and processes that can improve outcomes.

Maybe we can take a lot of pressure off of the regulation's weaknesses by doing these things in parallel and not necessarily targeting efforts on the regulatory change itself because when you remove the pressure from a regulation, it can be a lot more effective as written.

MR. FRANCIS: I totally agree with what you said and if I said something that seemed to imply anything to the contrary, I hereby take it back. I don't mean there are no improvements that can be made. Quite the contrary. I believe there are major improvements that can be made in many, many regulatory areas. I just think one has to go and take a grain of salt about how much -- of a thousand regulations how many are likely to be fruitful targets for change. The answer is probably a fairly small fraction.

I'll give you a small example. One of the arguably more unfortunate regulatory excursions in the Federal Government is in the Clinical Laboratory

Improvement Act whereby the Federal Government regulates laboratories. The impetus of that act was some bad behaviors by some large laboratories. The statute as drafted applies to all laboratories including auto-analyzing machines in physician offices.

I got a secretarial award for minimizing the burden on physician offices of our regulation. Okay? I'm not saying that regulation can't be improved further insofar as it affects those 300,000 medical practices, but there's probably not a lot more you can do, but there is an alternative and I wouldn't want to try to change it to a performance-based system for physician offices. They've got enough problems. The alternative is to go to the Congress and say, "That's silly. Let's change the law."

DR. LAWLOR: I just wanted to get that out there. If I could just do the last piece and then I'll please yield.

Another example you've just got to recognize is this cross-subsidization of payments in different areas and we've done a lot of work there in

the recent years in the department and the agency to remove the pressures on one reg that are being confused by people's concerns about the dollars so we better target the payments and reduce a lot of the pressures on some of these regs.

MR. FRANCIS: I'm so glad you mentioned that. The nursing home issue. A big problem in the nursing home context is state payment rates for nursing homes. It's budget pressure, it's Medicaid, and it's very tough to have adequate staffing if you don't have a budget.

DR. SIMON: I'm going to take one more question from the panelists. You guys are getting warmed up and that begins to concern me as the official timekeeper so you're going to have to -- this is the be-careful-what-you-ask-for lesson. What we are going to try to do just to make sure that we keep somewhat on schedule so that we can respect the time of the other folks who are still waiting in the wings is that I've been asked to keep the Q&A to roughly about the same period of time as the original presentation. If I cut you off, you get the first dibs on the next side. I've

got Chris down sort of as next. Then, Ted, you get sort of the first ballot on the next round.

DR. CONOVER: Okay. I want to thank you for all your comments about our work. I agree with a lot of the limitations of what we've done. I do think the exercise was helpful in terms of identifying specific domains where the ratio of cost to benefits was maybe excessive.

I also agree what you really want to measure is the incremental cost of the regulation, what would people not have done otherwise. When we did our case study work, that is exactly the way we were trying to frame those questions. What I will say is from that case study work is it's not always easy for these people in the trenches to articulate what that incremental cost is but it's a good point. I guess I'll just leave it at that.

DR. SIMON: Thank you very much.

Walt, thank you. Again, to echo a theme that you're going to hear from me and probably the panelists as well throughout is that in submitting your written comments, which we would welcome any revisions,

to the extent that you can quantify and be precise when you cite impact, that will be to the benefit of this entire exercise. I appreciate your comments and thank you.

Our third speaker is Sandra Fitzler, and I apologize if I have mispronounced your name. Did I get it?

MS. FITZLER: No.

DR. SIMON: No.

MS. FITZLER: It's Sandra Fitzler.

DR. SIMON: Fitzler. Oh, I thought that was an F. I apologize. Thank you.

MS. FITZLER: Senior Director of Clinical Services from the American Health Care Association. We are a federation of state health care associations for long-term care. Our members are about over 10,000 nursing care facilities, assisted living facilities, sub-acute facilities, and homes for the mentally retarded and developmentally disabled.

We are a quality and strive for a quality organization. We commit to quality first which is a covenant for quality care for the long-term care

profession. Thank you for having me here today so I can share some comments. My comments are going to be on some specific examples of where regulation has impacted the cost of delivering care.

Skilled nursing facilities are subject to some of the most extreme regulatory oversight in the nation. Every regulation requires extensive paperwork and compliance and administrative requirements. In doing so it does take qualified care givers away from doing their job of care giving.

We believe that there are more than 130,000 pages of Medicare and Medicaid rules and instructions. We are just looking at what we are supposed to do, state operation manuals, clarifying memos, change memos, etc., etc. This is for skilled nursing facilities. This is three times the length of the IRS tax code and the federal tax regulations combined. When you think about the difficulty of delivering care and following the rules and getting it right in long-term care, it is very difficult to do that.

The Medicare Cost Report is an extensive

time consuming and federally mandated report that requires many staff hours and individuals who are trained as accountants to complete it accurately. However, since the implementation of the prospective payment system the report is unnecessary if we are still doing it because reimbursement to long-term care is based on cost. It is estimated that eliminating this one reporting mechanism we could save the profession about $18 million per year.

The original intent of the nursing home survey and enforcement system was to be resident centered, outcome oriented. What we have ended up with is an oversight system that is very subjective, process oriented, and punitive.

To alter this we recommend that a system should be developed that recognizes and seeks to improve and reward quality care. This will foster an environment of partnership and in the long run it will save significant dollars to nursing care facilities and to tax payers.

The Minimum Data Set, the MDS, is an especially complicated system. It's there to assess

residents but it's also used for reimbursement, care planning quality measurement, research, and survey uses it. It is a simple tool that is supposed to do everything and in the process of doing everything it really doesn't do anything very well.

It is such a complex process that it requires the RAI manual in order to code it. That manual is over 500 pages so, you know, when you are not sure how you are supposed to code something, you lift up this heavy manual, you are looking through the manual trying to find your answer, and then after you've done that, then you have to ask the question, "Was there a clarification on this issue that changes the way I code it?" Now you are going to look for that. This is so complex a process that even CMS has hired contract to look at MDS accuracy at a significant cost to taxpayers.

The MDS and other required record keeping are so time consuming for providers that our members report that it requires about 30 minutes for each hour of patient care so record keeping is 30 minutes of each hour of patient care.

Since the introduction of the MDS nurses that were previously dedicated to direct patient care are now just doing the MDS all day. Mr. Mulholland, you talked about being interested in how regulation can change behavior and MDS is one. I don't believe it was ever the intent with the MDS that a nurse should be an MDS nurse.

Because it is so complex, because there are so many rules associated with coding, we do now take a nurse away from patient care to make them the MDS nurse. Even an association has sprung up supporting the nurses that do this type of work. This is critical when we talk about an environment where we have a national nursing shortage. If we have over 16,000 nursing care facilities across the country, we have now taken 16,000 nurses that we really need doing patient care and making them do paperwork all day.

The Medicare three-day stay regulation forces many frail and elderly individuals to remain in costly hospital settings when the skilled nursing facility is the most appropriate place of care. We are forcing them to stay in a more costly care setting just

so they can meet this requirement so their nursing home stay will be paid for.

Implementation of the new Medicare Part D prescription drug plan is on the horizon and we believe it will be considerable on the administrative burden on skilled nursing facilities. The burden will include tracking and documenting all the prescription drug plans that patients are participating in.

Now, when you think about this, this is not an easy task for long-term care because over 50 percent of our patients have some form of dementia. It's not just going to the patients and say, "Tell me what are the drug plans you're on or where do you get your drugs?" They can't tell you and half the time the family is not going to have all that information at hand. This is just rolling out right now and we cannot quantify the economic impact of this. We feel that the impact will be significant.

The last area is nurse aide training programs. Currently under regulation a nurse aide training program can be terminated if the facility is deemed out of compliance at a certain level on survey.

What is important about this is that out of compliance can have nothing to do with training, CNA training. It can be a dietary issue. Yet, the nursing facility still loses the capacity to train.

This is critical because what we are trying to do is have trained people and to ensure that there is a mechanism to have trained people in the facility. Yet, if we lose the ability to train, that is very difficult to do. We also have care givers who are retiring. Again, we have an older work force. We have a nursing shortage. At the same time we have all the baby boomers who are going to be retiring and are going to put demands on long-term care. We have to straighten out this training issue and this will be a tremendous cost savings if we can do that.

In addition to that, when facilities lose their ability to train, we are now forcing individuals who want to become CNAs to take training programs not provided by the facility at alternative sites. Many of these sites are cost prohibitive for these individuals so they cannot even afford take the training course even when we want to hire them.

I thank you for the opportunity to share a few of our concerns about regulation.

DR. SIMON: Thank you for your very specific testimony.

I'm going to now open this to the folks who I cut off first so, Ted, you get --

DR. FRECH: I'll pass.

DR. SIMON: You'll pass. Mike.

DR. MORRISEY: I'm curious since you represent more than just skilled nursing facilities and the whole range of substitute care providers, I'm curious as to your thoughts on certificate of need in the nursing home and sub-acute area.

MS. FITZLER: That is an issue that I know we've had discussion on. There are pros and cons to the CON issue and that is state specific but that's as far as I can tell you about that.

DR. SIMON: Mark and then Chris.

MR. HALL: I don't know anything about reimbursement and record keeping and what have you in skilled nursing facilities so this question may be naive but still, in general, with respect to the burden

that you described regarding coding in the Minimum Data Set, I'm wondering how different that is from the type of record keeping and the procedures you need to go through for private paying patients. Do you do essentially the same thing or is it much simpler and more straightforward for private paying patients?

