CENTERS FOR MEDICARE AND MEDICAID SERVICES

PRACTICING PHYSICIANS ADVISORY COUNCIL
Hubert H. Humphrey Building
Room 705A
200 Independence Avenue, SW
Washington, DC 20201
Monday, May 19, 2008
8:30 a.m.

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Open Meeting

Dr. Bufalino: Welcome to the quarterly meeting of the Practicing Physicians Advisory Council. We thank all of you for taking the time out of your schedules to share this experience and we know that you're all busy active in your practices, and we thank you for taking that time to come to Washington to help provide some input to the agency. We thank you also for the new group of folks that have joined us and this morning we have the privilege of inducting those new members. And what we thought we'd do today is because we actually have a special guest who's going to come and do the swearing in ceremony, but we thought we'd take a moment to maybe go around and ask the five new members to introduce themselves, where they're from and what you do. Why don't we begin with Janice.

Dr. Kirsch: Hi, I'm Janice Kirsch. I'm an internist and I work at Women's Health Center in [inaudible noise] City, Iowa. And I have a strong interest in primary care, diabetes management, [inaudible noise] and mental health issues.

Dr. Howard: I'm Pam Howard. I'm in Allentown, Pennsylvania. I'm a burn surgeon and I do trauma and critical care.

Dr. Giamio: I'm Joe Giamio, I'm from Palm Beach County, Florida. I do pulmonary and critical care medicine.

Dr. Standaert: Hi, I'm Chris Standaert. I'm from Seattle, Washington. I'm in physical medicine, and rehabilitation.

Dr. Smith: I'm Fredericka Smith. I'm from Los Alamos, New Mexico, and I do hematology[?] and internal medicine for rheumatic disease patients.

Dr. Bufalino: Thank you. And the rest of you characters we know. My name is Vince Bufalino, and I'm going to ask the chair, the Counsel for Year, and I'd like to take the privilege of beginning the morning by introducing the Deputy Administrator for the Centers for Medicare and Medicaid, Mr. Herb Kuhn. We're thrilled to have Mr. Kuhn here. He takes this special time out of his extremely busy schedule to spend it with us when we're in town and we thank you for that and we thank you for the direct access to

1 you to be able to discuss some of these issues with you, either first hand or sidebars, and so we thank you
2 for making yourself available to the Council, and let me begin by asking you to have a few remarks.
3 Welcome
4 Mr. Kuhn: Thanks Dr. Bufalino and good morning and welcome, everybody, to Washington for
5 this meeting of the Practicing Physicians Advisory Council. Thank you, too for once again, agreeing to
6 chair the Council this year. We appreciate that leadership very much. Also I want to welcome again—I
7 know I saw some of you at the last meeting, but all the new members, and particularly as you were
8 introducing yourselves, as we say it every time, this is the Practicing Physicians Advisory Commission, so
9 you all are taking time from your busy schedules yourselves to come here and do this, but it was
10 particularly noteworthy to notice that two of you are coming from the West Coast, or near the West Coast
11 areas, and I know that's a lot of travel for both of you, so thank you for the time that you're taking to do
12 this. It's much appreciated as we go forward here.
13 I think if you look at today's agenda, you really begin to see a lot of the pivot in this organization.
14 And what we not only CMS, but I think what the health care community at large are trying to do in terms of
15 beginning to change how we pay for healthcare services in the future. And a lot of this is captured in this
16 whole notion that CMS is really trying to evolve or change itself from being nothing more than a passive
17 payer of services to becoming really an active purchaser of healthcare and that's a big change for any
18 organization, but it certainly is an enormous change for an organization the size and scope of CMS as we
19 go forward. And so if you really think, and kind of the history of the Medicare Program, dating back to
20 1965, where we first started paying on usual and customary services, and that carried us pretty well for a
21 couple of decades. But I think everybody noticed in the late '70s, early '80s, that change was needed, and
22 along came the Prospective Payment System, and shortly thereafter, the RVRVS System, because change
23 was necessary to begin trying to drive more efficiency and better outcomes in the system. And now, two
24 decades later, people are looking at change once again. And I think what PPAC is all about, I think what
25 CMS is all about, and some of the others is beginning the effort to write a new chapter in terms of

healthcare, but the new chapter, at least in Medicare, as we begin to think differently of how we're going to drive and pay for value, not volume of service as we go forward. And so you see that a lot in today's agenda, you've seen that a lot in the agenda for the last two years, but I think this one even gets a sharper focus as we think about the future and where we're going to go with this program on a go-forward base. So from reasonable and customary to RVRVS to Prospective Payment, now to Value Based Purchasing, and I think it's a logical maturation for the program. And we appreciate your all's service to help us kind of continue to move in that direction. So with that, again welcome to the new members. We look forward to swearing you in this morning, and welcome all of you, appreciate your service today.

Dr. Bufalino: Thank you. Should we, maybe we could go down and ask Jeff, any morning comments?

Dr. Rich: No, other than just to echo Herb's welcome and thank you and also as thoughts are on the direction of the agency, and since we are in Washington, I will yield my time to my colleague. [laughter]

Swearing in of New PPAC Members

Mr. Weems: All right, well good morning everybody. I'm glad to be here today and good to see all of you. I'd like to personally extend my appreciation to those of you who are continuing your commitment as we work on the many things that confront this group and our healthcare system. In an effort to refine our approach to planning these quarterly meetings, I recently met with our leadership team to think about a strategic plan. Our goal is to bring the most relevant information to you and get the benefit of your expertise. Among the many issues that we identified for the PPAC strategic plan are demonstration projects, of which we announced a couple, recently, PQRI and the RAC Program, just to mention a few.

Today's meeting is largely focused on quality and I'm glad that our chief medical officer, Dr. Barry Straube will be here to talk to you later this morning. But at this time, I'd like to proceed and bring forward our five newest members of the Council. As you know, this past quarter, one our four PPAC

members resigned so in addition to replacing the four outgoing members, we're also have a slot to fill. So it's my pleasure to introduce the new additions, and to bring them forward and we'll take the oath.

Joseph A. Giamio, did I get that right? Good. Dr. Giamio is a board certified pulmonologist and works in private practice in West Palm Beach Florida. He is past president of the Florida Osteopathic Medical Association and has served on various committees.

Dr. Pamela Howard. Dr. Howard is the Assistant Medical Director, Chief of Burn Research in the Lehigh Valley Hospital Burn Center. Her distinguished career as a general surgeon with special focus on burn patients provides a unique and important perspective to the Council. Welcome.

Janice Ann Kirsch, Dr. Kirsch. Dr. Kirsch is a board certified internal medicine physician, practicing in Mason City, Iowa. Dr. Kirsch's professional interests include Type II diabetes, depression and chronic pain syndrome.

Frederica E. Smith, Dr. Smith. There you are. From my home state of New Mexico. Dr. Smith is a rheumatologist who has been practicing in Los Alamos for the past 32 years. Dr. Smith's practice serves patients in rural areas through northern New Mexico, and will bring to the Council unique perspective on providing medical services to these communities.

And Christopher Standaert, Dr. Standaert. Dr. Standaert maintains board certification in both physical medicine and rehab, and electro-diagnostic medicine. He's an experienced physician and an academic. He'll bring a meaningful contribution to shaping Medicare regulations as a member of the Council.

So I'll ask you to stand please.

[Members assemble for the Oath and are sworn in]

[Photographs taken]

Dr. Bufalino: OK, we can take a deep breath. The ceremony…and now you are officially voting members, so we will begin the morning. So and recognize Liz Richter, who is always with us at the

meetings and helping provide guidance to us as we all continue to learn about the inner workings of CMS. So we thank you for that.

We will move forward on the agenda, and jump right into the Update, Dr. Simon, who's the executive director of the Council and has been a key ally and someone that we have for years used as a contact all my time, we thank him for his time and insight and his direction, and we ask you to begin the response to last meeting's resolutions.

PPAC Update

Dr. Simon: Thank you, Dr. Bufalino.

Agenda Item 63C-1. PPAC recommends that CMS present to the Council, at its May 2008 meeting, the preliminary data on PQRI participation and other statistics through November 2007, that were reported by the Physician Performance Information Center. The CMS response: CMS will present to the Council at its May 2008 meeting preliminary data on the 2007 PQRI participation.

Agenda Item H-1, pertaining to hospital measures, physician, and quality. The Council requests CMS provide at the May 2008 meeting more detailed data on participation and reporting from the 2007 PQRI. The Response: CMS accepts PPAC's recommendation and the requested information on PQRI participation will be presented at the May 19, 2008 meeting.

Agenda Item 63E-1, NPI Update. PPAC recommends that CMS 1) closely monitor the rate of claims rejected following the March 2008 deadline; 2) share the information the rejection with the physician community in a timely fashion; 3) allow the use of legacy provider numbers only, in essence, in lieu of the NPI if the rejection rate immediately following the March 2001, 2008 deadline exceeds a reasonable amount; and 4) not reject claims in situations in which practices have experienced enrollment backlogs. The response: CMS closely monitor reject results, following the March 2001 deadline, and shared the results with provider associations. The agency meets every two weeks with some provider associations, such as the AMA and MGMA to discuss the status of activities, and share information. Rejection rates following the March 1st deadline did not suggest a need for any relief and individual

provider issues were handled on a case by case basis. Currently, over 99% of all Medicare claims are coming in with an NPI, either the NPI only, or an NPI with a Legacy pair. We continue to monitor the data as we move closer to the next deadline, which is May 23rd. And after the May 23rd, 2008 deadline, CMS will reject any claims that contain a Legacy ID in any field on the claim. CMS has issued temporary guidance to Medicare contractors that will facilitate the handling of enrollment application corrections and we have established NPI coordination teams at each contractor to further prioritize and facilitate corrections.

Agenda Item G, the RAC Update. 63G-1, PPAC recommends that CMS make available the specific rules for evaluating evaluation and management codes for subsequent RAC audits, with particular attention to the definitions of the components of history, physical examination, medical decision-making and whether the 1995 or 1997 Evaluation & Management Rules will be applied. The response: CMS has not yet made a decision regarding a review by the Recovery Audit Contractors of Evaluation & Management Codes for level of service. Before a RAC would be given the authority to review Evaluation & Management Codes for level of service, CMS will communicate with PPAC and the AMA. If CMS were to decide to allow the review of Evaluation & Management Codes by the RACs, CMS would direct the RACs to use the same review methodology utilized by the comprehensive error rate testing, commonly called the CERT, by the CERT contractors, carriers and Medicare administrative contractors. That is to use the 1995, or ’97 Evaluation & Management guidelines, whichever is more advantageous to the provider.

63G-2. PPAC recommends that CMS report back to the Council detailed analysis of data from the RAC audits and the RAC performance evaluation contractors to refine claims identification on the basis of unique, specific practice patterns and to provide education to improve the accuracy of claims submission. The response: CMS has released to PPAC the Fiscal Year 2007 RAC status document, which can also be found on the RAC webpage on the CMS website. CMS will soon be releasing, in the month of May, 2008, a more detailed RAC demonstration evaluation report that will include analysis of the RAC demonstration for its inception. CMS will share this report with PPAC once its released. In addition, CMS will require

1 future RACs to post to their websites information about the vulnerability areas they have detected,
2 including a reference to the specific policy that is being violated. Medicare claims processing contractors
3 can use this information to develop their error rate reduction plans, which may involve more data analysis,
4 automated review, and complex review and/or provider education. RAC issued vulnerability information
5 will help providers ensure that they are submitting correctly coded claims for services that meet Medicare's
6 medical necessity criteria.
7 63G-3. PPAC recommends that CMS streamline the process for physician appeals of RAC audit
8 determinations. The response: CMS believes that the appeal process for RAC determinations should be the
9 same as the appeal process for carrier and MAC determinations. However, CMS will work to make more
10 information about appeals of RAC determinations available in reports and on the CMS website.
11 63P-3. PPAC recommends that CMS RACs reimburse physicians for the costs of all medical
12 record requests. The response: The cost of complying with medical record requests is not separately
13 reimbursed because it is bundled into the payment for the medical service that was provided.
14 63P-4. PPAC urges CMS to revise subsection e-9 on staff performing complex coverage review,
15 to ensure denials of Medicare claims based on medical necessity should be reviewed by a physician in the
16 same specialty and licensed in the same state as the physician whose claim was denied. The response: CMS
17 requires that qualified clinicians, such as nurses and therapists, and all Medicare contractors, including
18 RACs, perform medical necessity reviews, consulting with physicians or other specialists as needed. CMS
19 does not believe that mandating 100% physician review would yield a better clinical outcome for our
20 Medicare beneficiaries.
21 63P-5. PPAC recommends that CMS change the minimum amount that RACs can attempt to
22 recoup in overpayments to $25, consistent with the minimum amount of debt eligible for referral to the
23 Department of Treasury. The response: CMS will continue to monitor the administrative burden on
24 providers, as we evaluate the RAC program. CMS is currently considering changing the minimum per

claim amount, where a RAC can request a medical record to $25. RACs could still review claims on an automated basis, if the claim was between $10 and $25.

Agenda Item P, the Wrap Up and Recommendations, 63P-1: PPAC that CMS clarify and define where the physicians do supply durable medical equipment, prosthetics, and orthopedic supplies under the DME POS fee schedule, as part of their professional service, as opposed to physicians acting as commercial suppliers, are subject to all of the requirements of DME POS competitive bidding final rule, including the requirement for accreditation. The response: The law did not give CMS the authority to acknowledge physicians as already having already met the quality standards and thus be exempt from accreditation. In general, such suppliers shall be required to comply in order to furnish any such item or service for which payment is made and received, or retain provider, or supplier numbers used to submit claims for reimbursement for any item or service, for which payment may be made under Medicare. Exemptions have been provided in the Competitive Bid Final Rule, to allow physicians and treating practitioners to furnish crutches, canes, walkers, folding manual wheelchairs, blood glucose monitors, and infusion pumps as part of their professional service. Physicians who act as commercial suppliers of DME POS as opposed to furnishing items as part of their professional service, are subject to all of the requirements of this final rule.

63P-2. PPAC recommends that CMS take immediate steps to ensure that practices do not experience cash flow interruptions as a result of the transition to NPIs. The response: In those limited situations where Part B practitioners experience severe cash flow interruptions, CMS contractors and regional offices should be contacted to discuss how to best resolve the issue until the clinician's system, and CMS's are properly cross walked and the NPI is functioning. We may also suggest that providers fully assess their own readiness and the readiness of their clearinghouse or billing service, if they use one, to ensure that they are well prepared for the May 23, 2008 deadline.

That concludes the recommendations in the report from the March 3rd meeting, Dr. Bufalino.

Dr. Bufalino: Thank you, Dr. Simon. Any questions? Leroy.

Dr. Sprang: And I have a strange question because I didn't really know the answer on the durable medical equipment. I'm going to give you an example of gynecologists put in pessaries. Would that be considered a durable medical equipment, and would it be an exception or, we do that on a common basis and I don't even know if you know, because I don't know.

Dr. Simon: I don't, I'm not sure we can find that out, but if the physician is acting as a commercial supplier, then he or she would need to meet all of the elements that are contained in the Final Rule. If you're providing it as part of a professional service, then it would be viewed as part of the supplies that you provide during the professional service.

Dr. Sprang: OK, it's definitely a professional service, and obviously we have to fit the specific kinds and need to have different ones there because some work and some don't work, so you really don't know on that patient until you try different ones. So that's certainly part of the professional service.

Dr. Simon: We can—

Dr. Sprang: I just want to find out if we do get reimbursed from it, because it costs us about fifty bucks a piece.

Dr. Simon: If it's part of the professional service, yes, then it would be exempt, and you would be eligible for reimbursement. If the pessaries are being supplied as part of a commercial service, not part of your professional service, then the physician would have to meet the elements that pertain to those companies or vendors that serve in a commercial capacity.

Dr. Ross: Dr. Simon, I'm just trying to clarify that again, staying on the same theme. Most of the stated items are basically anciliatory type items such as the crutches, the canes, the walkers, etc. Many of the products that are dispensed out of the office include surgical shoes, orthotics, other items, but I'm gathering that if this is part of the daily care for the patient and not a commercial "enterprise," that that is covered no matter what the specialty may be. Is that pretty acceptable?

Dr. Simon: The, when we reviewed this topic, again, I think that supplies that physicians may provide as suppliers are under consideration at this time by the agency, but those physicians are still held to

the same standard as commercial suppliers. If you're providing those supplies as part of your professional service to a patient, then it is exempt.

Dr. Ross: Then it is exempt. And do they have to get accredited or not?

Dr. Simon: Physicians are not exempt from the accreditation process.

Dr. Ross: OK.

Dr. Bufalino: Other questions?

Dr. Przyblski: Ken, I have a question about 63P-3 and a comment was made that medical record requests are not separately reimbursed because they're bundled. This is an example, like many other things, of added responsibilities that offices are being asked to shoulder, yet there's not really been an update in practice expense for the non clinician providers, non clinician workers that would be doing this. Last time I think that that data was updated might have been I think late, whenever the last SMS survey was done. So how can one say that it's already being accounted for when any extra personnel that may have been hired over the past 5 plus years has never really been accounted for the practice expense component?

Dr. Simon: I think that when the reimbursement was designed for the services that are provided—in this instance it would typically be evaluation and management services, or surgical services for that matter, the, it's felt by the agency that those costs are captured through their pre- and post-service elements of the service that's provided.

Dr. Przyblski: But this is, to follow up, is something that's new that's being asked. So RAC is requesting medical records. Presumably that's going to non clinical staff to do, and prior to the RACs' existence, they weren't responsible for it, so obviously it's a new cost. If new people have to be hired, then it is a new practice cost and the question is how does that get captured?

Dr. Simon: I guess the question is, is the practice hiring someone simply for the purpose of extracting medical records for the RAC?

Dr. Przyblski: I would suspect not, but over time, since the last time that the SMS survey was in place, more and more demands have been placed on clinical records, so we don't know whether there are

people that have been hired that weren't initially reflected in that survey is the point that I'd like to bring up.

Dr. Simon: I'll take that point back to the Program Integrity section for their consideration.

Dr. Przyblski: Thank you. And that may be solved with the new survey that's going out and we will be able to see whether there are more personnel reflected in current practice than previously.

Dr. Snow: Regarding Item E-1, I've got a question about the Legacy provider numbers. Does that include UPIN numbers? I've never heard that discussed by our CMS carrier in our region. They're talking about this new PTAN, whatever that is, sort of figured out what number's associated with that, but I've never heard anybody say anything about the UPINs. Do they have to take the UPINs off of our claims now, do you know?

Dr. Simon: Well, you will use just the NPI number beginning May 23rd.

Dr. Snow: OK, so UPINs as well as those other numbers go.

Dr. Simon: Yes.

Dr. Snow: I appreciate it.

Dr. Smith: Does that refer on a claim if you're doing a consultation, you have to identify the referring physician, and does that mean that one has to now use the referring physician's NPI number as opposed to the referring physician's UPIN number?

Dr. Simon: Yes.

Dr. Smith: OK. So we have to find a list of those somewhere. [off mike remarks] It's on line for everybody?

Dr. Bufalino: Anything else? OK, let's move on to the PRIT Update. Dr. Rogers usually joins us, but he's out of town today and we've asked Matt Brown to join us. He's the health insurance specialist with the Physicians Regulatory Team, and I would ask Matt to address the issues.

1 PRIT Update

2 Mr. Brown: Good morning. Good to be here. Again, Matthew Brown with the Physicians
3 Regulatory Issues Team for the new members here. We're a small group that to pretty much sum it up is
4 established to make practicing under the Medicare program an enjoyable experience. [laughter] At least
5 less burdensome. Dr. Rogers is on a much deserved vacation. He's a practicing physician still, emergency
6 room doc, at Sibley hospital. He's also in Air Force Reserve, so he's a busy person, that's why I say much
7 deserved.

8 Dr. Rogers does a lot more comical cartoonish things with the presentation, so forgive me if mine
9 is a little bland than what you're used to. Let's see if we can get started. Our current issues is, we have the
10 NPI issue, and I think we're going to talk more about this, well the next speaker will, so these numbers are
11 a little out of date. This is April 11th. We had 98.7% of the claims with the NPI number. But we're finding
12 that not all the NPIs had a crosswalk, so if it's an NPES issue, then that's pretty easy to fix; make a phone
13 call, go on line. If it's a PECOS issue, enrollment issue, that's going to be a little bit more difficult with a
14 855 Form and again that process takes longer and is less cumbersome, so NPES easier, PECOS a little bit
15 more difficult.

16 Just an update on simplifying enrollment. The 855 Form is now available to save on line if you
17 don't have the complete Adobe Suite, and that was not the case before. And we contacted staff in Baltimore
18 and they were able to make that change. So that should be a little easier there.

19 IXPC is available to verify anyone who's going to be using the PECOS web. So PECOS web is
20 not up and running at this time, but we encourage you to get set up on IX so that when PECOS web is
21 available, you can have a smooth transition there. And again of course, the whole convenience versus
22 security is the issue with the online applications; how do we make the system convenient, but also still
23 secure, as secure as possible?

24 Dr. Snow: Excuse me, what is that ISASPC?

Mr. Brown: It is the Individuals Authorized Access to CMS Computer Services, Provider Community.

Dr. Smith?: Which means what? [laughter]

Mr. Brown: To use our computer services, you have to be, you have to establish an account. This next issue as you can see has been an issue since September, 2006. That's a PRIT record. We're still almost there. This is a hang up with the lawyers for different government agencies; DOJ, etc., so we keep pushing and we hope to have something soon. It's been difficult. It's kind of out of our hands at this time, but we just keep making the phone call and just trying to bug as many people as we can. So we'll have something for you when we have it. This next issue, HPMA brought it to us and I think it's a pretty good issue. It's dealing with our refund and recoupment notices that we send out to providers and notices do not have the what we think is the pertinent information for the billing staff to then go back and do the accounting. The forms that, the notices that we send out for the recoupment and refunds has a file number. That's an internal tracking system. It doesn't have the beneficiary's name. It doesn't have the original claim number, which makes it more difficult to go back and decide which claim that's associated with. Right now, the only way to do that is to use that racking number that we use and go back to a previous correspondence to see if those tracking numbers match up, or providers are calling the carrier to try to get information. And all this of course is time consuming and burdensome, so we've been working with staff in Baltimore to try to see what information we can have on these notices, because the Medicare remittance notice has the beneficiary name, the date of service, and I think the HIC number as well, so we have the information. It's just a matter of, they know more about the claims process than Bill and myself, so trying to figure out what can we possibly put on those notices that can make it easier and we thought it was going to be a simple request. But as with most things in the huge healthcare system like we have here, it's not always as easy as we think so. We'll wait to hear back from them and then we'll give an update to see what we can do to make it easier for providers to associate those original claims.

1 This next issue, chart abstraction, I believe this was MGMA brought this to our attention, and they
2 wanted clarification to their providers, regarding the guidance on private fee for service requests for chart
3 abstractions, and the contractual issues of if the provider is to signed into a written contract with the private
4 fee for service, if they're just deemed a participant, due to seeing a provider who's enrolled into the private
5 fee for service plan, and the guidance we've given is for the provider to check with the, check to make sure
6 that the beneficiary is associated with the private fee for service plan before service if you can, and we're
7 also want to hear from other providers out there to see if this is an issue. If the private fee for service plan is
8 asking for the chart abstractions, we feel that it should be not excessive. But we haven't really heard much
9 from the provider community that this has been happening Right now it's theoretical, so if we hear from
10 this and hear from other providers and this is indeed a larger issue, then I think we can push forward and
11 get a more concrete guidance. But right now, we're suggesting that providers just check before hand to
12 make sure that you're not deeming yourself a provider through the fee for service contract. And again, if
13 you are in a written agreement with the fee for service, to private fee for service, excuse me, plan, then you
14 will have to adhere to the contractual obligations there.
15 This was brought to us by a pulmonologist and she was having problems with the, when
16 prescribing a higher dose than the FDA label amount, and it's kind to sum this up, we can't do anything if it
17 exceeds the FDA label amount. Pharmacists do a pretty good job of checking that and calling the provider
18 to find out indeed if they intended to prescribe that large a dose, and if that's the case, there's an appeal
19 process, which again is time-consuming, but there's a good reason for that. And again that's the FDA's
20 prerogative So our suggestion was there is a way that you can request a change through the FDA, through a
21 citizen notice and on our end there's not much we can do as far as the PRIT CMS. We can offer guidance
22 and give them contact information, that type of information. But that's something that has to be done on
23 their own if they want to push forward. We can again, just make sure they have the correct contacts. So
24 we're waiting to hear from this pulmonologist to see she's going to proceed with that citizen notice to FDA
25 and we'll just see what we can do from there.

And this is just some key websites here. Hopefully most of you are familiar with our website. We keep our active issues and our past issues on the website, so you can always check to see what we're working on. We have the dates of each update under the issue, so you can see the steps taken and where we're headed and the response we've gotten so a good website to know and hopefully you'll check that and pass that to your colleagues.

And then this is just our contact information. Again, hopefully you are already familiar with at least, Dr. Rogers, he's been doing this for I think 4 or 5 years now. I'm pretty new to this so you might not have my contact information. But feel free to send us an email. We do a lot of case work these days. We try not to pass the buck too much, so if you're hearing something in your respective jurisdictions, states, whatever, just give us a call, send an email. We can look into it. We have the contacts with the carriers. We have a good relationship with the carrier medical directors. A lot of times, our providers are having trouble just getting in touch with someone at the different carriers, and we kind of know how to navigate that. So feel free to give us a call, let us see what we can do first, so you're not going in circles and again, that's what our office is there for, so feel free. And if there's any questions.

Dr. Bufalino: Questions for Mr. Brown? Dr. Snow?

Dr. Snow: Matt, you made a comment about the NPI crosswalk problems with the 23rd of May being Friday, I believe, you indicated almost 99% as we heard early of claims having NPI on them. Do you know how many of those have NPI only? That is, no Legacy numbers?

Mr. Brown: I was at a meeting on last Wednesday and a number was given. And someone attempted to write that number down and they said it'll probably change tomorrow, so I think I will wait—I think there's an NPI update after me. So I'm sure they'll have the most current information. I'll let them speak on that.

Dr. Snow: Thank you.

[off mike chat]

Dr. Bufalino: Other questions? Dr. Howard?

Dr. Howard: On the stuff we have with the FDA [unintelligible 42:20], if a physician has a problem and they should go to the FDA with those issues, the reason I bring this up is that recently we were using a antibiotic in pediatrics, and as you know, there's not a lot of research that's ever done in pediatrics, so and we found that we were actually under dosing antibiotic, because we took levels. Which is something the hospital's paying for, but I think is that the only way for us to go back and get these things changed?

Mr. Brown: There is an appeals process. You can go through the appeals process with the carrier. The Medicare appeals process. But each time, you would have to go through that process for each claim. So if that's something that is backed by the science, then there's a way to bring that to the FDA to possibly have that changed, so that the FDA label dosage can be extended or increased and then it wouldn't be an appeals process. It would be denied each time. So.

Dr. Bufalino: Other questions? Great. Thank you for filling in for Dr. Rogers. You did a great job. Thank you for being here. You know we'd like to today follow a format where after each of these, we pause and take a moment to talk about any resolutions you may want to put in place, and may not have them ready, but we could as we go along, we'll kind of do them concurrently as the day goes along, as opposed to piling them all up and doing them at the end of the day. So if there's something around the topic that is being presented, then we'll probably follow with a little discussion and an opportunity for you to put some resolutions in place. Obviously, we can always go backwards and go back and catch something if you come up with something later, but they're there.

Dr. Ouzounian: Well, I 'd like to make a resolution. It's not necessarily specific to the topic at hand, but it's specific to the concept in general. It's been discussed before and suggested that it would be complied with, but I'd like to make the resolution that PPAC recommends that all items to be discussed and their entire be distributed to all PPAC members no later than two Fridays before the meeting, which would be approximately 10 days before the meeting.

[seconds]

Dr. Ouzounian: And I'm sorry. Let me amend that. We'd also like the AMA testimony also by that time.

Dr. Bufalino: Thank you. I think probably the one area that would be some difficulty will be the resolutions that are the responses that Dr. Simon puts together, because it takes a pretty significant approval process and I think that's probably the biggest burden in terms of an inside agency thing from my understanding, but we hope that we can meet those guidelines. Discussion.

Dr. Sprang: Just add a friendly amendment that the goal would be two Fridays ahead, but at a minimum a week before. Are you, Tye is that a friendly amendment from your point of view?

Dr. Ouzounian: Well, a week before is a Monday. If you get it the Friday, you get an extra weekend to look at. If you get it the Monday, whatever you guys want.

Dr. Sprang: Ken, what do you think is realistic?

Dr. Smith: I would argue that a previous, the previous weekend so that you have a block of time there. I mean I ran into the problem of I'm leaving Saturday morning and this thing came in late Friday night, and so there I am. And it if it's the week before and something's missing, that's still better than not having anything. I mean if for some reason, the responses to the recommendations can't come through until the last minute that's only 3 or 4 pages to read, but the rest of the material would be available earlier.

