U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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TOWN HALL MEETING

"ECONOMIC IMPACT OF HEALTH CARE REGULATIONS"

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THURSDAY,
FEBRUARY 2, 2006

The Public Meeting was held in the Sonoma Ballroom, Lobby Level of the Hilton San Francisco Fisherman's Wharf Hotel, 2620 Jones Street, San Francisco, California at 10:04 a.m.

MODERATOR:

CAROL SIMON, Ph.D.,

EXPERT PANELISTS:

CHRISTOPHER J. CONOVER, Ph.D.
H.E. FRECH, III, Ph.D.
MICHAEL A. MORRISEY, Ph.D.
DAN MULHOLLAND, M.A., J.D.
WILLIAM D. ROGERS, M.D., FACEP

SPEAKERS PRESENTING COMMENTS:

ANDREW ROBERTSON, M.D.
BARBARA PAUL, M.D.
MELINDA STAVELEY
CHARLENE HARRINGTON, Ph.D.
SERGE TEPLITSKY
DAVID WOODS, Ph.D.
JOSEPH HAFKENSCHIEL
KEITH PUGLIESE
RON DODGEN
PEGGY GOLDSTEIN
STEPHEN CORNELL

I N D E X

P R O C E E D I N G S

10:04 a.m.

DR. SIMON: Good morning. Welcome to the Fourth Town Hall on the Economic Impact of Health Care Regulations. My name is Carol Simon and I am going to be your moderator today, and all around traffic cop.

We have a full agenda, and the subject of the agenda is basically to listen to you folks, to listen to testimony on the impact of health care regulations: their costs, their benefits.

This project, which others will speak to a little more broadly, is part of a larger endeavor that has been in fact requested by Congress.

The Town Hall Meetings, the public comments are part of a process in which we are examining evidence geared toward a report that is aimed to streamlining health care regulations, streamlining in order to reduce the burden on providers, and to free up resources to improve the quality of care and to continue to protect patients and health care outcomes.

The agenda today is pretty simple, and so I'm going to go over a few of the sort of ground rules here. For those of you who intend to prepare comments, I hope that you signed up outside. There was a sign-up list as you registered. I am going to be taking the public

comments in the order in which you signed up. If you have any time constraints or other issues, please see me at the break, and we'll try to accommodate them the best we can.

We have a reasonably full house today, and so we are going to try to allow time so that everybody has a chance to present their comments. No voice is more important than the other.

So the ground rules are something like this. I'll call your name, I'm going to ask you to introduce yourself, tell us who you're from, who you're representing. I'm going to give you about five minutes, and those five minutes are to review your statement. Many of you, I know, have more to say than that. So if you don't talk as fast as I do, or we don't quite get through your time, I encourage you to leave a copy of your comments, or to send them to us via electronic mail, and I'll make sure that you know exactly where to send those.

In your packet is an e-mail address that is associated with this project. So the comments that you present today, or comments that you think about when you leave the room, or evidence that you and your colleagues have back at your office, we need to hear from you. So please submit the testimony, your commentary to the public web site as well.

So I'm going to give you like five minutes, and

there is a spiffy little light system up there, and I called myself a traffic cop for a good reason. The light goes on at green, at three minutes it goes to yellow, at four minutes I start waving madly at you, and at five minutes we ask you to sum up.

The gentlemen up here are part of our panel of experts, and their role is to help us in many ways clarify some of your comments in the context of the larger project. So at the close of your comments, I'm going to turn the podium over to our experts for a little bit of Q&A. They are going to have collectively five minutes, and that's frequently harder for this group than it is, indeed, for me.

So what I'd like to do at this point in time, though, is to introduce a couple of folks from the Department of Health and Human Services, and from the Regional Office of HHS who are going to tell you a little bit more about the project.

We'll then go to our panel of experts and let them introduce themselves to you, and then we're going to start off with your comments.

So I'd like to call on Ruth Katz who is from the Assistant Secretary for Planning and Evaluation's Office in the Department of Health and Human Services and Ruth will tell us a little bit more about the project, and give

you her welcome. Ruth?

MS. KATZ: Use that mic?

DR. SIMON: This mic will be on in a second.

MS. KATZ: Okay. Great.

DR. SIMON: Thank you, Ruth.

MS. KATZ: Thank you, Carol.

I want to start this one the way the Oklahoma City one started because it was such a great way to start the day.

Carol got up, and she started the wonderful shpiel that she just started to kind of get everybody going, and this woman in the audience -- there were about 100 people there, 120 people there -- this woman in the audience yelled out, "You have a beautiful smile." And it was such a great way to start the day, you know. So we'll start like that.

(Laughter)

MS. KATZ: Carol?

DR. SIMON: It really was great. So if anybody wants to offer a little --

(Laughter)

MS. KATZ: She just -- it was so shocking and surprising. Carol said, "Thank you. Thank you very much." But it just set us off on a nice tone.

Good morning. Thank you all for coming. It's

amazing. I noticed this at the last one. As Carol said, this is the fourth and final of our Town Hall Meetings. It's very generous of people to share their very valuable time to come and talk to us. We realize that you're doing this to help us help you, and it's very good for us; very generous of you.

The purpose of this meeting, as the other three, is to quantify -- seek your help in quantifying the economic impact of federal regulations on the health care industry.

As Carol said, my name is Ruth Katz, and I'm from the Office of the Assistant Secretary for Planning and Evaluation. This project is about bureaucracy, how much bureaucracy, good bureaucracy, bad bureaucracy, so I'll share with you my title.

My title is Deputy to the Deputy Assistant Secretary for Disability, Aging and Long-Term Care Policy in the Office of the Assistant Secretary for Planning and Evaluation. So it's kind of long.

DR. SIMON: Your five minutes are up.

MS. KATZ: Okay. Yeah.

(Laughter)

MS. KATZ: Yeah. There's bureaucracy for you.

ASPE is -- has been asked by the Congress to run this project. We're kind of a good place to do it. We're

a policy advisor. We are the Secretary's policy advisor, and we have the wonderful good fortune of having a little bit of money to do some research too.

So what we can do is figure out policy issues, policy questions, and if there -- if it is possible to try to address them with data with information, ASPE's the place to look for that data, to collect it, to analyze it, and then to try and bring that back to the policy process. It's an incredible opportunity for us, and for people who talk to us too.

As we began work on this project, we realized that many things have changed over the past decade in health care, and one of the things that just doesn't seem to change is regulation. It's always there. We get complaints about it, we get complaints that there's too much, complaints that there's not enough. We hear about it all the time.

Why does the government regulate? We get questions about it, whether regulation distorts practice, or contributes to good practice, and we like to touch base with people, and hear back from people about this.

Our previous excursion into health care regs was the Secretary's Advisory Committee on Regulatory Reform, SACRR, which produced this report in late 2003. I don't -- is it still available? Can people get hard copies?

You can get the on-line version but not hard copy? Yeah. Okay. The hard copies are out, but you're welcome to come and take a look at this too, and you can read it on-line.

There were 255 recommendations that came from a very broad swath of people providing input, and 84 percent of those recommendations have been implemented, we're very pleased to say, to streamline federal programs.

The majority of the recommendations of course, because it's health care, related to the Centers for Medicaid and -- Medicare and Medicaid services. And as a result, CMS's outreach -- I think as a result of that process, and our other work CMS is doing -- CMS's outreach and information sharing processes that they used prior to the development of rules and regulations has probably even altered and gotten broader.

We're very glad that Bill Rogers is here today with us, and our friend from CMS, and actually all the panelists are here, and we're pleased that they're all with us today.

So anyway, with SACRR behind us, and with this book, and implementing these recommendations behind us, we are looking now, because we have been asked to do so by the Congress and because it seems to make sense, at the economic impact of regulation. This is a real tough question.

After we accepted the assignment to examine the economic impact of regulations on health care we started to plan how to do it. So we had to -- we had a very short time frame to do it, and a lot of decisions to make, and a lot of work to do.

So the first thing we thought we would do is that well, you know, we could just do a literature review on this, although there's not a whole lot of literature, but we could just go do that and check we've done it.

But it seemed better to come back to people, the people in the industry, the consumers, people that are on the other end of that regulation that they see all the time. Talk to them and hear from them.

One of the problems of working in Washington is that you deal in two dimensions and they are 8-and-a-half by 11, and it's really nice to get out and talk to three-dimensional people who are out there in the world. I wish we could do it everyday, because every time I do it I hear things, I learn things from people and it helps me do my job better. It helps all of us do our job better.

Thinking that we wanted to do more than just ask people to talk to us in person, talk to us on the web site we went ahead and published a notice in the "Federal Register" seeking comment and quantification. So that's the big kind of hook here, is that: Can you quantify the

economic impact? And you'll hear all of us, and members of the panel, and Carol, “But can you give us numbers? Can you talk to us about the economic impact?” And that's really what we're looking for.

And our final decision in this project to get more information was to make what we're calling some "house calls," a series of case studies which Carol and folks from Abt are helping us with to see if we could get past, get deeper even, beyond what we hear here, and then take that with us and talk to people in case studies.

I do want to credit some people here. Abt deserves enormous credit for the work that they're doing, Carol Simon. Jessica Kasten has also been a big player here. David Newman.

The folks that greeted you at the door, Vanessa Timmons and Bridgette Saunders have really stuck with this project and done a great deal of work.

I want to acknowledge Adele Simmons from our office, from ASPE, for all the great work that she has done.

And mostly I want to acknowledge you and thank you ahead of time.

I was thinking about Carol's smile, and she is like Snow White. She's just so great. She's so sweet, and she's so wonderful at the beginning of your five

minutes, and as the clock starts to go, she turns into Cruella deVille, okay? The federal government is not Cruella deVille, but -- so that's why we hire a contractor to do this evil job. She will stop you at the end of five minutes, please keep that in mind.

Anyway, thank you so much for helping us with this data gathering, and I look forward to hearing from all of you today.

DR. SIMON: Thank you, Ruth. I certainly have a lot to live up to at this point now. No magic apples during the break please.

Okay. I would also like to welcome Mr. Emory Lee who is --

MR. NEWMAN: Carol.

DR. SIMON: Well, I thought I turned it on, and I didn't.

I'd like to welcome Emory Lee. Emory is the Executive Officer from the San Francisco Regional Office of Health and Human Services. Did I get that right?

MR. LEE: Right.

DR. SIMON: Excellent. Mr. Lee?

MR. LEE: I'd like to welcome all of you to Region -- on behalf of Region IX to this very important Town Hall Meeting. I bring greetings from our Regional Director, Calise Munoz who is in Arizona today and

couldn't be here, but she serves as the Secretary's personal representative in Region IX, and as a -- part of her responsibility is working with the state, local, territorial, and tribal governments in our region on the oversight and coordination of our department's program.

I'd like welcome all the speakers and the attendees today, certainly the distinguished panelists here from -- coming to California, and to our host, the Assistant Secretary for Planning and Evaluation.

This is a part of ASPE that I haven't dealt with. They're -- ASPE is really important for us, because we look to them for issues and guidance on things running from homeless policy -- homelessness policy to self-governance for tribal governments on departmental programs that they could very possibly administer themselves, and so we'd like to acknowledge them.

And building upon your two-dimensional analogy, we encourage and tell people in central office to contact and work more closely with the regional offices because we are the three-dimensional part of the department, and we have the on-the-ground experience in working with people.

We have a few of the representatives from our Regional Office here today. I'd like to just acknowledge them: Diane Caradeuc from CMS. She's the Acting Associate Regional Administrator for Medicare Financial

Management.

We have Nicole Lockey, who's the Special Assistant to the CMS Regional Administrator. Janet McDonald who is our Food and Drug Administration Public Affairs Director for Northern California. And a young intern who's working in my office currently, Cami Lee who is an emerging leader on assignment out here from Washington, D.C. from HRSA, from our Health Resources Services Administration.

It's really fitting that the final Town Hall Meeting is held here in California. California has such a huge health care industry and it has certainly a lot of innovations underway, including all the health insurance demonstrations that our counties have been providing health care to children in particular.

We also have the cutting edge on the part of the health care, everything from biotech to stem cell research to health information technology. And so the meeting here today obviously is going to be very important because we need to design programs, we need to draft regulations that are sensitive to the economic impact of those regulations.

Too often times you read in the newspaper, everything is -- everything that you see and read are budget oriented, the budget deficits, the cost control steps that are being taken.

You know, Congress -- the House yesterday passed a $39 billion budget cut that's going to affect everything from student loans to crop subsidies, to in particular, of interest to work, obviously is Medicaid.

We -- as a matter of fact, our Regional Director was in Sacramento yesterday appearing before a state joint legislative hearing having to do with the Medicare prescription drug costs related to that.

And so town hall meetings like this are important because we need to have it at the front end. We want to avoid the litigation. We want to avoid all the burden that is eventually going to come to all of us if, in fact, there are cost overruns.

And so I look forward to -- I looked at the list of the attendees who had signed up, or registered for this program. It's a very, very impressive list. It represents a cross-section of health care administrators, providers, physicians, practitioners, and so I really look forward to hearing today from -- your comments, because as we need to work together to be able to keep costs under control, and most importantly to bring health care in a very -- deliver health care in a very economic and safe way. Thank you.

DR. SIMON: Mr. Lee, thank you. Thank you for giving us our charge. So as my son would say, let's rock

and roll.

I'd like to introduce to you our very distinguished panel of experts who, as I said have -- could speak on these topics in their own right, and we're not going to give them more than five minutes at a shot to do so.

Their role here is to help clarify, to ask some questions, and in many ways to be an assistant to those of us who are now then going to try to use your information to craft a larger picture of the problem in health care.

So may I introduce -- let's start with -- we'll do this alphabetically, as much as I'm fond of the end of the alphabet. Our first panelist is Dr. Christopher Conover, a professor of economics at Duke University. Chris, do you want to -- and those are all on guys, or they should be.

DR. CONOVER: Good morning. I'll leave it to you to deduce whether I'm up here representing Dopey or Sleepy.

I've done work on all sorts of health services regulation, but what I've done most recently is this compilation of literature, and in your packets is a little summary of what we found.

I too like hearing from three-dimensional people, and these town hall meetings are very interesting

to me. I look forward to hearing your comments today.

