CENTERS FOR MEDICARE AND MEDICAID SERVICES

PRACTICING PHYSICIANS ADVISORY COUNCIL
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Room 505A
Washington, DC
Monday, March 3, 2008
8:30 a.m.

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Open Meeting

Dr. Senagore: Good morning. If I can ask the committee members to take their seats, we'll go ahead and get started so we can stay on schedule. Good morning. I'm Dr. Anthony Senagore. I'm the Chairperson of the Practicing Physicians Advisory Council. It is my pleasure to welcome you to Washington, D.C., on this occasion of the 63rd meeting of the Council. I'd like to extend a cordial welcome to all of my colleagues and fellow Council members. And as always, I appreciate your willingness to adjust your schedules in these very busy times. I know that CMS appreciates our comments and participation and we do have the opportunity to influence regulations, and provide instruction for issues that affect our colleagues as practicing physicians.

Before we begin, just a few housekeeping issues. As you know, for several of us, this will be our last meeting; me, Dr. Jose Azocar, Dr. Peter Grimm, Dr. Geraldine O'Shea. And I'll take the Chair's discretion and thank both CMS and my fellow council members for the opportunity to serve. It's been a great opportunity to participate and I've learned as much working with all of you, and hopefully, I've contributed a fair bit, at least keeping order in the room during our sessions. If any of my colleagues that are also going off, would like to say a few words, now would be a good time.

Dr. Grimm: I'd just like to thank the committee, all the members of the group. It's been a great privilege to serve with you and I wish you well in your endeavors and would be glad to help in any way in the future that I can.

Dr. O'Shea: I like to that, too, and a resounding thank you to my colleagues that sit around the table. When you do good service, you always get more than you give, and so it's been a learning experience. I've learned from each and every one of you, and I just bid you hopefully a fruitful and what can I say, hope you sleep well the night before because there's going to be lots more to come from CMS, and please do know that you have all of our support if there's ever anything that a prior member can help for, be a resource of, and again, thank you very much for your service.

Dr. Azocar: Yes, good morning. I want to thank you for this opportunity to learn and the support from all the people from CMS and from my colleagues from the PPAC committee. It has been a great learning experience, and appreciate very much the support, and thanks.

Dr. Senagore: I'd like to extend a welcome to the new members who are observing today, and they'll be seated at the next council meeting; Dr. Pamela Howard, Dr. Joseph Giamio, Dr. Fredericka Smith, and Dr. Christopher Standard. And you'll see their names there on the cards. They are here with us today as part of their orientation. They'll be sworn in at the meeting on May 19th.

As you look at today's agenda, we have a number of issues; some new, some old, to review for CMS and provide our advice and feedback. The specific topics include an update on the National Provider Identifier, the NPI, and the Recovery Audit Contractor, the RAC Audits, Hospital Measures, Physician and Quality, an Update on Health Assessment Tools, and Health Information Technology. We'll also of course have our rousing quarterly update by the PRIT, as well as the latest report prepared in response to our recommendations from the prior meeting on December 3, 2007. And as always, I'm sure you'll give all of this your measured and considered discussions. So at this time, I want to stop and welcome Mr. Herb Kuhn, Deputy Administrator for the Centers for Medicare & Medicaid Services. And Herb is joined by a new member of the team, Dr. Jeffrey Rich. Dr. Rich is the new Director for the Center for Medicare Management. I would also like you to know that Dr. Rich is a thoracic surgeon and I can't tell you how delighted we are to have a fellow colleague here participating in our quarterly meeting, and providing his expanding perspective on agency goals and initiatives. And we also have I believe Ms. Elizabeth Richter with us today, and she is the Deputy Director in the Center for Medicare Management. Mr. Kuhn?

Welcome

Mr. Kuhn: Dr. Senagore, thank you. It's good to see all of you again and let me first start out by on behalf of the Centers for Medicare and Medicaid Services, thank you for your leadership as Chair of this committee, and thank each and every one of you that have been on the committee, who are going to be departing. This is your last meeting. Thank you for your active participation. As we talked about this every

time we have a meeting, this is the Practicing Physicians Advisory Committee. You're all in active practice. And I know it's a big sacrifice for you to take a day or two away from your practices, at least 4 times a year to come and participate in these meetings. So thank you very much, those that are leaving, for your service. And welcome, to the new members as well. We're thrilled to have you here. And the fact that you would take the time to come to this first meeting before you're actually on the council, to participate, and look forward to swearing you in at the May meeting, and have your active participation as we go forward. So again, thank you all for your participation and your leadership.

I too, want to acknowledge Dr. Jeff Rich, who is now starting I think your third week? Jeff came on as the new director for the Center for Medicare Management. As you heard, he's a cardiac and thoracic surgeon, practices down in the Tidewater area, and I know Jeff has not been getting much rest, because while he was with us all last week and will be with us all this week, and every week thereafter, I think he was on call and working all weekend as well, so I think he's really burning it 24/7, but we're thrilled to have another physician leader in the management team within CMS, and I know you'll all enjoy working with Jeff throughout the stay and in the future for these meetings as we go forward.

As we start this new year, and you look at this agenda, as you all see, there's no shortage of issues that we're going to be grappling with this year, as we go forward. The NPI, many of you are aware that on March 1, on Saturday, we flipped the switch, and all across this country, carriers are now requiring both the NPI and the Legacy number at a minimum, or the NPI only in order to process Part B claims. We made the switchover on January 1 for institutional providers, but on March 1, it happened for all other providers as we go forward as we deal with this issue. As we get ready for the full and complete implementation of NPI on the 23rd of May. You all have been very helpful, helping us think through as we process this issue over the last year and a half, two years. You also have been very helpful to us as we've thought through ways to better communicate with the provider community on this issue. This is an important time for our changeover here, and you'll get a full and complete update at the meeting today as we go forward, because there is a potential for claims rejections, as a result of people not using the NPI properly as we go forward

and so you'll hear more about that, so that's a good agenda item today. You'll also hear about the RAC program, the Recovery Audit Contractors. This is one that you all, too, have heard many times about in the past. You've helped us in terms of developing policy on this. We are wrapping up the 3-state pilot. We issued a national report last week, with kind of the updates on this program, which is very helpful, but we're ready to take it nationally. You all have helped us in terms of designing on this program, but also helped us really think about the fact that this is more than just going out and collecting dollars that were overpayments, what about underpayments? So there's truly puts and takes through this whole process and you've all helped us identify that to make sure that it is a balanced program. And you'll hear more of an update today in terms of the RAC Program.

You'll hear a lot about the PQRI. The Physician Quality Reporting Initiative. And although this program just began last July, we did provide some information last week in terms of physician participation, at least through November of last year and what we see out there, so you'll get a full update in terms of the program participation rates, and as we think on a go forward basis how we want to deal with this, and get away from what we think and what you've all shared with us. The claims based system of reporting, the quality measures on G codes, is there a better way we can do that in order registry work? And again, we're thrilled to have Dr. Rich here, because of his leadership with the thoracic surgeons and their rich registry that they have, but also think about EHRs and better ways in order to make it easier for you to give us that information as we go forward. So more information on that. And then finally, I know we'll hear a lot of discussion not throughout the day, but presumably in the ending comments from outside organizations, that talk about what we face this year in terms of the SGR. As we know, we've got 2 important milestones this year. Congress delayed the fix for only 6 months this year goes through July, and then of course, we've got another reduction in store for January of next year. Some of you may have already noticed that on Friday, we issued our annual letter to MedPAC by statute, as of March 1, we were supposed to give them our projections of what we think the SGR will be for the coming year and this time it's FY '09, and we issued that letter and put that information out there, so once again, the debate is before

us. We'll be working with Congress and others, but I suspect we'll hear lots of good comments from you all as well as you share with us stories and information about the impact not only on your practices, but colleagues you have around the country. So that again, Dr. Senagore, thank you for your leadership, and I'll turn it back to you.

Dr. Senagore: Thank you. Dr. Rich? Any comments for us?

Dr. Rich: Sure. Good morning to the members of PPAC and the audience. Thank you for having me here. As Herb said, and thanks for your kind words Herb, I've been on the job, this is the beginning of my 3rd week, and I can say that many things have written to the level of high importance, both from Carrie Lane Jack, the administrator, and from Herb in my first 2 weeks here, but this was very high importance. I said this is a very important part of what I need to do and integrate your thoughts into fair payment policy and issues that are brought before us and the practicing community. So thank you and make sure that you realize that this is an important council to us. I wanted to reiterate Herb's thankfulness for the people who are retiring. I know I'm a practicing physician, or have been, and still are to some degree, and I know it takes a lot to come out of your practice and come here and it's a whole different mindset. There's a lot of issues going on back home for you and I do appreciate that and recognize that, and welcome to the new members as well. There was one person, Dr. Rodbard, who has elected to leave the Council, and I wanted to acknowledge her, and thank her for her input over the years and I forgot to say thank you to you, Dr. Senagore, for your great leadership as chair of the council. So we hope to work together in the next year at least, to create fair payment policy, improve the healthcare for our beneficiaries.

Just as way of background, as Herb said, I'm a cardio thoracic surgeon. I trained in general surgery at Mass General and cardiac surgery at Stanford, and have practiced for 17 years in the Tidewater area. I'm the head of heart transplant program, Left Ventricular Assist Device Program, and do adult cardio-thoracic surgery and have led some of the quality initiative there within the state of Virginia for the last decade, and have worked closely with a lot of the quality alliances, and a lot of your organizations, professional organizations and societies to address the issues around quality as well as cost containment in

health care. So I look forward to continuing to work with you on that. As Herb said, I was on call over the weekend and actually did an emergency case yesterday, so I still feel what you feel on a daily basis. I feel the pain, I sometimes feel the gain, but I understand the issues and I want you to know that I'm available, and please feel free to call me at any time if you'd like. So thank you.

Dr. Senagore: Thank you, Dr. Rich. Ms. Richter, any comments?

Ms. Richter: I think we should get started.

Dr. Senagore: Good to go? [laughter] OK. At this time, I will invited Dr. Kenneth Simon, the Executive Director Practicing Physicians Advisory Council and Medical Officer, in the Center for Medicare Management, to present the responses prepared by the Centers for Medicare and Medicaid Services to our December 3rd PPAC recommendations. Dr. Simon.

PPAC Update

Dr. Simon: Thank you. Good morning Council members.

Agenda Item 62D1: PPAC recommends that CMS use the Physician Assistance and Quality Initiative Fund to partially offset the planned negative update for 2008 and allow physicians to benefit from the fund. The CMS Response: Section 10182 of the Medicare Medicaid and SCHP Extension Act of 2007 revised the Physician Assistance and Quality Initiative Fund. In coordination with Division D of the Consolidations Appropriations Act, no Physician Assistance Quality Initiative Fund money is available for the Medicare Physician Fee Schedule payments in 2008 or 2009. The 4.96 billion remaining in the PAQI fund is currently designed for expenditures during 2013 and is only available for an adjustment to the update of the conversion factor. Section 101B extended the physician quality reporting initiative in 2008. Eligible participating professionals will be paid from the federal supplement Medical Insurance Trust Fund an amount equal to 1.5% of the Secretary's estimate, based on claims submitted not later than 2 months after the end of the reporting period of the allowed charges for covered professional services, furnished during the reporting period.

Agenda Item 62E1: PPAC recommends that CMS develop a simpler, better, alternative approach to the ASC payment system, planned to take effect in 2008, such as paying ASCs a defined flat percentage of what is paid to hospitals for each year that would not vary each year. In developing a new ASC payment system, we needed to balance the desire for a simpler system with the need to establish the system within the statutory framework. The Medicare Modernization Act mandated revised ASC payment system implemented for 2008, was designed to align the ASC payment policies with those under the Hospital OPPS payment system as closely as feasible. The revised ASC relative payment weights are based on the relative payment weights for ambulatory payment classification groups, used for Medicare payments to hospital outpatients departments under the OPPS system. However, the ASC payment system diverges from the Outpatient Prospective Payment System in a few notable ways. The MMA required that the revised ASC payment system be implemented budget neutral for calendar year 2008. The statute requires a 0% update to the ASC payment system until calendar year 2010. CMS is providing a four year transition to the revised ASC rates for those services paid in calendar year 2007 to ASCs. A flat percentage of OPPS payment rates to hospitals as the payment rate for ASCs at this point would be inconsistent with the statutory requirements.