Dr. Simon: Yes, I think I had conversations with Dr. Bufalino this past week. The response report requires clearance through several components of the agency. And usually the final component that reviews it is the Office of General Counsel. It's unpredictable the time that will be taken to clear it through the Office of General Counsel, because that, the responses may require additional refinement by the presenters who presented the topics before this panel at the prior meeting and so in this particular instance, the clearance came through on Thursday and the responses were sent out Thursday. So they were sent out as soon as we received the clearance but it's unpredictable. I think there will be an effort to try to provide you with the presentations sooner, but with the response report, it really just depends to some extend on the internal processes that occur with the agency.

Dr. Bufalino: Motion and second, all in favor?

[Ayes]

Dr. Bufalino: Any opposed?

Ms. Trevas: Were any of the amendments made?

Dr. Bufalino: The motion was the table.

Dr. Ouzounian: The motion was 10 days and I think it stood at 10 days.

Ms. Trevas: OK.

Dr. Bufalino: OK. Any other resolutions? No. We're a bit ahead of schedule and we actually have Cathy Carter calling in for the next session, so why don't we just take a 10-minute break here. We're going to contact here and whether we can get her on, otherwise, Dr. Straube will kind of step out of order and jump in. So why don't we just take 10 seconds, 10 minutes [laughter] and be back.

Break

Overview of CMS Quality/Value Agenda

Dr. Bufalino: OK, so let's get started again. Ms. Carter is going to be a little later, and so we've asked to adjust the agenda, so we're going to begin the two presentations by Dr. Barry Straube. Dr. Barry Straube is the Chief Medical Officer of CMS and a nephrologists and transplant surgeon who's been on the other side of the fence with many of you and he joins us now to begin our conversation today about the quality agenda, and so we'd ask Dr. Straube. Thank you.

Dr. Straube: Thank you, Dr. Bufalino. And hopefully you can hear me OK. My voice is not always the strongest. Good morning to you, welcome to Washington again. I want to add my welcomes. Actually Dr. Bufalino, you've made me even broader in my skills. I'm a transplant physician, not a surgeon. And a nephrologists. I trained initially in internal medicine, practiced for years in San Francisco, at a large hospital there, Presbyterian Pacific Medical Center at the time, it's now California Pacific Medical Center. And I've been heavily involved with physician hospital governance as well as clinical

practice, performing many roles in that setting. I was Vice President of Quality Improvement at a large HMO for about 5 years and I've been with CMS for a number of years in my current role, as Chief Medical Officer, and also I'm the Director of the Office of Clinical Standards & Quality. So I have two titles for the past three years. In the Chief Medical Officer role I have interactions directly, I report to the Administrator, and serve functions across the agency, not just for Medicare, but for Medicaid, SCHIP and everything we do in the agency. Within the Office of Clinical Standards & Quality, we have not really come before PPAC all that often, but we have a number of functions that really we're going to want to continue to get input from you on. We do all the coverage decision making for the Medicare program within OCSQ and the coverage in analysis group. We write clinical standards for the Conditions of Participation, conditions for coverage for all healthcare facilities in the United States. We also do quality regulations that pertain to all settings in addition to just the clinical settings. We have a Quality Measurement Health Assessment Group. You're going to be hearing from Dr. Michael Rapp, who works in my office talking more about PQRI, but we're doing a whole host of activities in developing quality metrics and health assessment surveys and other quality work. We have the Quality Improvement Group, which runs the QIO program and the ESRD Network program in the United States, and much to talk about there, and then finally, we have an Information Services Group, which is charged with collecting quality data, most notably for the hospital quality initiative, the reporting hospital quality data for the annual payment update, so called RACDAPU Program, one of the worst acronyms I think we have. And they also are collecting data for PQRI and for other projects that we'll be talking about coming forward.

So with that as a background, I come before you again with my clinical background and will much appreciate any inputs you have for us on the topics we're going to be talking about today. I wanted to start off a little bit though with whenever I have to appear before various groups, it takes me back to the early part of when I joined CMS. Tom Scully was our administrator then, we were known as the Healthcare Financing Administration or HCFA for short, and Mr. Scully decided that we should change the image of the agency, and the obvious first way to start, just like changing the manager in baseball, is to change the

1 name of the agency, so there actually was an internal discussion among career staff as to what the new
2 name might be. I think the most commonly mentioned name was the Medicare and Medicaid Agency, or
3 MAMA for short. [laughter] But the MAMAs of the world, including my own, I don't think wanted to be
4 associated with HCFA at the time, so we came up with CMS, the Centers for Medicare and Medicaid
5 Services, and of course the first question most of us had as well as all of you is what happened to the
6 second M, and I suppose that's what many people think of federal government, that we lose things or don't
7 follow up, but it is CMS, but I don't want to forget any of us to forget that the second M is for Medicaid
8 and the SCHIP program, and that we do do a lot more in addition to just the Medicare Program. I think it's
9 very important as we go forward, and I think you would agree with me in representing your practices, and
10 your colleagues' practices, that getting alignment and getting some commonality of the measures and
11 hopefully to some extent, the policies, procedures, etc., is a worthy goal, so we are CMS and we have not
12 forgotten what the second M stands for. I do think though some of you may be aware, probably most of you
13 aren't, that there was a contest at the same time that we were talking about changing the name internally,
14 that the AMA actually had, I'm not making this up, they went to their membership, and the AMA
15 membership had some suggested names for us. [laughter] So let me just tell you a few of those that I am
16 able to say here in public. One was Bleed Doctors Dry, or BDD for short, a second was the Office of
17 Physician Servitude, or OOPS for short. Some people said, Just keep HCFA, that's appropriate, but it
18 doesn't stand for Healthcare Financing Administration but it stands for Here Comes Further Aggravation.
19 And then finally, there was another suggestion, which actually I at the time, since I was new to the agency,
20 could resonate with was the Select Health Administration Finance Team, or SHAFT for short. [laughter] So
21 we did pick CMS. We do recognize that people have different opinions than some of us internally do, but I
22 want to say that one, the name change itself, I think brought about a cultural change within the agency.
23 Under Mr. Scully, there was a very definite effort on responsiveness, that was the term he used most often.
24 And I think PPAC among other efforts that we've tried over the years, the PRIT, our Open Door Forums,

any number of efforts we are trying to be responsive to all of you and to practicing physicians, as well as many other people in the United States.

The second piece though is I think we've had a bit of a pendulum shift over the last few years, back from what was very definitely a provider-focus, and we continue to have the provider focus, but we're slowly getting back to a patient-focus in concert with the institute of medicine aims for quality healthcare. So I wanted to share a little bit with you at a very high level initially, but we can drill in as much as you'd like, what we're doing in the quality arena, going to tee up again the discussions that you'll have this afternoon on PQRI and in general value-based purchasing, going into a bit more detail than I will this morning. And as I go along, I've really combined both the overview with physician reporting on our website into one presentation so I will pause at various times, but feel free to raise your hand and bump, jump in if you have questions or comments as we go along.

OK, well the first slide going back one there just again reiterates, we used to be the Healthcare Financing Administration, but now CMS and we provide as you know, benefits for over 80 million Americans in the three major programs that we administer; Medicare, Medicaid and the SCHIP Programs. We spend over $650 billion a year now on services. It's approaching $700 billion rapidly. And there are three main buckets that we have been associated with; the first one of which you're very familiar with. I think PPAC has focused mostly on issues that pertain to our healthcare benefits administration. We pay the bills for healthcare in the Medicare sector. But I've listed a few sub-bullets for you here that as you've come to learn, those of you who've been on the Council for some period of time, and those of you who are new will learn, it's not just setting payment rates, but it's doing a whole bunch of other complicated processes, including conducting research on financing, and alternative forms of research, and again, you'll hear about that this afternoon, particularly in the Value-Based Purchasing arena. We do oversee our contractors. You're heavily involved with giving advice on that. And we have a heavy area, you've already talked a little bit about the RAC program, but we're looking for identifying fraud and abuse, or the improper use of the payment system if you will. But we do a lot more at the agency that I've come to learn

over the years I've been here. And another area are beneficiary focused activities. And hopefully as we go, talking about some of the quality issues today, which we believe are first and foremost focused on beneficiaries and patients, and their families, that PPAC will increasingly as we go forward give us advice on these beneficiary-focused activities. We're increasingly putting out information for beneficiaries about what benefits they're entitled to and making sure they're aware of those so they use those benefits. But increasingly, we're also giving out primary health education. We feel that they should know things about health conditions and how to take care of those conditions in order to best use the benefits they have.

Something we'll be talking about today and going forward is healthcare data for choice. Before a few years ago, there was literally nothing available to Medicare beneficiaries in most of the general public on quality of care, cost of care, pricing of care and the value of healthcare, so we've ramped that up and I'll talk a little bit about other sectors and we'll get into the physician office arena as we're going forward there. Of course we've had traditional functions of advocacy for beneficiaries, we have appeals and grievances, and we look out for patient rights issues in addition and we'll be increasingly doing that, and in fact, if we have time, the grievance and complaint system is something that if we can't talk about it today, that's certainly an issue I would propose Ken that we would want to add in the future. Because there's a lot of discussion from the Hill of wanting to reform how our QIO program, for instance, handles complaints from Medicare beneficiaries for quality of care issues. The Hill and many patient advocates would like to have far more information share than we have traditionally shared, so this is something this Council can certainly advise us on. We're focused on preventive services more than ever. You may or may not know the original Medicare Program in fact had no preventive services in the program. It was after a period of about 15 years, that Congress added some sequentially preventive services to the Medicare Program. We still don't have coverage for all preventive services that are out there. So that's an area that we're heavily involved with. And of course, personal health records were in the beginning stages of seeing how we can drive that process let alone fit into the process of development and adoption of personal health records. But a complicated expensive area.

This is a slide with a third bucket that I think over the years people have not completely identified with CMS. But increasing are, and in fact, in many ways, our focus and our resources are more and more being focused on these particular quality arenas. I've listed only some of them, but you can see, we oversee laboratory testing in the CLEA program. We, my group as well as the Survey & Certification group in the Center for Medicaid and State Operations, oversees healthcare facilities, and whether they're accredited and whether they're able to seek Medicare reimbursement. We have 53 quality improvement organizations, currently, across the United States and in some of the territories. We have 18 end-stage renal disease networks overseeing quality of care in renal dialysis facilities. We have organ procurement organizations, obtaining organs for transplantation. We formerly had the quality improvement systems in managed care, but the Medicare Advantage Program has a heavy component of quality improvement and quality oversight. We have multiple demonstration projects. We were thinking of presenting those to you today, but we just didn't have enough time. So that's something we'll talk about more. We're heavily involved with health information technology, both the promotion but also the adoption and practice redesign that needs to go along with implementation of electronic medical records in offices. We're heavily involved as you'll hear this afternoon, in quality metrics development, the endorsement of quality metrics, and the implementation of quality metrics, whether it's for quality improvement, whether it's for choice of consumers, or payers, and where they have healthcare available, or whether it's for incentive programs, to try to promote better quality of care, including as I've put in the last bullet, value driven healthcare and pay for performance.

So why are we doing this at all? I think I still get lots of people saying well, what's the point? Why are you doing all this complicated stuff? Coming into provider settings and potentially disrupting what is difficult enough to perform, that is good patient care everyday. So let me present a few slides which I think will represent the imperatives for why this agency has felt it has to get involved in quality and value of healthcare more than it has traditionally.

This slide, simply on the left hand panel, you'll see, the growth in spending as a percentage of Gross Domestic Product, you can see that we're about 16% of GDP spent on healthcare. And of course, our actuaries estimate that we'll be at 21% of GDP by 2015. Simultaneously, you see the blue bars on the left hand panel, the growth in total spending on healthcare in the United States. And again, you can see an asymptotic curve here so far, with growths from miniscule amounts back in 1960 when I was in early grammar school and some of you folks weren't even alive, but we're now up to over $2.1 trillion this past year. On the right hand panel, you'll see where it's spent. It's still primarily in doctor offices and hospitals, but there's a growing amount in the prescription drug arena, and as the baby boomers age in home health and nursing home care and I think we'll see some shift of this pie as time goes on, with everyone of course competing for a piece of the pie.

This slide shows payment sources historically, and as you can see on the left hand side, starting in 1960, state and local accounted for about 14% of total health care spending and it's really been fairly constant over the years. But what's changed significantly is the middle yellow area, which represents federal spending, which is 10.5% in 1960 and you can see in 1965, when Medicare and Medicaid were enacted, there was a sudden surge in federal spending, and there's continued to be a growth in federal spending since that time. Now representing 32% and climbing in times of total healthcare dollar expenditures.

This slide shows the growth. The total bar that you see here, starting in 1970 and projected out to 2030, shows the number of people being served by Medicare, and again, if I had a ruler up there, you can see that this is not a straight line growth chart. It's a bit asymptotic, again, and the total number of Medicare beneficiaries will nearly double by 2030 from 40 million or so today, to nearly 80 million in 2030. There's another important lesson I think though on this particular slide, and if you look, the purple parts of the bars represent the traditional Medicare that most people think of, which is over the age of 65. And of course, that continues to grow, but what I've represented here is something that was barely present in 1970, but is also growing exponentially to a certain extent, are the other population in Medicare, which is the disabled,

and also those with end stage renal disease. The patients I took care of. And you can see that that becomes an increasing percentage of the total population of Medicare as we go forward. What this means is that in addition to focusing on the elderly, and the unique issues of their care, and the unique costs of their care, I think we have to pay attention that we are covering the disabled and those with end stage renal disease. And they have different needs, and they're different metrics, and they're different issues taken into account when we try to treat them. So I think that our overall program will change somewhat just by the demographic change that you're seeing there. And I might put in a plug. I suspect many of you are probably not aware as most Americans aren't, but we have an estimated, the last estimate came out last fall. There's an estimated 24 million Americans with chronic kidney disease, currently. That's more than there are patients with diabetes. Some of those have diabetes, but not all. So the epidemic of diabetes that we talk about on a daily basis, I think we have an epidemic of chronic kidney disease and that yellow portion of the bar could grow much more significantly if we don't address those needs right now.

This goes back, the first slide I showed you, we're at about 16% today. This is 2002. I haven't updated it in a while. But the lesson is the same. You can see that the left hand bar represents the United States, where we're at 16% of GDP right now, growing to 21% in 2015. But the relevant thing here is look at the other developed nations in the world. And how much they spend as a percentage of their gross domestic product on healthcare. And as you can see, they're 2/3 to half of what we spend, and yet in spite of spending far less per capita, or as a percentage of GDP, those countries will frequently have metrics of healthcare that exceed what our metrics are and we often, although not always lag on a number of healthcare metrics. So we're spending up to twice as much as other developed nations, but the bang for the buck is much less and in fact, we're no better than or worse than sometimes.

This is Beth McGlynn's work that was published in the *New England Journal*. It's getting to be dated itself. This was about 4 or 5 years ago. About 4 years ago. And what Beth McGlynn showed, this was in the *New England Journal*, on the left hand slide, she was looking at the care in outpatient physician offices rendered for a number of medical conditions overall, and after a number of visits she was measuring

1 whether the care they got was in conformance with practice-based, evidence-based guidelines that were
2 consensus derived by national parties, not just opinion. And as you can see overall, for all types of illness,
3 only 55% of the time, one-half of the time, were patients receiving patients in conformance with guidelines.
4 If you look at the individual conditions here, the best performing one in the cohort that she looked at was
5 breast cancer care, but I would say that's horrible. One out of four women are still not getting care in
6 conformance with guidelines and if you look down at some of the other conditions, you're only one out of
7 four, one out of three patients are frankly getting care in conformance with guidelines. Yes?
8 Dr. Smith: Can you address the issue of how much of that was physician and how much of that
9 was patient compliance issues?
10 Dr. Straube: She didn't look into that—
11 Dr. Smith: Because that to me is the one [inaudible 22:55] in trying to make that analysis.
12 Dr. Straube: Well, I think that if she did look far enough that it wasn't let's put it this way, it was
13 not patient compliance that drove all of those results. There still was a lack of attention to guidelines and
14 there have been many other studies that show that many of us are not aware of most recent guidelines.
15 Dr. Arradondo: She was looking at the process more than outcome, so process was physician
16 determined. You have these data mostly physician determined. Do you have these data for Medicare and
17 Medicaid?
18 Dr. Straube: This was across the board—
19 Dr. Arradondo: Yes, I was aware of—
20 Dr. Straube: But again, anecdotally, at least, but some series too, we clearly know the guidelines
21 aren't being followed as often as they should and it varies depending on the setting and study. Yes, sir.
22 Dr. Ross: Aside from potential geographical distribution or compliance, what about access? Did
23 the study show or did it reveal anything about access to physician care and that was the reason why in this
24 case 75% did not get care for a potential hip fracture? Or 50% of the people are not getting diabetic care,
25 beside compliance?

Dr. Straube: This particular group were people who in fact had access to care and were being seen on a regular basis in a physician office, so it didn't, of course address that particular question.

Dr. Ross: So these people did have access to care? It was not a question.

Dr. Straube: Yes, and it was multiple visits, so there were numerous opportunities to affect the obtaining of care. It's a shocker.

Dr. Ross: Something's wrong.

Dr. Straube: There is. Are you—you're probably saying with the study?

Dr. Ross: No, not the study, with the system, with the situation.

Dr. Williams: [off mike] financing, is that more retrospective, you know, reporting data that you find out after the fact, or is it any prospective research that is done to find out if you can impact something before it gets to this level.

Dr. Straube: Well, the research being done in our demonstrations and the other research that I alluded to in the slide, most of it prospective so that there's a system set up, it has to be budget neutral to not add additional costs generally, and we test the reimbursement system and outcomes of that system going forward. I'll mention one or two later on in the slide set. Yes?

Dr. Kirsch: Just going back 2 slides. You were showing the estimated percentage of a patients anticipated to be under the disability and the chronic renal disease group. When you look at the growth of the number of people who are on disability, do our numbers within the US match up those around the world, or do we seem to have more of a culture disability problem in this country?

Dr. Straube: I don't know the answer specifically to that question. Interesting question, though. OK. So next slide. So this one, this slide and I've been using this, this is from Jack Wenburg and Elliot Fischer at Dartmouth for those of you familiar with the *Dartmouth Atlas*, and they just issued their most recent version about a month, month and a half or maybe two months ago, this is a little bit older, but the slides don't change from year to year, and what this one shows if you look at the map of the United States, is the costs or the inpatient hospital service total cost per Medicare beneficiary enrollee, across the United

States. The darkest red color is the highest expenditures. It averages out to about $3,000 per Medicare beneficiary per year and in these darkest red areas. It varies even within the red, but that's the average. And then lightest color areas up there are about $15, $1600 per Medicare beneficiary per year. So you can see there's a tremendous variation in the expenditures for hospitalizations of Medicare beneficiaries across the United States, and most people when they firs see this slide, their first reaction, like mine was, I think the first time I saw it was oh, different costs of living, that's the explanation. But of course if you look carefully at this you can see that's obviously not the case. You've got high expenditures up in the northern most parts, most rural parts of the country, with very low costs of living. If you look down at Texas and the Gulf area, Mississippi, Alabama and so forth, you'll see very high hospital expenditures here also. So what Fischer and Wenburg have been saying for years is that there's just this tremendous variation, which is very surprising, given a fact, again, that we've got standardized, evidence-based medicine that we all increasingly have learned over the years in medical schools and through our continuing medical education. We've got access to the Internet, we've got all sorts of things that we all should be privy to this common base of medicine and yet we have this difference in expenditures of dollars for Medicare beneficiaries.

Dr. Kirsch: Does that represent where the enrollee, person enrolled lives, or is that based on where the hospital's located?

Dr. Straube: That's based on hospital expenditure, so hospital locations. Getting at snowbirds and those kinds of things. Yes?

Dr. Standaert: Has this changed over time? I've seen graphs like this for just about every field. This is from 1995. All the things you mentioned about evidence-based medicine computer access, wasn't even there, we didn't have evidence-based medicine in 1995 as any sort of driving force at all. So this is all pre-that. Is there any, you'll get to it sure. Your next slide, there's almost an inverse relationship between density of sort of cost and care versus quality. Is there any data with change over time showing that if you sort of apply the quality measures you talk about, you alter these things over time? This data's, you know, 13 years old now.

Dr. Straube: Yes, sorry, I should have updated the slide. Especially for this group. Because you're more astute than some groups at noticing the dates. But it really hasn't, in terms of the general pattern here, the general message to take away. Now, of course it changes within a given hospital system, or otherwise, and we'll get to where some of the trends are going I think in some cases. So again, without being too specific on each individual area where the dollar amounts etc., this is a general pattern of variation. That's the main message here.

If we go to the next slide, although this is not in color, this was worked on out of the Office of Clinical Standards, that I run now, several years ago, and what we did was to take the performance on the hospital quality measures, of which there were 10 at the time, and if you look at this slide, the darkest color areas, are the 4th quartile, that is the worst performing hospital areas in terms of hospital quality metric performance. Again, those metrics were the first phase, the infancy of quality metrics, so they're not where we'd like them to be, but they were the best we had at the time. And the lightest color areas are the highest performing areas on the hospital quality metrics. And although this doesn't map out exactly one to one, it's a different presentation of the data, there's still some intriguing sense that the areas that have the highest expenditures in fact, also have the lowest performing hospital quality metrics. And in fact, if you just don't take these two slides, there is an increasing amount of literature, which suggests that there may be in many instances, an inverse relationship between the amount of money being spent on healthcare and the quality outcomes. In fact, I was just at a very interesting session. I represent CMS on the Board of Directors of the National Quality Forum, and we had a special session after the board meeting last Thursday, where there were a number of Wall Street folks in looking at various delivery systems across the United States and relating their quality outcomes to anywhere from their revenue amount, that is high revenue systems versus low revenue, big systems versus small ones, in other words. But they also look at their bond ratings and other information and again it was very interesting how there was this relationship between strength of financial status, bond ratings, etc., with quality outcomes. So there's going to be a whole bunch of

information on variation and what are the factors, I think that relate to improved quality of care? Spending more money doesn't appear to be one of those factors.

So in summary, this is again back to what's the imperative for us as an agency to want to concentrate on quality and value? So in summary we spend more per capita on healthcare than any other country in the world. In spite of those expenditures, US healthcare is often no better than, and often inferior to other nations that spend half as much as we do, and it often doesn't meet evidence-based guidelines. There are significant variations in quality and cost across the nation. We don't have good explanations for why that is, but we would probably want to expect, as a national payer, to see less variation across the country. And there's increasing evidence, as we've just discussed, that there may be an inverse relationship between amount of money spent on healthcare and the quality we see. We're responsible for a growing, a very rapidly growing cadre of beneficiaries in Medicare and in fact, we are in the Medicaid program also. So we feel that in partnership and collaboration with other healthcare entities, we have to try to address these issues that we've outlined here. Now one other thing I don't have on this slide set but I should be adding is you're all aware that the Medicare trustees met recently, and again, the most recent estimate of when the Medicare trust fund will run out is 2019, a short 11 years away from now, should this country not do something to deal with that. And I think the other kind of stunning factor that they mentioned, which has been mentioned in the press, but probably people haven't talked about quite as much is that actually the revenues coming in to pay for Medicare care are now fewer than those going out, paying for care. That's as of this year. So this spigot or the tub is losing its water. So another imperative.

Well, Mark McClellan, when he was our administrator, he took it from the responsiveness era, to getting us to focus on quality and value. Kind of talked about the concept of CMS as a public health agency and again, not really meaning that CMS would go out and concentrate on organizing flu clinics and screening for other preventive services. We are involved with that, and we feel it's very important, but this was a broader concept, which I think we continue to focus on and that is trying to understand that in addition to driving the Medicare program, anything we do affects the commercial sector. Certainly affects

Medicaid and affects the entire healthcare system. So we have to consider, and this is again, why PPAC, among other advisory groups, is very important. What we do in Medicare and Medicaid will affect the commercial healthcare system and we have to be very judicious and aware of what we're doing because it will drive those. But we feel we have to do that, or we should do that, working with other folks, to improve and focus on quality, focus on value, definitely focus on efficiency, and at some point, likely Congress will charge us I suspect on focusing on cost-effectiveness. We do not make coverage decisions currently using cost-effective criteria, but there continues to be talk about doing that at some point on the Hill.

So with all those imperatives and with our wanting to be a public health agency, and wanting to drive quality, what we have heard and you folks have heard of course also, is that Congress as well as private sector employers, who pay for care, have observed that over the years, there have been many opportunities to improve the quality of healthcare services, as well as outcomes and efficiency in healthcare, but what their view is, and to some extent it's correct, is that in spite in some increasing reimbursement for healthcare services, across the board, let's not pick on physician reimbursement as having increased as much as hospital or nursing home or other segments, but if you look at globally, there's been increased expenditures, yet no uniform or widespread improvement in the quality of care, over a commensurate period of time. In fact, we've seen an increased utilization of services in many instances to compensate for the lack of increase in reimbursement. So we've seen a net increase in overall healthcare expenditures. So I think the Congress and employers are certainly looking to CMS but also to healthcare providers to demonstrate that we have the ability and the will to improve quality while avoiding unnecessary costs and complications. Now, I'd like you to keep that in mind as Dr. Rapp and Dr. Valuck and others this afternoon talk to you about value based purchasing, PQRI, etc., I view as a difficult issue for all of us to try to grapple with, but if we try to grapple with it together, and we demonstrate to Congress we are being responsible here, I think that will go great leaps towards Congress looking more favorably on payment form, and so forth.

So what have we done about it at CMS? Well, we have implemented what's called the CMS quality roadmap. Our vision is the right care for every person every time. And as you can see here, we have the 6 aims of the Institute of Medicine that we're using as guideposts, if you will, for our quality programs.

We have 5 strategies that we're using; first of all we work through partnerships. We can't do it by ourselves. Both because we don't have enough resources to do it by ourselves, but more importantly, we need to take advantage of the talent and the ideas and the perspectives of everybody who's involved with healthcare, including providers, including beneficiaries and patients and including a whole host of other folks.

The second area that we'll talk about today in some detail this morning and this afternoon is we feel very strongly about the need to publish quality and cost measurements and information as the basis for supporting improved quality of care. We'll be talking about that.

Number three, very important, something that this Council has of course focused on since its inception, is that we have to get away as Mr. Kuhn was saying earlier this morning, from being a payer of volume to being a payer of quality. But in order to do that we have to reform the payment system. That's what this third bullet really says, and if we do so, it's probably incumbent that it's not just reforming the individual silos that we reimburse, hospital silo, the physician silo, the nursing home silo and so forth, but it's somehow recognizing that there are multiple folks in multiple silos, and we somehow have to redistribute the payment across multiple providers.

The fourth strategy is we have to somehow assist practitioners in making care more effective and less costly, and we think that the promotion and adoption and utilization of health information technology is the prime way to do that; all the way from gathering data to monitoring the quality of care to being able to initiate quality improvement initiatives.

And the fifth strategy, the last strategy, falls under the coverage group that I oversee, where we have to use evidence-based medicine to try to promote the availability of new technology, particularly if it improves outcomes and/or makes care more effective. So we're streamlining our payment systems, trying

to rely more on evidence-based medicine in all of our decision making, whether it's payment coverage, quality initiatives, quality measurements, and so forth.

Compare Website on Physician Performance

So where are the areas we've focused on? Well, I've listed them all here, hospitals, nursing homes, home health agencies, dialysis facilities. We've been doing these for years. And physician offices is a new area of course, so that that's what I'd like to get some feedback from you all this morning on where, how we're doing, where you feel we may be headed, what your concerns are about that, and what we ought to take into consideration as we go forward. There's a couple of things on these bottom bullets I wanted to mention. First of all, public reporting to CMS is not at all new. We have hospital compare, nursing home compare, home health agency compare and dialysis facility compare sites, on our over all Medicare.gov website and those have been there for a number of years now. So the public has had access to a number of metrics, most of them in the hospital setting. Actually in dialysis facilities, we've had a fair amount of information present there for 4 or 5 years at least now, and increasingly in nursing homes and home health agencies. How many people here have ever gone to our website to look at our compare websites? OK, so not everyone. Some have. I have personally gone there not in my role of being a CMS employee, but to use them for my father, for my father-in-law and for my mother-in-law respectively, and although you can hear the same story from many CMS colleagues that we've used these on a personal basis in addition to I think being very proud of them on a professional basis, too. And I'll tell you, although I wish there were more there, it came in very handy in terms of trying to pick a specific facility that they had a choice of going to. So I'd encourage you to take a look at those, especially as we talk with you about physician offices and what we might do in terms of a website that we'll publicly report how things are going in physician offices. And I'll get to that later.