DR. SIMON: Great. Thank you, Chris. Our second panelist is Professor Ted Frech from U.C. Santa Barbara.

DR. FRECH: Thanks. Yeah, I'm from U.C. Santa Barbara, so I came the shortest distance of the people on the panel, although in the fog it didn't seem that short.

I do a lot of economic research and consulting in health care, in health care regulation, hospital competition, physician competition, Medicare reform, nursing home reimbursement, a whole bunch of areas. I've been doing it for a shockingly long time.

DR. SIMON: Thank you, Ted. Our third panelist is Professor Michael Morrisey from the University of Alabama at Birmingham.

DR. MORRISEY: Thank you. And with a Ph.D. from the University of Washington, it's always nice to be back on the West Coast.

Unlike Ted, I've only been working on the issues of hospital and health insurance markets for 25 years, and my interests in regulation have revolved around certificate of need, state insurance mandates, mandates with respect to managed care plans, and most recently, medical malpractice.

DR. SIMON: Great. Our fourth panelist, for a

bit of a change of pace is Mr. Dan Mulholland. Dan is an attorney with Horty Springer.

MR. MULHOLLAND: Thank you, Carol. Hello everybody. Our firm represents hospitals and their medical staff leaders in boards around the country, and we have an opportunity, if you can call it that, to see the effects of the regulatory system on a day-in, day-out basis. So I very much look forward to your comments today.

DR. SIMON: Thank you, Dan. And last, but not least, we have Dr. William Rogers from CMS.

DR. ROGERS: Thanks. It's not often that alphabetical order puts me at the end, but this is a -- I guess this is a sort of biased group here, huh? At least alphabetically.

I'm a practicing emergency physician. I worked full-time practicing clinically and running emergency departments until 2002 when I accepted an offer from Tom Scully to dramatically reduce my income tax exposure by coming to work full-time for the federal government.

I continue to work clinically, though. In fact, I worked four shifts last week in addition to my regular federal job.

But my main job is representing providers at CMS, making sure that the regulators at CMS understand the

reality of the business that providers are in, and the reality of their clinical challenges, and I do a lot of traveling in that role. This is just one more opportunity for me to find out what the community we serve sees as problems with the program.

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

All right. I'd like to begin the public testimony portion of our program. When I call you, you can take your choice of the microphones that are here.

Please repeat your name for -- in many ways for the folks who are recording this on public record in the back. Tell us who you're from, and watch the little lights in front of you. Again, I'll be giving you approximately five minutes, with five minutes for Q&A.

So, if I could call Dr. Andrew Robertson to the microphone? Dr. Robertson.

DR. ROBERTSON: Thank you very much. I'm a neurologist by training, and currently a health care consultant. I work Joint with Commission Resources, and in addition, the California Hospital Association co-sponsor representative in the California Technology Assessment Forum. And that latter point is what brings me here.

I have developed a keen interest in evidence-based medicine, and the use of good information in the

both management and regulation of health care delivery.

As we all know, health care is extremely complicated, and we have an expensive but very varied system here in the States. I would like to appeal that we can reduce that complexity and promote better services for beneficiaries through the use of good information.

Whether it's new drugs, which are expensive, or new technology, which consumes a lot of capital, the benefit of using evidence-based medicine that will provide data to improve decision-making from regulators through providers to patients will improve our ability to spend wisely, and provide better services for more people in the future.

Gathering evidence-based medicine will need a number of particular points to be considered by those involved in regulating, and writing policy:

That is, adequate data protection for those medical records that are included in the gathering of evidence-based medicine. This will mean continually reviewing and making user-friendly regulations such as HIPAA;

Continuing to support provider ownership hospitals and physicians of the primary data;

And continuing to push harder for evidence-based medicine to be gathered from an electronic medical record.

Furthermore, I believe that the excellent program with reimbursement with evidence development that CMS has currently embarked on is a program that deserves more attention and more support. This will benefit beneficiaries and taxpayers. It will reduce the misuse of capital, improve the efficiency and efficacy of care, and ease access and care decisions for beneficiaries. Thank you.

DR. SIMON: Thank you. Well, this is actually a record. I don't think we've had a speaker who has left time on the floor. So we applaud you in the spirit of economic efficiency for your -- the efficiency of your remarks.

May I turn to the panel first. Chris?

DR. CONOVER: Thank you for those remarks. I'm curious. Is there something about -- and most of what you said was sort of complimentary, and sort of future oriented. I'm curious about whether -- are there specific ways in which regulation now, you know, isn't doing the right job, or you know, are there specific examples of how we can improve regulation right now?

DR. ROBERTSON: The cost and complexity, for example, in implementing HIPAA, if we get to consider how that plays in the future, we might look for simpler ways of codifying and regulating that.

You've already commented as a panel that the issues of medical malpractice present some economic challenges. I believe that if we were to improve access to medical records, the electronic medical record, that there needs to be appropriate separation from any litigation-focused, as opposed to research-focused access to the record.

We don't want to open Pandora's Box and find that the opportunity to gather good information that will improve health care is closed by self-serving, or misperceived risks by any of the stakeholders, be it a patient, be it a physician, be it a hospital, or be it a researcher involved in looking at new technology.

I'm reminded that the electronic age has made life more difficult. I discovered that my bank now requires if I'm to access cash when I travel overseas, pre-notification so that their fraud alert systems don't block my ability to get cash.

As we proceed with data that's digital, and quick, and easy, appropriate controls, and appropriate thoughtfulness of the regulations needs to be considered early in the process to make sure that it is rolled out smoothly and easily.

Did I answer your question adequately?

DR. SIMON: Mike, and then Dan.

DR. MORRISEY: Could you speak a little more about provider ownership of the primary data as opposed to say, insurers or a state agency?

DR. ROBERTSON: Well --

DR. MORRISEY: Or consumers for that matter?

DR. ROBERTSON: Or consumers. Well, I think the consumers have some good access in the current regulation. Insurers can request copies of records, but the access belies the ease and the ability to process the data, and in order for, for example, the generation of evidence-based medicine, which relies on good randomized controlled trials, or longitudinal case studies on the exact data for each patient subject to a new drug, or a new technology, requires a lot of trust and a lot of good access.

Two-thirds of the time new technologies brought before a California Technology Assessment Forum has no adequate data. They can pass the FDA, which requires safety equal to existing technologies, but it doesn't prove benefit from the additional expenditure, or adequate safety.

And the only way we're going to get to this is when good research is done on the primary data as soon as possible, which means that two-thirds of the new drugs and new technologies need to embrace this early on, and they're not. And part of the reason is there's a little

bit of concern by many providers that they don't want to release this information in such detailed a form.

We need adequate protection for that. We need positive encouragements. We need thoughtful processes.

DR. SIMON: All right. Dan?

MR. MULHOLLAND: Doctor, I'd be interested in any comments that you have about the extent to which federal regulation, in particular the fraud and abuse laws, the anti-kickback statute, and to so-called Stark law might impede connectivity between doctors and hospitals.

And a specific example, a lot of doctors are looking to hospitals for assistance to wire their offices into the hospital, upgrade their information systems, their EMR systems. But if a hospital is doing that to a doctor who refers to them who's not an employee, that raises some fraud questions.

I know that the government came out with some very limited proposals to lighten that up in November, but I'd be interested in your comments from seeing this on a regular basis as to whether you think that that's a -- any kind of impediment to the kind of electronic medical records system that you're advocating, which I think makes a lot of sense.

DR. ROBERTSON: Here in California, the

corporate prohibition against employing physicians, hospitals cannot employ them directly, has created a slightly different environment.

I was a shareholder member of Hill Physicians, an IPA, and I have recently been associated with Sante IPA, and they are an exclusive IPA to the hospital system I used to work for.

Both those entities, which I know in more detail than others, are choosing to diminish physician reimbursement for a short period of time, one, two, three years, to capitalize the placement of a single electronic medical records system for their providing physicians.

I think by chance, rather than good management, that clearly is a superior way of doing things than what may be happening elsewhere in the country. And as you are alluding to, many hospitals have a closer working relationship in other states with their physicians on the medical staff, and their primary care physicians, and this raises the whole issue of, as you point out, Stark II infringements, which could cause them to take complicated legal steps to sidestep it, but the basic tenant is that there could be concerns on all sides that this is not a healthy working relationship.

I would encourage regulators to consider how they support physicians better capitalizing this, or

continue to push forward with the Veterans Administration software program that is inexpensive, and if there was adequate support, might be a reasonable alternative for some groups, or rural areas.

DR. SIMON: Great. Thank you very much. Other questions from the panel?

Dr. Robertson, thank you very much for your time.

DR. ROBERTSON: Thank you for your time.

DR. SIMON: Okay. And I will ask Dr. Robertson, but also remind all the panelists, that if you have brought with you written comments, written copies of your comments, please make sure you leave them with one of the ladies outside before you leave. If you wish to submit them to our web site, that the address is in your packet, and please see me, or any of the other representatives out there if you would like any additional information.

Our second speaker is Ms. Barbara Paul. Barbara?

DR. PAUL: Thank you very much. It's a pleasure to be here this morning. I'm Dr. Barbara Paul, and I am an internal medicine physician, currently the chief medical officer for a company called BEI, which is the parent company for Beverly Health Care Nursing Homes, AseraCare Hospice and Home Health, and Aegis Therapies. I

have provided hard copies of my comments, and I think maybe the panel has them.

Before I took this position, I was at CMS, and in fact, led the Physicians Regulatory Issues Team before Bill took it over. I also launched the Nursing Home Quality Initiative, and Home Health Quality Initiatives for Tommy Thompson and headed up the Quality Measurement Group there, working a lot with hospital measurement.

Before that, I was an internist in full-time practice in Napa, California, actually. So I bring that perspective to my comments here today, both as a physician, as a senior policy person at CMS, and as well now as someone who's in the trenches with a provider.

My comments are really in three parts. Just three points.

First, I would like to offer an alternative framework to the sort of less/more debate about regulation.

Secondly, I would like to give you an example of conflicting regulations.

And then third, talk about an example of gaps in regulation.

So -- and I am speaking primarily here for the long-term care sector, and I'm -- my understanding from these hearings is that you're hearing a lot from the

nursing home sector, and I'm sure you're hearing both testimony regarding less regulation and testimony regarding more regulation.

And we do, in the nursing home area, need to improve the care in our facilities, and regulations do help us to improve that care. But the best thinking about quality improvement is much more inclusive than thinking that additional regulation upon regulation is actually going to truly improve care.

And I would like to give you the strategies that are listed on my -- the handout that I have for you, there's seven of them that are actually employed by CMS to improve care. It includes regulation. It also includes appropriate payment and payment policies.

But it also includes technical assistance, which for CMS is the Quality Improvement Organization Program, rewarding superior results. Increasingly CMS is implementing pay for performance and other rewards for superior results.

The whole push towards standardization, which I think is incredibly important for enabling good-hearted care givers to be able to do what they need to do, to have that underlying standardization. And the federal government is in the unique position to really push that underlying standardization.

Collaborations and partnerships, and then informed consumers.

And that list is not my list. That is a list that was created by the quality team before me at CMS, and is a list, however, that I relied on when I was there, and I continue to rely on it in my work in my current position, and it really makes the point that regulations are only one part of improving quality.

And this -- and nowhere is this more apparent to me than in the nursing home sector where for years the response to an issue or a problem is another regulation. And it has led to a paradoxical problem, which is that people, both surveyors, regulators, as well as people working in nursing homes therefore believe that the lack of a deficiency on a survey means good care.

And I think this is a misperception. We know -- particularly I think clinical people know that that's not necessarily the case. In fact, there can be a better way to do something than the way that's going on right now that does satisfy a regulator or a surveyor.

And it's only by applying these other strategies that we will get where we need to get to in nursing home care in terms of the quality that everyone wants. So that's my first point, which is to look at that framework.

Secondly, conflicting requirements. There's a

situation right now under Medicare Part D with nursing homes in which we are required to provide the medications prescribed for a patient.

On the other hand, prescription drug plans, we have moved from one Medicaid formulary to maybe a dozen in our facilities. They are allowed to have closed formularies. They are allowed to have a variety of hoops for the physicians, or others have to jump over to prescribe him that.

We are caught in a bind, and CMS is working through a lot of these issues, but this is a bind that simply Part D does not work in the nursing home setting right now. And I'd encourage you -- I know you're getting a lot of testimony about Part D -- encourage you to send the message back from you that CMS really needs to look at the nursing home setting differently. It is a different entity than the ambulatory-based care that most of Part D is responsive to.

My third point has to do with silos. As you know, Medicare operates the program through silos, and I see my red light, so -- I have my comment here. There are opportunities by using this other framework to break down those silos, and again, I think it gets you out of the less/more debate, and into a more holistic conversation about improving quality.

Thank you.

DR. SIMON: Thank you, Dr. Paul. Panel? Chris?

DR. CONOVER: Again, you've provided some excellent suggestions in terms of sort of re-imagining how we go about this.

But in terms of concrete things, going to the survey process as an example, and you allude at the end of your paper to, you know, trying to ferret out bad apples.

And it seems like in the other town hall meetings that the basic picture I'd gotten was that we're requiring a lot of good apples to jump through a whole bunch of hoops in terms of survey, et cetera, et cetera, in order to detect a few bad apples.

And I'm curious whether you sort of share that view, and if that's true, then what are the implications with respect to the survey process? I mean are there specific things that can be taken out of the existing layers of regulation right now?

DR. PAUL: I think that you'll have others, and probably have had others who are much more sort of intimate with the survey process and hopefully they can provide you some real detail.

I do think that the survey process does need to be continually looked at and not asked to do so much, and separate the effort to find the bad apples from the effort

to help assure highest quality care. And it's perhaps the latter is done by using these other strategies, and not thinking that you're going to do all of that with the survey process.

It really does -- the current survey process -- and I know CMS has launched a pilot program to reconfigure the survey process a little bit, and I don't know how that's going. It was launched in just one, or two, or three states just in the last couple of months. So that certainly deserves looking at.

I think that part of the message here for me is that in the void of a lack of additional quality-related information about nursing homes, there's much too much reliance on what's going on in the survey. And so even before I were to get to lessening the survey -- and I'm sure there are people who could talk about how to sort of right-size that -- I would encourage an expansion of the picture that's being created.

