CENTERS FOR MEDICARE AND MEDICAID SERVICES

PRACTICING PHYSICIANS ADVISORY COUNCIL

Hubert H. Humphrey Building
Room 800
Centers for Medicare & Medicaid Services
200 Independence Avenue
Washington, D.C. 20201

Monday, August 31, 2009
8:30 a.m.

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MS. DANA TREVAS, Rapporteur
Magnificent Publications, Inc.

A G E N D A

Morning

Open Meeting

Dr. Bufalino: Welcome to the Practicing Physicians Advisory Council, my name is Vince Bufalino. I'm the Chairperson, and I want to welcome all of you to today's meeting in these august surroundings. We finally got a big room with enough chairs for all the guests and nobody shows up, so I guess that's as you would have it. But at any rate, we thank all of you for being here. This is the 69th meeting of the Council, and pleased to have an opportunity for us to have some dialogue. I'd like to thank all of my colleagues from around the country for taking time out of your schedules to be here in Washington to join us for some dialogue and we thank you for that. As you know, we have a significant agenda today around a number of issues that we'll be discussing. We're getting feedback from CMS as to our recommendations from our last meeting, along with discussions around PQRI, e-Prescribing, DMEPOS, Competitive Bidding Program, the Medicare Physician Fee Schedule, the Outpatient Prospective Payment Schedule, and the Ambulatory Surgery Fee Schedule. So among those fee schedules will be discussed today, we'll also have some time to cover the RAC audits and an update from Dr. Rogers on PRIT. So we, as always, look forward to your comments and recommendations for the discussion on the part of CMS. I would also like to say thank you to our Director of the Center for Medicare Management, Jon Blum, who's joined us. Jonathan is at his second meeting of this group, and we thank you for taking the time out of your very busy schedule. Not only is he running Medicare Management, but he's also running the Drug & Health Plan Choice Division, so he has double duty. So we thank you for taking this time out of your schedule. We look forward to some opening comments from you to kick off the meeting.

Welcome and Opening Remarks

Mr. Blum: Thanks Vince. Thank you Vince. I want to also thank the folks that came in on the Council and many of my CMS colleagues. I think today is a very timely meeting and a very important meeting for all of us. For example, today is the closing period for comments for two very significant rules; the 2010 Physician Fee Schedule and also the 2010 Outpatient Prospective Proposed Rule. We expect to hear many comments. We expect to have a very robust conversation this morning. CMS fully understands that both of these rules are very significant. They are sparking lots of interest and lots of comments, and I want to assure everybody here on the Council, and also folks in the audience, that CMS will take every comment seriously. We will look forward to your input, look forward to your feedback. We don't diminish

for a second that these rules, the 2010 Physician Fee Schedule in particular, will have some very, proposes to have some very dramatic changes to how we pay for physician services, and so we fully realize that we're going to have a very full robust conversation and I look forward to that this morning.

The agenda this morning is full. And we have a lot going on here at CMS. And we have a very active agenda, both in terms of health reform debate that's happening now in the Congress, but also in our day to day work here at CMS. We're going to have a discussion about DMEPOS competitive bidding. That is one of my highest priorities this fall, and next year, to make sure that it gets implemented, that it goes smoothly, and that we have a very transparent process, both in the DME community, but also in the physician community, because a DME claim starts with physicians. We're also going to hear about our progress regarding the RAC auditing progress, and just to kind of put it into context, we're in a world where there is very low tolerance right now for fraud and abuse in the Medicare Program. There is a feeling that there is too much fraud in the program and that CMS needs to do a much better job, and a much more aggressive job. This is one of the Secretary's highest priorities right now, to ensure that CMS is working very well with the IG, the Department of Justice, and so I think your input to how we make sure that we strike a different balance, potentially, in how we think about fraud and abuse. We have an obligation to pay claims timely, to ensure that we have a very transparent process, but the same time, we need to make sure we're doing everything that we can to ensure that claims are appropriate, that providers are legitimate. I welcome your feedback, your input to how CMS strikes that balance going forward, because we are in a world from the White House, from the Congress, from the public at a time when we're asking the public to pay more, or the change the way that they think about the healthcare system, we have to ensure the public that the trust funds are being managed well, that premium dollars are going to healthcare services, and so we need to be making sure that CMS does everything that it can to ensure that claims are legitimate, that providers are legitimate, and I expect that to be a very active conversation today. Again, I want to thank everybody here. I want to thank folks in the audience. It's good to see people here. We try to get the best room in the building for everybody, and hopefully, we succeeded. But just want to thank you all, and look forward to your input, your feedback. This Council is very important to me, very important to CMS, and I welcome the conversations that we're going to have later today.

Dr. Bufalino: Thank you, John. In addition, I'd like to introduce Liz Richter, who as you know, is the Deputy Director for the Center for Medicare Management. We're always thrilled to have Liz here. She's been a steady participant in our meetings over the time I've been here and we thank you for that. And she's traditionally been a woman of few words, but we always give her an opportunity to say good morning.

Ms. Richter: Oh, well why break with tradition? I think we should just get started.

Dr. Bufalino: Thank you. Let me just, before we begin, just ask a question that was a curiosity of the group last night, as to either Jon or Liz might help us with an answer. Is there any word on the replacement of the two members that have finished their terms, since we're down two at this meeting, and wanted to know whether anyone's heard as to the progress on the next appointments?

Ms. Richter: We've made a lot of progress. It's close. And I would expect that you will have new colleagues here for the next meeting.

Dr. Bufalino: Great. Thank you. Thank you for that. Okay, moving on, next I'd like to introduce Dr. Ken Simon. He's the Executive Director of PPAC and Medical Officer here at the Center for Medicare Management. Dr. Simon's here to review the responses of CMS to our recommendations from the last meeting. Dr. Simon.

PPAC Update

Dr. Simon: Good morning to the Council members and to the public. Reviewing Agenda Item H, which covered the Recovery Audit Contractors Update. 68H-1: PPAC recommends that CMS assess the time required of physicians and other providers, the resources involved, and hence the cost per physician or provider, to comply with the existing regulatory burdens posed by the Physician Quality Reporting Initiative, the Electronic Prescribing, and the RAC Medical Records Request. The CMS response: Our estimates of the cost to eligible professionals associated with participation in the 2009 PQRI and e-Prescribing Incentive Programs was included in the collection of information requirement section and the Regulatory Impact Analysis section of the calendar year 2009 Medicare Physician Fee Schedule Final Rule, with comment period, which was published in the *Federal Register* on November 19, 2008. For both the PQRI and the e-Prescribing Incentive Programs, we believe that the cost of participation is outweighed by the incentive payments that are received. For example, for the 2007 PQRI where eligible professionals

could earn an incentive payment equal to 1.5 percent of their total estimated allowed Medicare Part B Physician Fee Schedule charges for services furnished July 1, 2007 through December 31, 2007. The average incentive payment was $634.69 per eligible professional. With a 2 percent incentive payment in 2009, calculated based on services furnished during the entire calendar year, we would expect the average PQRI incentive payment and e-Prescribing incentive payment to be approximately $1,700 per eligible professional per incentive program. Consequently, eligible professionals who participate in both e-Prescribing and the PQRI incentive payment programs could earn approximately $3,400 in incentives on average. By comparison, reporting a PQRI measures group with four measures for 30 instances, that is using the Consecutive Patient Sample method, would enable a practice to earn approximately $1,700 as noted above, while only costing a medium practice about $258 to submit the required quality data codes on their claims. This equates to an extra $1,442 for the year after expenses, or $48 per patient for each of the 30 consecutive patients in a measures group. Additionally, CMS will consider this recommendation and seek input from AMA and other stakeholders to determine the appropriate methodology to assess the provider burden associated with RAC additional documentation request letters.

Agenda Item 68H-2. PPAC recommends that CMS be required to assess the time required of physicians and other providers, the resources involved, and hence the cost per physician or provider to comply with the proposed regulation before implementation. The response: Under the Paperwork Reduction Act of 1995, CMS is required to provide a 60-day notice in the *Federal Register* and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget for review and approval. Section 3506 of the PRA of 1995, requires that we solicit comment on the following issues: 1) the need for information collection and its usefulness in carrying out the proper functions of our agency; 2) the accuracy of our estimate of the information collection burden; 3) the quality utility and clarity of the information to be collected; and 4) recommendations to minimize the information collection burden on the affected public, including automated collection techniques. In keeping with the Paperwork Reduction Act, we have included in the 2010 Medicare Physician Fee Schedule Proposed Rule, the burden analysis for PQRI and requested comments. The 2010 Medicare Fee Schedule Proposed Rule is available as a download on the PQRI website, which is located on the CMS website, CMS.HHS.GOV.

Agenda Item 68H-3. PPAC recommends that CMS reconsider its decision not to pay physicians for the cost of copying medical records in response to RAC requests. The CMS response: CMS considers these costs as part of the indirect costs of the practice expense. At this time, CMS does not provide a separate payment for this service.

Agenda Item 68H-4. PPAC recommends that CMS require the RACs to provide data on CMS overpayments for durable medical equipment, prosthetics, orthotics, and supplies that distinguish between overpayments to physicians versus DMEPOS suppliers, and that such data be provided by January 1, 2010, and reported at the subsequent PPAC meeting. The response: CMS currently believes that we will be able to retrieve this type of data in the RAC national program. If reviews of this type have occurred prior to the first PPAC meeting in calendar year 2010, CMS will bring the data to the Council's attention.

Agenda Item K, DMEPOS Surety Bond Policy and Implementation. 68K-1 PPAC recommends that CMS include on the DMEPOS supplier enrollment form an option to indicate the applicant is exempt from the accreditation requirement (in addition to the existing boxes of accredited and nonaccredited). The response: CMS will revise the Medicare Enrollment Application to clarify that the exempt suppliers should check the box designated (the enrolling supplier is not accredited in Section 2(g) of CMS 855S Form).

Agenda Item 68K-2. PPAC recommends that CMS adopt language that would put in place a permanent exemption from DMEPOS accreditation requirements and surety bonds for physicians and licensed healthcare professionals, who provide DMEPOS to their patients as part of their professional services. The response: With respect to surety bonds, physicians are already exempt from the bond requirement to the extent that they meet the requirements of Medicare regulations. We are somewhat uncertain as to the complete listing a provider/provider types that PPAC includes within the term "licensed healthcare providers," though we suspect that it is limited to nonphysician practitioners. We note that most nonphysician practitioners, for example, podiatrists, optometrists, etc., are exempt from the bond requirements as outlined in Medicare regulations. Those practitioners or other suppliers who do not fall within such exemptions are non exempt, because, as we stated in the preamble to the surety bond Final Rule, there is nothing in Section 1834(a)16 of the Social Security Act that evidences a Congressional Intent to exempt them from the bond requirement.

Agenda Item N, The Wrap Up and Recommendations. And this seems to be the bulk of the report here, Mr. Chairperson. Agenda Item 68N-1. PPAC recommends that CMS provide to PPAC at the next meeting, statistics on fraud and abuse, involving physicians in the Medicare Program. The response: CMS will provide a presentation today on fraud and abuse during this meeting. The Medicare Program contracts with Program Safeguard contractors and Zone Program Integrity contractors to detect and deter potential Medicare fraud and abuse. The contractors identify potential fraud and abuse using a variety of methods, including proactive data analysis, individual provider claims analysis, and medical record review, beneficiary complaints review and review of potential fraud and abuse identified by law enforcement. It is important to note that the contractors only identify potential fraud and abuse, as actual fraud and abuse is determined through the judicial process, pursuant to a civil or criminal action brought by the Department of Justice. If potential fraud and abuse is identified, the contractors follow the process outlined in the Program Integrity manual. For example, Chapter Four of the manual describes the activities contractors follow as appropriate for conducting investigations to substantiate allegations and determine if a case is appropriate for referral to law enforcement. The investigative methods described in Section 4.7 include reviewing a sample of the provider's recent claims, and the corresponding medical records, conducting beneficiary interviews, reviewing previous communications between Medicare contractors and the provider, etc. Depending on the findings of a particular investigation of potential fraud and abuse, the contractor may refer the case to the Office of the Inspector General, or another law enforcement entity. Once a case referral is made, the length of time that passes until there is a resolution of the case varies, depending upon what actions are taken by the OIG and DOJ. In some cases, a resolution may occur quickly, such as when a provider reaches a settlement with law enforcement or law enforcement determines that litigation is not appropriate, and refers the case back to the contractor for a speedy administrative action. If DOJ pursues litigation, the resolution may take several years. If a referral to law enforcement is not appropriate, the contractor may initiate administrative action on the provider. Administrative actions include pre-payment claims review, post-payment claims review, payment suspension, overpayment determination, and recommendation of a provider enrollment action, such as deactivation or revocation of billing privileges. CMS monitors the potential fraud and abuse identified by its contractors at an aggregate level across all claim types; Part A, Part B, DME, Home Health Activities, etc., to identify national trends and potential

vulnerabilities that may affect multiple contractor jurisdictions. CMS does not monitor the identification of potential fraud and abuse, at an individual provider level, however CMS is actively involved in the operational execution of certain administration actions on individual providers, such as payment suspensions and overpayment determinations.

Agenda Item 68N-2. PPAC recommends that CMS present information on the statistical accuracy of the data supplied in the Physician Resource Use reports. The response: Ensuring statistical accuracy of the data supplied in the Physician Resource Use measurement program is one of CMS's top priorities. The Resource Use Reports are based on actual paid claims data and therefore reflect payments made by the Medicare Program. CMS understands that the peer comparison groups need to have a minimum number of patients and episodes to be statistically reliable. One of our requirements is that each physician must meet CMS's minimum threshold requirements in order to receive a Resource Use Report. CMS appreciates PPAC recommendation to present information on the statistical accuracy of the data. Further, CMS utilizes the expertise of senior level statisticians, both internal and external to the agency, to consult on the use of the Medicare Fee-for-Service claims data used in the Resource Use reports.

Agenda Item 68N-3. PPAC recommends that CMS and the RAC providers develop a special logo for correspondence to differentiate the RAC program from other CMS related program requests for information. The response: CMS does not have sole discretion to begin utilizing a RAC-specific logo. CMS has chosen to use the CMS logo as well as the RAC's individual corporate logo. In addition, CMS has decided to indicate in bold type at the top that the letter is from a RAC. All RAC contractors will also post a sample of their additional documentation request letters and demand letters to their websites to further assist the providers in identifying the request is for a RAC audit. CMS will send the link to the RAC page, located on the CMS website to the AMA for distribution to all of the medical specialties.

Agenda Item 68N-4. PPAC recommends that CMS include risk adjusted physicians resource use data for attending physicians in academic medical centers to recognize the risk, benefits, and expenses of training residents and medical students. The response: CMS has recognized benchmarking as one of several key factors to ensuring the peer comparisons on the reports capture physician resource use in a fair manner. CMS's research into the topic of benchmarking has illustrated that it's critical to have benchmarks that are large enough to contain enough patients and episodes to produce statistically reliable data. To date, the

benchmark CMS has used in resource use reports do not consider peer groups separately by type of setting, for example, academic medical centers, because those peer groups did not yield a large enough sample to derive statistically valid data. CMS will continue to examine this issue, as we develop reporting approaches.

Agenda Item 68N-5. PPAC recommends that CMS present an update on resource use reports to physicians especially with respect to any planned public release of this information, any plans to correct the attribution methods to reflect more accurately the physician's peer group for comparison, and any plans to correct the attribution methods to reflect the physician's actual contribution to the cost of care attributed to him or her. Response: CMS will continue to work collaboratively with the physician community on development, implementation, and maintenance of the Physician Resource Use Measurement and Reporting program. Through our contractors, CMS has held face to face sessions with individual physicians and groups of physicians to gather feedback about the reports. Specifically, CMS has gathered physician input on various attribution methodologies. To date, physicians have indicated that the attributions of cost assigned by CMS's calculated accurately based on the attribution rules that are applied. Further, those physicians that participated in the pilot program support the policy considerations behind the attribution rules that CMS has chosen, including recognition of team-based care. Though CMS has selected two attribution rules for the program to date, CMS continues to test the additional attribution methodologies, to further refine the program. Section 131(c) of the Medicare Improvements for Patients and Providers Act, commonly called MIPPA, gives the Secretary the authority to disseminate resource use reports on a confidential basis. CMS currently does not have plans in place to publicly release the data used in the resource use reports. We disseminated approximately 120 reports to selected physicians in April of 2009. A prototype copy of the report is publicly available on the CMS website. We have also disseminated an additional 120 reports to physicians in six geographic sites in August of 2009. The reports provide summary and drill down information that identifies physicians as either high-cost outliers, low-cost outliers or within the median range. Further, the reports educate physicians on which cost of service categories in essence, ambulatory visits, inpatient hospitalizations, outpatient hospital services, imaging services, skilled nursing facility stays, home healthcare, etc. may be contributing to their resource use classification, be it low, median, or high. Furthermore, CMS recently issued the calendar year 2010 Medicare Physician Fee

Schedule Proposed Rule, where we discuss a number of policy issues related to resource use reports, including 1) the use of quality measures in addition to cost of care measures, and 2) reporting to groups of physicians in addition to reporting to individual physicians.

Agenda Item 68N-6. PPAC recommends that CMS provide information on how the Value-Based Purchasing program factors prevent its services into its cost utilization studies. The response: CMS has included a cost-of-service category analysis within the current resource use report prototype. To date, the cost-of-service category analysis does not concentrate on preventive services. Including preventive services may rely on information that the individual procedure code level. Through our rigorous feedback process, physicians have indicated that receiving information on individual procedure codes is not feasible. However, CMS may test preventive services as one of the cost of service categories in future versions of the resource use reports.

Agenda Item 68N-7. PPAC recommends that CMS require hospitals to notify the treating physician and the patient when a patient's inpatient status is reclassified as outpatient. The response: Condition code 44 is a billing code used on an outpatient claim to indicate that the hospital has changed the patient's status from inpatient to outpatient, consistent with the criteria for use of the code. One of the requirements for the use of condition code 44 is concurrence of the physician responsible for the care of the patient with the determination that an inpatient admission does not meet the hospital's admission criteria and that the patient should have been registered as an outpatient. Another is that the decision must be made before discharge while the beneficiary is still a patient of the hospital. These prerequisites for the use of condition code 44 are consistent with the requirements in the hospital Conditions of Participation in the Medicare regulations manual. This paragraph provides that the physician or other practitioner responsible for the care of the patient must be consulted and allowed to present their views before the utilization review committee or quality improvement organization that makes this determination that an admission is not medically necessary. It also requires that the hospital provide written notification of the decision about the admission or continued stay to the patient, the hospital, and the physician or other practitioners responsible for the care of the patient, no later than two days after the decision is made. In addition, we have advised in the manual guidance that it is also appropriate to include the practitioner who admitted the patient if this is a different person than the physician or other practitioner responsible for the care of the patient. The policy

and guidance for the use of condition code 44 are located in the Medicare Claims Processing manual, chapter one, section 50.3.

Agenda Item 68N-8. PPAC recommends that CMS preclude the RACs from recouping overpayments to physicians based on coding errors that result from reclassification of a patient by the hospital from inpatient to outpatient. The response: CMS is responsible for reducing payment errors and protecting and strengthening the Medicare Trust Fund. If a RAC submits the Part B coding error that was associated with a Part A inpatient claim to CMS, and CMS approves the new issue for widespread review, it would not be in the best interest of the trust fund if CMS precluded the RAC from collecting an improper payment.

Agenda Item 68N-9. PPAC recommends that CMS provide to PPAC the result of its research on the applicable statutes, regulations, policy statements, and precedents regarding PPAC's March 2009 recommendation on penalizing downstream providers. In essence, PPAC recommends that the RAC process be modified to exclude extending demands for repayment to subsequent consulting physicians for an index case for a particular surgery, procedure, or consultation. The response: CMS has researched this issue and determined that currently, we do not have a policy that would allow a RAC to automatically demand repayment from consulting physicians for which the primary surgery/procedure is denied by the RAC. However, a RAC may make an individual claim determination that the services were not rendered, were not coded correctly, or were not reasonable and necessary based on the medical record documentation submitted.

Agenda Item 68N-10. PPAC recommends that two years before releasing resource use reports, CMS notify physicians that the information will be publicly released and provide an opportunity for physicians to provide feedback that is included as part of the public record that is released. The response: CMS currently does not have plans in place to publicly release the data used in the resource use reports. Further, section 131(c) of MIPPA gives the Secretary the authority to disseminate resource use reports on a confidential basis.

Agenda Item 68N-11. PPAC recommends that potential reports on drug utilization be generated concisely, and that an effort is made to avoid multiple communications. The response: CMS has included a cost-of-service category analysis within the current resource use report prototype. To date, the cost-of-

service category analysis does not concentrate on drug utilization. Similar to including specific preventive services, including drug utilization may rely on information at the individual procedure code level. Through our rigorous feedback process, physicians have indicated that receiving information on individual procedure codes is not feasible. However, CMS may test drug utilization as one of the cost-of-service categories in future versions of the resource use reports.

Final Agenda Item 68N-12. PPAC recommends that CMS provide PPAC specific data regarding the periodic monitoring that CMS does to determine what percentage of Medicare beneficiaries have reliable access to medical services. The response: CMS is sensitive to the implications of the potential negative updates on access to care. CMS periodically monitors beneficiary-reported experiences on their ability to access needed care. Using longitudinal data from the Consumer Assessment of Healthcare Providers and Systems Survey for Medicare Health Plans, we will be able to examine and monitor at the state level whether beneficiaries are reporting changes in their access to care. In addition, we would note the Medicare Payment Advisory Commission examines patient access to physician care in the Annual March Report to the Congress. In its recent March 2009 Report, MedPAC reported that results from its 2008 survey indicate that most beneficiaries have reliable access to physician services, with most beneficiaries reporting few or no access problems. MedPAC also indicated that other national surveys show results comparable to the MedPAC survey. CMS has hired additional personnel to assist and review in our current methodological review process, and explore new ways to better enable us to design an updated analysis for monitoring beneficiary access to care.

This response concludes the report from the last meeting, Mr. Chairperson.

Dr. Bufalino: Thank you, Dr. Simon. Probably a record for the longest report that we've had in a long time. Any comments or questions? Roger?

Dr. Jordan: Mr. Chairman, I just want to commend CMS on addressing the surety bond and the accreditation issue in such a timely manner on the 855S Form, which I believe has already been posted. And hopefully this will reduce some of the confusion. I'm sure not all of it, but and streamline the process and possible denials that have occurred in the past, so yeah, I want to thank you for addressing it so timely.

Dr. Bufalino: Thank you. Other comments. Seeing none, we'll move on the agenda. We ask Dr. Rogers to join us. Bill Rogers, the Director of the Physicians Regulatory Issues Team is here for his quarterly update. Welcome, Bill.

PRIT Update

Dr. Rogers: Thank you very much. It's nice to be here. I'll try and give the shortest report in history. I guess because we're doing such a good job here at CMS, I don't have an enormous number of issues, but I do have some new cartoons which is probably just as important. The first issue, this is an issue that I was starting to work on actually your last meeting. It was a difficult issue. It had to do with the failure of some Medicaid programs to accept crossover claims, automatic crossover claims from Medicare. And because Medicaid tends to pay very little, it seemed particularly unfair to require physicians to file crossover claims in paper, so it seemed important to check and see what was happening in the 50 states and in the territories to these crossover claims, and it was very difficult to figure out where crossover wasn't happening. It required a lot of phone calls and a lot of letters and a lot of support from the Healthcare Billing Management Association and the Medical Group Management Association were very helpful in polling their members. It turns out that there are only 3 states where there's a problem; New York is fixing their problem, and they expect to have it fixed by December and they'll be automatically accepting crossover claims. New Jersey was and they recently changed their requirement for the way the claim form is submitted to New Jersey Medicaid, which is now preventing automatic crossover, and we're working with New Jersey to try and address that issue. And then South Carolina, and we still can't figure out why it's not working in South Carolina, but the automatic crossover's not working there. But working with the state Medicaid programs is difficult even in times when state budgets are a little more flush and so this is proving to be a challenge, but we think it's really important to get all of the Medicaid programs accepting automatic crossover.

This is going to be a more and more important issue as we use the enrollment process as a way of making sure that physicians are legitimate practitioners. And this was brought to me by pediatric emergency physicians and surgeons, and the problem is of course, if you don't submit a Medicare bill for 12 months, you're automatically deactivated. So if you have a pediatric surgeon who seldom takes care of a Medicaid patient, then does a complicated cardiac operation on a child who has Medicare because of

disability, submits the bill perhaps for a pretty good sized fee and something that probably has a extended global period, and then the payment, the fee can't be paid because the person's, unbeknownst to them, been deactivated. We will pay that claim as long as the physician begins the enrollment process within a month. But this is still a problem because if the billing process is not efficient and the physician doesn't get the bill out right away, the physician might not be aware that they've been deactivated. So we're still talking about this with the enrollment staff and it's going to be an important issue to address for a lot of reasons, so we're continuing to focus on this.

I've got a number of trips over the next few months, talking to, most importantly, the Kansas City Medical Group Management Association. Art was pleased to see me headed to a flyover state, and I'm pleased to be there. Some of the best barbecue in the world in Kansas City. But most of my visits are going to be to California, sorry Art.

So that's the extent of my report and I look forward to being here for the rest of the meeting, and any issues that you want me to take up I'll look forward to working on them.

Dr. Bufalino: Thank you. Any comments, questions for Dr. Rogers? We do have one.

Dr. Ouzounian: Bill, it doesn't involve me, but it has this issue of the provider that doesn't provide care for 12 months and I just think that's something that you really need to work really hard with. It's too big a disincentive for that provider to even bother. I mean the answer's going to be hey, I got disenrolled, I'm not going to take care of the patient. It's going to create an access issue. It's just way too much work for him to do. He enrolled once. He's got to take care of the patient. For him to have to fill out the application process again is too burdensome.

Dr. Rogers: I agree. And I also worry about the lost fees. Pediatric neurosurgeon might not take care of very many pediatric patients in Medicare, but then does a complex procedure, and spends a lot of time and then finds out that they're not going to get paid for it because pediatric surgeons tend not to treat a lot of Medicare patients, seems unfair to the surgeon. So I agree, I think it's something that we should be able to find a fix for.

Dr. Bufalino: Anyone else? Thank you. Moving right along, we're going to move to the PQRI discussion and introduce our next speakers. Dr. Dan Green, and Ms. Latousha Leslie are joining us. Dr. Green is a board certified ob/gyn and is currently serving as the Medical Officer and the Acting Division

Director at CMS for Quality Measurement and Health Assessment, is in charge of working with various areas around quality reporting, electronic prescribing, and health IT. Ms. Leslie is a registered nurse with eight years in the acute care nursing experience, currently serving as a technical lead for PQRI. And also joining us is Andrew Morgan, who will be spending the opportunity here to talk about e-Prescribing. As you are aware, this program is in the process of being implemented across and we're asking Mr. Morgan to join us. He's been a Project Officer for CMS since 2006 and involved in the e-Prescribing pilot. So we thank all of you for joining us today, and welcome.

PQRI Update

Dr. Green: Thank you very much. Thank you for inviting us and obviously there's strength in numbers, so PQRI, we're ready for you guys.

Dr. Bufalino: Bring 'em on!

Dr. Green: So basically what we want to do is we want to give you all an overview of our proposed PQRI Rule for 2010. So basically going to review the changes for 2010 in the Proposed Fee Schedule in our rule and also look at the e-Prescribing incentive program and how that's changed or how we proposed it to change in 2010. Our 2010 PQRI rule can be found under the payment policies under the Physician Fee Schedule and other revisions. And there you see it's listed. It was published on July 13, 2009, although it was available actually the end of June in electronic format. It addresses the proposed changes to the Part B payment policy, including the PQRI and e-Prescribing incentive. We did publish a correction notice on August 5. It was basically correcting technical errors and there's the reference there as well. So our public comment period ends today at 5:00, so if you guys have nothing else to do, you can be typing away while I'm speaking and getting your comments in to us. I would encourage certainly as much participation the comment process as is possible. The rule can be found and there's the website up on the slide. And again, we do encourage public comments, but the period does close today at 5:00.