Recommendation 62E2: PPAC is concerned that Medicare patients receiving brachytherapy for prostate cancer at an ASC will be denied care as of January 1, 2008 because the Final Rule does not require payment of such sources. PPAC recommends that CMS address this issue, immediately, for example by maintaining the current methodology or implementing a temporary solution to allow patients to receive timely care. The CMS response: According to CMS final ASC payment policy, ASCs receive separate payment for brachytherapy sources that are provided integral to a covered surgical procedure. Moreover, a Q&A clarifying the physician self-referral policy is posted on the CMS physician self-referral website, to make clear that the implantation of brachytherapy sources qualifies for the physician self-referral exemption for implants under our regulations. Because sources of brachytherapy qualify for this exception,

a urologist would not be prohibited from referring a patient to an ASC in which the urologist has an ownership or investment interest for a brachytherapy procedure.

Agenda Item J, Stark Update. 62J1: PPAC urges CMS not to issue additional rules that further complicate the Stark Self-referral rules, by adding more layers of confusion and regulation that discourage efficient and innovative quality healthcare. The CMS response: CMS strives to ensure that its physician self-referral regulations are not unduly complex and do not unnecessarily discourage efficient and innovative quality health care.

62J2: PPAC recommends that CMS delay implementation of the anti-markup provisions to evaluation the substantial impact of these changes on health care providers, especially those in group practice. The response: In a Final Rule published January 3, 2008, CMS delayed the implementation of the revisions to the regulations except for the anti-markup provision relating to the purchase technical component of diagnostic tests, and the anti-markup provision relating to the technical component and professional component of anatomical pathology diagnostic testing, preformed in space that is used as a centralized building as defined in the regulations for purposes of complying with physician self-referral rules and does not qualify as a same building.

Agenda Item P. 62P1: PPAC recommends that CMS report the analyzed results of data from the 2007 PQRI at the May 2008 PPAC meeting, and additional data at the August 2008 PPAC meeting. CMS plans to report the analyzed results of the 2007 PQRI at the first PPAC meeting following completion of analysis of the final results, which will probably be available by the August 2008 meeting, recognizing that preliminary raw, unanalyzed data had been provided to special societies over the past week. CMS feels that once this data has had an opportunity to be collated, reviewed, analyzed and digested, then it will be an opportunity to share the completed data with the Council in order to obtain the full benefit of guidance and advice from the Council.

62P2: PPAC recommends that CMS implement a rapid and direct NPI outreach plan with emphasis on small and rural providers and reconsider the revalidation process that began in October 2007

until the enrollment problems associated with NPI Medicare matching are thoroughly resolved. The response: CMS is committed to ensuring that all Medicare physicians and other healthcare professionals, including small and rural practitioners are kept fully aware of all aspects of the NPI implementation. To meet this requirement, CMS has built an extensive information delivery network, through which consistent and accurate information is delivered to the broadest Medicare Fee for Service provider audience possible. Our three primary sources for delivery of information are the Medicare Fee for Service contractors, who communicate to Medicare billers regularly, CMS regional offices, and the CMS central office. We have a 4th partner in the provider organizations and associations, like the AMA and MGMA. CMS has 18 provider-specific list serves with over 100,000 subscribers. Medicare contractors have similar tools along with provider newsletters, provider specific list serves, with over 470,000 subscribers, and ongoing provider education activities. Partnering with national and regional healthcare provider associations significantly extends our outreach efforts. To date, we have entered into partnerships with 115 national healthcare related associations, including the National Association of Rural Health Clinics, the National Rural Health Association, the AMA and the MGMA, and over 2000 state local associations. Our provider partners agree to disseminate Medicare news and NPI related messages to association members, publish the information in association newsletters, and post links to the information on their websites. Additionally, we issue our messages through the CMS NPI outreach subgroup, which includes staff responsible for Medicare Advantage Plans, Quality Improvement Organizations, State Survey and Medicaid Agencies and the work group for Electronic Data Interchange. Since initiating NPI related provider outreach activities more than a year ago, we have distributed 26 NPI related outreach messages, using this extensive network. These messages have included helpful tips and information that providers can use as they implement the NPI in their business practices. All of our current and past communications, and frequently asked questions can be viewed on the CMS NPI web page, which is located on the CMS website. In terms of educational materials, CMS has issued 44 MLN matters national articles over the past 2 years. These nationally consistent articles use easy to understand language to help healthcare professionals understand NPI related policies and are

extensively marketed through a dedicated MLN matters list serve with over 32,000 subscribers. We have also created a training package that consists of 4 PowerPoint presentations, on topics such as subparts and data dissemination, as well as fact sheets and tip sheets on various aspects of the NPI Final Rule and its practical applications. All NPI educational resources have been announced via the network described above and they have become available and are easily accessible on the CMS NPI web page. Finally, we have hosted 6 NPI roundtable conference calls, to field questions from health care professionals regarding Medicare's transition to the NPI. These calls have been and will continue to be open to the public and announced through the various mechanisms described above. We welcome individual providers as well as provider organizations to these calls. NPI news is also discussed on an ongoing basis as the CMS open door forum and the parallel Medicare contractor asked the contractor calls. Our approach is deliberately redundant to assure that we provide the provider community with an opportunity to be updated on the activities pertaining to NPI. We plan to continue to outreach activities described above. We welcome further suggestions from you in ways to reach small or rural providers.

62P3: PPAC recommends that CMS work with Congress to 1) ensure immediate action to produce at least 2 years of positive updates and avert the 15% cut to the Physician Fee Schedule over 2008 and 2009, and 2) repeal the sustainable growth rate altogether, and replace it with a system that produces positive physician payment updates that accurately reflect increases in medical practice costs as indicated by the Medicare Economic Index. The response: The formula for the SGR in the Physician Update are dictated by statute. We are required to follow this methodology when calculating the payment rates under the Physician Fee Schedule. We look forward to working with Congress, the physician community, and other interested parties as we continue to analyze appropriate alternatives to the current system that can ensure appropriate payments while promoting high quality care without increasing Medicare cost.

62P4: PPAC recommends that CMS apply the budget neutrality adjustment to the conversion factor for 2008 and subsequent years. The response: Section 1848 C2b22 of the Act requires a budget neutrality adjustment. Regardless of whether the work budget, neutrality adjustor that is a product of the 5-

1 year review of work is applied to the work relative value units or the conversion factor the values
2 associated with the work will ultimately be decreased. Since the work adjustor is applied across all RVUs
3 and since the work adjustor is applied outside of the actual RVUs, as an additional adjustment, the
4 application of the work adjustor to the RVUs does not alter the relativity among RVUs. Achieving budget
5 neutrality by adjusting the conversion factor would have the affect of reducing payment for all services on
6 the fee schedule. This would include reductions in RVUs for a number of services that have no physician
7 work and were therefore outside of the scope of the 5-year review. We believe it would be unfair to impose
8 additional reductions resulting from budget neutrality on CPT codes that have no work values associated
9 with them.
10 62P5: PPAC recommends that CMS be aware of areas of concerned with proposed durable
11 medical equipment, prosthetics and orthotic supplies and their regulations, including competitive bidding
12 and requirements to provide surety bonds to provide DMEPOS service. It is impossible for healthcare
13 providers to compete against larger businesses, whose sole purpose is to supply medical equipment,
14 therefore providers should be exempt from the accreditation process on the basis of their training and from
15 the competitive bidding process. PPAC urges CMS to remedy this situation by amending the Final Rule.
16 The response: The law did not give CMS the authority to acknowledge physicians as having already met
17 the quality standards and thus be exempt from accreditation. In general, such suppliers shall be required to
18 comply in order to furnish any such item or service for which payment is made and received, or retainer
19 provider, or supplier number used to submit claims for reimbursement for any item or service for which
20 payment may be made under Medicare. Exemptions have been provided in the Final Rule to allow
21 physicians and treating practitioners to furnish crutches, canes, walkers, folding manual wheelchairs, blood
22 glucose monitor devices, and infusion pumps as part of their professional service. Physicians who act as
23 commercial suppliers of DMEPOS as opposed to furnishing items as part of their professional service, are
24 subject to all the requirements of the Final Rule.

1 62P6: PPAC recommends that CMS reevaluate and reduce the 1.4% productivity adjustment to
2 the 2008 Medicare Economic Index, and the reduction for future years. The response: The Office of the
3 Actuary has concluded that the reevaluation is accurate. The Actuary Office reevaluates the appropriateness
4 of the productivity adjustment in the MEI each year and it has concluded that the adjustment is valid. The
5 MEI has contained a productivity adjustment since its inception in 1973. The rationale in technical
6 appropriateness of the current MEI productivity adjustment has been well documented in the *Federal*
7 *Register*. Moreover, CMS recently partnered with the Assistant Secretary of Planning & Evaluation to
8 sponsor analysis of physician-specific productivity. The results of this effort were presented at a conference
9 of stakeholders in October 2006. A highly respected panel of experts concluded that the use of the 10-year
10 moving average for private non-farm business sector, multifactor productivity was not an unreasonable
11 proxy for physician specific productivity. Papers from this research effort are expected to be published in
12 the forthcoming winter edition of the healthcare financing review. CMS will continue to monitor, on an
13 ongoing basis, the reasonableness of the use of this economy wide measure of multi-factor productivity, for
14 purposes of adjusting the MEI.
15 62M1: This is quite a long report, Mr. Chairperson. PPAC recommends that CMS reinstate the
16 facts exception for eprescribing and work with Congress to provide financial incentives to facilitate wider
17 adoption of eprescribing. The response: In response to industry concerns that the exemption for computer
18 generated faxes was hindering the movement toward computer to computer eprescribing, we proposed in
19 the Physician Fee Schedule June 2007 NPRM to eliminate it effective January 2009. In the Physician Fee
20 Schedule Final Rule, with comment in November 1, 2007, we did not eliminate the exemption entirely,
21 allowing computer generated faxes to be used during the periods of network failure. During the time period
22 allotted for comment following the issuance of the June 2007 Proposed Rule, we received one comment
23 that indicated that the elimination of the exemption could be problematic in performing certain eprescribing
24 functions. Absent receipt of any other negative industry feedback during this comment period, we
25 proceeded to work toward the elimination of the exemption, except as noted above in cases of network

failure, to be effective January 2009. However, we have since been informed by various stakeholders that the elimination of the exemption for computer generated faxes would have an adverse effect in certain instances, and they have provided us with more specific information regarding its economic and work flow impacts that were not forthcoming during the public comment period. In particular, pharmacies have indicated that the use of computer generated faxes for a significant volume of refill requests and that eliminating the exemption would require them to revert to paper faxes, when the prescribing physician does not have eprescribing capability. We are now in the process of examining and considering this data. We expect to address this issue through the rulemaking process prior to the January 2009 effective date, once again affording an opportunity for public comment. Under the financial incentives, to facilitate wider adoption of eprescribing at this time, funds have not been appropriated by Congress to provide direct grants and/or other incentives to providers to implement eprescribing under Medicare Part D. However, other incentives such as regulations that provide exceptions to the Anti-Kickback Statute, and the Stark Federal Physician Self-Referral Law are in place, and can pave the way for industry to share technology and other health IT resources among entities. We also note that providers may participate in and receive incentives through the 2008 physician quality reporting initiative. This project included measures for patient compliance with therapy, which can be supported through the utilization of eprescribing transactions, such as fill status notification. CMS announced the 5-year demonstration project on February 20, 2008, that will provide incentive payments to encourage small and medium-sized primary care physician practices to use electronic health records. This project was a major step towards moving towards moving toward an electronic reporting system, aimed at reducing medical errors and improving quality of care.