The second thing is, of course these are silos and I think one of the things that you will see that we've already embarked on, but you're going to see this very more decidedly in the next 2 to 3 years is the recognition that patients don't get care in just one setting. They navigate multiple settings and we have to

1 improve our system, such that we can guide them and monitor them and measure the quality of care, across
2 settings as they navigate those settings. So we have a number of projects and issues that we're doing, that
3 will focus on cross setting quality and efficiency, and care coordination and care transitions as we go
4 forward.
5 And then last bullet that's essential for all of the above, too, is that when we make our payment
6 decisions, when we make our quality metric choices, when we choose to implement quality improvement
7 initiatives, we have to rely on evidence. Initially, I think we're doing a lot by the seat of our pants because
8 we don't have the evidence. But we have to start gathering the evidence and looking at it critically, before
9 we keep going forward, because we may find that many of the metrics we're using are not valid, or are not
10 particularly actionable, or not helpful, or they may be biased. There can be all sorts of things. So we have to
11 be very evidence –based as we go forward.
12 We've been working and I'm not sure how much you all are aware of, but we believe very
13 strongly in the use of quality alliances. So the main ones that I've listed here is the agency has participated
14 in, and there's a growing number of public private partnerships that are growing, but we've been involved
15 with the second bullet, the broad national quality alliances; the hospital quality alliance, the ambulatory
16 care quality alliance. The Quality Alliance Steering Committee, which is an attempt to somehow align
17 HQA and AQA, and then we're involved, I've listed in the 4th bullet a number of specialty focused quality
18 alliances and they're growing by the day. There's a nursing quality alliance that's trying to get going;
19 there's, we just had an internal meeting here, a public health quality alliance that's going to be starting at
20 HHS and so forth. But the main thing is, in addition to doing what we're doing and having our advisory
21 councils like this, we also think getting out and being involved in these national very board stakeholder
22 alliances is important on forming the agency on any number of issues. And that includes the main focus of
23 these alliances, which is trying to develop consensus driving quality and efficiency measures; identifying
24 what they are, prioritizing which ones we should develop quickest, developing those measures, endorsing
25 them at the National Quality Forum for national use, and implementing them in quality improvement

1 programs, again, for quality improvement, for consumer and payer choice, and for incentive programs to
2 promote quality.
3 So this all is part of what started now over 2 years ago, when the President spoke to the American
4 Hospital Association, and announced what has become the administration's so-called transparency
5 initiative. He spoke 2 years ago, talking about wanting to make more cost and quality and price information
6 available to consumers, employers, payers and other folks in the United States. And this resulted in a
7 Presidential Executive Order in August of 2006, that all federal agencies were required in fact, to
8 implement initiatives to make more quality and cost information available to the American public. It ended
9 up on Secretary Leavitt's four cornerstones, so called, that the department and CMS has been focused on.
10 And the four cornerstones I've listed here. It's publishing more information on quality, second bullet is
11 publishing more information on cost and price, the third is promoting interoperable HIT systems, and the
12 final cornerstone is providing incentives, and of course most notably financial incentives to promote higher
13 quality efficient care.
14 So what's going on that's somewhat aligned with that in addition to what we're talking about
15 here? Well, the Secretary has developed what are called and this is predicated mostly on the department's
16 view that all healthcare is local ultimately and we can make national policies which should apply, to give
17 some consistency to how things are approached, but ultimately, it's down to your offices with a patient
18 sitting there across the desk or on the examining table with a whole host of other people involved, but it
19 still is very, very local. So rather than having these big national quality alliances, the Secretary charged us
20 and other parts of the department, with trying to reach out and see how we can try to engage and mobilize
21 local healthcare focus on quality of care and value of care. And there's lots going on across the nation, but
22 that being driven by HHS is first of all about 6 or 7 or 8 months ago, maybe it's even more at this point, we
23 designated, it's now upwards of about 150 communities across the United States. The Secretary designated
24 as being so-called community leaders in healthcare. And this just recognizes that they've got a group of

stakeholders come together, are discussing how to improve healthcare in the community. They are recognized by the Secretary and designated as a community leader.

But the next phase that we envision is for these community leaders to become more sophisticated and to graduate, and become what has been recently designated as chartered value exchanges, or CBEs. And this is where the local collaboratives have a much more coordinated and focused effort on quality improvement and use of aggregated quality data, that is private sector, quality data from commercial health plans and commercial insurers, Medicare data, Medicaid data, etc. We're trying to find ways to aggregate all of that data; have a much more robust data set than the private sector alone could do, or even we as Medicare could do on our own. There are 14 that have been designated so far as CBEs. They are being provided assistance by the Agency for Healthcare Research & Quality, ARC, and they're getting a first run in a month or two of Medicare data that they will be able to combine with commercial data to get this aggregated dataset for a total of 12 quality metrics in physician offices going forward. We're aligning this with our electronic health record demo, which you'll be hearing more about later today.

And this is, so that's going to be growing, and the Secretary envisions there being increased number of community leaders which will become chartered value exchanges over time and will be able to start this trend on a local level of quality metrics and use of quality metrics to improve quality care.

We have a side project that we did through AQA, called the Better Quality Information for Medicare Beneficiaries, pilots. And this has been going on for about a year and a half now, with pilots having been designated in Wisconsin, Minnesota, Indiana, Massachusetts, Arizona, and California, and these are actually taking in a much more formal manner, we're giving them Medicare data and they're getting commercial healthcare quality data at a local level, and aggregating that and learning about the complexities of data aggregation on the one hand, which is much more complicated than folks thought it was before. We're learning many new lessons on this. And this includes some of the difficult issues of attribution; how do you pick which physician is responsible for a given metric? Especially when Medicare beneficiaries sometimes see 30 or 40 physicians in a given year? So there's many seminal questions, and

1 we should have some results out in the early fall of lessons learned from this, which are very, very relevant,
2 and we'll come back to PPAC and report on the outcome of that, because this is bread and butter for a
3 physician office, in terms of the problems that we're identifying here, and the need to address those
4 problems before we get too heavily into quality data aggregation and public reporting.
5 So let me give you just a few things and Dr. Bufalino, want to have a, OK, good. I'm going to
6 quickly run you through, so what have we done so far? And what are some of the early lessons are? And
7 then we get in, I'm teeing it up again for the afternoon session on PQRI and value-based purchasing. But I
8 did want to have some discussion about what I've said and more importantly, reporting of physician
9 metrics once we get into those.
10 So we were involved starting about 4 or 5 years ago with the National Voluntary Hospital
11 Reporting Initiative, so-called at the time, where hospitals were asked by the agencies and organizations
12 I've listed here to voluntary report up to 10 hospital quality measures for public reporting on the CMS
13 website. And this ultimately became the Hospital Quality Alliance, which is still in existence and has a
14 meeting coming up in a few weeks. After about 2 or 3 years of cajoling, begging, pleading, any other
15 number of tactics you can think of, there were a total of 10% of US hospitals who were in fact voluntarily
16 reporting one or more of those 10 possible hospital metrics to CMS. Not a very successful approach to
17 things. Congress saw that, talked with us and with the others listed up there and decided that in order to get
18 robust participation, they really needed to pay for reporting. So the Medicare Modernization Act of 2003
19 Section 501(b) added a 0.4% incentive, .4%, now that's, the hospital would get their normal annual
20 payment update for their DRG payments, but if they reported, the 10 hospital metrics in place at the time,
21 they would get an extra .4% per DRG payment. Doesn't sound like a lot of money. For a hospital, it turns
22 out, it's a fair chunk of change, particularly if they have a large volume. So after putting that incentive,
23 within about 6 months, we went from 10% reporting 1 or more, to 95% reporting all 10 measures that we
24 had at the time. And that has continued to be around 95% of hospitals reporting. The incentive, Congress
25 increased it in 2005 from .4% to 2% on top of their normal update. We now have, I'm sorry this slide is out

of date, we have 30 hospital quality measures required for the annual payment update and that will be more. We're anticipating it'll probably be up around 42 to 45 total measures, somewhere in that range that they'll be reporting, and they get the extra 2% update. I think what this shows is volunteerism doesn't seem to work for quality reporting, and publishing, but pay for reporting does work, and hold that thought in mind because when you think about PQRI this afternoon, see that Congress already went from not paying any money to adding pay for reporting, and then you'll hear about the value-based purchasing program we proposed to Congress in the hospital setting. The next step would be for performance. So that will likely be on the physician side, the same sequence. Yes?

Dr. Przyblski: Your last slide says Pay for Reporting works. If at .4% payment, 95% hospital participation was achieved, you've obviously achieved the level of payment that's incentivizing them. Why would it therefore be necessary to increase it to 2% if you had success at .4%. Now it sounds like you're overpaying for that incentive.

Dr. Straube: You'll like my answer because it goes back to the question you asked earlier about unfunded mandates. Remember that the measures went from 10 to 30, so I think a lot of logic had to do with paying for the burden and that involves chart abstraction and a number of employees in the hospital, etc. So it was recognizing as we put more burden, there needed to be more reimbursement to cover that.

Dr. Przyblski: Thank you.

Dr. Straube: So. Another example, our premiere hospital quality demonstration. Premiere hospital trained 260 participating hospitals, wide variation in hospital demographics—large, small, urban, rural, academic, community, and so forth. Thirty-four hospital quality metrics. I've listed the five major domains here in parenthesis with the number of metrics for each domain. The hospital scores were actually all of the metrics within each of the domains, were rolled up into one score, so there were 5 domains with a score. The top decile got a 2% bonus for being in the top decile. The second decile got a 1% bonus, this is on top of their DRG payment. So they had no money at risk. This was a bonus payment. However, it was only recognizing the two top deciles. There could be hospitals in the lower deciles who would improve, but

wouldn't be able to get the incentive bonus. I mean that's another problem. What are the results? First year in blue is the baseline, and as you can see in the two intervention years, there's statistically significant improvement in each of the 5 domains. And we have extended, I think if you go to the next slide, there is a 3-year extension of this demonstration where we're going to be looking at new incentive models. The most notable one I think, is looking at rewarding hospitals that may be in the bottom decile to begin with, who have no hopes of getting into the top decile, but if they have significant improvement, we feel that they ought to share in some of the bonus incentives for having an absolute or relative improvement from wherever they started, raising all boats, kind of concept.

This is an interesting one. Some of our staff in addition to others, this was a year ago in the *New England Journal* published information and if you look here, this is the heart failure metric of the hospital quality reporting. On the blue scares you'll see by quarter the improvement in those hospitals that were strictly participating in the hospital quality reporting initiative and the improvement going forward. And you'll see there's a significant improvement associated while they are publicly reporting. Now, whether this means public reporting caused the improvement, I don't think we can go that far. But there has been steady improvement concomitant with the timeframe of public reporting. The interesting part of this slide though is the yellow gold diamond and this was a matched cohort of hospitals that were in the public reporting piece, but were also premiere hospital demonstration with pay for performance on top of it. And again, doesn't prove the point completely, but as you can see, there is a significantly greater improvement in those hospitals who were involved with the pay for performance program in addition to just the public reporting and pay for reporting program. So perhaps evidence that pay for performance leads to greater improvement than public reporting alone. Perhaps.

Next slide shows pneumonia, same kind of findings and the next slide shows a composite of all 10 hospital quality measures which shows a similar kind of result. We've had a number of things you'll hear about; the Deficit Reduction Act of 2005 with Hospital Value-Based Purchasing. Demonstration projects and gain sharing, a whole bunch of other things that we're focused on. You'll also hear more detail about

1 the physician quality reporting initiative, which again, remember started as a voluntary program, known as
2 PVRP, the physician voluntary reporting program, where we had almost no participation, not to PQRI,
3 which you'll hear in its first year had 16% of eligible physician offices participating and half of those, it
4 appears will qualify for the 1.5% bonus payment. So half of those who agreed to participate. Some didn't
5 participate ultimately. And we've got some enhancements in place, which we think will be very attractive
6 that you'll hear about this afternoon. To have physicians participate. Hopefully we can get the reporting up,
7 we will continue to refine the metrics that you'll hear about. We'll continue to refine the burden and how
8 we report metrics and that program will be something that will demonstrate to Congress that all of us are
9 serious about meeting their challenge to get better quality care and focus on these issues.
10 This is the most recent thing, which just extends PQRI, the Medicare Medicaid SCHIP Extension
11 Act for 2007. You'll hear about that this afternoon from Dr. Rapp. So I wanted to end here with 2 slides
12 and then open it up. I'd most like to get reaction on the concept as I told you earlier, we have had in place
13 for a number of years, public reporting of quality information and now cost information on a number of
14 settings, hospitals most prominently, dialysis facilities, nursing homes and home health agencies, but the
15 agency, the department, the White House, the Hill and many public consumers, consumer advocates, and
16 employers would like us and would like everyone to start focusing more on physician office public
17 reporting. I was at a health plan and Vice President Quality Improvement as I told you earlier and we were
18 reporting physician report cards ten years ago, and I'm sure many of you have been involved with some
19 activities like that, but they have been problematic, not the least of which is they will often be in conflict
20 with each other and disagree on the same office, for the same kind of care. So we're going to be going into
21 this very carefully and judiciously. And what we have been talking about for frankly a couple of years is at
22 least the broad, broad concept of having a comprehensive physician compare website. We would strongly
23 urge, this is kind of our first, but it'll be a rapid outreach to get input on some of the ideas that I'm about to
24 present and what people think and what are the pitfalls and what are your concerns, as we go forward. The
25 initial concept that's been raised is that we complement the physician quality reporting improvement

1 program information by putting up a site on our website, which will list the bullets that I've listed here. It'll
2 first list whether of course a physician participates in Medicare or not. But more importantly, it could list
3 whether a physician office or an individual physician has agreed to participate in PQRI. We think that that
4 shows at least a commitment to the general concept of wanting a public transparency, etc. More
5 importantly, if a physician office receives the incentive payment—it's one thing to have an intent to
6 participate, but if one doesn't participate and qualify for the incentive, it seems like those who participate
7 and qualify have done more than those who just agree. So the 3rd bullet says that we would want to put up
8 which physician offices have in fact received an incentive payment under PQRI. We do not, I want to stress
9 the 4th bullet, do not, have, are not proposing at the present time to post any results. We see PQRI as a
10 strictly voluntary program, where we're trying to give feedback, as you'll hear this afternoon, on the results
11 of the metrics, that hopefully can be used on an individual anonymous basis by physician office to improve
12 the quality of care in their office. Do the metrics need to get better? Of course. Are they satisfactory right
13 now? No. But given we have what we have, we're trying to deal the best we can to get this system up and
14 going. So we would not publish at the present time any individual metrics, results of those metrics, etc.. Of
15 course, this lead to longer term, a lot of questions. And ultimately, of course, the end game is that there's an
16 expectation by multiple, multiple healthcare stakeholders, that for all settings of care, we have measures of
17 quality of care and price and cost information in a public venue. So that's the ending. But it's not the end
18 game in the next 3 months, 6 months or even a year. The simple going forward that we're proposing is just
19 what I listed there and that's what I'd like to see comment on. And obviously there are many, many
20 questions as we develop a physician compare website that we have to get advice from folks, we have to
21 align with other reporting initiatives and processes, the measure selection and the maintenance, there's all
22 sorts of questions there. How the format is displayed on the website, how beneficiaries or others may
23 interpret that has to be gone into. Attribution is an incredibly important problem to get beyond, validation
24 of data, once we're actually validating data, there's legal issues, there's unintended consequences that we
25 want to avoid, and then the uses that this will be used for are numerous, and may lead to unintended

consequences too. So I've opened up Pandora's Box for all of us, but I hope it's just a crack, and it's simply, we would much, much welcome your input and discussion on this very simply physician compare concept of simply putting up whether or not physicians have agreed to participate in PQRI and if they have, whether or not they qualified for the bonus incentive going forward.

Dr. Bufalino: Thank you Dr. Straube, let's open this for conversation. Lots of hands up. Chris?

Dr Standaert: Yes, that was a lot of information you just gave us, and a simple thing is not…but I have a question goes back to some of the things you covered. So if you go back to the guidelines issue in that very dramatic slide of guidelines. Guidelines in some ways are very problematic, because if you look at like concussion for example, there are like 5 different sets of guidelines, none of which really make sense. Look at how many high school kids who play football have a concussion are managed by a guideline, actually would hope the number's extremely low. These guidelines are not well done. And there's a lot of internal conflict between different groups who sort of set up their own guidelines. And evidence-based medicine, for all the good it does, there are a lot of holes in what we don't know in our knowledge that make it problematic to sort of weight things one way or another when you really don't know the answer, and if you get down to your last question, you get down to sort of physician status, and PQRI measures, and you know, physicians are in a very competitive market place for the patient. The hospitals are as well, the bigger systems are. But from a physician standpoint there are a lot of things that sort of effect whether a patients will see us and stay with us, and there's a whole patient satisfaction issue. And I don't see patient satisfaction compared to quality measures, for example from a physician standpoint. And if your patients aren't happy with you, whether or not you have very good quality measures they're not coming back and they're not sending their friends back. And that's a problem. And patient goals are driven by different things than the payers' goals. If you have a patient coming in who sees commercials on TV for a drug who sees ads or things about various devices that should be put in them or implanted in them, they come in asking for them. There's a different sort of negotiation with that patient about how to proceed. And there's some issues there in terms of conflict of a doctor. If you have a complicated patient practice, if you have a

1 different sort of social structure within your community that has different demands than the patients, you're
2 going to have somewhat different physician performance. They're going to do different things, and I think
3 you be very careful of the measures, because if you go back to the basis of how we decide measures and
4 parameters and guidelines, it isn't, it looks very cut and dried, but it isn't very cut and dried for many,
5 many of the things we treat. And I think you ought to be very careful with how you weight those things and
6 how you balance that out, because again, the doctors are under multiple sort of competing forces when they
7 practice. Does that make sense?
8 Dr. Straube: Yep. I have some very important points I can respond to a couple of them, too. On
9 measures development, go back that I've stressed that we're working with these national collaboratives to
10 try to develop them. I didn't mention the physician consortium for practice improvement, the CPI, the
11 AMA has. That's a very important development phase and that's by specialty of course, so that specialty
12 organizations primarily are doing the nitty gritty base work for each of the specialties, it goes to PCPI,
13 there's some consensus endorsement there. We are working with PCPI and Dr. Rapp will tell you a little bit
14 more about that this afternoon. So and then it goes to AQA, which kind of pre-endorses them, and then it
15 goes to the National Quality Forum, which allows for more input from physicians, as well as broad group
16 of stakeholders. And then it comes back for implementation. So I think there's multiple points that a lot of
17 the issues that you're alluding to do get discussed. Whether they get dealt with adequately or not remains to
18 be seen, but in terms of measures development, there's ample ways that physicians can get involved with
19 the measures development process. I think we can't all of us can do a better job perhaps of making that the
20 average office more aware of what's going on in this arena and perhaps participating in the process in so far
21 as they might like to. Now, you've raised another excellent point, and that has to do with patient experience
22 of care. We have of course, the longest patient experience of care that's been out is the HCAP survey from
23 managed care, excuse me, the CAP survey from managed care, which is done for health plans. I, having
24 worked at a health plan, now being on this side and having been in an office before, I find this particular
25 patient satisfaction survey the least helpful of any of them that I could think of. But Congress mandated it

1 over 10 years ago. It is helpful, but it's helpful only at a plan level. It doesn't get down to a physician
2 office, or an individual physician level, so it only shows patient satisfaction with the administrative issues
3 of the health plan, and/or the broad group of providers that kind of get evened out, the good and the bad
4 kind of counter act each other in some instances. What we've announced, the Secretary announced over 2
5 months ago, and we announced in concert with the hospital quality alliances is the HCAP survey, the
6 hospital consumer assessment of health plan, like survey. And that is going live in fact momentarily in
7 terms of it presents on our hospital compare website patient, actually it's already on the website, hospital
8 experience of care that patients have. So it's hospital specific and it lists that. We have under development
9 a dialysis facility, CAPS survey, there is a skilled nursing facility and home health agency CAP survey, and
10 we've just started to talk about having an ambulatory CAP survey. It would be a physician office,
11 obviously, CAP survey. That's in the very early development, that's something we can as we go along
12 bring back to PPAC and get your input on also, so we are thinking of that, but that's to come a year or two
13 probably from now.
14 Dr. Bufalino: Tye?
15 Dr. Ouzounian: Just a question as I lead into this, Mr. Chairman, when do you want
16 recommendations? You want to do questions and recommendations?
17 Dr. Bufalino: Let's give Straube about 5 or 10 minutes and then we'll have some resolutions.
18 Dr. Ouzounian: OK, well I have a question and a great deal of concern, and it has to do with your
19 physician compare website. I'm not saying it's a bad idea on a go forward basis, but I'm concerned that
20 you're taking this PQRI data that was presented to the physician community for one reason, and now
21 you're taking the information that you've garnered out of that and you're going to put it on a website. Now,
22 I as a physician, and many others elected not to participate for a variety of reasons. Because I elected not to
23 participate, I'm therefore not quality. OK? So if you're going to put that data up there, you need to advise
24 the physician community with ample notice that this is what we're going to do with that. And you didn't
25 tell us that. You just said you know, here's some data you can collect and we'll give you 1.5% if you meet

1 these benchmarks, and I elected not to and many others didn't elect not to and many others didn't elect not
2 to, in fact 84% elected not to, for reasons you don't actually know. And if you're going to take and put that
3 data up there, you need to give us the warning that that's how you're going to do it. And I'm not saying it's
4 wrong to do it, but to take data that was collected historically and all of a sudden put that up there, and
5 those guys those 16% are good and the other 84% of us are bad, it's just not fair.
6 Dr. Straube: And that's one of the reasons we're here. Again, I wanted to stress that we're not
7 putting up results data. But your point is well taken. I understand completely what you're saying and I
8 suspect that'll be a resolution.
9 Dr. Ouzounian: Yes, I suspect it will be, too. [laughter]
10 Dr. Straube: By the way, we don't intend, it isn't just this we're going to come to PPAC today and
11 that's the advice and consent. We're going to be having a whole series of interactions with multiple
12 physician stakeholders, whether it's specialty societies, the AMA, other organized medicine organizations,
13 individual input at the physician, excuse me at a regional office level, having an open door forum. There's a
14 number of ways we intend to try to get input for, so thank you.
15 Dr. Ouzounian: But you got to give us notice.
16 Dr. Smith: Yes, I have a similar concern as Tye's, but I'll take that a step further, which is that of
17 the people who tried to do it, nobody knows yet who succeeded and who didn't, right? Nobody has a clue
18 yet. You may have a clue. None of the physicians have a clue. And that means that if you posted the data
19 from last year's pilot program, and half of the offices who did it didn't meet the goal, that makes them
20 sound even worse. Then it's not even that they're not listed as having participated. They're listed as
21 participating and failing, which has horrible implications, and to me that's even worse than not being in the
22 participating section. And I'm saying this from a personal standpoint, because we tried to do this. I have no
23 clue whether the huge amount of time that I personally invested in it paid off or not. So I haven't done any
24 of it in 2008, because I was spending a minimum of an hour a week, sometimes two, trying to list this.
25 Never did get over the tangle of as a rheumatologist, I have to keep in mind that the patient has diabetes

with renal disease when I'm choosing meds, and so I list diabetes as the diagnosis, but does that mean that I'm penalized for not reporting on the diabetes? Or not? I haven't a clue still, and I never could find anybody who could give me that answer. So I feel that the program as it was set up was confusing, and that's one of the reasons the participation rates were low. Having people who tried to do this reported as failing would be appalling, and not giving us a couple of years to figure out how to do it, do it correctly, paying us for the time it takes to do it, and then when you have really accurate representative data, discussing the question, whether it's appropriate to post it or not, I think that's the direction to go. Not your pilot project data, or even this year, when people aren't doing it, many people I know who tried it last year, aren't doing it yet this year because they don't know if the time they invested was worth it.

Dr. Straube: Thank you for those comments. I think one of them, regardless of if, when, we might do something with this, I think that gets back to my point about how it gets presented on the website, too, is extremely important because I didn't say anything about whether we'd report whether people passed or failed, it was strictly whether they had agreed to participate.

Dr. Smith: No, you said specifically here, physician receipt of incentive payment, which means they passed or failed.

Dr. Straube: Well, they received an incentive, which is, which means they did more than those who agreed to participate.

Dr. Smith: No, it doesn't mean they did more, it means that they filled them out in a different way and theirs worked and the other guys' didn't.

Dr. Straube: Well, if you want to call that a pass or a fail—

Dr. Smith: It's a pass or a fail.

Dr. Straube: See that's my whole point—

Dr. Smith: It's very explicit.

Dr. Straube: No, it depends on how it's presented on the website. You may interpret it that way—

Dr. Smith: That's how patients will interpret it.

Dr. Straube: Well, not if we word it differently. It's not necessarily a pass or a fail, as one option. We'll have to get into the nitty gritty of whatever. But I think again, the comments made about people who didn't participate. That's a good one because people had concerns. I think to me someone who even agreed to participate at least was, that's a plus, doesn't mean that people who didn't it's a negative, but it's a plus for the people who did, and those who were able to figure out how to get an incentive payment back, that perhaps is a plus, too. But that's what we need to discuss.

Dr. Bufalino: Let's not debate that. So it's Pam, Jan, Jeff, Joe, and—[laughter] and we're going to be done in less than 10 minutes, so you're going to have to limit your comments.

Dr. Howard: I guess I just want to know a couple things; I want to know I guess your overall goal of that part of the website is so that patients can go to that website, is that where you're going with that? I mean is that, that's really what it's designed to do. What's happening now? Do you see a lot of patients going to the website? You just asked us in this room, and I think 3 people raised their hand. So I guess my concern is you're saying you want this to be for patients. I don't know that many patients that go to the website. I know my mom refuses to go on the Internet, so she won't ever use it. And I'm worried about that piece of it. It also speaks to what she's saying in that you know, who's going to look at it and how easy is it going to be for them to understand what you're saying on there, especially when it relates to physicians? I'm going to rattle my questions off since we don't have a lot of time. I happen to be in a large group and if my large group of 100 and something people run by a practice group management system says we're not going to play, then I'm not going to have control over that as a physician. I think I provide very good quality, and I don't think my metrics are necessarily met and that's a concern to me as well. You're correct about the information getting out to people. I've been to meetings recently and I tell people I'm on this committee and they don't know what this is. So there's a lot of issues with information getting out to people, especially in a timely fashion. And also that now you're saying you're not going to do these results data, but that it might happen in the future. And I have a lot of concerns about is that going to be something that's going to come back to us where we can discuss and do we actually, are we even going to have any

control over that or is that just going to be implemented and it's going to go out there and roll out and we're going to be in the stage of trying to react to something that's already happening?

Dr. Straube: Just to quickly answer those. One, we're just in the beginning stages as I said, the concept of a physician compare website. It's the only provider setting that doesn't have a public, some kind of public reporting currently by CMS, so I think the expectations that I tried to outline from the Hill, and elsewhere are such that I suspect that this is going to happen at some point in the future. I don't see how the physician office setting will not have some need to be publicly accountable. But that remains to be seen. This is the first discussion. It's helpful. Your comments, we'll take those back. We will continue to present as we go along to PPAC, and we're consulting a lot of other people also.

Dr. Kirsch: Just a few comments. First of all, you know when you're looking at quality within a hospital setting, the onus is really on how the hospital manages the care as far as the outcomes; that person's already in crisis. When you're dealing with an office setting, it's a very different beast entirely. So much more of the outcome is based on how well the patient does and how well they comply, and so when you're looking at the outcomes you need to recognize that the patient owns a good deal of the care and the physician can do the very best that they can but that needs to be a consideration. Secondly, there are already other reporting systems out there, and I would really encourage you to be sure that you're in line with other reporting that is going on and I would start it very simple as far as the measures go, and next just recognize that the technologic potential to extract that information—the potential's a lot greater than what is already out there. My experience with reporting systems is that there are some computer systems that you can just easily pull that information out. Some of the computer systems are not designed that way, and so there's great variability out there.

Dr. Bufalino: Let me take the prerogative. Unfortunately, we have a phone call from Baltimore that we need to deal with at 11:00. So Dr. Straube is, I think going to be here for a bit today, and we're going to have both Dr. Rapp and Dr. Valuck kind of tying this whole quality thing, so maybe we will pause

these questions and pause the resolutions, deal with this phone call, and then kind of come back if you don't mind. Is that OK with you, Dr. Straube?

Dr. Straube: Yes, I won't be able to be here for much of the afternoon sessions. But perhaps after—

Dr. Bufalino: Well maybe we can do the call and then kind of come back and resurrect that.

Dr. Straube: Great.

Dr. Bufalino: I'm sorry for the disruption but we've kind of delayed the call a half hour already. So let's pause there. Thank you for your time, Dr. Straube and we'll kind of re-resurrect it. And then we'll jump in. Dave you're going to correct us in to Cathy Carter. So we're going to shift back to discussion on the NPI and we're going to connect to Cathy who's in Baltimore. Cathy is a 30-year CMS employee, working on information technology. She's in both on the Managed Care and the Fee for Service operations. She's the Director of Business Administration for the Management Group in the Office of Information Services. So, she manages the systems used to process Medicare claims and house the Medicare beneficiary data so—

Ms. Carter: Hi, this is Cathy.

NPI Update

Dr. Bufalino: Cathy good morning. Thank you for joining us. We have done your introduction while we were connecting with you. Thank you for taking the time. We'd love to have your thoughts on the NPI.