You'll notice if you look in the proposed rule, and you compare it to past versions of PQRI, we're looking to encourage physicians and other eligible professionals to report and participate in PQRI. And we're doing that by trying to make it easier for the eligible professionals to do so. So Latousha's going to go through some of the changes, a little bit more specifically. But we do recognize that there is a bit of a burden on practitioners, particularly using the claims process. Not so much from a time standpoint, but in

terms of trying to familiarize themselves with the codes and also selecting the measures. In 2010, as is the case in 2009, there is a 2 percent incentive payment. So this would be 2 percent of the eligible professionals, total covered Part B charges for Medicare. There are three proposed mechanisms in our new rule. The claims-based reporting mechanism, which was the original PQRI option. We've also proposed to continue the registry-based reporting, and not to get off subject, but our registry experience, at least at a high preliminary level, from 2008, you may recall that the MIMSE legislation actually required us to accept registry information for production as opposed to just testing, which is what we had originally planned. We had very good results. I don't have the actual results to share with you, except to say that we qualified 32 registries last year; 31 of those 32 decided that they would submit quality data on behalf of their eligible professionals for 2008, and I'm happy to say that all 31 registries were successful in getting the information in to us and in the proper format. So this is our first foray if you will into the registry experience, and it was a very, overall was a very good experience. As such, in 2009 we are continuing the registry-based submission, which we've heard from eligible professionals that they feel that it's an easier way to report. Many of these folks have already been using registries and this is just another benefit that they can derive from their participation in the registry. This year, we have qualified 74 registries, so we more than doubled the number of registries that were qualified in 2008, not to mention we've also listed on our website the names of the registries, the methods that they tend to report on that is individual measures versus reporting groups, or measures groups rather, I'm sorry. And also we've tried to list the measures that they are intending to report. All in an effort to make it easier for an eligible professional who would like to participate through a registry. They can go on our website and find the registries that may cater to what they're looking to report. It'll save them some time, obviously, in having to do their homework and actually find the specific registry that meets their needs.

We have proposed in 2010, this is new, that we would allow EHR-based reporting for individual, this would be for individual measures, reporting only. There are 10 measures that we have specified electronically. We are currently in the process of testing our EHR, submission of quality data from EHRs. We're working with several vendors and basically what will happen is we're looking to see whether they can successfully get the quality data in to us and whether we're able to accept it at the time as well. And we will be looking, based on our comments and based on the testing experience, will help share our decisions

in terms of whether or not we in fact do use EHR-based reporting for 2010. But we're, the testing has been going well so far, and we're encouraged by that.

The proposed reporting period is January through December of 2010, although there are other reporting periods, we'll talk about now. There is another alternative reporting period of July 1 through December 31. Now folks opting to use this reporting group would be able to do so through claims, reporting the measures groups, or if they want to report individual measures, they'd have to report that through a registry. Registries will be able to report the six-month option again, for individual measures or measures groups, but for claims, it would only be through measures groups. If we adopt electronic and are able to accept electronic health record quality data, that would be a one-year reporting period.

I'm going to pause here and turn it over to Latousha, my tag team partner here and she'll cover the next part.

Ms. Leslie: Hi. I'll be going over the proposed criteria for satisfactory reporting of individual measures. There will be three mechanisms for reporting; claims-based, registry, or EHR. Reporting period will be 12 months, January 1 through December 31 of 2010. The proposed criteria for satisfactory reporting, report at least three quality measures, or if you're reporting claims, report only one or two measures if fewer than three apply. Report each measure for at least 80 percent of the applicable Medicare Part B, Fee-for-Service patients seen through the reporting period. Report at least one PQRI measure for at least 15 Part B Fee-for-Service patients seen during the reporting period. This 15 Medicare Part B Fee-for-Service patients, this is new criteria. We're setting a minimum patient sample size criterion. Continue with reporting for individual measures. Their mechanism is via registries. This is the 6-month reporting period; July 1 through December 31 of 2010. The criteria for satisfactory reporting include reporting at least three PQRI measures or report each measure for at least 80 percent of the applicable patients during the reporting period. Fee-for-Service patients will report at least one PQRI measure for at least eight Medicare Part B Fee-for-Service patients seen during the reporting period. The minimum sample size is decreased to eight for the six-month reporting, versus the 15 minimum sample size for the one-year reporting. The proposed criteria for satisfactory reporting for measures groups: Measures groups can be reported using claims or registry-based reporting. The reporting period is 12 months; January 1 through December 31 of 2010. The criteria for satisfactory reporting is report at least one PQRI measures group, and a measures group is a

group of measures with the same clinical condition or like clinical condition, includes at least four measures for at least where there are common denominators to report. For instance, we have a CAD measures group, we have diabetes measures groups, we have several measures groups and I'll get into the specific measures groups as we go forward, but that's how we define a measures group.

Additional proposed criteria for satisfactory reporting. Report each measures group for at least 30 patients seen during the reporting period. And this has been revised. In 2009, we required the measures group of the 30 patients to be consecutive patients. But we found that eligible professionals were having difficulty determining the consecutive patient count. So now we're going to propose that you don't have to do consecutive patients, it's just 30 patients. So you can pick 30 patients whether they're consecutive or not. It will help ease the burden of trying to figure out is that the next patient reported or did you skip a patient. And we start the asterisk on the 30 patients because if eligible patients report through claims, the patients must all be Medicare Part B Physician Fee Schedule, Fee-for-Service patients. Claims is not itself any other patient besides Medicare, but for the registry reporting, you can report all payer data, all payer-type patients. It must include at least, we have a minimum number of Part B Fee-for-Service patients, that much be included in those for registry reporting.

The proposed criteria for satisfactory reporting for measures groups continue for claims and registries one-year reporting, January 1 through December 31. The criteria for satisfactory reporting: report at least one PQRI measures group, report each measures groups for at least 80 percent of the applicable patients for Medicare Part B Fee-for-Service patients seen during the reporting period. Report at least H measures groups for at least 15 Medicare Part B Fee-for-Service patients seen during the reporting period. This has been revised for 2009. The requirement was to report at least 30 Medicare Part B Fee-for-Service patients for the 12-month report. Proposed criteria for satisfactory [interruption] measures groups claims their registry-based reporting mechanisms for the six-month reporting period, July 1 through December 31 of 2010. The criteria for satisfactory reporting is: report at least one PQRI measures group, report each measures group for at least 80 percent of the applicable Medicare Part B Fee-for-Service patients seen during the reporting period, report each measures groups for at least 8 Medicare Part B Fee-for-Service patients seen during the reporting period. And this has also been revised. 2009, the criteria was to report 15, at least 15 Medicare Part B Fee-for-Service patients.

For proposed 2010 PQRI individual quality measures, we have proposed 172 measures. Eight measures are new, they're registry-only measures. They were inadvertently omitted from the first posting of the proposed rule, but were added via the correction of the proposed rule in the *Federal Register* as of August 5, 2009. The individual measures also include, we have 50 registry-only measures, and some measures are registered only because of the difficulty in reporting them through claims and the difficulty in analyzing the measures through claims. So some measures are designated for registry only. We have 10 measures for EHR-based reporting. And there are 30 new measures. In 2009, there are 151 measures, so in all, we've added 30 new measures, proposed for 2010. We're retiring seven measures that are in 2009 that won't be, we're proposing not to be in 2010: measures 11, 34, 94, 95, 143, 144, and 152. And we retire measures for several reasons, namely, if a measure has a high rate of reporting errors, low rate of successful reporting, difficulties in analyzing, and we've gone to the measure developer to advise him on updating or modify the measure to make the measure easier to report, but the measure still has difficulty. So we made a program decision to retire the measures. And the measures keep the same number. So if these measures are retired in the final program, there won't be measure numbers 11, 34, it'll just skip over so there's no confusion as what was 11 last year, will there be a different number 11 for the subsequent year.

We also included a list of the categories for the new proposed measures that address these topics. They are, these 30 measures mentioned above, consist of measure on thrombolytic therapy, referral for otologic evaluation, cataracts, coronary artery disease, heart failure, cancer staging, HIV and AIDS, preventive care, and functional communication.

We are proposed to retain the seven 2009 PQRI measures groups, and they are: diabetes maltose, chronic kidney disease, preventive care, coronary artery bypass graph, rheumatoid arthritis, perioperative care, back pain, and additional measures have been proposed for the diabetes and preventive care measures groups. We're proposing six new measures groups. They are coronary artery disease, heart failure, ischemic valvular disease, hepatitis C, HIV and AIDS, community-acquired pneumonia. And for registry-only, we have a few measures groups only reportable through registries. Those are the coronary artery bypass graft, the CAD, heart failure, ischemic valvular disease, and HIV and AIDS. And also continuing with 2008 and 9, the measures groups for the back pain measures groups are only reporting through a measures groups. They're not reportable through claims.

Now I'll go over what we're proposing for the group practice reporting [unintelligible] for PQRI. MIPPA, as section 1848(m)3(c) to the Social Security Act, to require that CMS by January 1 of 2010 establish and have in place a process under which eligible professionals in a group practice shall be treated as satisfactorily submitting data on quality measures for reporting period, if in lieu of reporting PQRI measures. The group practice reports measures determined appropriate by the Secretary, such as measures that target high cost, chronic conditions, and preventive care, in a form and manner and at a time specified by the Secretary. MIPPA also proposed a process and measures that are modeled after PQRI, proposed a process of measures that are modeled after the CMS Physician Group Practice and the Medicare Care Management Performance Demonstrations. What we are proposing is, to participate in the reporting option for the physician group practice reporting, we propose that a group practice be defined as a tax ID number with greater than or equal to 200 individual eligible professionals or NPIs. The group practice would be required to self-nominate within the first quarter of 2010, have an active IX user account, provide CMS with a—CMS or CMS designee—with a group practice tax ID numbers and a list of the NPI numbers for all the eligible professionals who will be participating as part of the group practice reporting option. We also are proposing that the group agree to have the group's PQRI performance results publicly reported.

The reporting mechanism for group practices reporting would be required in 2011 and the group would be required to complete a pre-populated data collection tool which CMS will pre-populate, using claims data, select the patient sample, using the same sampling mechanism that's used in the current Physician Group Practice Demonstration Process. We load the tool with the information for the group and provide that to the group. And the reporting period would be the 2010 reporting period, so we use the 2010 claims data to pre-populate the two and conduct the sample. The reporting criteria would be the group would be required to report on all 26 measures included in the tool and the 26 measures address diabetes, heart failure, CAD, preventive care and hypertension. The group would be required to complete the tool for at least 411 consecutively assigned beneficiaries per disease model and preventive care measure. The tool will be loaded actually with an over sample of 50 percent, so 605, 610 patients would be in the tool, but the practice would be required to report on at least 411 consecutive [unintelligible] beneficiaries.

Now we'll turn it over to Dan. He'll continue with e-Prescribing.

Dr. Green: Before we get on with that, there is a handout out front, PQRI made simple, which was authored by one of CMS's finest Medical Officers, so since I don't get to hold up the baby anymore after I deliver, this is my baby. But it really does help to explain the measures groups because they are a little bit tricky when you first look at them. However, when you really get into it is an easy way to report, and I'm sure you would all agree, if you're reporting several measures on one condition, it gives you a better opportunity to measure who well you're treating that particular condition. So it's a nice option for providers, but it is a little bit tricky to learn, and again there is a document out front that might be helpful.

So turning to the 2010 e-Prescribing incentive program, there is a separate 2 percent incentive payment, so in addition, if an eligible professional is participating in PQRI as well as the e-Prescribing program, and is successful in both programs, they would actually be eligible to earn a 4 percent incentive, 2 percent for each program, obviously. Our proposed reporting mechanisms include the claims-based reporting with we have in 2009. Additionally, we proposed accepting the quality information regarding e-Prescribing through a registry as well. We did hear, certainly from the registries as well as from some eligible professionals that they thought that that would be a nice option for them, particularly if they were taking advantage of the registry option already. We've also proposed accepting the e-Prescribing information directly from an EHR. However, obviously that's condition on us being able to accept electronic health record quality data in the first place, so if we are able to accept it for PQRI, we will accept it as well for the e-Prescribing incentive program, however, it's important to note that it is an option for the vendors that are currently undergoing testing. That is to say we have not made it a requirement that they be able to report the e-Prescribing quality data from their EHR. So we'll have to see who's able to do it—well, first, obviously, if we're able to accept the EHR data in the first place, and then, if so, which vendors would be able to report the e-Prescribing measure as well.

So for 2010, we've proposed changing the criteria slightly for successful e-Prescriber. In 2009, we had three G codes, and we required eligible professionals to report one of these three G codes on at least 50 percent of their eligible instances. And we heard from the provider community that they thought that this was an excessive burden, and in an effort to try to address those concerns, we propose to eliminate the three numerator G codes for 2010. Rather, we will be creating a new G code that indicates at least one prescription was generated during the visit, using a qualified e-Prescribing system, and we've proposed that

an eligible professional would need to report this G code on at least 25 Medicare patients during the course of the year. So if really would reduce the number of times that the eligible actually has to report and it would tell us that a prescription was sent electronically during the reporting period, which again is what we're looking for. It's less helpful to know that no prescriptions were generated during the visit for every visit that the eligible professional took care of patients. It's better to know that when they did prescribe, they actually e-Prescribed. So this I think will give us a better measure as well as reducing the burden on eligible professionals. Additionally, we are proposing to expand the denominator codes to include home health visits, as well as nursing home codes, and there was one additional psychiatric code that was added. The home health physicians were very vocal in their concerns regarding ability to participate, since many of these docs don't actually maintain an office and one of the requirements for the e-Prescribing program is that at least 10 percent of your Medicare Part B charges consist of codes that appear in the denominator. So if they had no E&M codes like your 99213, 214, or 204, etc., they never were able to reach that 10 percent threshold to put them as a possible participant in this program. So again, we want to encourage e-Prescribing across the board, not just with the office-based physicians. So in an effort to do that, we've expanded the denominator codes. Hopefully it will enable them to participate.

And again, as I just discussed, we're eliminating the requirement to report on 50 percent of applicable cases, at least that's what we've proposed, and as I mentioned also, 25 times during the reporting period, that at least one prescription was sent electronically. And that's kind of a nice thing, too, just to take a second. Because there were times that eligible professionals actually did e-Prescribe, but then they had to give the patient a controlled substance, let's say. So some of their prescriptions did go electronically, but perhaps due to state or local regulation, they actually had to handwrite a prescription. So in that instance, even though, again, it's a pay for reporting program, the eligible professional would have had to use the G code, which says some or all prescriptions were handwritten, and again, since we're trying to encourage electronic prescribing, the provider wants to say hey, look I'm doing e-Prescribing, I'm doing the right thing, but they had to report the G code because they got tripped up with perhaps having to prescribe a controlled substance. This will make it a little bit cleaner, because even if you have to write a controlled substance, but you do send, let's say, the patient's Atonal electronically, they still would be able to report that for that particular patient. So the incentive only applies to eligible professionals, as we discussed,

whose Medicare Part B charges include at least 10 percent of their total charges from codes that appear in the denominator. So again, that was the home health issue that we discussed previously. For the physician group option for e-Prescribing, I'm going to turn it back to Latousha. She's our expert on physician group practice reporting.

Ms. Leslie: e-Prescribing Group Practicing Reporting Option: Section 1848 in 3(c) of the Act also applies to reporting of e-Prescribing measures starting in 2010. We propose that only group practices participating in the PQRI group practice reporting option would be able to participate as a group practice for the e-Prescribing incentive program. The group practice will be required to report the e-Prescribing measure at least 2,500 times during the reporting period for the group practice to be considered a successful e-Prescriber. Incentive payment also applies only to groups whose Medicare Part B Physician Fee Schedule allow charges for services in the e-Prescribing measures denominator, are greater than or equal to 10 percent of the group's total 2010 estimated allowed charges.

I'll just back up one. Note that for e-Prescribing participation in the group practice reporting option, the group practice will not have to complete the tool that will be used for PQRI. The e-Prescribing measure will be reported via claims as it is currently. It will not be included in the tool which will have the 26 measures for the four disease topics that I went over for PQRI.

Public reporting of 2010 PQRI and e-Prescribing data: We proposed to publicly report names of eligible professionals and group practices whose satisfactorily report in 2010 PQRI as required by MIPPA, group practices' PQRI performance rates, the names of eligible professionals, and group practices who are successful e-Prescribers as required by MIPPA. The 2010 Physician Fee Schedule Final Rule, the policies for the 2010 PQRI and e-Prescribing incentive program will be finalized in the 2010 Physician Fee Schedule Final Rule with comment period. The Final Rule is expected to be published in the *Federal Register* on or around November 1, 2009.

Some key websites and contacts for references: the PQRI website is www.cms.hhs.gov/PQRI. The e-Prescribing website is www.cms.hhs.gov/erxincentive. We also have a Help Desk for PQRI and e-Prescribing. The Help Desk number is 1-866-288-8912. The hours are 7 a.m. to 7 p.m. central standard time. They can also be contacted via email. It's QnetSupport@STPS.org. I think this concludes our presentation. Any questions?

Dr. Bufalino: Questions. Please. Art?

Dr. Snow: I've got two. The first one has to do with this group practice reporting options and you talk about the groups having in essence more than 200 providers in those groups. Those are huge groups in my experience. I'm a solo practitioner and I know a number of small groups or even solo individuals who might be interested in using that option, but why are we not considering groups—why do we choose groups only that large?

Ms. Leslie: We modeled the program after the current physician group practice reporting option, that demonstration out of ORDI. We looked at CMS claims data, starting with 2006 and 7 to look at the number of group practices, based on the size of NPI or eligible professionals practicing under the groups. So we set the threshold at 200 because this is our first year of this group practice reporting option. So we didn't want to cast the net too broad to allow group practice to be defined as two or more practices. So we set the threshold at 200 to see how it's going to work with the 200. Then tweak it down and get it ready for 2011 and maybe propose it for a lower number then than 200 group practices, but then at first stab, we want to treat it such as a pilot or a test, way we did registries, and then further refine it and open it up to smaller practices.

Dr. Green: Also just if I may onto that, when looking at the conditions that the group practice demonstration requires a provider to report on, if you were to look at an individual practitioner, or even a small group of two or three docs, they may not forget the 600 and some patients and 411 if they have to report on, obviously they have much smaller number than that, but when we looked at some of the data, some of the Medicare participants, the eligible professionals, don't treat patients with certain conditions. Again, you'd almost need to get, I don't know that 200 is the magic number, but you need to get to a larger group size to capture all the conditions that the group practice model is based off of and certainly then in significant numbers. You wouldn't want, for instance if you only had two diabetics in your practice, and let's say for whatever reason, both of them were well controlled, or as well controlled as you might like, you wouldn't want that data reported as a reflection of how you care for the patients. So when you get down the smaller numbers, it gets to be much more difficult to get meaningful data out because you may just not have the patients have the same conditions in appropriate numbers.

Dr. Snow: Understand. My second question has to do, and I didn't see anything on your slide, it's my understanding that claims-based reporting is going to be eliminated or is recommended to be eliminated after 2010. What's the reason for that?

Ms. Leslie: For PQRI, PQRI is incentivized through 2010, not that claims-based reporting will be eliminated beginning 2010.

Dr. Green: I will say this. We are looking at different reporting options. You can tell, I'm sure by the slides, we're encouraged and are looking forward, if we're able, to accept data from electronic health records. I think it's consistent with the Administration's push toward electronic health records and I think as practitioners, we would all agree that that's likely a worthy place to be going in terms of collecting information from electronic health records. It's certainly much easier for eligible professionals to get the quality data from electronic health records. We can get more meaningful data. And I'm focusing on EHRs. But I should include registries in that. We can get much more meaningful data and really start looking toward outcomes as opposed to just these process measures that we're restricted to for the most part in claims. I mean, if you're looking at a complication from a particular surgery, for instance, no provider has the ability to hold on to his or her claim for three months to see whether the patient had a complication in the post-op period, whereas if you're using an EHR, or a registry, you certainly have that option, because you can send your bill in, get paid, have your office continue to function. Because I practiced, you need to have the income coming in obviously to continue operating in your office, but still and all, if we were to use strictly claims for those kinds of measures, we can't collect them. And in addition, there's other measures. For instance, Latousha mentioned the HIV/AIDS measures. Those measures require a provider to see the patient twice in I believe it's a 60-day window. Well, again, it's difficult from an analytic standpoint to see that the provider actually accomplished what the intent of the measure was, strictly through claims. We had a medication reconciliation where if a patient is discharged from the hospital within 60 days, we want that primary care doc, especially, but any doc, to do a medication reconciliation. Well, we found that providers were reporting just a medication reconciliation independent of whether or not the patient had been in the hospital, because either they didn't understand the measure, or they were unclear whether the patient had been within the 60-day period or outside the 60-day period so again with registries and EHRs, we think that there will be, it'll make it easier for eligible professionals. So you'll

notice again in the 2010 proposed rule, some of the measure groups are only for registries, or registries at this point, not for EHRs. To say that we're going to eliminate claims completely, I'm not sure I would make that statement at this point. Certainly it's not proposed for 2010, but we do recognize we can get better information from the other modalities. Sorry for the long-winded answer.

Dr. Smith: I have two questions also. One is on your slide 20 and there's a comparable thing on the group practice reporting option, but it says "the incentive payment applies only to eligible providers whose Medicare Part B, whatever that is, allowed charges for services in the e-Prescribing measures denominator greater than 10 percent." I don't understand what that means, what the words mean.

Dr. Green: Well you weren't supposed to. I'm kidding. Let me see if I can put that in English for you. Basically, to be eligible to participate in the e-Prescribing incentive program, 10 percent of your charges have to be comprised of codes that appear in the denominator of the e-Prescribing measure. So let me give you an example. Let's say you're a gastroenterologist, and you do $100,000 of Medicare charges in 2009, let's say. So of those $100,000 worth of Medicare Part B charges, and that stands for Physician Fee Schedule, the PFS, let's say $85,000 of it is attributable to colonoscopies or other endoscopies. But $15,000 of it is attributable to office visits; your 99212, 213, 214, etc., or your 202, 203, 204, and I think consultation codes are in there as well, which, these would be the three most common groups of codes that a GI doc would be that appear in the denominator. So $85,000 is colonoscopy. $15,000 is comprised of these other codes. Well, these codes all appear in the denominator, so by virtue of 15 percent of your total Medicare Part B charges for the year, you'd be eligible to participate. If on the other hand, $95,000 were comprised of colonoscopies and other endoscopies, and only $5,000 these office codes, you would not be eligible to participate in the e-Prescribing—

Dr. Smith: So you're saying basically the E&M codes is what you're looking at.

Dr. Green: The codes in the denominator. Now that's not to say that you'll only be paid the 2 percent on those particular codes. It would 2 percent of all your Medicare Part B charges, so the whole $100,000 if you will.

Dr. Smith. Okay. My other question is actually related to this year's program, and I think it's a concern that I expressed previously. But one of the comments in discussion of this year's program was that if Medicare in reviewing a physician's reporting decided that "not enough prescriptions had been submitted

electronically," the physician would not be eligibl,e and that was not a very clear statement to begin with. It's not a number and it's a broad concept, and anybody could decide that it wasn't enough. The issue came up in some of the discussions I've had with physicians, because a lot of prescriptions are dealt with outside the office visit. The physician gets a phone call from the patient or gets a lab report, and has to deal with a prescription. The physician may send that in electronically, but of course it isn't captured on the claim, because no claim is filed for the phone call, since we're not allowed to bill for phone calls. We'd love to be able to bill for phone calls, and then we could capture those data for you. But I don't know how Medicare is assessing when it's "not enough," that are sent.

Dr. Green: I'm not sure where you got the information from before, but I think I understand your comment and question. We're not looking certainly for 2009, we're not looking to see that you e-Prescribed X number of times. We're looking to see that you reported in at least 50 percent of eligible instances, so those 9921, whatever the codes we just kind of talked about, if that's the type of practice that you have, we would be looking to see, there may be patients that you never write prescriptions for. An internist, obviously, you can imagine or family practitioner, is going to be writing quite a few prescriptions. If you're an orthopedic surgeon, I'm not saying you're not writing prescriptions, but you're probably going to write your nastraroidals, you're probably going to write some narcotics, but narcotics, obviously you can't e-Prescribe. But if you have a qualified electronic prescribing program in your office, you would be able to still, and you meet the 10 percent denominator, you would still be able to meet the intent of the measure. There's a code that says no prescriptions are generated during this visit; that all were sent electronically, or that some or all were handwritten, and it could be the patient request. I mean, look, I practiced in Baltimore and we had quite a few snowbirds, so if it were September October, and I were writing my patient a maintenance medication, they often wanted it handwritten because they wanted to take it to Florida, where they were going to go for the winter and turn it in to the pharmacy down there. They were unsure which pharmacy they would even be using. So I couldn't have even e-Prescribed it if I wanted. So again, we're looking for 50 percent reporting. There is no magic number for 2009. Now you will notice again that we talked about the 25 times in 2010, and if that is actually finalized in the Final Rule, I think it gives CMS a little bit of a snapshot, but it also is not overly burdensome for the professional. If you're

using your e-Prescribing system 25 times, you're using it. People are not going to just take it out, dust it off, and use it 25 times just to get their 2 percent. Chances are, you're using it.

Dr. Bufalino: The question I have is, at least as of last week, when I talked to my staff, we still hadn't heard about the 2008. Do you have an anticipation as to when we're going to hear? Obviously tomorrow is September 1, it's pretty hard for us to change our 2009 reporting when we don't know what we did in 2008. Your thoughts?

Dr. Green: You want to do that one?

Ms. Leslie: The 2008 incentive payments and feedback reports will be available October 5, of 2009, so another month. The feedback reports will be available via the portal. We'll also have an alternative mechanism for getting feedback reports out to those solo practitioners who are having the trouble getting hung up in the—I did—the IX, Identity Management System we have called IX, getting the password. So we have an alternative method that will disclose all of the details on because we're still testing the process. We'll disclose the details on our September 17, National Provider Call. We understand that this is a big delay from, you reported in 2008, now it's going to be fall of 2009 you'll be receiving your feedback reports, telling how well you did and your incentive payment, if you did earn an incentive payment. Because the claims process that we based our information on, we have a twelve-month reporting period and the statute allows us or requires us to have to wait until all claims are submitted for the twelve-month reporting period of 2008 by the end of February in 2009. So we don't get that data until April of 2009 for reporting in 2008 to begin analyzing the files and testing and creating the feedback reports and the incentive payments. So we do that in about April, May, and June is when we come up with our last test file, in June. Since we're adding on the 2007 rerun, we're looking at those eligible professionals who did not earn an incentive in 2007, because we discovered some analytic fixes that we could do on our back end systems to rejoin split claims, to look at all the diagnosis on the claims form, so that additional folk would qualify. We applied those 2007 analytics to 2008, so that also caused a delay in proving out the feedback reports and payment file, which pushed everything back to the fall. So that for those who didn't qualify for 2007, you could potentially qualify now and receive an incentive payment. Those incentive payments and feedback reports will be available in November of this year. So October for 2008 payments, November for 2007 payments, and both the 2007 and 2008 feedback reports will both be available early October.

Dr. Bufalino: Obviously we know that this was a new program, and there's obviously a startup period, but as you go forward, since this is continued to be funded now into 2010, do you anticipate a more efficient system, since we continue to struggle with the fact that we don't know how well we're doing? Do you think as we go forward into 2010, this turnaround will likely be better?

Dr. Green: It'll likely be better than it is this year, again, because hopefully we won't have the 2007, obviously, rerun to incorporate, as well as the analytic fixes that Latousha discussed. But as she also pointed out, we have to keep the files open, if you will, until the end of February, partly to capture charges that may come in, which would increase the eligible professionals incentive payment, and also, of course if there are quality data codes on those claims as well. So right there, we don't get that file until April, so while I do expect it to improve, I don't think it'll be October of next year, I think it'll be earlier. To say that it's going to April of next year, I think is unrealistic. One thing I would suggest though, for folks that do participate through a registry, that is one of the added features of the registry. We can really use it for quality improvement insomuch as they can give interim feedback reports basically on a quarterly basis, because you're submitting the information and they're calculating it fairly quickly. So again, I don't want to speak to any specific registry, but some registries could offer the information on a monthly basis, quarterly, semiannually, whatever, and it does enable eligible professionals to look and see not only how they're doing from a reporting standpoint, which of course is important from PQRI, but also from a quality standpoint, so it really accomplishes the intended purpose of PQRI anyway, which of course is to improve quality.