62M2: PPAC recommends that CMS report to PPAC its plan of action to correct patient access cuts forecast by the AMA resulting from unsustainable cuts to the physician Medicare reimbursement. CMS is aware of the potential implications of the negative updates on access to care. We are monitoring beneficiary access to care in the Medicare program. To address the beneficiary perspective on access to care, two beneficiary surveys are available; the Medicare Beneficiary Survey, MCBS, and the Consumer

Assessment of Health Plan Survey, CAHPS. These surveys provide information on whether the respondents are experiencing difficulty obtaining needed services. The MCBS is a national survey that has been continuously available since 1991. CAHPS is also a national survey, but the largest sample size allows for the generation of statistics at a more local level. To address the physicians' perspective on their willingness to treat Medicare beneficiaries, CMS has relied historically on the periodic physician survey administered by the Center for Studying Health System Change, and will continue to do so if the Center for Studying Health System Change continues to administer this survey.

62M3: PPAC recommends that CMS allow carriers flexibility to ensure enrollment applications do not stall or result in unnecessary rejections, especially given the untold numbers of practitioners that are being asked to reenroll. Response: CMS has instructed its Medicare Fee for Service contractors to process complete Medicare provider supplier enrollment applications that contain all supporting documentation, including the electronic funds transfer authorization agreement, and licensing information, within prescribed processing time frames. CMS requires that its contractors process 80% of initial enrollment applications within 60 days or less and 80% of changes in 45 days or less. In order for a contractor to meet this standard, providers and suppliers must submit a complete application at the time of filing. For an enrollment application to be considered complete, 1) all applicable sections of the CMS 855 form and fields, including check boxes, within a section, must be filled out at the time of filing. 2) the application must contain an original signature, and date of signature, and 3) contain all supporting documentation listed in Section 17 of the enrollment application. CMS is also developing an Internet-based enrollment process. By establishing an Internet based enrollment process, CMS will allow providers and suppliers, except supplies or durable medical equipment, the option of enrolling or making a change in their Medicare enrollment information via the Internet.

62M4: PPAC recommends that CMS carefully monitor the industry's overall ability to use only NPI numbers by May 23, 2008, particularly the readiness of Medicare and those billing Medicare. The response: CMS will continue to monitor industry NPI readiness, including Medicare Fee for Service

readiness. We monitor NPI metrics very closely and stand prepared to address any problems, should they arise.

And that, Mr. Chairperson, concludes the report from the December 3, 2007 PPAC meeting.

Dr. Senagore: Thank you, Dr. Simon, delivered in the spirit of Tolstoy. [laughter] Are there any comments from the Council as to the recommendations? Yep, Dr. Ross first?

Dr. Ross: I'll yield.

Dr. Senagore: He's yielded his time already. OK.

Dr. Przyblski: I have a comment on 62P4 and a question on 62P5. On 62P4, I'm sure CMS recalls that this was a request that was made by the RUC itself at the end of the last 5-year review to make changes to the conversion factor rather than the work adjustor, and although you again make comments about why this might disadvantage services that do not have any physician work RVU, it does not acknowledge the problems of having it adjusted in the work adjustor versus the conversion factor, such as the following: As we all know, work RVUs are a calculation of time times intensity, so as a result of changing the work RVUs, since time is not changing, since that was measured in surveys at the RUC, you are therefore changing intensities arbitrarily in the Fee Schedule, and when services are looked at in the future, those intensities are no longer the same intensities that the RUC has been accustomed to using. So that's one problem. Another problem is that the PLI RVU are actually calculated in part based on the work RVU, and I have not yet seen a calculation but suspect that physicians who are at high levels of PLI payment are going to be more adversely affected by a work adjustor than those that have lower PLI costs. Finally, third party payers often peg their payments on a variety of factors, and one of those in negotiations can be RVUs. So when RVUs go down, automatically, third party payer payments also go down. If it were done to the conversion factor, then it would have no affect on third party payments, so these are adverse consequences of hiding a reduction in payment in a work RVU adjustor, rather than in the conversion factor.

As far as the question on 62P5, at the end of the recommendation, there was a comment that describes an example of exemptions provided in the Final Rule. Is that an all inclusive list of exemptions or

are they examples of exemptions. For example, is casting, cervical collar, thoracal lumbar orthosis considered similar exemptions or do they have to be specified in some way in a Final Rule?

Dr. Ross: And if I could just add to that, what I was going to, I wanted him to start, but the technical language at the end says physicians who act as commercial suppliers of DMEPOS as opposed o furnishing the items as part of their professional service are subject. So if a physician is providing the service in the office, whether it's a collar, whether it's an orthosis, whether it's even a multiple shoe for a diabetic, whatever the issue is, if it's part of the service, are they exempt, as opposed to the commercial suppliers? According to this language, that's what it says, so I wanted to get a clarification on that, specifically the last sentence says: Physicians who act as commercial suppliers, yes if they're going to be suppliers, that's one thing. As opposed to furnishing the items as part of their professional service are subject to all the requirements of the Final Rule. So if they're providing the service as part of their office are they exempt from the Final Rule?

Dr. Simon: That was the language that was used in the Final Rule, and that's the understanding, yes, that they are exempt, for those that are providing the products as part of their professional service, integral to the patient's care.

Dr. Ross: OK. Thank you.

Dr. Senagore: Any other comments or questions? Dr. Sprang?

Dr. Sprang: On 62M1, PPAC and specifically related to the eprescribing and eliminating batches. We brought that up at the last meeting because when we first head it, recognizing, and I practice in the Chicago area, in many of the physician's office are using the eprescribing through the fax. If they didn't have that available, they would probably just go back to the old-fashioned paper prescriptions, and I think that was pointed by some of the additional people, and I just want to kind of emphasize the importance of that, because a lot of the pharmacies, you can't have direct eprescribing computer to computer, unless there's a bridge between the kind of system you have and the kind of system the pharmacies have. And many times that does not exist, and you'd have to build bridges between each of the different, 100 different

computer systems that are out there. Some of the larger pharmacies, Walgreen's, etc., may do that. Small pharmacies, independent pharmacies, couldn't possibly do that. So if you eliminate the ability to use faxes, you're going to really force people to go back to paper, and you're actually doing less, going in the wrong direction instead of the right direction.

Dr. Senagore: That certainly remains an infrastructure issue yet. There are no industry standards for many of the smaller providers. Any other comments? Dr. O'Shea?

Dr. O'Shea: I have something about 62P1. In your report, Dr. Simon, you reiterate again that CMS plans to report the analyzed results. Physicians have gained access to the preliminary participation results as of November of '07. This comes out of the Physician Performance Information Center, and there are much information of interest to us within this report and having said so, I am actually ready to make a recommendation again, unless the Council would like to wait until later.

Dr. Senagore: No, that's fine. Go ahead.

Dr. O'Shea: PPAC recommends that CMS present with the Physician Performance Information Center team, the already released interim PQRI participation and reporting statistics. This will allow members of PPAC to review the reported data measures and assist CMS as they respond to needed changes, such as eliminating the per measure CAP.

Dr. Senagore: Is there a second?

[second]

Dr. Senagore: Any discussion?

Dr. Przyblski: Is there a time certain, like May meeting?

Dr. O'Shea: I will again reiterate at the soonest available time, and I put that in there—you know you're right on, he already said May, but you're right on. And I would like to have this at the May meeting.

Dr. Senagore: Assuming that friendly amendment, we'll edit that appropriately. Dr. Simon?

Dr. Simon: Just one comment to share with the Council, the information that has been provided that Dr. O'Shea alludes to only includes information up until November, so it does not include the entire

reporting period, and with that understanding, that was one of the reasons why we did not elect to share that information with the Council at this time. It only includes information up to November. It's raw data. It has not been reviewed or analyzed by anyone and so no one really knows the, has digested it at this point, and so we thought that it would be better to have the complete reporting period and have the data analyzed before sharing it with the Council so that we could obtain useful input from the Council.

Dr. Senagore: Any other discussion on the motion? All in favor, say Ay.

[Ays]

Dr. Senagore: All against? The motion carries. Any other comments or questions regarding the report by Dr. Simon? Seeing none, we will move on. At this time, I would like to move to our next agenda item, which is the Physician Regulatory Issues Team, the PRIT update, by Dr. Rogers, who is the Director of the PRIT in the Office of External Affairs. And he's kind enough to address the Council most every quarter with the most up to date information. Welcome, Dr. Rogers.

PRIT Update

Dr. Rogers: Thank you, Dr. Senagore. It's a pleasure, and a little bit sad to see some of you all leaving. I've really enjoyed working with each of you who are leaving the committee, but I'm pleased that I will probably see all of you. I was just speaking to oncologists in California on Tuesday, and who was there keeping everybody honest and focused, but Barb McAneny, still doing great work. [laughter] So we'll just see each other in different venues, I'm sure, going forward.

We've been quite busy the last couple of months, particularly busy dealing with NPI issues and the preparation for the March 1st, not May 23rd deadline, which just passed, and making sure that we did everything we possibly could to make physicians aware of that deadline. We've also been very busy with RAC issues, although I've got to say, Connie Leonard and Melanie are doing such a great job of managing that program as best it can be managed, that it's been a much easier job than it would be otherwise, and applaud them for their hard work on that. We've also been trying to help with creating good regulations having to do with tamper proof prescriptions because those of us who practice medicine know we're not

1 going to have a Medicaid prescription pad and a nonMedicaid prescription pad, so all the tamper proof
2 regulations only apply to Medicaid. They're really going to affect our daily practice, even if we don't have
3 many Medicaid patients and my concern was that since the states had the authority to have their own
4 regulations, that if we didn't help to encourage as close to a common standard as we could, that we might
5 find 51 different standards out there. I practice, I'm going to the emergency department tonight to work,
6 and it would be pretty hard to do if I had a Virginia prescription pad, a DC prescription pad, and a
7 Maryland prescription pad and had to use the right one and make sure the patients didn't go to the wrong
8 place to get their prescription filled.
9 As I said, one of things that we've been involved with, and Ken did a report on this, is making
10 sure that we did everything we possibly could to make sure physicians were aware that as of March 1st, if
11 they had a mismatch in the NPI Legacy number crosswalk, that they would not get paid, and we did the
12 normal things that we did with the list serves, but we also worked with ACP, AFP, MGMA, Health Care
13 Billing Management Association, other specialty societies, so that each of them could craft articles or other
14 appropriate material for their members. We worked with magazines, *Part B News*, *Emergency Medicine*
15 *World Report*, our *Internal Medicine World Report* and other magazine to make sure that they printed
16 articles pointing out that March 1st was a very important deadline. The *Hippocrates* even sent out an
17 electronic announcement to *Hippocrates* subscribers about this. So we did everything we possibly could, as
18 Ken said. It's actually much more than 43 articles now. But as of the date that we had to put our
19 presentations in, that was the correct number. But we've also outreached in a lot of other ways, and we're
20 going to have an update and we'll find out just how well we did.
21 This is just an example *Part B News*, did a good article about this. We had MedLearn, MLN,
22 sorry! MLN articles about it, so hopefully we'll see just how it looks now that we're probably starting to
23 see some rejections come through. This was one of the issues that I'm very excited about: Simplifying the
24 Work of Enrollment. Primarily this has to do with PECOS live, the online ability to file 855s and to change
25 your enrollment information. I'm really excited about this. It's been a challenge, I think, for our staff that

1 our implementing this because there have been big security concerns, making sure that the physician-
2 specific information is only accessible to that physician and that the physicians have control over it. So
3 there's been a little bit of a slip in our deadlines, but they're still working very hard to get this out and I'm
4 sure it's going to be out in the near future. I am excited that we just released expectations that we have for
5 processing times, and they're significantly faster than the paper form. We expect with the paper forms that
6 90% of forms will be processed in 120 days. Our expectation with the web-based is 45 days, so that's going
7 to be great. When you bring a new person into the practice, you might actually start to get paid before their
8 first birthday in the practice.
9 Active military physicians' ability to bill government payers. This has been frustrating because it
10 involves so many different agencies. Department of Defense is involved, Public Health Service, Health &
11 Human Services, and there are a lot of lawyers involved, so it's been hard to bring this to completion. You
12 can see the beginning date, we started this over a year and a half ago, and I still don't have an answer that
13 all of the attorneys involved are happy with, but we're continuing to be terrible nags on this one.
14 This was a new issue that we have, an interesting issue, and this is the sort of thing that I love to
15 work on because although these are not very exciting sorts of issues, they have huge, when you consider
16 that we're paying a billion claims a year, they have huge benefit in aggregate. When physicians get
17 recoupment or refund, apparently on the paper work that they get with the check, it is very difficult to go
18 back and figure out who the check, which claim the check originally applied to. And so we're working with
19 CMS staff to see if we can address that make sure that when the check comes, it's quite obvious which
20 claim the refund applied to. It's really important to the physician offices, and I've spoken to physician
21 offices about how they deal with this right now and they've been, it's been very cumbersome. They have to
22 save the original letter. They have to file that, then pull the letter, then sort of reverse engineer who the
23 refund applied to. So this is going to be fun to work on, and when we get done, nobody will be excited
24 about it except for 45,000 people who are processing physician claims.