Ms. Carter: OK, thank you and I really appreciate, the first thing I wanted to say was I really appreciate being able to do this remotely. I know it's probably causing some logistical issues there, but I appreciate it, because we're in all of our final preparations here for this week and so it was really helpful not to have to take the time to drive down there and back, so again I really do appreciate it.

Dr. Bufalino: No problem.

Ms. Carter: And do you have the slides on the screen?

Dr. Bufalino: We do.

Ms. Carter: OK. Just the first outline slide we don't need to go over in detail, so I would go to slide 3. And as most of you know, but I'll cover just a little bit of background here, that you know, Medicare has been assessing provider submission to NPIs for both primary and secondary fields on claims for quite some time now and we use these metrics that we've been collecting to make determinations about when we would require the NPI on all claims and so just in summary on January 1st of this year, we required the NPI on all the primary fields on claims that are sent to the intermediaries, the institutional claims and that meant that claims with only Legacy numbers on those fields would started to be rejected on January 1st. And at this point in time, we're getting 99.9% of all the institutional claims containing the NPI. And March 1st, we started requiring the NPI on the primary fields for the professional claims and in fact, the last time I came and spoke with you, was actually on March 3rd, it was the Monday after we had started that new edit and I know everyone was concerned at the time. But we did start rejecting any claims with Legacy only at that point and even though we did have some specific issues by and large, it has gone fairly well since March 1st and at this point, we have 98.8% of all of the professional claims now contained on NPI. And the other statistic is since April 7th, we have been sending out remittance advice to all providers, to institutional and professional providers with only an NPI on the remittances. We are not including an NPI on those remittance advice even though they might have submitted a Legacy number on the claim.

Medicare has been of course, also, I'm on the next slide now, on slide 5, Medicare has been monitoring the number of claims with NPI only. There has been a steady increase over the last number of weeks and at this point, 34% of claims have only an NPI for the primary providers. Now for carrier claims, that number is 37% and we think that this is very encouraging. The number has been increasing and if you consider that 60 to 80% of the claims that we receive come in through clearinghouses and in most cases, those providers that use those clearinghouses can only submit their claim one way, what that means is that by and large they're submitting both numbers to the clearinghouse and they're expecting on May 23rd for those clearinghouses to take off those Legacy numbers. We believe, there are some payers that really still

need that Legacy number, so they're not able to submit only the NPI just for Medicare. That means that we've got 8 million claims on a weekly basis. For example, these statistics were as of May 9th, the week ending May 9th, so that means almost 8 million claims were coming in with the NPI only. The other number that we've been watching closely is the number of NPIs on the secondary provider fields; those would be the attending and the supervising, the referring and ordering and those other fields besides the primary and at this point, 49.6 or almost 50% of those identifiers are NPI only and I've got a parenthetical there. There can be multiple secondary identifiers on a claim and these cases you really just cannot count the number of claims because not every one of those identifiers needs to be present on each claims, so in that case we're counting not the number of claims, but the numbers of identifiers; the number of instances. So we're about halfway to the goal on those fields and again we think that's a very encouraging statistic.

And I'll move to slide 6, the Legacy free day. Some of you may have heard about Legacy free day, which was May 7th. As I said, clearinghouses submit between 60 and 80% of all of the claims that come into Medicare and so we've been working with the clearinghouses mostly through [inaudible], a group that represents clearinghouses, and they've been very cooperative with trying to work with us and give us some experience to show us what would happen on May 23rd. And so those clearinghouses that were able to agreed to strip the Legacy number off of the claims before they sent them to Medicare. This was a Medicare only exercise, as far as we know, and that was so that the providers, as well as Medicare as a payer, could determine what would happen if we got a large number of claims with NPI only, which is of course what will happen on May 23rd. And for the most part, even though contractors reported a significant increase in the number of claims with NPI only, we did not experience significant numbers of rejects or suspensions or provider calls as a result of that exercise. So we think it was really a success. It was the result that we were hoping to experience and it is what we were hoping to experience on May 23rd. And then the final slide, slide 7, as of May 23rd, as you all know, CMS is going to fully implement the use of NPI, and at that point, only the NPI will be accepted on all transactions and that includes electronic claims, paper claims, the other transactions such as the 270, 271, that's the eligibility query, as well as the claim

status query. All of those transactions, if they contain a Legacy number in any field, whether it would be primary or secondary, that claim or that transaction will in fact be rejected at the front end of our claims process and again, we are assuming that the clearinghouses, most or all will be stripping those Legacy providers off for Medicare as well as for other payers, we believe. We do expect to have some issues on May 23rd. I think that you know certainly we're not going to be without some concerns. But we are taking a number of steps to make sure that we're ready. We're having daily calls, again, like we did after the March 1st date, we're having daily calls with all of our contractors. The teams are still in place at each contractor. The NPI coordination teams where they have a number of folks at their disposal to make sure that they can work through any issues that they experience. We know that there, again, there will be some experiences for some individual providers, but we're hoping through these measures, and through the data that we've seen thus far, that we will largely have a success and part of that is due to the work that some of the other associations have been doing, on their own and together with us. We've been meeting regularly with the AMA, with the Medical Group Management Association, with the I think it's the Healthcare Biller Management Association, I think it's the American College of Family Physicians, and various groups we've been having regular calls with them to exchange information about the experience that they've been seeing and they've been using a lot of our outreach materials. We've done an incredible amount of outreach on NPI and all kinds of list serve messages and we've tailored messages to every situation that we see occurring where there seems to be confusion and so due to the work that we've done here, the work our contractors are doing, and the work of those groups, we believe that we're headed to a successful NPI implementation.

So that's the end of the remarks and I'll be glad to take questions if folks have questions.

Dr. Bufalino: Thank you, Ms. Carter. I appreciate your comments. It was already the topic of conversation this morning, so I'm sure there'll be a few comments from the Council.

Dr. Smith: I have a comment that's directed specifically to the NPI, but I think it's a question about the broader issue of unfunded mandates, much the question you were asking earlier, Greg. I actually

sat down and looked at my office—I'm a solo practitioner. I've a nurse practitioner who works with me. But I looked at the costs my office has incurred in trying to implement the NPI number, and again, it goes far beyond this issue and so far we've put almost $10,000 into actual software upgrade costs, $9,623 to be precise and about $4,000 in my office manager's time trying to get this done. And I think that's a very large burden to impose on physician practices without some funding. I'm bringing it up not only because the specific issue, but because I think the same question extends to the RAC data and it extends certainly to EMR acquisition and health information transition. The other thing is that it has had the unintended consequence again from my office, but not limited to my office, of huge delays in claims; 4 months, twice. July to November and January to April 30th, we had no payments from Medicare. And that is big time trouble when you're talking about trying to run an office. I mean I was afraid we weren't going to meet payroll in April. And I heard from many practices in Northern New Mexico that this was the case and I know that one of the reasons we had so much problem was because our clearinghouse was jammed to the point where they couldn't return queries for weeks. They just had so many people in the cue that were having trouble. And I don't think Medicare or CMS has been given as much information by the clearinghouses about the impact that this has had, because I keep hearing that there weren't major problems. And clearly, there were, when you can't even get your question answered about why am I having a problem for 3 weeks? So I think it's something that CMS needs to be aware of and to take beyond the current point of the NPI number and think about it as you're looking at other initiatives; the ones that Dr. Straube was talking about, the EMR HIT issues.

Dr. Bufalino: Cathy?

Ms. Carter: Yes, I'm, I mean I appreciate the concerns that you're expressing, I guess I wanted to clarify. We certainly will follow up with the clearinghouses because we do intend to continue regular conversations with them. Are you saying that they did not have sufficient staff to be able to answer the phones, to be able to understand what your concerns were? Or were you talking about electronic replies back that you were trying to respond to?

Dr. Smith: They do not answer in our clearinghouse does not answer telephone calls. We send the queries electronically. And I don't know where the jam was when we did finally communicate with them. They apologized and said they just had so many that they couldn't get to them, which implies a staff issue, but obviously, they charge us X amount, and their staffing is based on us paying that amount and so if they suddenly have to triple their number of staff, they can't back bill us for that, so they don't add extra staff, so there's a lag in the system. And in our area, there are probably half a dozen clearinghouses that various offices are using and they were all having the same problem. It's not unique to one company.

Ms. Carter: These were queries as in email query to them?

Dr. Smith: It's an email query to them to which they respond by email but they were way behind because of the jam in the system.

Ms. Carter: If you would like to tell me publicly, that would be fine, or if you would like to give the name to someone that's there from CMS, to forward along to us, I would appreciate knowing that, the specific one you were having trouble with as well as those others, if you know specifically and we can try to address it. I'm sure they did experience an increase, but I had not heard of that specific problem, so—

Dr. Smith: I know mine, but I'll have to get the others. So I'll just send you a list.

Ms. Carter: OK, I would appreciate it, thank you.

Dr. Bufalino: Dr. Snow?

Dr. Snow: I've got one comment and a question. With 4 days from now the potential of claims not being paid looms large. I'm very concerned. I also am a solo practitioner, and I've had two things happen on March 1st. You started requiring the NPI. I got a new J5 contractor. My accounts receivable has gone up 80% since the first of March. I don't know why. Nobody seems to be able to tell me. I don't know if it's an NPI problem or an contractor problem. That's my comment. You indicate 34% of the claims contain the NPI only for the primary provider, which indicates to me many fewer claims contain NPI or at least some fewer than 34% contain the NPI only for all the fields on the claim. Now I've sort of heard from you that 2/3 of claims not being proper as of this next Friday is not a significant number, but then you said there's

not a significant number of problems that occurred on the Legacy free day. What is the precise number of problems on the Legacy free day that is not significant?

Ms. Carter: Well, I guess, let me see if I understand your question. What I said was we have a very large percentage of all of our claims coming in via clearinghouses and what we are assuming will happen on May 23rd is the providers that are submitting claims to those clearinghouses with both numbers, Legacy and NPI, the clearinghouses should be stripping off those Legacy numbers so that we will get NPI only. And so to prepare ourselves to see what kind of experience we would have, some number of clearinghouses, and again, we don't have specific data on the number of clearinghouses, but many of them did submit Legacy only to us that day, because we did see a spike of up to 75 or 80% at some locations, where it was NPI only and as a result of receiving all of those claims with NPI only, what we wanted to see was whether or not that caused us to see an increase in the number of rejects in claims or an increase in the number of suspended claims, or an increase in provider calls. And none of those 3 things really were experienced. So that was what I was trying to explain. Does that answer your question?

Dr. Snow: Well you said there was not a significant number, previously and now you say there were no problems. So I guess that does answer that question. I would respectfully suggest that your assumption that all of these problems are going to be taken care of by either the providers or the clearinghouses, is a big assumption. You don't know.

Ms. Carter: Well, you mean in terms of submitting? There will, there will probably be some claims submitted to us that contain Legacy numbers that we're going to have to reject.

Dr. Snow: Well I'm sure there will.

Ms. Carter: And when I said that the clearinghouses would take care of much of that, what I meant was if the provider is still submitting both numbers to the clearinghouse, the clearinghouse should in fact be stripping off the numbers so that the claim won't get rejected simply because it has a Legacy number on it.

Dr. Snow: That would be nice.

1 Dr. Przyblski: If the intent is to have 100% compliance with NPI numbers, what is the harm of
2 CMS ignoring Legacy numbers as opposed to actively rejecting claims with the numbers when an NPI is
3 also listed?
4 Ms. Carter: Well I think that's a question of what does full implementation of NPI mean in terms
5 of being compliant with the HPPA law and the regulation. And my understanding of the regulation means
6 that Legacy numbers can no longer be used by covered entities after May 23rd. so that's why our plan all
7 along has been to reject to claims or other transactions that include those numbers.
8 Dr. Przyblski: But ignoring them does not mean using them.
9 Ms. Carter: But that would mean though that covered entities would be submitting them and
10 covered entities would be accepting them because we're a covered entity.
11 Dr. Przyblski: Has there been a legal assessment of that?
12 Ms. Carter: I guess I could take that question back to our folks here that deal with the regulation
13 and the specifics of that. I actually personally don't know if somebody has specifically asked that legal
14 question. I guess I assume that it has been asked, but I don't have any [inaudible] about it. That has been
15 my assumption I think about what the industry and all the various groups that are working on NPI
16 implementation, that's what we've been assuming all along, and I think that's what the intent of the
17 regulation is.
18 Dr. Ouzounian: Yes, to follow up on Dr. Przyblski's question, the problem is that many practices
19 in many areas also deal with other carriers and the other carriers, especially the smaller carriers have told us
20 well, gee whiz, we're not ready, and we still need both numbers. So it's a tremendous burden on the
21 physician's office to have to comply with yours with no Legacy number, where there's another private
22 carrier that can't deal with the NPI number. And it's a burden to our software to do that.
23 Ms. Carter: We have been working with the other payers that we send out crossover claims to—
24 coordination of benefits—

Dr. Ouzounian: No I'm not talking about that, I'm talking about private payers that our offices deal with.

Ms. Carter: I guess I was assuming that the vast majority of, we have 400 and some trading partners and those really represent a, maybe not all, but a large number of the other payers. In fact, I guess it's over 500 of these other payers. So I was assuming those are probably the payers that you all are dealing with and we worked with them as we prepared to fully implement NPI and it is our understanding that all but like one are actually ready for an NPI only implementation scenario on May 23rd. that is, they are expecting us to send to them crossover claims with only the NPI on it and no Legacy numbers and that they can fully process claims without Legacy numbers. That would be their own Legacy or any Legacy numbers.

Dr. Ross: We had a similar situation that you've heard about before where referring physicians need to have their NPIs on the forms and unfortunately, we went through probably about a two-month period where we also had rejections, and it has been a labor-intensive process in our office where personnel have had to now research all the numbers of the referring physicians to determine when those physicians had seen our patients, because that's imperative when we send the claims and unfortunately, those numbers were not accepted, or were not included in our original claims, so we went through about two months of rejection and obviously the same situation that you've heard before where the cash flow went down to zilch and it's been a major, major headache in our office, and they're still trying to get those numbers and again, it's taken personnel because we don't have the software, or we don't have the computerization for that this time.

Ms. Carter: Have you made use of the NPI registry in order to find the—

Dr. Ross: That's how we're doing it, that's correct. Finally after our billing service person figured out what happened, unfortunately now we've had to go to that process, and that's how we're trying to rectify it. But it's taken days to do that, and then it's created a backlog of these claims that now have to be

resubmitted and obviously over a month, close to 2 months of claims have had to wait and now it's affected our practice. And I'm sure this has happened many, many other places as well.

Dr. Sprang: I'm an OB/GYN in a 32-person group, and I know our billing office has had significant issues, too. Specifically with Medicare and have not been able to get paid for a number of weeks. Because we're a big group, and Medicare's only about 10% of our patients, obviously cash flow hasn't been that bad, and we continue to go forward. There is an issue. And I think we have very good people in our billing office. I think unfortunately, I mean I've heard you use the word "assume" many, many times in this presentation and assume is a word that I'm sure you know has different meanings and I won't say some of them, but they're not good. And if it's, if those assumptions are not correct and 25% of people in the long run don't get paid and don't get paid for significant periods of time, if they have a greater percentage in Medicare patients, you're going to put those offices in jeopardy. The AMA has looked at it and they're still extremely concerned as well. They say they have received a lot of information from a number of different health care industry players. Everybody admits there's been significant improvement, but there's still a lot of questions about whether they're really going to meet this deadline on the 23rd. I also realize people only do things when there is a deadline, but the reality, if you significantly impact cash flow, it's going to create a lot of hard problems. The other issue that was brought up is maybe it could still accept both, even though the goal is the 23rd, rather than actually just shutting off the spigot on the 23rd if there's both an NPI and a Legacy system in it, and to that point, I'd like to make a recommendation.

Dr. Bufalino: Please.

Dr. Sprang: PPAC recommends that CMS allow physician practices and others to continue to submit transactions that contain both Legacy and NPI numbers for a minimum of 6 additional months after May 23rd and 2, closely monitor the readiness level of covered entities and take all appropriate steps necessary to ensure that the industry does not experience wide scale disruption in claims processing and payment during this time.

[seconds]

Dr. Bufalino: Thank you. Discussion?

Dr. Ouzounian: Dr. Sprang, would you be willing to separate that into two recommendations so they could respond to them separately?

Dr. Sprang: Of course, be fine.

Dr. Ouzounian: It divides where the…

Dr. Sprang: Right, just where I said number two.

Dr. Bufalino: Any other comments? Dana you want to read those?

Ms. Trevas: PPAC recommends that CMS allow physicians practices and others to continue to submit transmissions—

Dr. Sprang: Transactions.

Mr. Trevas: that contained—transactions? Transactions, that contain both Legacy and NPI numbers for a minimum of six months after May 23rd.

Dr. Bufalino: That's one.

Dr. Sprang: Correct.

Ms. Trevas: Second. PPAC recommends that CMS closely monitor the readiness of covered entities and take appropriate steps necessary to ensure the industry does not experience wide scale disruptions in service and payment.

Dr. Sprang: Wide scale disruption in claims processing and in payment during this time.

Ms. Trevas: Thank you.

Dr. Bufalino: Let's take those collectively. All in favor?

[Ayes]

Dr. Bufalino: Opposed? Thank you. Both are passed. Gregory.

1 Dr. Przyblski: A corollary recommendation to propose: PPAC recommends that CMS determine
2 whether compliance with regulation prohibits CMS from simply ignoring Legacy number submission
3 rather than rejecting claims containing both NPI and Legacy numbers beginning May 23rd.
4 [second]
5 Dr. Bufalino: Any discussion? Want to reread that?
6 Ms. Trevas: PPAC recommends that CMS determine whether compliance with regulations
7 prohibits CMS from simply ignoring the Legacy number on a submission, rather than rejecting claims that
8 contain both the NPI and Legacy numbers beginning May 23rd.
9 Dr. Bufalino: All in favor?
10 [Ayes]
11 Dr. Bufalino: Any opposed? Thank you. Comments, other resolutions? Dr. Snow?
12 Dr. Snow: PPAC recommends that Medicare continuing accepting claims and other transactions
13 with both NPI and Legacy numbers until it is apparent that the vast majority of claims are being processed
14 successfully with only an NPI number.
15 [second]
16 Dr. Bufalino: Discussion?
17 Dr. Ouzounian: You want to quantify that before you [inaudible 40:44] on it, something probably
18 higher than 90%?
19 Dr. Snow: Ninety-five. If you wish a number.
20 Dr. Ouzounian: Well, majority is 51%. [laughter]
21 Dr. Bufalino: Other comments? Would you mind rereading that one?
22 Ms. Trevas: PPAC recommends that CMS continue to accept claims and other transactions that
23 contain both a Legacy and NPI numbers until it is apparent that at least 95% of the claims are processed
24 successfully with only the NPI number.
25 Dr. Bufalino: Motion's made and seconded. All in favor?

[Ayes]

Dr. Bufalino: Opposed? Dr. Standaert.

Dr. Standaert: Is there a mechanism for notifying physicians rapidly that the sole reason for rejection of their payment was the inclusion of a Legacy number? And then a mechanism for which they can also rapidly resubmit, rather than going through a whole [tune? 41:52], when they get a rejection, they don't know why it rejected. They figure it out, they have to figure out it was Legacy. Then they got to resubmit the whole thing. Is there a means to sort of directly get back to the provider promptly, that this is the only reason it was rejected and they need to eliminate this?

Ms. Carter: Yes. That information should be included in the error codes that come back on the claim and it does happen immediately and it will say that it's because of the NPI. I don't have the specific edit numbers, but in the electronic response back to the submitter, whether that's the provider directly or to the clearinghouse or vendor, whoever submitted the claim, that information is included.

Dr. Smith: I think what comes back on the claim is something, I think it says C016 or something like that, that says incomplete information was provided. It doesn't tell you what. It simply says incomplete information, and you don't know what that means.

Dr. Standaert: That message also has to get back to the provider, not just the…

Dr. Giamio: I'd like to second that. When we get these reports, these error messages, they only say that there's been an error and we have to print a report and then when we do get that report, it doesn't list completely all the errors on that particular claim. Is it possible for us to get all the errors listed per claim instead of having to resubmit a report, find out that there's yet another error on the claim and have to resubmit a report, another error? Is there a way that we can get a complete report on each claim?

Ms. Carter: There are certain edits that are set up to reject up at the front end, and this is one of them. It's not really possible for us to edit everything single field on the claim and everything about the claim. There are certain things that are done up front. I don't really know the details of exactly which ones are done there. I can find out and we could provide you guys some information about the error messages

because I do believe it referenced the NPI. I don't know the exact words that the code translates into, but I do believe it references the NPI when the NPI is missing from the claim.

Dr. Giamio: Is it possible for us to have all of those errors listed at some point, or is that not possible by your system?

Ms. Carter: I think it's definitely possible to know what the error codes are and what they mean. Again it depends on who's getting your errors; whether or not those are coming to the provider. They would come back to the provider if the provider is the one that submitted the claim themselves, but again frequently it's the clearing houses, the vendor, that's submitting them and they're getting back an error response that has codes in it to which it should have, whoever's feeding that back would have information about what those codes mean.

Dr. Giamio: But they would only list the one code at a time and it would kick it out. So you'd have to possibly there's a possibility of having to resubmit claims a number of times until they are completely clean.

Ms. Carter: Well, I mean I don't, this is, it's not any different really for NPI than it is, than it's been for anything else. I mean we didn't establish a new thing. I guess I shouldn't say what the details are because I don't know for sure. I can find out what the error code is for NPI, specifically, and what that message says at least from the system that we use to process carrier claims.

Dr. Giamio: Yes, I guess I was getting to the broader question of can they give us a report that would list all the errors on that claim instead of just saying that there has been an error? Is that—

Ms. Carter: Well, what I can find out is which errors you get a report on with, what is it that we're editing for, up front that would get all as part of that error report. And I'll just have to investigate that and see if we can provide that information. We have sent out [inaudible/noise 45:40] codes about NPI on our list serve messages and in our outreach materials over the last year and I think we did that most recently with the March 1st date, when we started rejecting claims that didn't have an NPI. And I believe we let folks know what those error messages would be. I just don't have them here.

Dr. Standaert: Again, on the same line, to get some of what Dr. Giamio is saying, is the entire claim reviewed and then rejected because it has a Legacy number? Or as soon as they see a Legacy number, they just summarily reject, then you have to correct that, then you have to resubmit, then it can be re-rejected again for other errors. I mean is there a way to clean up that process so if the only problem really happening is just a Legacy number, people know promptly that's all it is, and if they erase that their claim can be accepted and they can resubmit quickly. Does that make sense? Is the process clean, can they select out just that one thing so people know how to correct this rapidly because that's really the issue. If you summarily rejecting thing just because you see the Legacy number, and you don't review the rest of the claim, it compounds the delay factor and you're really going to cause a cash flow problem for a lot of people.

Ms. Carter: Well, again, I will try to obtain some information about which items we edit for at the front end and what's looked at as a group before we reject a claim. I think what you're ultimately talking about is being able to do a complete scan of the claim, a complete processing even though we might not pay it and you know, provide an assurance that we've looked at the entire claim and everything on there is OK and go ahead and pay in 2 weeks when it comes off the floor, and that's really not the way the claims process is set up. There are certain things we reject for at the front end and then there are other things, such as medical review and other things that you need; all kinds of pricing and other files for which we can't do until it goes through the process. So I will try to find out for you which items are edited for at the front end, and I do believe we look at all the fields for NPI, you know, initially. I just am not sure what else is up there at the front end. But I can't guarantee—I mean this claims processing systems were not designed to do that; to go through the entire process and then tell you what is wrong and guarantee that after that point we are not going to find anymore fault with the claim. But I'll try to find out what it is we do look for.

Dr. Bufalino: Ms. Carter, can I ask you to email that answer since unfortunately the time is short because of the 23rd, would you mind getting an answer out to the members of the PPAC Council in the next week?

1 Ms. Carter: Yes, I mean I'll get the answer as soon as possible.

2 Dr. Bufalino: Thank you. Dr. Howard?

3 Dr. Howard: PPAC, I'd like to recommend that PPAC, if their contingency time frame terminates
4 on May 23rd as currently planned, that Medicare closely monitor as rejection rates and claims processing
5 interruptions immediately following the deadline and be prepared to allow claims to be resubmitted with
6 the NPI and Legacy numbers together if there are significant interruptions in that process. And I don't
7 know if we can to quantify significant or not, and that they report that back to PPAC.

8 [second]

9 Dr. Bufalino: Second, OK. Any discussion on that?

10 Dr. Snow: I would suggest that we include in there if the claim rejection or suspension rates
11 increase more than 5% over the baseline, they be prepared to accept both.

12 Dr. Howard: OK.

13 Dr. Bufalino: OK, friendly amendment, you comfortable?

14 Dr. Howard: Yes.

15 Dr. Bufalino: Anyone else want to add to that? John?

16 Dr. Arradondo: I didn't want to add to it. I'm just cognizant of the fact that some of the resolutions
17 we are making might require some decision making on the part of CMS [laughter] and for instance if CMS
18 takes 6 months to make the decision on our first one, it's already nullified. So that would be my most
19 germane question that I would ask of this whole series—I don't know what the decision making process
20 within CMS is.

21 Dr. Bufalino: Dr. Simon, would you like to add—would someone like to respond to that?

22 Dr. Simon: I think at this juncture, we will, I will work with Cathy Carter to see if we could obtain
23 the information that was requested by the Panel over the course of the next week as it pertains to finding
24 out the order of edits and how that impacts the claims processing process for when claims are submitted. In
25 terms of the other questions, I think that I'll address those with the leadership and we can communicate

with the panel if need be electronically prior to the next meeting to let them know of the decisions that'll be made.

Dr. Bufalino: That would be great. So can we have a vote on Dr. Howard's resolution?

Dr. Ouzounian: I believe there was a request to read it back.

Dr. Bufalino: I'm sorry. I skipped that. Yes, please.

Ms. Trevas: PPAC recommends that if the contingency time frame terminates on May 23rd as currently planned that Medicare closely monitor the rejection rates and claims processing interruptions immediately following the deadline, and be prepared to allow claims to be resubmitted with the NPI and Legacy numbers together. If there are significant interruptions, significant being a claims rejection or suspension rate more than 5% over baseline, and that that information be reported back to PPAC.

Dr. Howard: Yes.

Dr. Bufalino: Thank you. Any additions or corrections?

Dr. Przyblski: Just that addition reported it back to when? Next meeting presumably? Or sooner if somebody wants—

Dr. Bufalino: OK?

Ms. Trevas: Yes.

Dr. Bufalino: All in favor of the resolution. Oh—

Dr. Standaert: Resolution says allow things to be resubmitted with the Legacy number as opposed to changing it to allow submissions with a Legacy number initially? So they're still going to then reject every Legacy number; you're going to send it back with the Legacy number on. Is that what you're after, or are you getting them to say that the error rates going up to high, we need to accept the Legacy number for now and clear this up?

Dr. Bufalino: I assumed that that's what we were saying.

Dr. Standaert: The resolution says resubmit claims, which means they've already been rejected once, not to allow future submissions with a Legacy number. I'm just getting at the distinction he's trying to find.

Dr. Bufalino: What's your pleasure?

[chat off mike/laughter]

Dr. Przyblski: You could offer submitted or resubmitted, that'll cover both.

Dr. Howard: Right, let's do that. Good catch though.

Dr. Bufalino: All in favor?

[Ayes]

Dr. Bufalino: Any opposed. Thank you. Can we go to one, we'll ask one because we'd like to spend 10 minutes on Dr. Straub's issues, so one last comment.

Dr. Sprang: My last comment is just that it has been kind of sad, this is obviously extremely timely, it's going to be effective this Friday. We have made recommendations, but it's not likely that enough of CMS leadership are going to be able to look at them between now and Friday. If in the first few days it's obvious that a great number are being rejected, I would hope CMS leadership would kind of then extend the NPI and the Legacy for some period of time until we can actually kind of get it resolved so that we don't have a significant change in cash flow for all these practices.

Dr. Bufalino: I think we've made our position adequately. [laughter]

Dr. Sprang: I'm just being explicit. [laughter]

Dr. Bufalino: With four resolutions, I think we've got it clear. So thank you all for that. Thank you Ms. Carter for your time and patience and we appreciate and we hope to hear from you soon.

Ms. Carter: Thank you.

Dr. Bufalino: Let me take the prerogative. We've got 10 minutes before we have an absolute walk out date to go to our designed lunch, so we'll start with Karen, John, Tye.

1 Reprise of Issues on Compare Website on Physician Performance

2 Dr. Williams: Dr. Straube, you commented earlier that the international community spends less, a
3 lower percentage on healthcare for the GDP than we do, and that presumably they have higher quality, I
4 believe from your subsequent slides after that. Is there a way that we could get comparative quality
5 incentives, initiatives, and outcome from the international community. In other words, what are they doing
6 and compare it to what we're doing to find out if we're doing something different in the quality arena that
7 maybe we don't have to reinvent the wheel. Does that makes sense?