Dr. Bufalino: Obviously, though, the concern is how well CMS adjudicates that data and while you may get feedback from the registry, which I understand you're accepting most of them today, the real question will be, how well will that match with your analysis of the data, and so, and although it gives you a glimpse, it sure doesn't tell us, will we be paid for—

Dr. Green: You're absolutely right. We do, we are looking at the crosswalk of the data. We also recognize however, that the data's not going to match 100 percent. There's going to be some discrepancies in terms of how claims that we get versus what registry reports—you can imagine if you're covering for Ken, let's say and let's say you're both internists. Ken's managing this diabetic patient. She comes in because she has an upper respiratory infection to see you, so you do a focus visit for the upper respiratory

infection, don't really do much with the patient's diabetes, because again, she's there for a sick visit. A registry, by virtue of knowing that the patient is a diabetic, could include that patient in your population, versus on the claim, you may just put URI and your E&M code and that's the end of it. And appropriately, you didn't treat the diabetes. So you can see right there, for instance, would be an opportunity for a mismatch. So basically we recognize it's not going to be 100 percent or one-to-one match and we're looking at the acceptable tolerance levels. Similarly, we allow for the measures groups as Latousha pointed out, it doesn't have to be all Medicare patients, it could be patients with other types of insurances, as long as at least two of the patients have Medicare Part B. We can't match up Blue Cross claims, of course. So again, there's another example where we recognize that we're going to have to trust the registries. Now the registries are certifying that the information or testing that the information is true an accurate to the best of their belief. There is an opportunity, CMS maintains the opportunity or the right, if you will, to go in and audit a registry. That's not on the drawing board at this point.

Dr. Bufalino: As a follow up to that, to look at e-Prescribing, what is your anticipation of the cycle, for those of us that embraced it—my practice writes 5,000 e-Prescribed medications a week and we're all curious as to how long will it take for them to figure out that we've circled one of the three G codes and be able to turn this around?

Ms. Leslie: The turnaround time for e-Prescribing for those who participated in 2009 is the same with PQRI for 2009. We're looking at midsummer, 2010, providing our feedback report is in incentive payments. Because we get the file the same time, the 12-month reporting, we get the file—reporting ends end of February, we actually get the tap file April. So it's going to be midsummer.

Dr. Green: And the other thing is I mean one of the nice things about the proposed change with the 25 prescriptions, I mean conceivably let's say in the first week of January, you meet the requirement. You've e-Prescribed on at least 500 of your Medicare patients in your group or whatever, and again, it's 25 per provider. Still and all, there's a cost and a time associated with running these reports, and at the same time, sometimes when we start trying to create these special reports, if you will, we run the risk of bumping the main production, so while we might be able to qualify people on an ongoing basis, it would end up that the folks that didn't meet the requirement till the end of the year would be bumped out well beyond the summer of next year. So it's a balancing if you will.

Dr. Bufalino: It just seems that eased up the reporting and made it so much easier, that a six-month reporting mechanism might make some sense, much like you've done the six-month opportunities today, where you could then by the end of August or September, have an assessment for the first month of that fiscal year and be able to turn that information around more quickly.

Dr. Green: I mean it's a great suggestion, and certainly I'm being serious not to be flip, but if you have an opportunity before 5:00 today, please feel free to submit the comments. It is something that we will consider. Again, great suggestion, we do pay the percentage, the incentive payment if you will, based on the length of the reporting period. So again, even though you might meet it in the first week, that doesn't mean we'd only pay you an incentive for the week. Of course we'd pay you for the whole year. Gets to be a little bit tricky if we specify a reporting period, but again, that's more for the—

Dr. Bufalino: Would it suffice for us to make a recommendation as part of the Council today? Would that meet the 5:00 reporting deadline?

Dr. Green: Do we have our legislation people here?

[off-mike response]

Dr. Bufalino: Thank you. Other questions. Sorry to dominate the conversation. Pam?

Dr. Kirsch: With multi-specialty groups, how is that going to look for say for a person who's a subspecialist, versus a family practitioner in that multi-specialty group? Who's going to be maybe dominating, putting more volume into that group data? How are you going to—

Dr. Green: You mean more of the charges?

Dr. Kirsch: Right. I mean you're going to get more information from them, they're going to be doing more e-Prescribing, they're going to be doing, so how's that going to look to the group? Are you going to just do this as a group?

Ms. Leslie: Group reporting will be, the incentive will be based on the 10, the amount for the tax ID number, which is a roll-up of all the NPIs or eligible professionals who are participating under that 10, and the incentive payment would be provided in a lump sum. So it would be up to the multi-specialty group to determine how to distribute out, or what eligible professionals provided the majority of the services for those patients, but we will require that no matter how many specialties in your multi-specialty group or

how many eligible professionals contribute to completing the data, that 26 measures for the 411 patients. That'll be a decision for the 10 organization to determine.

Dr. Green: And again, if you think about it, I believe one of the conditions is diabetes. It looks like you're a surgeon. So while I'm sure you're doing a lot of e-Prescribing, and doing all your perioperative stuff from PQRI, I don't know, and certainly not trying to, but your average surgeon probably would not be managing diabetes on a day to day basis, except for when the patient's in the hospital. So kind of [inaudible-cough] but that's going to be up to your group ultimately to decide how to apportion the incentive payment.

Dr. Giaimo: I'm in a situation that a lot of physicians—I'm a solo practitioner down in South Florida, and a lot of people who have been early adopters of the EMR systems are finding their systems are changing significantly. I'm probably going to have to shift to another system. With that, I know we haven't had the incentives that have come to us from our initial early adaptation. How will they work that out, as far as if we switch to a different system? Do we get reported on from the first system, that may not be updated or…

Dr. Green: Again, I assume you're referring to ARRA?

Dr. Giaimo: Yes.

Dr. Green: I'd love to be able to answer that question. But this is a PQRI talk. What I would suggest is, I mean I can speak to it from a PQRI standpoint. If you look at our EHR measure in PQRI, we specifically for instance, have that you could be using a system that met a certain level of functionality but didn't have to be CCHIT certified. We felt strongly about that just for the exact, just for what you stated. We didn't want to penalize early adopters before CCHIT was around or before they had an opportunity to look at a bunch of different systems. As we move toward the future, the Secretary will be establishing the certification criteria for any EHR in terms of the payment, again, I really can't speak to that, but that will all be coming out in an ARRA rule, and I'm sorry I can't address it beyond that.

Dr. Giaimo: Do you have any idea when that ruling will come forward, or is there…

Dr. Green: I believe, maybe I shouldn't guess. But I think the proposed rule sometime between December of this year and May of next year, but please don't hold me to that. I'm really not sure.

Dr. Bufalino: Other comments or questions? Thanks all of you for joining us this morning. We appreciate the conversation. Thank you.

Dr. Green: Thank you for having us.

Dr. Bufalino: I think maybe we'll just take our 15-minute break now unless—the DMEPOS people are probably not in the room. [crosstalk] I apologize. Sorry. I'm sorry, I got the idea that Dan delivered it so, go ahead.

e-Prescribing Update

Mr. Morgan: From what I've heard in the room so far, it seems like a few of you in here are pretty adept in e-Prescribing already, so I don't know what I may tell you may be any news to you, but what I wanted, was asked to do today was just go over some of the updates of the standards of the e-Prescribing program under Part D. I work in the office of E-Health Standards & Services, where I'm the e-Prescribing lead. This office used to be called the Office of HIPAA Standards, so you can understand what we do here. We do a lot of standards work, work with a lot of standards organizations to get this stuff moving forward.

So what I want to talk a little bit about today was Medicare Part D prescribing program. I want to talk a little bit about the standards that we have in place and some of the recent changes to new standards that we have adopted. I also want to talk to you a little bit about next steps. It has to do with some standards that we are currently testing in a pilot program, and some of our work with the DEA, the Drug Enforcement Agency, with the issue of the controlled substances, and lastly, I left you a little contact information if you have any questions afterwards.

Since coming to CMS about four years ago, I had to learn a new language, and that was acronyms. Everything is shortened and in the first few months I was there, I had no idea what anybody was talking about, so I threw a couple of these up here just because this is what I deal with everyday. I deal with the National Council of Prescription Drug Programs, which is NCPDP. They are voluntary-standards-setting organization, which I am a member of. They mainly focus on e-Prescribing standards. They do telecommunication standards, which is the billing standard, that the pharmacies bill, their claim, the pharmacy claims, and a lot of DUR activities go along with that billing standard. I work closely with the National Committee on Vital Health Statistics, NCVHS in the MMA. When we adopt a standard within the MMA, we have to bring it forth to the National Committee of Vital Health Statistics and they make

recommendations to the Secretary on those standards. The Drug Enforcement Agency, this is, been working with them for the past four years, in trying to change the law regarding controlled substances. Currently you are not allowed, it is against the law to prescribe these medications electronically. And lastly, the Medicare Prescription Drug Improvement & Modernization Act of 2003, MMA, which created the e-Prescribing program.

What is e-Prescribing? E-Prescribing, the definition we use is a prescriber's ability to electronically send a clean prescription directly to a pharmacy from the point of care, and it's also a transmission of prescription, or prescription related information between prescriber, dispenser, pharmacy benefit manager, or health plan, either directly or through an intermediary, using electronic media. What is not e-Prescribing? Secured email, we don't consider that e-Prescribing. Faxing, traditional paper faxing, we don't consider that e-Prescribing. We do allow for computer generated faxing to be allowed as e-Prescribing. What that will change in 2012, in 2009 Physician Fee Schedule we had, no 2008 Physician Fee Schedule we had suggested that we remove the computer generated fax as an exemption in that only physicians who were using the script standard to send their claims were to be considered electronic claims. In early 2009, we heard loudly from the pharmacy industry, saying that would create an undue burden to them because they used fax servers a lot of occasions to send refill requests to the physicians. After discussing it with the industry, we came to find out it was like an $88 million dollar burden per pharmacy if we lifted this exemption, so in 2009, we put the exemption back in place, and because of with MIPPA and incentives, we felt like we wanted to give the incentives an opportunity to succeed. But we did, however, say in 2012, we would be lifting that exemption, because that's when the disincentives would kick in under MIPPA if you're not e-Prescribing.

Under our regulatory requirements, the Title 1 of Medicare Modernization Act, the Section 101 gave us the authority to establish a voluntary e-Prescribing program. What I mean by voluntary is physicians and pharmacies, it's voluntary for them to participate in e-Prescribing. If they choose to e-Prescribe, they must use the standards that are adopted through, that CMS adopts through regulation. Plans, however, have to support it, all the adopted standards. The Act requires that the electronic transmission of prescriptions and certain other information for covered Part D drugs, as prescribed for Part D eligible individuals, meet standards. So what we're saying here is that if you're seeing a patient and their Medicare,

even though they're not covered, they have a Part D plan, they are eligible under the plan, because they meet the requirements.

And throughout 2004 and 2005, we had many testimonies through NCDHS on the first round of standards that we would adopt for the program. It was decided that we would adopt industry-tested standards, transaction standards that were being used in industry on a regular basis. And we came up with three. The first one was NCPDP script standard, version 5.0. This is a transaction that goes between the physician and pharmacy. It's actual electronic prescription. The second standard that was adopted was the X12, the 270-271. It is an eligibility standard that goes between the physician's office and the plan, or Part D sponsor. The third foundation standard is the NCPDP telecommunications standard, or telecom standard. It's version 5.1 and it's noted that this is a HIPAA standard as well as the X12 standard above it. This standard is used for billing the claim and is eligibility standard and benefits inquiry that happens between pharmacies and Part D sponsors.

The Final Rule, those were the three foundation standards. In 2006, we pilot tested what we called six initial standards for a year. We had five grants that went out with the partnership of AHRQ. We tested them for a year. We decided through the testing of those standards, we came up with the next round that was in statute that we would adopt additional standards by April 7 of 2008. Of those initial standards, we adopted a medication history response that formulated benefits, a benefit check. You can find out if a medication is on formulary, co-pay amounts. It doesn't give true co-pay amounts in most cases, it may give a little dollar sign, one, two, or three dollar signs. It gives tier benefit information, whether medication is on generic or brand-preferred or nonformulary. We adopted the RxFill response. At the time when we adopted it, it wasn't widely used in practice, but it did work, and it worked well with the other standards. What RxFill does is if a physician wants to know if a beneficiary has gone to the pharmacy and picked up the medication, the pharmacy can ping back a message to the physician, letting him know that the medication was dispensed. Within that, we retired NCPDP 5.0, and we replaced it with version 8.1. While this script standard is constantly changing, I think they're up to version 10.6 right now, and I was at the last group meeting and they're now talking about version 11. So it is constantly changing. And we also adopted use of the National Provider Identifier, the NPI, as an individual identifier. We're asking for the individual NPI on the prescription.

What are some of the next steps? Two of the foundation standards, actually three of the initial standards that we tested—RxNorm, Structured and Codified Sig, as well as the electronic PA—did not make it through the pilots. They had some issues and they were not working well with the other standards, so at the time we decided not to adopt them, but two of the three worked pretty close to being used. They just needed some tweaking, so they went back to the standard SDOs. We tweaked the standards from what we had found out in the pilots and now we're currently retesting RxNorm, which is a way of crosswalking the drug name to the NDC number at the pharmacy, so when the prescription comes across, it will automatically pick the NDC number that that pharmacy has in stock, so there will be less rekeying, when the prescription comes in. And Codified Sig, which is the directions. We're trying to see if it can be standardized, a way that the directions are written on e-Prescribing. What happens a lot of times is the text field, free text field is being used and when it hits the pharmacy, sometimes it tends to be garbled, and it prompts a phone call and so what we're trying to do, and e-Prescribing tries to do, is trying to eliminate some of those phone calls then make a more efficient work flow.

So as I said, some of the modifications were made as a result. In February 2008, we convened a panel of industry experts to meet on the next steps for these standards. About a year ago, RAND, Dr. Bell at UCLA, Griffin School of Medicine was awarded the contract to pilot test the structure in Codified Sig, and RxNorm, as well as the NCPDP Script version 10.5. We continue to develop the prior authorization business and process for the standards. I currently can tell you that there is a new prior auth, electronic prior auth standard that has been created. It has been created at the task group level at NCPDP, and in November, it will be brought forth to the work group in New Orleans to be voted on a draft standard so it can be tested. This is a new model. The old model was based upon three other old standards. It was kind of a kludge of HL7, NCPDP Script, along with X12 and it was just too burdensome when we tried testing it. Some other recent activities is NCVHS has sent a letter to the Secretary to adopt Script 10.6. Just a little background on this: long-term care is currently exempt from e-Prescribing under Part D, because of their prescribing workflow. It can go from a physician to desk nurse who then enters it into the system. It goes to the pharmacy. So long-term care said it was just too burdensome for them if we allowed them to do it in 2005. Since then, long-term care community in the industry has worked very hard through NCPDP to update the script standard to allow for this workflow, and currently that is version 10.6. And we have heard testimony

from NCVHS last February, they had written a letter to the Secretary, recommending that we adopt 10.6, and so in future regulations, we may do that. And also we're looking at what future standards that are out there that are identified and see if we could use them in e-Prescribing.

Here's the fun slide: e-Prescribing under controlled substances. By the time, I've been working with the DEA as long as my youngest daughter has been alive. So in 2005, I started working with the DEA to work out a solution, actually our office to work out a solution so we can allow physicians to use e-Prescribing for controlled substances. We've held some town hall meetings back in 2006. We've been to the Hill quite a few times for testimony. There's a few Senators, Senator Whitehouse is very interested in getting something done. But some good news is September 2008 DEA has put out a Notice of Proposed Rule Making, NPRM, and the comment period closed in September. So that's good news. Some of the bad news was some of what they advocated seemed to us to be a little burdensome, they have advocated a solution of two-factor authentication, very high security, they wanted some in-person proofing to make sure that who you say you are, you are, and they advocated a two minute time-out. And what they meant by that is as long as the system stayed idle, it would time out and you would have to reauthenticate. This grew a lot of opposition due to comments and they came back to us and said that's not what they really meant, so we'll see what they meant by that. In October of that year, 2008, HHS convened a work group of some folks from my office as well as from ONC to work with the DEA on some of the issues and to go through the comments that came in from industry. We have helped them understand how e-Prescribing through our perspective, through patient care, and they've tried to help us understand what they need through law enforcement, hopefully that we can come together and come out with a good rule. What some of the things that HHS has been advocating through the rule for controlled substances is it has to be interoperable, with existing e-Prescribing systems, and our major concern is we want it to be scalable, we want it to work throughout the healthcare system without imposing an undue burden, and we want it to help most of all, to adopt e-Prescribing adoption. What we don't want as a rule that comes out, that may be burdensome that would actually throw up more barriers in it than what it caused beforehand.

Where do we go from here? From a standards perspective, we finished the initial standards suites. We're currently testing the last two of them, and we've been working on getting electronic prior auth ready to be tested. We still continue to work with the DEA today, to put out a Final Rule on controlled

substances. We are looking at lifting the long term care exemption, to continue to monitor effective use of standards and we also continue to work with the standards setting, development organizations, and NCDHS on additional standards requirements.

And here you can go on this website and go look at all the e-Prescribing standard regulations. There was one put out in 2005 as well as in 2008. And some other e-Prescribing—it also will link you to the PQRI sites too, for the incentive. And that's it, any questions, I will take them.

Dr. Bufalino: Thank you. Sorry for the initial oversight—

Mr. Morgan: That's okay.

Dr. Green: Just one quick thing, I'm sorry to jump on what Andrew said. Just want to clarify because I get this question at least three times a week, still. e-Prescribing and faxing. If you have an electronic prescription program in your office and you type out a prescription, print it out and then fax it over to the pharmacy, that does not count as e-Prescribing. What Andrew was referring to is if it's sent over a network, let's say, and the network converts the electronic message that you sent, into a fax and sends it to the pharmacy, so to the best of your knowledge, it was sent electronically, that still counts as electronic prescribing under our program. But not you faxing it directly from your office. Sorry.

Mr. Morgan: That's okay.

Dr. Bufalino: Thank you. Questions, comments anyone?

Dr. Kirsch: [inaudible] practices and standards. What do you envision that making? [laughter]

Mr. Morgan: That's been the question. There's two different ways, there's what we have, what has been built was a model where you prescribe a drug, say a like Prilosec or something, and it's usually on prior auth, what would happen is that the plan would send criteria back to the physician, where then on e-Prescribing application you can put in what is being asked for, sent back, and then either approval or denial is then transmitted back. What currently happens is you know, you write the medication goes to the doctor, then the patient takes to the pharmacy, there's PA flag hits, then you got to call the doctor, and we're trying to make the workflow a little bit better. Instead of waiting for that denial at the pharmacy, we're trying to head that off while the patient is still in the physician's office, is what we're trying to achieve with that.

Dr. Williams: What about hospital-based physicians? I'm an anesthesiologist?

Mr. Morgan: Is that him or me?

Dr. Williams: Anybody, I mean what's—

Mr. Morgan: The e-Prescribing program for Part D is ambulatory based.

Dr. Williams: So if an anesthesiologist writes a prescription for an outpatient to go home, then that would count—

Mr. Morgan: Currently, as long as it's not controlled or anything like that, yes, they could.

Dr. Green: The problem with it actually counting though, if you will, in our e-Prescribing incentive program, you wouldn't be billing one of the codes that would put you in the denominator of the measure, by virtue of administering the anesthesia. So now if you were working let's say in a pain clinic, that could be, again as long as it's not a narcotic, because then you'd have to write it at this point, but again, if you were seeing patients in an outpatient setting in a pain clinic, you may actually bill a 992 whatever, in which case, again that patient would be eligible to be reported on from an e-Prescribing standpoint, but again, 10 percent of your charges would have to be made up of those codes, so it wouldn't be like once a month you go work in a pain clinic, it'd have to be at least on an ongoing basis.

Dr. Bufalino: Other questions, comment? Thank you again for joining us this morning. Glad to have you. We will take a 15-minute break and reconvene at 10 to 11.

Break

DMEPOS Competitive Bidding Update

Dr. Bufalino: Just in an effort to keep us on schedule, next I'd like to introduce Lorrie Ballantine, who has been with the agency over the last 15 years, working at various projects. She was part of the Program Integrity Coverage Analysis Group and now with DMEPOS and she's here to talk to us today about the status of DMEPOS Competitive Bidding Program. Thank you for joining us this morning. Welcome.

Ms. Ballantine: Oh thank you. Thank you. This presentation's going to provide a background and goals of the Competitive Bidding Program. I'm going to give a brief overview of the program and the projected timeline of important events. I will briefly discuss the bidding process and how the program will affect beneficiaries. In 2008 Congress implemented the Medicare Improvements for Patients and Providers Act, MIPPA, which mandated limited changes to the Competitive Bidding Program, and I will highlight these changes for you. And in addition, I will explain how to locate a supplier in your area. I tried to give

this presentation not a whole lot of details, more towards something the physician community would be interested in. I think I have to start with a little bit of background on how the current fee schedules are established. According the Omnibus Reconciliation Act of 1987, fee schedule amounts for DMEPOS were established based on reasonable charges of claims submitted before 1986. These prices are adjusted yearly by the annual consumer price index, CPIU, or an amount determined by Congress. For new items added after that time, we either had to identify a comparable item, or accept a manufacturer's suggested retail price to establish the payment amount. Neither method has been without controversy for new items and has resulted in excessive payments for certain items. For years both the Government Accountability Office and the Office of Inspector General have issued reports stating that CMS pays too much for certain DMEPOS items. Therefore in 2005, the Medicare Modernization Act established the Competitive Bidding Program to be phased in beginning with 10 of the largest MSAs. So the goals of the Competitive Bidding Program: 1) to ensure Medicare beneficiaries have access to quality medical equipment at lower cost. From the program, we anticipate savings for the beneficiary, the Medicare program, and the taxpayers. Under this program, CMS will only contract with qualified, accredited suppliers that meet all of the competitive bidding requirements, thereby helping to deter fraud, waste, and abuse. For the first time, Medicare will allow the marketplace to determine an appropriate payment amount for competitively bid DMEPOS items. A main goal of the Competitive Bidding Program is to set appropriate market driven prices.

This is just an overview to recap that the new Competitive Bidding Program changes the way Medicare will pay for DMEPOS by replacing the current DMEPOS fee schedule payment amounts in certain areas with a competitively bid single payment amount. We did conduct round one, and we had a projected savings of approximately 26 percent for all the items that we bid.

This is a little hard to read, but I think it's a really interesting slide. It identifies, just for certain products, the savings that was realized. For example, Medicare currently pays on average, $199 per month for an oxygen concentrator. Under competitive bidding, the payment was reduced to $141, saving the Medicare program $47 a month per beneficiary, and saving the beneficiary approximately $12 a month. At the end of the three years that we rent concentrators, we currently pay $7200 at the end of three years. Under competitive bidding, it would have cost approximately $5,000, so that does represent a pretty big savings for everyone involved. The same thing was seen for hospital beds. We currently pay $140 a month.

That price was reduced to $99 a month, saving the program $33 per bene, and saving the beneficiary $8 a month. The biggest savings was seen in diabetic testing supplies. The current payment is $83 per month, and that would have been reduced to $48 a month, saving the program $28 a month and the beneficiary $7 a month. For this product, we only bid replacement testing supplies, leaving the beneficiary with a choice of monitors.

So upcoming events and some time lines. The registration for the competitive bidding rebid of round 1 opened on August 17. To date, we have almost 500 suppliers signed up to bid. Our target date to open up the bid window is 12-21-2009. We plan a 60-day bid window, which is targeted to close 12-21-2009. After the bidding window closes, we will begin an extensive bid evaluation process. We plan to announce the single payment amounts in June of 2010, and in September 2010, announce the names of the winning suppliers. Our goal is for the single payment amount to be effective in January 2011.

I'm just going to briefly outline the eligibility requirements that a supplier has to meet to be able to bid and we awarded a contract. Suppliers must be Medicare enrolled suppliers, with an active National Supplier Clearinghouse Number. They must be accredited by the September 30, 2009 deadline, and possess a $50,000 Surety bond for each location by October 2, 2009. Suppliers must also possess all required state licenses for the states in which they bid before they submit a bid.

Now I'll briefly outline the bidding process. Bidding will be done by HCPCS codes grouped together into product categories. These are similar to the policy groups established by the DME MACs. A single payment amount will be determined for each code based on the median of the winning bids. We will award contracts to qualified bidders with the lowest bids. These suppliers will become contract suppliers. We will select a sufficient number of suppliers to meet the projected demand in an area for the items. And in awarding contracts, we've made special consideration for small suppliers. Our goal is for 30 percent of contract suppliers to be awarded to small suppliers. By small suppliers, we define that as annual revenues of $3.5 million and we did that in regulation.

So how will beneficiaries be affected by competitive bidding? Beneficiaries who live in or visit the CBA must use a contract supplier. Therefore, some beneficiaries may have to change suppliers in order to receive payments from Medicare. We have included a grandfathering process in the program. Those currently renting DME equipment or oxygen have the choice to stay with their current supplier if the

supplier chooses to be a grandfathered supplier and continue to furnish the rented item. The program makes an exception for physicians who furnish certain items: canes, crutches, walkers, glucose monitors, manual folding wheelchairs, and infusion pumps that are given to their patients as part of their routine services. These physicians do not have to bid or be part of the Competitive Bidding Program to continue furnishing these items, and the Competitive Bidding Program does not affect which doctors Medicare beneficiaries can use.

So to ensure quality, one of the goals in developing the program was to build in protections for beneficiaries. One such protection is a nondiscrimination clause in each contract. A supplier must offer Medicare beneficiaries the same items they provide to their other customers. We believe this allays some of the concerns and criticisms that Competitive Bidding Program will result in lower quality products being provided to beneficiaries. We believe the quality and service may become more important to contract suppliers who will now be competing to gain market share. Another beneficiary protection allows physicians to prescribe a particular brand or mode of delivery to avoid an adverse medical outcome. If the physician orders a particular brand, a contract supplier must provide this brand to the beneficiary or work with the physician to comply with this requirement. If need be, they must find another contract supplier who can furnish the brand that the doctor orders.

So now I'll discuss some of the changes made by MIPPA. It made limited changes to the Competitive Bidding Program. We implemented, I guess everyone knows, that we implemented round one of the Competitive Bidding Program beginning July 1, 2008. Two weeks into the program, Congress passed MIPPA, which delayed the program. The contracts that were awarded were terminated, retroactively, and payments were reverted back to the Medicare fee schedule amount. MIPPA does require us to conduct round one rebid in 2009 for the same items and areas with a few exceptions. They exclude Puerto Rico from bidding, and negative pressure wound therapy from the next round of bidding. Group three complex power wheelchairs were excluded permanently. And also this is outside of competitive bidding, I'll just also mention that MIPPA also made changes to the accreditation process by allowing CMS to exempt certain eligible professionals who also service as a supplier, from the accreditation requirements. We've issued a fact sheet—this is, like I said, outside of the Competitive Bidding Program, it's not my area of expertise, but we did issue a fact sheet that defined the eligible professionals, which were now exempt.

They include such groups as physicians, PTs, OTs, qualified speech-language pathologists, physician assistants, nurse practitioners, clinical nurse specialists, and there's a whole list of other professionals that were exempt from the accreditation under MIPPA.

So one of the problems we encountered in round one was that suppliers did not submit a complete package of financial documents and they were disqualified from the program. So to address this, MIPPA included a process for CMS to provide notice to certain suppliers of missing documents and give them an opportunity to submit these documents so they won't be disqualified the next round if they adhere to that. And another change in MIPPA was to establish the same exemption for hospitals as provided to physicians in the final regulation. Hospitals are exempt from bidding if the hospital furnishes crutches, canes, walkers, folding manual wheelchairs, blood glucose monitors, and infusion pumps to their own patients, when date of admission or discharge. So how to locate a contract supplier. I thought you might be interested in knowing that we do have a tool available on the CMS website to assist beneficiaries, physicians, referral agents, and other prescribers, so you can now, information on competitive bidding will be part of the supplier locator tool. Prescribers can locate the names of winning suppliers by zip code or by supplier name. The supplier locator tool can be found on the Medicare.gov website. It's under the Supplier link, and it's an easy-to-use tool to locate suppliers. We plan to include manufacturer brand information on the tool so that you can identify the brands of products contract suppliers will be providing.

We try not to duplicate information on the various websites, so for providers, suppliers, and referral agents, information about the program can be found on the CMS website, or the competitive bidding implementation contractor website, both of which are listed here. For beneficiaries, we use the Medicare.gov website to provide them with important information on the program. So there's my contact information. You have my name and number's right there if you have any questions.

Dr. Bufalino: Questions, Frederica?