MS. FITZLER: For the private pay patients, you know, you look at the plan and what are the requirements of each plan so that can differ. That is a small population in long-term care. The majority of the population is Medicaid. That is over 60 percent, about 65 percent. Then Medicare which is about 20. And then the rest of the patient population is divided on those who are on an insurance plan or private pay. What most facilities do is they do utilize the MDS.

MR. HALL: Across the board.

MS. FITZLER: Yes.

MR. HALL: Now, would you be willing to speculate as to why that is the case if they don't have to do that and if it's such a burden, why do they do it for the ones they don't have to?

MS. FITZLER: That is an interesting question and I really have never given it a lot of thought, but obviously the MDS is regulated. It's regulated so when the survey comes into the building, they are going to look at your MDS and have you done it. There is a focus on it and it is standardized. I'm not going to say everything is negative about the MDS because it's not.

It is a way to standardize assessments at certain times. Even when they are sent to the state, those ones that no one else should see are then deleted from the system. I think it's just an easier system to handle it that way. I believe that regulation has impact that area.

MR. HALL: Okay. Thanks.

DR. SIMON: Chris.

DR. CONOVER: Well, a lot of your comments mirrored what we were hearing in our case study interviews so that makes me feel good that we were talking to people who were representative of what's going on in the industry. Your specific statistic about 30 minutes of paperwork per hour of

care, what does that come from?

MS. FITZLER: This is what has been reported but we look at the MDS. Now, if you're a trained nurse and have been doing this for a long time, you can do the MDS quicker than someone who is brand new. With the nursing shortage and the turnover issues we have, we always have new people so it does take them longer.

So you do have MDS reporting but then you have other kinds of reporting and record keeping that you need to keep as a nurse in the facility. That would be supporting documentation to support that MDS because that MDS is only assessment in a particular period of time so you do need to have daily documentation that backs up your findings.

DR. CONOVER: Okay. I'm sorry. I was asking an academic question which is what was the source of that specific estimate?

MS. FITZLER: Oh, that is a report from members. No, that is not a study.

DR. CONOVER: Your organization surveyed your members and that was the average estimate or

something like that.

MS. FITZLER: Yes.

DR. CONOVER: I see.

MS. FITZLER: Can I just -- but I did see one reference to that in a piece of work completed by the DOL. That was done under study for the DOL so I did see something similar to that. I believe that there are studies out there.

DR. SIMON: Rich.

DR. LAWLOR: We've had a high number of anecdotal reports on that scale. I appreciate you bringing that up, Chris because that is a quantifiable metric that we can start to consider. To try to answer the question why do all patients -- why would we use the MDS on all patients, there's a couple of different reasons there.

No. 1, you pointed to issues with new staff in training. What that boils down to is the culture. I mean, you've got to be efficient and if you use the same measurements over all patients, you can actually hope to save time, I believe, is one of the incentives there.

Anyway, you brought up a very important point relative to the consideration of regulations and the impact on costs and so forth and that is when you use the example of the MDS and the RAI manual to understand it and learn how to use it, you pointed to the potential for needing to look for changes and alternative instructions that agencies would put out whether it's us at CMS or the state even that might want to tweak things on that.

Maybe it's not the state there. That is not the regulation talking but that is sort of all the different information being thrust at you trying to use the measurement tool. I think that is where a lot of times, too, we can look for improvements in the system that aren't regulatory. Thanks for bringing that up. I lost my train of thought so I'll stop. There was one more important point but, hey, it can't be that important.

DR. SIMON: I'll tell you, we turned the timer on you guys and you fell in right -- you know, a little bit of empirical feedback makes this better.

MR. MULHOLLAND: It's the effect of

regulation.

DR. SIMON: I don't know. We can start debating all of this.

Thank you very much for your comments, Ms. Fitzler.

Our fourth speaker is Fran Kirley. Mr. Kirley.

MR. KIRLEY: Good morning. I'm Fran Kirley. I'm President and CEO of a long-term care company called Nexion Health based in Eldersburg, Maryland. We operate 41 nursing homes in Louisiana, Colorado, and Texas.

I can probably answer a lot of questions about MDSs or whatever. I'll give you kind of -- I don't have any written comments but just verbal comments. In terms of the certain survey process, I have been here since about 10:00 this morning.

I have four surveys in my building today all on self-reported issues that we called in because we are a company cognizant of the fact that we want to make sure the state is aware of what goes on in our buildings on an ongoing basis. When you call a survey

in you get a follow-up survey from the state. All of those issues we think will be minimal but it takes time away from providing hands-on daily care.

I operate 40 facilities. I average at least three surveys per building per year. That is not level playing field in the hospital industry. I operated hospitals for 20 years. If I saw a complaint survey in my 20 years of being in a hospital, I can't remember it.

We are held to a much higher standard of performance in terms of survey compliance. The survey process is subjective and punitive when they come in regarding a complaint survey that is called in today that we may have a suspected abuse of a patient, a patient abuse issue.

For example, today they may come in and look at the dietary department unrelated to the issue we called in. They come in and they have full reign of any opportunity they want to look at. With all due respect, we run a great organization but we're not perfect all the time every day. I think the process needs to be streamlined and effective. We need to

reward organizations that improve quality.

We have spent the last 18 months becoming a restraint-free company. However, every time I admit a patient from the hospital I have to educate the family on why we do not use bedrails. Real issues. Again, the playing fields of what regulations should be across the health care continuum and not specific to individual entities or industries or professions based upon licensure.

The survey process is difficult. Again, it's punitive in that they come in and they really try to implement their personal philosophy of what is going on in their particular state. We have surveyors come in and say, "We gave you a tag because we don't like the forms you're using."

The forms may be effective but it may not be the forms they like. We changed that particular form the next time and the next surveyor comes in and says, "I don't like the form you're using. This is my recommendation." There is a lot of subjectivity in that process that causes us to obviously have trials and tribulations of how to run our business.

I work for a large public company that was in this industry. We had 70 manuals. We have nine manuals in Nexion because, again, it's not about the manuals or about the regulation. It's about the delivery of the services we provide every day. I'm not convinced that thousands and thousands of pages of regulations really are focused on the delivery of care. I'll give you some specific examples in a few minutes.

MDSs. I have 40 buildings. I have 45 MDS nurses. I only have 40 Director of Nurses. The MDS nurses need to be RNs, a skill set that is hard to find in our industry. Yet, we have to hire those people because it is mandated that in every patient in all of our buildings have to have MDSs done because, again, when they come in to do the survey, they will look at the MDS data to identify potential patients that they like to pull records on so that they want all of the patients in all of our facilities under the MDS model.

It is extremely time consuming and in buildings where we have high acuity, high Medicare utilization, we sometimes have to have two to three MDS

coordinators. In addition to that I also have a regional MDS team that makes sure their focus is to train the MDS people to be able to do their job every day. I think 30 minutes a day for an hour of care is probably a realistic estimate. We are basically in our company paying the second highest position RNs to do administrative work and not provide direct hands-on care.

MDS coordinators do not do direct care in our institutions. They do nothing but document that the care is being provided and making sure that the nurses in the care delivery system are making sure they are doing the documentation effectively. The MDS model is not an effective tool. I don't have a solution for you of what it should be.

A couple of other comments. Cost reports. We are paid prospectively in state operated as well as federally. Yet, we do cost reports. I have an auditor sitting in my office today who will be there for two weeks to do nothing but do a Medicare Cost Report and, yet, that data does not do anything in terms of prospective payment.

It is a bureaucratic process that I think is a waste of time and money. It is also done on a federal basis and it is also done in each of the states I operated in. They come in and they spend a nice two weeks up here in Baltimore. He says he loves to come to our building -- this is a Louisiana auditor -- because it's a great time of year to see the foliage. I'm not sure he is providing any value to anyone at this particular point in time. Nice gentleman but, again, I'm not sure it's of value.

Let me talk about some regulations. I'll give you a great example. We have a regulation in our industry that says you will have to provide meals at five hours between breakfast and lunch and lunch and dinner and 14 hours from dinner to breakfast. Sounds like a great rule.

We offered as a new company -- we've only been in existence five years -- that we were going to do freedom of choice. These residents should have the ability to decide some basic things in their life like when to eat breakfast. We went to the state of Texas and said, "We would like to implement a program that

would say we are going to offer breakfast from 5:00 a.m. in the morning to 8:30 a.m. Then we are going to offer lunch from 11:30 to 2:00 and dinner respectful of those hours."

They said, "You can't do that. The rule says you have to serve dinner five hours after lunch and breakfast needs to be 14 hours after dinner." We basically did a lot of work with the state and convinced them that are freedom of choice to allow the resident, who is a mature 65, 55, 85 year-old mother of most of us, should be able to make the decision of when they want to eat because maybe they get up at 5:00 in the morning. Maybe they get up at 9:00.

We put this program together called freedom of choice for dining in our Huntsville, Texas building. We said we are going to start it on a particular day. The survey team came in with four or five surveyors to make sure that we weren't going to do anything to harm the feeding of these folks. We've been doing that now for about two years.

I have no more weight losses in my building. I have no more weight gains in my building.

People can have what they want to eat for breakfast between 5:30 a.m. and 8:30 in the morning and, yet, guess what's happened? The building now has a waiting list. The residents are much more content and happy because they have some control about what they are doing.