8 Dr. Straube: Yes, oh definitely. I think that is going on currently with a number of these quality
9 alliances, quality initiatives. National Quality Forum is an example, has implemented something called the
10 priority partner initiative and they're trying to identify what healthcare priorities we, as a nation, should
11 focus on. So in the process of doing that, some of the work groups that have been established, are in fact
12 looking at issues that may have been actionable and dealt with in other countries that we might want to
13 choose as priorities.

14 Dr. Williams: Is it at the stage where we could get a report back of some of their preliminary data
15 on that?

16 Dr. Straube: Well, you mean to PPAC?

17 Dr. Williams: Yes.

18 Dr. Straube: I don't think we're really asking for any input on that particular issue. I went over all
19 of that data just setting the stage for why we're doing what we're doing. We don't have any current
20 initiative that's specifically looking at international data. We've looked a little bit in the end stage renal
21 disease world because there are some metrics for dialysis facilities that specifically are better in other
22 countries and we're factoring that into long term planning as to what measures we want to choose here. I
23 supposed we're using it a little bit. We're in the process of just beginning a strategic plan internally for how
24 we will pick what quality metrics need to be developed over the next 3 to 5 years, and that will inform that
25 effort also, but it's a small part of a bigger effort and given our own resources to do a specific report, we're

1 probably not in the process of doing that, so it would be work that we couldn't really do. But we are taking
2 that into consideration.
3 Dr. Arradondo: My questions relate to your slides 20 and 16, 16 and 20 and then a comment on 10
4 and 12. I'm prepared to make a resolution. I was not optimistic we were going to get back to Dr. Straube.
5 And I'll just preface the resolution, and if it's a question that can be responded to. On slide 16, the strategy,
6 CMS quality road map of strategies; the third strategy reference taking steps, help patients and providers
7 take steps to improve health and avoid unnecessary costs. And my question was what specific incentives
8 does CMS plan to use to providers and to patients to improve health? The business of process and
9 outcomes was raised earlier by one of our colleagues and several of our colleagues, and CMS has shown
10 that giving incentives to hospitals result in some sort of behavioral changed. So my question was that, and
11 I'm prepared to make a resolution, recommending that CMS provide significant specific incentives,
12 including process and outcome incentives to physicians and patients, to improve health. That's, and there
13 was a kind of a, and then I'm prepared to make a resolution relative—
14 Dr. Bufalino: Let's stop and take point one. And do I have a second?
15 [seconds]
16 Dr. Bufalino: OK any discussion about his? Dana would you mind rereading that? I'm sorry
17 Dr. Ross: Just a comment on his resolution. It was a point that I was going to make and want to
18 concur with Dr. Arradondo about the fact that hospitals had a 10% and then went to a 95% rate of
19 compliance on the PQRI and went from a .4% to a 2% bonus situation, whereas doctors still only have a
20 1.5% bonus. So this goes along with what you're saying. The incentivizing for hospitals is greater than the
21 doctors, and we should make a better situation for the doctors when it comes to financial incentive.
22 Dr. Straube: If I could just interject, remember that we, CMS don't set those percentages. That's a,
23 that was in statute Congress and we just follow the law.
24 Dr. Giamio: I think that's one of the reasons why in addition to many other reasons, I don't want
25 to take up time the resolution, why you may have less compliance from the individual practitioners.

1 Dr. Rich: Just a point of clarification. There's not new money for hospitals to do this. There are
2 market basket update is reduce by the amount on the annual basis and if they don't comply with the
3 reporting then they don't get their annual update. OK. Docs, the PQRI is new money. It's in above
4 whatever your market basket update which happens to be minus 10% in July, but it's new money, so
5 there's a difference between. There's a true incentive for docs, and there's a negative disincentive for not
6 reporting for hospitals. Does that help clarify?
7 Dr. Giamio: …reason why they had such a good compliance rate.
8 Dr. Rich: Right and for them to achieve what's due, what's usual and customary updates for them
9 on an annual basis, they had to report. For docs, it was voluntary and if they did it they would get 1.5% in
10 addition to whatever they received from—
11 Dr. Ross: But that raises the points that I was going to make earlier and that is that hospitals have
12 the manpower, they have the resources, they have the computers, they have the weight to make this
13 reporting much easier than an individual solo practitioner who doesn't have the financial resources, the
14 computer, the software, and the personnel to do these things and that's what's made it so difficult in this
15 first year of reporting.
16 Dr. Bufalino: John, let's try to close up your resolution. Did you want to have another comment on
17 it?
18 Dr. Giamio: I just gear it toward preventive care and management, so how would you focus the
19 resolution? What parameter could we use for preventive medicine in outcomes? Is there a way for—
20 Dr. Bufalino: Dana would you like to re read it?
21 Dr. Arradondo: Well, there are 2 pieces. One, one of the reasons I didn't put dollars in there is
22 because I am aware that that's not set by CMS. And I didn't want that to be used as an excuse. Number
23 two, there are other incentives beyond dollars, and adding dollars is what Congress tends to do, except
24 sometimes, and so doing things that would save dollars is something that CMS in fact could do that doesn't
25 require changing its rules. It's rather interesting. It's like you drug the number horse so that your horse can

win, as opposed to speeding up your number one horse, kind of thing. There's more than one way to get the same effect and I didn't say the dollar bit because I was aware of that, but I did say significant incentives. And that's something the CMS could advise Congress, because Congress does seek your input from time to time and we know that but you also said that, and CMS could say well these are the five things that we think would be significant. You're the experts. So to speak, except when certain special interests come in and convince Congress that they're the experts. Otherwise, you're the experts. So the CMS could inform Congress in this advice and consent matter before they make rules. That was the reason I didn't put specific dollars. Only referenced it because Congress and you had already done it and it looked pretty positive from the hospitals' perspective, but then they have a much easier way to deal with the way you were incentivizing them. Individual practitioners have a more difficult way, so the word "significant" was an informed choice of words by me.

Dr. Bufalino: Dana would you re read it?

Ms. Trevas: PPAC recommends that CMS provide significant specific incentives, including process and outcome incentives, to physicians and patients to improve health.

Dr. Bufalino: OK, you've heard it, all in favor?

[Ayes]

Dr. Bufalino: Anybody opposed? No. OK. John go ahead.

Dr. Arradondo: Thank you, Mr. Chair. Relative to slide 20, where you're talking about the Healthcare Transparency Initiative by the agency, by the administration? In fact this was the Secretary's initiative, you referenced, and the very first one the four cornerstones included information on quality. I wanted to ask the question, but prepared to make a resolution, and it relates to what some of our colleagues have already said, is that quality is affected by both process and outcome measures, presumably outcome being a good portion of that, but not necessarily. And physicians and other providers have an input more or less on the process side, not a whole lot on the outcome side, and for that matter, sometimes not enough on the input side. We won't talk about that. And I was prepared to say that the healthcare, we recommend that

1 the Transparency Initiative information on quality should use both process and outcome information that's
2 kind of simple. But I was also prepared to put e.g., or i.e., e.g. in this instance, including recorded patient
3 compliance information and other similar information. I mean simple things like appointment kept rate,
4 which many providers keep. You look at 10 visits and it turns out that there were 14 appointments, and it
5 gives you an immediate recorded appointment kept rate. Little bit more difficult is the compliance and for
6 the more sophisticated interaction, the adherence rate. But again, the recorded rate, that's the only
7 information we have. It's what's in the record. And if the record says we recommended walking to improve
8 the health of a person with diabetes or hypertension or hyperlipidemia, and the patient reports that they
9 haven't started walking yet, and I didn't say weight loss, which is somewhat an objective measure, of how
10 well diet and exercise works, just to deal with those 3 important matters, recorded, that would help balance
11 the process versus the outcome information, when it comes to listing that if it's going to be listed as a
12 quality matter. So the resolution would recommend that in the healthcare transparency initiative,
13 information on quality should use both process and outcomes information and then put in an e.g., really just
14 an example, not to define it.
15 Dr. Bufalino: A second for that?
16 [Second]
17 Dr. Bufalino: Adjustments?
18 Dr. Kirsch: Yes, I would argue against providing the outcome information. I would elect that for
19 right now we're only ready to start putting out the process information. What you're describing as far as
20 noting patient adherence to care and such, that sounds wonderful, but it's terribly unworkable at this point.
21 We're just really not sophisticated enough to put that out. I think you know, be able to put out processes in
22 diabetes management, such as are you ordering the A1Cs? Are you doing the LDLs? You know just
23 starting with the simple measures. Are you complying with what's recommended, I think would be fine and
24 we'd get everybody on track into coming up with processes for better care of something like diabetes. But
25 we are not ready to be putting out the outcomes. I would say just put out process information.

1 Dr. Giamio: As a caveat to that, though, the problem is if we're going to submit this information,
2 it's going to be transparent, then if you have a population that's highly noncompliant, it will make that
3 physician appear as if they're not meeting that standard, where it's actually their patient population. So I
4 agree with John's—there needs to be some kind of component there that would be able to balance that.
5 Dr. Kirsch: I would argue by showing that the physician follows through with the process
6 accomplishes that. As far as being able to measure adherence, that is very, very difficult and to put out
7 those measures, you can show that so many, such and such percentage of the time, you got the A1Cs on
8 time, such and such percentage of the time, you ordered the LDLs, that you're following through with the
9 processes that are recommended but then on the other hand to try to document to show that the patient
10 adhered, or to try to define what your population base is is very difficult. And we're just starting this. I
11 think just report the process information.
12 Dr. Giamio: So just to clarify for me then, so if, as long as you order those tests, then that is the
13 report of a click-off, it's not the fact that they were actually attained.
14 Dr. Kirsch: Yes, right.
15 Dr. Giamio: So if we understand it, and that's how it will be reported that these things were
16 attempted, you know, eye exams, podiatric exams, things of this nature.
17 Dr. Kirsch: Right.
18 Dr. Giamio: So is that the information that CMS is planning on reporting then or is it actually that
19 the patient did go and have that test done and it was in their chart? Is it the fact that it was attempted and we
20 ordered it? Or is it the fact that it was actually attained?
21 Dr. Straube: Well, again, in the short term, the PQRI process, which again, you'll hear about after
22 lunch is much more the former, in terms of it it's just an attestation basically that certain services were
23 offered. It doesn't always say that they were attained. The long term, clearly we're interested in focusing on
24 outcomes, efficiency measures and other things that we can't collect so easily right now. So again, it's your
25 call in terms of what you would—

Dr. Bufalino: The hour's late, so John, one last comment.

Dr. Arradondo: Thank you, Mr. Chair. The reason I wanted to put that there is kind of, I don't need to bond with Tye, but we've talked about a number of things [laughter] and it's one thing to say what we're going to do, it's another thing to say oops, we're also going to report this 3 years later. We don't always know what's going to be reported. CMS doesn't always know, so it's not like CMS is doing bait and switch, or switcheroo. Sometimes others request information that we all have, have either submitted or collected, and then all of the sudden it's being shown through everyone. So in the spirit of transparency, it's kind of nice to get what's desirable out there. What one of my colleagues here is talking about is the state of that, and Oh god, I could give you a speech. In fact, I get paid to give that aspect of the speech on how poor our system is on the measuring outcomes. But on the other hand if someone decides to measure outcome of diabetes care by deaths, that's very simple to measure. If they decide to measure outcomes by amputations, by care in the wound care clinic, all of those are billable matters that are easy to pick up, that's an outcome that can't be denied. If they want to measure it by visit to ophthalmology for maintenance, the yearly recommendation, or which by the way the primary care physicians ought to be doing and shouldn't just leave to the ophthalmologists, but more importantly measure it by number of laser treatments to the eye because of angiogenesis, related or attributed to diabetes. That can be an outcome because it reflects vision and productivity, etc. So their outcome isn't as static as we would want it to be and there's a lot of outcomes data out there depending upon who is making the definition. So in a sense kind of what I'm hoping we would do is to help CMS inform some of the people in our instance, help inform CMS about the nicety of using both process and outcomes. We have a little more influence over one that we do over the other, but ultimately, if someone is the head of the system, and this is actually one of my two last comments, my question was going to be slide 12, is CMS seeking to become a health system? But if there were a health system, the health system would probably want to make its effectiveness argument based on outcomes much more than on process. So it, this resolution would get at the notion, say

1 we're cognizant of both process and outcome and CMS if you're going to be transparent, please be that
2 way yourself.
3 Dr. Bufalino: [off mike remark 05:52] Can we vote on this motion and put this away and then
4 come back in the afternoon and spend a little more time on it at the end?
5 Dr. Kirsch: Is it better to move for an addendum, I mean for, to be able to make a change in it, it's
6 just as it stands, OK.
7 Dr. Bufalino: All in favor? Read?
8 Ms. Trevas: PPAC recommends that the health care transparency initiative information on quality
9 use both process and outcome information and do you want to include the parenthetical phrase?
10 Dr. Arradondo: That for example, I think is useful and information. For example, recorded patient
11 compliance information measures.
12 Dr. Bufalino: OK. All in favor?
13 [Aye]
14 Dr. Bufalino: Opposed?
15 [No]
16 Dr. Bufalino: I think the Ayes have it. Thank you. Let me end this by saying Mr. Weems is back
17 to take pictures with all the folks that were inducted this morning. So please begin by getting back up to the
18 flags and taking picture. We will start promptly at 1:15 with Dr. Rapp's presentation. We'll meet for lunch
19 in 325.
20 Dr. Ouzounian: Can we come back to this?
21 Dr. Bufalino: We can come back. Dr. Straube, thank you very much.
22 Break
23 PQRI Update
24 Dr. Bufalino: So we'll begin the afternoon session. We ask to introduce Dr. Michael Rapp. Dr.
25 Rapp is the Director of Quality Measurement and Health Assessment Group at CMS and Dr. Rapp as many

of you know has been an ER physician in his former life, and still with an active clinical practice out there dabbling at 2 in the morning with the rest of the world, although not very often 2 in the morning. But still taking his shifts in the ER. And we are thrilled to have him back. He has been very much involved with the PQRI. We've heard from him a number of times and glad to have him come back and give us an update so that you're forewarned, we've had already enough conversation about the PQRI, so we're anxious to hear what you have to say.

Dr. Rapp: OK. Thank you for the introduction and I know you've had some discussion already about PQRI. I'm here to update you on a few things. Since the last time that I was here, we have implemented several authorities that the MMSEA statute, which extended the PQRI Program required the Secretary to implement, so that's been done and I want to update you on that, and also the Council was interested in some of our experience from the 2007 reporting program. So I brought with me, one of my staff, Rachel Nelson, who's been knee-deep in a lot of the details of the reporting and getting those materials together and so she knows probably as much in terms of the details of that as anybody so I will after I've done my part, I'll let her give you some information on what some of the experience was from last year and we'll be able to respond to I think some of the questions that you might have. OK, so let's go to the first slide.

We'll go through this fairly rapidly. The Physician Quality Reporting Initiative, just as a reminder, was authorized in the legislation at the end of 2006, authorizing for 2007 a 6-month period for a 1.5% incentive payment if quality measures were reported. For 2007, we had 74 measures, which were consensus developed and endorsed, broad applicability to over 95% of physician part B services and they depend upon the services rendered, not a specifically designated specialty. And you have our website there that has an abundance of information available for you.

The basic reporting criteria under the statute were three measures; reporting 80% of the time for applicable patients if less than 3 measures applied to the physician, than 1 or 2 measures. The incentive payment applies to all of the services rendered by the practitioner during the reporting period. Not just

1 those on which the reporting is made. So that's an important thing. But also conversely, it's only necessary
2 to report on the measures themselves, on the patients for which the measures that one is reporting on apply.
3 Our preliminary participation data, and Rachel will go into more detail on this for you, was that in for 2007,
4 approximately 16% participation, which meant that an eligible professional—an eligible professional does
5 not just include physicians but a broad range of practitioners submitted at least one quality data code. We
6 expect that the majority of those participants are likely to qualify for the bonus. The first question that I
7 normally get asked: Well, why didn't more qualify or why won't you, wouldn't it be expected that more
8 would qualify for the bonus? Well there's a variety of reasons, but the main thing to just bear in mind is
9 there is an 80% reporting rate requirement, so if a professional reported on a measure, but left out a bunch
10 of patients, then there wouldn't be satisfactory reporting in terms of qualifying for the bonus.
11 For 2008, we were required by the original TRISHA legislation to select measures. Secretary was
12 some 119 were selected for 2008, which are 117 clinical measures, 2 structural measures, again, broad
13 applicability and particularly for the structural measures. This statute did a couple of other things. MSEA
14 first of all it eliminated the cap on the incentive payment, not of particular importance for you now, except
15 to know that there is no cap and that there's no per measure amount anymore. That created, I think some
16 confusion or uncertainty on the part of physicians in terms of how much reporting they would have to do
17 since there was a per measure amount, it was felt that well you need to report lots of measures so you don't
18 run into that cap. That issue is gone. And I think some of the data we'll give you shows that there was what
19 I would call excess reporting and sort of an abundance of caution to make sure that people didn't fall under
20 that cap they reported probably more times than they needed to. The incentive payment this year will be
21 1.5% without respect to any cap of allowable charges in the reporting period, the initial reporting period
22 that we established was for the entire year of 2008, but I'll get to some alternative reporting periods that
23 MMSEA required us to establish.
24 I think one of the main points that I want to make today is there are quite a few different ways to
25 participate in the 2008 PQRI. Not just the one option implemented through the 2008 Medicare Physician

Fee Schedule Rule, but also in fact, 8 new options. We have two reporting periods; the whole year and half a year, we have not only claims-based reporting, but registry-based reporting that I'm going to go through here briefly.

So again, two reporting periods; 12 months, the whole year; 6 months, the second half of the year. Three claims-based methods of reporting and 6 registry-based methods. So in particular, that will give even physicians who to date haven't thought in terms of 2008 reporting will be able for the most part to participate this year. Again, the two alternative reporting periods. Three claims-based options, so when one is trying to approach this from a physician standpoint, I think it's important to sort of go through the different options and just make your decision and then focus on that. Get your if it's claims-based, have your office system set up in a way that you can do that. But the three reporting options for claims-based are one) the whole year, which I mentioned earlier, three measures, for 80% of applicable patients, or if less than 3 applied to the practitioner report, one or two measures. The second half of the year reporting period is something new and this was based upon MMSEA and what we needed to implement and what we were required by the statute to implement was 1. alternative reporting periods and alternative reporting criteria for measures groups, or for registry-based reporting. So now, on the claims, we're going to talk about measures groups.

And the two additional options that you see here for reporting measure groups and the reporting criteria are: you report 15 consecutive patients, or 80% of eligible patients. So as you can see, 15 consecutive patients, hopefully would be something that would be relatively easy for physicians to report on where we have measure groups. Measure groups are broadly applicable measures for diabetes, preventive care, ESRD, and CK, chronic kidney disease. So as I'll go through with you, for the second half of the year, using claims, if the practitioner reports on 15 consecutive applicable patients. In other words, if it's a diabetes group, it has to be diabetes patients. But for prevention, of course it can be really any patient. So there is broad applicability and I think that you probably will agree that this should be a way that the most practitioners without really tremendous burden would be able to participate effectively in PQRI, yet

1 also give worthwhile information with regard to the quality of patients, that Medicare beneficiaries are
2 receiving. We put in 80% of eligible patients for the measures groups as well, just because although 15
3 consecutive patients would seem like something that could be done, we didn't want to have technical issues
4 cause problems for physicians, so if the physician reported 8 patients and then inadvertently skipped one
5 because of the claims-based reporting system and then reporting 8 more, as long as it added up to 80% of
6 the eligible patients for the reporting period—for the reporting period—for those measures groups, then
7 that would qualify. We're looking—we have 9 different ways—we look at is as 9 different ways to succeed
8 rather than 9 different ways to fail. We are going to evaluate each of the reporting methods so that if the
9 physician didn't qualify this way, we'll look to see did they qualify using this reporting option.
10 These slides just go through the details of this which I won't spend a whole lot of time on. But this
11 is a whole year, three measures or less than 3 if less than 3 apply to the practitioner. This is the, these are
12 the measures groups, 15 consecutive patients. Now the one thing about reporting measures groups is we
13 had to have some technique where we would know that the physician was now seeking to start with 15
14 consecutive patients, so for that we have G-codes. Each of the four different groups has a G-code. Diabetes,
15 ESRD, CKD, preventive care, and with the first of the 15 consecutive patients, we ask the for to
16 successfully report, as necessary, to report that G-code. A G-code does two things; one indicates that this is
17 a measures group that I intend to report on and 2, this is the first of 15 consecutive patients that I am
18 looking to report on. That way, from an analytic standpoint, the contractors can find them and look for the
19 patients. Again, 15 consecutive patients for diabetes means 15 diabetes patients. If you see a patient with
20 diabetes in the next 20 have back pain, sore throat, heart disease but don't have diabetes, that is determined
21 by what you put in the claim. If you don't put diabetes in the claim, only way we know that the patient has
22 diabetes is because for that patient when you report it, you put in an ICD code, diabetes. And so that's how
23 the denominators in generally are formed. These measures groups are made up of individual measures and
24 we are about to publish a document, which will show you in certain cases, the individual measures have
25 some want to call extraneous codes, that aren't core codes that make up those measures groups, so we're

just going to publish a document soon that will demonstrate that for you so you won't have to go through the individual measures to figure out what the denominator for the measures group is. You can just look at that single denominator.

Claims-based 80% of applicable patients for our measures group second half of the year—that's the third claims-based option. This just gives you the scenario of how the reporting would work. The physician decides what measures group he or she would be interested in, picks out the second half of the year, that's the only reporting period for which the measures groups via claims are available, puts down the appropriate G-code and then, this is a point I didn't make yet. That is, the measures groups all have more than 3 measures. Like the diabetes group has 5 measures. It's necessary to put down all 5 of the pertinent CPT2 codes, for diabetes. For that one patient. And you can put it down all on the same claim form.

Dr. Smith: You can't. You can only list four.

Dr. Rapp: Well, I'm going to have Rachel discuss that a bit with you, but yes you can, but—

Dr. Smith: Because that's all it takes. That's all the blocks there are.

Dr. Rapp: Pardon me? Why don't you answer the question Rachel?

Ms. Nelson: OK, basically, first of all we're talking about not diagnosis codes, but rather procedure codes. The quality data reporting codes or numerator codes, are HCPCS level 2 codes or they're CPT category 2 codes, but in other words, they are reported on service lines on the claim. The four blocks that you're thinking of are the diagnosis blocks at the claim header. And although there is an 8-item limit on the electronic transaction claim which most practitioners use, that is separate from how many different procedure codes you could link to any of those, say, 4 on the paper claim.

Dr. Smith: So what you're saying is that these measures are not your diagnoses. It's not like you're screening eyes or—

Ms. Nelson: Correct—what happens is, specifically to the measures groups, if you have a patient, and you treat them for one of the diagnoses of diabetes that is in the measures group denominator, then the measures group measures apply and what you would report would be the clinical values that let us know

how that patient is doing say on their eye exam? Did they have an eye exam? Did they, what was their LDL, what was their blood pressure? Those are translated into CPT category 2 codes and reported on the service lines, all linked back to the same diagnosis of diabetes that threw them into the measures group.

Dr. Rapp: So there are some technical aspects of actually reporting the codes. One of the good things about the claims process is you could report them now if you want to, and you could see, you could try reporting with requisite number of codes for a particular patient and make sure that your system works and they all go through. There have been some issues with regard to clearinghouses and so forth. When we get to the preventive, there are 9 measures there, but that is not really an issue with regard to CMS's ability to accept the information but more sometimes issues with regard to clearinghouses and so forth. And it might be beneficial to if you're looking to report the measures groups to just make sure the system works right for you and you don't have any of those issues. Do you have anything to add about that, Rachel?

Ms. Nelson: Just that that is a good idea to if you're interested, try every one of the CPT category 2 codes you would need to use to report the measures and make sure you get the remittance advice back that is, there's a very specific remittance advice, and basically what it says is there is no payment allowed for this code because it's for measurement purposes, and be sure that you get that all the way back through your clearinghouse and into your hands and that'll let you know your clearinghouse can handle all the codes.

Dr. Rapp: OK? Yes.

Dr. Kirsch: How often are you reporting on this? Is this once a year, is this quarterly? How often do you need to keep submitting it?

Dr. Rapp: It's the reporting period. It's the relevant reporting period. So in this case, what we're talking about here for claims reporting measures groups, we're talking about the 6-month reporting period.

Dr. Kirsch: Six months.

Dr. Rapp: In this case, however, of course since we're dealing with measures groups, you don't really get into that. You just report them 15 consecutive, for 15 consecutive patients, 15 consecutive different patients with diabetes and you're done.

This is a claims form. This has a PIN number there, but you basically trying to make the point that G-code, which is circled is something that you need to report to initiate the measures group, and then you also have to include your NPI number.

So now I'm going to switch gears. We've just talked about claims-based reporting and measure groups. The MMSEA statute required us also to identify registry-based reporting, alternative reporting criteria for registry-based reporting as well, and alternative reporting periods. Now registry-based reporting you're probably fairly familiar with registries, but just in case some of you aren't, there are a number of organizations that maintain registries so that collect the data over time, in the statute, the TRISHA statute originally, they made reference to the Society for Thoracic Surgeons registry, which has been going on for quite a number of years where they, the physicians and cardiac surgery programs report data. It's maintained, it's got a lot of beneficial aspects to it because one can keep track of things over time, and give feedback to the physicians and so forth, and so Congress was interested in making sure that we didn't undercut registries and particularly also not have doctors do things twice when they're already doing them. And so Congress required the Secretary to address registry-based reporting by 2008, which we did by indicating we would test it, but at the end of 2007 went a bit further and said, in fact, for 2008, you need to actually implement registry-based reporting. That would qualify for the incentive payment. So we did that. And for registry-based reporting, there are 6 options. They basically parallel the other claims based options but we're able to deal with the entire year for individual measures as well so here they are: two reporting periods. The whole year on the left, the half year on the right, and for either the whole year or the half year, one can report on a minimum of three measures. In this case, we're not accepting 1 or 2 measures, but a minimum of 3 measures. If one does individual measures. Or a measures group, an alternate here, if it's an entire year it would be 30 consecutive patients, or 80% of applicable cases. If it's a half year, 15

consecutive patients, just like for claims. Now, how do registries work? The registries collect the data from the practitioners and of course, unlike claims, which there's some contemporaneous aspect to it because physicians are going to want to submit their claims around the time that they see the patient, So they can't, they have to sort of keep going all along. But a registry, in fact, the registry could get the information from the practitioner at the end of the year. In fact, they do have to get, since they have to deal with the entire reporting period, they'll have to at least update the information at the end of the year. So what that means form a practical standpoint, for physicians and other eligible professionals that are interested in participating, it's not really necessary to deal with a registry, to have already started dealing with a registries, and in fact one can wait to whatever time is agreeable between the registry and the practitioner.

So this I'm not going to go through in detail of the same things, but basically, all of the different criteria for registries that were operational for claims apply for registries. One exception as I mentioned, no individual measures that only would be 1 or 2 measures. It has to be a minimum of 3. And the other aspect of it for the consec—same thing with the groups; the one other modification or additional option here for registry based reporting is the consecutive patients can include non Medicare patients. There's a lot of belief that you should actually look at the practitioner's entire practice to be able to assess their performance, rather than just only a subset of their patients. That's not practical from a claims standpoint, but it is practical from registries. It does make our validation process a bit more complex, but nevertheless we're introducing this for registry-based reporting. So in so far as you submit to a registry, and they include non Medicare patients, that would be allowable under this alternative and there are some registries that assess physician performance that way.

Fifteen consecutive patients applies to the second half of the year for registries, just like for claims. There's no G-code that has to go along with the registry-based reporting since that is a technical aspect that's necessary for the claims, but it's not necessary for registry for us. Measures groups apply to registries just like individual measures. So here are the four different measures groups; diabetes, end stage renal disease, chronic kidney disease, preventive care. The measures for diabetes are the three control

1 measures for hemoglobin A1C, LDL, and high blood pressure, dilated eye exam, and urine screening for
2 micro albumin. So the idea here with the measures groups is as opposed to kind of random selected
3 measures that when you report on a Medicare beneficiary, using a measures group, you're addressing all of
4 the care that at least the measures address appropriate for the beneficiary rather than just one or another of
5 those aspects. So looking at it from a perspective of long term, realizing that the goal here is to assess the
6 quality of care rendered to Medicare beneficiaries, it's better to have things like this that you could assess
7 the care rendered to the patients as well as ultimately be able to compare the care rendered by the
8 practitioners. And those are the end stage renal disease measures. CKD measures. And preventive care
9 measures—there are 9 of them. Again, there's basically no diagnosis denominator for preventive care
10 measure groups. So as long as you have in your denominator, one of the procedure codes, which apply to
11 the prevention group, that means that this type, this measure can be broadly submitted by practitioners and
12 also it's of course a high area of in terms of priority for the Medicare program and for HHS in general,
13 prevention. And the only sort of nuance here is 3 of these measures apply only to women and for those, the
14 15 consecutive patients, it's 15 consecutive people you report if those people happen to be men, there are 6
15 measures that are reportable, and if they happen to be women, there are 9.
16 Registry time line. A key points for you to know is that we have posted the requirements for
17 registry. We're doing some testing for registry but the testing doesn't really directly pertain to the registry
18 for submission for payment and so what this means is that we have to go through a self-nomination process
19 and a brief qualification process for registries. We wish we had the ability to tell you today who the
20 registries would be that you could use, but we can't do that because of course this was rather late in terms
21 of when Congress required us to do this. So we have to go through this process, but by August 31st, we will
22 announce those registries that are qualified for submission of quality data under the PQRI Program for the
23 incentive payment. We'll put that on our website and at that point you will be able to look on that and see
24 who you could use for that. The actual submission by the registries to us won't be until January and
25 February of 2009, after the reporting period has taken place, after the registries have gotten the data from

the practitioners, and after they have calculated the performance results and given them to us. In this case, for the registries, we are not going to calculate the performance results, but rather the registries are going to calculate the performance results and give them to us. And the reporting results as well, satisfactory reporting and what the performance rates are. We tested a couple of options, I won't go into this, but one of the options was that the registries gives us the performance rates rather than we calculate the performance rates based upon data. We're using only that one for the payment part.