Dr. Smith: I'm somewhat concerned about how this affects particularly rural areas. I'm thinking about New Mexico, obviously, because that's where I'm from, but it's not applicable just to that. If you have a supplier of say home oxygen equipment, who has to drive two hours each way, four hours round trip on winding mountain roads to deliver oxygen to one person, that person's cost is dramatically higher than somebody who's in the city of Albuquerque, who may be able to deliver oxygen to 50 people in the course

of a day without driving half the distance. You can cover a lot of distance in Albuquerque, but not winding mountain roads. And so I'm a little concerned that it may have an impact on our patients in the rural areas, if their semilocal provider is basically put out of business because that company can't afford to compete with the big provider in Albuquerque, but then the big provider in Albuquerque discovers it can't afford to provide the service for what it bid for because it didn't realize what it was getting into. And that to me is a very serious concern. I suspect it's true in 50 percent of the states.

Ms. Ballantine: Yes, we recognize that. And also, the areas in MIPPA that I talked about are areas that we've actually issued regulations on. One of the things that Congress also included in MIPPA are some pretty stringent restrictions of where we can conduct competitive bidding and where we can't. And they've defined rural areas as an area where we can't, areas with low population density, areas that are not considered competitive. So we will be looking, before we determine, we have to start out with the Metropolitan statistical area, and then we carve out what we call the competitive bidding area, and we really scrutinize an area. For example, the Riverside County, we divided, we took the desert out of the competitive bidding area just for that reason. We used that Riverside Metropolitan statistical area, but we carved it out to make it so that it really is a competitive area that we actually conducted competitive bidding in.

Dr. Smith: I'll point out that you confuse me a little, because I interpret MSA as Medicare Service Area, not Metropolitan Statistical Area. If I'd gotten that, the question might have been irrelevant.

Dr. Ross: Yes, two questions please. The first question deals with the general suppliers, and the order by the physician. What types of provisions do you have that are in place when the physician orders a specific modality or durable medical, or an appropriate substitute, and they're not met? I've actually seen this happen where an order is specifically written and a substitute is made, and it's not as good as it should be, or the materials are a lesser quality, or it's not made appropriately, and so the patient comes back to me and is not really pleased with the product, and then I have to make all these recommendations, all these prescriptions back to the supplier and it's time wasted. It's time wasted for me. It's time wasted for the patient. What types of provisions do you have for that specific scenario?

Ms. Ballantine: That's the physician authorization provision that I did discuss.

Dr. Ross: Yes, exactly.

Ms. Ballantine: So you can actually describe what product you want, what brand, and I'm think the supplier locator tool would also help you locate suppliers that have the brands that you're interested in.

Dr. Ross: So what I'm saying specifically is, I'm not talking about the physician supplier, I'm talking about let's say in this case, a scenario of an orthotic brace shop. The physician refers the diabetic or the patient to brace shop for specific insole or shoe, in this case. But the order is not fulfilled correctly, or it's not filled appropriately and the patient's dissatisfied. The doctor's not too happy about it. Patient goes back again, patient has paid for the product. So what type of provisions do you have to try to remedy the situation?

Ms. Ballantine: Well, we actually have a contract with these suppliers, and I think that could happen inside and outside of competitive bidding, that scenario you're describing, and what we see in Medicare is the HCPCS code that describes the product the best it can, so that's what we see on the claim. We don't see the brand identified on the claim, so that could happen like I said either way. But under competitive bidding, they are required to provide if a physician orders a specific brand, to avoid an adverse medical reaction, then that supplier's obligated to do that. And if we find that they don't do it, we have a contract. We have a contract with them—

Dr. Ross: So, do you survey the physicians? How do you investigate the matter? Or do you have to get a letter from the doctor saying that the doctor's not satisfied with the product? Or the patient has to write a letter or how do you review this?

Ms. Ballantine: Well, we would hope that we would get calls. We have our competitive bidding implementation contractor is available to take calls like that for complaints. We have 1-800-MEDICARE that takes beneficiary complaints. We would appreciate definitely hearing those kind of things and I think we have a bigger stick in competitive bidding to address that, because that is actually a requirement of the contract.

Dr. Ross: Okay. The other question I had was you threw out another Competitive Bidding Program problem, and after you mentioned Puerto Rico, you mentioned about a negative pressure wound modality. It wasn't on your presentation. Can you elaborate on that particular modality, because I actually use that.

Ms. Ballantine: The negative pressure wound therapy was—we cannot bid that in this next round. We can bid it in future rounds, however MIPPA requires that a study be done to compare the different kinds of products on the market to see if they really are similar. So until the study's done, we won't be doing negative pressure wound therapy in this next round of bidding. We moved from one of the products that we were going to bid.

Dr. Ross: Are you looking for more evidence-based information? What are you looking for?

Ms. Ballantine: Well, there's several pumps on the market.

Dr. Ross: Right.

Ms. Ballantine: And there's been a lot of I guess, there's been discussion that the one pump is far superior, according to the company, than the other pumps, and I think we need to just—and that they're not all the same. So I think that decision needs to be made before we could rebid this.

Dr. Ross: But it will be reimbursed for the beneficiary if we prescribe it? If we're using negative wound therapy?

Ms. Ballantine: It's outside of competitive bidding, so it won't be included in the program. So yes, it's still being paid for by Medicare.

Dr. Ross: I see.

Ms. Ballantine: Yes.

Dr. Ross: Thank you.

Dr. Standaert: Question, you said physicians can continue to [inaudible] certain competitive bid items not being awarded a contract. Is that a finite list or is, I mean physicians, say in orthopedics, you can have a variety of different fractures, or splints, or cervical collars or things that people really need to have before they leave your office to give out. Is there a finite list that restricts what you can use, or is it just sort of you can supply broad categories of things that you may need to treat emergent conditions?

Ms. Ballantine: And actually the list that I spoke about, MIPPA did some other things. We only implemented the parts that I spoke about, so far. There will be another rule that comes in and implements some of the other conditions of MIPPA, and one of them is that we should be excluding off-the-shelf orthotics. A physician can prescribe off-the-shelf orthotics outside of the program. That we have—it is and that's why it wasn't done. The rule that we issued implemented just the self-implementing parts of MIPPA

that were very simple so we could get, parts of MIPPA, which means it's just parts that don't take any, a lot of notice and comment, rulemaking, because it's pretty much on its place, the way we have to proceed. So we implemented all of those parts. There's some other parts that will take notice and comment rulemaking and that part, that will be included in there when we define the—

Dr. Standaert: So is that, when the rule goes into effect will that exemption be in there, that's what I'm trying to follow. So will the exemption be there, that there's another rule that has to come that will allow an exemption for various orthotic—

Ms. Ballantine: It's going to be another rule that has to come out that will define.

Dr. Standaert: So will there be a period of time where we can't do that? When as a physician there's no exemption to give somebody for example, a cervical collar when they come in with cervical fracture and they can't leave your office without the collar.

Ms. Ballantine: In the competitive bidding area. But we are not bidding off-the-shelf orthotics at all. We're not bidding them, so they are outside of competitive bidding.

Dr. Standaert: So they don't apply, so the whole—

Ms. Ballantine: They don't apply. Right now, they're not part of the next round of bidding. So they're off, you can do whatever you're currently doing with off-the-shelf orthotics.

Dr. Bufalino: Anyone else? One last question. In round numbers, we've been exposed to at the Council here, that estimates of a billion dollars is spent annually on wheelchairs and three billion on oxygen. You have a rough idea as to what the competitive bidding process has provided to the agency in terms of savings?

Ms. Ballantine: We've estimated it at different points in time, so I'm not real sure. Having it been delayed that sort of messed up our estimates, but we were estimated between $900 million, I believe, saved the first year, I think that was the number. I'm not, it's somewheres in that ballpark. We have projected it in lots of documents, I just don't recall right off the top of my head.

Dr. Bufalino: Thank you.

Ms. Ballantine: But it's real numbers.

Dr. Bufalino: Any other questions? Thank you for joining us this morning.

Ms. Ballantine: Thank you.

Dr. Bufalino: Moving forward, we'd move to the next presentation on the Physician Fee Schedule, the NPRM and invite our next two representatives. First of all, we welcome back Cassandra Black, who has been here a number of times. Cassandra's the Director of the Division of Practitioner Services in the Center for Medicare Management. She and her staff are responsible for the comments on the NPRM and the publication of the rule. Joining Ms. Black is Mr. Marc Hartstein, who is Deputy Director of the Hospital and Ambulatory Policy Group. Mr. Hartstein's been involved in Physician Fee Schedule since 1990, according to my legend, which is a long time for anybody to be involved in anything, so he has had a variety of experiences, all the way through the drug deployment and is today, responsible for $200 billion in Medicare expenditures, over 900,000 in providers. Thank you both for your expertise and we look forward to your presentation. And Dr. Hambrick is here with us. I'm sorry I didn't have you on my little thing here. We're glad to have you join us, she is Medical Officer in the Hospital and Ambulatory Policy Group, and glad to have you join us.

Dr. Hambrick: Thank you.

Physician Fee Schedule NPRM

Mr. Hartstein: Okay, well thank you very much for that nice introduction. As introduced, I am Marc Hartstein, I'm the Deputy Director of the Hospital and Ambulatory Policy Group in the Center for Medicare Management. I work closely with Cassandra on my left, and Edith Hambrick on Physician Fee Schedule issues, and I've been informed that we're currently having some technical difficulties with our presentation but that I should proceed apace.

Dr. Bufalino: We actually all have the presentation, so we can follow you along if we don't get the live feed.

Mr. Hartstein: I understand hand outs were available, so many people in the audience may have them as well. And you are correct, I have been working at different points in time on the Physician Fee Schedule, since 1990 with a couple of absences in there. And I have presented to the Practicing Physicians Advisory Council a number of times in the past, too, so it's a pleasure to be back here and present to you once again. I'll give you just a quick update of the items that are in the Physician Fee Schedule proposed rule this year, which is on your slide two. Physician Fee Schedule proposed rule is actually an excellent vehicle for addressing a lot of regulatory issues over time because the program is so large and so complex

and there are so many issues that are in need of constant updating and refinement, and here's a list of some of the issues that we're covering in this year's Physician Fee Schedule proposed rule. Obviously, we're covering the Physician Fee Schedule, provisions related to the Medicare Improvements for Patients and Providers Act, a number of Part B drug issues, end stage renal disease, durable medical equipment and then some other specific provisions of MIPPA that are related to Physician Fee Schedule, and then miscellaneous other items. I think the proposals that have gotten a significant amount of attention in the proposed rule during the comment period are some of those that I'm going to speak about up front, and those are related to Medicare Payment for Practice Expenses, and again, just continuing on slide three, more overview of some of the things that Cassandra and I will be talking about. Practice Expense, Relative Value Units, we've made some important changes to malpractice this year, updating the malpractice relative value units new survey information. We made a number of specific coding proposals, additional MIPPA provisions, specifically related to the Physician Fee Schedule and then Physician Fee Schedule update issues. This is the second time that Cassandra and I have presented on the Physician Fee Schedule proposed rule, and the last time we presented, I decided that I would do the Physician Fee Schedule update issues and that she could do everything else, and one of the reasons I wanted to do that was because the Physician Fee Schedule update issues are the ones that are the most universally popular and everything else has lots of controversy associated with it. So I took my prerogative of supervision and I said you can do all the unpopular stuff, but after doing that, I've decided this time I'm going to take on some of the controversial issues as well. So I'm going the Physician Fee Schedule update issues, since I have a lot of expertise on that, but I will be taking on some of the practice expense issues, which have generated a lot of discussion and attention. And I'm sure Cassandra's happy that I'm taking on more of the weight of some of those issues.

So for 2010, I think everybody's familiar on the Practicing Physicians Advisory Council, with the Physician Fee Schedule update and the sustainable growth rate, I know it's been a perennial issue for a number of years, and Congress always steps in at the last moment and addresses it before there's a large reduction in the Physician Fee Schedule update. Sometimes they don't step in right away, they may step in a few days or weeks after the Physician Fee Schedule update is established, but it has certainly been going on in this manner for several years. Right now, the estimated Physician Fee Schedule update for 2010 is

minus 21 percent. Obviously a significant concern to the physician community. It is under a statutory methodology that that reduction would occur, so it's not really, not within the Secretary of Health & Human Services to avert that because it happens a statutory formula. However, what we did do is we examined very, very closely our authority under existing regulations to see if we could do anything to try to mitigate the affect of the sustainable growth rate system on future Physician Fee Schedule updates. One of the perennial issues that's been around for some time is that we've gotten lots of comments from people who've asked us to remove injectable drugs from the sustainable group rate. The sustainable growth rate, it's a target system. It includes things that are commonly furnished by physicians or in physicians' offices, and it includes more than just Physician Fee Schedule services. It includes Physician Fee Schedule services and a number of other types of services that are paid under different payment methodologies. One of those types of services is injectable drugs, or Part B drugs. Self-administered drugs are covered under Part D. We're talking about the types of drugs that are administered by physicians in their offices. Those drugs over time have grown very, very rapidly, particularly in the early part of the days of the SGR system. The SGR system was established in the Balance Budget Act of 1997, the base year is '96, '97, and the injectable drugs have grown, were growing very, very rapidly in the late 1990s and the early part of this decade and as a result, they were causing spending to be significantly above the target, resulting in a reduced Physician Fee Schedule update. Over time, Congress has averted that reduction, as I've said a few time, however they haven't allowed the additional spending associated with averting the reduced update to be incorporated into the target, which meant that future updates would then be larger negatives. In this case, by removing drugs from the sustainable growth rate retroactive to the 1996, 1997 base year, we're taking one category that was fairly small at the beginning of the SGR system but that has become much larger because of their rapid growth. We've been able to remove those drugs from the SGR and take one category of services that have grown at a much higher rate than other Physician Fee Schedule services, included in the target, and really affect the update, not in 2010 but in future years. So for 2010, our projection of the update will still be minus 21 percent. However, our projection of the update for future years will be significantly improved as a result of our proposal to remove drugs from the SGR. I've gotten a number of questions as to why it doesn't affect the update for 2010, and the reason is just because spending and the different between spending and target is just so significant, that even though you're removing a large

amount of spending from the target, it still does not bring spending and target in line, but because it brings spending closer to the target, it will make it easier for us to project higher update in the future years, so no affect this year, but certainly a benefit in subsequent years.

Some of the practice expense proposals. Physician practice expense information survey. And this is one of the proposals I think has gotten a lot of attention because of its redistributive payment impacts. The American Medical Associations, they've conducted a new survey, the PPIS, Physician Practice Expense Information Survey in 2007 and 2008. It's a multispecialty, nationally representative practice expense survey that uses a consistent instrument and methods similar to the prior survey that we were using to value physician practice expenses, the socioeconomic monitoring survey. We were encouraged, well, two years ago, we received a letter from a number of specialty societies, asking us for our support in the AMA undertaking this survey. And this year's, now that the survey's completed, in this year's notice of proposed rulemaking, we have proposed to use the revised practice expense survey to update the practice expense methodology. This is, it's very complicated to understand how the practice expense methodology works, and how the survey interacts with it. We have two sources of information. We have estimates of practice expense inputs for direct practice costs associated with individual services, and then there are indirect costs, the types of costs—the building, the heat, the light, the types of things you can't associate with individual procedures, but the types of things that a physician practice has irrespective of whether or not they provide individual services. And I think where the survey comes in and where it becomes very important is the allocation, the indirect cost allocation. So how we calculate the portion of our payment that's related to indirect cost. Inclusion of the practice expense per hour data as I said previously, has significant redistributive affects. A number of specialties have raised concerns to us about the quality of the survey data. A number of other specialties have come in and felt that the survey was, that was a rigorous survey performed scientifically and should be used. So we've gotten comments in both directions, suggesting to us that we should both use the survey and a number of comments who raised concerns about the quality of the survey and said that we should examine it more closely before we decide to implement it.

The next proposal has to do with equipment utilization. Equipment utilization is a factor in the practice expense relative value units. What you do with equipment, is you get the total cost of the equipment, and you try to come up with a per-minute cost and allocate it to the equipment by the number of

minutes that the equipment is in use. One of the important factors in determining the cost per minute is how often the equipment is in use. If the equipment is in use less frequently, then equipment would have a higher per-use cost. If it's in use more frequently, then it would have a lower per-use cost. We have been using an equipment utilization assumption of 50 percent. There had been some questions raised about whether that was a valid assumption. The Medicare Payment Advisory Commission did some research on this topic and did a survey of some diagnostic equipment, and indicated to us that they felt that the, that we should adopt an equipment utilization assumption that is higher than 50 percent, based on the information that was in the MedPAC study, we decided to adopt an equipment utilization factor of 90 percent. Again, number of people have come in, commenting to us about that, providing information to us, suggesting that maybe the equipment utilization is different that what we proposed. But again, MedPAC did some research on this specifically related to diagnostic equipment, however, we felt that the MedPAC research also applied for therapeutic equipment worth a million dollars or more, the idea being that if you're buying an expensive piece of capital equipment, one million dollars more, the likelihood is that it's going to be in use more than 50 percent of the time, more like 90 percent of the time. And they certainly had information from some of the diagnostic providers that that was the case. And I'm going to turn it over to Cassandra Black for a discussion of many of the remaining issues.

Ms. Black: Good morning. I'm happy to be with all of you again today. As Marc mentioned, I'm going to cover other provisions in the NPRM. The first one of these is our update of the malpractice RVUs. In the rule, we're proposing to implement the second five-year review and update of the malpractice RVUs. Our contractor gathered 2006 and 2007 specialty-specific malpractice premiums data from 49 states and the District of Columbia. This year, the proposed methodology generally follows the same approach we used when we developed the resource-based malpractice methodology. One of the refinements this year is that we were able to collect data on many more specialties. Previously, we had data on the top 20 specialties. This year, we have data on 44 specialties, which represent 90 percent of all physician services. Another refinement is that we're proposing to use the malpractice risk factor of the dominant specialty for services with less than 100 occurrences. Previously that data had been dropped.

The next issue has to do with malpractice RVUs for the technical component services. Currently these are based on the historical allowed charges. They had not been resource-based because we had not

been able to get a source of data. For a number of years, we've sought a data source on the malpractice costs of technical component providers such as IDTFs and a comment last year, a commenter told us about a source of premium data for the malpractice costs made by medical physicists. So our contractor contacted this insurance provider, and we were able to get data. So in the NPRM, we're proposing to use the medical physicist's data as a proxy for the malpractice cost paid by nonphysician suppliers because we think this data better reflects the malpractice costs paid by technical component providers, instead of using the charge-based data that we have been using. Medical physicists are involved in extremely complex services, such as intensity-modulated radiation therapy. We think that based on the complexity of the services, we believe that medical physicists are involved in some of the highest or most complex procedures that would be covered under the technical component. So we think this is a good proxy. Once again, we're coming back and soliciting comments on additional data sources for the malpractice premiums paid by technical component providers.

The next issue has to do with some coding proposals that we made. And the first issue has to do with consultation services. And as you all know, I'm sure, a consult is an Evaluation & Management service furnished to evaluate and possibly treat a patient's problem. Consults are primarily billed by specialist. A consult must be documented by the requester and a written report must be given to the requesting professional. There's been ongoing confusion about when it's appropriate to bill a consult code, as opposed to an initial E&M service, when a transfer of care is involved. Both inpatient and office outpatient consult services pay higher than initial hospital care and new patient office outpatient visits, although the associated physician work is clinically similar. Originally consult service required a greater degree of documentation but what we've done is to change the documentation requirements and make them less formal. So now the documentation requirements are essentially similar. We eliminated payment for consult codes in the outpatient setting in January 1 of 2008. Instead, hospitals billed for new or established visit codes. In the NPRM, we're proposing to eliminate the use of all consult codes, inpatient, office, and outpatient, for all places of services except for Telehealth. Instead, we will instruct providers to bill the codes for initial hospital care and initial nursing facility care the first time he or she sees the patient. Previously, only the admitting physician could bill these codes. In the office setting, a provider would bill a new or established patient visit code. This change will be implemented in a budget neutral manner. It would

not increase or decrease Physician Fee Schedule spending. Under our proposal, physician work RVUs for new and established office visits would increase by about 6 percent and initial hospital and facility visits would increase by about 2 percent.

The next issue has to do with the initial preventative physical exam, or the IPPE. The IPPE was revised in 2009, as a result of a MIPPA provision. But we did not propose to change the valuation of the code at that time. Instead, we sought comments from the public on whether it should be changed. And we received comments from several medical societies, that the value of the code should be changed. So we're proposing to increase the work RVUs for the IPPE to be the same as a Level IV new patient office visit.

The next issue has to do with the provisions of MIPPA 139, which is improvements for teaching anesthesia programs. Right now, if an anesthesiologist personally performs a service alone, or is involved in a case as a teaching anesthesiologist, with an anesthesia resident, payment for the anesthesiologist service is made at the regular fee schedule rate. Payment is made on the basis of anesthesia base units and time units, calculated from the actual anesthesia time of the case instead of work practice expense and malpractice RVUs. Effective January 1, 2010, MIPPA establishes a special payment rule for teaching anesthesiologists. It also provides a directive to the Secretary, about payments for certified registered nurse anesthetists, or CRNAs and it also has a provision that specifies the periods when the teaching anesthesiologist must be present during a procedure to receive payment at 100 percent of the fee schedule. We're proposing to implement the special payment rule, and allow payment at the full fee schedule amount, if the teaching anesthesiologist is involved in one resident case, which isn't concurrent to any other anesthesia case, or each of two concurrent resident cases, which aren't concurrent to any other anesthesia case, or one resident case, concurrent to another case under the Medical Direction payment rules. We didn't propose any other changes to the Medical Direction rules.

For the CRNA provisions, we're proposing to implement a new payment policy for teaching CRNAs, which would be similar to the special role for teaching anesthesiologists, which would pay the teaching CRNA the regular fee schedule for involvement in 2 concurrent cases.

The next issue has to do with the anesthesia handoff provision. Currently, the teaching anesthesiologist may be paid at the regular rate for his or her involvement in a single resident case. The teaching anesthesiologist must be present with the resident during all critical portions of the anesthesia

procedure and be immediately available to furnish services during the entire procedure. Our manual instructions allow different physicians in the same anesthesia group to provide parts of the anesthesia service and for the group to bill for the single anesthesia service. We believe this policy may also be in force in teaching hospitals. From a quality standpoint, we don't believe that multiple handoffs among teaching anesthesiologists during a case that involves the training of anesthesia resident would be optimal. We proposing that only one teaching anesthesiologist be present during all critical or key portions of an anesthesia procedure and that another teaching anesthesiologist could be immediately available to furnish services during noncritical or key portions. We're also soliciting comments on how the continuity and quality of care are preserved during handoffs as well as limitations on the maximum number, factors, or variables contributing to the anesthesia handoffs. We'd also like to receive any studies that have examined this issue of handoffs.

The next issues I'm going to talk about have to do with cardiac rehabilitation provisions. That's covered under MIPPA, Section 144. Currently, cardiac rehabilitation is covered based on the national coverage determination. So MIPPA Section 144(a) amended coverage of the current cardiac rehab program, and it also establishes coverage for intensive cardiac rehab, beginning 1-1-2010. Section 144(a) requires that both programs include cardiac risk factor modification, a psycho-social assessment, and an outcomes assessment. Cardiac rehab services must be provided under written individualized treatment plans. If they're provided in a physician office, the physician must be immediately available to furnish assistance. If provided in the outpatient setting, direct physician supervision is required. To qualify for coverage, intensive cardiac rehab programs must demonstrate positive outcomes in peer reviewed literature. Some examples of this would be positively affecting the progression of coronary artery disease, and reducing the need for coronary bypass surgery. The physician who oversees the program must be licensed in the state in which the program's offered. They have to have appropriate expertise in the management of individuals with cardiac pathophysiology, and they have to have training and proficiency in cardio vascular disease management and exercise training of heart disease patients. We're seeking comment on the precise level of expertise in training necessary for staff.

Intensive cardiac rehab programs would need to apply to receive CMS designation as qualified, and they would need to be reevaluated annually.

For general cardiac rehab, we're proposing to allow up to 36 one-hour sessions, with up to two sessions a day, with no less than two sessions a week, over 18 weeks, with contractor discretion to expand to 72 sessions for 36 weeks. The provision of the intensive cardiac rehab programs is covered in MIPPA and it specified, as a series of 72 one-hour sessions, up to 6-hours a day, over up to 18 weeks. We aren't proposing any changes to the existing cardiac rehab codes. For the intensive cardiac rehab, we're proposing to create two new level 2 HCPCS codes. The statute requires that the payment under the Physician Fee Schedule will be based on the outpatient fee schedule amount. Payment under OPPS would be approximately $38. The Physician Fee Schedule payment would be multiplied by the appropriate locality.

The next issue has to do with pulmonary rehab. Section 144 of MIPPA provides coverage for pulmonary rehab, furnished on or after January 1, 2010, for Medicare beneficiaries with a diagnosis of moderate to severe chronic obstructive pulmonary disease. The statute specifies that a pulmonary rehab program must include physician prescribed exercise, education or training, psycho social assessment, and outcomes assessment, and a written individualized treatment plan. Pulmonary rehab will be covered in the physician office, and outpatient setting of the hospital. MIPPA also specifies that the physician who oversees or supervises the program must have expertise in the management of individuals with respiratory pathophysiology, and be licensed in the state where the program's offered. The Medical Director must have training and proficiency in chronic respiratory disease management and exercise training of chronic respiratory disease patients. For payment for pulmonary rehab, we are proposing to allow up to 36 sessions, approximately 2 or 3 a week, at a minimum of 60 minutes each, no more than one a day. We're also proposing to create a new Level II HCPCS code to pay for this service, which is pulmonary rehab, including aerobic exercise.

The next provision has to do with MIPPA 152(b) which is kidney disease patient education. Section 152(b) authorizes coverage for kidney disease education, effective 1-1-2010. We're proposing to define kidney disease patient education as face-to-face educational services provided to patients with stage 4 chronic kidney disease. We're proposing that a qualified person is the physician, nurse practitioner, or clinical nurse specialist. In a rural area, it could also include a hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehab facility, home health agency or a hospice. We're seeking public comment on the appropriate level of education, training, and experience necessary for providers.

Kidney disease patient education services must include the following: training on the general kidney physiology and test results, psychological impact of the disease on the beneficiary and their family, the management of co-morbidities, renal replacement, therapeutic options, diet, fluid restrictions and medication use, and encouragement of patient active participation in the management of condition. For kidney disease payment, we're proposing to allow up to six face-to-face 60-minute sessions. We're proposing two G codes for individual and group kidney disease education. We based our proposed pricing of these codes on medical nutrition therapy. We're proposing to pay all providers of kidney disease education service at the Physician Fee Schedule rate.

There are some other issues in the rule as well. With respect to potentially misvalued codes, we discuss several approaches that are in process to address these issues, as well as we propose some changes to several codes, but the site of service has been revised. We plan to continue our work with RUC on these issues. We also sought comment on the creation of the standing panel of experts separate from the RUC to review relative value units. Finally, we proposed some additions to the Telehealth services list. And the last slide contains the websites, where you can find the fact sheet on the rule as well as the rule itself, and the last final slide contains my contact information. Thank you.

Dr. Bufalino: Dr. Hambrick, any comments?

Dr. Hambrick: No, just awaiting those wonderful questions that I'm sure are coming.

Dr. Bufalino: Well, obviously, there are a number of very vital issues to the physician community that were just presented, so I think we will hope that you engender some opportunity to have us comment and question you about those. Let's begin.

Dr. Kirsch: Okay, well, I have three items. First, very quick. Three items. First of all I want to thank you for realizing how undervalued the New to Medicare physical was. When do you expect to implement the new fee schedule on that?

Ms. Black: January 1, 2010.

Dr. Kirsch: Oh January 1, okay. Second thing is the AMA PPIS survey, my understanding is that those results haven't been made available yet. I also wanted to make the point that the AMA is also going to be examining that data for geographic variation, and I certainly hope CMS will take a look at that and take some of that into consideration. The last item, it's under the equipment utilization, and perhaps you

can help define a few terms for me. I understand that when you do something like an x-ray procedure within the office, that there's a technical component. I take this 50 percent to 90 percent is the technical fee on performing that procedure?

Mr. Hartstein: Yes, correct. So yes, the x-ray would have a professional component, which would be the physician's interpretation of the image. And then the technical component would be for the taking of the image. For professional technical component services, the interposition's interpretation isn't going to include any equipment, supplies, or staff, clinical labor, direct expense, it's just going to have the indirect portion, because the direct portion of the service is associated with the technical component. So yes, the equipment would be one of the direct costs that's associated with the technical portion of the service, and the x-ray equipment is generally going to be less, as far as I know, less than a million dollars, so it's not going to be affected by the equipment utilization assumption. The equipment utilization assumption will only affect equipment that is a million dollars or more.