Right now we have survey data, and we have a dozen or 16 measures on the web site which talk about the lack of bad things happening.

What we need is more measures of quality that are much more inclusive of the true clinical picture in that facility, how well are they doing on diabetes care, heart failure care, what is the patient and family

experience of care? Things like that. And I think only by getting to there will we be able to then sort of relax a little bit, and sort of let down a little bit of the emotion here and right-size the survey process.

DR. SIMON: Thank you. Bill?

DR. ROGERS: Thanks. Barb, you're absolutely right about the problems with the survey process, and it's also a snapshot, and as a snapshot, it's hardly reflective of what goes on during the other 364 days in a year.

I think we have a huge opportunity here with the dissemination of electronic health records to automate our sort of quality -- our quality measurements in nursing homes, as well as in doctors' offices.

And this may be a great opportunity to reduce regulation and to reduce intrusive surveys in favor of actually looking at outcomes, looking at interventions, looking at who's getting colonoscopies, who's getting pap smears, and all that stuff will be easy to extract painlessly and automatically once the electronic health records are disseminated.

DR. PAUL: And on that point, again bringing it back to nursing homes, I think a couple of messages. One is that the underlying data has to be common in cross-settings, and for so long, nursing homes have been over there, and in fact, in the RHIOs, the regional health

information organizations that are springing up around the country, there's one in Indianapolis that I'm somewhat familiar with because we have -- our company has four nursing homes in the Indianapolis area.

I learned about it. I was very excited. I found out that they -- nursing homes where nowhere on their radar screens. Doctors offices, x-ray, lab, hospital, pharmacy. So we are as a company working to get ourselves into that RHIO.

I think one thing that can be done is to make sure that that happens around the country so that those underlying data elements and standardization, and then that data sharing that could exist today starts to happen across into nursing homes, and stop this perpetuation of seeing nursing homes as something, sort of an afterthought, and you know, 40 percent or so of admissions and discharges in nursing homes are to and from hospitals. They're the same people. We have to look at it through the person's eyes.

DR. SIMON: Other questions from the panel? Dr. Paul, thank you very much.

DR. PAUL: Thank you.

DR. SIMON: Melinda Staveley.

MS. STAVELEY: Staveley.

DR. SIMON: Staveley. Well, thank you.

MS. STAVELEY: Thank you. I also respond to Stumply, Stovely, it matters not.

(Laughter)

MS. STAVELEY: Thank you for the opportunity today. My name is Melinda Staveley. I am the President and CEO of Rehabilitation Institute at Santa Barbara, a small free-standing rehabilitation -- physical medicine and rehabilitation provider, 50 years old in our community. My clinical background is nursing, and I have 24 years experience in physical medicine and rehabilitation.

Today I am here representing the California Rehabilitation Association with 42 inpatient rehabilitation facility providers in California and the Western Alliance with over 60 inpatient rehabilitation facility members.

Collectively, the CRA and Western Alliance members serve over 21,000 acute inpatient rehabilitation admissions each year. This is a small number compared to acute care, but we believe a very important number in the health care continuum in our country.

The patients served in the CRA and Western Alliance member facilities require the high-touch rehabilitation therapies and sophisticated, specialized physician and nursing services at a pace, intensity, and

sophistication that cannot be duplicated in other health care settings.

Patients receive high quality coordinated programs provided by an interdisciplinary team of rehabilitation professionals with the goal of achieving functional independence, and a rapid return to the community.

The Medicare criteria for admission to inpatient rehabilitation facilities are very specific. All patients are evaluated against these criteria for admission and must meet them. The criteria, and I'm sure you know them, are that they -- that a patient needs the intensity of medical care that requires frequent, sometimes daily physician review, and 24-hour specialized rehabilitation nursing care.

Patients must require and be able to participate in a minimum of three hours of therapy. And treatment must focus on community discharge and be achieved in a relatively short period of time.

When I first started, 24 years ago, the average length of stay in rehabilitation was indeed eight months. The average length of stay nationally now is 11 days. That's all patients, highest level spinal cord injury to most benign, if you will, stroke patient who is going to go back to work even.

The adverse impacts of Medicare regulations to inpatient rehabilitation facilities both economically and to access of care are dramatically demonstrated in many ways. I'm going to quickly cite a few and then focus on one.

The automatic 50 percent reduction in payment. If a patient is discharged to a skilled nursing facility, or back to an acute care hospital, obviously negatively impacts inpatient rehabilitation facilities who in good faith provided quality care only to experience the deficit in the cost-to-reimbursement ratio because of circumstances requiring the patient to be discharged to an other than community setting, which are outside of either the physician's, or the facility's control.

The restriction to only 13 CMS approved diagnoses prevents access, despite physician beliefs that the acute rehabilitation care team and process will assure a beneficial, functional and economic outcome not only for the facility, but the patient and their family, and thus, the community.

Care providers are required to pay interest on dollars paid to them by CMS when the stay is denied if the dollars are not repaid to CMS within 30 days. However, conversely, CMS is under no obligation to pay interest to providers when it takes sometimes up to four years in

reviewing and reversing denials.

There is onerous duplication of medical necessity review by the fiscal intermediaries prospectively, and now the new recovery audit contractors retrospectively.

The specific governmental regulation, however, that we would like to address today is the 75% Rule. This rule requires that 75 percent of all admissions, not just Medicare patients, must fall into one of the 13 CMS approved diagnoses.

This rule has impacted rehabilitation providers economically in limiting the patients who may be admitted as well as patient/family access to the appropriate level of care to meet their needs.

According to the Moran Company publications, new estimates of the impact of the 75% Rule on inpatient rehabilitation services volume -- you will get all this in my written notes -- there has been a decrease of 7.7 percent, or a reduction of 30,000 patients served across the nation.

The total number of patients of all insurance categories, that's just Medicare, probably is closer to 40 or 50,000 patients. This reduction in number of patients served is representative of a far greater number that was actually articulated as hopefully to be achieved by the

changes in the application of the 75% Rule in CMS's documents, in discussing with us why the rule was being applied differently.

The dollar savings therefore exceeds the dollars expected. This savings, however, we would let you know is achieved at a significant and sad cost to those many individual lives throughout the country who have been denied access to acute medical rehabilitation, and we would submit and will quantify for you that the rehabilitation, medical rehabilitation at this level of care that was not achieved did not create savings, but rather cost the community in the long-run with rehospitalizations.

Thank you very much. I'll be happy to take questions.

DR. SIMON: Thank you very much. I'm going to start with Chris and then go to Dan.

DR. CONOVER: Just to clarify, is the 75% Rule relatively new, or it's been on the books for a long time?

MS. STAVELEY: No. The 75% Rule has been on the books now, I want to say about eight years. I don't have the date, the year, in my frontal lobes at the moment.

DR. CONOVER: All right.

MS. STAVELEY: About eight years.

DR. CONOVER: But then the related question is

are the private payers that you have, are they different than Medicare in terms of they -- how they handle all of these various issues that --

MS. STAVELEY: Our experience is that private payers follow Medicare's lead, always. And that's been true for 24 years. As each one of the changes that Medicare determines happens, the private payers jump on board.

Now, do we have the opportunity to discuss the patient, and the need, and have a receptive voice depends on our relationships with the private payers, those medical directors, and frequently they appear to us to have far more understanding of the benefit of the rehabilitation process over the long haul for their subscriber.

A major problem there, of course, however, is that the long-term actuarial, you know, look that insurance carriers take is not long-term. That subscriber may be out of their program, so what do they care if it's going to save somebody else money ten years from now, or five years from now.

DR. SIMON: Thank you. Dan?

MR. MULHOLLAND: I'd like your comments on the extent to which, if at all, the complexity of the reimbursement system imposes additional cost on

rehabilitation facilities. I think you've articulated well the substantive issues that come up. But are there additional compliance costs that are associated with, say, tracking your admissions to comply with the 75% Rule?

MS. STAVELEY: Absolutely. Someone was talking about accreditation and licensure, and I can quantify that. I can go back and quantify your question as well, although I can't do it today.

We dropped the Joint Commission -- we being Rehabilitation Institute at Santa Barbara -- we dropped it. We're a 38-bed free-standing small little outfit. It was costing us with staff time, et cetera, close to $50,000 to participate in the Joint Commission.

So compliance, we have a compliance officer. HIPAA, we have a privacy officer. Those are salaries. We have the tracking that you talk about, absolutely.

MR. MULHOLLAND: You know, we don't want you to go home and do a homework assignment because that would be imposing additional costs on you, as we all are aware.

MS. STAVELEY: Well, that too. But if it will help in the long-run, we have it all.

MR. MULHOLLAND: If you have it readily available --

MS. STAVELEY: No, no, we have it all, and we'll provide it.

MR. MULHOLLAND: It would be helpful. Thank you.

DR. SIMON: It would be.

MS. STAVELEY: Is it helpful for an individual hospital to provide it? Or is it more helpful for CRA to composite it?

DR. SIMON: I think both actually would be very helpful.

MS. STAVELEY: All right.

DR. SIMON: Great. Ted.

DR. FRECH: It's nice to see someone else from Santa Barbara.

MS. STAVELEY: Yes. Hello. Nice to see you.

DR. FRECH: You have outpatient facilities, too, right?

MS. STAVELEY: Yes. We do both inpatient and outpatient, and community outreach service in contracted ways, yes.

DR. FRECH: Right. Right.

MS. STAVELEY: Yeah.

DR. FRECH: I want to talk to you later about that, but --

MS. STAVELEY: Good. All right.

DR. FRECH: One question that came up in my mind is some HMOs at least claim that they have case management

people who kind of more or less will do what's in the interest of the HMO and the patient and not follow real specific rules. Have you had better luck with them than with other private payers?

MS. STAVELEY: Interestingly enough, the private HMOs, no, we have not. And in our opinion, their weight of what benefit they're looking for is definitely the cost to the HMO, not the benefit to the quality outcome for the patient.

The one agency that really understands us and works very well with us is Health Authority in Santa Barbara County, which is the waivered Medicaid program, one of the most -- one of the earliest ones approved by the feds and one of the most successful my understanding is, and they get it.

They also know that they're going to have that patient and family for the long haul, because we know that most people don't ever get out of Medicaid. Also an unfortunate comment, but true.

DR. SIMON: Bill?

DR. ROGERS: I have to explain a little bit the thought behind imposing the 75% Rule.

As the grandchild of one grandparent that rehabbed from a hip fracture in a skilled nursing facility rather than an inpatient rehab facility, and another

grandparent who rehabbed from a stroke in a skilled nursing facility, it costs about $18,000 to rehab somebody from a hip fracture in an inpatient rehab facility, and about $10,000 in a skilled nursing facility.

Many, many less serious problems can be rehabbed at less expense to the taxpayer in a skilled nursing facility. What the 75% Rule intends to do is to make sure that the inpatient rehab facilities are concentrating their special expertise, equipment, staff on those patients who really could not be adequately rehabbed in a less expensive environment.

And I think, although it's not perfect, I think it was necessary, because there was a huge growth in the use of inpatient rehab facilities more expensive than it is to rehab patients who would have rehabbed just fine in good skilled nursing facilities, and it became a growth industry.

Obviously you guys haven't grown, and you probably weren't involved in that feeding frenzy that was going on, but there was, and I'm sure you would agree, a feeding frenzy that was going on nationally, bellying up to the trough of taxpayer money, and something had to be done to stop it.

MS. STAVELEY: Yes. If I may just comment back to you. Absolutely. But this is an example of regulation

being applied to weed out the few who were feeding frenzy and destroying in the process those who were not.

So in Santa Barbara, at Rehabilitation Institute, over six percent of our admissions come from nursing home failures that have gone home, and the family has no clue what to do with them, and they've been rehospitalized again because we have to have them from an acute rehab -- acute hospital setting.

So it isn't working everywhere.

Now, I agree with you, and we're very careful. We do not admit, as our medical director calls them, straight vanilla strokes, or straight vanilla hip fractures. We admit people with complications, and whose families need the education and training. That's as big a part of the care as is the actual medical nursing intervention, is helping people learn and know how to take care of their person coming home with a stroke, or a spinal cord injury.

That's what the recidivism is based on for the most part, is care giving incapacity, because no one has taken the time to work with them and train them.

DR. SIMON: Thank you. Panel? Thank you very much, Ms. Staveley.

MS. STAVELEY: Thank you very much for the opportunity.

DR. SIMON: And we look forward to getting your comments. If you would like any help in terms of where to submit them or how, or any questions, please feel free to see me, one of the -- the gentleman in the back who's shaking his head and waving at you, or any of the representatives from Social & Scientific Systems.

MS. STAVELEY: I will do that.

DR. SIMON: Great. Thank you. Okay. Charlene Harrington.

DR. HARRINGTON: Thank you very much. I'm a Professor of Nursing and Sociology at the University of California, San Francisco, and I'm here to represent myself as a researcher for over 25 years looking at regulation and enforcement issues, particularly in the nursing home industry, and as a former regulator who was in charge of regulation in California under the days of Jerry Brown, whom some of us would like to forget but --

(Laughter)

DR. HARRINGTON: But anyway, I'm here to talk about -- my view is that we -- the regulations are not really a problem in our nursing homes as much as the enforcement is a real problem.

Because nursing home quality of care has been a problem for -- since the 1970s that it's been identified, Congress finally passed the Nursing Home Reform Act in

1987 following up on a -- recommendations of an Institute of Medicine Committee that I was on that recommended to reform the survey enforcement and the regulations, and the enforcement system.

As part of that new law Congress established in the intermediate sanction procedures, which is the civil money penalties, and other sanctions like denial of payment so that you wouldn't have to try to force a nursing home to close entirely, but you could issue sanctions to try to bring about compliance.

And as you know, regulation for nursing homes is very decentralized. It's a joint federal/state responsibility where CMS establishes the regulations, the oversight and the budget, and the state licensing and certification agencies carry out the actual survey process, and the enforcement process.

In 2001, as a member of the Institute of Medicine, I was on another committee on -- of long-term care quality, and we reviewed the regulation and the enforcement system for the country, and we confirmed that we thought the regulations for nursing homes were adequate, but the enforcement system is extremely problematic.

I thought about bringing a stack of papers that I have written, and the GAO, and the IG, and all the

people have written over the last 15 years just to show you it would be that high, saying that we do not have a good enforcement system out there.