Here are the registries that are currently undergoing testing. This is testing for the test. This does not mean that these registries will necessarily be ones who can submit for the incentive payment. It's probably likely since they are engaged in this, but it's not necessarily the case and by the same token, conversely, it doesn't mean that just because a registries not on this list, that they will not be able to submit for payment. You'll have to just wait until August 31st before you'll know that for sure, on either those on this list or any others. Payment, it's the same 1.5%. There are as I said 9 different possible permutations of ways that the physician could qualify. If the physician qualifies under any of the options, they'll get the 1.5% for the applicable reporting period and if it's for more than one reporting period, for the longest reporting period. You can't stack 'em up and have the whole year and half a year.

Dr. Kirsch: So if you report on 2 factors, if you report on diabetes and preventive care, you only, the max is 1.5, you can't double it up to 3.

Dr. Rapp: Exactly. So what are we trying to in terms of our goals for 2008. We of course, would like to have an expanded participation of PQRI and much of what we've done is designed to accommodate that. During 2008, we're expanding the measure in terms of development and for 2008 payment, we've implemented registry-based reporting, the alternative criteria, and further more we are preparing to accept in 2009 EHR reported measures. I think that's something that's very encouraging and very exciting for us because really EHR reporting one would look to as the way you, where you'd like to get in the future. Claims-based reporting, we feel is hopefully temporary. It'll probably be around for quite a while, and it does give everyone a chance to participate, but in the long run, EHR reporting will be very beneficial, not

to mention the fact that you're going to primary source data, rather than doing any secondary source data. So we're going to implement that, that is that's what we're planning to do for 2009.

I think a couple important messages: 1) it is not too late to begin reporting. First of all, I mentioned the alternative ½-year reporting period. But also, I wanted to mention that of our 119 measures, 60 of them only require reporting once per reporting period. They're patient-level measures, diabetes is an example. If you report once during a reporting period on a given patient, one is done. So that means, for example, you will see after May 19th, 80%, or at least 80% of your diabetic patients after this date, you could still qualify for the entire year by reporting on 3 of those diabetes measures. Certainly report on 5, but just by reporting on 3 of those measures, for 80% of your diabetics, which is defined by you send in a bill with their diagnosis of diabetes, you would be able to qualify. But let's say that's out for some reason. You still have the many cases, the alternative half-year reporting period available and of course, this doesn't even get to the registry base, since the registry will apply to all measures, as long as there's 3 applicable to you, the registry really gives everyone a chance to participate, even starting quite late in the year.

I've just gone over the successful reporting before, just to mention the claims-based submission for services that it has to deal with services, December 31, 2008, the submission will take place ending February 28th, 2009. That is the last date for submission of claims-based quality data code and registry's the same way.

So if you're interested in reporting, just a way to approach it is try to make a decision if you want to do claims or registry, individual measures of measures groups, for the full reporting or part year. Pick 3 measures of one measures group that applies to your practice and make the necessary office system adaptations that are necessary to do that. I think by focusing on actually what is necessary to do, and we have lots of information on our website which makes that clear, I think you have the best chance of being able to successfully report as I mentioned. We did our best, to try to make it something that does work for doctors, at the same time provides valid information to us that we can use to evaluate performance ultimately. Certainly this is something that's still in the development stages, in terms of the measures, how

1 things work, the calculations. We're just getting the data together for 2007 for the first time. So I appreciate
2 any, we get a lot of input and feedback, and we value that. We work actively with virtually every medical
3 surgical specialty society that there is to help make sure that there are measures that work for the doctors.
4 We use consensus based measures that are for the most part developed under the AMA PCPI umbrella, but
5 not exclusive, but certainly for the most part, we're actively engaged with the American Medical
6 Association. We have regular provider outreach calls and so forth. As I mentioned, we have lots of
7 information on the website. We're eager to have physicians participate and we're eager to have it be able to
8 be something that you can do in a way that's not overly burdensome for you and that you can successfully
9 report.
10 I'm going to switch to Rachel, and I know that you're interested in some data with regard to
11 participation, so I'd like to have her spend a few minutes telling you about and then we'll take any
12 questions that you have.
13 Ms. Nelson: I did make a few copies of a handout that is probably more densely detailed than we
14 have time to get into here. What it is is an overview of preliminary 2007 participation information based on
15 claims for dates of service July through November, with claims processed through November. As
16 mentioned, the participation rate is about 16% of those who could have. Some less sophisticated, less
17 finalized peaks we done at later claims data indicates that the 16% is holding and I personally would
18 predict we would be in the vicinity of 16% participation when the final analysis for 2007 is run and that is
19 for all eligible professionals, physicians and non physicians who could have reported any one of the 74
20 measures. Of those who participated, and remember we define participation as those who reported at least
21 one quality data code for at least one measure one time, of those, almost all, somewhere in the vicinity of
22 90%, it doesn't necessarily compute from what you're looking at here, but it's around 90%, actually
23 submitted at least one of their codes on a claim that it belonged on, which is to say they didn't report a
24 diabetes code on a patient with asthma but not diabetes, or vice versa. We had pretty good participation
25 from around the country. Most participants reported, I will say around 3 measures. The actually average

1 looks to be holding steady around 3.5 measures per individual professional. Participation varies by region,
2 but one of the popular questions that I get is what is the urban rural split. We've not yet begun a robust
3 program evaluation analysis that would tell us that on anything like final data, but we can tell you from the
4 preliminary, which you can glance at on the detailed second sheet, that we had pretty healthy participation
5 in the regions that are the densest in eligible professionals such as Atlanta and Chicago, or as dense as any,
6 I should say, and we also had pretty healthy participation from regions like Kansas City in states like
7 Nebraska and Iowa. We had, I didn't mention it on here, but you'll look on the handout, you'll see that we
8 had very healthy participation in North and South Dakota, which are extremely rural. We also had very
9 good participation in Indiana, which is a mix and Tennessee and North Carolina. So, we had a lot, we had a
10 healthy participation. We had participation spread across specialties and across professions as well as
11 across the country. It does vary by clinical topic, and we did notice that measures applicable to anesthesia
12 care, eye care and emergency care seem to have the highest rates of participation, but remember the
13 measures are not specialty specific and that's why we refer to it as them being applicable to types of care.
14 For example, anesthesia care could be provided by an anesthesiologist or a nurse practitioner or in some
15 very rural areas, the surgeon themselves or in other circumstances, the surgeon himself.
16 The high view, because I want to leave you guys time to ask me questions rather than me try to
17 speculate what each audience wants to hear, some preliminary observations that we had in terms of
18 participation was that professional society support tends to increase participation. As noted earlier in one
19 way or another, billing systems, and billing service vendors can either help you or be an obstacle to you in
20 successfully reporting your quality data codes, including whether or not they were able to handle the
21 national provider identifier in a timely way. We know they were significant issues many people had who
22 would have liked to have participated, but we can't tell they participated because their clearinghouse
23 couldn't handle the NPI, didn't pass it on to us. I don't know how many people that affected, but we do
24 know that at least anecdotally, a few. There was uncertainty, as mentioned before about the program's
25 future, that was the barrier for many professionals. And one other thing to note is that when we refer to

over reporting of the measures, we don't penalize for that. If you report on every single one of your diabetics, rather than age, rather than worry about how old they are compared to what the measure says. If that's what makes it easier for you to make sure that you get 80% of the diabetics in the age range of the measure, then that seems to have been an effective strategy to support reaching at least 80% on the measures you were trying to report, though again, that seems to be qualitative, based on anecdotal and other knowledge that we have, and is not based on a final evaluation of the data. We just now have the final data and are in the process, I should say, of some of the processing that will be necessary to actually issue payments on it and issue participant feed back and the program evaluation type of analyses, we'll need to follow that. And that's really all I had prepared to say as an overview of what you're looking at on your handouts. I'm ready for questions.

Dr. Bufalino: Thank you both for that. We'd open this for some conversation. We have 5 to 10 minutes.

Dr. Howard: I just want to ask, so you're definition of participation is one time, they got one code in the right box?

Dr. Rapp: That's how we're defining it—

Dr. Howard: I just want to make sure I got that.

Dr. Rapp: That's not successful reporting.

Dr. Howard: Right.

Dr. Rapp: But in terms of what we're calling participation. It's an effort to be involved. But—

Dr. Howard: No, I'm curious about that because I'm just wondering how many people of that subset that participated by your definition actually successfully did that. You have a pretty low participation percentage, but how many…

Dr. Rapp: Well, we estimate that to be slightly over half. That's what our preliminary data indicates. So we expect that of that 16%, a little over half of that will successfully report and therefore qualify for the…

Dr. Howard: Yes, I guess I'm just concerned with the participation.

Dr. Rapp: It's just a way of describing, let's put it this way. 84% didn't seek to submit quality data codes at all. So that, but let me just make a little comment about that. The 84% we did look at that, who was in, because people frequently ask me about the 16% but they don't ask me much about the 84%. And that's I think one our interests—what about the 84% that didn't. Well it turns out that around half of that 84% saw 50 or less Medicare patients during the second half of the year and 25% saw 10 or less. So when you just look at 16% of the NPIs, you're talking about every NPI out there. It doesn't really even mean that practitioners that see Medicare patients hardly at all, but as I say half of the 84% saw 50 or less patients. So I think we can understand that maybe our optimal number is really not necessarily what you might think of in terms of hospitals, because hospitals are general facilities. They all have large number of Medicare patients except we don't deal with children's hospitals particularly for obvious reasons. But it's sort of similar, so I think that 16% might strike you as that's kind of low, but when you think that your universe is all NPI numbers and not necessarily those practitioners that are really actively engaged in treating a substantial number of Medicare patients, I think top number will come down quite a bit below what you think you might have 90 or 95%. It would probably be more in the range of 50 or 60.

Dr. Ouzounian: This comment actually is a carry over from the discussion we had before lunch and through lunch, and I'd like to lead into a resolution. I'm not sure how much the left hand talks to the right hand. I got a hunch that they probably do talk to each other. But you've made a presentation about the PQRI and we heard a presentation about what's being contemplated to do with that data, and put it in the public domain with some implications to physician quality, and that's not something the physician community was told about when this option was given to us. So with that concept in mind, I would like to make a resolution that PPAC recommends that in the event that any PQRI data is going to be put into the public domain, and made publicly available, that physicians have knowledge of that at least 2 weeks, 2 years in advance of it reaching the public domain.

[second]

Dr. Bufalino: Discussion?

Dr. Przyblski: I assume you mean physician specific PQRI data as opposed to hospital PQRI data that's already of public domain.

Dr. Bufalino: That was implied if we could make that amendment, I would appreciate that.

Dr. Bufalino: Would you reread that—I'm sorry, Chris?

Dr. Standaert: My question too then would be not just to give us notification but there's no, some sort of appeals process or other way to clarify the data. Because what they've just said is people who didn't have like, for example if the clearinghouse couldn't handle NPI, even if you tried, it got thrown out. So it looks like you didn't try. And so if they don't accept the data for some reason, or your data doesn't go through for some other reason, it comes in the sort of pass fail thing—did you pass it and meet this bar? Or you didn't meet it. You're going to fall into the fail category and so if they put this data in but there's very little sort of role for physician recourse or physician sort of feedback into the system, saying no you said I didn't pass but that's because—it leaves the physicians really with nowhere to go. They say we're going to put it on. You got 2 years whether you like it or not it's going. And there's no way to sort of modify what happens inside that box.

Dr. Ouzounian: I would agree with you. I'm a kind of a splitter rather than a grouper, because we do that as a separate resolution?

Dr. Standaert: Yes, OK.

Dr. Bufalino: Dana, you want to read that?

[Unidentified speaker]: which I second, by the way. [laughter]

Ms. Trevas: PPAC recommends that in the event that any physician-specific PQR data be placed in the public domain or made publicly available that physicians have knowledge of that at least 2 years in advance of reaching, of the information reaching the public domain.

Dr. Ouzounian: Does it need to say provider instead of physician? Does physician include the podiatrist?

Dr. Rapp: In the statute, they're eligible professionals. Physicians and other eligible professionals if that's what you're trying to deal with the statute that--

Dr. Ouzounian: Then it needs to say "physicians and other eligible professionals."

Dr. Bufalino: All in favor? I'm sorry.

Dr. Smith: I want to make sure. I hear that they could do that, they could release this year's data two years from now. Under what you just said and I think or at least what I would hope it would mean is that they could not release data for 2 years after all physicians were made aware that during the reporting period to be released, these data would be used.

Dr. Ouzounian: I accept that friendly amendment.

Dr. Smith: OK. Because I think that's what we want.

Dr. Ouzounian: That's what I'm trying to say. Just not very articulately.

Dr. Smith: Because it does us no good at all if they release this year's data.

Dr. Ouzounian: No it doesn't

Dr. Standaert: [inaudible] I mean we need to put the word "prospectively notified" or something, maybe even notified before they even say that they're going to collect the data, that they're going to release the data they will collect. That's what I think she just, the word prospec—I don't know if prospective is the right word. Be told before the collection of the data that this data will be released.

Dr. Ouzounian: That's what I'm trying to say.

Dr. Standaert: I'm just not sure what the right wording is there. Prospectively? Yes. Physicians and other healthcare providers, healthcare professionals be prospectively notified that the data to be collected will be used at least 2 years before the collection of that data. Before the release of that data. Something like that.

Dr. Ouzounian: Thank you.

Dr. Bufalino: Can we go it on that motion? All in favor?

Dr. Smith: Well Dana has to scratching her head as if…

Ms. Trevas: Yes, I'll work it out.

Dr. Bufalino: We'll adjudicate at the end. All in favor?

[Ayes]

Dr. Bufalino: Any opposed? Thank you. Other discussions?

Dr. Ouzounian: Well there's a motion on the table.

Dr. Bufalino: Oh, I'm sorry, second motion.

Dr. Standaert: Yes, the second motion.

Dr. Bufalino: Why don't you think about that motion.

Dr. Standaert: Yes, let me think about that.

Dr. Kirsch: I just have a question, a clarification. I just want to understand the 80% rule a little bit better. You were saying with type 2 diabetes, that you can tell by the ICD 9 codes who has diabetes and can determine 80% from the claims on that. How do you do the preventive care? Is that all comers, 80%? Or how do you, or 80% that you start the reporting process or from what group do you pick the 80% when you do the preventive care?

Dr. Rapp: It's the procedure codes, so there's a limited subset of CPT procedure codes like office visit codes, principally. So as long as they're in the office visit code, they fit into the, there's no denominator ICD9 codes. So it's anybody that fits in those procedure codes. So if it's your standard office visit, E&M code, it's 15 consecutive, literally—

Dr. Kirsch: And you happen to do a move [accept? 49:44] that person, then gets put into that 80, that pool from which the 80% is pulled from.

Dr. Rapp: It has to do with, you just need to look at what the denominator codes are, so I think they're basically your standard office visit codes and some others and you just, if you put down on the claim for that patient, one of those procedure codes, then they're in the denominator. If it's for some reason you put something totally different down that's not in that set of CPT procedure codes, then it wouldn't, so you just need to look carefully—

Dr. Kirsch: So anybody that fits in that category of any of the 9 items, if they have a CPT code that falls into that, they become part of that pool then from which the 80% is pulled from?

Dr. Rapp: No, the pool comes from the denominator, made up of, it's first of all consecutive patients, but it's the pool of consecutive patients as determined by, when you bill for them, are you using any of these probably 10 or so different procedure codes in billing for that patient? If you're not, then they're not the next patient. If you, let's say we only had 1 procedure code, which is intermediate office visit. It's not like that, but let's say it was. So the 15 consecutive patients for which you bill an intermediate office visit, they would fit in the denominator. If you bill something else, like I sewed up a laceration, they wouldn't fit in there. Unless you also billed an intermediate office visit code. That's what it's the billing codes that get them in the denominator.

Dr. Kirsch: OK.

Dr. Rapp: And once they're in the denominator, 15 consecutive patients that fit in that denominator. So like in the diabetes, what gets in the denominator is the office visit kind of codes usually, plus a diagnosis of diabetes. And so if you, if the second patient you see that day doesn't have that diabetes code, then they're not a consecutive patient.

Dr. Kirsch: It's more straight forward diabetes, with preventive care codes, it's a little bit different. You could see someone for their high blood pressure and that day give them a flu shot and say oh I need to give you your Numilvax and so then you've done one the things that are reportable on.

Dr. Rapp: No, you report all of the preventive care on that same—

Dr. Kirsch: Right, but that gets that person into the pool.

Dr. Rapp: The office visit code. If you put an office visit code in there, then that gives them the pool. If you don't put an office visit—I don't want to quote what the denominator is because you just have to look at the codes because we have the 119 measures and I don't have them committed to memory, but that's what you need to look at.

Dr. Bufalino: Greg, last comment?

Dr. Przyblski: You made a comment that 50% of the non participating physicians saw fewer than I thought it was 20?

Dr. Rapp: Fifty.

Dr. Przyblski: Fifty Medicare patients. In the 16% that did participate—

Dr. Rapp: In the second half, in the second half of 2007, according to our preliminary data.

Dr. Przyblski: And the 16% that did participate, what was their volume of Medicare patients?

Dr. Rapp: I don't know.

Dr. Przyblski: Because if it's the same number then that's not really a good explanation as to why they may have chosen not to participate.

Ms. Nelson: That particular analysis, the analysis that you're looking for is schedule to start running after we finish the who qualified for an incentive payment, just to get them out.

Dr. Rapp: And I'm not saying that's the explanation. I'm just saying it could be an explanation on low volume of patients. And I also want to make one other point in terms of the participants. There is a physician group practice demonstration. And the physician group practice demonstration itself involves a lot of data collection and that data collection, those who participate in that data collection, just the way the demonstration works are also qualifying for PQRI through that. And so some of the statistics on who's participating, how many, and so forth, so that's another several thousand that are actively participating through the physician group practice demo, and also both large practices and small practices.

Dr. Bufalino: Well, we're going to save your resolution for the end of the day and we've got an 80-slide presentation that's, we'll save the resolutions for the end.

Dr. Smith: Can I ask one quick question and maybe I'm being naïve here, but Medicare doesn't pay for preventive care, so if you do preventive care on this patient, is that going to kick out the whole claim?

Dr. Rapp: Well, Medicare does pay for, Liz is the expert on what we pay for and what we don't—

Dr. Smith: I know you pay for flu shots and pneumo vacs and so on, but

[crosstalk]

Dr. Smith:…pay for preventive breast exams, so you order a screening mammography, is that going to kick it out as a non—

Dr. Rapp: [inaudible crosstalk] screening mammography.

Dr, Simon: There are a number of preventive screening tests that Medicare pays for—

Dr. Smith: Yes, I'm aware of that. I'm aware of that you do, but there were some things on this list that looked to me as if they ran the risk of like inquiry regarding tobacco use and advising smokers to quit and weight screening and follow up that Medicare doesn't pay for. I mean they'll pay for a diagnosis of diabetes or hyper lymphodemia or something but.

Dr. Bufalino: thank you both for being here. We appreciate it.

Dr. Rapp: You're welcome.

Dr. Bufalino: And thank your patients for keeping us moving along on the agenda. Next we have Dr. Valuck. He's joining us again. He's been here a number of times. Actually this is the new renewed skinny Dr. Valuck. [laughter] who's a medical officer and senior advisor for the agency and we're glad to have Tom back. He has extensive experience MD, JD, as has Dr. Rapp. They bring their expertise both in the clinical and the regulatory side so glad to have you back, Tom.

Hospital Value-based Purchasing

Dr. Valuck: Thank you. Thank you Mr. Chairman, and it is good be back in front of the group. I promise you, I'm not going to talk extensively about all 80 slides so I won't throw you that much off track. But I do want to provide a high level over view of the initiatives that we have going in value-based purchasing that are complementary to the PQRI that you just heard about and where the PQRI really fits in to that higher level overview. So I'll be with, I believe the second slide has the over view. I'll begin with just a quick review of what we're looking to accomplish through our value-based purchasing, connecting quality to payment. And touch on demos and pilots and then spend some time particularly on the VBP

1 programs that are centered on hospital services, and then I have a few closing slides, which we may or may
2 not get to. So Heather I'm going to be moving very rapidly here.
3 You heard about quality improvement roadmap this morning, and in fact this slide duplicates one
4 that you've already seen, you just recall that our vision for quality and connecting quality to payment
5 really, I'm not just talking about when I use quality, just clinical effectiveness or just patient safety,
6 although those are very important. But also efficiencies I think, so cost of care, as well as patient
7 centeredness and the other dimensions of quality.
8 The next slide has the 5 strategies of the quality improvement roadmap, value-based purchasing is
9 clearly one of those, and then those initiatives are related to the other four strategies as well. The next slide
10 has the program goals from the perspective of the 6 key dimensions of quality. But it also brings in the
11 transparency point here, this point that I know we've been talking about today, around the importance of
12 getting good information out to consumers and to others to make better evidence-based healthcare
13 decisions. The next slide is I do want to spend a little bit of time here, because you take all of that vision,
14 strategy, goals discussion, those kinds of documents that we all have in our organizations and you have to
15 boil it down to what does that really mean? Well, it really means that we're transforming the program from
16 simply being a passive payer of claims, or like an indemnity insurer, to a more active purchaser of higher
17 quality more efficient healthcare. And we have some tools to do that that we've been given in our
18 authorities from Congress. Clearly measurement is the foundation of value-based purchasing and then
19 payment is a piece of that, but so is public reporting, our Conditions of Participation, which you can think
20 of structure standards, coverage policy and direct provider support through the QIO program. Then we can
21 use those authorities in various ways to inform the kinds of initiatives that you see like our Pay for
22 Reporting programs for physicians and hospitals, moving toward Pay for Performance and other things that
23 we're currently demo-ing, like gain sharing and bundled payment, and so on. So why are we headed in this
24 direction?

The next few slides are the support for value-based purchasing. And this is a place where you as an informed participant in the healthcare sector, where we don't need to spend a lot of time. We know we have a quality improvement arbitrage and opportunity there. We know we have the opportunity to avoid unnecessary costs and probably more importantly from our perspective, as fiduciaries for the Medicare Program, we know that our payment systems are a part of the problem. So we need to look at the misalignments and the, what an economist might call perverse incentives, in our payment system and through application of these various tools to advance the goals that we've talked about in terms of quality and cost.

The next couple of slides are maps, one of which you saw this morning, that just lay out the cost of care variation in this slide, and in the next, the quality variation. And it adds up to a disconnect between the use of our resources, as displayed in the next slide, and what we would like to be providing in terms of the value of what we're buying. Then just is a reminder that this isn't just an initiative of this administration. But it runs broad and deep. I'm starting to get a lot of questions about OK, so we're going to have a new President. When's this all going to go away. [laughter] Well, when you look at the ongoing interests of Congress over several different Congresses since we got, for example, the physician group practice demo authority and [BIPPA? 03:32] and early part of this decade and all the way through every one of the major Medicare bills, the advisors to Congress and the administration like MedPac and the Institute of Medicine, providing very strong support to continue to push us in this direction and not only for the Medicare Program but for the whole healthcare sector, and we learn from the private sector and they're learning from us. So this is broad and deep and we'll continue to push forward.

So if that's the direction, then we have some demonstrations and pilot projects that are helping us understand how to do it in the most effective way to achieve the goals that I discussed, that the next couple of slides really are just to demonstrate that we have again, across many different settings in lots of different approaches. Hospitals, physician practices, nursing homes, home health, end stage renal disease, care coordination, disease management, gain sharing, data aggregation, role of EHRs, medical home, etc. Lots

1 going on there. So there's a big investment to figure out how to apply these tools in ways to advance the
2 value of the services.
3 Premiere Demo, again, that was discussed this morning. So we can move on. So that's the goals
4 and how we're looking at approaching the opportunity. We already have some ongoing initiatives that
5 we're working on that we have statutory authority for. And the hospital arena really is what I call the road
6 map for how we might implement value-based purchasing across our various payment settings. So I'm
7 going to be focusing of course today, on the hospital setting. But just to put it in perspective, we also have
8 the PQRI, which you see there, physician resource use, so figuring out how to add the cost of care measures
9 to the kinds of measures that Mike was discussing with you in the last presentation. And then we already
10 have a home health Pay for Reporting going and some of you will be aware that we have various Medicaid
11 value-based purchasing initiatives happening through the state run Medicaid Programs. Over half,
12 approaching 2/3 of the states have some component of value-based purchasing or Pay for Performance in
13 their state Medicaid programs.
14 So let's talk about the hospital setting. So in the early part of this decade, hospitals began reporting
15 a starter set, as they called it of 10 measures, which was initially a voluntary program through the Hospital
16 Quality Alliance, and Congress looked at that in the Medicare Modernization Act of 2003, put in place a
17 payment differential for hospitals that reported on that starter set of 10 measures and then that material
18 would be publicly reported on the compare website. Over 98% of hospitals participated for that .4%
19 differential payment. The next slide you see that in 2005, the Deficit Reduction Act, Congress extended and
20 expanded that Pay for Reporting program for hospitals. The differential's now 2% and the measure set has
21 been expanded with further consideration being given in the current round of rulemaking to expand the
22 measure set again. In terms of the hospital value-based purchasing move from a Pay for Reporting to Pay
23 for Performance, we were mandated in the section 5001(b) of the DRA to design a report or design an
24 approach that would be reported to Congress for true Pay for Performance or value-based purchasing for
25 hospitals. And I'm going to spend some time on that. Mikes going to talk about the measures piece of that

and then I'd like to also talk about hospital-acquired conditions for a few minutes, so that you can see where that fits into hospital value-based purchasing.

I mentioned the legislative background, from the Deficit Reduction Act, so we can move on to the next slide. We got a group together to look at the various pieces of the plan that we would be putting together and had contractor support put in place, and then the next slide shows our milestones and deliverables. We begin with an environmental scam of current practices in the hospital sector, private sector typically. We did an issues paper, and discussed the issues in a listing session with the stakeholders and that led to an options paper, which we also discuss with the stakeholders and then designed the report and submitted that to Congress on November 21st.

This is just a quick overview of the model. Here's where I slow down a bit because I want you to understand how the model would work because we would need to figure out if we would move, for example, on the PQRI from a Pay for Reporting into a Pay for Performance model. We might do a similar kind of scoring in incentive determination. So first of all, the hospital would be required to submit data on all of the measures that would apply to that hospital that are part of the measure set that would be selected and then we would score each of those measures from 0 to 10 points, based on either attainment or improvement. It's an important concept because it isn't jus the high attainers that would have the potential to earn points on a measure by measure basis, but those who showed significant improvement could also earn points. Then the points would be aggregated within the category of measure, for example, clinical process measures or HCAP measures, or outcomes measures, and HCAPs is the survey of patient experience within the hospital, the patient satisfaction survey. And then we would weight each of those categories and sum them to give the hospital a total performance score. That total performance score then be used to determine and incentive payment using an exchange function. Now I have slides to explain each of these steps, but that's the gist of it. Measures, measurement data is scored, aggregated, and then that aggregate score is translated into an incentive payment.