I will now roll that out in all my buildings in Texas and every single building I have to write and get a waiver of the regulation to be able to do that. I'm not sure that is effective regulation in terms of providing effective care. I think that is kind of one example.

Other examples of freedom of choice is we don't allow freedom of choice for our residents. Residents that live in our nursing homes should be able to decide a lot of things about their daily activities but, yet, we've regulated and, again, there may be reasons why we've regulated that. The meal is the best example I can give you.

Restraints, again, is a good example. We are restraint free but it's difficult to educate families when they come back from the hospital and say,

"Why does my mother in the hospital have bedrails?" Good question. I can't answer why they do that. There are a lot of freedom of choices issues. I think we as a body need to look at regulations to allow people the freedom of choice. The other issue I have is really leveling the playing field.

DR. SIMON: Mr. Kirley, I'm just warning you that we are running a little short on time so if --

MR. KIRLEY: Two minutes. Leveling the playing field. We need to make sure everybody is held to the same expectations of quality and outcome. Again, as you look at regulatory issues, we shouldn't be looking at -- we should be looking at regulatory issues from health care, not hospitals, assisted living, nursing homes, hospices, etc. I think we've got to look at how we can standardize and use the best practices from each of those entities to make everyone successful. Thank you.

DR. SIMON: Thank you very much. Chris and then Dan and we'll go from there.

DR. CONOVER: I understood you to say that

the surveyors want you to do the MDS on all your patients and so I'm confused because I thought the other testimony was saying they don't have to but maybe for efficiency reasons they choose to.

MR. KIRLEY: Some states mandate that MDS is done on all admissions in nursing homes. It's state-operated and mandated because they like to collect the MDS data to identify which patients they will then come in and do an evaluation on. When they do their annual survey, they will come in and give us a list of patients that they would like us to pull records on. They pull that data off the MDS.

DR. CONOVER: So from the standpoint of federal regulation this problem isn't coming from the federal side of the fence.

MR. KIRLEY: Not that I'm aware.

DR. CONOVER: Okay.

MR. KIRLEY: No. It's mandated by the state.

MR. MULHOLLAND: Just a quick question, Mr. Kirley. I imagine your program or corporation has a corporate compliance program?

MR. KIRLEY: Yes.

MR. MULHOLLAND: What would you estimate you spend annually on your corporate compliance program?

MR. KIRLEY: Well, we have a team of -- not only do we have a corporate compliance officer but we also have field individuals. I would say we have three full-time equivalents probably. Our general counsel runs it all the way down to two clinical nurses. I would say it's about a quarter of a million dollars a year in a 40-company organization.

DR. SIMON: Mark.

MR. HALL: Could you give either now or later an FTE estimate on how much staff time is consumed with responding to inspections over the course of the year and that sort of thing? Better to do it more precisely than off the hand.

MR. KIRLEY: Today in Huntsville when the surveyors walked in today everybody in that organization is focused on the surveyors so, again, it totally consumes every facility so I would tell you it's probably 10 percent of my annual cost or greater

is spent on just managing the survey process.

It's an enormous amount of time, energy, and resources because what happens is when they come in they can go anywhere so everybody needs to be prepared within the facility. We always like to have a corporate person if it's really a critical survey at the location so that's not counting the corporate support that is there as well.

DR. SIMON: Rich.

DR. LAWLOR: Thanks. I think that was a good question that Chris clarified on states mandating that MDS in this case example. But then I don't think the answer is as simple as saying is this a federal requirement because we've got a sort of momentum going where states and private payers in general mimic federal regulatory standards so that's kind of food for thought there.

Then you pointed out getting a waiver for the dietary schedule issues. Is that a state waiver?

MR. KIRLEY: Yeah. Every state that we've rolled out that freedom of choice we have asked the state that we will not be in compliance with a five-

hour and 14-hour meal issues.

DR. LAWLOR: Okay. Maybe considering yourself a pioneer in that area and then asking the question is that a fair process to go through. I mean, has it been streamlined at this point? It is easy for you to get that waiver?

MR. KIRLEY: No, because every time the surveyors come in we have to prove to them that we've got a waiver and then we have to educate them to understand why we are providing that particular meal time in a different model. They are trained over here as you will do it a certain way.

They survey in Texas 1,600 facilities and they come to my 23 and then we have to educate them and spend a fair amount of management time explaining to them why our process is different. Then they always don't have the waivers. They always don't have the information and, therefore, it is somewhat of a bureaucratic nightmare for us each time we get a survey.

They can come in for an unrelated issue and they say, "How come everybody is eating meals?

It's now 9:30. You are supposed to eat the meal at 7:00." We've got to go through that process every single time so there's not a good methodology to manage that waiver method.

DR. SIMON: Other questions from the panel? Mr. Kirley, thank you very much.

MR. KIRLEY: Thank you.

Our next commentor is Rene Cabral-Daniels

MS. CABRAL-DANIELS: Good morning. I don't know if this is on. Can you hear me okay? Okay.

First thing I would like to say is -- my name is Rene Cabral-Daniels. I'm the Director of the Office of Health Policy and Planning with the Virginia Department of Health. I thank you for inviting me for comments today.

The first thing I would like to say is I have an appreciation for the hard work that is involved with federal regulations. I used to work for Health and Human Services in the Office of General Counsel attached to CMS. I know that a number of the regs that came across my desk were very well researched and of

high calibre.

I don't think sometime some of the issues are with the written word with regard to regulations but what I'm finding now that I've left the dark side -- just kidding -- with the state, what I found is that it's sometimes the implementation of the regulations by the different agencies that pose the greatest problems.

I'm glad to hear, first of all, that the issue is not to look at where so much the regs are excessive but looking more at quality. I think the biggest problem is sometimes looking at where the regs are inappropriate. We'll talk about that in a minute. I think that maybe there should be a campaign looking at the quality of regs.

I know the feds often talk about having things evidence-based and maybe some of the regulations should be evidence-based in looking at whether they have quality. But the three areas where I think it's very difficult, at least as a state policy maker, is with regard to designations when you are looking at the regulations.

Here is where the states are really helpful to providers. There are regulations that say, "If your area has been designated as a geographic primary care health professional shortage area, then all the physicians that practice in that area get an automatic 10 percent Medicare incentive payment bonus."

Now, because the states are responsible for administering that process, all the questions come to our office regarding -- they will be addressed to the states and not to the federal policy makers that make the rules regarding how those designations are set.

I think with regard to any time when states are asked to be a partner in the process that they also be asked to be involved in the NPRM decision making process. I know people will say that will violate FACA. I really, first of all, don't think it will if you do it right. Second of all, if getting your partner involved in a process before it becomes law violate FACA so maybe you should look at the Federal Advisory Committee Act, revising that to some degree.

The same is true for the Title VI with regard to the linguistic appropriate services, making sure that providers have interpreters. Here is another area where we find in the state of Virginia doctors are very willing. There is not an unwillingness to want to comply with the regulations. Resources are really a big issue here, to have an interpreter available for every language that might walk in the door. Especially when you consider a state like Virginia is ranked 8th in terms of refugee resettlement so we've got people from all over the country and here are the doctors that are trying to comply. This is becoming a greater problem throughout the nation as more states that traditionally did not have a lot of immigrants now do.

I worked in a hospital in Boston for a while and I spent more time trying to serve as an unofficial translator and interpreter in the emergency room that I had to take my name off the list because I spent so much time down there. I know this is really a big issue for providers.

Another where states have some challenges

with regard to being an advocate for providers and really helping providers is looking at health resources and services administration with the state offices of rural health.

With the different federal regulations there are over 200 different definitions depending on the program, I think, at the last count for the definition of rural. Some of the more popular definitions of rural will show that parts of the Grand Canyon are not considered rural by that definition.

I think, once again, maybe in looking at when you are drafting the regulations that I think state policy makers could be really wonderful advocates but they need to be involved early on and not once the regs are out. That's it.

DR. SIMON: Thank you very much, Ms. Cabral-Daniels. I would ask if you don't have written comments to submit currently if you could submit them to us through the website or other means subsequently.

Can I open this to the panel? We are wearing you guys out.

MR. HALL: Getting close to lunch.

DR. SIMON: Yes, it is, indeed. Any questions? Okay. Thank you. Actually, this gives me an opportunity before our official lunch break to make a couple more announcements. If there are folks in the audience who have not signed up and intend to give testimony, I encourage you to do so. As a matter of fact, I require you to do so because that is the way in which we identify who in the audience wants to give written testimony -- verbal testimony. It is getting close to lunch, isn't it?

There is now coffee in the other room as well, as well as water, so we are sort of racheting ourselves up the luxury chain here, but not so much as to get under the microscope of the Federal Government which is funding this. We are going to take -- I think this is probably an opportune time for us to take a approximately 45-minute lunch break.

We have folks who are signed up to present their comments after the lunch break. I apologize if you have been sitting through the morning. I hope that you have found this as instructive as I have but we are going to be taking a break. We will be reconvening at

-- we are leaving a bit on the early side -- 12:45 as planned. I will see you back there. Thank you.

(Whereupon, at 11:41 a.m. off the record for lunch to reconvene at 12:53 p.m.)

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

12:53 p.m.

DR. SIMON: I want to welcome everybody back to the afternoon portion of our program. We have had a chance to enjoy at least a little bit of the sunshine and pleasant weather.