The survey and certification process is not working because there's been a decline in the number of actions taken against facilities, it's gone steadily downhill. The scope and severity of the regulations have been rated down by state agencies.

And there was just a new survey, a new report by GAO last week showing that the downgrading of regulations and the enforcement actions, many severe problems are not referred to the federal government for any kind of penalty.

The OIG found that in the CMPs, civil money penalties imposed in 2000 and 2001, only 42 percent were paid, and 70 percent were reduced before payment for systematic reductions, appeals, settlements, bankruptcies and other things.

And I should mention that the fines are so low in most cases that they have no deterrent effect whatsoever.

We have just come out with a new study, and I have provided it to you and in my written testimony, showing that in 2004 there were 140,000 deficiencies, and I should say that 90 percent of facilities in the nation

are out of compliance with the regulations.

They were -- of all those deficiencies given, only two percent were given civil money penalties. Ten states didn't collect any civil money penalties at all. There's a huge variation.

Wisconsin issues civil money penalties for 19 percent of its deficiencies, while 10 states don't even issue them. So there's inequity across states.

And another problem is that the procedures are so cumbersome and bureaucratic that the states don't even want to use them. They report that other sanctions are more useful.

The states tell us that they are short by 20 percent of their budget, so that is one of the serious problems that we've found, is that the budget for the regulatory activities is completely inadequate.

So I see I'm out of time, but I think in summary it's the lack of enforcement that is the serious problem and the poor quality in general.

DR. SIMON: Thank you very much, Dr. Harrington. Mike?

DR. MORRISEY: Yes. You talked about some 10 states, I guess, who have not levied fines, but also suggested that they've used other approaches to dealing with nursing home quality problems. What have they done,

and is that likely to be a more effective approach?

DR. HARRINGTON: Well, some of these 10 states just don't do anything, but there are 11 states that issue their own fines and use their own fines. California is one, Washington is one. And Maryland, I'd like -- is a very good example.

They have a new state law that requires that when a fine is issued that the nursing home has to put the money in an interest bearing escrow account, and then they go through the appeal process, and then the -- whatever the decision is made, then the money is distributed if it -- so that's one way to solve the problem.

Because with the federal government, it can take two or three years to issue the penalty in the appeal process, and then they'll end up reducing the whole thing in the first place. So some states are doing a much better job themselves than the federal procedures. They really need to be overhauled.

DR. SIMON: Dan?

MR. MULHOLLAND: Just playing devil's advocate. One person's sufficient regulatory system is another person's denial of due process, and I'd just like to hear you comment on that. That if, you know, a nursing home thought that it had a legitimate objection to a citation, making it pay money into an interest bearing escrow

account is basically like sentence first, trial later.

DR. HARRINGTON: Well, I guess, you know, it all -- if it takes two and a half years to get justice on either side, that's not very -- it's not a speedy justice for anybody. I mean, you don't do that with a traffic ticket.

So I just think the whole -- there's something wrong with the process that it takes that long, and the whole thing needs to be fixed.

MR. MULHOLLAND: Well, one -- I'd like your comment on this. If you were going to increase the use of civil money penalties, what about earmarking part of that for a more efficient appeals process, say by getting more administrative law judges, or being able to speed the process along?

DR. HARRINGTON: Sure. That would be great.

DR. SIMON: Chris?

DR. CONOVER: You said that 90 percent of nursing homes were out of compliance in some fashion?

DR. HARRINGTON: Yes.

DR. CONOVER: Okay.

DR. HARRINGTON: Ninety percent are in serious noncompliance, and of that, about 12 percent of them are very bad, very serious.

DR. CONOVER: Okay. Is the impression you're

trying to convey that 90 percent of the nursing home facilities in this country are bad apples?

DR. HARRINGTON: Yes. Well, I'm not saying they're -- no. I'll say that 12 percent are bad apples, and they've been in the business for all this time, and it's because we have such an ineffective regulatory system that they're allowed to stay in year after year.

And then we know that 95 percent of all nursing homes in the country do not meet adequate staffing standards. You cannot have good quality of care if you don't have nurses and adequate staff.

So it's not surprising when you have such poor staffing, and it's actually gone downhill, that you're going to have poor quality.

DR. CONOVER: We've heard in other town meetings that because staff are, you know, filling out all these forms to do the survey process, that it's basically diverting their time, and so they can't give quality care. I'm curious what your reaction is to that?

DR. HARRINGTON: I – no. I would say that's nonsense. I mean, you know, they only survey a home, you know, between 12 and 15 months, one time every 12 to 15 months. I mean, there are other forms that they fill out, but bottom line is there's an incredibly high turnover rate of staff, and that's because there's inadequate

staffing. There's no staff to do the job. I mean, it's just -- that's the problem.

DR. SIMON: Other questions from the panel? Professor Harrington, I thank you very much.

DR. HARRINGTON: Thank you.

DR. SIMON: You said you left a copy of a new report?

DR. HARRINGTON: Yes.

DR. SIMON: Is it with the panel, or is it also with the individuals outside?

DR. HARRINGTON: Yes.

DR. SIMON: Excellent. Very good. Everybody held up their 8-and-a-half by 11's, so I can verify that they're here. Thank you very much.

Our next speaker is Serge Teplitsky. And how bad did I do that, I can't read your handwriting.

MR. TEPLITSKY: Oh, you're just great. Thank you.

DR. SIMON: Okay. Cool.

MR. TEPLITSKY: Good morning. My name is Serge Teplitsky and I work at Laguna Honda Hospital, which is a 1200 bed acute care hospital, and a distinct part nursing facility here in San Francisco, and it's part of the Department of Public Health.

Also I'm representing California Hospital

Association, and it represents acute care hospitals and dependents, or hospital-based nursing facilities in the State of California.

And I'll be very brief in my comments. And I know you've heard probably a lot about Medicare Part D, and how it affects skilled nursing facilities, free-standings, and hospital based, but I'm trying to bring a few points here, and based on my experience, and the experience of other providers, there are a few issues that we wanted to bring up.

And number one is the number of PDPs, or prescription drug plans. In California we have about 40 PDPs, in other states it's a bit more. And distinct for our skilled nursing facilities get stuck in-between the rock and the hard place in terms of finding appropriate PDPs and working with the numbers of formularies and other things.

For example, if you have only a few PDPs to contract, you actually gain better control over your formulary, but at the same time, you may lose reimbursement because you have only a few contracts.

When you have more contracts than you need, sometimes it creates problems with prescriptions, also drug storage, and some other issues that can lead to patient safety, and medication errs.

And the second issue is that the education of patients around Medicare Part D, and choosing the appropriate plans for them is becoming a big problem, because we are somewhat limited by regulations in this process. We can do only that much.

And especially for the hospitals that are operated by cities and counties. We serve a lot of indigent patients who have no families, a lot of homeless patients as well who come to us for skilled nursing care.

It is very hard to educate them, and especially here when you have such a melting pot of everybody, and you have different languages, a variety of languages, how do you work with those individuals to choose the right plan for them?

And they ask for our assistance because the regulations and the program is quite complex. I know you are working on it, and you have probably a lot of good efforts towards fixing all this, but at this point, it's not working the way it's supposed to be, and it's a new program, and it's completely understood.

So the suggestion here would be also pay a lot of attention to the multi-language need of this program. And I know on the Medicare.com web site you have instructions only in English, for example, and I'm not sure if there are any other languages that patients can go

and look at and get some education around the program.

So that would be my comments. Thank you. And I will be submitting those comments via e-mail.

DR. SIMON: Thank you very much.

MR. TEPLITSKY: Thank you.

DR. SIMON: Questions from the panel? Bill?

DR. ROGERS: Thanks. I've been very involved with dealing with physicians and other prescriber's issues having to do with Part D, and I share your frustration.

You know, unfortunately for us, the way the program is created, the -- at least unfortunately for us with this respect, the PDPs actually do the paying of the claims, and for obvious reasons, not doing something anti-competitive, Congress said --

(Audio malfunction - 10 minute recess.)

DR. SIMON: Thank you for your indulgences.

If I could ask, Serge, once again, and I've been asked by the audio folks in the back for the speakers to come up close to the microphone and make sure that when -- we do this so we have shorter people followed by taller people. So it's going to require a little bit of, you know, sort of manual adjustment there.

Anyway, I think we had just -- we caught just before the punch line of Bill's joke. No. Bill, if you could start with your questioning again, we'll just sort

of rewind this whole thing and see if we can pick up where we left off.

DR. ROGERS: So anyways, this woman walks into the pharmacy --

(Laughter)

DR. ROGERS: Well, you know -- and this is a great opportunity for me to modify the way I was saying that a little bit. But there's no question that there are an enormous number of PDPs that are offering services right now, and I think the number's going to diminish over the next couple years.

But for the moment, it does confront you with a large number of formularies to deal with and we have been advising providers to use the Epocrates software, which is available free. You can load it into a PDA or you can use the web serve version and it does a phenomenal good -- a phenomenal job. I was showing Ruth the software on my PDA this morning -- making it easy to figure which drug in a particular class is first tier and second tier.

And so to the extent that physicians adapt their prescribing patterns, we're going to see I think a healthy downward pressure on drug prices which is obviously something that we'd all benefit from.

The -- you know, with respect to the issue about advising patients on which PDPs to choose, you know, the

concern of the attorneys is that there are opportunities for people with financial interests in a patient's choice to steer them, and that obviously is something that can't be permitted legally.

So admittedly it seems like an intrusion into the clinical relationship of the patient, but, you know, this is something that has been imposed on us by attorneys who worry about these sorts of things.

And then the foreign languages idea is a great idea. I think we're in English and Spanish exclusively, and to the extent that we can find money -- I means it's remarkable that a program that's spending a billion dollars a day has trouble finding money to translate web sites, but I had to beg and borrow and steal to travel here to San Francisco for 12 hours.

So to the extent that we can find money to have those web sites translated into other languages, we should do that. You're right.

MR. TEPLITSKY: Thank you very much.

DR. SIMON: Thank you. I think we're good. Mr. David Woods.

DR. WOODS: Hi, I'm Dr. David Woods. I work at Laguna Honda Hospital with Serge, so we're here to team-tag you regarding Medicare D.

I'm the Pharmacy Director at Laguna Honda

Hospital, and come January 1st, we had 700 residents in the hospital --over 700 residents who were Medicare, Medi-Medis, almost all of them who were then auto-enrolled into one of the various drug plans.

What we attempted to do at Laguna Honda was to take a look at the formulary offerings of the ten PDPs in California that are eligible, that are allowed for the auto-enrolled people, and to really take a look at those formularies and see which matched the needs of our patients.

And when we did that, we saw that three plans clearly were superior to the others. And so what we attempted to do was to educate the residents, their families, their care givers about what was the best options for that, and almost all of them chose the plan which was most suitable for them.

What we found, however, is that with all the computer glitches that have occurred here is that there are a number --hundreds of people in our facility which didn't get in the right plan at the right time.

For example, this February 1st, yesterday, what happened was in January when again people -- we had 70 people who enrolled in various plans and 7 of them actually ended up in the plan that they wanted to be in February 1st. So that's 10 percent.

And so the cost for us is significant because then the hospital is stuck footing the bill for the medications for these patients until this gets straightened out.

What we're trying to do is provide the best quality of care that we can for these residents, but what then is happening is that it's costing us a lot more money to do that, and so what a lot of skilled nursing facilities are then forced to do is enroll with all the plans. And -- which is not in the best interest of patient care.

The whole bit about discussing and steering patients and residents into the best plan really is prickly for skilled nursing facilities and our staff, because our staff really don't have a financial interest in a plan. I mean we really don't have a financial interest.

What we're trying to do is work on the residents' behalf and help them assign or decide what is the best plan for them to be in and we really feel like our hands are tied when it comes to helping them decide and -- to the extent that we're allowed to help them decide and enroll.

Our people with dementia, for example, they really don't have the cognitive capacity to do this and

probably over a quarter of our people have, you know, dementia issues. And so how do we educate them and how do we help them make the best decisions for them when our hands are basically tied as far as assisting goes.

And then the resources that it takes us to do all of this assistance, to really help them get the best care that they can, is significant, from our social workers, from our eligibility staff, from our pharmacy staff. We try to match the drugs that they're on with the plans.

It's a substantial undertaking and the costs associated with that are labor and then drug costs if we're not reimbursed from the plans.

So what I would really -- I would really suggest that a different model needs to be made for skilled nursing facilities and distinct part SNFs, and I think that there needs to be some allowance, for example, a system that would require all MAPDs and PDPs to accept electronic, out-of-network claims from pharmacies in SNFs, so that no matter what plan the person is enrolled in, at least the pharmacy can be reimbursed for the drug cost.

So at least for that first 30 days or 60 days until they get into the right plan for them, we can be paid for their drugs, and if there was sort of one -- one sort of system where we could do that, I think it would be

enormously helpful and it would be great for the skilled nursing community.

Other issues that we found as far as plans not being able to manage -- they're not equipped to manage skilled nursing facility sorts of distribution systems and fill cycles and those sorts of things. They're very -- they're much more equipped and have been dealing with community pharmacy issues for many years, and the plans are adept at that.

The issues that we have is the operational needs in skilled nursing facilities are different. And so to get reimbursed, it's very difficult because our fill cycles are different. Maybe we dispense a seven-day supply. Some hospitals will dispense a 24-hour supply. Sometimes it's a 34-day supply in a different skilled nursing facility.

And plans reimburse 30 days or 31 days. You have to submit the claim within five or seven days of the prescription being written, and so trying to backfill for the previous month worth of drugs is not possible with some of these plans.

And then there's a lot of -- the other area where we're having a lot of confusion is regarding Medicare B versus D versus durable medical equipment and those sorts of things and getting denials from some plans

for drugs which are fairly immediate because there's confusion or authorization required.

DR. SIMON: Thank you very much.

DR. WOODS: Sure.

DR. SIMON: Panel. Dan.

MR. MULHOLLAND: Mr. Woods, I was wondering if you could estimate a little bit more specifically the additional costs that you incur as a result of all these Part D issues; in particular, have you had to add staff? Have you had to take staff off of other duties and then backfill for their normal duties? Can you quantify it in any way?