So this is again my contact information and also Matt Brown who works at the PRIT and look forward to more issues and hearing how we can help.

Dr. Senagore: Thank you, Dr. Rogers. Any comments or questions for Dr. Rogers?

Dr. Rogers: Oh, and I should say the fact that there were no cartoons in here does not represent a change in philosophy [laughter]. I was out of town doing speeches all last week, and Matt Brown did the presentation and I guess he's trying to ruin my reputation. [laughter]

Dr. Senagore: Very good. Thank you, Dr. Rogers. Based on that lead in, let's proceed with the agenda, and focus our attention on the National Provider Identifier. Ms. Cathy Carter joins us today to provide and update us on the NPI. Cathy is the Director, Business Applications Management Group in the Office of Information Services. Welcome Ms. Carter.

NPI Update

Ms. Carter: Thank you. NPI certainly seems to be the topic of the day. I can't count how many times it's already been mentioned this morning. The presentation that I put together back a couple of weeks ago is already somewhat dated because of the events that folks have been mentioning about the edit that went into place this weekend so I'm going to go through just the first couple of these slides, that's just the outline if you go to the next slide please. I just want to cover our implementation strategy and just give folks a little bit of background. And then we passed out, all of you should have hopefully a handout of the material that went out from CMS late Friday afternoon about the plans that we have for the coming weeks after the edit was implemented on March 1st. Our strategy for implementing NPI has been an incremental one over the last couple of years. The first phase was actually enumeration. And we had a lot of efforts going into making sure that people enumerated and got their NPI, and that's been going on now for the last couple of years. The second phase of the incremental strategy was voluntary use of the NPI, and it's been well over a year, year and a half since we've been accepting NPIs on claims. We started using those NPIs actually processing the claim using the NPI, back on October of 2006. The next phase was actually the requirement and you heard it mentioned already that January 1st this past January 1st, we were requiring

1 NPIs on claims that are sent to fiscal intermediaries for all basically institutional claims. That went off
2 really without a hitch. We didn't hear much about it. We were at about 90% of claims in December that
3 had—this is for institutional claims—that had an NPI, and with it by middle of January, we were up to
4 99.9%. So our next approach, you can see there was March 1st, and again, it's been discussed as of this
5 weekend, we put an edit in place at all of the carriers and the DME carriers as well, to reject any claim that
6 does not have an NPI. Now again, those claims can have a Legacy number still, but they must have an NPI
7 or they're going to be rejected. The last phase that's listed there require NPI only as of May 23rd. That's
8 what we're working toward now. All of these stages are in preparation for the ultimate goal, which was the
9 May, which is the May 23, 2008 date, and at that point, claims need to have NPIs in all the places on the
10 claim where the number goes and they may not any longer have Legacy numbers. So that's the overall
11 strategy and I would suggest you might want to just go ahead and turn that off. If people have comments or
12 questions, on the rest of the slides the information in there is really not incorrect, it's just background
13 information. There's outreach information, the website you know there's some data in there certainly that is
14 valid, but I was going to now go to the document that we handed out earlier this morning. And this went
15 out on list serves. All of CMS's list serves. It went out on all the carrier sites, everything centrally, to all the
16 associations, and as it's already been mentioned, we've been working with the associations, with the AMA
17 and the HBMA, and MGMA and all of the folks on our plans for March 1st, and again, just to make sure
18 you understand what happened as of March 1st, and unfortunately we do not have any results yet, because
19 the edit went in this weekend, we process today, those first sets of claims that will require the NPI and as of
20 tomorrow, those reject notices should be sent for any claims that do not have NPIs, should be sent to the
21 providers directly or to their billing agents. So we don't have any data as of yet on what the reject rate is.
22 The deadlines for submitting NPI again, it's critical that we get this March 1 date out of the way so that we
23 have time to then focus on the next piece of work, which is really to make sure that claims can be processed
24 without those Legacy numbers. The vast majority of claims right now are still being submitted with both
25 numbers. And what our systems do is look at that pair, that's submitted on the claim, look and see if it's in

1 the crosswalk, and if we can find that in the crosswalk, the claim will then pay. Things might work a little
2 differently when you submit just the NPI, depending on how many NPI-Legacy combinations that each
3 provider has. So what we're recommending is, if you're successful in submitting the NPI and Legacy pair,
4 that your next step should be to submit the NPI only. What we're anticipating is going to happen is for
5 about, for some percentage of claims that are processed, starting today, what'll happen is, some providers
6 still we are hearing, a very small number, hopefully a very very small number, do not have an NPI yet. So
7 they're not going to be submitting an NPI on the claim, and those claims will reject. Providers have had
8 almost 2 years to get that number and we believe that this rejection then will cause them certainly to take
9 some action. It could be that the providers don't have an NPI, or have one but have not submitted on the
10 claim. Those certainly will also be rejected, and then the other thing that could happen is the provider could
11 submit the NPI and there could be mismatches between their Legacy and NPI data. And those are the cases
12 that we are concerned about. Those are the cases that we have mobilized resource within CMS to address.
13 If those things are not consistent, if those two numbers are not consistent, if the data in those two different
14 databases are not consistent, then those claims are going to be rejected. We have been working with
15 providers over the last several months and we have certainly come across some of those cases. We have set
16 up teams at all of the carriers and the DME carriers to address those issues. We have additional folks ready
17 to answer the phones. We have teams in place so we're looking at the provider enrollment area, the EDI
18 billing areas, as well as other aspects of claims processing to make sure that when questions come in, we
19 have a team there to look at what the reasons are behind this. So even though I mean we're asking your
20 patience, and in fact the notices that went out say that we expect additional calls. We expect the call centers
21 to be very busy, and we're asking for your patience but we do have resources mobilized to deal with these
22 issues. The current status is we have 91.3% of Medicare carrier claims and 88.5% of DME claims that are
23 coming in with a Legacy and NPI, or at least the NPI. Now that data is as of about 2 weeks ago, so what
24 we're hoping is that in the intervening time, since we've collected that last bit of information, hopefully
25 we've moved closer toward 100% of claims coming with an NPI.

Our risk mitigation, as I said, we're expecting the toll free lines to be busy. We are having daily calls with the contractors, and that includes the provider enrollment area, as well as the claims area, so that we can get first hand information on a daily basis and report throughout CMS and we're all aware of what's happening so we can take action if we need to so that we can respond to questions, and so we believe that with NPI coordination teams that we have set up, that we should be in good shape.

In terms of the future, I did want to let you all know that the places, there are many places on the claim where the NPI is required. The edits that went into place this weekend covered what we call the primary areas of the claim—the billing, the pay to, and the rendering provider. Those are the three areas that need to have an NPI in order for the claim not to be rejected. On May 23rd, every place on the claim, including referring and ordering, attending, any of the other places where the NPI or an identifier is required, is going to have to have the NPI. We're not editing to require that on March 1st. So again, this is a stepwise approach, making sure that we take care of the most important areas first and that people get used to submitting their data, and we make sure what we have in our system.

The handout that I gave you, also includes at the bottom of page 3 and onto page 4 information about what to do if your claims are rejected. Now this is information that's helpful for you, helpful for all providers and it's also being used by our call centers. We have given them scripts to use and job aids to use, so that they're aware of the possible situations that can occur. We're telling them what data that the provider should have available if they call. So it says if these claims, the first thing that you should be doing is checking the enumeration information. That's the easiest thing to check. You can go on line to do that and make sure that the information that you put in when you enumerated actually is matching what is in your provider enrollment information for Medicare. If that needs to be adjusted, you can make changes yourself to that data. If that is correct already, or if you do correct it, then you can resubmit claims. If it still does not work, we're advising you of what the next steps are, and that is to call the carrier where you send your claims. And we've listed here, I believe it's 8 items that you should have available. The folks that are answering the phones are going to be collecting that information so that they can take action. They can get

back to you if necessary, and they can check the rest of the CMS systems and see what, identify specifically what might be wrong. So it's very important that you try and follow these instructions. Again, we're working with all of the associations and various outreach mechanisms to get this kind of information out. This is what the people that are answering our phones at the call centers are going to see. And again, the final message that I would like to leave you with, and I'd be glad to take questions, is we are expecting volume. We are expecting claims to be rejected, we believe that that step was necessary in order to get us to the May 23rd date successfully. We believe that there are a certain number of providers are that just not going to take action until their claims are in fact rejected, and if you have successfully been using your NPI, along with the Legacy, it is really important that steps be taken to go ahead and use the NPI only, so that we're ready for the May 23rd date. So I will be glad to take any questions.

Dr. Senagore: Questions for Ms. Carter? Dr. Snow?

Dr. Snow: I've got a couple of comments. One, the data 2 weeks ago in Kansas indicated 20% of physicians are not putting an NPI on their claims. And I think this is the problem that we've been concerned about since the program started. The solo and rural practitioners that we have primarily in our state. So what's going to happen as of now, I can't tell you, but we have another problem in Kansas, because we're part of the J5. So March 1st, not only do I have to do something different with my claims, I've now got a different carrier. So I been paid up until now, and if I make a change on this carrier, get rid of my Legacy numbers, and don't get paid over the next 5 weeks, I'm not going to know if it's a carrier problem, or it's an NPI problem, so practically, I think those of us in Kansas aren't even going to be able to test the system still sometime, the first couple of weeks of April. And that doesn't give us very much time if we're having difficulties in order to make this other major change that's coming up in the middle of May to the end of May. We're just very concerned about that across our state, and actually our four-state region. We're sort of being, all of us moved into the J5 new carrier on a different schedule. But unfortunately ours is March 1st.

1 Ms. Carter: Well, for the folks in Kansas, Nebraska, and Kansas City, Missouri, we actually took
2 steps because of risk mitigation because of the issues that you mentioned there with the transition, and we
3 are actually going to implement the edits that are March 1st everywhere else March 15th. So we are giving a
4 couple of extra weeks just in that area because of concerns about that March 1 date.
5 Dr. Snow: Quite frankly, I think that's going to make it worse. That means if we don't institute
6 those until March 15th, I'm not going to know if my claims are paid by my new carrier until about April 1st,
7 first week of April. Now if you move it to March 15th, then I've got an additional time period in there that
8 gives us a shorter time period to correct the problem before something new—
9 Ms. Carter: And that was our dilemma. We're looking at this as there's kind of a risk either way,
10 and in that particular area, we determined that because of the issues surrounding that transition, we would
11 wait a 2-week period. Now what that means is that certainly the NPIs can still be submitted and there won't
12 be a problem, we're just not going to reject claims if the NPI is not there for a period of 2 weeks and we'll
13 see, have time to determine how that transition goes. Now the one thing good, or bad depending on how
14 you want to look at it, for rejects is they happen immediately. Normally when we pay a claim, if we
15 approve it for payment, then it's sitting on the payment floor, and it is about 2 week period, but for a reject,
16 the reject will occur immediately, actually the day following our processing. So it won't take two weeks to
17 find out if they're rejecting.
18 Dr. Snow: Our previous carrier wasn't able to do that. Hopefully the new one will.
19 Dr. Senagore: Other questions? Dr. Sprang?
20 Dr. Sprang: Appreciate all the time and effort and energy you're putting into it, and obviously
21 some physicians in some groups are just kind of not acting in a timely fashion, but there are some
22 legitimate concerns and for some of the things, obviously concerns about cash flow and those kinds of
23 things, so I'd like to make a recommendation.
24 Dr. Senagore: OK.