We are going to pick up where we left off. While I still have your attention and before the post-lunch sort of low hits in, I want to remind you of a couple of very important things. First of all, I encourage you all to take a look at the ASPE website where the townhall meetings are posted. There is a lot of important information on there not only about this meeting and the process, an opportunity to submit public commentary, written commentary.

Again, even for folks who are not speaking today, I strongly encourage you because I know you all

have an interest in being here. You wouldn't be here if there wasn't some strong interest and probably some very solid evidence that brings you to this room. I encourage you to submit it to us because that is really the stuff that is going to get this process going.

It's where the rubber hits the road to use a phrase that has been used a lot of times. It makes our job a lot easier and a lot more salient in terms of bringing your interests to the light so I encourage you to submit testimony.

Also this is the first of three more meetings and they are geographically dispersed. We have another meeting coming up on December 8th in Chicago. Chicago is a lovely city. They actually have a baseball team that won the championship recently. Near and dear to my heart. That's my home.

I encourage any of you who either personally, or who are representing organizations, particularly who are sitting in the midwest, to come visit us on December 8th as well and there will be another opportunity to present comment as well as to hear comment.

From there we move to Oklahoma City the first week of January. From there to San Francisco so this is the beginning of a process that is designed to pick up a diverse audience across the country but we encourage you to participate in our subsequent meetings as well.

Again, we have water and coffee and I'm going to continue with the format that we had the last time where I'm going to be asking presenters to spend approximately seven minutes in their discussion and then open it to questions from the floor. Again, I encourage you to the extent possible to focus on strong evidence, quantifiable evidence, and federal regulation but I think we did a really good job this morning.

The next person on my list is Terri Maggio.

MS. MAGGIO: Good afternoon. Is this working?

DR. SIMON: Is it working, technical people? I think we're fine.

MS. MAGGIO: We're okay? Good. My name is Terri Maggio and I'm involved with the Jersey

Association of Medical Equipment Services. We are the folks that are at the end of the food chain in health care. I've been involved -- my background is medical records so I'm this detail freak. If it's not in writing, it didn't happen.

However, I've been involved in this industry for about 25 years and over that time period I have witnessed technology that allows us to literally bring a mini-ICU into somebody's home so we facilitate the discharge from the facility whether it be a rehab facility or a hospital, nursing home, etc.

The paperwork requirement on the part of manufacturers who developed the technology that we use in the home is a whole process unto itself. Once those products are recognized and coded, then there is a medical criteria attached to them.

Once that has taken place, I've seen an increase in the paperwork and the burden on the provider in their requirements to justify the medical need for the item. My comments relate to the documentation requirements for services that are both covered and not covered by the Medicare program.

I will also talk about the provider's cost involved in what I call transparent services which are the services we have to provide that are never reimbursed to do it right. First we need to identify the players and I refer to them as the five Ps. They are the partners and the partners equal the physician, the patient, the provider, and the payer.

It is important to note that the physician prescribes the orders without much detail. The patient expects the very best that American technology can bring to them in their home. And the payer has an expectation for documentation with detailed information and that varies from payer to payer.

Then the provider is responsible and liable to obtain, retain, and provide upon request proof of medical necessity. Since 1993 the Certificate of Medical Necessity, a form created by the Centers for Medicare and Medicaid Services and approved by the Office of Management and Budget, has been used to document and transmit the medical information or coverage criteria to support the services provided to the patient.

Providers use that tool to document medical need and providers must obtain medical information beyond that. It was always necessary that tool be supported by the medical record. CMS has recently removed the CMN as a tool to document this and providers must obtain medical record information to maintain supporting information for claims submission. This will increase the paperwork burden not only for the provider but for the folks the providers need to go to to get that information. While we understand the Medicare trust funds must be protected, we found that the information is duplicated many times. When requests are made for medical record documentation, they are sometimes many, many years old.

In order to protect themselves from liability providers would be forced to risk an audit that would be detrimental to them, or to delay the facilitation of services. It needs to be noted that we are the folks that get the call from the hospital that the patient is being discharged today. We have a two-hour window sometime to coordinate lots of care.

A suggestion to reduce the burden of the

paperwork would be for the program to set policy that don't duplicate information. In other words, why is it necessary for me to get information from medical records at the hospital and medical records from the doctor's office when the hospital already determined there is a medical necessity on admission? I'm duplicating that whole process by asking for it again.

A clear example is the hospital discharge and that is what we're talking about here. When a patient is hospitalized the services provided by the home medical equipment rider are in coordination with a treatment plan that's upon discharge.

There's two things that really need to be established at the time of discharge. The first thing is to get the equipment right and all of the DME providers do a home evaluation and they do a patient evaluation and assessment to find out what the patient really needs. They work with PTs, OTs, and other clinicians.

What we need to determine is is this a short-term need? That means the patient is recuperating from an illness or injury and we're needed

short term. Or is it an irreversible condition that they would need something longer term? Those two things can be determined at that time.

The other thing is to have the diagnostic information so that you get it right. I believe that it's not necessary to duplicate all that medical record information over and over again each time a patient receives a service. A discharge summary that contains the information for continuum of care should meet those needs and it shouldn't be getting an entire medical record which is what is going to be happening.

When a patient is in the home, of course, when they are seen in the home by their physician, then medical necessity needs to be established and then we need to have the physician, who is our partner by the way, provide the information we need and they need to understand the coverage criteria because in some instances it's very limited and very stringent.

It would be no different than the physician knowing the indications for prescribing a medication. The amount of documentation required here must substantiate the level of service and the

regulation clearly requires that the least costly alternative be provided and we al understand that.

There is a cost associated with the provider's cost of doing business. However, to increase the burden by requiring more than a detailed written order shifts the cost burdens to the physician, the provider, and other ancillary providers. I think that it would be sufficient for us to develop mechanisms to document medical need without duplicating that paperwork.

Carriers are requesting medical records under review. Under HIPAA many times health care facilities won't release those medical records to everyone. As a consumer of health care I don't know that I want my medical records in 17 different places. I think the medical record needs to be in the place where I'm being seen.

Beneficiaries who are also partners in this need to understand that the Medicare has stringent coverage criteria and we don't always educate them. They are told when they call the carrier that if you have a prescription from your doctor it's covered so

that's misleading to them. Sometimes they drive a want for something not understanding that they have to need it.

After all, their congressman or congresswoman has told them that their Medicare coverage is protected and they believe politically that they can have everything they want. We are the people that face those folks and say, "No, no, no. It can't be." They need to understand what the benefit is and how it's limited based on that medical necessity.

Payers must not use medical necessity as a catch phrase because they do. Usually what happens is that the services or the medical necessity criteria, whatever Medicare does, trickles down to all the other carriers and that usually ends up being a problem.

So we are concerned about duplicate paperwork, the coordination of coding which under HIPAA we have not had coordinated coding so, therefore, we have one carrier using one code and another using another code which reduces us to a paper claim instead of an electronic claim.

The last issue is getting a claim through

the system when we know it's not going to be covered and carriers routinely will ask for additional documentation that really isn't necessary. We know it's not covered. We just need to get to the secondary carrier.

I see the light blinking. I'm from New York and I should talk faster. Anyhow, to move on here, we understand the complexity of the program and certainly appreciate the need to support claims submitted for services rendered. However, we believe the process should not require duplicative information. We also believe that we don't have to have multiple things on multiple pieces of paper in multiple places.

We hope that the comments will be considered. I do have analyses of respiratory care and rehab care, the time it takes to do that, that I will provide later.

DR. SIMON: I would appreciate that. Thank you very much.

MS. MAGGIO: Thank you.

DR. SIMON: Mark.

MR. HALL: In addition just to the time of

filling out the paperwork, I'm interested in a point you made about possible delay in starting service while the paperwork is being completed. That delay might occur when a patient is in the hospital and transferring to home care or something.

MS. MAGGIO: Yes.

MR. HALL: What would be the consequence of the delay? Would the patient be stuck in the hospital longer than they needed to or would they actually be left without care?

MS. MAGGIO: I think what happens is the patient doesn't stay in the hospital because we are at the mercy of a referral source who says, "Do it today." Most of us are contracted with insurance companies and other carriers who say, "Do it today." If it's a Medicare choice plan, for example, we have contracts that say we have to do it in two hours.

Sometimes there would be delay when the patient is at home, but the delay of the discharge really the provider I think under the new rules without the Certificate of Medical Necessity the providers are going to be gun shy and there might be actually a delay

in the patient actually being discharged because sometimes the equipment actually goes to the hospital to facilitate the discharge. They can't go home without it. There is a coordination of care factor here with regard to that.

MR. HALL: Is there any -- is this just sort of a general risk or is there any documentation of delay actually harming anyone or some degree of cost caused by the delay?

MS. MAGGIO: I think we might have some documentation with delay with regulations on a state level with Medicaid because there is a prior authorization process so there might be. Of course, the regulations with Medicare and Medicaid funnel down.

The other issue is the cost involved just in the cost of gathering information based on the patient's needs, gathering that information correctly. When you are dealing with respiratory high tech patients or dealing with rehab patients, you do have issues that are different than grandma needs a walker to go home from the hospital. I think we need to quantify the level of service and the level of care.

DR. SIMON: Chris.

DR. CONOVER: I just wanted to clarify. You said you have some analyses of existing technologies. Going back to a comment that had been made in the morning, are your estimates going to be estimates for sort of the cost of the whole process or just the cost of what you would regard as the excess paperwork associated with the process?