DR. WOODS: At this point -- our pharmacy staff, for example, is a staff of 15 FTEs. At this point, it's required at least two additional full-time equivalents to deal with this initial hump.

Eligibility. Our eligibility workers and social workers, it's been I would say about a half-time person each in discussing options with residents. We're a large facility so -- but still I mean we're all small departments, and it's pretty significant.

DR. SIMON: Chris.

DR. CONOVER: I still don't have a clear sense about how much of all the things you've described are sort of one-time transition costs versus if you came back in a

year or two years, what on your list would you -- might you still be talking about or worried about?

DR. WOODS: So the things that I think that we'll be talking about in a year or so, say we -- our goal is to stick with three plans. Okay? That means whenever a person is admitted to our skilled nursing facility, we eat the cost of the drug until the following month because they have to enroll in that new plan.

So say today's February 2nd. They're admitted today. They're in a different plan. We haven't -- our pharmacy hasn't contracted with that plan, which means we have -- the patient has two options. They can get it from the hospital pharmacy and we don't get reimbursed; or they can get it from another pharmacy that may or may not meet the hospital's quality standards and requirements or may not be able to find it anyways. So there's that drug cost in that window until they enroll in the plan.

The other problem that we have is just the whole education about, okay, well, this is the best plan that meets your needs. The staff and manpower required to do that for every person who's admitted is substantial, and then following up to make sure that they get in the right plan. Like I said, this month out of 70, 7 were actually in the plan that they enrolled in.

And then going through all of the hoops to make

sure that they get where they're supposed to be in. Last month, it took us, you know, three out of the four weeks in the month to get it all straightened out for 700 people.

DR. SIMON: Bill.

DR. ROGERS: Well, just a good piece of news, the Secretary's announcing today that the transitional fills now are going to be 90-day fills for emergency circumstances. So that'll simplify life a little bit for you.

And there's no question that it has been a challenge from a computer standpoint because every enrollment requires not only that the pharmacy, the PDP's computer and Medicare's computer, but also the Social Security computer and also the computer that the pharmacies use to figure out what the co-pay is, all of those have to talk to each other and they all have to have identical data.

And if one person leaves a zero off or puts a capital "M" instead of a lower case "m" -- and you know, on December 30th, we had 100,000 people enroll on December 30th and we had 100,000 people enroll on December 29th.

But the system is working remarkably well for the vast majority of people. I mean they're filling about 40,000 prescriptions an hour. But I know that it has

really -- where it hasn't been working, it's been really very disruptive.

DR. SIMON: Okay. Other questions, panelists? Dr. Woods, thank you very much.

DR. WOODS: Thanks.

DR. SIMON: Okay. Let's call Joseph Hafkenschiel.

MR. HAFKENSCHIEL: Good morning. I'm Joe Hafkenschiel, President of the California Association for Health Services at Home and we represent California's home care providers.

Today I'd like to highlight three areas of Medicare regulations applying to home health care which present unnecessary burdens and costs. The first area is the Outcome and Assessment Information Set known as the OASIS, collection and reporting requirements.

Simply put, home health providers are required to collect and report far too many data elements and collect these elements for payors which do not use the data. This not only forces resources to be devoted to filling out paperwork rather than providing patient care, but is also driving nurses and other staff which are in critically short supply out of home health care and into other health care sectors.

We conservatively estimate the cost of

collecting OASIS data in excess of $300 million annually. The methodology for that cost estimate is contained in Appendix A. I have copies of our written statement.

We have three recommendations to reduce the OASIS burden. Number one, discontinue OASIS for Medicaid patients. Number two, limit OASIS to those data elements necessary for the Medicare payment system and outcome base quality assurance; and three, eliminate OASIS data elements which are unnecessary and improve other data elements which could be improved. And there's additional details on those recommendations in our written statement.

The second area I would like to focus on is the unnecessary burden of the bewildering set of notices home health and hospice providers must furnish beneficiaries when they need to reduce or terminate care. For more detail on the notices, see Appendix B.

The latest in the set of notices is the expedited determination notice which became effective July 1, 2005. This process requires the face-to-face delivery of a generic and detailed notice to beneficiaries within two days of when services end, even when this end of services was predicated in the care plan.

Beneficiaries have 60 days in which to provide certification from a physician of significant harm after patients request expedited reviews from quality

improvement organizations. Providers must furnish medical records to the QIO within 24 hours which are often never used because the beneficiary failed to obtain the required physician certification of harm.

While data on the burden of the expedited determination are sparse, a crude estimate of the burden of just the expedited determination process is nearly $100 million dollars annually. See Appendix C for methodology.

We recommend that CMS immediately suspend all beneficiary notice requirements and design a single form which can be given to beneficiaries at the start of care which clearly and concisely informs them of their appeal rights.

The third area of over-regulation I would like to discuss is the Medicare conditions of participation. In March 1997, CMS published proposed revisions to the COPs and stated their intent to move from a structure and process base requirements because they were moving to an outcome basis system of OBQI. We are still waiting for these requirements to be eliminated nine years later.

Among the Medicare COP requirements which present an unnecessary burden are requirements for clinical notes, progress notes, notice of patient rights, institutional planning, tracking and obtaining physicians' signatures, home health aide training, and home health

aide supervision every two weeks.

To provide an example of regulatory creep, the growth of the regulatory burden without analysis of the cost of the regulation, CMS published revisions to the State Operations Manual for Home Health on August 12th, 2005. One of the new provisions is entitled, "Application of Home Health Agency Conditions of Participation to Patients Receiving Chore Services Exclusively."

Buried within these provisions is this paragraph:

"CMS considers as a medical service any hands-on service, personal care service, cuing or activity that is in any way involved in monitoring the patient's health condition. As soon as the home health agency provides any Medicare service to an individual or any standard service permitted by federal law under the Medicaid state plan, such as personal care, we will consider the individual to be receiving medical care. The COPs will apply for all services rendered to such an individual."

These provisions would appear to mean that a Medicare certified home health agency providing a bath to an individual who is not receiving any other medical service would be required to meet all the Medicare conditions including the OASIS requirements previously described and the requirement to make a supervisory visit

to the patient's home every 60 days.

In conclusion, the growing body of federal regulations which apply to Medicare certified home health agencies and hospices are jeopardizing the continued viability of these services. The costs of complying with regulations are not factored into the payment system, and as you probably know, Congress yesterday eliminated the 2.8 percent annual cost of living increase for home health agencies.

The paperwork requirements are a major factor in driving nurses out of home health care because the nurses feel the time spent on paperwork detracts from patient care. We urge ASPE to recommend a systematic evaluation of the current regulatory burden in the home health sector and a crash effort to reduce it. Thank you.

DR. SIMON: Thank you. Panel. Chris.

DR. CONOVER: That was really excellent and I look forward to reading all your appendices, so I won't ask for details. But on your last point about paperwork driving nurses out, is that based on anecdotal evidence or is there some study of that?

MR. HAFKENSCHIEL: Our national association did a survey and I would consider it anecdotal evidence, but 40 percent of the people leaving home health care at the clinical level were citing the paperwork burden, and I

have that referenced in a footnote in one of the appendices.

DR. SIMON: Bill, did I see you stretching there or do you have --

DR. ROGERS: No. I'm sympathetic to the OASIS. We had researchers that developed OASIS come to CMS when Tom Scully was administrator and make an impassioned plea for maintaining every data point on the form. We removed some and I think we got it down to about, what, 187 pages or something now. But, you know, clearly there may be an opportunity there for reduction.

Some of the other things, it would be interesting if we have any patient advocates here, to talk about how they feel about deregulating the home health industry. They might have a different perspective.

MR. HAFKENSCHIEL: Well, I'm not calling, let me be clear, for deregulation of the industry. I'm not naive enough to think that that's ever going to happen.

I'm saying eliminate the regulations that have absolutely no cost benefit and just get in the way of delivering patient care.

DR. SIMON: Further questions. Ted.

DR. FRECH: The regulations here remind me a little bit of the nursing home regulations and they seem kind of driven by a tremendous fear that there are some

bad apples out there that are going to do just terrible things.

And for the nursing homes, there's at least sort of anecdotal evidence that that does happen sometimes unfortunately. This is the third one of these I've been to. I missed the one in Chicago with the blizzard. It was too bad. But we haven't heard any examples like that for home health care.

So I'm sort of asking you if there are even like urban legends that there's major bad apples and major health problems being caused by bad home health care.

MR. HAFKENSCHIEL: Well, let me respond to that in a different way and say that the current system of regulation in home health care is totally ineffective in keeping the bad apples out of the industry and is extraordinarily burdensome to the good providers. So it's just not working.

DR. SIMON: Other questions from the panel? Mr. Hafkenschiel, I appreciate this. You left -- the copies of your reports have been left with --

MR. HAFKENSCHIEL: I have four copies and I'll leave them with the people outside.

DR. SIMON: Excellent and one with the gentleman in the back who is nodding his head --

MR. HAFKENSCHIEL: Okay.

DR. SIMON: -- would be excellent. I also want to echo the appreciation for your detailed comments, your calculations, your attempt to quantify. Qualitative evidence is important. Quantitative evidence appears to move more regulatory bodies, and I, you know, I state that as a plea to folks who are in the audience who can provide to us some quantifiable burden.

Saying things are costly is important because then it helps us in our other phases of this study to identify where we need to drill down. Telling us how costly puts some, not only additional clarity, but some real emphasis on what the burden indeed may be as well as telling us your methods for getting to that point because this is a scientific study and we need to be able to not only measure but to validate and compare.

So I appreciate efforts to reduce things to numbers that can be reduced to numbers and not to push the techniques beyond where they are indeed applicable.

And so with that sort of thought, we've reached the noon hour, or for those of us from the East Coast, the middle of the afternoon and we're truly confused. We're going to take approximately an hour break for lunch in one of any one of the numerous places around here that you probably know better than I do.

We're going to reconvene at 1:00 o'clock. I

currently have on my list another five or six individuals who are slated to give comments. I suspect there are others who have signed up in the meantime.

If you want to know where you stand on the list, please come see me. I'd be happy to give you that information. Otherwise, have a pleasant lunch and I'll see you back here at 1:00 o'clock. Thanks.

(Lunch recess)

DR. SIMON: Everybody had a pleasant lunch. I think I'm going to call the afternoon session into order.

I currently have four more individuals signed up to give testimony this afternoon. Then what we're going to do is provide about, oh, 15 minutes plus for our panel to comment back on some of the main themes and take-aways that they've distilled from the day's discussion and open it up briefly to any questions that may still exist from before.

So if that works for you guys, we'll get going. Okay.

I always found it a daunting thing to be the first speaker after lunch, so with that in mind, I'd offer my welcome and my apologies to Keith Pugliese -- is it --

MR. PUGLIESE: Pugliese.

DR. SIMON: Pugliese, oh, gosh. I did a terrible job of that. Keith, if you would introduce

yourself.

MR. PUGLIESE: Okay. For this daunting task. So I am Keith Pugliese. Good afternoon. I'm Manager of Compliance and the Privacy Officer of Brown & Toland Medical Group.

Brown & Toland is a multi-specialty, independent physician network clinically integrated. We have approximately 1,500 physicians in our network here in San Francisco.

I have three main messages that I would like to offer, the first being the HIPAA Privacy Rule currently does not address interoperable electronic health records with particular respect to the use and disclosure of information in an individual's EHR.

There are potentially multiple different type of models that incorporate interoperable EHRs. For example, one model of an EHR is used by a provider or used between providers who are rendering care to a patient. Another model, for example, is sometimes called a personal health record or PHR which would be owned by an individual. A consumer.

Additionally, there is discussion about having EHRs integrated with PHRs, trying to have a holistic electronic record from both a provider and patient or consumer viewpoint, all that information in there.

But generally the idea is for EHRs, PHRs to be portable, that is available to a provider and/or patient wherever the patient is located, whenever the information is needed to be accessed, across a community and across multiple communities, from provider to provider, whether within an organized health care arrangement, quote/unquote, to use a term from the HIPAA Privacy Rule, or outside such an arrangement as determined by the health care needs of an individual.

Brown & Toland has done due diligence in putting safeguards in place for its own community EHR and PHR as part of its developing San Francisco RHIO, but HHS should please issue guidance to clarify how an interoperable EHR model could be considered sufficiently safeguarded and secure as far as HIPAA's allowances for uses and disclosures of PHI is concerned. So that was one message.

Second, many physician organizations are heeding Dr. David Brailer's call to implement health care IT initiatives. For example, Brown & Toland is spearheading a rollout of its EHR tools and other health care IT tools as part of the developing RHIO I just mentioned to its contracted physicians as well as to other providers in San Francisco Bay area community or what can be considered, to use the HIPAA phrase again, as an organized health care arrangement.

Brown & Toland's view is that it wants to do what is best for its community providing EHR tools for providers and patients throughout the service area. There have been those who have called for relaxing Stark provisions, to allow hospitals to implement EHR to physicians. While this may be necessary in some specific market areas, HHS should note that in many market areas -- I would add particularly in California -- HHS that -- I'm sorry. I lost my place for a second -- that in many market areas -- sorry.

HHS should note that in many market areas physician organizations have on their own volition funded and led or are leading the implementation of EHRs and other health care IT tools to their provider community.

And so there would be no market need to exempt a hospital entity from Stark requirements in those type of areas -- market or service areas. So if HHS should consider relaxing Stark provisions for the purpose of implementing or supporting or funding EHRs or other health care IT programs for physicians, then HHS should not allow such an exemption to be issued if a physician organization, for example, is already funding and implementing such health care IT initiatives.

It is in the interest of public health to minimize dollars issued for health care IT initiatives

that might otherwise be allocated for the provision of health care services. So that was two.

And then lastly, Brown & Toland encourages HHS to consider the AMGA's proposal -- AMGA, the American Medical Group Association -- their recent proposal for a pay-for-performance or P for P program based on a coordinated care approach that particularly rewards the organized multi-specialty physician group model, whether the physician group is a staff model group or a network of individually contracted physicians.

Clinically integrated physician network models are key to providing coordinated care to Medicare beneficiaries across the suite of Medicare advantage products. HMO and regional PPO included, when I say Medical advantage products.