Dr. Kirsch: And what would that be? I mean give me an example. I'm having a hard time imagining it. CAT scanners—

Mr. Hartstein: Potentially—

Dr. Kirsch: And MRIs, right.

Mr. Hartstein: PET scanners, MRIs, some radiation therapy equipment could be over a million dollars.

Dr. Kirsch: Why did you pick one million dollars, not a lower fee?

Mr. Hartstein: The information from the, our understanding is that when MedPAC did their surveys, they looked at expensive equipment, a million dollars or more, and found that equipment that's high cost equipment that's, is typically in use more than 50 percent of the time. Low-cost equipment can be in use a lower percentage of the time. I don't know if they specifically surveyed lower cost equipment, but they certainly found for the higher cost equipment that the utilization is higher than what we were using.

Dr. Kirsch: I'll just point out that my understanding is that the technical components are reimbursed with, based on you geographically. So there's a lot of geographic variation on those technical fees. And so someone buying x-ray equipment in Iowa is reimbursed at a much smaller rate for the technical service, than for what they're being paid to even purchase the machinery, compared to somebody

out on the east or west coast, and that there's a lot of variation in that, and I guess I would encourage you to look at dropping that number from a million dollars to lower, because really it doesn't make sense to have that geographic variation on those technical components anyway.

Mr. Hartstein: There is a geographic practice cost index that's used to adjust Medicare fees based on geographic differences in the cost of practice. Those geographic practice cost indices are going to be an average of the type of things that vary geographically, and other things that don't vary as much geographically, so the index is intended to take into account the geographic cost of the difference in practice.

Dr. Kirsch: Except these technical components when you're being reimbursed for performing the procedure, not for your technical fee for reading it, that also have geographic inequity. I'll ask you to look into that.

Mr. Hartstein: Okay, well thank you for your comments. I'm certainly not going to comment on whether our geographic payments are inequitable or not inequitable, just suffice it to say that we do have an index that's intended to recognize the difference in the cost of practice between areas.

Dr. Bufalino: Other comments? John.

Dr. Arradondo: I have a couple questions actually. Going back to your slide 10, page 10 in our handout where you talk about the initial preventive physical examination. What was the rationale for setting that at a Level IV as opposed to a Level V for a new patient, since the effort is pretty much equivalent?

Ms. Black: Oh well we felt that the work involved was more similar to a Level IV. Edith did you have any—

Dr. Hambrick: Currently, as you know, it's set at a Level III, and as you also know, when you do the IPPE, you can bill any other level visit that for any of the other services that you do, so you can bill up to a Level V visit in addition to the IPPE. In this case, if we go through with the proposal, to bill a Level IV and an additional Level V visit, at the same encounter with the patient. We feel that there is some overlap in questions and history, not physical, certainly, but in history and that. So that's I think why the Level IV. Plus, I'm sure it was suggested that we raise it. Some people said a Level IV, some people said a Level V, we just felt Level IV is appropriate.

Dr. Arradondo: So if I'm understanding this, you are seeing that as pretty much an add-on to the other medical disease care activity, as opposed to a primary activity itself.

Dr. Hambrick: Generally what we've been told is that while the patient is there, they do the IPPE, and they address any other problems that the patient might have at that visit. So as you know, IPPE is sort of a check list of a lot of things that the patient, preventive medicine, EKG, those types of things, which can be billed separately. So yes, a lot of providers have told us they do them at the same time.

Dr. Simon: And with the IPPE, that payment in essence reflects a base payment, keeping in mind that Medicare currently has about 15 screening tests that are statutorily approved that can be separately billed at the time that the IPPE exam is also performed, so that in the case of a woman, if she has a PAP smear, or a screening pelvic exam, in the case of a male, if he has a prostate exam, if they have diabetic screening tests done or lipid profile done, all of those tests are separately billable in addition to the IPPE, so the payment rate for the IPPE in essence acts as a floor payment, recognizing that there be a host of other screening tests that will be performed during the conduct of that IPPE, which the physician will also be able to receive separate reimbursement for.

Dr. Arradondo: The context of my question of course is elsewhere you speak about prevention, and I realize the habit, the norm of paying for procedures and processes, but prevention kind of goes beyond that, and if you're going to pay for the thinking and patient interaction that will set up ongoing health promotion disease prevention activity, then making that parallel the new patient is a reasonable approach to it. And I know I didn't make comments in your panels where you made this decision, but that's another matter. That's where I'm coming from, on page 17, of your slide 17, I was wondering in the same vein, I didn't see specifically, and I realize you didn't get too specific, but you got specific enough, and I was wondering why not add commentary or a note about at least secondary prevention in this most preventable of diseases, chronic obstructive pulmonary disease? Many notions, your requirements for the rehab program includes, but there's no commentary or reference to, reasonably visible reference to even secondary prevention and that's 80 percent preventable disease.

Ms. Black: Well, many of these things were specifically covered in the statute, so I think this part was actually done by our coverage group. But I think these are the things that are specifically spelled out. Edith, did you have things to add?

Dr. Hambrick: And we also, as you know, pay for smoking cessation, and those types of things, but the main reason for these things being mentioned is it comes right out of the statute. So in addition, as we said, we have smoking prevention that we pay for counseling, so those would be in addition to those provisions from MIPPA.

Dr. Arradondo: Yes, I appreciate being statute-bound, but this is an opportunity for, I mean you are the 800 billion dollar entity, I don't want to use the G word, but this is an opportunity for you to influence the people who direct you, Congress. It's just a proposal. So putting it in at least would show them that you're thinking. You know, you get criticized unfairly often, and yet you know kind of what the deal is. So this would be an opportunity there, and I'm not even putting words in my colleague's mouth over here. He could give all chapter and verse on both the prevention and the treatment.

Dr. Hambrick: And we'll take those comments back to the Coverage & Analysis group.

Dr. Arradondo: On page 19, I'm wondering, kind of coming from the same vein, but there's a bit more practical aspect to that. On the second paragraph, you start your patient education services at stage 4, chronic kidney disease. Is that statute bound, too?

Ms. Black: Yes, it is.

Dr. Hambrick: And some asked why not stage 5 or 3? But that's what the statute says.

Dr. Arradondo: Without impugning the intentions of my colleagues, say at the National Kidney Foundation Board, one set of colleagues, this is, this would be the comment that a nephrologist with the greatest interest in dialysis would have, this particular, as opposed to say a nephrologist who had a greater interesting controlling and limiting kidney disease, in which case you would want to start this at chronic kidney disease level three at the least. Maybe two. But definitely level three which is a broad GFR30 to GFR60 expanse of kidney disease, that in fact, is a point at which a lot of prevention can be done, as opposed to four, which almost inexorably moves on to five and six dialysis. So that would be an opportunity to at least let our nephrology colleagues know that there is an earlier secondary preventive opportunity here that really is being missed in a big way by starting at level four.

Dr. Hambrick: We'll pass that along as well. And perhaps Congress can, will hear these remarks as well when they amend the—they'll do something about that, but.

Dr. Arradondo: Okay, thank you, Mr. Chairman.

Dr. Giaimo: I wanted to try to address the consultative services and try to get some more background from that if we could. Dealing with consultative services in the hospital, particularly, it seems to me that there would be a significant difference in the level of in some degree of technically of how you approach the patient, from a primary's perspective to a subspecialist's perspective, and I'm wondering how we can justify that the cost would be the same for that. I mean not only the intensity sometimes of the patients you deal with, but also the level of liability that you assume when you get involved in these cases, and that's what I'm trying to come to grips with; how these were equated the same, how an initial visit is an initial visit, because they're not really all that way. A neurologist coming in to see a patient may spend a few hours going through their neurologic exam, which would be must different than another subspecialist doing their exam, or a generalist doing their exam. I'm trying to find out how that would be quantitated in this new methodology. It doesn't seem like it would really value that work that was done that adds to the quality of care of that patient.

Dr. Hambrick: Well as was mentioned in the rule, there has been a lot of controversy and discussion about which physician should be able to bill the consultative services, on what days they should be able to bill those services, and as you know, the AMA recently got rid of subsequent consultative codes and went to subsequent hospital care, which had the effect of changing the reimbursement for consultants when they provide those services. There's also been a lot of discussion as you say about is it a transfer of care? In which case, the person comes in, they have to review the whole medical record and that type of thing, and then they might not be able to bill an initial hospital visit; they might have to bill a subsequent hospital visit. So with all that controversy, and the lack of a proposal from the AMA, as to how to resolve some of those issues, we decided that elimination of the consultation might allow everyone a level playing field in this sense: When you come to see the patient the first time, whether you're the consultant or the admitting physician, you get to bill an initial hospital visit. In some instances that was not able to be done. And as we also mentioned, we put the work values for those services—they weren't lost, they were put back into initial hospital care and initial outpatient visits, and established patient visits, so those RVUs are not lost. The reasons that we mentioned in the rule have been mentioned here were that we were trying to bring clarity to the billing process for the physicians. Secondly, the documentation requirements initially for consultative services were much higher. Now that's less, because they've been equalized across those

services, and so we felt that this would be a proposal that would get rid of a problem that has been brought up for the last three or four years and also provide more money in the system within those initial visits.

Dr. Giaimo: It seems that it would limit somewhat of the value of that. Because I think that your, the work of a consultative, an intensive consultative service sometimes will not be valued, and it will be difficult to get those services then, from physicians. It's going to be hard to ask somebody to come in and spend that quality of time with the patient and assume those levels of liability if they feel that they're not going to be compensated for that time, when somebody can do a routine initial office visit in a fixed period of time and maybe a consultative service, maybe take two or three times that period of time, because of the complexity of the case. That's why a colleague is asking you to see them, because it's very, rather complex and they need that assistance. So I don't think all are the same. Is it a time, can I make a recommendation?

Dr. Bufalino: We'll finish this and then we'll open for some recommendations.

Dr. Hambrick: Just so that you also know that there's the flip side of that, that not to impugn any colleagues, there are some who have more limited scopes of expertise, dermatology, perhaps, others, where they of course were getting the same consultative services as someone who was a neurologist, or someone who was doing [crosstalk]

Dr. Giaimo: Or a number of different field. No certainly. And a dermatologist may have a very focused exam and then that should be reflective in how they bill, at what level of consultative code they bill. So I think that [crosstalk]

Dr. Hambrick: Or inpatient—

Dr. Giaimo: Certainly there's a need, but I think that there's some more work that we can try to do with this. But I'll—

Dr. Hambrick: Okay, thank you.

Dr. Bufalino: Let me address this from a cardiologist's perspective, and put my chairman's hat aside and just talk for a moment about the fact that the rule as it sits, is obviously going to have a significant impact on specialty physicians around the country and some of us had looked at it, and let me just look at it from a cardiology perspective. The PPIS, as its been rolled out to us from 2002 to 2005 predicts that the average cardiology practice, reduced to practices expenses by 40 percent. Now I've been running a physician practice for 15 years, 50 physicians, and I can tell you in no given year have we ever

had a reduction, let alone a 40 percent reduction in our expenses at delivering the practice of medicine. And so that brought from our perspective the data into some question. And what we understood is that 145 surveys were sent back in and only 55 were accepted and the other 90 for whatever set of reasons were excluded. And of the group that you used, about 25 percent of those had no expenses for nurses or technical support in their office practice, providing pretty unique cardiology practice, at least in the private practice setting, I don't know anybody that doesn't have nurses and technical support in their offices, let alone staff to provide testing. So some of those may be academic practices that are in hospitals where those costs have been translated to the hospital, and not part of their practice. And so from our perspective, along with the fact that the average number of hours worked per year, range from 1700 to close to 3000 and cardiologists are at that upper edge of that survey group and yet the costs were averaged across a number of hours, or at least that was my understanding of it. So from our perspective, at least on the cardiology side, estimates for many of the practices in the country, are a 26 percent reduction in revenue, that will precipitate the end of private practice, or at least as we know it today, and many of the folks will be moving into integrated systems. And maybe that's the intention and/or some of those folks will be scaling back their practices considerably. So I think part of this, which looks to be the largest redistribution of payments in the history of the Medicare program, we would just hope that the payment group relooks at this data quite carefully in an effort to try to understand the impact on many of the specialists. And I just represent one of many specialties that have been affected by this. And so one of the questions I had was that I understand that there's some supplemental data that is being considered or being looked at or being asked for, or the details of the Medicare survey and so I just wondered whether or not you had any thoughts or comments on that.

Mr. Hartstein: Thank you very much for your comments. I guess one thing I would say, certainly, it's a comment, we're at the end of the comment period and now we're at the point where we're going to have to evaluate many of the comments that we received, including some very similar to the ones that you just made about the use of the survey. A number of specialties are commenting and have suggested that the survey is a good survey and it's reflective of their practices expenses, and it follows scientific surveying principles and so forth. A number of commenters are suggesting that the number of responses that we got was insufficient in that it's not a representative measure of the specialty, and we're going to certainly evaluate all of these comments. A number of, I'm not sure what supplemental data you're referring to. A

number of specialties, our previous survey was the AMA socioeconomic monitoring survey. The statute put in place a process that required us to accept supplemental data from specialties so they could go out and do their own independent surveys. Cardiology was one of the surveys that did do an independent supplemental survey of their specialty in addition to the MSMS and so we were using supplemental data for a number of specialties. We are no longer using that supplemental data for the specialties that were included in the PPIS survey. The PPIS survey, multi-specialty process, using a consistent surveying instrument, we felt that that was the best measure of data to use for the current practice expenses. For some specialties, that meant that we were using data from the SMS survey that could have been lower than what they had gotten from the supplemental survey. The supplemental survey could have been higher than what we got from the prior SMS survey, so again, a number of public comments surrounding all of these issues. We're going to certainly have to consider a great variety of comments because that's what we got, is a great variety of comments about what we should do in the Final Rule; whether we should use the survey, not use the survey, whether we should transition, not transition, all kinds of comments have come to us, and that is the point of a public comment period, is to find out what the public thinks about all of these proposals to consider all of the information that has come to us and I can tell you from working at CMS for a very, very long time, that CMS certainly reads and considers all of the public comments. And we frequently do make changes in the Final Rule based on those comments. And when we don't, we do our best to explain why we decided to adopt the Final Rule policy that we did.

Dr. Bufalino: Thank you. Jeff?

Dr. Ross: I would like to add to my two colleagues and [inaudible] public comment. They've spelled it out pretty well, but just from my vantage point, as an example of what we're talking about, if you see yourself in a hospital situation, leaving a long day of maybe eight, ten hours in the office, now you're going to the hospital. You're not spending 15, 20 minutes, 30 minutes, maybe even an hour seeing that patient. You may be seeing an hour to two hours. You've got medical legal issues. You're taking on much more responsibility for the care of that patient than you do in the situation in the office, where you may be spending 15 minutes, 30 minutes, evaluating the patient and then making the recommendations. The patient may be coming back to your office. The time that I see my patients in the hospital may involve calling other doctors, other physicians, looking up lab tests, MRIs, lab work, basically running around the hospital,

chasing people, trying to get that patient in patient's care really under wraps. So there's a much more involved entity to consultation versus an initial hospital visit, where you just go in, look the case over, look the chart over, evaluate the patient, make the recommendations. I sometimes have to call other doctors in and make those recommendations. I have to make phone calls to other doctors, like internal medicine. It may be infectious disease. It may be a surgeon, whatever, and what I'm trying to say is that the consultation is totally different than the initial hospital visit. And I think when you look at the amount of effort that goes into that visit for that particular consultation, it's a totally different entity than what you've spelled out today.

Dr. Hambrick: Thank you for your comment.

Dr. Snow: Let me start by saying that I guess I'm—let me announce my conflict of interest. I'm a primary care physician, so in a lot of ways, I love what's happening in this rule. It may enable some colleagues to choose to replace me as I go out of practice in the next few years perhaps, but quite frankly I've got great concerns in particular, about the consultation aspect of what you're doing here. I think many comments that have been made are certainly very true. I practice primarily geriatrics. Ninety-nine percent of my patients are Medicare patients. Most of them in a nursing home setting, many of them in hospital, very few in the office, because Medicare doesn't pay me enough to run an office, quite frankly. But I'm concerned about my ability to take care of these patients, because the consultants that I use, and many of them have indicated they're going to become unavailable, and they certainly will become unavailable at the nursing facility because of the lower reimbursements there. We're lucky enough to get some of them to come out to the nursing facility to see patients, but I suspect they will not at all, and I think the American Medical Directors Association, of which I am a member, feels strongly that way also. Even in the hospital setting, many have expressed the intent that they may reduce their consultative abilities with this reduction, and therefore the quality of care that will be delivered to my patients. So even though, as I've indicated, I certainly appreciate and feel that we have to solve the problem of how to more adequately reimburse primary care physicians across the board, or quite frankly, we're going to have nurses provide all of the primary care in this country and in the very near future. We have to solve that problem, but I think to do it in this somewhat radical way, that probably needs a little more time to figure out where we are. The consultation issue came up last year, the AMA has made already some changes, I understand, in their CPT

Editorial Committee, to change this transfer of care as part of the consultation, but we haven't even had time for that to go into effect yet, and then we're talking about getting rid of the codes. I think we're moving a little bit too fast in that direction, and I would urge extreme caution in the name of patient care, quite frankly.

Dr. Bufalino: Thank you. Karen?

Dr. Williams: I have a question and then a couple of comments. On slide 11, under CRNA payment policy, you say you propose a new payment policy for teaching CRNA, similar to teaching anesthesiologists, which would pay the CRNA the regular fee rate to be involved in two concurrent cases. Does that mean that you're going to maintain the existent payment differential between CRNAs and anesthesia physicians by paying the full base units for each case, plus the time times the conversion factor?

Ms. Black: Well the existing CRNA payment rules will stay in place. MIPPA requires us to have a special payment rule for CRNAs, so this is how we're proposing to implement it, to pay the teaching CRNA the regular fee schedule rate for involvement in two concurrent cases.

Dr. Williams: Yes, but is there still an existing differential between the anesthesiologist and the nurse and how that's done? Base unit plus time, times the conversion factor?

Ms. Black: It's my understanding that basically the CRNA and the teaching CRNA, and the teaching anesthesiologist are already paid in a similar way.

Dr. Williams: I like to first of all commend you for the wonderful work that you've done in trying to resolve issues in a very complex and different payment structure, obviously, for anesthesiology. Specifically, as it relates to teaching anesthesiologists involved in supervising one resident versus two residents, versus a resident and then the nurse anesthetics or an anesthesia assistant. I just wanted to remind my colleagues that since 1994, that anesthesiology teaching programs were receiving payments that were actually cut in half whenever an anesthesia attending was overseeing two concurrent residents. And the payment policy created financial hardships for anesthesia programs across the country, significantly contributing the closure of about 28 programs over that period of time. You also may recall that in 2006, I believe it was, a few times we brought up and advised CMS to attempt to correct this issue. CMS's response ultimately was that they felt that it would be better handled by Congress. So in 2008, Congress approved, as part of MIPPA, the Medicare Anesthesia Teaching Funding Restoration Act, which is part of

what your discussion was, and that you appropriately stated that anesthesia teaching physicians must be present during all critical and key portions of the procedure and that different physicians of the same group could provide some type of transitional care for noncritical portions of the procedure, as I understand it. Now the issue I think that you have now is that there is concern about the quality of care and the way that handoffs are conducted, as you discussed. One of the issues that I'd like to bring up is that historically, as part of anesthesia training, part of our training as well as at the attending level, we consistently, whenever we hand off the care to another provider, go over the patient's medical history, the current procedure that's going on, and any difficulties that have occurred. What we anticipated would be the next step, should blood transfusion be needed, does a person need some vasoactive medication. All that goes on before care is handed on to the next anesthesia provider. All that in a teaching academics environment, obviously is also overseen by the ACGME and the RRC, which tightly governs how we teach residents regarding the efficiency, but also obviously the quality of care, given the facts that we're training human beings to give critical care on patients. So those things are tightly regulated by the RRC etc. The issue of quality, I believe has not been raised before. I don't think it was an issue in the past ever that I know of, as far as discussions here or at discussions at the Congressional level, and in fact, part of what came up, I think with the Institution of Medicine report, in 1999, where anesthesiology was sited as one of the key medical subspecialties that actually improved patient safety and quality, part of that came from a study back in 1982, I believe it was, Cooper, who essentially studied handoff issues, and sited that the process of relief during administration of anesthesia more frequently led to favorable outcomes of potential problems than the initiation of them. And that has to do with the fact that in an academic environment, we often have very, very long cases. There can be critical portions at the beginning of the case, as you know, critical portions at the end of the case, sometimes critical portions in the middle, if they're unexpected, and for instance, if we're doing a radical mastectomy with immediate reconstruction, there can be a general surgeon involved, finishes his or her portion and then a plastic surgeon will come in, so the proposal to have one anesthesiologist, I'm assuming you are meaning the one who initially started the case, be involved, let's say at the beginning of the case, perhaps that anesthesiologist now hands off the care to another person, because that person is now the original anesthesiologist might get called up to labor and delivery suite, to deliver care there. We appropriately hand off care to another colleague, say, a cardiac anesthesiologist, who works

down in the general OR, but doesn't go up to labor and delivery. We go up into our labor and delivery portions and maybe during that time, something critical comes up. The quality of the anesthesiologists that are an academic institution that are overseen obviously not only by the hospital, but also by these review commissions that I'm telling you about, have to be obviously at a certain standard, so that that anesthesiologist that I have now handed off the care to is obviously able to care for this patient that I've left in their hands while I'm upstairs administering in the labor and delivery suite. The converse might also be true; I don't do cardiac anesthesia. I might be doing a case where my cardiac anesthesiology colleague might be doing a case where then something happens in the cath lab. As you know, we're not just in the operating room, we're in the cath lab, we're in interventional radiology, we're labor and delivery, we're in the ER, doing trauma cases. So my cardiac colleague now gets called to the cath lab to go do something I have no subspecialty training in doing. They, then, will hand off after appropriate discussion, the care to me, go off and do whatever's appropriate for them at their skill level to do in the cath lab, etc.

Getting back to my IOM report, one of the things that they cited, in quotes is that "anesthesiologists are confronted with safety issues, presented by the need for continued vigilance during long operations, but punctuated by the need for rapid problem evaluation and action in the face of fatigue and sleep deprivation, and competing institutional and professional patient care priorities," and they did that by application of human factors to improve performance. So in other words, anesthesiologists didn't really invent the handoff, they just perfected it from what was already going on in the industry. Another example is airline pilots. They a long time ago studied the fact that if airline pilots were up for more than 20 hours at a time, that their vigilance was actually decreased, and not increased, and so that was another reason that anesthesiologists, long ago, put into place the procedures that we have now. So I would like to suggest that the appropriate handoff is a decision best left to the physicians in charge of the patient and also to the hospital that obviously is having their staffing requirements in other places outside of the operating room that requires anesthesiologists, and eventually I'd like to make a recommendation, when you find that it's appropriate.

Dr. Ouzounian: I just had two comments about the consult issue, which haven't been raised. One is that if you're going to redistribute the RVUs to the follow up visits and the new patient visits, that there's a whole bunch of 90-day global codes, which my society does a lot of and there's a lot of E&M built into

those codes and if the E&M is going to be increased on a stand alone basis, it needs to be appropriately rescaled for the 90-day codes and I don't believe that that's in your proposal. That's number one.

Number two, I can appreciate that you will redistribute the RVUs from the consultations to the new patient visits and the follow up visits, and that the impact on the Physician Fee Schedule from Medicare's perspective will essentially be revenue neutral. My concern is that private carriers will follow what Medicare does. They usually do that. And this is going to be a tremendous bonus to them, to further inflate their already inflated profits, because what they're going to do is they're going to say, oh, look at that. Medicare doesn't pay for consults. We're not going to pay for consults. We're going to do it as a follow up patient visit. But they're not going to be as gracious as you and they're not going to redistribute those RVUs to the other codes, and they're just going to put it in their back pocket. And I'm concerned that there may be some providers in this room that do 90 percent Medicare, and my situation it's about 10 percent. So it's not going to be revenue neutral for me, because the private carriers, which make up 90 percent of my practice, are going to eliminate the consults and are not going to redistribute those RVUs, and I think you need to take that into consideration.

Dr. Hambrick: Thank you.

Ms. Black: Thank you.

Dr. Smith: I just wanted to comment in addition to the comments that have already been made about inpatient consultations, that the same rule really applies to outpatient consultations, they can be enormously more complicated than a standard new patient, and I'll use rheumatology because that's my field. If a new patient comes in with osteoarthritis, that's no big deal. If a patient is referred for management of bad scleroderma, I may have an inch of records to review, I may have five consulting people that I need to talk with on the telephone, not just send records to. That's much more time-consuming than a straightforward new patient. It seems to me that part of the difficulty is defining how physicians are billing consultations. If you're saying that a single system very focused consultation is being billed incorrectly, and I'm not saying that it is, but if that's what's driving this, perhaps the better way to look at it would be how to make sure that the codes are being used correctly rather than eliminating them. I mean I do recognize on the time issue that if someone spends two, two and a half, three hours with a patient, which all of us have done at one point or another, the one has the option of adding the prolonged service codes, so

that you can capture that time, which in turn captures some of the complexity, but I think that for many specialties, and perhaps for family practitioners or general internist doing a preop evaluation on a patient with multiple medical problems, as a consultation for a surgeon, there is quite a bit more work involved than just a straightforward new patient.

The second comment I wanted to make is about practice expenses. And I hope that CMS is going to relook at this issue and say that somebody needs to make sure that the data you have which we haven't, from the PPIS, we haven't had the opportunity to examine that, and see whether we think it's flawed. We think from the outcome that it's flawed, but we haven't had a chance to examine the data. And I certainly hear from talking with people all over our state and our whole southwestern region, that there's nobody whose practice expenses have gone down at all. I'll use our cardiologist as an example. The standards after providing echocardiograms for 34 years now all of the sudden the cardiologist had to send the technician off to become certified in doing this, and this added $10,000 in expense. This is not a drop in expenses. I don't think anybody argues that making sure people are certified leads ultimately to quality of care, but it certainly adds to the expenses. We had to add another half FTE in my practice just to keep up with the increased paperwork that the increasing regulations are adding. Every little regulation adds a little bit of work, and we finally said people are quitting because they can't handle this workload. We have to add an FTE. That's not a decrease in expense. So you can probably look at some of the data that Department of Labor uses, the Workman's Compensation Insurance Companies use to tell what people's staffing is; whether they did actually drop staffing. I don't think they did, and there are data out there telling you how many people are employed by physician in a given specialty. In other words, there are ways to cross-check and make sure that things really have a valid basis before you implement a dramatic reduction in practice expenses, and I would hope you would do that rather than just throwing it on.

Mr. Hartstein: Thank you. Just a quick comment on that. The practice expense methodology is complex and it's also budget neutral, so even though the practice expenses for a given specialty may not have gone, may have gone up, what we pay for practice expense may have gone down because of the relative relationship among the survey information compared to what happened with all other physician specialties. The other factor that needs to be considered is what is the distribution between direct and indirect expenses because that also has an impact on it, so in the case of cardiology, the tables reflect that

it's a lower practice expense per hour. In the case of some other specialties, where there may be some redistributive impact, where the revenues from Medicare are going down, the practice expense per hour could have gone up and the distribution between indirect and direct may have changed. So because it's a budget neutral system, what's really relevant is how the practice expenses change relative to other specialties and the distribution of those costs. So it's not necessarily, we're saying that for all of the specialties that are getting a reduction that that's because their practice expenses went down. It could be that they just didn't go up as much as other specialties.

Dr. Bufalino: We'll take Chris, and then maybe we'll do some recommendations because the hour is late.

Dr. Standaert: I want to present a different concern or a different way of looking at some of this, from a number of perspectives. I think my concern in a lot of what you propose and what has been done before is that you are strongly disincentivizing people to care for the complex patient. And I think this started with never events, and medical complications, and disincentivizing hospitals from taking care of difficult patients, and you get into eliminating consult codes, which my colleagues pointed out, disincentivizes people from taking care of complex patients. You get to the imaging thing and you put a dollar amount on an imaging device and you pay a lot, you have much sort of higher reimbursement for dollar amount than another. You may encourage, you may be discouraging overutilization of high cost devices, but you may be encouraging utilization of lower quality devices by making such a big division. And I think just in general, there's a, I understand the issue of doing a lot of this, to get rid of some of the statistical outliers, which seem like they're sort of, that's where the fraud and abuse range sort of hover in the outliers. But complex patients hover in the outliers and when you care for complex patients with ongoing medical problems and multiple medical problems, who need multiple specialties, many of them would be sitting here to care for them, where there's a collection of activities, it can be seen as a way to again strongly disincentivize care of the complex individual, which I think is a problem.