MS. MAGGIO: How we have it broken down is broken down for a small ticket item and then we build on it until you get to the high tech equipment and we can correlate that to the actual cost of the equipment as well so it's how you correlate that. Most providers if it's respiratory they will have respiratory therapists on their staff that do the clinical evaluation. If it's rehab technology, they may have certified rehab technicians that actually evaluate a patient. I think you have to look at the incremental levels of the service being provided.

DR. CONOVER: But all I mean is that even with that regulation, wouldn't you go through -- just in terms of providing quality service wouldn't you be

going through some process in any case? The issue is whether regulation is making you do more things that you think are unnecessary.

MS. MAGGIO: And we can show that the regulation has increased the number of things we must do in order to deliver a service.

DR. SIMON: I think particularly identifying those which are duplicative would be extremely useful.

MS. MAGGIO: Okay. Thank you very much.

DR. SIMON: Other questions? Rich.

DR. LAWLOR: Thanks.

MS. MAGGIO: I thought I was going to get away.

DR. LAWLOR: This is a great topic. A couple of things you brought up included the elimination of CMN and how that, in your opinion, increases your paperwork burden requirements. In that vane you talked about the expectations of your documentation, what you carry, the requirements. They are very payer to payer and we are just one of those payers, as Medicare, for example.

I think the question also needs to be when you look at the regulations is who has the paperwork and documentation burden really versus who has the payment accountability because you brought up the idea of carriers or medical directors looking for documentation to support products and then you have to step back and say what is a regulatory agency's ability to impact potential fraud and abuse concerns.

You have to sort of determine whether we have the authority to require previous paperwork generators to sort of be at odds for your payment. I think you brought up a good point about carrying multiple pieces of paper. Nobody disagrees with that redundant paperwork issue. The promise of IT is not here yet and we think the more we can incorporate that, that redundancy can be reduced. I think, again, look at the regulation versus what's our authority to do something about the problems that would happen if the regulation wasn't there.

MS. MAGGIO: And we understand that. I understand the protection of the Medicare trust funds. I understand that wholly. It's just a matter of do I

need to have 35 pieces of paper and if I don't spell out -- if the regulation -- it's implementation.

If the implementation doesn't spell out clearly exactly what I need, then how do I gather that and if from provider to provider it's different, we are all in a bad learning curve and then there's no accountability and then your trust funds are not protected. That's the concern I have.

DR. SIMON: Other questions? Thank you very much, Ms. Maggio.

MS. MAGGIO: Thank you.

DR. SIMON: Our next commentor is Janet Wells.

MS. WELLS: Hi. I'm Janet Wells. I'm the Director of Public Policy with the National Citizens' Coalition for Nursing Home Reform. Listening to Mr. Kirley this morning I felt again that consumers and providers live in a different universe when it comes to nursing home regulation.

Our statement, too, deals with regulation in Texas and a very, very different perspective. Our organization has been working for 30 years to try to

improve the quality of care in nursing homes. We are very active in passage of the Nursing Home Reform Act in 1997 and have worked very hard over the years with providers and labor groups, health care professionals to implement that law.

In 2003 we worked with one of our member groups in Texas, Texas Advocates for Nursing Home Reform, to document 83 cases of nursing home residents who had been severely neglected and abused in their nursing facilities. We are attaching a copy of that report to our testimony today and would urge the panel to look at it.

In this report, which we call Faces of Neglect - Behind the Closed Doors of Texas Nursing Homes, we found that the cases typically involved under staffing, always a serious problem in nursing homes; failure to prevent or treat pressure sores or the unrelenting pain that went with the pressure sores; failure to notify patient's doctors of changes in their condition or to follow doctor's orders; and falsification of medical records.

Although pressure sores were the primary

outcome of neglect in the cases that we featured in this book, it also includes half a dozen cases of sexual assault and two deaths by bites due to fire ants. As horrendous as the situations were, rarely did the Texas Health Care Department take any action against the facility that was involved.

It's rather amazing to look at the cases that we documented versus the situation that Mr. Kirley described this morning where the facilities felt that they were being harassed for even small deviations from regulation.

For example, Kalinia C. was an 89-year-old homemaker from Tyler, Texas, who had Alzheimer's disease. She was admitted to a nursing home with no pressure sores. The facility virtually ignored doctor's orders to reposition her and she developed nine pressure sores. Although she was in extreme pain, the staff also violated her doctor's orders for pain medication. The Texas Health Department never took enforcement action against the facility which had routinely falsified wound treatment records for hospital expenses for over $76,000.

Gertrude H. was 87, also a homemaker, when she was admitted to a Longview nursing home. She also had no pressure sores at admission. She developed eight pressure sores including one 10 inches in diameter and three-quarters of an inch deep. Gertrude H. was hospitalized four times for dehydration, lost 90 pounds in one year, and died from infected pressure sores. The state denied payment for new admissions to the facility as a result of the neglect of Gertrude H. but it never sought reimbursement for the cost of her care. Her hospital expenses totaled almost $96,000.

These were relatively inexpensive hospitalizations. We had one case where the cost of care was $231,000, another $272,000. Earl D. of Corpus Christi, who was a Baptist minister, was only 60 when he was admitted to the facility with Alzheimer's disease and diabetes.

His doctor testified that his gangrenous pressure sores, 61-pound weight loss, five hospitalizations for dehydration, and death due to infected pressure sores, constitute a knowing abuse of the elderly. His hospitalizations cost over $143,000.

Jesus S., who was 80 was a retired rancher, had his leg amputated because of severely infected pressure sores. His hospital expenses including three admissions for dehydration were over $115,000. These cases just go on and on.

In none of these cases did the Texas Regulatory Agency attempt to recover the cost of the abuse and neglect. In very few of the cases did it exercise any of its enforcement authority under Medicare and Medicaid Nursing Home Reform Act regulations.

While these cases may appear to be extreme, the latest Government Accountability Office report on nursing home care reported that 20 percent of nursing homes in the country have been cited for actual harm to residents or for immediate jeopardy of harm.

However, the GAO, the Inspector General, and others who look closely at nursing home enforcement doubt the accuracy of the 20 percent figure because other research has demonstrated so often that facilities are not cited when harm occurs or, if they are cited, there is not an appropriate penalty.

There is also another troubling footnote to Faces of Neglect. If you look at the book a lot of the faces are African American or Latino. Last year the researchers at Brown University published a report that I don't think has gotten nearly enough attention in the discussion of racial disparity and health care. They found that 40 percent of African American nursing home residents are in the 15 percent worse facilities, the ones with the worse staffing, the poorest care, the most likely to close voluntarily.

This is a critical problem that has been very overlooked. These researchers are concerned about going to a pay-for-performance type of reimbursement system that rewards some facilities and penalizes others because of the quality of care may decline even worse in those facilities that are not recognized.

Faces of Neglect suggest that the cumulative cost of failure to enforce quality of care regulations is causing extraordinary suffering by nursing home residents is also placing an economic burden on taxpayers. We would strongly urge that ASPE and OMB examine the high cost to Americans of

under staffing and noncompliance and poor enforcement.

DR. SIMON: Thank you very much. Mike?

DR. MORRISEY: Thank you. We heard this morning the discussion that the nursing home market has seen less occupancy in the last few years with the advent of assisted living and the expansion of the continuum of long-term care. I'm curious whether you've seen or have been able to document whether the quality of care in nursing homes has gotten worse, gotten better, or largely stayed the same as a result of the change in the market?

MS. WELLS: I don't think I can answer that. I think you could suppose that might have occurred. People who can afford to pay privately for care clearly are going in great numbers to assisted living facilities where there are more options for at least an attractive facility in a private room which is rare in nursing homes.

I don't know that we've seen large increases in the proportion of residents who are on Medicaid but I think it is possible that to the extent that private pay residents may drive quality in

facilities because people who can afford to pay for their own care are demanding more that there could have been a decline but I don't know. I think that is certainly an issue for research.

DR. SIMON: Dan?

MR. MULHOLLAND: Thank you. Ms. Wells, do you see any difference in the incidence of these kind of adverse outcomes between for-profit and nonprofit nursing homes or nonprofit and governmental nursing homes? Any statistics on that that you are aware of?

MS. WELLS: There have been several studies including one by Charlene Harrington at the University of California at San Francisco who has shown that by using surveys as indicators that private pay facilities -- excuse me, nonprofit facilities statistically do provide better care and Government facilities also. Investor-owned facilities, according to the statistics, provide a lower quality of care.

DR. SIMON: Rich and then Chris and then Ted.

DR. LAWLOR: I think it's clear that you are making a point on the front end -- rather than

maybe what the regulations actually say or ask people to do. My question is when you think about the compliance of the facility relative to the regulations, and you brought up demographic issues on residents, you have to be concerned about management performance issues, the availability of the staff and the region where the facility is located, too.

It seems to me that you're pointing to the weak link being enforcement in the final analysis rather than the regulation requirements on the facility and maybe the facility's inability to do it is not as much important as that. Is that correct?

MS. WELLS: As I said, we worked very hard for the Nursing Home Reform Act and it took a long time after we were founded to actually get that legislation in place and we have worked very hard on the regulations. We think it's a very good law and we think the regulations are good.

We think the nursing home industry and consumers and health care workers all worked together to pass that law and we have all worked together collaboratively on the regulations. We don't think

it's a problem of the law except in one area and that is the failure of the Government to require minimum staffing ratios.