Moreover, HHS should consider increased direct compensation to physician groups coordinating care for chronic care patients and that compensation should be as the AMGA proposes rewarded on the following measures:

(A) structural measures, such as EMR systems, patient registries, home health monitoring devices, et cetera; (B) process measures, daily monitoring, case management, medication management, et cetera; and (C) outcomes measures including reduced hospitalizations, readmissions, reduced nursing home admissions, that sort

of type of outcome measurements. Thank you.

DR. SIMON: Great. Keith, thank you very much. Panel? Mike.

DR. MORRISEY: You've talked about concern about hospitals entering the market for IT services in the dimensions that you mean it. Are there particularly compelling I guess economies of scale or other reasons why what would seem to be competition should be limited?

MR. PUGLIESE: Well, I mean, if the reason behind considering relaxing certain Stark provisions is so that these tools, these health IT tools are therefore made available to physicians that otherwise wouldn't be made available. If that need doesn't exist in the market, why duplicate or have multiple efforts of the same.

It's not such much a concern about competition, but it's just saying hospitals are not necessarily the appropriate entity to do this, the only entity to do this.

In California especially, there are many what's called multi-specialty coordinated care physician organizations, Brown & Toland is one, but there are many others who are taking on this initiative and it's just -- please keep that in mind when you start thinking about relaxing Stark.

DR. SIMON: All right. Ted and then Dan.

DR. FRECH: Okay. This is actually on the same

point. Is Brown & Toland and other big multi-specialty groups that are doing these IT initiatives, are they then giving it away to their competitors? Is that what you're saying? So that the competitors don't need a hospital connection or some other source?

MR. PUGLIESE: Let me answer it in this way using Brown & Toland as an example. You'll have, let's say, a small incorporated private practice. Maybe there are half a dozen physicians there.

Since we're an independently physician -- you know, contracted physician network, there might be four of the six who are contracted with Brown & Toland. Well rolling out, for example, an EMR, or certain electronic billing systems, or other tools that we're rolling out, it wouldn't make sense for that practice just to have it for the four Brown & Toland contracted physicians and not all six. So in situations like that, all six would be offered that.

Also many of our tools, like our electronic health record is for all of the patients that these doctors see. Well, they're not exclusive to Brown & Toland. They see patients from our competitors, you know, from all different products, from all different -- they enter into the office from all different doorways, if you will, from the market. So in that respect, that's why we

consider it a developing RHIO if you will.

DR. FRECH: Okay. But for a competing organization that doesn't have any patient overlap, you're not going to give them your system. So they still need to be in the market for a system from somebody. Is that -- do I have this right?

MR. PUGLIESE: I think you might have it right. I'm not sure. We could talk more about it, but we have 1500 physicians in San Francisco, so, yes, there are physicians who we don't have overlap with.

DR. SIMON: Dan.

MR. MULHOLLAND: Just a comment on that. A lot of what you're talking about is unique to the West Coast because you go into most communities and smaller communities, the only connection and possibility that the doctors have to upgrade their systems is the hospital.

Let me ask you a question about your compliance program at Brown & Toland. Can you give us an estimate about your total budget, and that would be not only staff, but also additional things like legal fees that are associated with regulatory compliance?

I'd just like to hear, you know, how you have your compliance office organized and also whether things like HIPAA or the move towards EHR is imposing additional costs on you from a compliance standpoint.

MR. PUGLIESE: Well, that's a big question. I'll see if I can get -- in California-speak we're a delegated IPA. Okay. But most of the country doesn't know what that means.

So, for example, in the HIPAA world, Brown & Toland does not consider itself a covered entity under HIPAA. We don't see patients. Our contracted physicians see the patients. If they use any of the electronic transactions under HIPAA, they're a covered entity.

Having said that, in our compliance program we have adopted pretty much like the vast majority almost all of the HIPAA requirements. I'm -- I have the title of Privacy Officer. Since we're not a covered entity, I'm not required to be a Privacy Officer or should I say a noncovered entity is not required to have one.

We felt let's play it safe in that when questions or issues come up, let's make sure we have somebody to address these.

Since we're not a covered entity, we're not necessarily required to have HIPAA policies. We have them. Just so that we're clear on what the rules of the games are.

As a delegated entity, we act -- we do administrative functions on behalf of many health plans. In that respect, we have to abide by HIPAA.

So in terms of EHR, the cost is mainly in the rollout, the implementation, the IT staff. We have implementation teams that go out to these practices because we just don't flip a switch on. We help them adapt these tools to their practice, work flows, and needs.

And so that alone, that effort is approximately $10 million.

MR. MULHOLLAND: But just in terms of your own compliance budget, if you're able to share it, you know, to get a handle on the cost because you wouldn't have a compliance officer, no offense, if you didn't have regulations to comply with. And so that, you know, is at least an indirect result of regulation. It'd be helpful to have a handle on that.

MR. PUGLIESE: Yeah. It's hard to answer. I mean there's me and I have someone who reports to me. I have a legal department that's from us. I mean we're again -- I mean I don't have the figures right in front of me, but it's a smaller scale compared to, for example, a hospital or a health plan. That's for sure.

MR. MULHOLLAND: Thank you.

MR. PUGLIESE: Surely.

DR. SIMON: Other questions from the panel? Keith, thank you very much. Okay. Our next speaker is

Ron -- and I believe it is Dugan. Am I close, Ron?

MR. DODGEN: It's Dodgen.

DR. SIMON: Dodgen. D-o-d-g-e-n.

MR. DODGEN: That's correct.

DR. SIMON: Thank you.

MR. DODGEN: So I can't think of a better way to spend Groundhog Day. This is great being here in the City. My name is Ron Dodgen, and I'm Chair of the Developmental Services Conference of the California Association of Health Facilities, the acronym CAHF.

CAHF is a nonprofit professional association which represents the majority of long-term care facilities, skilled nursing facilities in the State of California as well as the majority of providers serving California's 8,000 ICF/MR beds.

I'm also President and CEO of Genesis Developmental Services. Genesis serves approximately 150 individuals with developmental disabilities, mental retardation.

I want to thank you for addressing this very important topic of the economic impact of health care regulations and how we might be able to reduce those and still at the same time impact quality of care. I also want to thank you for the attention that you afford me for these very few moments but important moments.

If we were to stack all the Medicare regulations ceiling to floor, we'd come up with a stack approximately 43 feet high. Compare that with doing the same process for the IRS Tax Code and all the tax regulations, the Medicare/Medicaid stack is about three times as high as the IRS Tax Code.

I doubt that we feel that that IRS Tax Code provides quality in tax measures, and I'm not sure, despite some of the earlier testimony that we've heard, that there's any type of empirical data in terms of the relationships of increased regulation improving quality of health services.

Today I'm going to offer comments regarding three items where regulatory burden and/or cost impact of health care could be reduced without affecting quality care in the ICF/MR environment.

The first area is the federal survey requirements for a six bed ICF/MR program. In a prior life, I also owned nursing homes, and I find it absolutely incredible that the survey process for a six bed ICF/MR program can take the same length of time as a survey process for a 59 bed SNF or a 99 bed SNF. I think this is an extraordinary waste of capital, waste of services, waste of resources, and waste of energy.

I would offer that some type of standard be

developed where application is made. If a survey on an SNF takes X amount of time per resident that that same standard be applied to an ICF/MR program.

Another interesting concept would be to survey ICF/MR providers as if they were a larger congregate facility. For example, take the total number of ICF beds any individual provider may have, base your survey sample on what that total is, and then survey that many clients in those different ICF/MR programs.

Standards are basically the same with most providers throughout all their programs. So I think that's an example of how regulatory burden could be decreased without impacting quality of care services.

It sounds like you guys are getting pretty beat up or pretty informed about the Medicare Part D issue. I won't belabor that too much except to say this: When the bean counters begin looking at cost savings, I'm wondering if there's any measures to determine programs that are actually continuing to use the federal dollars but are simply taking them out of different pots.

For example, here in California, the Department of Developmental Services is using federal dollars to pay for drugs that are no longer paid for under the Medicaid program. So I'm not sure where their savings is there.

And it's a program that has already been said,

really does not work in the long-term care environment. It is confused. It is difficult. We have some six bed programs with six separate pharmacies.

And simply trying to coordinate stat orders, physician orders from those six separate pharmacies and try to anticipate delivery to meet state and federal regulations from six disparate pharmacies, to maintain uniformity of regulations regarding labeling is an absolute nightmare.

Finally, I would like to address the complaint and survey process. At its inception and then again at rewrite with OBRA, which was, what, 1987, the survey process was intended to be a client-centered and outcome-oriented process.

If you were to be in one of my ICF/MR programs today and observing a survey process, you would find the experience very different. The survey experience is subjective. It is process oriented and, as we heard earlier in the day, punishment driven.

The cost of a survey process in this environment is extreme because survey compliance will never achieve satisfaction from clients. Survey noncompliance will always be a dissatisfier. Survey compliance will never be a satisfier. I'll explain if I can continue.

DR. SIMON: I'll give you another couple

minutes.

MR. DODGEN: Okay. The current Governor's -- and by example, the current Governor's budget in California calls for the addition of another 200 surveyors. So it's not going to improve quality, but I suspect under the CMS approval of the state plan, the federal government is paying some large portion of those 200 additional surveyors.

When individuals live in a program 24/7, even a six bed program, happiness and satisfaction of life are difficult to achieve within a service delivery model that is primarily medical in nature.

This is reflected in the complaint process. This is reflected in the survey process relative to the accumulation of data because when families complain, they're complaining about the unhappiness of their resident, and then they focus on what's not being followed in the regulations.

The current regulatory system only focuses on what is important for the individual. That's what we do as clinical people. We decide what's important for the individual, but we completely ignore what is important to the individual, and it's that issue of ignoring what's important to the individual that produces extreme complaints and increasing deficiencies on survey

compliance factors.

Let me just cut to the chase here and say that the current system is a true barrier to reaching a person-centered model of care. In California, this is evidenced by the preference of many within the DD/MR system -- service delivery system to prefer placement opportunities for residents in resources other than the ICF/MR environment because these programs are often viewed by supporting agencies as being nonperson centered in focus. Thank you for the additional few minutes.

DR. SIMON: Thank you. Panel? Chris.

DR. CONOVER: I just had one clarifying question. You say an alternative would be to perform ICF/MR surveys in a proportional time frame to --

MR. DODGEN: Right. For example, if a 99 bed SNF survey takes one hour per client or two hours per resident in a 99 bed facility, apply that same standard in an ICF 6 bed program two hours per resident.

DR. SIMON: Other questions? Clarifications? Bill.

DR. ROGERS: Well, I'd just say on the issue of the Part D, we're going to have to get authority from Congress to create a different system for the skilled nursing facilities or the home health care or whatever, you know, environment. It doesn't seem to be working and

before we're going to be able to change it, because it's sort of pretty much a one-shoe-fits-all situation right now.

MR. DODGEN: Shoe's too small.

DR. SIMON: Okay.

MR. DODGEN: Thank you very much.

DR. SIMON: Thank you. Thank you. Our next speaker, and I'm not even going to attempt the last name, which I can't read, Peggy? And, Peggy, if you would be kind enough to introduce yourself. I apologize.

MS. GOLDSTEIN: Thank you. I think that's a comment on my writing.

DR. SIMON: I -- it's either that or my aging eyesight. So I --

MS. GOLDSTEIN: No, no. I think it's my writing.

DR. SIMON: I apologize.

MS. GOLDSTEIN: My name is Peggy Goldstein, and I'm actually here on behalf of Mr. Floyd Rhoades who is the Chairman of the California Association of Health Facilities. Ironically enough, Mr. Rhoades is in survey today, so that's why he can't be here.

However, I am on the staff. I am the COO of the California Association of Health Facilities, and so I'd like to make a few brief remarks. Thank you very much for

looking into these issues. We think they are very important.

We're going to talk about four interrelated topics very quickly. Specifically, staffing in skilled nursing and long-term care facilities, of quality in those facilities, and the regulatory framework that oversees those, and also then the cost of those type of oversight.

We've submitted a detailed report and I will tell you that the two attachments to my comments were not written by me. They were written by a numbers cruncher in our office, Mr. Darrel Nixon. If you have questions, you can talk with him or talk to me and I'll get you to him because he's the numbers person who put those numbers together.

And I think they are very interesting. One of them has to do with staffing and the current situation of staffing in nursing homes. I think unlike what a former speaker said, staffing in fact in nursing homes is going up. In fact turnover is going down and in fact quality is improving.

And I think the idea that fewer civil monetary penalties, fewer deficiencies does not mean that we're doing worse. It means we're doing better perhaps.

And I would invite some other inquiry into that, whether that is not the case. I'm straying from my

written comments here.

An interesting thing is UCSF in August of 2005 did a rather exhaustive study of what was happening in the nursing home field, and I believe there were some researchers from here, even speakers from today, who were involved in that study.

And that study found that 29 percent of freestanding skilled nursing facilities in 2003 were meeting the minimum standards for staffing and that was an increase over the previous two years; that the average staffing hours had increased; that the staffing turnover had gone done from 84 percent down to 64 percent.

All of these kinds of issues that are occurring in long-term care and in skilled nursing in particular are probably due to several things.

One thing that they're due to is that in California there has been a wage increase law that allowed the facilities to increase wages in our facilities by an average of $3 over a two- or three-year period, so that there was more funding available to increase the wages to attract staff and to keep qualified staff. That's very helpful.

The second thing is that our residents are actually getting more higher acuity. That increases the need for more licensed staff, and in fact the licensed

staff in facilities has gone up over the last several years.

And then we have had a staffing requirement in California for quite some time. So it's on everyone's mind and there's a direct correlation between the amount of staff you have and the kind of quality that you can provide in a nursing home.

I will say though that the desire to set up ratios in our view is not the right staffing requirement to go to. Ratios -- a one-size-fits-all, my God, it's like Part D all over again. If you put in a one-size-fits-all program, in a desire to get to quality, you're not going to get quality. So just to say that.

There is an incremental cost to increasing staffing, and in our paper, we have the specifics that'll tell you at least in California what it would cost to increase by one-tenth of a percent the staffing for either a CNA, or an LVN, or an RN and those numbers are in there.

One might ask how the regulations are enforced and how they're supported, where the money comes from. In fact in California and throughout the nation, licensing fees are assessed on the facilities and then those fees are used to fund the enforcement process.