Dr. Sprang: PPAC recommends to CMS that 1) closely monitor the claims rejection rates following the March 1, 2008 deadline; 2) share information on the rejection rates with the physician community in a timely fashion; 3) allow claims to be processed with the Legacy number only if the claims rejection rate immediately following the March 1, 2008 deadline exceeds some reasonable minimal amount, and if it's really, if you're rejecting 20%, obviously there's a problem, but that's not part of the recommendation. So, you want me to read that one again? Got it? 4) Do not reject claims in situations where practices have experienced enrollment backlogs, where they're trying to get their NPIs and can't because they're having problems with a backlog. So do not reject claims in situations where practices have experienced enrollment backlogs.

Dr. Senagore: Is there a second?

[second]

Dr. Senagore: Any comments or discussion? Dana can you read it back for the Council, please?

Ms. Trevas: PPAC recommends that CMS 1) closely monitor the claims rejection rates following the March 1st deadline; that CMS share information on the rejection rates with the physician community in a timely fashion; that CMS allow use of the Legacy number only if the rejection rate following the March 1st deadline exceeds a reasonable minimum amount, and that CMS not reject claims in situations in which practices have experienced enrollment backlogs.

Dr. Senagore: Comments or questions? Call the question, all in favor say Ay?

[Ays]

Dr. Senagore: All against? Motion carries. Any other comments or questions for Ms. Carter. Seeing none, thank you for your presentation this morning.

Ms. Carter: Thank you, and we do intend to monitor extremely closely.

Dr. Senagore: I'm sure there will be intense interest in the results of the monitoring. Dr. Snow?

Dr. Snow: She mentioned a paper that was handed out. I don't think several of us have that.

Ms. Carter: It's 2 sheets, 2 sided.

Dr. Senagore: That side of the room was excluded—it was given on a need-to-know basis only, so… [laughter] We'll be sure that you get it. Thank you, Dr. Rogers. Since we're moving right along, we'll go ahead and take our next speakers as they are here. Our next speakers are Ms. Connie Leonard and Ms. Melanie Combs, both from the Office of Financial Management. Oh you're by yourself today?

Ms. Combs: I'm flying solo today!

Dr. Senagore: OK.

Ms. Combs: No Connie Leonard, just Melanie.

Dr. Senagore: Ms. Leonard got off the hook, then, OK. Anyway, Melanie serves as the senior technical advisor in the Financial Services group and has tasked with the assisting in the implementation of the RAC program. Before joining CMS, Melanie worked as registered nurse, as a medical record reviewer for the Maryland Peer Review Organization and for the Maryland Department of Health. And welcome Melanie and you can share our welcome for Connie when you see her.

Recovery Audit Contractor Update

Ms. Combs: I'll be sure to do that. Thank you very much for inviting me here today. Because we have the luxury of time, which often times we do not have, I will just tell you interrupt me if I get to a slide that you have a question on, and I'll either answer your question right then and there, or tell you that it's coming up on a future slide. Again, this is one of my favorite topics to talk about, improper payments in the Medicare Program. And I'll be talking a little bit about just background to make sure that those of you who are new and have not heard this presentation before have the right context in which to understand the RAC program. We'll be talking a little bit about some of the myths and facts that we've been hearing about over this 3-year demonstration project. I'll share with you some of the findings from our recent 2007 report, talk a little bit about some of the lessons learned during our demonstration, and then talk about the future and what you guys can expect.

In order to understand the RAC program and how it fits into Medicare, you first have to understand the Improper Payment Information Act. This is a statute that was passed by Congress a number

of years ago, that requires federal government agencies to measure the improper payments that they are making and to develop strategies for preventing those improper payments, lower the improper payment rate. And the IPIA defines improper payments as both overpayments and underpayments. And Congress gave CMS a new tool for identifying and correcting improper payments and that is the RAC program. The improper payments in Medicare last year, we estimate at over $10 billion, and while CMS has taken a number of efforts of the years, to try to lower that improper payment rate, it started out at around 13% back in the '90s, and we've now got it down to 3.9% and we're very proud of ourselves for having achieved that. But $10 billion is still a lot of money, and 3.9% is still too high and we really need to continue to try to reduce those improper payments in Medicare, and one issue that we continue to run up against with our regular carriers and fiscal intermediaries and MACs is that they're expensive. It costs money. We have to go back to Congress every year and say give us more money so that we can review more claims so that we can prevent more improper payments and of course Congress is always reluctant to give us more money. And so they came up with an idea a couple of years ago to be able to conduct more of these reviews, to identify more improper payments without costing any additional money to the taxpayer, and that was the contingency fee payment. That's what the RAC program is, how it's really unique, how it's really different from the carriers, the FIs and the MACs. They do the same kind of reviews, but they're paid differently. They're paid with contingency fees. They keep a portion of what they find, both overpayments and underpayments. The statute originally called for a 3-year demonstration program and then a new statute, TRICIA of 2006, Section 302 required that CMS, after the demonstration ended, turn it into a permanent program and make it nationwide.

The RACs are tasked with detecting improper payments in the Medicare program, both overpayments and underpayments, and correcting those improper payments. And by correcting, I mean collecting overpayments, and paying back overpayments. And they don't get their contingency fee just for finding it. They actually get their contingency fee after they've found it and paid it back. Or found it and collected it. The money has to be in the bank, either in the Medicare Trust Fund, or in the provider's bank

1 before the RAC gets their contingency fee. And CMS has really tried to use this demonstration program to
2 work out the kinks. To learn some lessons. Before we implement our permanent program, we really want to
3 make sure that we've got a good solid program that puts a minimum burden on providers, as we move
4 forward. And we see this as a continuous process. As many changes as we've made and as pleased as we
5 are with the improvements that we've made, we're sure that there are always going to be more
6 improvements, and so I welcome any input from you all today or in the future about ways that we can make
7 the program better.
8 Again, the mission of the RAC program is to detect and correct past improper payments, make the
9 trust fund whole, or make the providers whole, where improper payments have occurred, but more
10 importantly, to implement actions that will prevent future improper payments. That's really the secret to
11 this whole thing; is using the data, using the information that we get from the RACs and making changes so
12 that we can prevent future improper payments. Providers can use the data, to learn where they're
13 submitting claims improperly and they can fix it. They can make sure that when they submit claims in the
14 future, they do comply with the Medicare rules. CMS can use the information to find mistakes that the
15 claims processing contractors are making, and figure out where more provider education is needed, perhaps
16 where the rules are unclear and we need to make some changes on our part so that we can lower that error
17 rate and get that $10 billion in improper payments every year down. And of course, the taxpayers get a
18 benefit from this, because the trust fund is made whole for future beneficiaries.
19 There are a number of myths that have swirled around this 3-year RAC demonstration program,
20 that began in March of 2005. The demonstration program is scheduled to end March 28th of 2008, so just a
21 few more days left of the demonstration program, but quite a number of myths have grown up over this 3-
22 year demonstration and I'd like to share a few of them with you no. The first one is that the RACs make up
23 all their own rules and policies, and that they're completely unfair. And that's not true. The RACs use the
24 same policies as the regular Medicare claims processing contractors. They do not write local policies of
25 their own. They must follow the local policies that have been issued by the carriers, fiscal intermediaries

1 and MACs in that jurisdiction. Currently the RAC program is operating in 3 states, California, Florida, and
2 New York, and actually just recently we expanded New York RAC to also included Massachusetts, and we
3 expanded the Florida RAC to also include South Carolina. So there's a total of 5 states in the demonstration
4 now and each one of those RACs has to use the policies in those states. They have to use the Florida
5 policies for the Florida claims, and they have to use the South Carolina policies for the South Carolina
6 claims. They follow all the national policies, all the billing rules that are in the all the Medicare manuals,
7 they don't make up rules on their own.
8 Another myth is that the RACs use unqualified staff. And that also is not true. They use the same
9 types of staff that the fiscal intermediaries, carriers, and MACs use; that is they use nurses, therapists,
10 certified coders, and although at the beginning of the RAC program, they were not required to have a
11 medical director, each one of them realized about halfway through the demonstration that they really
12 needed a physician medical director to lead their review team, and each one of them hired a RAC medical
13 director and our future RACs will be required to have a physician medical director.
14 Another myth is that all the RAC reviews are done by black box computer edits, and that is not
15 true. Much of the RAC review involves clinician review of medical records. The last myth on this page is
16 that the RACs are going to be replacing the QIOs. And that is not true. The RACs' function is very
17 different; the QIOs function on quality improvement; the RACs are reviewing to identify and correct
18 improper payments that have been made in the past. One additional myth I'll throw in here is that the RACs
19 are redundant, that we don't need them, because they're doing stuff that Medicare contractors already do.
20 And we don't really see it that way. We see it that the CERT contractor, the Comprehensive Error Rate
21 Testing contractor does review claims, but they review randomly selected claims and the purpose of their
22 review is to measure error rate, to come up with that 3.9% error rate, and that $10 billion in improper
23 payments and so the CERT reviews are very different than the RAC reviews. The mission is very different.
24 Also the carriers, the FIs and the MACs do mostly prepayment review. They review the claims as it's first
25 coming in the front door; sometimes ordering the medical record, trying to prevent improper payments,

again, a very different mission than the RACs who are out there trying to collect improper payments or pay back underpayments.

Dr. Senagore: Excuse me, just a question for that last myth if I could. Do you have any examples of lessons learned that were transferred to an educational process? It would obviously be better for everyone if the error didn't error going forward.

Ms. Combs: One example that I can throw out is with Nulasta, that's a drug that apparently the code changed somewhere over the years, and at one time, if you billed for this particular J code, you were billing for a vial of Nulasta, 6 milligram vial of Nulasta. The code changed to be one milligram. You were supposed to bill for each milligram, actually I think it was vice versa. It originally started out per milligram, and they switched it to per vial. Some providers had their computer systems set for 6, because they were using one vial of Nulasta; it had 6 milligrams, so they continued to bill 6. When we noticed this problem, we issued an MLN matters articles and a computer edit to stop that; to prevent that; to educate providers that they needed to change their computer systems, and we put an edit on our side to stop those claims right up front before they got paid, so that's an example where education, getting the providers to bill correctly, and computer edits on the CMS side have really helped to prevent future improper payments.

Dr. Senagore: Thank you.

Dr. Grimm: Just about this statement about this myth, all RAC reviews are done by black box computer edits. But in the explanation that was handed out before, it actually said that most of them are done by computer editing. That the actual work of doing clinician review of medical records, takes a considerable amount of effort, and that very little of the work that was done to collect the current claims to date have been done by that method. That most of them have done by computer edits. And so would the correct statement here be that most RAC reviews today are done by computer edit, with some clinician edits? Would that be correct?

Ms. Combs: The terms that we use in our vernacular are automated reviews and complex review; automated review being those computer edits that are done without looking at the medical record, and

complex reviews, being those situations where a medical record is needed to do the reviews. I don't have the data to know what the percentages of automated reviews versus complex reviews, or what the dollar difference is. Perhaps the number of reviews would be on interesting statistic, but the dollars of the reviews involved in each type would be interesting. And I will see if I can gather that information and bring that the next time.

Dr. Grimm: It has a lot of importance in terms of your overall business. I mean it says in your own statement here that over half of them were due to result of incorrect coding, which is a, it's got to be a computer thing that you find out from that. You're not going to find that from a complex, most of the time, right?