The Government has been talking about doing that for over 30 years without success and have done a great deal of research which I also cite in our written statement showing that below a certain minimum level of care, which is about 4.13 hours of nursing care per day, facilities have the problems that I referred to. They are pretty much unavoidable so we certainly think the next step is to have Government-required minimum staffing ratios.

DR. SIMON: Chris.

DR. CONOVER: Aren't assisted living facilities largely unregulated right now?

MS. WELLS: At the federal level and often at the state level as well.

DR. CONOVER: So if I take your argument at face value it would seem like we would have all sorts of quality problems in assisted living facilities because, after all, they are not regulated and they aren't required to have minimum staffing ratios, etc.

Is that what we observe out there?

MS. WELLS: We certainly are observing it. As with nursing homes we are not observing it in every facility but if you just do a Google search on assisted living, you'll turn up many, many problems that are exactly the same as the problems you're having in nursing homes.

As people are admitted who require a heavier level of care, there are not enough staff. The staff who are there are not adequately trained to work with people who have multiple health care problems and medical needs so we are seeing a industry that seems like a turnover. We are almost back to 1965 in terms of regulation in the long-term care facilities where a lot of people are going.

DR. CONOVER: Okay. So if I understand your argument correctly, the problem on the nursing home side is predominately an enforcement issue so we have a lot of regulations. We're just not enforcing them well enough in your judgment. On the assisted living side apparently we don't have sufficient regulation.

MS. WELLS: In most states, no.

DR. CONOVER: Okay.

MS. WELLS: Assisted living really started out as housing for people who could largely take care of themselves with a little bit of assistance but it's really changing. A lot of the assisted living facilities really look like nursing homes.

DR. SIMON: Ted.

DR. FRECH: This is, again, a question of other instruments that affect nursing homes. Does Texas have certificate of need for nursing homes?

MS. WELLS: I'm not sure about that. I know that Texas historically was over-bedded so I think probably not.

DR. FRECH: Okay. That leads to the next question. Do you know if there are waiting lists to get into nursing homes for Medicaid patients?

MS. WELLS: I think at this point the occupancy rates are -- I can't remember the latest statistic I've seen but I think nursing homes in most states tend to have open beds and that's why we're seeing another problem in nursing homes which is the

admission of people who are totally inappropriate in a nursing home facility with elderly people. People with a history as sexual predators or with mental illnesses which cause violence and former felons and various other people who are being dumped into nursing homes.

MS. WELLS: I would like to add one more thing just in response to Mr. Kirley's presentation that CMS is taking seriously the complaints of providers that when they try to provide resident-directed care that surveyors are interfering. Karen Schoenemann at CMS is actually asking for examples of where this has happened. There is also a study being done by Rosalie Kane funded by the Rothchild Foundation that's looking at these kinds of issues. These issues are on the table and we are all concerned in looking at them.

DR. SIMON: Thank you very much for your thoughtful testimony. We look forward to the report that you are going to be attaching as well.

At this time I am going to just remind anybody I have one more individual who has signed up to present comment. We have the luxury of a little bit of

time, although I'm sure that you all have competing uses for it, but I would encourage folks that may not have spoken that if you wish to provide some comments, to please sign up and we have the luxury of being able to let you do so at this point.

Mary St. Pierre.

MS. ST. PIERRE: Thanks for the opportunity to give my comments. Although I came here unprepared, I was encouraged to comment and I will do so. I represent the National Association for Home Care and Hospice and our members are all types of home care providers, hospice providers, for-profit and not-for-profit hospital-based. I have been with the national association for 13 years but did spend 24 years before that with a home care agency.

I feel almost apologetic in making comments about the regulatory requirements that I'm going to address after the comments of the previous speaker. Maybe that is really a reflection of where the focus of the emphasis is on the regulations.

Maybe if we look at the conditions of participation we see that many of the requirements are

really structured requirements and they talk about quantifying and how often you do something and what do you do as opposed to addressing the quality of care.

The issues that I'm going to talk about are those things that seem to be almost unimportant in light of the prior comments that were made. I feel that maybe if we can get our regulations geared more toward quality as opposed to these day-to-day must do this, must meet these time lines, must do certain things at a certain frequency and focus in another direction, we'll be much better off.

I'm going to just address topics and I promise in my written comments I will quantify the cost to providers. I also want to be sure to mention, though, that I'm not only going to talk about the monetary cost but the cost in retaining health care personnel and particularly nurses.

A study was just released on the basis of loss of nurses from the field and their top complaints and their top stressors and No. 1 was paperwork. So I'm going to start with talking about OASIS. OASIS is the data set that is required.

It must be embedded in a comprehensive assessment that is completed by home health care clinicians, nurses, and therapists. It has along with the demographic items close to 100 items that must be collected. That is not an entire assessment.

There are many other components of a patient assessment that aren't part of OASIS. OASIS provides us with 41 outcome measures and my question is do we really need 41 outcome measures, many of which have to do with a person's ability to keep house and shop? Not medical measures, not measures of medical care provided.

Right now the OASIS is required for Medicare and Medicaid patients. However, APSE is in the process of analyzing a study they did on the benefits and cost of OASIS for the non-Medicare and Non-Medicaid patients so we might see that imposed on us again in the future.

There are issues related to the actual completion of the OASIS and who can complete it. There is a regulation that says that a nurse or a therapist can complete the OASIS unless nursing is ordered. If

nursing is ordered, even though the primary focus of care might be therapy, the nurse must complete the OASIS.

In addition, the nurse must complete the initial assessment but the initial assessment must be done before the OASIS started care assessment so unless the nurse and therapist actually visit at the same time, we might have to have a nursing visit for an initial assessment and an OASIS visit to do the comprehensive assessment after the therapist admits the patient.

Now, we are also talking about people going out to patients' homes to carry out these assessments so the issue that is in all of our minds these days is the cost of gasoline.

Another issue regarding the OASIS is that it is required every 60 days. Now, in our request for streamlining we have been given permission to cut down the OASIS data items for Medicare patients to the 25 needed for payment. However, for Medicaid patients they must go out and collect all of the OASIS data items even though on the 60-day recertifications that

data is not used to assess the quality of care.

The only time the OASIS is used is for two time points: admission and admission to the agency and transfer to a facility; or admission to agency and discharge from the agency. All of that data collected on those Medicaid patients is of no use.

Other requirements, beneficiary notices are now required and our concern, although we firmly believe that beneficiaries should be notified of when services are going to be discontinued or Medicare coverage is discontinued, there are times when two notices are required at the same event. We are going to be faced very soon with having to give a written notice to beneficiaries whenever the numbers of visits are reduced as opposed -- in addition to whenever services are terminated.

We have a problem with aide supervisory visits every 14 days but the aide doesn't have to be in the home so we have nurses running out to the patients' homes every 14 days, to what benefit we really don't know. Also, who can do that aide supervision? If nursing isn't involved, the therapist can do it but if

nursing is ordered, the nurse must go out and do it even though she doesn't have a visit scheduled during that time.

Then, finally, all of the information that's required to give to a patient on admission. An example I can use of how long an admission visit can be is when even though I've been in home care the best example I have is when my mother was admitted to home care and the nurse spent two and a half hours in the home and another two hours at her own home afterwards completing documentation.

Before she could even start my mother's IV she had to go through the release of information, permission to treat, the OASIS privacy rule, the HIPAA privacy rule, the advanced directives, the bill of rights, and the hotline number, and written notification of who the payer was. Just to give you a quick overview of what these requirements are.

Someone mentioned this morning about limited English proficiency and cultural linguistic standards and the cost of those. One provider sent me an e-mail not too long ago saying that her small home

health agency spent $20,000 for interpreters to meet those requirements just last year. That's it.

DR. SIMON: Thank you very much. Open to the panel. Dan.

MR. MULHOLLAND: I would just like your comments, Ms. St. Pierre, on federal regulation that might inhibit integration between different types of health care providers which seems to possibly address some of the issues that you raised about having to capture data two or three times in different forms for different purposes.

There's a Medicare rule and there's also some anti-trust rulings that limit the ability of hospitals to prefer their own affiliated home health agencies for referrals which puts a bit of a barrier in integration. Then there's the anti-kickback rules that pretty much silo every different type of health care provider, physicians, hospitals, home health, nursing homes, whatever.

I just want to know generally your comments from your experience and people that you've worked with as to whether these federal rules that

inhibit integration could possibly be reformed somehow to allow between flow of information or closer integration of care from start to finish rather than the siloed system we have now.

MS. ST. PIERRE: Certainly they could. The whole problem I see in terms of the referrals and hospitals favoring their own home health agencies is just a creature of competition in any business that is out there. Whether changing those rules, adding new rules, the requirement that hospitals give patients a list of home health agencies that are available in their community certainly then gives them the opportunity to have freedom of choice.

I don't know that in the end it really results in more patients choosing a free-standing home health agency as opposed to a hospital-based agency. Or the regulation once it's completed that will require its proposed rule now, the final rule probably will not happen in November so that means a new proposed rule and that would be that the hospitals must report the number of referrals that go to their own agency as opposed to the community agencies. Again, I don't know

how much good this will do in having a more level playing field as far as where patients receive their home care.