In California, private nursing homes pay about $215.32 per bed. That's $21,316 a year to pay for the

licensing and the regulatory oversight.

And in -- and there's a whole lot of information in my background about how we got to that, which you can look at it.

Just to mention that the Governor of California is suggesting an increase to $250 per bed next year for that function. We'll have a total of 966 licensing surveyor positions in California at that time, and the facilities at that point will be paying $24,750 a year, an average 99 bed facility, in order to support enforcement.

So there's a lot of enforcement out there and the facilities basically are paying for it. Those are private; not county or state. They don't have to pay.

Okay. Let me just mention that the cost of quality -- that there is a correlation between staffing and quality. And I see my red light is going on.

DR. SIMON: That's okay.

MS. GOLDSTEIN: Okay.

DR. SIMON: Take a deep breath and another minute or two.

MS. GOLDSTEIN: Our experience in long-term care, and this goes back to the regulatory issue. Staffing, good staffing, higher staffing does create better quality. Well-trained staff creates a better quality. But the problem that we see with the regulatory

system today is that it is as Mr. Dodgen said based on process, based on buildings, not based on clients, not based on residents.

And we would really suggest that some kind of a look at the current regulatory process be made and some pilot projects be allowed to go to a client-centered program. I mean if a client doesn't want to have breakfast until 10:00 o'clock in the morning, he should be able to do that. He shouldn't have to have it at 6:30 just because the regulations say that you have to have 14 hours between breakfast and dinner.

And it's those kinds of things that are why people -- one of the reasons that people are going to assisted living where there's virtually no regulation and no oversight because they can have breakfast at 10:00 o'clock if they want to.

So when you're looking at the regulations and coupling that with quality, it seems to me that it's time to do some really serious pilot projects that would help to bring us to a client-centered care instead of what we have right now.

On more quick point, Lumetra, which is our local California Quality Improvement Organization, has done a wonderful job in California of working with facilities to train their nurses to go to systems of care instead of

paper compliance, and has improved many of our quality measures in California and they continue to do that and I really applaud that effort of CMS to change the landscape by saying there is another way of bringing quality into the long-term care program.

Thank you and I'll be glad to answer any questions.

DR. SIMON: Thank you very much, Peggy.

MS. GOLDSTEIN: Um-hmm.

DR. SIMON: Mike.

DR. MORRISEY: I hate to ask what is an easy question to ask and I'm sure impossible to answer, but through all of your remarks, you talked sort of generically about quality getting better. How do you measure that? How does the field measure that? From the acute care side and from, you know, there's beginning to be work looking at satisfaction. There's looks and reasonably agreed to measures of heart disease and trauma. But my sense in long-term care is way -- anywhere near that.

MS. GOLDSTEIN: Well, I would say that we're certainly not anywhere near 100 percent quality, which is where we all want to be, and there are many ways of measuring quality. One of those may be, despite what some people say, if you actually are finding fewer serious

deficiencies, then you are finding a better quality of care.

If you have higher staffing, you're probably having a better quality of care. Customer satisfaction is an excellent way of doing it, and many of the companies are using those kind of measures to see, you know, what is going on and what is happening.

I just don't think that the regulations are the way that tell you whether quality is better. I mean there have been four studies in the last two or three years that have said, you know, quality is better. Staffing's up. Deficiencies are down.

So those are the only measures we have right now. The ability to measure quality has always been a problem, and most people say you know it when you see it, which is not satisfactory from a scientific point of view, but that kind of is where we end up.

DR. SIMON: Dan.

MR. MULHOLLAND: Just a follow-up question on that. I'm hearing from a lot of clients that are involved in quality assurance primarily in hospitals or PHOs or IPAs that you're beginning to have a Lake Wobegon effect with quality measures, that everybody's above average. That means either that the measures are meaningless or they're too easy to meet or they're commonsense and

everybody meets them, but it's hard to have another act to follow it.

And I wonder if you've seen that in some of the quality measures that are applied in the nursing home industry and what to do about it? And in particular, that becomes a problem when you start talking about pay for performance. Because if you're saying we'll pay the people in the top quartile extra at the expense of the people in the bottom quartile, if everybody's up at 99 percent, then very small differences could make a huge difference in reimbursement.

MS. GOLDSTEIN: Um-hmm. And that's a conundrum when you're moving into that kind of a system, although we do support the pay for performance type of system. But you're right. When you start moving everyone up, everyone's up, and at some point, you get to a point where you're not really measuring and you're not really doing what you had set out to do. I don't know what the answer to that is.

Just one more thing I just wanted to mention. I am the Part D guru for the nursing home people, and I didn't put it in my own comments, but there is something you can do in Part D. If you'd like to know what that is without the Congressional approval, there is a very big gap in Part D and that is the gap for people who come onto

Medicaid in the middle of the month, they have no -- no medication coverage until the first of the following month.

And the -- and CMS should be paying FFP to the states for picking up that gap and they're not right now and they could. So every -- I mean that's 10,000 new Medicaid patients came on the rolls in February in California. Now, those people depending upon when they signed up, when they became eligible in January, probably may have to wait till March to get medication coverage, and that's a big gap.

Mr. Rosenstein of our Medi-Cal division here knows a lot about it, and CMS could be paying FFP for that if they would.

DR. SIMON: Bill, do you have a comment?

DR. ROGERS: Well, we don't think we can. I mean, our lawyers say we can't. The way we're paying the states now is going to be through demo authority which if there was ever a tortured language, it's torturing our demo authority to make payments to states as a demonstration of a new way of paying for health care.

But because I think the agency realized what a hard situation it was for the states and how long it might take Congress to respond, we have tortured the language so that we can do it through demo authority, but we don't

have the authority to month after month after month, nor do the states want to continue to keep the infrastructure in place to do that.

Unfortunately the way the statute's written right now, unless the person signs up ahead of time, there is going to be a gap, but it's, you know, like getting your driver's license. I mean, you know -- but we're going to need to look at that. But I think, you know, that's a good point.

The other thing is, is it a federal regulation that 14 hours elapse between breakfast and supper? I'd be surprised. I'm wondering if this is another state regulation.

MS. GOLDSTEIN: Is that part of OBRA? Oh, okay. That may be a state -- you know, in California, we have our own state regulations and requirements and we are surveyed under both.

MR. DODGEN: Just to clarify, the regulation is a reverse. No more than 14 hours can elapse between breakfast and supper. So if you have a client, a resident who wants to eat dinner 5:00 o'clock one night and then doesn't want to eat breakfast until 10:00 o'clock the next morning, that's a noncompliance, and that would be a ding on the survey.

DR. ROGERS: Noncompliance with the state

regulation, though --

MS. GOLDSTEIN: Yes. That's a state regulation.

DR. ROGERS: -- not federal. Yeah.

MR. DODGEN: You know, I'm not sure if it's Title 22 or fed. I'll be happy to check that out.

DR. MORRISEY: But -- excuse me. We heard the same story --

MR. DODGEN: It's a federal?

DR. MORRISEY: We heard the story in Chicago, so I suspect that it's either multiple states or --

MR. DODGEN: It must be a federal then. Yes.

MS. GOLDSTEIN: Well, anyway it's the kind of thing that keeps you from doing things that the client would like you to do, you know.

DR. SIMON: All right.

MS. GOLDSTEIN: Okay. Anything else?

DR. SIMON: Anything else, gentlemen? No.

MS. GOLDSTEIN: Thank you.

DR. SIMON: Peggy, thank you very much. Stephen Cornell.

MR. CORNELL: Good afternoon. I am not in the medical field at all. I own a hardware store here in San Francisco.

DR. SIMON: The doctor on the panel takes a deep breath. You may be premature.

MR. CORNELL: I am -- my store is 100 years old. I have 12 employees. I get involved with small business politics. I have served as the President of the San Francisco Small Business Commission and with a lot of other small business groups in San Francisco.

This may be off the subject a little bit, but it's a forum where I think I can add something to it.

What I'm here to talk about is how can small businesses participate more in cafeteria plans and health savings plans. Today, I as an owner of a business -- and most businesses that I'm talking about are businesses that have less than 50 employees, even less than 20.

In San Francisco, 90 percent of all businesses have less than 20 employees -- the vast majority of businesses. And they're usually Subchapter S businesses or sole practitioner type businesses.

Under the cafeteria plans, we cannot use them as an owner. Under the health savings plans, we can use it, but it's after tax dollars. Not very attractive to the owner.

Most owners that I've ever met, talked to, will only do something if it really benefits themselves. The employees come in secondary. They'll be glad to do it, but it has to be something that benefits them.

So changing these regulations would be very

beneficial. How to do that, I'm not sure. This is a forum that I can come to talk about it a little bit. That's my message. Thank you.

DR. SIMON: Mr. Cornell, thank you very much. Actually this is, you know, one of the challenges that we face is that we haven't heard very much from small businesses or even large businesses, and there is some I think realistic belief and evidence that a lot of the burden of health care may intermediately flow through the provider community, but ultimately comes to rest on the business community and on the employees themselves.

And so your message is very important to us and we wish we had heard more of it. If you have friends and colleagues, encourage them.

But I'm going to turn to the panel because I suspect they've got some questions for you. Dan.

MR. MULHOLLAND: Yeah. I can sympathize because I'm a small business owner too in a law firm that's about 50 employees, but I'd like your comments on the degree to which the complexity of health insurance and various health benefit programs is a deterrent to small businesses getting coverage for their employees.

Beyond, you know, just the basic cost of acquiring it, there's a hidden cost of trying to understand your options, making sure you're complying with

all the rules that govern whatever plan you put in place, and, you know, that could be a deterrent as well.

I mean we're health care attorneys and we can't understand our health plan for our employees. We just sort of accept it on faith and we go along with it and pay the money.

But for a very small business, that could be a huge deterrent to providing coverage to people.

MR. CORNELL: It is. You got it right. If you can't figure it out, and you're attorneys, we certainly can't do it. I just -- most -- the contract I get with my insurance company, we use Kaiser, I just look at, you know, how much it's going to cost me, if there's anything highlighted that's going to be changed, and I sign it. Never read it. Never send it to the attorneys. It's a waste of time.

Anything that has more than a page in it for me to read, I don't bother. I mean I'm the law firm in my business. I'm the accountant. I'm the advertising manager, and I think that's -- and I'm 12 employees. I'm bigger than most of my fellow business people in San Francisco. So you can imagine -- yeah, it's a big deterrent to do out there.

And one of the ways you can go around it is you can have providers come in and say, well, we'll give you -

- you know, sign up with us. You'll have a cafeteria plan. You can do it through a payroll service, that sort of thing, and it's still mind boggling.

DR. SIMON: Mike.

DR. MORRISEY: Your comments about the owner of a small business being one of the key features in whether or not a small business offers coverage is certainly consistent with some survey work that NFIB did I think last summer that suggested, you know, something like 40 percent of small businesses that offered it felt that that was a key driving force.

One of the things that I wonder about in the small business market because it showed up in that survey as well is that a number of small employers tend to sort of quietly, you know, reimburse their employees if they buy health insurance in the individual market.

Do you have any sense of how common that is in the San Francisco area?

MR. CORNELL: I don't know that. I don't know the extent of it. I'll take myself. What -- again we provide Kaiser, but I also go to my employees and say are you getting your coverage from a spouse or veterans or something. If they do, then I will not provide them with Kaiser, but I will hand them a check every month and I'll -- it won't be the full Kaiser membership. It's half the

membership.

So they get that as a separate check. I figure it's better for both of us that way. So if somebody did some and say I, you know, I believe in holistic medicine, I'll do it this way and that way, I think I would give them a check for that.

DR. MORRISEY: Thank you.

DR. SIMON: Thank you. I believe we have gone through our panelists. Jessica, could you just double-check that there hasn't been anybody who's signed up in addition.

What I'd like to do now -- and the panel shouldn't be surprised about this since they're all veterans of prior occasions -- is to ask each of the panelists to sort of give us a little bit of a take-away on what they've heard and what messages we should carry back to ASPE and HHS, and then just to make sure they got it right, we're going to offer the audience to come back and correct, clarify, and question for a few moments as well.

Now, last time when I did this, I think I nearly knocked Bill off of his chair because I started at the end -- the opposite end of the alphabet, and so I'm not going to be so cruel this time and go by normal convention and ask Chris to start off with his take-away.

DR. CONOVER: Well, I got three take-aways. I think it is fitting that we're doing this on Groundhog Day, not only because we've been to other town hall meetings, but, you know, we could have had some of these discussions 10 years ago, 20 years ago, et cetera. It seems this keeps coming up.

So first take-away is that the implementation of Part D was screwed up, and the next time that we do prescription drug coverage for the elderly, we need to get that right.

Now, but more seriously, I hadn't heard this thing about Part D as it relates to nursing homes, so I certainly got an education about that. And I'm assuming Bill's going to fix all this stuff.

DR. SIMON: That's why I let him go last.

DR. CONOVER: Yeah. Exactly, right.

DR. SIMON: He gets to bat cleanup on this.

DR. CONOVER: The other theme I heard was the promise of technology and information, you know, in the future as possibly a way of deregulating eventually, that once we get these systems in place, maybe it puts less burden on regulation to improve outcomes and that sort of thing.

And I also heard a theme that I don't recall hearing in the other town hall meetings, but this just

idea of thinking about regulation a little bit more holistically and in the context of other things going on, and that if you do that -- you know, so regulation is just one tool in the tool kit, and if you can sort of beef up this over here, maybe there's less pressure on regulation and that may be to the benefit of us all.

DR. SIMON: Great. Thank you. Ted.

DR. FRECH: One of the take-aways from these -- I've been to three of these. As I said, I missed the blizzard -- was that there's something really special about nursing homes, home health, and today I found out, these rehabilitation hospitals, which is a pretty small category. I hadn't known much about them before.

And they're obviously very heavily regulated at least in form -- at least formally and regulated in terms of process not outcomes, and I'd say outcomes aren't even -- the way it's conventionally thought of, aren't even as far as we should go. We should be going farther than that, and I'll talk about that in a second.

On the other hand, they're formally regulated very heavily, but the regulations are so complicated that the enforcement is lousy, and I think there's a connection. If you have too many formal rules, you can't enforce them very well and you lose track of which are important ones and which aren't.