Ms. Combs: No, that's actually not true. Although that may be true on the physician side actually I don't think it would be true even on the physician side. Let me give you a hospital example, and then I'll give you a physician example. On the hospital side, if the hospital bills for excisional debridement, if that's what comes in on the claim, the DRG grouper will put it into a high paying DRG. If they bill for nonexcisional debridement, it groups into a lower paying DRG. But just looking at the face of the claim, you can't tell whether the patient got an excisional debridement or a nonexcisional debridement. The RAC has to write to the hospital, get the medical record, review the medical record, look at the actual description of what happened during the procedure, to see whether it actually meets the definition of excisional or nonexcisional debridement. Another example is with some E&M services. You can't tell by looking at a claim. And it comes in and it says I'm billing for a level 3 office visit, whether it was truly a level 3, or a level 2 or a level 4. You have to get the medical record to know if that particular situation was incorrectly coded. In the situation of physician E&M services, CMS chose to take off the take E&M reviews for the demonstration RACs. That will change with the permanent RACs, but with the demonstration RACs, we didn't feel like we wanted them going into the coding issues, the level of coding issues with E&M. We did allow them to review things like billing is a new E&M code when in fact it was an established patient. They had been seen in that practice within the prior 3 years. That's an example of a computer generated review.

1 They don't need to order the medical record to know if the person has been seen within the last 3 years.
2 They can tell that by looking at the claim history. So there are some examples of automated review and
3 complex review. And we will see if we can gather those statistics and report them out. The information that
4 I have in the slides today, and that are in the report that was posted last week are mostly FY 07 data only.
5 One-year data. There's a couple places where I've thrown in some cumulative data when I think it's
6 helpful, but most of the time, it's a snapshot of what happened in the demonstration in Fiscal Year '07. In
7 April, we plan to release an evaluation report of the entire demonstration, and so I'll try to use that as my
8 vehicle to report out the information that you're asking for, the automated versus complex. And if you
9 invite me back again, I would be happy to have a slide to show that information. Any other questions on
10 automated versus complex before I go on?
11 OK, the next myth is that RACs randomly choose which cases to review, and that is definitely not
12 the case. Because RACs are paid on a contingency fee basis, they are incentivized to find the claims that
13 are most likely to contain improper payments. Before they go into the expense of sending letters and
14 getting medical records and having nurses do reviews and all the paper work and all the hassle involved on
15 their side in trying to identify either an overpayment or an underpayment, they want to be pretty sure and
16 sometimes I hear provider groups or disgruntled providers say they're denying 90% of everything that they
17 ask for, 90% of the medical records that come in, they're denying. So they must be denying inaccurately.
18 They must just be having their computers deny them all. I see it just the opposite. I see that the 90% denial
19 rate tells me that they're doing a really good job of focusing in on the problem areas; not burdening the
20 provider to send in medical records that contain proper payments, but really trying to get the provider to
21 only have to send in medical records, when there is a very high likelihood that that medical record is
22 associated with a claim that contains an improper payment. The RAC uses their own data mining
23 techniques. They use OIG and GAO reports as well as the CERT reports, and just the experience and the
24 knowledge of the staff people to know where claims are most likely to contain these improper payments.

The next myth is that most RAC determinations are overturned on appeal. That is not true. Only 5% of the RAC determinations are overturned on appeal. But we hear this so many times, so often that I think it's worth spending a little time and digging into the data on this particular one. And so on the next slide, I've actually pulled out some of the data from our report just so that I can explain to you what this means, what this shows and why this myth came to be. This happens to be cumulative data, so from the beginning of the RAC program through September 30th of 2007, and you can see that the rows are for, the first row is for Part A, the second row is for Part B, and the last row is for all RACs. And if you look at that bottom room for all RACs you can see that there were 358,000 claims that had overpayment collections during this time frame. And in the next column, you can see the number of claims where the provider appealed, at only 40,000. You can see that means that 11% of the time, providers submitted an appeal. Most of the time they did not submit an appeal. Most of the time they either agreed with the RAC determination or for whatever reason decided that it was too burdensome, too much of a hassle, they were not going to appeal the determination. The next column is the number of claims with appeal decisions in the provider's favor, and that's 17,951. The last column is the percentage of overpayment determinations that are overturned on appeal. That's taking the 385,000 and the 17,000, and dividing those 2 and coming up with the 5% number. But it is also to say that if you compare the 17,000 to the 40,000 that in fact, 44% of the things that get appealed are overturned. That is partly because of documentation that the provider chooses not to provide to the RAC but later provides during the appeal process. That does include some instances where the RAC got it wrong. But that's what an appeal process is for. And we just wanted to make sure that we laid out to you the myth and the fact here that if someone tells you that half or all of the RAC determinations are being overturned on appeal, that's not quite right. It is fair to say that 44% of things that get appealed are overturned, but it is not fair to say that 44% of all the decisions that the RAC makes are being overturned on appeal. That is only 5%. Any questions on that slide before I go on?

Dr. Przyblski: What is Part A and Part B referring to, I don't want to assume—

Ms. Combs: I'm sorry, Part A would be the things that are filed to, billed to a fiscal intermediary, and Part B refers to the things that are billed to a carrier or a MAC.

Next slide talks about one-year numbers. This is FY07, the overpayments collected for $357 million. It may sound like a lot of money, but keep in mind there's $10 billion that are out there each year, so although we're thrilled that they found a sizeable amount of improper payments, it's still just a drop in the bucket compared to all the improper payments that we estimate are out there. If you take that $357 million and you subtract out the underpayments that got repaid to providers of $14 million and you subtract out the dollars that were overturned on appeal, $17 million, and you subtract out the cost to run the demonstration, which is mostly the contingency fees that are paid to the RACs, but also includes my salary and the cost of the appeals process and the cost of running a database so that we can make sure that the RAC is not reviewing claims that are being reviewed by QIOs or MACs or somebody else, if you do all those subtractions, you come out to $247 million that went back into the trust fund. And we think that's pretty good. When we first started this demonstration program, we didn't know if the RACs were going to be able to find anything, and if they did, we weren't sure if it was going to be cost beneficial after you considered the cost of the program and the appeals. When we look at these statistics, it tells us that the RAC program is doing pretty much what Congress intended. Congress had it right when they thought that this was going to be a good tool for Medicare.

Dr. Senagore: Since It's my last meeting, I can offer an alternative conclusion just for you to assume. [laughter] And not to refute the concept, but there are some claims that are inaccurate, but if you looked at the data alternatively you would actually say that a number of providers have simply made the conclusion that they do not want to expend any resources to try and fight it, and in fact if every claim was challenged, and you put in the 40% rate of overturn, you actually would decrease your net by half. So and again, they may not be inconsequential, instead of 10 it might be $5 billion, which is real money. But in addition, you have to calculate in, if you do a full economic analysis, what's the impact on the provider to go through that work for no added compensation? They've already done the service, collected whatever

reimbursement, now have to fight to reclaim what is truly theirs? So again, I wonder at the end of the day, how many net dollars actually go to the beneficiaries, which is the goal of the program.

Ms. Combs: I appreciate your alternative conclusion. Thank you for sharing. And I will point out that CMS did hear that particular observation about halfway through the program when we started to get some statistics in that we could really get our hands around, and although we were happy to learn that the appeal rate was relatively low, we did hear a number of people making the suggestion that you just made, and we decided that it was important enough for us to know how accurate the RACs really are in their decisions, without relying simply on the appeal process to tell us how accurate the RACs are. And so we went down the path of hiring a RAC validation contractor. The RAC validation contractor is not paid on a contingency fee basis. They have experience reviewing all types of Medicare claims, and we send them a random sample of claims that the RACs have reviewed and we ask them to re-review them, and let us know if the RACs got it right or didn't get it right. And although the RAC validation contractor didn't get in place until very late in the demonstration program, we will be starting it back up again, when we get into our permanent nationwide program later this spring. And we see that as a really key component to making sure that a) we have the right RACs in the program, if they can't keep their accuracy rates up, we need to get rid of them and not let them in our program, and number 2, make sure that we really have a good handle on truly how accurate our RACs are being without relying on the appeals statistics, which sometimes may hide potentially the fact that there could be some improper payment determinations being made that are inaccurate, and providers are choosing not to avail themselves of the appeal process for the reasons that you suggested.

Dr. Senagore: And that was really the construct of my earlier question is can we learn some significant lessons that are really educational ultimately, to correct recurring themes? I would assume there's a number of things that are consistently reported incorrectly across providers in that, if we can improve it that way there may be less need for this type of oversight and simply a way to identify those errors and prevent them from occurring.

Ms. Combs: Yes, we see that provider education is key. Using the RAC data to change provider behavior and change claims processing contractor behavior I think is going to be key to preventing improper payments.

Dr. Senagore: Sure. One question, then Dr. Grimm.

Dr. Arradondo: I had a question, you said the RACs use the same rules as the regular processors. It's my understanding and you indicated that they mine data to be more accurate for the improper payment selection, for the ones they think might fall into that category. My understanding is that one of the data mining things they do is look at the level of service profile and if a particular person, in a particular specialty has a level that's outside the norm, that would be a person they might want to look at. Is that one of their techniques for finding, is looking at someone who's outside the norm?

Ms. Combs: I don't know if that's true, but it would not surprise me. It's certainly something that CMS has encouraged the carriers and the FIs and the MACs to do for a number of years. I remember back in the late '80s when we issued an instruction to the carriers and we said one way to find improper payments is to take a particular provider's percentage of level 1 versus level 2, versus level 3, versus level 4, versus level 5 and see if that profile is very different or pretty similar to other providers in that same specialty. So it would not at all surprise me if the RACs were using that same kind of technique. Obviously, not with level of E&M, because they were not allowed to review those during the demonstration, but perhaps with excisional and non excisional debridement, perhaps that's something that they looked at as they were trying to decide which hospitals might be billing more improperly.

Dr. Arradondo: But as they go nationwide, they would be using the same rules in toto, which includes the level of service.

Ms. Combs: Absolutely.

Dr. Arradondo: One of the regular claims collectors, where several actually, in a recent seminar, indicated that in fact they use those regularly and they're useful. One of the questions that came up which I would raise here, is in order to decrease the number of times the appeal is overturned, you would need to

1 increase the accuracy of the original data mined; the use of that mined data, and one way to do that would
2 be to find out ahead of time whether this particular practitioner—this is particularly true for primary care
3 practitioners, the norm would be one thing for all the say, family physicians, in an area. But for all the
4 family physicians who practice sports medicine, they're level of service would be different; that's known.
5 For all the family physicians who practice a certain level of, I don't want to use the word "intensive" but a
6 certain level of geriatric care, care for older patients, their level often is known to be different for family
7 physicians, internists who practice pain medicine, their level of service is known to be different. And I
8 mention these 3 simply because they were 3 of the 6 or so to be reported to require more complex
9 intervention. So if the regular processors and when it goes nationwide, the RACs use just this one little
10 thing—it could be a telephone call, it could be a note, an email, to say how does your practice differ from
11 the norm of your specialty, they might save some time, because a number of the generalists will pick up a
12 piece of activity and do something. A family physician might decide to become an asthma doctor or
13 diabetic doctor, commonly done, but those 2 disease states, often require on the case of diabetes, if you
14 don't really use the prevention piece heavily, require complex medical intervention. And of course if
15 asthma gets to the physician, which it shouldn't in the first place, would require often a complex
16 intervention, and that person have a lot of patients in that particular area, would have a different level of
17 service profile. Just mentioning it as a potential saving. I've seen some medical organizations do that
18 internally when they were trying to deal with costs internally, and I wonder if the regular collectors and the
19 RACs might use a technique along that line. Simple telephone call. Is your practice different from your
20 colleagues?
21 Ms. Combs: I appreciate that suggestion. We have instructions out to our regular carriers and FIs
22 and MACs for them to take corrective actions to lower their improper payment rate using a number of
23 tools; prepay review is what many of you are familiar with in terms of what the carriers and FIs do, but
24 there's also another tool that we describe in our manuals, called comparative billing reports and it's the
25 very kind of report that you're talking about that sort of compares one provider to individual provider to

their peers, and you are correct that it may be the carriers and the FIs, as they're looking at the RAC data and they're looking at their data and trying to figure out what corrective actions they can take to reduce future improper payments in their area, if they see that there's a particular code or particular problem area that the RACs are finding a lot of in their state, they can run their data and they can produce those comparative billing reports and they can mail them to the provider, or they can pick up the phone and call the provider and say, just wanted to let you know, you look different from your peers. Can you help us understand why your billing pattern looks different from your peers? We're out here trying to make sure that people aren't billing improperly and we just wanted to let you know that you look different. If you are billing differently because you have that kind of subspecialty, then it's fine. But we just wanted to let you know that we're looking, we're watching, and so yes, I can certainly remind the carriers and the FIs that either making the phone call or making that letter, sending that report, that comparative billing report to the provider may be helpful in trying to figure out why those billing pattern differences are occurring.