MR. HALL: The example you gave at the end of the small agency that spent $20,000 on language proficiency, in that number and other numbers that you know they may give us, it's always nice to have a denominator, in other words, so if you could quantify in the information you send just the size of the agency in terms of its total revenues or total expenses that helps put the number in proportion.

MS. ST. PIERRE: Definitely. I will also try to get comparable figures from other providers of varying sizes. That is just for the translators. They also have to do staff training. Someone commented this morning that they used to help with translating. That is not permissible unless you have according to the regulations medical background training so that you are theoretically interpreting appropriately for medical needs. And in home care we are not permitted to ask families to translate.

DR. SIMON: Chris and then Rich.

DR. CONOVER: I'm just curious. In your industry I'm curious what your view is of the patient information strategy as a way of improving quality as an alternative to regulation. Do you see that as promising? What are the limitations of that, etc.?

MS. ST. PIERRE: Are you saying in terms of educating patients, educating consumers about their rights and about --

DR. CONOVER: And also putting out information about the use of quality metrics and putting that information out for consumers to use when they make a decision.

MS. ST. PIERRE: I think that is critical. I certainly used that information for my family members when looking at Nursing Home Compare and Home Health Compare. The only concern I have is whether, in fact, there are ways in place to assure that truly is accurate and correct information.

Certainly as far as survey goes you do have the official reports of the surveyors but when you get into MDS and OASIS, is there potential for gaming and is gaming going on? Are patients made to look

worse on admission and better on discharge?

And the comment that was made this morning about the humongous manual for MDS, we have the same thing with OASIS along with 150 plus questions and answers on how do you really answer this particular OASIS item. Part of my job is every day taking questions from providers, "If a patient has this and appears this way, how do I answer OASIS?"

DR. LAWLOR: Hi, Mary.

MS. ST. PIERRE: Hi, Rich.

DR. LAWLOR: I loved the way you opened it up sort of talking about process requirements versus trying to focus on outcomes for the patient. Of course, that is a big theme that our Administrator targets whenever possible in regulations. Then, of course, we hear different perspectives like the speaker before you on, "These are good regulations and these requirements are just what we need. They just need to be enforced." There are good ways -- I mean, ways to see good from both perspectives.

I guess I just wanted to hone in on one thing and ask you a question. You talked about the

requirements of the level of staff needed to do assessments and that's a cost. You have to pay more for better staff, certain levels of training for that staff.

Don't our comment periods to regulations in Government and HHS in particular allow for agencies and advocates to -- don't they allow for the agency to respond with our reasoning to concerns that people have when we do a proposed rule? Obviously we try these efforts now ad hoc and we have Open Doors, for example, to get input before you write proposed rules but is there an issue with the reasoning that comes back to the comments from stakeholders?

MS. ST. PIERRE: I'll allow the opportunity and I have to say I did comment some years back on why can't -- if a physical therapist can do an OASIS assessment and a comprehensive assessment on recertification and discharge and on start of care if there is no nursing ordered, then why can't a physical therapist do that on start of care if they happen to be there? Timing wise that is the most appropriate thing. CMS has certainly determined that they are qualified

to do those assessments but the answer to my comment, they didn't change their mind. It stuck.

DR. LAWLOR: My question is don't agencies like CMS and others provide appropriate reasoning in the depth that's required to respond? Why don't they stick with something versus changing it, for example?

MS. ST. PIERRE: I can't remember the rationale behind CMS sticking with, for example, that particular example. I just read the update for home health PPS for the next year and I have to say in reading through it, and I did it fairly quickly last evening after I got home, but I was left with the impression that the answer sometimes is "because."

DR. SIMON: Any other questions from the panel? Thank you very much.

MS. ST. PIERRE: Thank you.

DR. SIMON: We'll look forward to receiving your written comments.

At this point I would ask is there anybody else who has not signed up who is going to make a beeline for the back to sign up? I think we can perhaps make that process a little more efficient and

streamline some of the paperwork at this point. Apart from that, we have come to the close of our public commentary. I want to thank you all very much.

Oh, maybe we haven't. I'm getting a signal from the back. While we figure out whether we have another name on the back, I will sort of give you again a little bit of an overview of where we go from here. Physically we go to Chicago, as I've said, and we are looking for comments at this point. The public comment period is going to be held open through the web and for written commentary.

These are not the only forms under which you can provide commentary. You need not be present at the meeting. There are web-based and other based systems for providing commentary. I encourage you to go to the web and you may submit them electronically.

That is going to be held open through the middle of February so both for folks who are not here who you want to engage in this process -- thank you very much. A just-in-time delivery -- engage in this process I encourage you to do so and encourage them to submit through the web on the public comment period.

This will be held open through I believe the second week of February so we are able to retain your comments. In particular I have also heard from some individuals who are awaiting reports, who are awaiting other pieces of information that may be produced periodically. I encourage you to submit those as well.

We have another individual who would like to present comment, Laurence Lane. Thank you very much.

MR. LANE: Thank you very much. I expected to have a moment or two to put my thoughts together. I was at a meeting this morning.

DR. SIMON: I can ramble longer if you want.

MR. LANE: I'm Laurence Lane, Vice President of Government Relations, Genesis HealthCare. We provide nursing home, assisted living, rehab services, physician services in 12 states stretching from North Carolina to West Virginia up through New England. Genesis employs 36,000 individuals. The corporation is headquartered in Kennett Square,

Pennsylvania.

A number of Genesis employees, especially members of our clinical operation staff, assisted in the drafting of the formal comments to the Advisory Commission on Regulatory Reform that was submitted by the American Health Care Association. I assume those documents are part of the record.

That March 5 2002 submission identifies a number of specific areas that should be evaluated. I really just wanted to focus on five basic points to bring to the Commission's attention.

I've been involved in the health care side for over 40 years. I would say my first key concern is there appears to be a pervasive disregard for the protection to the Administrative Procedures Act. We are seeing increasing use of web-based transmittals, web-based information, and most recently under the implementation of Medicare Part D things called subregulatory guidance that provide no number, no date, sort of instructions from manna, from Heaven above, that all of a sudden materialize.

Perhaps the most classic example would be

the marketing guidelines for the Medicare Part D PDPs that clearly one has to question whether it has any weight of rule by interpretation. It conflicts in many cases with regulatory guidance. In this case it significantly conflicts with the regulatory and statutory requirements for nursing homes in terms of pharmacy management.

I would say this pattern of moving to informal communications is a serious one that undermines the integrity of the Administrative Procedures Act. I commend Rich and the people at CMS for the open door forums but still there is -- I come from the old school and the rules are the rules are the rules and there really should be comment periods.

I'm concerned for the sheer volume of regulatory guidance. I just looked back through my weekly reports on program transmittals issued in the last three months. It is not unusual to see an average volume of 20 to 25 program transmittals posted on the web-based CMS site per week which essentially says if you multiply that on a weekly basis, guidance is coming in streams with no one quite sure who reads it on the

other end.

My third concern is directly related to that and that is concern for the e-communications have empowered lower levels of Government to generate guidance absent quality control and absent a serious venting of the issue. If you look at those 20 transmittals per week that have flowed out over the last three months, and that's an average every week, you will find at least two or three of them rescind guidance given within a three to four-week period.

What that suggest to me is nobody has read them before they have been posted. Or if they have, they didn't read them carefully and that suggest that access to e-commerce has created a sort of going around what used to be -- again, I'll say I'm old school -- general counsel used to read things, used to advise on things. Actually what we posted ended up being right and not interpretations.

Fourth concerns restructuring and tax-focused management has undermined managerial and legal oversight of regulatory guidance. Classic example -- Rich is well aware of this because he's had to sit

through several open door forums where this has been the key topic -- there has been a new set of rules to deal with beneficiary notification of appeal rights. The 59-page clarification of what was the initial three-page memo has even those of us who think we knew what they meant absolutely mystified. One could go on for longer on that.

My fifth concern, the agency forgets that regulatory guidance is only paper when issued by Government. It becomes effective when we, the providers, are capable of interpreting guidance in the policy and procedures and in the day-to-day operations. Again, a classic example.

We ended up with rule promulgated related to immunization for nursing homes on a 15-day comment period with the rules being finalized on the second week of October, the web-based instruction in place on the 1st of October. We are now on the third change in the Raven software interpreting that guidance.

When you've got 36,000 employees across 215 sites, at least give us a day or two to take and help put our instructions in place. Another example,

we will have -- I realize some of this is law driven and some is regulatory driven -- the new grouper for the RUG-53 payment structure which probably means nothing to most of you, but the reality begins to be that will come out on November 21 but must be in place by our facilities to use on November 22. That is our complete payment structure system.

I would just say in closing the worm's eye view of the bird is significantly different than the bird's eye view of the worm. Stability is necessary for day-to-day operations. Instability caused by unclear Government guidance must be overcome. Government by silo is distorting care delivery.

Government by e-communication undermines the ability for concerned parties to be meaningfully involved in participation and comment, particularly when they avoid the Administrative Procedure Act protection, and the OMB rulemaking process. Government by hit or miss transmittals, which is one of my big bugaboos, leaves confusion. No one knows what the rule is.

I would appreciate the effort of the

Commission. I unfortunately have testified before these commissions for the last 25 years and I must admit I have not necessarily seen a reduction in rules and regulations. We do give care in spite of the rules and regulations, not necessarily because of it. Thank you.

DR. SIMON: Thank you, Mr. Lane. Let me guess, Rich.