Dr. Bufalino: Roger, do you want to begin the recommendations?

Dr. Jordan: This is going to be a recommendation regarding the physician practice information survey, and just a real quick couple of comments and I'll put my recommendation out there. This is a chance to take what was 26 specialties, ten or plus years ago, and now involving over 50, and using data

that is going to be able to provide an update to all providers uniformly and correct flaws that have been going on for over ten years, and I was not in that initial survey or any of the supplementals. So with that, PPAC recommends that CMS fully implement the data from the Physician Practice Information Survey, PPIS, to more adequately, excuse me, more accurately calculate the practice expense, PE, RUV and more fairly calculate reimbursement for all physician specialties. The data should be fully implemented in 2010.

Dr. Ouzounian: Second.

Dr. Bufalino: 2010? Or 2009? 10, I'm sorry. This is 9. Got it. Discussion on that? Obviously there are those of us that disagree. All in favor of the recommendation?

[Ayes]

Dr. Bufalino: None opposed. Okay. Others?

Dr. Kirsch: Just a little background at not this summer's, but last summer's AMA meeting, we, there was a resolution that was passed about the PPIS survey and a request to breakdown geographic data, and this is just a simple proposal that says, PPAC recommends that CMS review the AMA Physician Practice Information Survey's extrapolation of geographic data when it becomes available.

Dr. Ouzounian: Second.

Dr. Bufalino: Discussion? All in favor?

[Ayes]

Dr. Bufalino: Tye.

Dr. Ouzounian: It's my understanding that there is some consideration that an overview body for the RUC be made or that the physician work values be done by a different group, so I'd like to make a recommendation in that regard. PPAC recommends that if a supervisory body for the RUC is implemented, that PPAC would actually be the appropriate government body or group to supervise and overview the RUC.

??: Second.

Dr. Bufalino: Discussion? All in favor?

[Ayes]

Dr. Bufalino: Thank you. Others? Joe?

Dr. Giaimo: I actually had a two-parter here. First one is PPAC recommends that any move to decrease the compensation for consultative services will adversely affect the access to these services, and severely affect the quality of care for our patients and further study should be done before enacting any changes. There's a second part to this; they're actually two recommendations. Do you want me to take it—

Dr. Bufalino: Well let's take them one at a time. Second on the first recommendation, thank you. Discussion? All in favor?

[Ayes]

Dr. Bufalino: Thank you, part two?

Dr. Giaimo: Second part of it is actually in conjunction. PPAC recommends CMS work with the RUC to increase the reimbursement of services for primary care and general surgery specialties.

??: Second.

Dr. Bufalino: Say it again?

Dr. Giaimo: PPAC recommends CMS work with the RUC to increase the reimbursement for services to primary care physicians and general surgery specialties.

Dr. Ouzounian: I think you need to separate those.

Dr. Giaimo: To separate that out?

Dr. Ouzounian: Well they should increase everybody's reimbursement.

Dr. Giaimo: Well, I'm saying the concern about this initial topic, which was brought up. The fee schedule was that primary services were not getting valued enough, so what I'm saying what they should do is work with the RUC and these other services to further investigate this, as opposed to shifting the services and getting rid of the consultative codes.

[inaudible remarks]

Dr. Giaimo: Primary care was one of the underserved specialties that they've talked about, that's why, and also general surgery, because they haven't had people going into general surgery. That's why I picked those two specialties.

Dr. Bufalino: Other discussion? Did someone second it? Go ahead, Ken?

Dr. Simon: Point of information. The RUC values services that are delivered to it by the various specialty societies, and annually the RUC will then send the recommendations in terms of what they think

the appropriate valuation for those services are to CMS for consideration. CMS does not have seat, nor sit on the RUC, just as a point of information.

Dr. Bufalino: Other discussion? A vote, all in favor? How about we have a hand vote, thank you. All in favor, hands up? Four. Opposed? I think there's a fair amount of confusion here.

Dr. Kirsch: I guess I was just thinking to vote it down, and maybe we can discuss it and rework it.

Dr. Giaimo: I'm amenable to that.

Dr. Bufalino: Why don't we rework it over lunch and come back. That's fair, thank you for that. Others, Karen?

Dr. Williams: Certain things on the recommendation, but I don't start out with PPAC recommends, all right?

Ms. Trevas: I know.

Dr. Williams: PPAC believes that number one, the recent CMS statements questioning the quality of current academic anesthesiology practice are unfounded, and, two, that the intent of Section 139 of MIPPA was simply to restore full payment to academic anesthesiology training programs, based on current practice; therefore PPAC recommends that CMS implement Section 139 of MIPPA, without the additional criteria, requiring that only one individual teaching anesthesiologist who initially started the case, be present during the key and critical portions of the anesthesia procedure.

Dr. Bufalino: Is there a second?

Dr. Standaert: Second.

Dr. Bufalino: Second, thank you. Discussion?

Dr. Snow: Could you reread your recommendation?

Dr. Williams: Don't start from the beginning.

Dr. Snow: Yes, just the recommendation.

Dr. Williams: PPAC recommends that CMS implement Section 139 of MIPPA, without the additional criteria, requiring that only one individual teaching anesthesiologist, the one who initially started the case, be present during the key and critical portions of the anesthesia procedure.

Dr. Snow: Okay, thank you.

Dr. Bufalino: Any discussion? A vote. All in favor?

[Ayes]

Dr. Bufalino: Thank you. Others? Seeing none, we thank you for spending an awful lot of time with us today. Thank you very much. We appreciate that. We will so adjourned. We will be back from lunch at 1:20. Thank you.

Lunch

Dr. Bufalino: Let's begin. We're going to try to get ourselves back on schedule again, so thank you. Next, I'd like to introduce Dr. Christina Ritter, who's joining us, been with CMS for 10 years and she's been working on the hospital Outpatient Prospective Payment for a number of years, and in terms of a variety of issues related to that and we are glad to have her today talk to us about the OPPS Ambulatory Surgical Center, notice of proposed rulemaking and once again, Dr. Hambrick is going to join for question and answers, so Dr. Ritter, thank you for joining us this afternoon. Please.

OPPS/ASC Fee Schedule NPRM

Dr. Ritter: Yes, I usually run the numbers, but we won't bore you with too many of the calculations today. So this is just an overview of the proposed rule for calendar year 2010, for the Hospital Outpatient Prospective Payment System, and the Ambulatory Surgical Center payment system, they're done together. So it's both. On public display the same day as the physician rule, July 1. And published in the *Federal Register* on the 20th, and public comments close today at 5:00, so we're all waiting, and of course the two websites, in case you're interested in more information.

So just a brief outline of some of the highlights in the proposed rule. We tried to pick topic areas here that would be particularly relevant for this committee. The drugs and biologicals, certainly an area of great interest among the hospitals. Drug administration, radiopharmaceuticals, brachytherapy sources, physician supervision, probably the other hot topic in the proposed rule for Hospital Outpatient Prospective Payment System. The MIPPA provisions you recently heard Cassandra Black speak about, kidney disease education and the pulmonary and cardiac rehabilitation. This is the Hospital Outpatient component of those provisions. Proposal under, for type B emergency department visits, our partial hospitalization policy, quality reporting for a hospital in the outpatient setting, and a quick overview of the ASC payment system.

So quick background of course, the Hospital Outpatient Prospective Payment System, OPPS, pays hospitals for the resources that they provide, providing their component of the service, based on relative

payment weights, calculated for groups of services, APCs, that are similar in clinical characteristics and resource costs. They're smaller groups, clearly, than the DRGs, but not a fee schedule entirely. And we annually update those groups and weights using hospital outpatient claims data, cost report data, and the most recent wage indices. So key parts of our update this year are a 2.1 percent market basket as proposed, which would increase outpatient payments to hospitals by about 1.9 percent, some adjustments there to the market basket. And beneficiary copayments are projected to fall down to not much, 23 to 23 percent, a little bit of a drop there. There's a longstanding policy to try and reduce copayments in the hospital outpatient setting to the 20 percent that's comparable in other systems.

So drugs and biologicals, except radiopharmaceuticals here. This is the, like I said, one of the bigger proposals we have in the rule this year. The MMA of 2003 requires us to pay drugs and biologicals based on average acquisition cost, and permits us to adjust payment for pharmacy overhead costs. The actual amount of payment has been discussed each year and we have a new proposal on the table. The calendar year 2010 proposal is for ASP, average sales price plus 4 percent, for separately payable drugs over $65 per day. So the hospital outpatient has a packaging threshold, we package drugs under $65 per day for 2010, and pay separately for those over it. This proposal includes a proposed redistribution of $150 million from pharmacy overhead costs, currently attributed to packaged drugs and the estimated costs of separately payable drugs before the redistribution from hospital claims and cost reports was calculated at ASP minus 2 percent, so there's an issue at large with calculating the correct average acquisition cost for separately payable drugs, and we've proposed a redistribution to take them from ASP minus 2 percent to ASP plus 4 percent. ASP plus 4 percent is the current payment rate in calendar year 2009.

This is really maintaining the five level APC structure that we currently have for drug administration that we set in calendar year 2009, and includes some recalibration of various drug administration HCPCS codes among the five groups that are largely driven by the drug proposal that I just referenced, which was moving some of the drug money around in the relative weights, and because of that, we had to move some of the HCPCS around in the five-level structure, but essentially, it remains unchanged at this time.

For radiopharmaceuticals, MIPPA has required payment for therapeutic radiopharmaceuticals, of which we have eight. They are separately paid in the Hospital Outpatient Prospective Setting at hospitals'

charges adjusted to cost through calendar year 2009, so that provision will end at the end of this year. We propose to pay them at ASP plus whatever percent is determined in the Final Rule. Currently, the proposed rule is ASP plus 4 percent. The same methodology as other separately paid drugs and biologicals, and at the same time, we're proposing to begin voluntary collection of average sales price for radiopharmaceuticals. They've been explicitly excluded from submitting ASP data like other Part B drugs so far, for many of the complications involved in submitting ASP data for radiopharmaceuticals, however, the proposal that we put on the table was to submit a patient-ready or patient-specific dose amount, an average sales price for those amounts. And we had originally made that proposal back for calendar year 2009, and it was well received, but overridden by MIPPA in 2008. And then we packaged payment for diagnostic radiopharmaceuticals, which we've done since calendar year 2008 as well.

For brachytherapy sources, again, we have a MIPPA requirement that currently determines calendar year 2009 payment. We pay for brachytherapy sources at charges adjusted to cost, up through December 31 of this year. For 2010, the proposed payment is to base payment on median cost, which is the standard basis for all the APC relative weights, and because brachytherapy sources are not considered drugs or biologicals, we do make outlier payments for them. The hospital outpatient has a small outlier policy.

Besides drugs and biologicals, physician supervision probably was the other big proposal in the rule this year. 1861(s)2(b) authorizes payment for hospital services, incident to physician services rendered to outpatients, and in our calendar year 2009 rule, we restated and clarified our requirements for physician supervision, for hospital outpatient, diagnostic, and therapeutic services from April 2000, the beginning of the Hospital Outpatient Prospective Payment System Final Rule.

So the current policies are an expectation that all therapeutic hospital outpatient services, including those provided in critical access hospitals, are furnished under direct supervision of a physician in the hospital, and in all provider-based apartments of the hospital, both on and off campus. We have explicit regulations for provider-based departments, specifically direct supervision means the physician must be present and on the premises of the location and immediately available to furnish assistance and direction. But they don't have to be present in the room, which is comparable to the direct supervision requirement under MPFS with the replacement for the office suite. And that nonphysician practitioners may not provide

supervision in the provider-based department. This clarification in 2009 raised a lot of questions among the provider community, specifically about how to identify a provider-based department on the campus of the hospital, kind of where the lines would be drawn, and rural and critical access hospitals raising issues about the provision of services by nonphysician practitioners.

So our proposal, two primary refinements for calendar year 2010, for therapeutic services: First, that a nonphysician practitioner may supervise therapeutic services; that he or she may perform within the state scope of practice and hospital granted privileges, with the exception of cardiac rehabilitation, intensive cardiac rehabilitation, and pulmonary rehabilitation. And the specific nonphysician practitioners that we proposed would be the clinical psychologist, nurse practitioner, physician assistants, clinical nurse specialist, or certified nurse midwives. And that direct supervision on campus whether in the hospital or an on-campus provider-based department, means that the physician or nonphysician practitioner may be present on the same campus of the hospital, or critical access hospital, and immediately available to furnish assistance and direction throughout the procedure. So again, removing the on-the-location to really in the hospital on campus, and in the hospital, we've defined as being in the main building of the hospital, that is under the ownership, financial administrative control of the hospital, that are operated as part of the hospital and for which the hospital billed services furnished under their CMS certified numbers, which is the old hospital provider number.

And then for diagnostic services, the statute also authorizes payment for diagnostic services. Current policy for provider-based departments specifically is that Medicare will make payment when diagnostic services are furnished at an appropriate level of supervision, as listed in the Medicare Physician Fee Schedule relative value file. But again, we've explicitly identified it for provider-based departments so we proposed a refinement to clarify supervision for diagnostic services, which is that all hospital outpatient diagnostic services, whether provided directly or under arrangement, whether provided in a hospital, a provider-based department, or non hospital location, should follow the supervision requirements listed in the relative value file. And the direct supervision definition is the same as that for therapeutic services, so again, on the campus of the same hospital, and immediately available to step in and provide assistance and direction. The one exception here is there are a different set of regulations that do not allow nonphysician

practitioners to supervise diagnostic services, and so nonphysician practitioners are not authorized here under the proposal, to supervise diagnostic services.

So on to the MIPPA provisions. Again, there are some smaller hospital outpatient components that accompany the ones that were just discussed, including kidney disease education. The proposal here in the proposed rule is actually not specific to hospital outpatients, but all providers. One of the identified qualified persons allowed to provide kidney disease education is the rural provider of services, including hospitals, CAHs, SNFs, HHA, CORFs, and hospice programs. And those are rural providers, provided in a rural area, or redesignated as rural by statute. Our payment proposal for kidney disease education is to pay rural providers through the Physician Fee Schedule and because the rural provider is being recognized as their own individual, or their own qualified person, there's a single payment that's being made, either to the rural provider, or if provided by a practitioner, to the practitioner.

Pulmonary and cardiac rehabilitation. So again, the MIPPA provision for the new benefits for pulmonary rehab, cardiac rehab and intensive cardiac rehab, again, those services are furnished either in the physician's office or in the hospital on an outpatient basis, and other settings, although these are the two that have been identified so far. And the payment rules were just recently discussed for physician payment. For hospitals, again, we're proposing to continue recognizing the CPT codes that we currently recognize for cardiac rehabilitation services and they would continue to be assigned to the APC 0095, which is for cardiac rehabilitation, which has currently a payment rate, proposed payment of $38. The newly created G codes, we would also assign to APC 0095. While we collect data on the intensive cardiac rehabilitation costs, our rationale there was because it was a per session payment for both the G codes and cardiac rehabilitation, the general cardiac rehabilitation programs that the hospital resources would be comparable. And then for pulmonary rehabilitation services, the new G code for pulmonary rehab would be assigned to a new technology APC. It represents a new comprehensive HCPCS. Hospital outpatient does pay separately for various pieces of pulmonary rehab, but what this new HCPCS, we would assign it to a new tech APC, and we'd proposed a payment of approximately $15, which was based on the practice expense. So type B ED visits, so since 2007, we've recognized two different types of emergency departments under the hospital outpatient for payment purposes; one that recognizes the CPT definition of an ED, which is open 24 hours a day and available 7 days a week, and another, that is not open for that period of time, but

does incur an EMTALA obligation, and those are both type B EDs. We don't have very many of them, about 350 billing right now. Vast majority clearly are type A EDs. And for calendar year 2010, we're proposing a change from calendar year 2009, which is to pay all five of the type B ED specific HCPCS codes on their own APC. In calendar year 2009, we had paid the highest level type B ED, the same as the highest level type A ED. And this is a proposal to base it on its own median cost data, which came down a little bit lower than the type A ED. For partial hospitalization services, this is a continuation of our policy from calendar year 2009. We're proposing two separate APCs. One for days in which three services are furnished, and one for days in which four or more services are furnished.

Quality reporting. So building on the efforts across Medicare to strengthen the connection between quality of care and Medicare payment. By law, hospitals that fail to report the 11 required outpatient quality measures for calendar year 2009 will receive a two percentage point reduction to the calendar year 2010 payment update for most services and these 11 measures are seven emergency department and perioperative measures and the four new imaging efficiency measures. And then for 2010, for the payment update for 2011, we would continue our current measures and not propose any new ones, although we're seeking public comment on 18 new potential measures for future years. There's a proposal in the rule that discusses a validation approach that matches that that's available under the Inpatient Prospective Payment System, which is sampling from a fair number of hospitals and looking at a measure by measure validation study. And another proposal that would establish procedures to make the quality data publically available once it's collected.

And for the Ambulatory Surgical Center payment system, so this is the third year of a four-year transition for the ASC payment system that began in calendar year 2008. We revised the old system, which had been in place for a very long time and based payment on the OPPS relative value weights for the APCs, and we added about 800 new procedures at that time, and that was also based on a recommendation from the General Accountability Office, that we base payments for ASCs on the relative weights for the Hospital Outpatient Prospective Payment System. It's a budget-neutral system. It has its own conversion factor and its own budget-neutrality adjustments. By statute, we've been authorized to provide an update to the conversion factor before this year, and the update that we finalized in calendar year 2008, with the new system was the CPIU, and this year for the proposed rule, the CPIU was projected to be 0.6 percent, which

was also the MedPAC recommendation for the update factor. We expect total calendar year 2010 ASC payments to be about $3.4 billion. So because we're in the third year of the four-year transition, rates for services provided under the old system will be based on a 25-75 blend of the '07 rates and the new 2010 rates, and of course next year we'll implement the system in its entirety. We're adding 28 surgical procedures for coverage in the ASC payment system. There are some limitations on the services that are covered under the ASC system. They can't offer any safety risk to the beneficiary. They can't provide care at midnight, no active medical monitoring, so these are the ones that have been proposed to be added. And we propose to add six procedures to the office-based procedure list. These are procedures that are done more than 50 percent of the time in the physician office setting. They're paid under the ASC payment system and payment is made at the lesser of the Medicare Physician Fee Schedule, office practice expense amount, or the standard ASC payment rate. One more plug for the websites.

We were asked to provide some questions for the Council, and so here they were. How would you describe physician awareness of the different supervision requirements for diagnostic and therapeutic services performed in the hospital outpatient setting? And then how to disseminate information about the new MIPPA provisions, which were for us, certainly the kidney disease, the pulmonary, cardiac, and intensive cardiac rehab. And then the impact of the update under the ASC payment system and any information on how that transition is occurring.

Dr. Bufalino: Thank you. Anyone like to answer any of the questions or have your own comments? A lot of active interest in that. Suggestion on disseminating the information, I think, going to the specialty society—obviously you're listing on the website, but an opportunity to go to the nephrologists and pulmonologists, etc. is probably well worth it for them to at least as we've learned, we may need to communicate three or four different ways before we get the information to the physicians, so, I'm sure you've already thought of that. Any other thoughts, comments, questions.

Dr. Howard: I'll look into the ASC implications. I don't work in that setting so it's hard for me to really respond to that right now.

Dr. Bufalino: I think as far as the awareness of the physician supervision, I think we're all taught by our hospitals what we do or don't have to do, so that becomes the essence of it. And I think the accommodation of not having it in the same suite but in the building I think is a significant accommodation

for most folks who, on a need-ready access. And one little minor concern which you suggested that buildings connected to hospitals were okay as long as they were supervised by the hospital. But in many of the settings that we practice in today, the hospitals have divested themselves of those buildings, and although we all still live and work in those buildings, they're just not owned by the facility because they have found ways to capitalize them elsewhere and use the money for other sources. So you might consider that as an option. If it's connect, it's connected. I'm not sure they need to own it for it to function in the way you're intending it.

Dr. Ritter: Yes, we've certainly received that comment on the proposed rule.

Dr. Bufalino: Anyone else? Thank you for your time and effort. We appreciate it. Any recommendations surrounding that area, or anything else from this morning that needs to be brought up? Moving right along, we will introduce the next speaker, Kimberly Brandt is joining us. She's the Director of Program Integrity in the Office of Financial Management. Prior to joining the integrity group, we worked for five years at the OIG and various challenging jobs, Office of the Counsel, Special Counsel to External Affairs. We are pleased to have her join us today, share information about the agency's fraud and abuse efforts. I think you're supposed to be joined by a few other folks eventually.

Ms. Brandt: Eventually yes, but—

Dr. Bufalino: I think we'll start with you alone and give you an opportunity to update on us on Fraud and Abuse. Thank you for being here.

Fraud & Abuse Update

Ms. Brandt: No problem. Thanks. I'm glad to have the opportunity to be here. I do not have a handout, because the nature of the fraud and abuse efforts is ever-changing at CMS and with the department as a whole, so I thought I would give you sort of a up-to-the-minute update on what has been happening with our fraud and abuse efforts. Most of you are probably aware, but on May 20th of this year, Secretary Sibelius and Attorney General Holder announced a fairly significant and large scale anti-fraud and abuse initiative, that's a joint effort before the Department of Justice and the Department of Health & Human Services. The focus on that is on acronym called the HEAT, which is the Healthcare Enforcement and Prevention Action Team, which actually, we're missing the P from that, but HEAT sounds a lot catchier than HEPAT, so it's the Healthcare Enforcement and Prevention Action Team. And the whole goal

of the joint task force between the Department of Justice and HHS is really to focus on how we can work collaboratively, to be able between our two departments, to do more to leverage our limited fraud and abuse resources, and figure out how we can focus on the areas that are the highest vulnerabilities. In particular, the efforts to date have focused on the enforcement piece of things. In particular, the May announcement made it clear that there were going to be strike forces, which are going to focus on high vulnerability areas, such as Los Angeles, California, Miami, Florida, Detroit, Michigan, and Houston, Texas, and that is where the Department of Justice and the Office of Inspector General are putting forth a lot of their investigative and prosecutorial efforts so that they can go ahead and focus on prosecutions in those areas. The areas that we're focused on in terms of the types of prosecutions are durable medical equipment, home health agencies, infusion therapy, and independent diagnostic testing facilities. Those are really the four key types of places that the enforcement actions have focused on to date. You've probably seen a number of press releases over the last couple of months. There have been a number of prosecutions and indictments as a result of those activities. The Houston and Detroit taskforces are relatively new, so they're really just getting up and going, but they're really been focused on rings of organized crime type of activity. Most of what's happened thus far has been very deliberate, nefarious types of crime. This is not your garden variety doctor who's caught up in an innocent upcoding scheme. These are people who are doing a very deliberate game of manipulating the system, and are taking advantage of us by bilking us of millions of dollars by billing for services not rendered, by buying and selling beneficiary numbers, but actually buying and selling physician numbers in some cases. So a lot of this to date has been a very focused activity on sort of the high types of profile types of enforcement actions. However, at CMS, we have been focused not only on the enforcement piece of it, but also on the prevention piece, because as much as the enforcement piece is a high priority and certainly the Department of Justice and the Office of Inspector General are very focused on those high profile prosecutions, what we have been focused on at CMS is finding out ways that we can do an even better job on the prevention side of things. And so we've really been focused on three key areas from our perspective. We've been focusing on our enrollment activities, which I'll talk a little bit more about in just a minute, we've been focused on our analytic capabilities, how we can use claims information and data to be able to do a better job of program oversight, and lastly we've been focused on how we can

use that information from the analytics to put more edits in place and to be able to use it for better enforcement types of actions, to be able to stop improper payments before they're made.

So to go back on the enrollment side, one of our challenges at CMS has been that we operate in an any-willing-provider system, and so there really have not been a lot of authorities for us to be able to keep people out of the program or to take action against folks when they come into the program. So one of the big focuses of this HEAT initiative to date has been looking at ways that we can hopefully partner between the Department of Justice and Health & Human Services to come up with legislative proposals to put forth to Capital Hill to be able hopefully be able to advocate for other ways that we can look to strengthen our enrollment authorities. We, within CMS, have also been looking for ways regulatorily and otherwise, that we can strengthen our enrollment authorities and ways that we can do a better job of doing more on-site visits, and more verifications to ensure that the people who are enrolled in the programs are who they say they are, and that they're still in business. So we've really had a big focus on insuring that we have accurate and up to date information on those that we do business with. This has included going out and actually doing a series of on-site visits in high vulnerability areas to DME supplies and other high vulnerability types of providers and suppliers, and doing a massive revalidation effort where we've been asking physicians and other types of practitioners to update their information, particularly those who haven't updated their information with us in more than five years, so that we can make sure we have address information and up to date practice information on those individuals.

The second area that we've been focused on is analytics. And that's really been a big focus, because one of our biggest challenges from an oversight perspective, has been pulling together all of the various claims information that CMS has into one centralized repository, so that we can look across various geographic areas, service types, and other areas, to be able to look and see and where we have aberrancies or overutilization patterns. And if we do start to crackdown on fraud in a particular area, such as South Florida, which is one of our most prevalent high fraud areas, we see that as soon as we crack down on it there, it sort of morphs to another area of the country. And one of our challenges has been in tracking that morphing is that we haven't had all our claims data together in one place, because it's really been disparate among the various contractors. So one of our big focuses has been building an integrated data repository to bring those analytics together and to be able to have it so we'll have one data repository that will have all of

our Part A, Part B, DME, home health, hospice, and Part D prescription drug event data all in one place; to be able to look across various geographic areas, and across service types to see where the fraud moves. And then the last area that I mentioned is in the areas of edits and enforcement, and again, we'd like to be able to use our new analytic capabilities, looking across that claims information that we're pulling together to be able to help us to find out where we can do more in the areas of prepayment edits, to be able to stop improper payments before they happen, and to be able to determine how we can do a better job of utilizing our administrative enforcement actions, such as suspensions, overpayments, revocations, or deactivations, to turn people's provider numbers off where we see that there has been abuse occurring or to be able to suspend payments or take action to stop payments from going out the door, where we see that there is the potential for abuse to occur. With all of these enforcement actions, though, one of the things we have been spending a lot of time talking about at CMS is how we can continue to spread the word that this is something that focuses on a very small percentage of the Medicare providers. One of the struggles is that balance. How do we do the focus on the enforcement actions, while ensuring that the good providers and the providers who are excellent business partners with us and doing the right thing, don't have unintended consequences as a result of the enforcement actions. So we've really been focusing on working with the Centers for Medicare Management and the Provider Education group to determine how we can do more provider outreach and education and really focus on making sure that providers know where it is that we see issues that are occurring, how we can communicate those issues to physicians timely, and make sure that the honest physicians know what the rules are and how to do the right thing, but in the meantime, still working with our partners on the enforcement side, to make sure we're taking action against these particularly pervasive bad providers who are deliberately seeking to manipulate the system. So that's a very high level overview of what's been going on, but it is a very comprehensive effort that ties in to every aspect of what we've been doing at CMS, and I'd be more than happy to take any questions.

Dr. Snow: Thank you. Appreciate the presentation. And I think one of the things that may have precipitated your being here today was one of our recommendations at the last meeting where we specifically, PPAC asked CMS provide us at the next meeting statistics on fraud and abuse involving physicians in the Medicare program. Quite frankly, I think many of us have heard varying statistics. There's a lot of fraud and abuse going on out there, granted a few bad apples wherever. But the real

question in my mind and I think many of ours is how much of this fraud and abuse involves actual physicians? Or is it DME suppliers? Or some other providers? CMS along with I think, so many others, has forgotten that physicians are only one of those provider groups, and we seem to get lumped in with everybody. Can you provide any help on that line?