Dr. Senagore: Dr. Grimm?

Dr. Grimm: I think there's no question that this has been quite successful. What my concern is if I was looking at it as a business man, I would think this is a terrible business model. Because you're constantly, obviously eliminating your business by education and you should be able to—that's your goal is to eliminate your business. And I wonder if you've thought about that, because you're obviously catching the big fish with the nets right now. The fish are going to get smaller; all the fish are going to get smarter very quickly, and so your yield is going to be less with time, and what would be the motivation for your contingency fee contractors to continue business with you? And as a contractor, looking at it from that perspective I'd say, I'm going to stick in this business for 5 years and I'm outta here. And what's your answer to that? How are you going to deal with that?

Ms. Combs: We have thought of that, and I thought at the very beginning, as we went out with our Request for Proposals and we said we're doing this 3-year demonstration, come one, come all if you think you can do this work, submit a proposal. And I thought nobody's going to submit a proposal, they know

that after the first year, people are going to figure out how to bill correctly and they're going to not be anymore improper payments. And we got a whole bunch of proposal, from a whole bunch of really qualified people. And we chose the 3 that we thought were best. And we've been doing this demonstration. We've, we'll be making some modifications to the program going forward, but we have gone out with another request for proposal, to hire the permanent RACs, the four permanent RACs. I'll show you the map in a little bit, about the quadrants of the country that they will be covering and got a bunch of proposals again. People are still interested in doing this work and I don't know at what point things are going to change. I continue like you, to think that at some point, the RACs are going to get so good at this and the carriers and the FIs and CMS are going to get so good at using the RAC data to educate providers, to put in place the edits to stop the Nulasta problem, to really prevent improper payment that there will be no need for RACs. I dream of that day. I don't think it's going to happen next year. I don't think it's going to happen in 2 or 3 years, but maybe somewhere down the road, we'll get there, and I think that would be a great day. I'm sure OMB would be thrilled.

Dr. Senagore: Yes, working with our hospital coders, I'm not sure that that's eminent final conclusion. [laughter] Dr. Snow?

Dr. Snow: Just one quick follow up to Dr. Arradondo's. I think he's got a very important item there because for primary care physicians, I think this is extremely important and they're going to be audited if you will, on their E&M codes. But yet, you've indicated that you did not allow E&M coding during the demonstration. So that's going to be something brand new you're bringing in. What was the reason for not doing it and then doing it?

Ms. Combs: We think that E&M level of coding is very complicated, and we felt like as we were bringing up the RAC demonstration that we had our hands full with just trying to get all the normal stuff in place to make this demonstration work and we really didn't want to have to deal with the level of service issue. I believe that we're going to do the same thing at the very beginning of the permanent RACs. I think that we will ask each one of the RACs to come to us and tell us which issues that they would like to review,

1 and I think if the RACs were smart, they would leave off level of coding review on the E&M side to not
2 happen in the first couple of months of the permanent RAC program. I'm thinking that that might be a
3 really good issue for the second year or the third year of the permanent RAC program. I just think that it's
4 going to require a fair amount of coordination and work. We'll need the help of the AMA and you guys to
5 make sure that they're getting it right and to make sure that we're going out with the right educational
6 materials. I just think that it's going to take a lot of effort to try to make sure that the RACs are doing that
7 review correctly, and I'm thinking that's not the kind of review I'd like to see happen right off the bat. Let
8 me go through a couple more slides and then I'd be happy to take some more questions.
9 The slide that you see here talks about overpayments versus underpayments, and if you look at the
10 bottom row, you can see that there are a lot more overpayments collected than underpayments repaid. This
11 comes out to be about 96% overpayments, 4% underpayments in the random sample that the CERT
12 contractor pulls, it's around 91% 9%. So although it's not shocking that there are a lot more overpayments
13 than there are underpayments, I believe that the RACs still have a big to work to do to get up to the level
14 that we'd like to see in terms of finding underpayments. I think there are a couple of reasons why their
15 underpayments may be so significantly lower than we would expect from the random sample. Why was it
16 only 4% underpayments? Why didn't they get to 9% underpayments? I think one reason is the very issue
17 we were talking about, the E&M codes being off the table. I think once we put E&M codes back on the
18 table, that's where we see a lot of underpayments on the physician side. The physician is billing for a level
19 2 and it really is a level 3. I also believe that the RACs are very inexperienced at doing underpayment
20 review. They have lots of private contracts on the outside world with other health insurance companies,
21 looking for overpayments, but nobody has ever hired them to look at underpayments before . And they're
22 just not good at it yet, and so any suggestions that you all have about ways that the RACs can find
23 underpayments, we are absolutely open to. The RACs would love to hear about your ideas. They get paid a
24 contingency fee for finding them, so they're very open to any ideas. I will also tell you that you can tell
25 from this chart, that Connelly, who is the New York, Massachusetts RAC, HDI, which is the Florida, South

Carolina RAC, and PRG, the California RAC had relatively similar overpayment collection amounts. If you look at the total of $300, it was basically a third, a third, and a third. But if you look at the underpayment numbers, you can see that some of the RACs did a better job than others at collecting underpayments. They're a pretty competitive breed and I bet that the next bunch of RACs that come out will be looking at this and trying to make sure that they're able to collect more underpayments than their peers.

This is a really important slide. This takes the overpayment collections at $350 some million dollars and it breaks it down by provider type. And you can see here that 88% of the dollars collected were from inpatient hospitals and skilled nursing facilities. And actually, the SNF piece, if you were to break that out separately, is only about 3%, so it turns out to be about 85% inpatient, 3% SNF, and then you can see on the other side of the chart, it's 3% physician. Couple things I want to point out to the physician world here. Obviously, I'm sure that you guys are happy that you're only at 3%, as opposed to the inpatient hospitals who see that their numbers are significantly larger, but when you dig into that inpatient number, you can see that a lot of the inpatient hospital problem is because of very short inpatient stays that should have been outpatient. These are people who are admitted for 24 or 48 hours and based on a review of the medical record, the RAC is determined that it wasn't medically necessary for them to receive their treatment on the inpatient side. Perhaps they needed a little bit of traction or perhaps they needed some IV fluids, but it could have been given on the outpatient side. They did not need to be treated as an inpatient. And a question that I have for you and the AMA and other physician organizations is what is the role of the admitting physician in making that determination about inpatient versus outpatient? When I go and I talk to hospitals, a lot of times they say well we really don't have any control. If the doctor admits the patient, then we bill as an inpatient. And so it's really those doctors that you need to go talk to. It's really them that you need to educate. So I'm really looking for some advice from you and the AMA to help me really figure out what is the role of the physician community in this inpatient versus outpatient world. I see a hand over here.

Dr. Bufalino: I'd be glad to help you with that. You know I think the problem with is the retrospective review. So if you take a case that was admitted last week for 24 hours and discharge looked

like that person went home with not a significant diagnosis. It's easy after the fact to say, ah, that patient shouldn't have been admitted. But when that person arrived in the emergency room with nuance of chest pain or shortness of breath—in fact, one of the examples was somebody with shortness of breath, and they had a normal EKG and a normal chest X-ray, therefore they should have gone home, you know when you're face with the medical legal concerns of discharging that patient home, with an insignificant diagnosis and that patient has a cardiac arrest in the following 24 hours, and dies at home, it puts the burden on the attending staff, the emergency room staff, to screen that patient and try to decide is it real or is it not? And a lot of these turn out to be insignificant case, and so couple days later, it looks like this person shouldn't have been admitted, but at the time, when you're on the firing line, making the decision, it's a lot tougher to say let's let this guy go home today, because we think he's OK, although we're not sure. So it's unfortunately the clinical judgement that you're kind of stuck with as you roll in the door and you're not sure of the complexity. I can tell you a number of those cases that came in with funny pain, atypical symptoms, had a normal EKG, and turned out they have complex heart disease, had a pulmonary embolism, had some something that led them to have a complex diagnosis in the end, but presented with a soft presentation without a lot of findings. So it's pretty hard, and so I think you're going to be challenged to be honest with you, to go backwards because it's easy to second guess after the fact, but going in, it's tough.

Ms. Combs: Do you think that physicians are adequately documenting those cases where they really think the patient needs to be admitted because something is telling them that they might be, further investigation needs to be done?

Dr. Bufalino: Most of the ER physicians in our community are pretty much dictating a pretty significant note on entrance to the Emergency Room and then the attending physician in his history and physical is going to document why that person showed up and why they were uncomfortable sending them home. And many times, it's the judgement call of the ER doc, and you know, I defer to John here, but you know that ER physician's got to make a gut call—is this somebody OK to go home? I mean their biggest

1 liability is sending people home and having them die, or have a catastrophic event in the following 24 to 48
2 hours. And so with the fact that the inability to control torte reform in the United States, we're still
3 burdened with the fact that defensive medicine is costly medicine, and if we were able to take defensive
4 medicine off the table, in the United States, many billions of dollars could be put back in the trust fund—
5 much more than you're saving on the RAC side, but we're still burdened with that care.
6 Dr. Senagore: Yes, even if you took the liability side out of the equation, the other issue is you
7 don't get to bill your differential diagnosis, which may be extensive, and you may exclude all of that over
8 the success of 24 to 36 hours, and so retrospectively it looks like they weren't that sick at all, but you may
9 have a fairly long list of fairly significant diseases that had to be ruled out. You get no credit for that.
10 Ms. Combs: But wouldn't that be documented in the medical record?
11 Dr. Senagore: Maybe, but what that then requires is a complete review of the medical record,
12 because there's no way to identify that without the review of the medical record.
13 Ms. Combs: Yes, and in each one of these instances, these wrong setting issues, where the RAC is
14 looking at medical necessity on the inpatient hospital side, they do have the medical record in front of
15 them, and after the review of the medical record, they determined that the patient could have safely and
16 effectively been treated in the outpatient setting and did not need to be treated in the inpatient setting. So
17 they've got the full medical record that their looking at.
18 Dr. Snow: Yes, and it's a nurse that's looking at it, and not a trained physician who is aware of all
19 of these differential diagnoses that the presenting doc is initially dealing with. And that's a big problem we
20 have, I think usually with nursing staff and other lesser trained personnel, not physicians, reviewing these
21 to make these decisions.
22 Dr. Ouzounian: I'd like a little, help, a little clarification, just so I understand the math to make
23 sure I'm on the right page. I'm seeing the error rate on the provider side, that's facilities and providers in
24 the 3-4% range, am I correct in that?
25 Ms. Combs: That's correct.