DR. LAWLOR: We should all respond to this because of the value and humor alone. You know, the Government from time to time has been criticized as being too slow so when I hear about this failure to follow the Administrative Procedures Act because we are doing things in an ad hoc process informally as much as possible, increasing the volume of participation before and during rule development, I find it a big disconnect or dichotomy in your point there.

All the different roles of external stake holder involvement that we are trying to integrate and agreeably not perfectly yet but trying to find the effective sweet spots in these roles that we bring people in to work with us. Obviously the Internet has

a parallel to that, using it more often more rapid information deployment and exchange and so forth.

I must argue the counterpoint that this is good. It's going to speed up. It doesn't necessarily change the scale or the burden of regulations but it does increase information flow between the outside and the inside of the agency.

I would comment back that I had the pleasure of going down to South Africa when the Mandela government first came into play to spend some time on personal leave to help get the new South African government organized.

I remember visiting with a comedian who was spectacular. He pointed out that during apartheid we knew nothing and nobody knew what was happening. Now we have seven official languages. The news runs in seven different languages in 15-minute clips and we're not sure what the hell is happening.

As you look at the Open Door forums I will commend CMS. Probably the major, major change that CMS has done is its openness of communication and the Open Door forum. As Rich knows, because I participated in

several of these whether they want me to or not, if you were to itemize the number of tasks that are discussed, it's like any business. There is a lot of activities under way but if you are focused on what your primary purpose is, and our primary purpose is care giving, then you scale back activities that don't support the care giving function.

I would just suggest that if one cataloged the number of issues that come up in the Open Door forum in any one of the 12 or 15 panels, one would walk away with a litmus list of projects that from a managerial perspective says, "Are these necessary and do they help us on the primary mission of our agency?" You compound that by 50 states -- I happen to operate in 12 states -- and you can begin to see where the level of change that is occurring is not integrated as well as is our care mission at bedside.

DR. SIMON: Dan and then Chris.

MR. MULHOLLAND: You are kind of preaching to the choir as far as I'm concerned, Sir. One of the problems I have consistently had as a lawyer advising clients is trying to find what the rules are. I

remember 15 or 20 years ago it took a lawsuit to force the Government Printing Office to publish an index to the Code of Federal Regulations in the Federal Register.

One of the problems I have with the Internet, it's a sword and a shield. It's a great thing in terms of getting information out. The open-door forums are an example of that. I think some of the access that people have to the regulators now is helpful for clarification. But the big problem I see is simply trying to find where all the rules are. If you try to search for transmittals on the CMS website, it's just a basic key word search.

Unless you are very adept at it you get a lot of junk in trying to sort through all the information. It would seem to me that the technology is at the point where at least somebody could publish a concordance of all Medicare rules, transmittals, regulations, whatever, so at least we would know what the rules are. I find, and I would like your comments on this, it sometimes breeds contempt for the law that people throw up their hands figuring no one understands

it.

Somebody is going to get me no matter what I do so I'll do whatever I want. I don't know if you've seen this either in your facilities or reaction in some of the folks you work with in your organization to this avalanche that is really hard to go through to find out what a rule is when there is a rule as opposed to situations when it's whatever somebody says in the last audio conference.

MR. LANE: Well stated. Again, I have two bookcases in my home of CCH that used to publish this stuff in printed form at an affordable price. Through '98 I actually did know what the handbook provisions were. Since then it has gone to the computer and it does create some interesting issues.

And it creates some dilemmas, and that is you'll have fiscal intermediaries that will apply rules of thumb. When you ask, "Help me understand where is that," they sort of look at you and say, "Oh, was there supposed to be something there?" You are correct and I would give the classic example of when they converted the SNF manual over to the electronic version.

It took six months for CMS to realize that it left the whole section on how you bill for SNF services out of the new electronic version. What is more frightening that no one in the industry knew that until CMS actually published it which basically said nobody had looked at what was online.

DR. SIMON: Chris.

DR. CONOVER: I just want to be clear. I understand your concerns about circumventing proper procedures in terms of giving advance notification and sufficient time frames for comment and things like that. That is the downside of having instant access to the web.

On the other hand, assuming that the procedures were done correctly, am I to understand your concern to say don't ever use the web and we really ought to stick with the print because the print worked pretty well and that is what's reliable and we know where things are?

MR. LANE: No, quite the contrary. I would say that in my old age I have gotten adept at looking up stuff on the web. What I am suggesting is

there appears to be some need for better quality control. Secondly, more involvement of the Office of General Counsel in saying, "Um, this is not a clarification. This is policy."

That delineation between what is an interpretation of what is rule and statute which is generally a fairly bright line versus that which is murky guidance that is sort of moving beyond interpretation and becoming reg. really is something that needs to be looked at.

I'll give you -- the thing that perhaps most excites or incenses me is this beginning process of using subregulatory guidance that is pervasive through the implementation in Medicare Part D which essentially has no regulatory number on it so I can't say to you this is transmittal 37444503 and date. It is just paper with no office taking responsibility for issuing it and nothing that looks like an OMB number that deals with guidance.

We are implementing perhaps a trillion dollar benefit with such subregulatory guidance and as it relates to nursing homes it's very clear the

subregulatory guidance that has been issued back in March doesn't have a number, doesn't have a weight, and you don't know whether this means contractual obligation or interpretation. You don't know how it applies to the issue of must a PDP do this or should a PDP do this.

The regulatory marketing guidance that came out again, even though it was circulated for comment, in this case is deceptive and, in fact, counterproductive. We as a nursing home under reg. and law have an obligation, and under a new 185-page draft coming out of certification and survey as to what is the F tag for pharmacy management, at least something we've read, that says that's our obligation.

Yet, when one reads the substance of the subregulatory guidance, there is no reflection that we have a regulatory obligation to manage pharmacy in our buildings and no tool in that guidance to give us a role to exercise our responsibility.

DR. SIMON: Other questions from the panel? Mr. Lane, I am going to thank you for your

comments.

MR. LANE: Thank you.

DR. SIMON: I would also sort of to be a broken record encourage you to the extent possible when you prepare your written testimony if you can help us by quantifying from your firm's perspective the additional work that you have to go through as a result of some of the issues that you've raised. That would be most helpful.

Rich.

DR. LAWLOR: Can I ask our panelists a question?

DR. SIMON: Sure. Actually, you can do that and then I actually have had a request from somebody that I cut off in the field to ask one more question -- to raise one more point. I promised him 30 seconds and also the question of not to make me regret that. I'm going to defer to Rich first and then to Walt.

DR. LAWLOR: I didn't necessarily -- it's not very often that I get to sit next to smart people in economics which I find is extremely enjoyable. I

wanted to ask you guys relative to the idea of subregulatory guidance, and we have used a good bit of it in the recent past.

We have tried to vet it through interaction with everybody involved through a lot of dynamic conference types whether it's teleconference in person or combination, etc., etc. What should become of subregulatory guidance at this point that we've developed? What's the next step? What do we do? Do they become artifacts or should somebody say do something with this? Not necessarily codified in regulations but what should happen?

DR. SIMON: Dan.

MR. MULHOLLAND: If I could just comment on this as a practicing attorney, I think it should be very clear what subregulatory guidance is, what it means, and how far it goes. I find it helpful somewhat, too. A lot of different agencies give it but what you worry about is that it suddenly becomes law or the perception is that if somebody in the Government said something, then you better do what they say even if it isn't correct.

I think if there were appropriate disclaimers saying this is how we are interpreting this and it has a limited shelf life and if there are additional questions, there should be a fairly streamlined advisory opinion process. I know a lot of agencies have it. Some don't. Some have resisted it.

I think CMS resisted it even though the FTC, the OIG, the IRS all have procedures, albeit cumbersome to give specific guidance, but I think if there could be a streamlined guidance procedure that someone can rely on saying, "Okay, I have a letter from CMS that says I can do this. Nobody is going to get me if I do something wrong."

That would be preferable to the kind of amorphous subregulatory guidance that you sometimes see and nobody knows whether it's going to be in effect next week or who said it or how long it's good for.

DR. LAWLOR: I just want to point out that we have on our website an input mechanism right now. I believe it's still open. We are asking comments on how to produce guidance. FDA has done it. We were there.

A lot of the focus is in the coverage area but these are issues that are very parallel to the guidance we have used with Part D so thanks.

DR. SIMON: Other comments? Okay.

Walt, I give you 30 seconds.

MR. FRANCIS: Very quickly the two last commentors especially but some others, I know of a serious case of subregulatory guidance. There are apparently a lot of people who believe that there is a federal regulation that requires that health care providers pay for language interpreters. There is no such federal regulation and there probably never will be.

There is no regulation that says a family member can't interpret. There is guidance out there, some of it quite official looking, issued in the later part of the Clinton administration but there is no such regulation. You might want to explore, because I really think this is a big problem for a lot of people just what is official, what's required, what isn't, and that might be one regulatory area to specifically look at because it is a continuing problem.

DR. SIMON: Comments? Thank you. You did very well, 30 seconds.

We have reached the end of our program. I want to thank you all for your attention, for your contributions, and most importantly look forward to additional input from you, from your colleagues, and from the public because this is your opportunity and this is what our study rests on is getting solid evidence of cost and benefits of regulation so that we can put this into perspective. I look forward to seeing some of you in Chicago. In the meantime I encourage you to have a very nice day. Thank you very much.

(Whereupon, at 2:06 p.m. the meeting was adjourned.)