Okay. So I think the -- one implication of this is somebody needs to fund -- and this is a little self-serving. I'm an economist. I do this kind of work. But somebody needs to -- actually several of us do. Somebody needs to fund a major long-term study of this sector of the health care industry and how it's regulated and what the outcomes of the regulation are.

Now, when I said a minute ago that going to outcomes as they were conventionally thought of isn't far enough and that's because even at the level of the outcome, from the point of view of the patient, it's still a process.

Okay. What really matters is the patient's view of it, the patient's values. It needs to be patient centered in a sense, or as Mr. Dodgen said it needs to be ultimately to the patient's view not some mechanical physical thing that can measure the patient's satisfaction.

I think that's a very important idea. We've hardly ever gotten that far down the chain, and I think this enormous research project which should be funded and maybe will pay for my retirement if I get a small part of it needs to take that view.

DR. SIMON: Great. Thank you. Mike.

DR. MORRISEY: Actually my comments are much

along the same line perhaps because Ted and I went to lunch together. I was there for the blizzard, but I missed the crowd in Oklahoma.

But again the sense across all of the areas was that -- and I don't know if it's because other segments of the health care industry have sort of other venues in which they can sort of identify problems, but it's clear across all of the sites at least that -- well, between us all of the sites that we've been at that nursing homes, long-term care in general, home health, ICF/MR, across the board, there are issues here of longstanding.

And I would second the call for sort of not one giant study, but a number of studies that try to begin to look at some outcome measures of quality, that begin to look at some patient satisfaction, things that are better than the Lake Wobegon kinds of effects, and see to what extent the kinds of regulations that are in place make any difference or catch the bad apples.

It's amazing at least to those of us who aren't particularly familiar with this segment of the industry. There seem to be real problems that are pervasive across the country.

DR. SIMON: Mike, thank you very much. Dan.

MR. MULHOLLAND: Thank you. Just a couple of themes that I heard today that I think will help in the

study that's being done into the cost of health care. One is that it's important to distinguish between transition costs that are the result of either a new program or a new technology or both. I think you saw a lot of that in some of the testimony about Part D problems in nursing homes versus ongoing regulatory costs that are always going to be there.

The survey costs, the costs of compliance, the costs of regulatory uncertainty, those things are costs that will never go away, but in analyzing those, it's important to distinguish it.

The second is a theme that I heard from a number of the people who presented today, that regulatory costs actually could end up inhibiting policy initiatives like electronic health records, that if you don't address some of the privacy concerns that, you know, were never thought of when the HIPAA regs came out a few years ago, you could be holding back technology that would save lives, save money, and provide a more efficient health care system.

The Stark rules, other rules that inhibit providers getting together with one another to either share costs or do things together are another example of that.

But the real theme is one that I think we heard at all the programs -- and I was like Mike, I missed

Oklahoma City, but I went to the others -- is that a lot of the regulatory costs are the result not of the regulators themselves, although that's part of it. It's more the way that the law is written, that when Congress comes up with an incredibly complicated scheme like Part D, you're bound to have these issues just because they can never contemplate everything that would come up.

And I don't know that there's anything any of us could do about that. The budget bill passed yesterday and I think by a two vote margin and who knows what kind of mischief is in there.

One is that any nonprofit, tax exempt organization with more than $10 million in assets is now going to have to have an audit that will probably cost you a million bucks a year to certify that you don't have unrelated business income tax -- or unrelated business income.

So, you know, things like that pop up without anybody knowing where they come from in the way in which legislation's adopted in Washington and I think that has to be done, but it's something far beyond the pay grade of anybody here to handle.

DR. SIMON: Great. Thank you. Bill.

DR. ROGERS: Yeah. I really appreciate you all coming and educating us. This is incredibly useful.

You know, of the things that we heard today, it seems that two things, OASIS and expedited determination, are things that we might be able to do something about if we get a recommendation from this commission to look at those, and those are both things that probably could be modified to make them more palatable.

On the survey insert and the regulations concerning home health and skilled nursing facilities and the other sorts of facilities, I think what we heard in Oklahoma City was that because of the bad actors, most of the patients and their families would feel very uncomfortable with reducing the number of requirements and reducing the number of standards.

I mean even thinking about this 14-hour thing, I mean I know that if we were to say, you know, let's drop that because sometimes people like to eat breakfast at 10:00, somebody would say, well, there's this nursing home in, you know, wherever that's starving people and we need this rule.

So I really think that in order to fix that problem we need to think about a new paradigm for measuring and assuring basic quality, and it may be wound up with the implementation of electronic health records. But I think the industry needs to, rather than trying to manipulate state, federal, probably county, you know,

requirements into a manageable volume, I think probably throwing the old system out and replacing it with something more technologically advanced is probably the only way we're going to fix that problem.

And then finally on Part D, we were meeting twice a day with Mark McClellan until last week, every day of the week including weekends, and now it's down to once a day, but he's very, very engaged on this and very committed on this. And we may need more regulation in some parts of Part D and we may need Congress to give us some authority to treat some industries in a different way.

But we're going to make this work -- the Part D thing work. So -- and it's not going to go away. So let's hang in there and keep the comments coming. Thanks.

DR. SIMON: Great. Thank you very much. We have a few moments, and so I'm going to offer up a couple to the audience. If there's anybody who has a remaining question or a comment on anything they've heard in the last summaries. Barbara.

DR. PAUL: I have several comments I'd like to make. This is Barbara Paul and this is kind of a potpourri.

Part D, another suggestion under Part D with nursing homes is, you know, the formulary, I learned just

recently that the formularies, these are really ambulatory sort of, you know, healthy people formularies.

And the formularies have, for example, as tier one medications, medications that are Beers List medications. And it is just completely sort of upside down from a clinical standpoint -- I'm looking at Bill here -- to think that a physician has to jump through hoops to get to a step two or step three medication which is actually the right medication for a geriatric patient and have to explain why a Beers List medication shouldn't be prescribed.

And which makes me think that looking to the geriatricians and the geriatric pharmacists would be a very good way to cut through some of this if you don't -- if you're discounting some of what the industry is saying.

I also think standards -- if it's not a regulation, it's a standard. There are standards that should be met and the federal government has an ability to leverage that and needs to be leveraging the push towards standardization with its IT standards, language standards.

There's a standard for -- under Part D that's not being used that is a patient locator which makes it very difficult if we don't know where that patient is.

Comment about quality in nursing homes. Part of the problem with hearing that there's good quality and bad

quality and better and worse is that there are a lot of different ways to measure. There's lots of different snapshots.

I would suggest that there -- and so you can support whatever argument you want to make.

The quality measures that are published on the web site at Medicare, there is very good evidence that some of those are moving nicely, and the ones that move the most, that improve the most, are the ones in which nursing homes worked with the Quality Improvement Organizations.

The ones that moved next most were -- for nursing homes who worked with QIOs but not necessarily on that topic. But they worked with a QIO with those philosophies of quality improvement.

And then the measures that worked the least were in nursing homes that didn't work with a QIO. I do think the QIOs are a tremendous resource. I do think that Medicare and HRQ are moving toward a standardized patient or family experience of care surveys. Hospital CAHPS is being implemented right now.

I think pushing CMS to go toward an experience of care or quality of life survey for nursing home patients would be a really good way to get at what you've heard about today, and I think that the nursing home

community would welcome it. And I guess I'll just stop. I'm sure there are some other people who have comments.

DR. SIMON: Thank you.

DR. PAUL: If you have questions --

DR. SIMON: Bill, go ahead. I want to give Bill chance to comment on comments.

DR. ROGERS: The idea of having a geriatrician involved must be a good idea because Congress thought of it first. Actually in the law, it says that every PDP has to have a P&T committee and every P&T committee must have at least one member as a physician who is experienced in geriatric care.

So those formularies that you're looking at have been -- (A) are constructed on a backbone that was created by the USP with a lot of input from specialty societies including geriatricians, and every one of those PDPs has a P&T committee which can be addressed if -- you know, if there are problems with the formularies.

And that'll probably, you know, there will probably be a lot of fixing to do in the first six months and less fixing to do in the next six months, but every one of them has a geriatrician on their P&T committee.

DR. PAUL: The real risk I think for nursing homes is that it's already troublesome or problematic for us to get the physicians to even work in a nursing home,

and then you add silly paperwork, it just -- it starts to just move you down the wrong path in terms of quality of care. You're pushing doctors away from the very setting where you need to be drawing them in.

And then maybe it'll work out in six months or two years, but it's a problem right now.

DR. SIMON: Great. Barbara, thank you very much. I'm going to go to Serge and then to Keith.

MR. TEPLITSKY: Thank you, Carol. I want to comment on patient centered care and I cannot emphasize enough how important it is because I think there is a big shift right now in health care especially in the skilled nursing facility care where we should be paying more attention to patient care services.

And as an example, we have been working with Eden Alternatives through our Quality Improvement Organization in California, Lumetra.

And I think -- I met with the Department of Health Services here in California to talk about a greenhouse model that is quite popular in different states, but again there are so many regulations that preclude us from making this happening throughout the country.

And again now we have different options in terms of the community care and we have freedom initiatives. So

the whole paradigm is changing, but the regulations again stand in the way because they were created a long time ago and they do not jive anymore with the model we're trying to push forward.

And secondly, again, the kind of a customer satisfaction or a patient satisfaction piece is also important. Again, there was an attempt I know embedded into the MDS 3.0 is a couple of questions, or a few questions around patient satisfaction of -- about the quality of care.

I think to take one step further to ask skilled nursing facilities, some would work -- to work with patient satisfaction survey companies. For example, I know a lot of skilled nursing facilities who work with Press Ganey. And that's not only for skilled nursing facilities but acute care hospitals use this.

And that's another step forward to figure out what the patients or patients in the skilled nursing facilities actually want. Do they want to get up at 10:00 o'clock in the morning or do they want to get up at 2:00 o'clock and eat breakfast or lunch or dinner.

And I think that's where we need to pay more attention and get into this patient satisfaction survey even more instead of looking into -- I mean quality indicators and measures are important, but again the

patient satisfaction piece is missing completely from this model. So that's what I would suggest.

DR. SIMON: Serge, thank you very much. Keith.

MR. PUGLIESE: Two additional thoughts. One is that, and I don't know. This is impossible I know. You're writing regulations on a federal level and, you know, it's -- but the -- so you have to write a regulation that applies to a particular provider or program and it has to apply across the country, but unfortunately one size doesn't always fit all.

And there are pockets in the country that experiment or have models of delivery systems that are particular to those regions. Like in -- from Rochester, New York to California, the coordinated care, multi-specialty physician group model which when it comes to Medicare barely recognizes it and doesn't reward it or compensate it, and that really needs to be addressed.

Also I want you to be aware of -- I don't know how much further you're going to go in -- or is this the end of the line?

But here in California, two days ago, the California Department of Managed Health Care held its -- a meeting of its financial solvency status board in Burbank and where they're really -- their main focus this year is about trying to get more of a handle of what does this

mean quality? And outcomes? And efficiency? How do you measure these things really? And no one yet has really the answers to this.

You know, in California IHA started the pay for performance program that's now starting to catch on nationwide, and CMS is considering this for Medicare. But, you know, you may want to hold more symposia with, for example, you know, California's own regulators or certain organizations like IHA, the Integrated Health Association, here to find out if there are other pockets in the country in addition to California who's a little bit further down the road and has more information to share with you on this.

It's very complex, and I just applaud this effort that you're looking at these kinds of issues, but I think there's a lot more work that has to be done.

DR. SIMON: Great. Thank you very much. And actually that's a perfect segue for me telling you exactly where we do stand right now and doing a little bit of wrap-up.

In your packet -- and this is my attempt to reduce your regulatory burden on paperwork -- is -- this is the Carol Simon paperwork reduction act -- is I'm going to show you which piece of paper that is actually relevant here -- is a little statement here that talks about the

town hall meetings and public comments.

And the most important thing for you to recognize on this right now are the Web sites on which we are accepting public commentary. This is the last of the scheduled town hall meetings, and this is in many ways a capstone for a lot of what we have heard and as the panelists presented, there have been themes that have been echoed across the country. And those are indeed very, very powerful.

The opportunities for submitting public comment through the Web, and those are outside of the town halls, the Web sites are open for one more week.

And so for those of you who intend to submit us your comments in hard copy, to submit additional reports, I bring to your attention that the window of opportunity is not infinite. Indeed it is about seven days and that is very important in real time.

In terms of contacting your colleagues, you know, other folks in your profession who you feel also may be able to lend weight and evidence to our reports, again they should be -- the attention should be that we have approximately seven days.

And the purpose of this is that we are striving to do forward-looking policy as opposed to policy through the rearview mirror. All too often, we collect evidence

for so long that by the time we get done, you know, dissecting it, sorting it, categorizing it, reporting on it, and throwing it back to Congress and the various agencies that we've moved about two years down the road and the relevance is negligible.

We're trying to produce evidence, make recommendations, discuss the state of the world while the car is still on the road heading in the same direction. And so we appreciate your efforts being here today and the capstone to that is to provide us as quickly as possible the additional evidence that'll make our job that much easier.

Having said that, this is the last of our town hall meetings, and I want to take a moment personally to thank our panelists who, as you've heard, many of them have traveled around the country with us over the last, you know, three months and have certainly made my life much easier, have contributed immensely to this project, and I thank them all for their time.

And I finally want to thank you. I want to thank you for both taking your time today to give us the very important evidence that we need. This one phase of essentially the three-pronged effort is coming to a close. Two others are still underway.

We have a large-scale literature review, and to

put a plug in, we are also doing a series of on-site interviews and case studies. And if any of you would like to offer up additional evidence and define the personal burden that this entails, I encourage you to talk to me or to my colleague, David Newman, in the back because we would be very happy to hear from you in greater depth.

I also want to thank you for your attention, your organization, your attention to time for not turning me into Cruella deVille or I guess the Terminator -- well, I guess that has political connotations in this state and I best not go there.

And at the close, I simply want to thank you once again. I want to wish you all well and have safe travels and please send us information to the extent that you can. Thank you very much.

(Whereupon, at 2:14 p.m., the Town Hall Meeting in San Francisco, California was concluded.)