The next slide emphasizes the point that both attainment and improvement are relevant here, to engage everyone, including those who need to improve. The next slide gives some definitions but since you have this in written form, I'm going to be referring back to it, rather than talking to it as we go on to the next slide which lays out a graphical representation of the model. So this is how points would be earned on a measure by measure basis. This is a measure, pneumococcal vaccination, that's been in the hospital Pay for Reporting program for a few years now, so we have quite a bit of experience with it, and that experience, that empirical data can be used to set the attainment threshold that you see there and the benchmark. The attainment threshold would be the 50th percentile performance, so basically at the 50th at the 50th percentile, 47% compliance with the measure was 50th percentile. At the 95th percentile, which is the benchmark, the compliance in the empirical data was 87%. So the attainment threshold in the benchmarks set the attainment range. And if you see that range below in blue, if the hospital scores between the attainment threshold and the benchmark, they earn up to 10 points. Anyone scoring above the benchmark, would earn all 10 points. For the improvement range, that's hospital by hospital. This hospital I, the big improver here, their baseline score in the first year or the previous year was 21% compliance with this measure and so then that sets their lower limit for the improvement range. The upper limit for the improvement range is again the benchmark, and if they were to exceed the benchmark in their improvement, they would also get 10 points. But otherwise they can earn points on either the attainment range or the improvement range. This hospital in their performance year scored 70% compliance with the pneumococcal vaccination measure, so that would earn them 6 attainment points, but 7 improvement points, giving them the higher score of 7 for this particular measure. Now if you would look at the other clinical process of care measures and score each of those, and add those all together, then that would form one domain for the total performance score. Another domain would be as I mentioned, our survey location experience, and the next couple of slides show that HCAPs could be scored in a similar way. You look at a particular domain of the HCAP survey or dimension of the HCAP survey, in this case, Doctor communication, again, an attainment in threshold and benchmark, based on the empirical data and then

where the hospital scores determines the number of points they receive. There is a bit of a twist to this one. And the next slide because the HCAP survey is a cohesive instrument, there's the ability to add in another dimension here, which is intended to encourage hospitals to bring up their lowest scoring dimension. So we would actually award points based on how high the lowest scoring dimension was to again, encourage attention to that lowest scoring dimension. So then, like the process of care measures, the HCAPs measures dimensions could be summed as in the next slide, and then those dimensions could be weighted and summed for the total performance score.

So one of the decisions that needs to be made along the way is how you would allocate the points. In this case, we have in our report to Congress, we have allocated 70% of the weight to clinical process of care measures, and 30% to patient experience. As you would add in other domains, like outcomes or care coordination or whatever you would add in, efficiency, you'd have to consider how to reweight to get that total to 100% And then the next determination is how to translate that total performance score into an incentive payment. This slide just demonstrates how the summing could be done. But the next one is an example of an exchange function that could be used to translate that performance score into some sort of payment incentive. In this case, hospital A earned close to 60% of the possible performance points on their total weighted score, and then using this exchange function, that would translate into approximately 80% of the incentive payment earned back. So this is just one way to use a total performance score to determine some sort of incentive payment.

The next logical question is OK, so they earned 80%, but it's 80% of what, and we proposed in the plan in the next slide that we would base the incentive on a percent to the base operating DRG. So the next slide then shows that not all of the money would be allocated in the first round, since not all hospitals would earn 100% back, so there, if the intention was to keep the program budget neutral, then we would have to redistribute the remaining money, based on some approach or that savings could be considered shared savings for the program, given that it wasn't all earned based on meeting the benchmarks for the

measures, so it was less than the highest standard of care, so we would be paying less for that. The next slide is the part that I'm going to ask Mike Rapp to present.

Dr. Rapp: Well Tom went through the details of how the incentive program would work. Fundamentally, all such programs have to be based upon the measures themselves. So I'll go through briefly for you the measure, the selection considerations, the proposed processing for introducing and managing measures and BBP, the candidate measures for the fiscal year 2009 financial incentive, and additional measures beyond that, and touch on the small measures issue.

The starting point is to have measures that meet a number of criteria. And similar to in the PQRI, we focus on consensus measures that the NQF is the best standard that we have, NQF endorsed measures have various criteria that they looked for in terms of evaluating the measures, before they have them endorsed. So these are important scientific acceptability, feasibility, and usability but when you deal with something for value-based purchasing, these are criteria that are typically used on public reporting of measures, but when you think in terms of putting incentives for measures, you think in terms of other possibilities. The mere fact that you're adding an incentive to it creates, that is a financial incentive, creates a greater desire to make the measures better. It makes them more prominent even than if you simply are publicly reporting them. So what that led us to do was think about well what are the types of criteria above and beyond those basic parameters that you would need to have NQF endorsement. What else would you have to think about? Well, first of all, improvability. Obviously if you're going to put a financial incentive on something, the idea is that you want to make it improve and if you have only measures that are topped out so to speak, for which there's very high performance then they may not be too useful, although there is some argument even for financial incentives just to maintain high levels of performance for very important processes of care; controllability, the fact that the provider of the care would be able to control those processes. We also have to think about a potential for unintended consequences, even more so again, you're increasing the reasons why the providers would want to score well on these, so if you have possible unintended affects—and one example that we looked to in terms of the value-based purchasing plan was a

1 measure that was then current, which was antibiotics for pneumonia, given within 4 hours of arrival at the
2 hospital. There was some indication that that was causing practitioners in emergency departments to simply
3 give antibiotics without regard to whether the patient had pneumonia, in an effort to make sure that they
4 didn't fall behind on that particular measure. So we did not include that one, even though that was used for
5 public reporting. We did not include that measure. And contribution to comprehensiveness. There's an
6 interest in having broad applicability and not just a focus purely on a few narrow issues. So when you think
7 about the measures for value-based purchasing then, there's a few other factors. For public reporting,
8 you're going to collect the data and then once you've got enough data, that's reasonable to put up on a
9 website, like we will typically have several months of data before it'll be put up. But it takes a while to
10 collect that and evaluate it and calculate the measures. But when you're talking about value-based
11 purchasing, as Tom talked about, you have improvement points. For improvements, you have to have a
12 baseline for what you're going to improve against. Improve against. And so that takes time and then of
13 course you have to get the measure to the point that it is useful. In short, I would say what measures that
14 one uses for value-based purchasing has to have is stability. You can't have a measure that's constantly
15 changing in terms of what should be done to specifications and so forth and so again, it adds another
16 ingredient above and beyond what we have to deal with for public reporting. But this just sort of outlines it
17 that the development, testing, endorsement process, takes a certain period of time. Then you want to have
18 the measure implemented, and then you want to have the data gathered so that you can actually implement
19 the value-based purchasing methodology.
20 A point, just to make, that there's a broader universe of measures that can be used for public
21 reporting, and a smaller subset that's used for value-based purchasing. In the plan, all measures would have
22 to be submitted for public reporting, but not necessarily all measures would be used for the actual incentive
23 payment. Here is a set of measures, basically the proposed 2009 measures come from those that are
24 currently on hospital compare or then were on hospital compare. But over time, these would be expected to
25 be moved in and moved out. The practical fact that we're facing right now is the number of measures have

been in use for quite some time and as a result the process of care, such as aspirin on arrival and so forth, these have gone to the point that they are very highly applied processes for the care of these different conditions. Other measures are quite different in that respect. Thrombolytic agent within 30 minutes of the hospital arrival. Timing for primary percutaneous coronary intervention is another one for which there's quite a good distribution.

There is currently on hospital compare, two and soon to be three more mortality measures, 30-day risk adjusted mortality for AMI and heart failure. And we also have patient-centered care measures, the HCAP survey measures. The mortality measures currently are being developed, the measures are developed, but the process for incorporating them into the scoring methodology for value-based purchasing is currently been worked out. The HCAPs has been worked out but the goal is to have all of them together. HCAPs dimensions are just listed there for your information, a broad array of items that patients are interested in. Looking to the future, we're looking to develop measures with regard to efficiency, emphasize outcomes. We have some interest in additional emergency care measures, care coordination, patient safety, and structural. These are just measurement priorities and priorities in general for HHS and CMS and so as we look to the future, these are the kind of measures that we look to develop and also to incorporate in the value-based purchasing plan and value-based purchasing program if that's authorized by Congress. So I'll turn it back now to Tom.

Dr. Valuck: Thanks Mike. The last slide here in this particular subsection just is the URL for the hospital VBP report to Congress. The next subsection which has a lot of background material in it but I think some important points in it to take away about our hospital acquired conditions, payment policy as well. So we can move quickly through it, but it will help to make the connection I think between what we're trying to accomplish in the VBP plan approach that we just covered, which is based more on longitudinal measurement of quality versus this what I call claims by claims adjustments for the occurrence of certain hospital acquired conditions, basically claims by claim adjustment for patient safety. The next slide then just reiterates that this is part of value-based purchasing for hospitals, and just want to point out

1 the strong support that we've received from the public; the media consumers, purchasers, to continue to
2 push ahead with this policy, when we announce the first round of rule making on hospital acquired
3 conditions, last August. The next 3 slides lay out the high level of the extent of the program. So the next
4 slide is the Institute of Medicine's data on the extent of the problem. The following slide specifically
5 focuses in on hospital-acquired infections, with some CDC data and other reports in the literature and then
6 the next slide just shows that the delivery system is a big part of the problem; that hospitals do not
7 consistently follow the evidence-based recommendations, from, for example, CDC guidelines. So as
8 clinicians working in hospitals, I don't need to spend more time on making the case for the urgency. I think
9 we would all agree that patient safety is in urgent need of being addressed in whatever way. And this is one
10 approach. The next slide lays out the approach, our statutory authority is in the Deficit Reduction Act
11 again, together with the hospital pay for reporting extension and the authorization or the mandate for the
12 plan there's a third subsection in 5001 that requires us to do the two things that you see here, related to
13 hospital acquired conditions. One is to begin reporting an indicator as to whether or not the diagnoses on
14 the hospital claim were present on admission. That would give us new information, useful for a lot of
15 different purposes including public health and knowing what's happening in the community, versus in the
16 hospital. Also to inform a payment policy. And that's what the second bullet is about, that we are required
17 under the statute to select conditions that we would no longer assign a higher paying DRG to based on the
18 occurrence of one of those conditions, that it wasn't present prior to the hospitalization, that it was hospital
19 acquired. And then there are some additional criteria that we must meet in order to select those conditions.
20 The conditions must be high cost, high volume, or both, meaning that they have to be important to our
21 beneficiaries and to the Medicare program. They have to be assigned to the higher paying DRG, this is
22 payment initiative. And then the third is really the crux of this policy; that the condition must be reasonably
23 preventable through the application of evidence-based guidelines. So there's a lot in that 3rd criteria. And
24 first of all there have to be evidence-based guidelines that are generally accepted. And then, once those
25 guidelines are applied, there also has to be the ability to determine that the condition is reasonably

1 preventable based on those interventions. The next slide is just another way of stating those statutory
2 criteria. So I'm going to skip now to slide 57 because the intervening slides really just explain the statutory
3 criteria. And if it's not clear to you, I'd be happy to talk in more detail about that in our Q&A. But
4 according to the statutory criteria that we had, high cost, high volume, trigger the higher paying DRG, and
5 also reasonably preventable through the application of evidence-based guidelines, we selected these 8
6 categories of conditions during last year's rulemaking. The first 3 are part of the National Quality Forum's
7 list of serious reportable adverse events, and they're the ones that even the hospital industry, where I think
8 fairly supportive of adopting under this policy, so where there's a foreign object, unintentionally retained,
9 or an air embolism or blood incompatibility, partially because those are so rare as to be never events, but
10 partially because it's pretty black and white that there's some direct accountability there, those were
11 generally supported. The three infectious conditions raised a number of questions about whether or not they
12 were reasonably preventable; catheter associated urinary tract infection, and vascular catheter associated
13 infection, surgical site infection in one specific case was also selected and then we selected two conditions
14 that were not infections; pressure ulcers, actually stage 3 and 4 pressure ulcers also on the NQF's list of
15 serious reportable adverse events, as are a number of the trauma codes, codes of things that result from falls
16 like broken bones, concussion, and then other trauma codes, shock, burns, etc. So when these conditions
17 occur, starting October 1 of this year, we would no longer pay the higher DRG amount, based on the
18 occurrence of these particular complications if the only complications on the claim are those that are on this
19 list. So we believe that there are good public policy reason to encourage the prevention of these patient
20 safety incidents and thus they were selected.
21 The next 4 slides just lay out in the 3 columns here the information relevant to the three statutory
22 criterion. So the Medicare data that supports high cost, high volume, the Medicare data about the codes, so
23 the payment implication, and then the guidelines that are present. And then on slide 62, you see the 9
24 categories of conditions that are proposed in the current round of Inpatient Prospective Payment System
25 rulemaking for comment, to also be adopted for payment implications beginning this October 1st, for fiscal

1 year ’09 hospital claims for payment and you see we continue to push forward with certain infectious
2 conditions. Also DVTPE, iatrogenic pneumothorax, delirium, and extreme glycemic aberrancies.
3 Dr. Przyblski: As you’ve gotten into these infectious conditions on this slide, compared to the last,
4 it started off with never events that I think most logical people would say you should never operate on the
5 wrong limb; you should not retain a foreign body after an operation. One thing that’s always bothered me is
6 the ventilator assisted pneumonia and I’m sure others have other examples of that. I don’t know anybody
7 who has a stroke, who ends up with a GCS of less than 8, who gets intubated and ventilated for a period of
8 several weeks while they are comatose, who’s not going to get a pneumonia. And how to believe that that is
9 somehow the fault of the hospital or the practitioners seems to be very, very extreme, and I don’t
10 understand the logic, how some of these things have gotten onto the list.
11 Dr. Valuck: So our selection process included extensive consultation with the CDC about their
12 evidence based guidelines. We had a day-long session with the stakeholder community where we took
13 input about various conditions; some of these were discussed in last year’s round of rulemaking, some of
14 them were presented at various points, either during last year’s rulemaking or subsequent to that, either
15 through our work group or CDC or this stakeholder session that I talked about. At the current point, all of
16 these are presented to the public for comment and we’ve asked in each specific case for comments
17 regarding particularly that criteria 3, whether or not from that stakeholder’s perspective, that there’s a belief
18 that these things are reasonably preventable through the application of evidence-based guidelines and we’re
19 starting to get some of the comments in. I reviewed 45 of them over the weekend and found them to be
20 very enlightening. You would be surprised at the breadth of the responses. I guess if you put yourself, for
21 example, in the beneficiary’s position you might think differently about what should be considered
22 reasonably preventable. But we’re interested very much in your input so please comment.
23 So again we’ve got a number of slides here that lay out the discussion according the various
24 statutory criteria and then I just want to briefly reference the present on admission indicator reporting,
25 which starts on slide 69, because there’s a significant component of collaboration that needs to happen

between the hospital staff and management and the medical staff in the hospital environment in order to correctly code whether or not these conditions are present on admission. This is going to have an implication for hospital payment so you can bet that it's going to get a lot of attention. So we've begun working jointly with the AHA and their coding clinic for example, together with the AMA, PCPI, and others at the AMA to figure out a joint approach to getting the word out about how to appropriately code and document present on admission. So we don't need to get into the details of the coding of this, but on slide 73, there's a quote from the coding manual that is generally applicable. But I think it's particularly applicable in the situation of the present on admission indicator reporting that if there isn't complete and accurate documentation on the part of those who are legally able to make a diagnosis, then the code assignment can't follow, so very important role for the physician here in correctly capturing present on admission indicator information.

One last point that I want to make is about the connection between our hospital-acquired conditions and the NQF's list of serious reportable adverse events, which you all might refer to as the never events. In the next slide, so I would just point out that our criteria for selection under the statute, for the [inaudible/noise 37:14] are related to but are not synonymous with or not 100% overlapping with the NQF's criteria for selecting their serious reportable adverse events. In the use of our list for payment purposes is a little bit different than the use of the NQF's list, which was supposed to be for reporting for example to a state data base on the occurrence of these events. So connecting them is something that we've been doing to the extent possible through the things that we've adopted and the things that we've proposed, but I would point out that in terms of combating never events, the HAC payment provision is only one of the approaches that are currently under consideration. So we also have our Conditions of Participation, we have structure standards there, we've got the VBP planned model that you just saw, so we can turn some of these things, particularly those that tend to occur more often into longitudinal measures over time that we could incorporate into the VBP methodology. We've got our coverage policy. We've got our direct provider support through Quality Improvement activities, and then there was a President's budget proposal

about not paying for these kinds of things, which would be different than the HAC payment provision. So lots of attention going into patient safety in the hospital setting in this point in time. I'm going to end there so we can leave time for questions and answers. Thank you.

Dr. Bufalino: Thank you both. It's open for discussion.

Dr. Standaert: I didn't see it discussed in there. Is there a consideration or a denominator factor for sort of complexity of the patients. For example, I work at a, the hospital I work at is a level I trauma center community hospital. We're 2 blocks away from a private pay hospital. We see a very different patient population, and to expect similar rates of hospital related conditions, like pneumonia, like UTI, like DVT, to expect them to be similar between the two hospitals is absurd. The patients are radically different, and there's a concern from the hospital standpoint about hospital ratings, but I've heard surgeons also talk about their concerns about how this is going to reflect on their own personal individual sort of ratings once you get back to PQRI that the patient population they're confronted with is so much more medically complex, and much higher risk. You have overweight, diabetic smokers with multi-trauma and broken limbs, who have a stroke, who you know, they're clearly at much higher risk, and therefore to pin the development of all adverse events, not the never events, but the other adverse medical events, solely on either hospital or provider error is problematic from that stand point.

Dr. Valuck: So your point is a good one and it crosses both of the topics that were covered in terms of the hospital VBP plan as well as hospital-acquired conditions, and then it also is much broader in that it crosses all of the measurement efforts that we have. So let me address it from the point of the hospital initiatives first and then Mike may want to chime in on risk adjustment or case mix adjustment or whatever adjustments you're thinking of, more generally in terms of measurement. So in terms of the hospital VBP plan, we're using measures that are appropriate to accomplish their goals. So for example, the two domains that are currently a part of that plan because those are the ones that we have in place already are the clinical process of care measures, and are patient experience of care measures. Now both of those apply to all types of patients. In other words, if a process of care is appropriate for a certain condition, it

1 would be appropriate for a high risk or a low risk patient and presumably should be accomplished in all
2 types of patients. So the adjustment is less of an issue in the process of care measures, and that's primarily
3 what we have right now for the hospital VBP plan. As we would move into the outcomes domain, as Mike
4 will tell you, those outcomes measures are adjusted in the way to reflect the concern that you have. In terms
5 of the hospital-acquired conditions, on slide—and I know you have these slides in front of you so we don't
6 need to really go back in terms of the presentation. But there was an additional slide for discussion here. It
7 was toward the end, number 75 that looks at ways that we might take this fairly blunt on or off about when
8 a condition occurs that we would no longer pay more or not, that we could potentially scale that payment
9 differential. So if for example, in the hospital that you describe that sees the more complex kinds of
10 patients, there might be a way to determine when their patient might be expected to have their certain kind
11 of complication arise more frequently than the hospital down the street that's not taking those more
12 complex patients than their payment differential could be less than the hospital that would be expected to
13 have that kind of complication occur as frequently. So you can look at adjustment in order to make the
14 payment policy more precise. Ideally you do that at the patient by patient level. We're not anywhere near
15 being close to doing that in the current state of the art. You might look at doing it on a hospital case mix
16 type level, you might consider doing it on a community level, you might consider doing it just for the
17 National Medicare Program. Maybe the payment differential for something that is more like a never event
18 would be the all or nothing, maybe something that's more likely to occur, could be less of a differential.
19 Those are things that we're also asking for comments for in this round of rulemaking.
20 Dr. Howard: Yes, I just wanted to wanted to add to that. I think when I see patients that are in a
21 house fire and they're have an inhalation injury in their smoke, or they can to the hospital, if they don't get
22 a VAPS, that's a miracle. So I think that I have some big concerns about that issue. The candidate ones it
23 sounds like you might be looking at modifying these maybe in the future, but we have, we teach residents,
24 which we get reimbursed by Medicare for and a lot of times when you're teaching residents, they do things
25 that you don't want them to do, like drop a lung. So I have a problem with having the iatrogenic

pneumothorax in this category and VAPS as well because we just don't have control over that. So on one hand, Medicare is saying we're going to help you guys because we teach residents. We're going to support your program. But when you're teaching your resident, if your resident you know, drops the lung and not only that, but the patient population that we get. I mean it's not always easy to do that. And I think it's kind of going back to what was said earlier. You're getting into an area where medicine is not black and white. And a lot of times we're really challenged by what we're given, that I call the physiologic black box of that patient. There's a lot of things that that patient had that we don't know about when they come in the door that we may never find out about. And a lot of those things contribute and are co-morbidities that we find out from something that shows up 3 weeks later, or there's just a lot of factors that are not in play here that make me concerned about these candidate HACs and I guess that I would ask that at least maybe we look into some way to modify that. That would at least give some of us a chance who we know are going to have a patient population that's going to be challenging to deal with and we're going to lose a lot of money for the hospital because of our practice and our luck with our patients.

Dr. Valuck: There is a lot of complexity when you start to think into some of these complications and how it would play and how you relate that clinical picture that you all have laid out with payment policy and how the two interact. It's been fascinating quite frankly and we will be instructed by the comments. I guess one thing that I would say is that there may be certain things that we would adjust for, but we certainly don't expect that resident care would be one of the things that would decrease the level of accountability for the hospital or the attending physician.

Dr. Bufalino: Could you speak to where the website is to get comments before we—is that in here?

Dr. Valuck: The website to get comments.

Dr. Bufalino: For you to get comments on these issues.

Dr. Valuck: Yes, there is a place. I don't know if anybody's here who knows how to submit the comments electronically.

Dr. Simon: We will find out and we will [crosstalk]

Dr. Valuck: I'm sorry, did I have the old slide in there? That's very important. I thought I had corrected all of the versions that had been sent out. The end of the comment period is June 13th. So it's incorrect on the slide that says that the end of the comment period is July 13th, that's slide 77. That should be June 13th.

Dr. Bufalino: Then hopefully we can within the week try to get out the correct access since there's some folks with some passion about this that we'd like to get some written comments sent to you.

Dr. Giamio: I'd just, to reemphasize some of the previous statements. I mean we're talking about trying to give antibiotics to patients within 4 hours of them coming to the hospital. There's going to be a high utilization of antibiotics in the communities to the members colitis, staph infections are now community infections, really that you're seeing coming bouncing back to you so I think it's going to be very difficult to delineate some of those things. It's a very tough job, so we have to direct everybody to this website to give you information, is that how you would like us to do that?

Dr. Valuck: For the, this particular website is where we have our information related to the implementation. There's a different place for you to submit comments, which we're going to be distributing to you all for your input.

Dr. Bufalino: Other comments. Dr. Smith?

Dr. Smith: Like in the 63, 4, 5, 6 etc. slides, you list $135,795 per hospital stay for ventilator assisted pneumonia. Is that what you're paying the hospital for that complication, or is that what the hospitals are billing you for that complication?

Dr. Valuck: Because we have not previously had a present on admission in here to figure out what was or wasn't present on admission before, we don't know exactly what the savings is going to be or what the additional payment is just related to that condition. Those are the average payments made when that condition is present on the claim as a secondary diagnosis. So it could be that they came in with one of the scenarios that was discussed, or post any other kind of procedure associated with any other kind of medical

1 condition. That's the average payment that was made for patients that had that secondary diagnosis on their
2 claim. We will be teasing all that other out though as we get better information with the present on
3 admission indicator and so on so these will be more focused on these kinds of table sin the future.
4 Dr. Bufalino: Last question.
5 Dr. Kirsch: [unintelligible] candidates, you've got delirium, but you only have 480 cases is that a
6 typo?
7 Dr. Valuck: No that is a result of the fact that that condition is not often coded. So one of the
8 things that we're finding is, I talked about the matching, the clinical scenario with payment policy. There's
9 a kind of a middle piece that tries to connect the two, and that's the coding system and our ability to gather
10 information is only as good as a) the structure of the coding system, b) the documentation that we put on
11 the records that the coders use and c) the coder's ability to capture that consistently. And sometimes the
12 payment incentives either encourage or discourage things being coded appropriately, and so that's
13 something that we're taking into consideration in the development of this policy.
14 Dr. Bufalino: Dr. Ross had a clarification.
15 Dr. Ross: Just a clarification on the stage 3 and stage 4 ulcers. Would these newly acquired ulcers
16 in the hospital, versus those that may have been let's say been proceeding at nursing homes of SNF units or
17 other types of facilities? And how did you differentiate those?
18 Dr. Valuck: So, the point is and I'm glad you brought this up because this is a good way to
19 illustrate the different roles in this and how the policy would play out. The payment policy is only applies
20 to conditions that were not present on admission. So this gives the incentive for the person who's caring for
21 the patient, presumably the time that the admitting physical is done, to do a complete assessment of skin
22 integrity to know whether or not something was present on admission, because if it is present, and it's
23 document, and it's coded that way, the hospital would continue to be paid. If it's not, then the opposite
24 situation. So in terms of public policy and thinking about our world, and using payment incentives to
25 promote better quality, presumably that attention to that would promote a better review at 2 in the morning

in the emergency department when the patients being admitted of the skin integrity to determine whether or not the condition was present on admission.

Dr. Bufalino: Thank you both for being here. Appreciate it. And I'm sure they'll be around a bit if you have some other questions. I'm going to take the liberty of skipping the break, because a number of you have early flights, so please be comfortable to get up and get a cup of coffee. And we'd ask Jody Blatt to join us for the last presentation. Jody is a senior research analyst and project officer at the Division of Payment Policy and the Office of Research and Development. Among her many responsibilities, she is currently designing and implementing the CMS electronic health record demonstration project. In addition, she's involved in the present demonstration project that Medicare Care Management Performance. So thank you, Jody for joining us.

Electronic Health Record

Ms. Blatt: Thank you very much for having me. Already today several of you have heard a couple of times reference to the many demonstrations that are going on at CMS. In particular, I've seen a couple of references to the electronic health records demonstration. It is one component in the administration's broad health HIT strategy in an effort to ensure that most Americans have access to a secure interoperable EHR by the year 2014. I want to start out at the outset by saying what this demonstration is not. And what it's not is a grant program to pay for hardware or software, but rather a Pay for Performance program to document the impact of financial incentives on the rate of adoption of electronic health records. And an effort to show that we can get better value for our healthcare through the use of technology. It's not intended to fully cover the cost of hardware or software, but we do hope that it will provide some incentive to physicians who are on the cusp or will help defray some of those costs that we know practices in particular small to medium size practices face in the transition to electronic health records.

This demonstration is modeled on the Medicare Care Management Performance Demonstration, or MCMP. That demonstration is currently operational in four states; Massachusetts, Arkansas, Utah, and California, and it started on July 1st of this past year with 700 small to medium-sized primary care practices,

1 covering approximately 2300 physicians and the average size practice is just over 3 physicians per practice.
2 There are a couple of differences. That demonstration is a 3-year demonstration. This is a 5-year
3 demonstration that will be implemented in 2 phases. The first phase will start later this year and the second
4 phase will start a year from now. We will be recruiting up to 12 sites, and a site is a state or a region. Some
5 of you may have been involved in or heard of the Secretary's recent trips around the country to encourage
6 participation in this demonstration. In fact, today, there was a press release. We've received over 30
7 applications from different sites, multi-stakeholder collaborative organizations to become sites where we
8 will implement this demonstration. We will announce the sites in June and I'll talk a little bit more about
9 that later in the in presentation. We do hope to recruit approximately 200 practices per site, 2400 in total
10 and I'll talk a little bit more later about the evaluation but it will involve the randomized design so that
11 there will be approximately 100 treatment groups in each site and 100 control groups in each site. I'll just
12 point out right now that practices that are participating in the Medicare Care Management Performance
13 Demonstration as well as this demonstration, as well as another Pay for Performance demonstration, we
14 have the PGP demonstration, are waived from participating in the PQRI program, and basically what that
15 means is by participating in this demonstration, they have access to that same set of incentive funds so they
16 don't have to report twice, but they can earn the 1.5% based on their performance in this demonstration.
17 Again, that's a waiver we got for the demonstration so that these practices wouldn't have to be dual
18 reporting. And to reduce some of their burden.
19 In terms of the practices that are eligible to participate in the demonstration, the focus is on those
20 that are small to medium size and for the purposes of this demonstration, that's approximately less than 20
21 providers per practice, and we are including nurse practitioners or physician's assistants if they bill
22 Medicare independently. We are looking at primary care and that includes internal medicine, family
23 practice, general practice, gerontology. Medical subspecialists can participate if their practice is
24 predominantly a primary care practice. And we doing because we are relying on specialty codes in our
25 system and we do know that there are those medical subspecialists such as cardiologists and

1 endocrinologists who are out there who are still a predominantly primary care practice. But I'll talk a little
2 bit more in a few moments about the clinical quality measures that we're going to be asking providers to
3 report on and so it really is a primary care focused demonstration.
4 In terms of beneficiaries who are going to be partici—I want to point out a couple of things as
5 well. In order to participate the practice must have at least 50 fee for service Medicare beneficiaries for
6 whom they provide the predominant amount of their primary care and again that's in order that the
7 financial incentives become large enough to have an impact on the practice. And the practice in order to
8 apply to participate in this demonstration need not have an electronic health record at the time they apply.
9 Most of them will have the intent to implement one hopefully over the next 2 years, I'll talk a little bit
10 about the requirements for that.
11 When we talk about the 50 minimum beneficiaries, they must be fee for service and they're
12 Medicare beneficiaries that have part A and B. It includes dual eligibles and Medicare must be the primary
13 payer. And again the incentives in this demonstration are per beneficiary type incentive, so this becomes
14 important as we get into some of the details of payment. I'm going to do everything fairly quickly, given
15 the time this afternoon, but if you do have questions, feel free. We can get into as much detail as you want
16 later on.
17 As I mentioned this is a Pay for Performance demonstration and there are 2 separate incentives
18 that are incorporated into it. The first one is an incentive for the implementation and adoption of health
19 information technology, specifically a CCHIT certified electronic health record system, and for those who
20 are not familiar with CCHIT stands for the Certification Commission for Healthcare Information
21 Technology and they certify ambulatory care, health record systems that meet certain standards. The
22 second incentive is a quality based incentive, for reporting on 26 clinical quality measures that relate to the
23 care of diabetes, congestive heart failure, coronary artery disease and preventive services, and these are the
24 same 26 measures that we're using in the Medicare Care Management Performance Demonstration and we

have a lot of documentation on the specification for those measures and the data collection tool. I'd be happy to talk about that at any extent if you want later on.