Ms. Brandt: Sure. In terms of the actual statistics, I will have to get back to you to give you an actual statistic. I don't know that we have an exact breakdown of the number, because oftentimes physicians can be part of an overall scheme. I mean a lot of times, for instance, one of the things that we've seen is that you will have physicians who are on retainer to a DME supplier who basically agree to sign off on orders and that's a very small percentage, but it's again, something where we'll see that we have physicians who have agreed to take a certain amount of money per month in exchange for signing off on orders for a DME supplier for patients that they never see, and so that's one of the types of fraud in which we have seen physicians. But it isn't something where I can tell you it's 1 percent, versus 3 percent of the total amount of fraud at CMS. I think that the amount is to a certain extent unquantifiable because I don't think we break it out by how many are physicians, versus how many are suppliers, versus how many are home health agencies. But we can certainly get you some information about convictions that have occurred. And then also some information about how many of the suspensions or administrative actions we have taken really to physicians.

Dr. Snow: Could I make a recommendation now? Or I have one whenever you would like to receive it.

Dr. Bufalino: Sure. Go ahead.

Dr. Smith: Could I make a comment about that, first?

Dr. Snow: Go ahead.

Dr. Smith: One of the problems and one of the reasons we asked for this breakdown is because the implication in the press is that it's physicians. It really comes across that way. So that's part of why we're asking you for a really detailed breakdown so that we have something to defend ourselves, I guess.

Ms. Brandt: And to the best of our ability, I will be happy to try and provide you with the statistics as much as we can, but again, part of that is depending on a lot of the press breakdowns are on indictments

and that is different from actual convictions or prosecutions, so we'll attempt to work with our enforcement partners to get you as detailed of information as possible.

Dr. Snow: PPAC recommends that CMS provide to PPAC at the next meeting statistics on the fraud and abuse involving physicians in the Medicare program.

??: Second.

Dr. Bufalino: Second, thank you. Any discussion?

Dr. Ross: Yes, there is discussion.

Dr. Bufalino: Please.

Dr. Ross: Just to that, I was the one who proposed this on the last occasion and Ms. Brandt, I think over a year ago when we were up in Baltimore, we got the statistics based upon physician fraud and abuse on DMEPOS. And the number was very insignificant. But what's transpired in all this time has been there's been a lump between physician and DME suppliers because of the fraud abuse issue. So this was the reason why this information was so sought after, why the first recommendation was made, and why Dr. Snow is repeating that recommendation again today.

Dr. Bufalino: And for a vote—all in favor?

[Ayes]

Dr. Bufalino: Thank you. Any opposed? Other comments? Questions? Thank you Ms. Brandt, for being here.

Ms. Brandt: Okay, thank you.

Dr. Bufalino: Our next group, familiar face. Commander Casey is back for a conversation along with Patricia Fenton and Dr. Polansky is joining us today. Commander Casey as you know is commissioned Corps of the U.S. Department of Public Health, initially serving as an insurance specialist, and now has assumed the role of technical advisor for the division. She currently serves as Deputy Director in the Division of RAC Audit Operations. Joining Commander Casey is Patricia Fenton, nurse consultant in the Provider Compliance group, along with Dr. Polansky, who joins us again, was here in June. And Dr. Polansky's the Medical Director of the Provider Compliance Group in the Office of Financial Management. Provides direction and leadership for the administrative contractors and the RAC contractors both Parts A and B. Thank you all for joining us again and glad to have you hear for an update.

RAC Update

Cmdr. Casey: Well good afternoon. We're also glad to be here to provide a both, a review of the RAC program, and provide an update, and also to introduce you to our Contractor Medical Directors here on the RAC program. I know you may have many questions that you might want to ask our RAC CMDs, so I will be very brief as to what our updates are in the RAC world. First, I'd like to just briefly go over the review phase in schedule map, and then I will talk about some other program updates, and then I will have each of our Contractor Medical Directors introduce themselves, tell you a little bit about their background, and then tell you about their responsibilities, that each of their RACs are. The review phase in schedule, we had talked about it in the past. There are four RAC regions, and we have begun implementation of the RAC program in many of the states across the country. CMS decided that we would take a staggered approach to the types of audits that we would perform in the country, and currently we are looking at doing automated issues, which are our very easy black and white issues. They're issues that there's certain policy that a provider is not appropriately complying with. We have also told the RACs that they can slowly now start to begin to do what we're calling DRG validation reviews and those reviews have just recently started in the August timeframe for some of our states and we also are planning on doing the medical necessity reviews, but those reviews will not take place until after the first of the year. So no medical necessity reviews will take place until January 2010, and there's more details. I have it on your slides. I'm not going to sit here and read word for word, and basically this again, is based on the colors on your map as to how this review phase in strategy will work. If there's any questions, I'll be glad to address those at the end.

The next program update I wanted to provide today is to actually tell you that all RACs have been given claims data. I believe we mentioned that at the last PPAC meeting, and that data is through early 2009, however, 73 new issues have actually come in to CMS that have been proposed. We have approved some of those issues. Last time I didn't have anything to report to you, but today I actually do. We have approved some issues for the RACs, and they are, but we have seven for HDI which is Health Data Insights. They're our Region D RAC. They have seven approved issues that have been posted to their websites. We have Connelly consulting, our Region C RAC that has eight approved issues, and their issues have been approved for the states of South Carolina and Florida. And lastly, our Region B contractor, CGI, has three approved issues in the states of Indiana, Michigan, and Minnesota. To date, all RACs have their

toll free number that's operational. All RACs have websites that are functional, and to date, CMS has conducted over 95 provider outreach sessions, and actually that was as of 8-17-09 that we had completed over 95 provider outreach sessions. CMS does hope to complete the majority of our outreach to all 50 states by the end of this fiscal year. I believe we only have two or three states following the end of the fiscal year, and then we will have completed our outreach in every state in the country.

And with that, I would actually like to turn it over to our RAC CMDs, each of them is going to come up to the table. I'm sorry, question?

Dr. Smith: Yes. You said it's colors on the map, but the maps we have are black and white, so can you tell us—

Cmdr. Casey: I apologize. I thought that might cause some confusion. We have what we call, normally it looks yellow, but that looks like pea green. I don't know, not a very nice color green. It's usually yellow. They were our first states to go live. Then we have the striped states, the green and white states, they're the next states with an implementation schedule. And then the last states are blue states, and they were basically our plan for outreach, as well as our plan for the review phase in strategy. So in other words, in the yellow and green states, we've actually allowed automated and complex review to occur a little bit sooner than in the blue states, because it was based on when we actually performed outreach in that state.

Dr. Bufalino: Other questions for Commander Casey? I'd actually like to ask you, some ideas of some of the new things that you've approved?

Cmdr. Casey: Yes. We approved code J2505, which is Nulasta, we approved an issue for urological bundling. It basically was a situation in which the LCD says we'll only pay for this one code if this other code is billed, and some things like that. I believe, Tricia can you think of anything else? Go ahead—oh there was a blood transfusion code that we looked at, that basically said you can only bill this once a day and it was billed for multiple times. There was also some therapy codes that basically the code descriptor itself says this code can, you can only bill one unit, however several units of that code were actually billed, so those, any code over one were denied. So those are some of the issues.

Dr. Howard: I've been asked on more than one occasion now, how this works between RAC and CMS? In other words, can CMS ask you to look into specific issues, or how does this relationship work,

and who's overseeing what part of it? I mean maybe that's a question for Ken. I just get asked a lot about how this, the tree diagram of this…

Cmdr. Casey: Well, CMS does not have authority to mandate that a particular RAC look at a particular issue. Certainly we can suggest areas that other contractors have found to be a problem area and certainly suggest that a RAC take a look at that, but basically each RAC can choose what type of issues they want to look at based on their own internal resources. However, if a RAC does choose to look at a certain issue, they do have to come in through what we're calling the CMS new issue approval process, and this is a twofold process. If it's a DRG coding issue, or if it's one of these automated what we're calling an easier black and white type of issue to look at, they come in and are evaluated by another contractor called a PRI, Provider Resources, Incorporated. They assist CMS in looking over the claim samples, and looking over the policy guidance. And CMS then ultimately makes a call on whether that issue gets approved. If it's a medical necessity issue, those type of issues will go to a CMS internal board, and that internal board will be the ones that will make the final call on whether they believe the RACs should look at it on a widespread basis. And that internal board is composed of CMM, CAG, which is our Coverage and Analysis Group staff, as well as we have a board member from OFM, and Appeals that sit on that board and make that decision as to whether the issue should go forward.

Dr. Howard: What if you have a complaint with a RAC, or you have an issue? Is that something that goes back through CMS or is that something that goes through—

Cmdr. Casey: Generally speaking, what we've told providers when we do our outreach session is if you have a complaint about a RAC, first of all let them know, and see if they can't resolve it but we've also provided at every outreach session a point of contact in each RAC region, which is actually the region's project officer. We've included the information in our slide presentation, which is also posted to the Web, that has a point of contact for a provider. If they've contacted the RAC and the issue has not been resolved, they are to contact the CMS RAC Project Officer.

Dr. Kirsch: Do you have an update on how much money has been paid, how much money the RAC has collected and how much money has been paid back?

Cmdr. Casey: Well, to date, we haven't actually truly had any collections yet.

Dr. Kirsch: Okay.

Dr. Snow: I understand the E&M codes are still potential sources of audit by the RACs is that correct?

Cmdr. Casey: RACs do now have in their statement of work, the authority to review E&M codes. There was some confusion. People had said, oh no, the RACs aren't going to review E&Ms because in the demonstration RACs were not allowed to review E&M codes. However, as we go forward in the national program, there is a potential for a RAC to select a particular E&M code to review. Again, that issue would first have to be approved by the New Issue Review Board in order for them to review it.

Dr. Snow: Okay. Supposing that an E&M review was done and let's say the choice was to review level four codes in the office setting, and the audit from the RAC indicated that it should have been a level three? What is the recoupment going to be? The total amount paid for the level four visit, or the difference between the three and the four.

Cmdr. Casey: The difference. And the contingency fee would be based on that difference, not the entire amount.

Dr. Bufalino: Would you like to introduce the RAC contractors?

Cmdr. Casey: Sure would. At this time, I'd like to introduce Eugene Winters. He is our Contractor Medical Director for DCS, which is our region A RAC. Dr. Winters, you want to come to the table.

Dr. Winters: Thank you, Marie. Good afternoon. My name is Eugene Winter, and I am the CMD for Region A. My background is such that I'm board certified in Internal Medicine, have practiced internal medicine and noninvasive cardiology for more than 20 years. Five of those years were in an academic medical setting. I have been with Medicare for more than nine years now. I have been a Contractor Medical Director for Medicare Part B, in Tennessee, also in Florida for Medicare Part A and Part B, and most recently, I was the Medical Director for the qualified independent contractor, QIC, Medicare Part A was the western jurisdiction. My responsibilities are such that my overarching assignment is to ensure that there is solid and strong clinical representation at the RAC. This includes clinical leadership and expertise and guidance as it comes to regulatory issues as well as clinical issues and the interpretation of policy and regulations, especially national and local coverage determinations.

Furthermore, I am involved in all levels of the audit process, which means participation in the identification and the submission of the issues that are identified to ensure that all laws and regulations and

policies apply, to participate in setting up the edit parameters and to set up the medical review guidelines, also interact with a large number of consultants, specialty and subspecialty consultants, to ensure QA and QI and to support the appeals process. I also take part in the training of the clinical staff and the customer service staff, participate in provider outreach and communications and specifically will be available to interact with providers during the discussion period. I also work in partnership with CMS to improve the Medicare program, collaborate in writing and overseeing policies and procedures, and I will keep up and do keep up with medical practice technology and the regulatory environment. And I do it all with a smile. [laughter] Thank you.

Dr. Bufalino: Thank you. Questions for Dr. Winter?

Dr. Howard: When you consult with the 35 available medical specialty consultants, how do you identify a medical specialty consultant? Are they people like for us to be on this committee, we have to have so many Medicare patients and so many people that we have, work with, we have to have a certain amount of Medicare patients in our populations. So how do you identify your consultants?

Dr. Winter: Well, primarily the consultants are identified based on their expertise in the particular case, and this can come depending on what the review entails, the specialty and/or subspecialty, the identification of the consultant may also be based upon the recommendation of a provider who is being audited and might request a specialty consultant to be involved. So there is no set procedure right now, as to how these folks are identified. There is a number of them on the staff and available, and on contract, and resources will be requested and invoked as necessary. So if you are asking me directly, are they identified based on the proportion of patients who are Medicare in their practice, that would not be likely, but possible. But primarily based on their expertise.

Dr. Bufalino: Other questions for Dr. Winter? Thank you for joining us.

Dr. Winter: Thank you.

Dr. Seaward: Good afternoon everybody. My name is Percival Seaward. I want to thank you all very much for inviting us here today. Having spent the last couple of months on outreach programs, it's quite nice to have a group of colleagues to talk to for a change. Briefly speaking, I'm board certified in general surgery, and also a Fellow of the College of Medicine of South Africa, as well as a Fellow of the American College of Surgeons, and this would explain my strange accent. I am an American. I came to

America in 1979, naturalized. I have grandchildren who are American, so we really, I've really begun to think and act like an American, but I don't speak like them. Unfortunately, I can't get rid of that accent. I received my medical training at the University of the Witwatersrand in Johannesburg, South Africa. Emigrated to America in 1979, as an assistant professor of surgery and Chief of Surgery for LSU, New Orleans. They put me out at a place called Lake Charles and I stayed there for about three years, had a wonderful time and then decided to come up to Cleveland. And I've been in surgical practice for over 30 years and got to a point in life where I felt it was time to perhaps stop clinical practice and go into something quieter. Now my training includes teaching of medical students and residents, both in my home country, South Africa, and in the USA. Actually I shouldn't call it my home country. This is my home country now. I joined CGI in 1998 as a part time executive consultant and medical director, and over time, I increased my commitment to become a full time member of the healthcare group. I'm currently the Director of Consulting for CGI, Federal, BPS Healthcare Division, based in Cleveland, Ohio. My experience at CGI has included physician auditing of complex reviews, consulting for CGI clients, assisting in educating our professional auditors, and representing CGI for provider teleconferences and ALJ hearings when necessary. So that's basically my background. My responsibilities as a CMD for the RAC B Region, basically a CMD is expected to have an understanding of national coverage determinations and local coverage determinations, and other Medicare policies. Second of all, the CMD must be able to provide good clinical expertise and judgment. Thirdly, in addition to the first two requirements, the CMD must be a source of medical information. That means, in my opinion, primarily, ready availability and the RAC audit staff must always have easy access to their regional CMD. They must be able to walk into your office, and you must be able to give them information where they need it. And so I think, I regard that as a fairly important aspect of being a CMD. I must also be able to provide good clinical review judgment and this is very important. And this is to prevent aggressive auditing by the audit team, and to eliminate as many gray areas as possible from the auditing process. This is something that I've been with CGI for 12 years, and it's come up time and time again, you have to watch your auditors and train them to audit in fair fashion, and to do it in a nonaggressive way. Another job for the CMD that is that they must be able to make decisions on questionable claim review situations. They must be willing and prepared to be readily available to the providers for one on one discussions involving difficult cases. And I have been in the Outreach Programs,

encouraging the providers to tell their physicians if they have a problem, to contact us and so that we can discuss it and possibly they won't have to appeal their result, it might be given to them at that stage, if we have the suitable information. Another important role the CMD is to be involved in vulnerability recommendations and this involves revision of known vulnerabilities, or the introduction of new issues to the Medicare claims system. They must be prepared to recommend any corrective actions, with regard to NCD, LCD, or other system edits, as well as recommending provider education. The CMD is expected to be involved in claim adjudication briefings, that means interaction whenever necessary with the relevant personnel who are involved in the appeal processes. Further obligations require that we keep abreast of current medical practice by continuing our medical education. And this hopefully will induce us to apply this knowledge to the RAC project. We are encouraged and expected to interact and share problems with the CMDs of the other RAC regions and to participate in RAC CMD clinical work groups, and if requested, we are to add input to the National Coverage and Payment Policies. The final, I feel, a very essential responsibility of the CMD, is to be part of outreach programs, and this allows the provider organizations opportunities to meet and interact with the CMS RAC key personnel, to ask and hopefully to get answers to their questions and be updated from time to time, and to see that CMS and CGI are attempting to be as transparent and informant as possible. We want you to know what we are doing. And I think this is very important. You need to know what we are doing. And we intend to ensure that our auditors have access to up to the minute medical knowledge, that will enable them to make correct decisions that are based on current medical knowledge. So in conclusion, I feel sure that we will attempt to apply all the medical knowledge that we get and clinical review judgments to every aspect of the review process to ensure that they are consistent with statutory regulations, are fair, are based on good cause and sound clinical review judgment and can be supported by currently acceptable medical practice guidelines. I hope you will accept and understand that in the long run, we can all benefit from this program, while preventing overpayment and underpayment, and indirectly improving provider proactive education. And thank you very much for listening to me.

Dr. Bufalino: Questions for Dr. Percival. Yes?

Dr. Standaert: Just so understand this industry a little more, I'd never heard of CGI before this. What is the nature of your company, and how does this particular venture dovetail with other interests of the company?

Dr. Seaward: Well, CGI is IT, information technology company. They have, the parent company started in Canada and eventually expanded and gradually moved into America. They have several divisions of information technology, but their healthcare unit has been going for 15 years and has been mainly sort of, shall I say, based on the Cleveland unit, which has been going for that length of time. The work involves dealing with various contractors to help them look for deficiencies or mistakes in their cases that they have to pay for. We've done a lot of work with the Blue Cross and Blue Shield companies at the various states all over the states of America. Does that answer your question?

Dr. Standaert: I think so.

Dr. Bufalino: Other questions? Janice?

Dr. Kirsch: I want my memory refreshed about the oversight. Are you overseen by CMS or by the RAC providers?

Dr. Seaward: CMS is overseeing us in a very, very definite and helpful fashion. I think Jesse might be able to answer this. Each RAC area has its own project manager, or project officer they call them? And they tend to, we interact with them whenever we have to but usually on a weekly basis, we have calls together with them. They always accompany us when we go out into the field for an outreach program and they do their own presentation before we get the opportunity to let them have our presentation. They help us, basically we have to ask them first, can we do this, before we actually do it. So we are responsible to them in a way.

Dr. Polansky: Let me just embellish that a little. I think what Percival is saying is absolutely correct. First and foremost they are contractors of the Medicare program. And there's a couple implications of that. One is that they have to follow all our policies and procedures, clinical and otherwise. Two, there's a very active oversight process, and one of the things we're emphasizing today is something called the New Issue Review Board. So before any RAC embarks on a review of a particular clinical, coding, or payment issue, that has to go through the agency for approval, including the policy owners at the agency, and that's I

think a process instituted after the demonstration program, which had a lot more latitude in terms of what the RACs explored. So this is a program of the agency, managed by the agency in a collaborative fashion.

Dr. Kirsch: I guess my question is, is Dr. Seaward a separate contractor from the RAC provider or who pretty much determined him for the job? Who has oversight if there's any—I'm sure you're going to do a lovely job, but if there were any job performance issues, I mean who's overseeing?

Dr. Polansky: Ah. Well, I'm not sure what you mean by a RAC provider. Maybe you can help me with what you're asking in terms of that.

Dr. Kirsch: Well, I mean basically we have folks who are contracted to do the audit. So our auditors, are they separate contractors from medical directors?

Dr. Polansky: Well, Dr. Seaward works for one of the RAC contractors.

Dr. Kirsch: I think that just answered my question.

Dr. Polansky: Okay.

Dr. Seaward: In fact, I'm full time with CGI.

Dr. Polansky: And not to complicate your life, because these are obviously good questions, some of the RAC contractors have subcontractors that help them with specific targeted activities, and there's a whole chain of accountability and contracting procedures that have to be followed before we're willing to entertain those kinds of arrangements. So you'll be hearing from Earl Berman later, one of the Contractor Medical Directors, who works for one of the subcontractors.

Dr. Bufalino: Thank you, Dr. Seaward.

Dr. Seaward: Thank you.

Dr. Lee: Good afternoon everybody. My name is James Lee and I am the CMD for Connelly Healthcare. And my background, I'm board certified in Emergency Medicine, and I practiced military medicine for five and a half years, and then I practiced—I have been practicing civilian emergency medicine for the last two and a half years or so. I am a full time CMD for Connelly Healthcare, but I also still practice civilian medicine in an academic emergency room as well as a small rural emergency department. I have over two years of RAC experience. I was the Medical Director during the demonstration for Region A, joining in June of 2007, and I am obviously the RAC Region C Medical Director. I'm also a registered pharmacist, and I practice clinical pharmacy very occasionally, as well as retail pharmacy once

or twice a month. My responsibilities include providing medical interpretation and clinical guidance with the application of Medicare regulations and rules. I research medical literature to review advances and changes in the clinical medical practice. I participate in the development of audit protocols and parameters. I interact daily with all of our audit staff, performing complex and automated reviews. I coordinate the consultations with all the medical specialists and subspecialties that we have. I support the quality assurance program to ensure accurate audit determinations. I lead auditor clinical education process for all RAC audit issues. I attend and participate at all RAC outreach presentations, and I respond to all provider inquiries regarding the clinical judgement. I collaborate with CMS, other CMDs and Medicare contractors regarding Medicare policies, procedures, and quality improvement projects. And finally, not listed is ultimately, I am the provider advocate for Connelly Healthcare and the RAC Project for Region C.

Dr. Bufalino: Questions for Dr. Lee? Chris?

Dr. Standaert: I have a few. I'll just give him one at a time then. A couple of you have mentioned you go through sort of literature and clinical guidelines and all this sort of thing to come up with things. I mean clinical guidelines sometimes are very helpful, sometimes are well thought out, sometimes are advocated by a position, by groups of a particular position. They're more of a position statement of a group than they are truly, they're not always necessarily an evidence-based best practices, they just sort of mandated or even uniformly accepted by the medical community. And I could see where you would get conflict by following guidelines that don't necessarily get uniform acceptance in the medical world, that lead to decisions that things should be done a certain way, and people not doing it that way may fall into the bounds where they would catch your attention, I would assume. That'd be the whole point in doing that. Now how do you square that sort of thought process?

Dr. Lee: For myself, it's easy because I still practice clinical medicine as well, so I see it as a practicing physician. So if it's a gray issue, I don't like staying on the fence, I will usually go with the provider side and lean toward the provider, and even in making my judgment for the RAC. Especially if it's a conflicting policy between a statement paper versus what an LCD may say, but if they're in conflict, that's usually how—I'm still providing practicing physician.

Dr. Standaert: So if your decisions are made in part on the guidelines as opposed to—I mean there clearly are—like looking at some of the things that have already been approved, they're coding issues. The

code says you can't do more than one of this. That's a coding issue, that's not a clinical practice issue. That's not a judgment issue, that's a coding issue and those are different things.

Dr. Lee: Right, the coding issue, if it's clearly stated than it shouldn't be more than one, then it's—

Dr. Standaert: It's a fairly cut and dried issue, which doesn't engender sort of argument amongst the clinical world [crosstalk] I assume is that were more of the attention is paid? I guess I'm curious about the role of sort of looking at guidelines to sort of go after physician behavior.

Dr. Lee: They're the black and white right now, the medical necessity we haven't gone into yet. But the black and white issues right now, those are the simple ones.

Dr. Polansky: Let me add something on this, because I think you're getting at the question of what role do practice guidelines play in the review process?

Dr. Standaert: Well, sort of how, there's the whole question of how, I mean we've had this before. How do they go fish—let me just ask you, how do you guys go fishing? How do you decide statistically which things to go after? In our own heads, what are probability issues in terms of how likely are they to go after certain issues in coding and people have brought up E&M codes and things before, and it seems to me that when looking at, they're using, several of them have stated they go through literature and look at clinical guidelines and I'm assuming they're using those as a way to start culling through the data on utilization, to say what's appropriate utilization, what isn't appropriate utilization, when again those aren't necessarily cut and dried issues like you can't bill more than one unit of something, you can't bill more than two units in 24 hours, you can't, which are purely coding violations, which if you read the coding book, they shouldn't be doing it. And I've seen this for other sort of procedural things, where OIG reports will say people aren't meeting coding issues and OIG isn't focused so much on is it inappropriate in a given patient? Which is more what you get into with the guideline issue; it's the whole issue of how clinical practice judgement decisions on that, play into what is just deemed inappropriate care and therefore not reimbursable. Does that make sense?

Dr. Polansky: I think I'm understanding, and obviously, as I think we've said, there are issues the RACs will address, which will be related to coding, where there's a fair amount of clarity in terms of decision making. There'll be issues in terms of payment policy. That often, hopefully we will have that

kind of clarity. Things do get more challenging when you start getting into what's reasonable and necessary both on in terms of medical necessity as well as in terms of what documentation the agency may require. There's one thing that grounds all this discussion that I think we all want to highlight. First and foremost, the RACs have to follow our policies. So it's very important that this distinguished group of CMDs track what's going on in practice, track what's going on in terms of the clinical trial and other types of literature, but force first and foremost, the program is guided by the body of policy at the agency. And that's principally the national coverage decisions and local coverage decisions. So when in fact, they do embark on those kinds of reviews that deal with reasonable and necessary decision making, it'll be first and foremost the NCDs and LCDs that guide that, and if the policies are clear, and one of the reasons we have the New Issue Review process is to ensure if they're going to embark in that area, that the policies do allow a fair amount of clarity in terms of what's covered and what's not. Policies are not always perfect. And the new issue review process is meant to ensure that if the RACs do pursue a certain policy area, that we feel we're on solid ground to do that both in terms of the clarity of that policy, as well as to ensure that there hasn't been new and evolving information that hasn't yet been integrated into that policy. So I think in terms of answering your question, in terms of the more challenging areas for you that deal with the discretion and clinical side, they're really grounding in our LCDs and NCDs, and there, hopefully if the policies are well written and we would allow them to go forward, we could all agree on what the policy is and what's reasonable and necessary and what's not.

And the other thing you're hearing—rather than giving one presentation, we're having all four come to you because to some degree, the individual temperaments of the organizations have a role, though I will assure you, the statement of work, which they all need to follow, have key responsibilities that all the CMDs have to do but beyond that, they have the ability to embellish that. That's part of allowing people's imagination in organizations to be highly effective. Does that help answer that? And we can certainly talk a little more about that if that's necessary.

Dr. Bufalino: Other comments, questions? Thank you, Dr. Lee.

Dr. Lee: Thanks.

Dr. Evans: Hi, it's nice to be here. Thank you very much for inviting us. I am Ellen Evans, I am the Corporate Medical Director for Health Data Insights. Health Data Insights is the region D contractor.

We have the northwest portion of the United States, and I believe about five your physicians on this Panel are in our area, so I'll look forward to working with you. My background is I am actually I was trained in Texas. I'm a board certified family physician, trained in family practice, and also in geriatrics. I have a certificate of added qualification in geriatric medicine. I've taught in addition to practicing the range of medicine, from rural emergency room, to clinic care, delivering babies. I've concentrated my practice mainly on geriatric care. So I've been medical director of skilled nursing facilities, I have provided geriatric consultation in the home, and the ALF and the inpatient setting as well as providing that whole range of care in the inpatient setting and in all of those other settings as well. I was actually actively practicing at Creighton, and teaching in the Family Medicine Department, also working with medical students residents in the Creighton University Program, and they have Allied Professionals, so working with nurses, physical therapists, pharmacy, teachers, and students. But I was busy doing all that, and I was approached about looking at Mutual of Omaha. They needed a Contract Medical Director. My first reaction was no, why would I do that? But I'd been teaching about Medicare and interested in Medicare, so I went ahead and looked into the position and I did go ahead and become the Vice President and Medical Director for Mutual of Omaha's Medicare division. They have been one of the largest fiscal intermediaries with Medicare since the beginning of that program. I saw that division through its transition to WPS, where they began the J5AP MAC program, and then I joined the RAC, or actually Health Data Insights, they were ending their RAC demonstration work. And all of that just to say I have a strong geriatric and practice background that I bring as well as that experience developing policies.

At Health Data Insights, this is a lot of things on the slide, but I'll just hit the three key areas, or three hats that I wear at Health Data Insights. As the Medical Director, my primary responsibility is leading our healthcare management team. That's our group of reviewers, and they're all, as required in our statement of work, RNs, certified coders, and I supervise all of the review work that's done, and we have advisory boards who have worked with us as well. It's physicians practicing in the community and so just oversee that whole process. I have engineering background so that in our company, only does healthcare auditing, but we have a really strong IT department and it works really well with our clinical, so that with my engineering background, with the IT company and that clinical work that we do, we've developed some very nice processes to allow us to facilitate the review work that's done and also have feedback and both to

the reviewer individually as well as to the leadership and to me. My team knows that I'm very much involved. I have regular meetings with them, and they know that I want to hear about anything and learn about it right away. The second hat that I wear is with our Quality Management Program. Health Data Insights considers that one of our most important overall corporate objectives, and that's to have continued quality improvement and so I've listed a few of the things that are involved in there, including that Medical Advisory Board, that I'd mentioned earlier. The quality management in some respects overlaps with our healthcare management team in those reviews and reporting that I mentioned. All of our reviews have inter-rater reliability, that's a peer review. Our findings have a second review within the organization, and we have oversight of all of that. Our review, it was mentioned earlier, or it was talked about what we use to do our reviews. And again, what Dr. Polansky said is exactly correct. We follow CMS rules and regulations, statutes, the NCDs, the LCDs, and so while we keep abreast of the clinical literature and guidelines, we use that information to help but it neither makes a finding nor makes a non finding. We look solely to the CMS regulations and the guidance there. The third hat that I wear is I lead our query development, which is, we call them queries in our company. CMS now calls them the New Issues. But those are the topics that we audit and I lead our team, which is headed by claims specialist in the different areas, and as you can imagine with me involved in the healthcare management, the quality management and the query development, it operates in a nice feedback loop, where as we're developing queries, we interact with the review team, both to let them know what would be something that they could anticipate as far as review work coming forward, as well as get that feedback from the clinical team on the aspects of the review that we're looking at. I think the important thing of me leading the query team is that, with the practice experience I have and the contract and policy development experience that I have, coupled with the claims analysts that we work with our team as well as the IT team, we're able to refine and identify more and more the audit areas that we need to look at and be sure that we're looking at those correctly. We're excited to be working with CMS and we're excited about their new issue review process and have been working closely with them as go forward. I appreciate any questions that you have, and I do thank you very much for allowing me to present here.

Dr. Bufalino: Thank you. Questions for Dr. Evans?

Dr. Standaert: I'm one of the five in your geographic area, and no offense, but frankly I hope I never hear from you.

Dr. Evans: You probably won't because I bet you're going well.

Dr. Standaert: Question on appeals process. So if, how difficult is it or will it be for a provider who has a problem with a RAC request or determination to actually get through to a clinician or somebody else who has authority to actually help them with the problem? Rather than sort of put them back through a paperwork pipeline? That's part of our concern, the amount of work it takes to actually get through questions or problems and how much energy and effort we would have to put through, our staff would have to put through to resolve an issue.

Dr. Evans: Okay, that's a very good question. I can speak for Health Data Insights. As I mentioned, our company only does healthcare auditing and we have more than 25 years of experience doing that. Our leadership is actually reflective of my credentials in that they come from the provider community. Our president's a nurse and has been in clinical practice and been on the provider side of care, so that our board members as well, our attorney, and so we understand the provider side of that, so first and foremost the selection of our issues, we go for those issues that are very clear. Our long history, the types of audits that we've been doing the longest, very low appeal rate because it's very clear, and when we have done a determination, whether it's an automated, where it's just on the face of the claim, or whether it's a complex review, where we've requested records, in either of those cases, we give a full description of the exact reasons, what we did, what we changed if it was a coding issue, or what the, we cite the reference if there's been a complex review determination, so that when the information is given, it's very clear. Our provider services representatives have more than 15, well almost 15 years average experience, and when they review, I mentioned that we're an IT company, when they get a call, they're able to pull up the actual, the letters, the claims, any other calls that have been handled, so that it's not like starting over and explaining something de novo, they actually, and they've also been trained on the queries, and trained on the audits and they know what the current issues are that are going forward. So first of all you get a clear audit. There's a reason for the audit that is clear, and the majority of providers and CMS agree that that's the case. Then the second thing you do is you get clear information about what the audit showed and why there was a finding. And then the third step is when you call in, you talk to someone who has that clear

information, that same information that you have, and then our provider services area, our reviewers across the company, they know Dr. Evans wants to hear about it, Dr. Evans wants to be involved. I think some of our success in the RAC demo and as a company doing healthcare audit is because of communication. That's important, and if one provider is calling in with a specific problem on an audit, if I can talk with him and figure that—and just in the process, we make sure it's not, I didn't understand this number or what am I supposed to do now? It really is, I've got an issue. If that's the case, and I hear about it and there's something that we need to change, we can do that quickly because I've intervened early. And then the other thing I would mention both because you're providers and you work with other providers, is that discussion period. CMS has provided a discussion period that's peculiar only to this contract, to the RAC contractors, and so the appeal process, any reconsideration of our review goes to another one of the claims processing contractors, and it works its way up to the ALJ, etc., but in addition to having that appeal process, providers are able to call in to the RAC and request a discussion period, and our goal is to have that discussion period be something that you can give us new information and we can proceed quickly and basically if it's something we can overturn, to do, and make kind of stop the process of the paperwork that follows from that. So I hope that answered.

Dr. Standaert: [off mike] appeals process isn't that uncommon from the data we got from the RAC demonstration project. There have been a number of appeals actually from our perspective. And so you said two things, if you find out about it, you can intervene, or you're inclined to intervene based on your personality or your interest, and then you mentioned something else about a, whatever the discussion thing—

Dr. Evans: Discussion period.

Dr. Standaert: My question was how difficult is it from a provider perspective to say this is not okay, I don't understand this, it isn't okay with me. I need to talk to somebody who can help me with this, and get to somebody who clinically understands what you're talking about so it's not speaking to the RAC, speaking to the auditor that has all the same data you have but has the directives of the company doesn't really help you much. So how, what is the process to get you past that rapidly so you can efficiently get to somebody who can really answer your question, not just what does this paperwork show? Because I have the paperwork, that doesn't help. Does that make sense?

Dr. Evans: I understand. And I guess what I was trying to say was I think that we'll be doing clear audits, you'll get clear information about the audits, but you have a question about it, you would want to give us written information for your discussion period, if you have additional information so we can review that, but if you've done that and you've gotten the information you need from talking to the provider services, they can escalate that up to me. It's not difficult. And it's not a problem because of the types of reviews that we're doing and because of the available information and what we provide you in our reviews. So it's, you get the, you do the review. Say if we did happen to have one of your claims and you'd sent the information [off mike remarks/laughter] and so he had one reviewed, and there was something peculiar to that, and he would have had, if there were records requested, he would have provided those, we would have given him the details for this. He, I would hope, take advantage of the discussion period, call in say I'm having a discussion, I'm sending you information, I'd like to talk to your medical director and then pretty quickly we'd get a schedule set up.

Dr. Standaert: So that's all you do, you request a schedule set up.

Dr. Evans: Mmhmm.

Dr. Standaert: Okay, thank you.

Dr. Arradondo: I wanted to ask this question originally of Dr. Polansky, but I didn't, and so I thought I would ask Dr. Evans and maybe Dr. Polansky will comment. But I wanted to get, well partially because you'll becoming from Data Insights, and you have your query group, so I'm curious as to, I would like to know what you think the appropriateness of the following scenario would be. The RAC selects a number of charts to be audited. That person thinks it's a reasonable number from what I hear, it's maybe two or three times a reasonable number, but that's okay, and discovers no actionable findings. And then comes back and requests five or six times the first number of charts and audits again. I'm curious as to your judgments as to the reasonableness of that. By the way on the second, larger number no actionable findings were discovered either. And I guess the implication is as the segue from Chris's commentary, what is the recourse to that? And that's the CMS question, kind of that I wanted to ask originally.

Dr. Evans: Okay. I think Dr. Polansky is right when he said if you want the short answer or the long answer. I think that for the same issue, for you to have records for the same issue that got requested over and over again when there's no findings, that would not be reasonable. But I want to do is take that

question as an opportunity to explain the difference from the way Medicare's been for years and years and decades to what the RAC program brings to Medicare, and that is that providers are used to claims processing contractors processing their claims. And in that scenario, what those contractors do is they run a data analysis looking at providers and comparing providers. So this cardiologist would be compared with that cardiologist and the other hundreds or thousands that are in that pool. These stand out, so these are selected for what's called a probe, and records are requested because it looks like that provider's billing in an unusual manner. So that provider is probed, records are received, their reviewed and there's thresholds at CMS has agreed upon, if there's this many findings, then they go to what's called, they'll have education and they'll go to a targeted review and when that's done, and the point for CMS is to train the provider how to bill correctly if there were an error. Now if the initial records when they reviewed the records found out there wasn't any problem, that would be the end of it and there shouldn't be continued look at those. The RAC program is different in that we don't compare providers. We don't do an analysis of all the cardiologists or all of the inpatient rehab facilities, or all of anything. What we do is we look at claims. CMS processes 4.5 million claims per work day, and HDI Region D gets about a fourth of those, and we have been given data back to the beginning of, well, back to October 2007 forward and so that's a lot of information and what we do, which I really didn't really cover in our query development, one of the questions is how do you develop those. What we do is a data analysis and we look at the claims. We look at the claims information, these codes, these dates of service, these lengths of stay, these procedures, etc., these modifiers etc., so we look at the patterns of the claims, and from that we find that there's these connections that shouldn't be there because there's a policy that says so or because correct coding initiative says these don't go together and then we say, okay, CMS, here's our samples. We want to do an audit on, there's duplicates. One of these is allowed per year and we're finding ten of these per year. And so CMS says that's reasonable, go ahead and look at those. And so then we send out letters and our audit to those providers who have duplicates of that service. And if you have duplicates last year and we have sent you letters for some of those, and then you have duplicates this year and next month and next month, and you keep doing it, we will keep sending, you will keep having findings on those duplicates. But if you have no duplicates, and you have billed correctly, you don't get any letter from us.

Dr. Snow: Excuse me, what's a duplicate?

Dr. Evans: Well, for instance, in the RAC demo, we actually had this: seven appendectomies, billed and paid by Medicare, same day, same patient, same provider, same hospital.

Dr. Snow: I have a lot of duplicates, because CMS doesn't pay it the first time and they don't pay it the second time and don't—

Dr. Evans: I said seven paid, and seven billed and paid. None of us in this room would argue that one is correct, but certainly not seven.

Dr. Snow: I want them getting all seven of my appendix out. [laughter]

Dr. Evans: But we'd do it as one procedure. You'd have an add-on code. You wouldn't have seven open and shut.

Dr. Howard: You talk about the appeals, you have a low appeals rate. And how are you looking at your RAC and saying these are my standards, this is what we should be looking for to make sure we're on track with how we're doing? And then, subsequent to that, are the RACs comparing themselves? In other words, is your region, if you have a low appeals rate and you seem to be on track and you're accurately finding these providers or whatever the situations that are actually at fault, are the RACs going to compare how they're doing or is there a RAC, let's say they have a high appeals rate—I mean how is that process going to occur.

Dr. Evans: I think it's probably a two-part question, probably one from HDI in particular and then maybe do you want to take, Dr. Polansky, the other? The answer is yes on both. For HDI, our goal is to have no appeals and to have, not to have no appeals and have no overturns at appeal. Our goal is 100 percent accuracy, 100 percent effective reviews. But we're human beings also. And so that's our goal. We have, as I mentioned with my engineering background and with our being an IT company, we have built in reporting that shows us what your appeals rate, what your discussion periods, rebuttals. I'm aware of every rebuttal. We have a same day, next day policy on rebuttals and when we don't do our actual appeals because they go then to the next contractor, or it would be a fair appeal, but we know about those because the case record that we've developed is forwarded, and we find out the results of those and feedback into reviewing, we look at the case and feedback, what do we find on the analysis, what do we need to change? For the RACs in the national, our payment is related to a completed, nonappealed case, so if you talk about incentives, we're incentivized not to have anything overturned. Well, the way to do that is to be 100 percent

effective and efficient. That's our goal and we have feedback and reporting for that goal. Do we meet it? Not 100 percent, but we're close and my goal is always to be better than we were before?

Dr. Polansky: Let me embellish that. Appeals are an important indicator that one, we expect the RAC contractors to follow and integrate into their assessment of what things to review and how to review them, so that's part of the expectation of the contractor. As part of our oversight of the program, we also monitor the profile of appeals. And it's not a perfect indicator, the appeals process is far from perfect, but it's a valuable window in understanding if the program is working. So we have spent a lot of time building infrastructure to make sure we can get better information from the appeals processes, and we look at it closely. And it's factored in as sort of how we view the performance of the program and the performance of our contractors. So it's a point we're very sensitive to.

Dr. Ouzounian: I'm a little confused. It's not necessarily just directed at you, it's from all the talks we've heard, and the examples you cited are pretty straightforward. So I'm a surgeon and sometimes in error I will bill an E&M visit the day before a procedure and your computers are real good about not paying that for me. 90 days afterwards, I'm pretty good at counting on the calendar, but sometimes at 88 days, I'll bill an E&M visit and your computers are real good at finding that. Most of the examples that you've cited are examples that never should have been billed. Maybe they were billed intentionally, maybe they were billed in error and never should have been paid in the first place. If you can only bill a service one day, once per day, and the provider bills it four times per day, your computer should have caught that in the first place. Your computer never should have paid seven appendectomies in the same patient by the same doctor at the same facility on the first day. So there's two glitches; one is the provider who billed it, two is your computer, well not your computer, their computer that paid it, but then when you go and audit that, it's kind of a nondiscussion, there's nothing to appeal. The doctor that says I took out the same appendix on the same patient seven times, it's going to be hard to explain. You haven't given us examples of things that are maybe a little gray, maybe the records medical justification, combination of procedures performed on the same day. You really have not discussed that, nor have your colleagues today.

Dr. Evans: Okay. We haven't. And that's, we have new issues forwarded to—this is a new program, the RAC was a demo. This is a new program. We've been told that and it's—

Dr. Polansky: Just make sure we frame the question. I'm not sure what the—

Dr. Ouzounian: You've given examples of what you're doing and I don't think any of us would sit here and dispute the examples of what you're doing. If the rules are that you can only take out one appendix in the day in one patient, when somebody takes out seven and you guys ask them for money back on six, there's nothing inappropriate about that request and I don't think there's anything the provider should be doing to appeal it, but you haven't given us examples of other audits that we could potentially appeal.

Dr. Polansky: I think what you're talking about, and Marie has spoken about this several times is, the intent of the program is to implement the RAC program in its early stages with issues that are much more concrete, that are not contentious, so things like duplicate claims, these surgical, global procedure rules. But ultimately, the program will get to areas that there may be differences of opinion on, and the kinds of things that we routinely see in the carrier and FI worlds of reasonable and necessary. Sort of like the question from earlier on, and ultimately the RAC program will go there. There may be issues on the appropriateness of admissions. There may be issues about a particular patient who got a pancreatic transplant that didn't comport with the national coverage decision. Certainly, to this point in the RAC program, in fact it has not begun in earnest, we haven't seen those issues. And what Marie said is it's not until January of 2010, that in fact complex reviews will begin, and it's typically when we say a complex review, that's where an actual medical record is necessary, where the contractors will be providing what we call clinical review judgment, and that's where perhaps there'll be some more vigorous discussions. But as we get people comfortable with the program, we are going to be dealing early on with the much more concrete issues with coding and payment policy. That's not to say we probably will not be back here talking about how we're beginning to deal with issues regarding reasonable and necessary decision making, and if ultimately the program is going to be successful, we are going to have to figure out responsible and judicious ways to adjudicate those through the RAC program. Are we?

Cmdr. Casey: I just wanted to make one point of clarification. We are doing a complex review for DRG coding validation. That actually is starting this fall, and that's done by a certified coder. It does involve medical records, so there will be some requests for additional documentation. It is not the level of review that Jesse's referring to in terms of reasonable and necessary, that won't occur until after January 2010.

Dr. Polansky: That's a helpful clarification, because obviously there will be records, but those are not going to be medical necessity decision making. That'll be once again, adding a layer of safeguard that if we're doing some of those more complicated coding issues, we're going to require the RACs to get the records to make sure they get their decision correct.

[off mike comment]

Dr. Snow: You made the comment that your intent is not to have any appeals so that you don't have the possibility of them being overturned, I guess that's a financial decision, because you kind of implied you don't get paid until they've gone through the appeal process. The RAC doesn't, is that correct? First of all.

Dr. Evans: I know that if anything's overturned on the appeal, there's no payment to the RAC.

Dr. Snow: Okay, so I assume you don't get a payment until—

Dr. Evans: And there will be appeals because they're going to be.

Dr. Snow: Well, I think the demonstration project indicated they were about 14 percent that were appealed and that's quite a high number if one out of six or so is appealed, and I would suggest, may no be true, and we probably need some data on this, that those that are not appealed, certainly does not in my mind indicate the provider thought they were incorrect and that you were correct, but it may be the hassle factor. I, as a solo practitioner, and I would suspect that the smaller the practice, quite frankly, the less likely they are to appeal because of the hassle factor, the cost involved to do so, as opposed to let's say Dr. Bufalino's 50-cardiologist practice, which is probably going to appeal darn near everything. [laughter] So there may be a real bias, well he's got bigger dollars and he's a tough guy. He's from Chicago. So there may be some biases there and quite frankly it would be helpful, I would think, for CMS to get some information back to us to see if that kind of holds to where there is marked disadvantage, again, for small practices.

Dr. Evans: If I could just mention two things in response. One is the demo, I can only speak for HDI, and the demo, our appeal rate wasn't that high, but initially we had a large number of appeals because we were looking back four years, as we were instructed, but three years is actually what's allowed, and so we had some of those overturned, so there's some nuances of those numbers of appeals that I would say we're going to see different as we go forward in the national but I would like to emphasize what may or

may not have been told to you earlier, and that is that in the new program, CMS and maybe it's not my role, but I'm excited about this opportunity, and in the new RAC program, the RAC validation contractor is right along with the program and involved. It has been mentioned, at least today I heard that they do look at the, some of the new issues for CMS and make recommendation to them, but you may have been told earlier, but I didn't hear it today, and that is that the RAC validation contractor will also be doing re-reviews of our reviews, and so that again, we haven't even started those, but my understanding is that after that base year, they will be doing those reviews initially and reporting back to us so I'm excited in my quality program to have that additional information for us. But going forward after the base year, there will be yearly accuracy reports from CMS from that validation contractor, which will capture those very issues that you raise where maybe there's not very many appeals, but maybe there is an issue. And so that will occur. And so I think CMS has done some very robust things to go forward making sure that the RACs and the providers are doing what's necessary.

Dr. Polansky: Dr. Bufalino, we have one other presenter, are you aware that—maybe we can hold questions so that you can get a real—

Dr. Bufalino: Why don't finish the last one.

Dr. Evans: Thank you all very much. And it's a hot seat.

Dr. Polansky: It's a little confusing because there are four RACs but we have five actual CMDs coming today because one is a subcontractor that works for two of the primes, but we thought it was important that the group got real flavor for the clinical leadership behind the scenes.

Dr. Bufalino: Thank you.

Dr. Earl Berman: With permission of the Chair, I'd like to go ahead and have Chris's question. [laughter] I'm Dr. Earl Berman. We already 10 minutes over, so whatever. I work for PRG Schultz. I'm the Medical Director for them, and we're subcontractor to actually three of the primes, A, B, and D. As you can see by my background, I went to school at the University of Georgia, Go Dogs! I got a Bachelor of Science in Microbiology. I actually got an all-but-dissertation Masters in Virology there. I went to the Medical College of Georgia, got my MD degree and taught at the medical college in private practice in Augusta, after I did my residency in Savannah, Georgia. I have practiced in the diverse backgrounds; I was Hospice Medical Director, I'm a hyperbaric-trained physician, I'm board certified in Internal Medicine

with a subspecialty in Sports Medicine. I've been involved with hospice and education, the epic certified trainer, educating physicians in end of life care. I am a Fellow of the American College of Physicians and I am currently employed by PRG Schultz, as I mentioned. Prior to that I was Medical Director for Georgia Medicare, with Cahaba GBA. I also, about a year and a half ago, testified in front of this group, as part of the demonstration project. So with permission of the chair, I'll take Chris's questions and then we'll move forward.

Dr. Bufalino: Maybe just before Chris's question, Sir, could you clarify your role as a subcontractor? What makes you different than the other folks we just met?

Dr. Berman: As far as being a Medical Director, there's no difference. We do not have a contract with CMS. We have contracts with the prime contractors that you heard from, for Region A, B, and D. They have oversight of what we do and how we do it. For example, if we come up with a new issue, that new issue is sent to them, the look at it, approve it, and then send it on to CMS. All communications with CMS are chartered through our prime. They are, as part of the contract, required to do QA of a certain percentage of our claims adjudications. And they have an oversight of us, so we really do not have a contract with CMS per se, our contract is with the prime contractors. I was invited to come speak, just because I will be doing business in three of the four regions and CMS thought it would be important for you all to hear my accent.

Dr. Polansky: That's a wonderful question. We were hoping you would ask that by bringing Earl here, but we take the issue of subcontractors very seriously, and their very serious stringent contracting requirements. The contractors, the primes, do not have tremendous latitude in who they subcontract with. In fact, those things are approved. And furthermore, we're not doing a fair amount of on-site clinical review judgment training, so we're prepared for some of the more complex decision making. And in fact, Earl is exposed to the same standards as all the other CMDs in terms of those obligations. Though maybe Earl can just speak very quickly to sort of transparency like in terms of customer service, if there's an issue how that would play out.

Dr. Berman: Thank you. In the states that we're doing our main activity, we actually write the letters. It will come on the prime's letterhead, but the letter would actually come from us. Just remember, all communications with providers go through the New Issue process, so any letter that a provider would

see has been approved by CMS as part of the new issue process. There's no de novo or out of the air kind of communications. All letters for medical records, all demand letters, all results letters, the template of those letters have been processed through CMS as part of the new issue process. We also have a call center, so if for example if you're in Vermont, which is one of our states, that we do for Region A, if you call the call center, and you're identified as being from Vermont, that call is routed to our call center, seamlessly, so you're actually speaking with us, but you've called a general region A call center number. So it's a pass-through transparent pass through with communications. If a Vermont audit is performed and someone wants to speak to me, they would contact me, they would not go to the region A Medical Director. So it's a transparency and a pass through that's all worked through the prime contractor. That clear? Or as Jesse would say, transparent?

Dr. Polansky: And the point of that is if you need to get to Dr. Berman to talk about that case that his team reviewed, you don't want to speak to the Region A Medical Director, you want to speak to Earl and that's important that that's how the program functions.

Dr. Bufalino: We're well past our allotted time for this and so we're going to ask Frederica to wrap us up, how's that?

Dr. Smith: I have a question and a comment and then a couple of recommendations. At previous meeting, PPAC had recommended a limit on the number of charts per provider that could be requested, because the original proposal was heavily skewed against small practices. Where does that stand?

Cmdr. Casey: We're still continuing to go with our plan of having a certain number or percentage of medical records per different provider types. We have taken PPAC's recommendations under consideration, but at this time, there has been no change in the medical record limits that were described at your last meeting with us.

Dr. Smith: When do you anticipate looking at that further?

Cmdr. Casey: We actually have been continuing our discussions both with the AHA and AMA, regarding exactly how the medical record limits will work, however, there has been no change to the current plan. We have talked about using tax identification numbers, but again, that plan has not been finalized. When it is, we will update, we'll have an update on that CMS HHS/RAC website, if there's any updates to the medical record limits.

Dr. Smith: I wanted to just comment on one of my concerns about, I guess I'll call it the reasonableness of the process, and this is from the conversation about someone who was reviewed under the RAC demonstration project. There may be safeguards in place that would prevent this kind of thing, but the initial episode was a request for 15 charts from a sole provider, but a provider who was affiliated with a larger group. He was a satellite to the larger group, so that may be how they could get 15 instead of 10. Those charts were reviewed, they then requested, the RAC requested 85 charts complete charts with all inpatient and outpatient records, hospital orders, copies of angiograms, other studies in 15 days, which is really tough and particularly in a sole provider office. The parent group of the satellite clinic hired an attorney at this point, ultimately those 85 charts were reviewed and found to have no problems, but the RAC said they were going to continue to escalate the investigation. And the group had by this point, spent $130,000 out of pocket on this process and therefore, the lawyer whom they had arranged to work with, said the he felt it was appropriate to settle with the RAC rather than try and pursue it further because it was just going to cost them more money. And so that leads to the question of oversight from CMS. And I would like to propose that PPAC recommend that CMS provide PPAC information on its oversight, how it conducts oversight of the investigations that are held by the RAC, and its guidelines for when investigations must be terminated, if no problems have been found. That's recommendation one.

Cmdr. Casey: I just have question. If I may ask. The RACs should never have entered into a settlement process with any provider. I'm not sure whether the entity that was actually auditing those claims was actually a RAC.

Dr. Smith: It was a RAC.

Cmdr. Casey: Do you know which state was?

Dr. Smith: I know exactly, but I'm not going to say in public.

Cmdr. Casey: Because I'm a little bit concerned, because no RAC has the authority to enter into any type of settlement with a RAC. If that was to take place, that would have to be done by the claims processing contractor, which would be the MAC or the Carrier. So I'm not sure—it just worries me because they have no authority to do so, not in the demonstration or in the—

Dr. Smith: I don't know that the check was written to the RAC. It may have been written to somebody else, but it was because of the RAC's proposal to escalate the investigation further that that occurred. So my—

Dr. Bufalino: Do we have a second?

[second]

Dr. Bufalino: Second, thank you. Discussion? All in favor?

[Ayes]

Dr. Smith: My second recommendation, PPAC recommends that CMS establish a neutral arbitrator at CMS outside of the RAC, to whom physicians or other providers can appeal for assistance when the RAC investigation seems unreasonable.

Dr. Bufalino: Second?

[Second]

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

[Ayes]

Dr. Bufalino: Thank you. Any other discussion for these nice folks? Seeing none, thank you. Thank you Commander Casey, Dr. Polansky. We appreciate having you. Thank all of you for coming today. We appreciate a chance to meet all of you and look forward to any further interactions in the future. Thank you for that.

Wrap Up & Recommendations

Dr. Bufalino: We are approaching the end of our agenda and I just wanted to, I know the hour's late, but I'd like to just take a moment, to just make sure there are or are not any other recommendations. There is no written or oral testimony to be provided today that CMS was informed by the AMA was too busy to prepare anything for today. And so we are here at the end of our agenda. So Art, other recommendations, we'd be glad to entertain those.

Dr. Snow: PPAC recommends that CMS explain its use of a 10 percent threshold for attribution in its resource utilization reports instead of the 25 to 30 percent threshold recommended by the Leapfrog Group and NCQA and the 35 percent threshold that MedPAC employed in its analysis.

Dr. Bufalino: Second? Second, thank you. Any discussion? Hearing none, all in favor?

[Ayes]

Dr. Bufalino: Thank you. Please.

Dr. Snow: Number two, PPAC recommends that CMS provide data on the number of appeals of RAC decisions by the RAC contractor, and if possible, by size of the appellant practice, upon at least an annual basis, more frequently if possible.

[Second]

Dr. Bufalino: Thank you. Any discussion on that? Go ahead John.

Dr. Arradondo: [inaudible] the number of appeals and the percent of overturns.

Dr. Snow: I would assume that's part of the proposal.

Ms. Trevas: Do you want to add that language?

Dr. Snow: Yes. I consider that very friendly.

Dr. Bufalino: Friendly amendment accepted. Any other discussion? All in favor? Thank you.

Dr. Snow: Number three, PPAC recommends that CMS provide data on the Validation Contractor Reports for each of the RAC contractors on at least an annual basis.

[Second]

Dr. Bufalino: Anyone else? Discussion? Hearing none, all in favor?

[Ayes]

Dr. Bufalino: Thank you. Other recommendations.

Dr. Snow: And last but not least, I would like to commend CMS on their choice of the room today. Quite frankly having Internet access has been fantastic and I've received a number of emails and reports and things having to do with our meeting as a matter of fact and I would ask that PPAC recommend CMS continue using this meeting room for future meetings due to the facility we can conduct business in.

Dr. Bufalino: We're going to ask Liz to take that personally to the top.

[second]

Dr. Bufalino: It has been motioned, seconded and is enthusiastically supported. Thank you. Other recommendations on a serious note. Okay. The hour's late and I see we've already lost half of the folks and about the rest have already wrapped up their computers and are on the way out the door, so maybe we will

send the recommendations to everyone by email within in the next several days for your thoughts and approval, if that's acceptable. If not acceptable, then I guess we'll stay.

Dr. Simon: Any subsequent changes, we need to do it now.

Dr. Bufalino: Okay.

[off mike discussion]

Dr. Bufalino: Then we'll take a break and stay around for the approval process. Let's do that.