In terms of the first incentive payment. We will be conducting with our demonstration practices an annual office systems survey. It's a survey that is currently under development but it's based on a very similar survey that was used at the doctor's office quality IT program by the QIOs over the past couple of years. All of the practices that are participating in this demonstration will do this survey annually and we estimate it'll take 30, 45 minutes. We are going to ask our control group practices to complete this survey at the end of years 2 and 5. The control group practices in this demonstration will not have access to the same financial incentives, so they will be paid for completing this survey in order to get the response rate up. We are requiring that all practices that are participating; those that are in the treatment group, not those that are in the control group, implement a CCHIT certified electronic health record by the end of the second year of the demonstration in order to stay in it. So at the end of the first year, we will do the office systems survey, practices that have not yet implemented an EHR, will be able to stay in the demonstration but they won't receive an incentive payment. By the end of the second year, in order to remain in the demonstration, they will be required to have implemented a CCHIT certified ERH and that's something that we would like your input on, because in order our measurement of having implemented on CCHIT certified EHR requires them to do 4 minimum functions—minimum functionality and so I would want to get your input on what that should be. The office system survey again, we haven't finalized it, nor have we finalized the scoring system yet, but the way we'll be designed is that those practices that score higher on the survey will get higher incentives. Our goal is to not only get practices to implement EHRs, but that those EHRs not become electronic file boxes on their desks so that while we will have some minimum functionality, we really want to move people along to continuum, so that they are using those EHRs in much more sophisticated ways to manage their patient population as a population and not just on a visit by visit basis.

This slide summarizes our current thoughts about what the basic minimum functionality would be and that would be that they're using the EHRs for recording visit notes, for the ordering of lab of diagnostic

1 tests. Now that does not mean that they must be ordering them online to Labcor interoperatively, but that
2 they're recording the ordering of that test, and they're recording the results of that test, not that they have
3 necessarily online connection, although if they did have online connection, that's an example of something
4 that we would see as a higher level of functionality that would earn a higher score on the office system
5 survey, and in term higher payment. Similarly the recording of other diagnostic test ordering and results,
6 such as radiology. And finally the recording of prescriptions. Again that wouldn't be fully prescribing, fully
7 prescribing would result in higher scores on the office systems survey and again, higher incentive
8 payments. But at least that the patient that you prescribed a certain medication and it's in the system.
9 Again more sophisticated uses would score higher on the office systems survey and higher on the
10 payment, and our goal is to get people from paper to using an EHR to fill the basic functionality and over
11 the 5-year course of the demonstration to progress along the continuum so that they're using it at a higher
12 and more sophisticated level.
13 The clinical quality measures again are the same 26 clinical quality measures that we're using for
14 the Medicare Care Management Performance Demonstration. They're measures that have all gone through
15 and NQF review process. Some of them are owned by the NCQA. Some of them are owned by the AMA.
16 Some of them are owned by CMS. We are not making up our own measures, we are keeping to the same—
17 in the effort to be consistent with other data collection efforts out there using the measure owner's
18 specifications and requirements. We will not be reporting the measures until the end of the second year.
19 And at the end of the second year, when we will be doing Pay for Reporting only. It's in the year's 3
20 through 5 of the demonstration that we will be doing a Pay for Performance and we've just gotten through
21 the Pay for Reporting component on the Medicare Care Management Performance Demonstration and we
22 really have found that that's a really good way in a fairly to be honest, non-threatening way, where the
23 payment is contingent purely on reporting, not on whether someone scores 80 or 90%, but to get used to the
24 data collection methodology and to get used to the measures themselves. But in years 3 through 5 there will
25 be a Pay for Performance component to this. All of these measures, the specifications for them are out on

1 our website right now for the Medicare Care Management Performance Demonstration and again we've
2 been using them with large practices as well as small practices. We have developed a clinical data
3 collection tool. We call it the Performance Assessment Tool. It was actually developed by the IO
4 Foundation for Medical Care. We found it fairly user friendly. Again, we've used it with small practices as
5 well as large practices. Practices can key in the data or they can import it directly from an electronic health
6 record. We also made the specifications available last year to a lot of the EHR vendors and as we have been
7 using this more and more with more demonstrations, we have found an increasing amount of interest from
8 the EHR vendors to make it fairly turn key to put into production the ability to create the files that we can
9 import very quickly to make the reporting much easier for practices. And we envision that continuing as we
10 progress with this demonstration and more vendors become familiar with it.
11 In sum, these are the incentives. They vary by year. Again, at the end of the first year, we will only
12 be doing the office systems survey. Practices will be eligible for an incentive based on their score on the
13 office systems survey. If they haven't yet implemented an EHR, and aren't using it for the core
14 functionalities, they won't be eligible to receive any payment then, but they can stay in the demonstration.
15 At the end of year 2, we will do the office system survey again, but we will also require the reporting of the
16 26 quality measures. If a practice by that point has not implemented a CCHIT-certified EHR and are not
17 using it for the core minimum functionalities, they will not stay in the demonstration and again, reporting
18 the clinical quality measures, that's the incentive for the HIT is conditional upon the reporting of the
19 clinical quality measures by the end of the second year.
20 Starting at the end of the third year and at the end of the third, fourth and fifth years, we will be
21 requiring scoring and the performance measures will be contingent upon the performance on each of the 26
22 clinical quality measures. There will also be an additional payment for the use of the CCHIT-certified
23 EHR, and our hope is that we will see those scores go up over the period of time for more sophisticated
24 uses of electronic technology and we will require a minimum quality performance in order to receive the
25 HIT bonus. We really see HIT and electronic health records specifically as a vehicle to improve the quality

of care, just have a box, even if you're using it in what seems to a sophisticated way, but not to an end to receive any, to improve the quality of care to Medicare beneficiaries, we don't see the benefit in that. The goal is really quality of care. That said, again we're using the same scoring method on the clinical quality measures we're using in the MCMP demonstration. The minimum is fairly low, it's 30% composite score in each of the categories; diabetes, congestive heart failure, coronary artery disease, and the preventive care measures and that goes up each year, so that composite score 40% at the end of the 4th year, 50% at the end of the 5th year. We also don't expect that however 100% on any of the measures so anybody scores 90% on the composite or above is eligible for the full incentive payment. So I think we've developed a scoring system that encourages improvement but also doesn't penalize for those people who are already at the top. It really looks to bring people up from the bottom, but again as you go higher, you get more payment.

This is probably what people are most interested—one of the exciting things is that there's finally a fairly substantial incentive on the table here. Practices that are participating in this demonstration, over the 5-year course of the demonstration are eligible to earn up to $58,000 per physician, up to $290,000 per practice over the 5-year course of the demonstration. So the end of year one, the incentive for the adoption of electronic health records, practices, if you reading across the first row in this slide are eligible for this incentive in each of the five years in the demonstration, up to $5,000 per physician, up to $25,000 per practice. In year 2, in addition to the office systems survey incentive, they're eligible for an additional $3,000 for reporting the clinical quality measures up to $15,000 per practice and then in each of the years 3 through 5, practices are eligible for an additional $10,000 per physician, up to $50,000 per practice for the performance on the clinical quality measures. You'll see that again, while practices with up to 20 physicians are eligible to participate in the demonstration, it really is biased toward the smaller practices, because it maxes out at about 5 physicians. And that's intentional. We believe that at the smallest level, those are the practices that really have the greatest financial barriers to implementing HIT and we want to provide it—we didn't want all of the larger practices getting acc—disproportionately getting access to the funding.

Mentioned before that this is, we will have a randomized control design for the demonstration. We are the Office of Research Development and Information and we are going to be evaluating this. We have contracted with Mathmatica Policy Research for an independent evaluation of the demonstration. We will, applications will be coming in from physicians starting in the first 4 sites, which are part of phase one, later this year. Once we determine whether a practice is eligible, we will be doing a stratified randomized assignment, to either the treatment or control group. The factors we will use for stratification probably things like practice size, whether they start with an EHR or not and whether rural urban, similar type of sort of physician demographic criteria. Practices that are in the control group will not be required to do any reporting. They won't be eligible for the incentives either, but they won't have any of the reporting requirements. They only thing they will be asked to do is at the end of the second and fifth years, complete the office systems survey and we will be paying them for their time for that.

Again there are no requirements or restrictions on EHR implementation, with the exception of those that are randomized to the treatment group in order to stay in the demonstration, they need to have a CCHIT-certified EHR and be using for those minimum functionalities by the end of the second year. But again practices in either the treatment or control group can participate in other Pay for Performance programs, in fact one of the things that we hope to do is leverage the impact of this demonstration by encouraging similar programs in the commercial and private sector.

As I mentioned before the Secretary and the Administrator recently did a across the country trip to encourage communities to participate in this demonstration. We are looking to select up to 12 sites through this competitive process to identify community partners who will help us recruit physicians to participate and again that's another area that we'd like your input on. We know it's particularly because of the randomized design, it's going to be some challenges out there to recruiting. We received applications last week was the due date, and we hope to announce the sites in early mid-June. The 12 sites. We will be dividing those 12 sites up into two phases; the first 4 sites we will implement this year, the second 8 sites, the remaining 8 sites will be implemented in phase 2, starting in the fall of 2009.

Just some of the criteria and the role of community partners that we're looking to select. Their role is really going to be to assist us with outreach education and recruitment of practices. That's first and foremost. And that will occur again in the phase 1 sites this summer and fall, we'll be meeting and working with them to development a recruitment strategy. We also hope that they will work with us to help leverage the demonstration and take advantage of private sector activities to increase the impact of the demonstration. One hundred treatment practices, or even, is not, can be a drop in the bucket in some large areas, we know that. But we also have some tools out there that we will make available; the office systems survey, our data collection tool for the clinical quality measures. And we really hope that more of the private payers will take up the banner and implement similar programs. Our actual recruitment activities are going to vary by site. That's the whole purpose of having locally based community partners who know their communities best and know what will be the most effective way to reach out for them. We also know the challenges in our recruiting because there is not separate funding for the community partners, but we are hoping to work with organizations and multi-stakeholder groups that are already geared toward doing this, whether this be health information exchanges, charted value leaders and other groups such as that that are interested in promoting health information technology with physicians.

Again we're not looking, we don't have a specific eligible organizational structure that we're working with. We are looking basically for groups that have some sort of track record and can help us reach out and educate and recruit physicians. They clearly need to have ties to the primary care physician community. I've started looking at some of those applications this weekend and I've been pleased to see that almost all of them are coming in with strong representation from the primary care community in their area.

Just quickly, I've mentioned, touched on this just earlier. We are implementing this demonstration in two phases; each phase will be five years long. We will be recruiting practices for the four phase one sites, starting right after Labor Day and the first demonstration will actually start in June of 2009, taking

1 this through May 31st of 2014. Phase 2 will begin a year later with us recruiting physicians in the remaining
2 8 sites in the fall of 2009, and that demonstration will run June 2010 through May 31st of 2015.
3 That slide just gives you some links. We do have a demonstration website. There's fact sheets out
4 there. One can sign up to automatic email alert so when we do announce the sites in a couple of weeks,
5 you'll get an email whenever we update anything on the website, we will put it out there. We have Qs and
6 As. We also have an email box, so if you have any questions, you can reach either myself or my colleague
7 Debbie Van Hoven. We check that mailbox regularly, so if anybody has any questions about that
8 demonstration, that's available there. If you go to the CMS.HHS.GOV evaluation reports, and stop here on
9 the URL, we do have a demonstration website generally, and you can see all the demonstrations we're
10 doing. In particular, if you search on Medicare Care Management Performance demonstration, there is that
11 website that has all of the information and links to the clinical data collection. I know that's something
12 everyone's probably very interested in. There's a lot of detailed specifications. You can link to a bulletin
13 board we have that's housed with the IOWA Foundation for medical care and download a sample of our
14 data collection tool, so if anybody is interested in that, there's a lot more detail available about those
15 measures and the tools there. There's also detailed information on our website on the scoring system that
16 we're going to be using for at least for the clinical data collection, because we are using the same scoring
17 system as we're using for the Medicare Care Management Performance demonstration. We haven't yet
18 finalized the scoring for the office systems survey but all of that is on that website.
19 These are really the two areas that we would like some of your input. I'm happy to answer any
20 questions you have about the demonstration, but I'd also appreciate any feedback you'd like to offer about
21 the kind of functionalities that practices should have; what should be our minimum, and also what things
22 you think are most important in terms of priority for rewarding at greater levels as we look at, as we look to
23 develop our scoring. We clearly want to make sure that we're not paying for electronic file boxes or
24 software that's just sitting there, but what do you think is the most important thing in terms of transition
25 and progressing through that. I'd also be interested as we look to announce our 12 sites and we're going to

be meeting with them over the summer in terms of developing a recruitment strategy, some thoughts you may have either today or as you think about later on to send to our mailbox, recruitment strategies. We know we're going to have challenges, particularly since this isn't a grant program. It's not money up front, it's money after the fact; practices will have to have their CCHIT-certified EHR in place before they can begin to see any incentive payment, so we do hope to defray some of the costs, and we hope the financial incentives will encourage people to move quicker in terms of adopting an EHR but it's not upfront money. We also know that there's a challenge, because it's a randomized design. So but I'd appreciate any input you have in terms of vehicles or thoughts about recruiting.

Dr. Bufalino: Ms. Blatt thank you very much. Let's open this for some conversation. Comments, questions?

Dr. Kirsch: Is it too late to apply to be recruited into the pilot program, when you're talking about recruitment, are you talking about after the pilot?

Ms. Blatt: Right now, what we are recruiting are sites, community partners, geographic locations that want multi-stakeholder groups that want us to come in to their location, whether that be a large metropolitan area or a whole state or an area that covers states. That is too late. Those applications were due May 13th. We are not yet though recruiting physicians and there's been a lot of confusion about that. Once we announce the 12 sites, we won't be recruiting individual physician practices until just after Labor Day.

Dr. Sprang: Having gone through this, the last year introducing an electronic health record into my group, I just say when you actually get down to actually picking groups, you've really got to make sure that at least one or two of the docs in the group are really strong advocates for it, I mean champions, because it really not easy for, if you don't really have a strong champion, it's not that easy to do it and put it in place and they're just going to fall off to the side.

Ms. Blatt: Absolutely. This is a voluntary demonstration. Some of the practices that apply are going to be ones that have already implemented EHRs, and hopefully will move them more along that

continuum to a more sophisticated use of that EHR or to take greater steps to expanding some of [inaudible] are already interested or beginning to look at that. One of the things I'm pleased to see is many of the community partners that have submitted applications are also going to be providing technical assistance and helping practices select an EHR, figure out what meets their needs best, but I would agree. It is voluntary though.

Dr. Bufalino: Just from my own experience, some of the functionalities that you might think about looking at, because I think a lot of practices are going to have a champion or two but not have everybody engaged, and I think you might want to measure some percentage, whether it's 80% or 90% of the docs have to play ball in order for them to be there because we have plenty of circumstances where 3 guys are using it and the other seven aren't. And it's a miserable failure. One group I just talked to yesterday is 10 years, has been attempting to implement an electronic record in their setting and they still are walking around with big thick charts. Two, I think a very important thing that we learned early on is that it's really about process change on the staff side. So unless you change the process that the staff, and then in turn the physician goes through, you're really not going to implement a change in how they delivery it everyday and so that would be another simple thing for you to measure, but something that has some value.

Ms. Blatt: Those are some of the kinds of things that the office system survey that we're working on get at; how they're using it to either manage and coordinate care, provide alerts or other best practices, so those are some of the things we are looking at. I will say a practice can participate in the demonstration even if all of the doctors don't want to. So we're allowing that.

Dr. Bufalino: Of course. It was just you'd want at least a majority of the folks at the table. And the other thing that you may suggest is other little functionalities that can help that practice streamline their lives. For us, you know we use the virtual prescription refill desk, so that's totally electronic so somebody sits with a headphone, types in the messages—no more pink slips—that chart is searched right from that desk. Yes the Lipitor should be refilled, documents the Lipitor's refilled, and calls the drug store. Those little silly things that we learned the hard way streamlined our lives, made it more economical to deliver it

on the process side, aside from the cost of delivering this initially, it was really about how we did a better job taking care of practicing every week.

Ms. Blatt: In the MCMP demonstration, all of the practices that are participating are also participating in the QIO's DOQIT program, which provides technical assistance in process change. Because I would agree with you. It's not just a matter, unless you change how you practice, to take advantage of health information technology, not necessarily going to see these benefits. And again, some of the things we're seeing in these applications coming through is the type of technical assistance that will help practices take most advantage of the technical capabilities. I would agree that's very important.

Dr. Standaert: I guess one of the things to do is the technical assistance. I don't know how within the scope of your study you can do it, or how much you can give them. But giving them technical assistance on how to do this and particularly as a, listing all the PQRI stuff, if you have this group of people who are motivated to go do this for CMS, they're probably the same people who might be interested in all the PQRI things and documenting everything, and I don't know how much you can help them with software but somebody come in and say look you're getting this system if you do this, this, and this, and include these on your intake sheets you can get at the PQRI and help them refine down what they need to get into their sort of data collection and software to meet PQRI requirements, you're giving them, they get multiple incentives get struck at the same time and you might find even much more compliance and enthusiasm. So—

Ms. Blatt: Technical assistance per se is not, I want to clarify, is not part of the demonstration, although the community partners will be providing it more generally in their communities. We're looking purely and we have to be careful about that the one variable is the financial incentive. But that said, we are doing a lot of that. We have a webinar for example that we're doing actually on Wednesday if anybody's interested in signing up for it. We still have some lines open with a practice that's been participating in the physician group practice demonstration, practice from Springfield, Massachusetts that's participating in the MCMP demonstration and someone from the Rochester IPA, and it's basically what small practices need to

succeed in P for P and if anybody's interested in that, send me an email through the EHR demo. I can get you a link for how to sign up for it. It's Wednesday, and if someone can't listen to it, you can always download it, but we are trying to provide assistance to practices; what are the things that other practices have learned to make them successful in reporting and making the reporting burden itself easier on them. But these practices will not have to participate in PQRI in terms of submitting claims. What they do is submitting the codes according to PQRI. They will be eligible, should they want to be. I mean it's at their choice to get access to that extra 1.5% based on their performance in the demonstration under the demonstration rules. Because we're getting data directly from electronic health records, or from charts depending on how they want to give it to us. So if they get 90% of the potential incentive for a year, let's say $9,000 out of the $10,000, whatever, in a given year, they'll get 90% of the PQRI bonus, it's just an added pool of money, but they will not have to report twice.

Dr. Bufalino: One other question, will you be providing feedback to the individual practitioner on how well he's doing. In my world, every quarter, each doc gets a report card that tells them how well they're doing and they always, just the incentive of trying to do better than last time.

Ms. Blatt: Sure we get, we actually just got through giving practices for their baseline reporting in essence a report card showing how they scored on each of the measures and we will be providing some benchmark data and our baseline data for MCMP we didn't provide benchmark data because quite frankly, I don't think the quality of the data, this first year is valid enough to give a benchmark, but we will be giving that going forward. We also provide, it's more than just reporting and a score, we give practices the list, they know, we determine who they report on. We have a detailed methodology for patients' election reporting, and they know which of their patients got for example mammograms or didn't get a certain test, so they can take that step for the next year so they know who needs those mammograms going forward; who needs that, has a high LDL level or whatever. So it's more than just giving them a score. Hopefully we're giving them some information of who are their patients and how they did. The data collection methodology; seven of the measures can be reported, using claims data, but we also, the other 19 require

chart based data in all or in part. Our data collection tool gets prepopulated, so they know exactly who to report on, we give them claims level data that could support the reporting for example, the cancer screening, colon cancer screening measure is partly claims based, but in total it's not, because we don't have all of the claims going back far enough potentially do it. That said, we provide providers all of the data that we have in our claims system that will make it easier for them to report. Similarly we don't have lab values but we do have dates of lab tests to help people report. The mammography measure is one that for example is claims based, but if the physician knows that a patient at 63 got a bilateral mastectomy and therefore is ineligible for the measure, but it's not something that we have in our claims system, they can take that patient out of the denominator. So they know, the providers know from the moment of reporting, all of the patients involved in the denominator and can tell us if Mary Jones is not suitable for that measure. There are some of the measures require, you're allowed to have system or medical exclusions. They can exclude patients. And I can go into at some point off line if anybody is interested the whole detailed methodology. But allows for a lot of patient, physician input and also physician feedback on individual patients, so they can improve their score for next year.

Dr. Bufalino: Thank you very much. Thank you for joining us this afternoon. Appreciate it.

Wrap Up & Recommendations

Dr. Bufalino: So let's spend the next 10 or 15 minutes bring together some wrap up resolutions and then hopefully we will be able to circulate those to everybody before they leave. So let me go around the room and begin and this is sort of an open period. Any resolutions you'd like to put on the table, whether they are and just some suggestions, things we did not cover; we did not cover the physician compare website. So anybody that's thinking about a resolution there. The two other areas were PQRI and Value-based purchasing—we covered none of those. And then finally, obviously this electronic record demonstration. So Janice?

Dr. Kirsch: I'd like to respond to the AMA report and I think we definitely need to do some sort of response to the anticipated payment cuts. So I propose PPAC recommends CMS support immediate

1 Congressional action to avert the pending Medicare physician payment cut scheduled for July 1st, and
2 replace it with a positive update of .5% update for the remainder of 2008, followed by a 2009 update that
3 adequately reflects increases in medical practice costs. And Dana I can go ahead and give you the wording
4 on that. OK.
5 [second]
6 Dr. Bufalino: Any discussion? All those in favor?
7 [Ayes]
8 Dr. Bufalino: Thank you. Others?
9 Dr. Snow: In view of medical necessity determinations being highly subjective and requiring
10 extensive clinical review, PPAC recommends CMS remove medical necessity determinations from the
11 RAC reviews.
12 [seconds]
13 Dr. Bufalino: Discussion? All in favor?
14 [Ayes]
15 Dr. Bufalino: Opposed? I'm sorry, Dana, did you get that?
16 Dr. Standaert: This goes back to the second one, going on Tye's, but PPAC recommends that
17 physicians and other professional providers be provided with a comment and appeals process prior to the
18 release of any PQRI data and that this process be reviewed by PPAC before its adoption.
19 Dr. Bufalino: Repeat it again?
20 Dr. Standaert: PPAC recommends that physicians and other health providers be provided with a
21 comment and appeals process prior to the release of any PQRI data and that this process be reviewed by
22 PPAC before its adoption.
23 [second]
24 Dr. Bufalino: Thank you. Discussion? Hearing none, all in favor?
25 [Ayes]

Dr. Sprang: Just a couple of things here. We were talking a lot about obviously quality improvement and that will be an ongoing discussion going forward and something that PPAC will continue to be involved in. And I think in my institution, sometimes a lot of things when things are to be reported or discussed that some of the physicians have concerns that those really will improve quality, if those are reported, obviously we want to do the right thing and want to make sure that the things we're doing will actually improve quality. So the recommendation: PPAC recommends that as CMS goes forward with its discussion of their quality roadmap and strategies for QI, they include some evidence that the issues under discussion actually improve quality.

Dr. Bufalino: Read it again.

Dr. Chris Standaert: Quality of care? Quality of what?

Dr. Sprang: Improve quality of patient care.

[second]

Dr. Bufalino: Discussion. All in favor?

[Ayes]

Dr. Sprang: Can I make another recommendation.

Dr. Bufalino: One more.

Dr. Sprang: Again, related to RAC. When Ken Simon gave the report earlier and said that the different things that RAC is looking at, they are looking at E&Ms, he pointed out that if they did decide to do it they would include both the 95 and 97 criteria, which I think would be extremely important if they go forward. But he also pointed out that they're continuing to look at whether they should go forward or not, whether it's a good idea. Because of the numerous variations in time and quality and effort, it would seem very difficult to review that preliminary without actually have the chart and making it more complex. So I'm actually going to recommend, PPAC recommends that CMS not allow RACs to review E&M services.

[second]

Dr. Bufalino: Thank you. Discussion? All in favor?

1 [Ayes]

2 Dr. Bufalino: Thank you. Others?

3 Dr. Ouzounian: This is relation to Dr. Valuck's presentation on value-based purchasing. PPAC
4 recommends that any items selected for reductions or inclusion in the value-based purchasing be open to a
5 public comment period; that the recommendations be published in the proposed rule so that the specialty
6 societies may comment.

7 Dr. Bufalino: Did you get that? Second?

8 [second]

9 Dr. Bufalino: Second, thank you. Discussion? Hearing none, all in favor?

10 [Ayes]

11 Dr. Bufalino: Thank you. Others? Dr. Snow?

12 Dr. Snow: PPAC recommends that CMS preclude RACs from reviewing any claims within the
13 prior 12 months and only authorize reviews for claims processed in the past 12 to 24 months, so as to allow
14 fiscal intermediary and other reviews to have been completed prior to RAC reviews.

15 Dr. Bufalino: Again?

16 Dr. Snow: OK. PPAC recommends that CMS preclude RACs from reviewing any claims within
17 the immediate past 12 months; and only authorize reviews for claims processed in the 12 to 24 months
18 prior period in order to allow fiscal intermediaries to complete ongoing reviews of claims during that time
19 period.

20 Dr. Bufalino: Second?

21 [second]

22 Dr. Bufalino: Second, thank you. Any discussion? All in favor?

23 [Ayes]

24 Dr. Bufalino: Thank you. Any others? Dr. Ross?

1 Dr. Ross: Just to add to Dr. Hirsch's resolution, if she would be kind enough to allow this to be
2 added—
3 Ms. Trevas: Can you tell me which one that is, please?
4 Dr. Ross: That was the first resolution on the CMS support of Congressional action to avert the
5 Medicare physician pay cut. That PPAC recommend that CMS again support measures that involve updates
6 that should not increase the size or duration of Medicare physician payment cuts in future years. That CMS
7 support and recommend to Congress that the time needed to pave the way for longer term reform of the
8 Medicare physician update formula.
9 Ms. Trevas: Just that last phrase again, please?
10 Dr. Ross: To recommend that CMS—recommend to Congress that the time needed to pave the
11 way for longer term reform of the Medicare physician update formula.
12 [off mike discussion]
13 Dr. Smith: Well you've got to have a verb in there somewhere. [laughter]
14 Dr. Bufalino: You want to abbreviate it?
15 Dr. Ross: That it is time, that the time is needed to pave the way for longer term reform of the
16 Medicare physician update formula.
17 Dr. Bufalino: Got that?
18 Ms. Trevas: I do.
19 Dr. Bufalino: Thank you. Second?
20 [second]
21 Dr. Bufalino: Thank you. Discussion? All in favor?
22 [Ayes]
23 Dr. Bufalino: Thank you.
24 Dr. Ross: Also, Mr. Chair?
25 Dr. Bufalino: One more.

Dr. Ross: It's not a resolution. Just at our next meeting, I would propose or ask that again a clarification of the DME POS take place with a representative who could further clarify the language that was stated during this meeting today.

Dr. Bufalino: OK.

Dr. Ross: Doesn't need a resolution.

Dr. Simon: We already have plans to do that.

Dr. Ross: Thank you very much for doing that.

Dr. Bufalino: Any other resolutions? Great. So. Dana, question? So we did an awful lot of these at the end, are we capable of generating that and passing that out before people leave or not?

Ms. Trevas: Can you take a 20-minute break?

Dr. Bufalino: If we take a 20-minute break, I don't know how many people will still be here, but whoever's here is good.

[Unidentified speaker] We could have them emailed to us?

Dr. Bufalino: We could have them emailed, too. I think if it's going to take that long. Why don't we email it to everybody. And I just wanted to make sure that there isn't somebody from the AMA that was going to speak on behalf of the proposal, of the recommendations. OK, thank you. So we work on those. We will email those to everybody. Let me ask Dr. Rich if he had any last comments to wrap up the meeting?

Dr. Rich: No, I thought it was a great meeting. Lot of insightful comments. We have some work to do.

Dr. Bufalino: Great. Well thank all of you for coming, thank you for taking the time away from your schedules. I'd like to take a moment to thank the staff for the arrangements, for the everything from the breakfast to the cookies. Thank you for all that. Thank you for audio and for our resolution, putting those together, thank all of you, and I want to thank the professional staff for their excellent presentations. We continue to be informed by all those efforts. So thank you for all those efforts and we will hope to see

you in August. 65th meeting will be in Baltimore. So look for that change in your travel plans. We get to go to the home court as they say. That's about it, thank you all. Have a good day.

Adjourned