1 Dr. Ouzounian: So you talked about a little while about hiring a contractor to look at the RACs
2 work. And you didn't tell us what the RAC's error rate was. What is the RAC's error rate?
3 Ms. Combs: I don't know because we didn't get the RAC validation contractor hired until very
4 late in the game. But once we have a year's worth of data to report, I will make that publicly available. I
5 will report that.
6 Dr. Ouzounian: OK, but if you look at a 3% error rate on the provider side, and if you look at
7 physicians, their error rate is I think exceedingly small, and obviously the RAC needs to be held to a much
8 higher standard, because of what you're doing to the physician community. So I would be very curious to
9 see what that error rate is.
10 Ms. Combs: Sure. I will make that available when we have it.
11 Dr. Ross: I would just like to echo Dr. Bufalino's comments about the, not just the medical legal,
12 but even just last week I had a long discussion with a cardiologist who does invasive work on our diabetic
13 population. When you're looking at the possibilities of a DVT or if you're looking at a possible pulmonary
14 emboli or if you looking at an ischemic leg, to do a procedure in the office may be the easiest way to do it
15 for the patient, but the complication rates go up significantly, and the potential loss of a limb goes up
16 greatly if that patient were not brought into the hospital and had the doplars done and check for DVT and
17 either revascularized or have a plaque removed or whatever needs to be done to save that limb rather than
18 doing the procedure in the office, and then facing the consequences thereafter. I've dealt with that on a
19 number of occasions, have had discussions, and unfortunately, I've been on the back side of it, and wish
20 that I had admitted the patient prior to. So that's a real good case in point, and it's happening to many of the
21 specialties, where we try to do as many in office or outpatient procedures as possible and then have to pick
22 up the pieces thereafter. So I think that's something you need to keep in mind.
23 Plus I just wanted to add one comment, or requestion. Dr. Sniff asked the question on the last
24 meeting about the contingency fees for your group of reviewers. Is that all on contingency, or are there any
25 fees that are being paid of the 77 million that are directly paid, or is it all contingency?

Ms. Combs: The RACs get zero dollars from CMS directly they get budget of nothing. So it is all contingency fee for them.

Dr. Ross: So that 77 million was pure contingency fee—

Ms. Combs: Well, I don't know, did you all get a copy of the RAC status document in your background materials? I'm not sure if that was part of it. This is available on the website, www.cms. I see it right there, what tab is that? I'm sorry. Tab G is where you can find the RAC status document and I will point you to the page that breaks out the cost so you can see exactly how much was contingency fee, how much was, it's page 21 of the 2007 RAC Status Document. Table 4-1 shows that the RAC contingency fees were $71 million, the Medicare claims processing contractor costs, that would be mostly appeals and processing the overpayments and underpayments, $3.9 million, and the RAC evaluation contractor, the RAC validation contractor, the oversight expenditures, came to $2.5 million.

Dr. Ross: So about six and a half million dollars above, the difference. And last statement, Dr. Arradondo mentioned something that I think that was positive about how you can help, and you mentioned about phone calls directly to the practitioners and comparing. How often do you go to medical societies and actually talk about these issues on how they can improve their rate of review and to try to prevent those reviews from taking place?

Ms. Combs: As often as I can and I'm anticipating that as we go nationwide—

Dr. Ross: Sure that's part of the money for your staff and the future, too. That'll keep the business going by the way.

Ms. Combs: I'm guessing that I'm going to get lots more invitations as this begins to roll out nationwide.

Dr. Ross: Right. I think that's a great way of doing it.

Ms. Combs: Thank you very much. Let me take one more question and then I'm going to go back to the slides. Go ahead.

1 Dr. O'Shea: I just have to also concur with Vince that the doctors have real liability. When they're
2 coming into the emergency room, I'm usually getting most of my admits from emergency room doctor, and
3 if they only even respond to the oxygen with this atypical chest pain, you're going to have a non Q-wave
4 MI, so we actually have to look at some 23-hour admits. We know that we have observational codes for
5 that, and not to be too cynical or just to quip, if CMS wants to accept some of the liability when I make the
6 decision, no this is not going to make their acceptable level, and the patient will say I will sue CMS and not
7 my doctor, for making this decision to send me home with non Q-wave MI, then I will be glad to send them
8 home, but until then, I have to assume all responsibility, and again, this is the same patient that I have to see
9 them in the office in 2 or 3 days. When they come in, I can build up the scenario or down, but truly if we
10 could have more examples of what it is that CMS is looking for, because I honestly have a small hospital
11 where we're constantly, especially this year with the flu, been inundated and have no hospital beds, and the
12 criteria, sometimes we can probably be accused of letting a lot of people go home because we had no beds
13 available. So I'd like to see some more concrete examples. But until that time, I feel it is my responsibility
14 and that's where it holds, and I'll probably still go on making mistakes.
15 Ms. Combs; I will do that. I will try to get as many examples as can, both for my future reports
16 and for when I go out to speaking engagements, with all provider types, but especially physicians. Let me
17 take a couple more slides and then we'll go back to some questions. The next slide talks about the types of
18 errors that are found. It's mostly incorrect coding and medical necessity with a little bit of other. Other
19 would include things like duplicate claims, and not very much of a problem with no documentation or
20 insufficient documentation. Couple of the examples; duplicate claims. Physician submits 2 claims for the
21 same beni for the same service and the carrier pays them both and the physician gets paid both. That
22 shouldn't happen. Excessive units, that's like Nulasta, we were talking about earlier. Vestibular function
23 tests. This was an example where the local coverage determination said that the provider should only bill
24 one unit per day, only one unit per day was considered medically necessary and the provider billed for
25 multiple. Multiple surgeries. This is an interesting example. This is where the mistake was made by the

Medicare claims processing contractor. This is a situation where the provider goes in and they do a single operative session, but during that one operative session, they do three things; and the billing rules, the payment rules says that the provider is supposed to get paid 100% for the first one and 50% for the second one and 25% for the third or 50% for the third. But instead the Medicare claims processing contractor paid 100%, 100%, 100%. That's not right. That's an improper payment and a number of those particular situations were found where the provider was submitting on separate claims, but there were situations where all three were on the same claim, and so perhaps there's some provider education that's needed to encourage providers to submit on one claim because it's a little easier to see the picture of what's going on and get it paid correctly, but clearly Medicare claims processing contractor needs to have edits in place to catch that problem in both situations; whether they're all coming in on one claim, or they're coming in on separate claims, the Medicare claims processing contractors need to be applying the payment rules as CMS has laid them out.

Here's what you can expect from CMS over the next couple of slides. The demonstration is coming to a close. December 1 was the last day for medical record requests. February 1 was the deadline for Part B demand letters, and February 15th was the last date for letters to facilities. Those will obviously continue through the process, through the rebuttal process, through the appeals process, and the last day that the RACs in the demonstration program will be around is March the 27th, just a few days from now. The permanent RACs will be starting up soon. We are currently in the procurement process. I hope to be able to make an announcement sometime this spring about who the four new RACs are. And we'll then begin pretty extensive provider outreach in a gradual way.

You can see on this slide which states will be first, which states will be second and which states will be third. Let me start by talking about the A, B, C, and D. Region A will be one RAC. Region B will be a second RAC. Region C will be a third RAC. And region D will be the 4th RAC. And although it looks like some areas are significantly bigger than others, if you take the claim volume, and the dollar amount of those claims, it comes out to be roughly equal. So it's about a quarter, a quarter, a quarter, and a quarter.

Each RAC will have a quarter of the country. And then within each one of the jurisdictions, we have divided it up where some will be starting immediately. This slide says March of 2008. But I think that will actually be probably April or May before the permanent RACs actually begin work. Some states will start up in October 2008, and other states in January 2009. These dates would be the earliest date that a RAC could come to town, but there would be no requirement that the RAC necessarily start work at any particular state. We will leave it up to the RAC to design their strategy for reaching out to the provider communities explaining to the providers, letting the providers see the kinds of letters that are going to be coming, making sure the providers know where to send their medical records, when they get those requests, and so on.

The dates were picked, or the states for each group were picked partly based on where we had RACs in the past, in New York and California and Massachusetts and Florida and South Carolina, and also partly because of our MAC transitions. For example, you can see that California here is not listed as one of the first states to go. Although we thought that we've got a RAC there, the providers understand the RAC program, that would be a perfect place to put a RAC, there's a MAC transition that's going on there. And just like I heard someone talking about earlier how it's really hard when a provider has multiple transitions happening at once, our goal is to try to keep things as clear and clean as possible from the provider's perspective and so when a MAC is getting ready to start, we would like the RAC to not be there for 3 months before and 3 months after. Given that, our procurement timelines may change in the RAC program and the MAC procurement timelines and start-up and strategy dates may change, all the dates on this calendar and all the colors on this map, may change. It all just depends on where we are with our procurements and where they are with the MAC transitions. This particular map is posted to our website and I would anticipate that anyone who wants to follow this program closely check the website every couple of months to watch on the changes.

This is an important slide. I'm going to take a minute on this one. These are the lessons that we learned from our demonstration program, and the changes that we're making to the permanent program,

1 going forward. The first one talks about the look back period. In the demonstration, there was a four-year
2 look back period. RACs could look back 4 years from the time that the claim was paid. In the future
3 permanent program, that will only be a 3-year look back period, so when they start up in say April of 2008,
4 they will be able to look back to all the claims that have a claims processing date within 3 years of that
5 date, except that the next line says that there's a maximum look back date. In the demonstration program,
6 we did not have a maximum look back date. When the RAC started, they were able to look at the full 4
7 years. In our new permanent program, there will be a maximum look back date of October 1, 2007. So
8 when the RACs first start this spring, they will only be able to look back as far as 10-1-07 and as,
9 obviously, the time moves forward, that 6-month period becomes a 9-month period, becomes a year, 2
10 years, 3 years, but then it will never be any more than 3 years.
11 The next row talks about whether or not the RACs are allowed to look at the current fiscal year
12 claims. They were not allowed to look at current fiscal year claims in the demonstration program. We were
13 worried about 2 different review entities reviewing the same kinds of claims. We feel like we have the right
14 system in place to prevent those kinds of situations from happening. We've got a data base that all of our
15 review entities have to feed their data into to make sure that we don't have the RACs reviewing a claim that
16 CERT is looking at, or the RAC reviewing a claim that a PSC is looking at. And so we feel like, we feel
17 pretty comfortable with allowing them to review current fiscal year claims. That also provides more current
18 data so that we can see where providers are making mistakes and where claims processing contractors are
19 still making mistakes. The next one talks about medical director and coding experts. Both of them were
20 optional under the demonstration RAC program, although each one of the RACs chose to hire certified
21 coding experts and medical directors. But it will be mandatory under our permanent RAC program.
22 Medical record limit per month or per 45 days was optional and set by each one of the RACs so it varied
23 from RAC to RAC, and we learned that that didn't work out so well under the demonstration program, and
24 we've decided that it will be mandatory. It will be set by CMS and it will be a sliding scale, based on size.
25 We think that whatever number we might pick for a 700-bed hospital is different than what would be the

1 right number for a solo practice physician's office. And so the next time I come and talk to you I'm sure I
2 will have a slide to talk about what the medical record limit will be for providers in the RAC program. A
3 discussion with the RAC medical director, regarding the claim denials. That was optional under the
4 demonstration program. But will be mandatory under the permanent program. Some of the issues that
5 we've been talking about today are some of those clinical judgment issues, and we think it's important for
6 providers to know that they can have a dialog with the physician at the RAC about how decisions got made.
7 Vulnerability reporting, that's what we call when the RAC has a particular problem area, like I discussed in
8 a couple of the examples, with multiple surgeries or with Nulasta, it was fairly limited vulnerability
9 reporting and it happened at the end of the year. It will be mandatory going forward and it will be much
10 more frequent. We feel like we need to get the data out of the RAC as quickly as possible so we can feed it
11 back to the providers and the claims processing contractors, so the providers can submit claims correctly
12 and claims processing contractors can process claims correctly.
13 The next one is that the RAC must pay back their contingency fee if the claim is overturned at the
14 first level of appeals. That's what happened in the RAC demonstration program. We got a lot of negative
15 feelings from providers that that wasn't fair and that we should extend that to all levels of review, and we
16 have decided to do that under the permanent program. We felt like we really couldn't under the
17 demonstration program because as you know, to get into the second level, and then the ALJ review process,
18 often times takes years and it was only a 3-year demonstration, so during the demonstration program we
19 limited it to paying back the contingency fee only for overturns at first level of appeal. It will be all levels
20 of appeal going forward.
21 The next one is a web-based application that will allow providers to see the status of their cases.
22 We had no such thing under the demonstration program, but we think it's really important going forward to
23 have that in place. It will be mandatory that each RAC develop this website, and it has to be up by January
24 1st, 2010. We anticipate that the RACs will bring it up slowly and sooner than that. It may not be fully
25 functional until 2010, but we think that some information will be up by 2010. You heard Dr. Rogers talk

earlier today about how PRIT is struggling with a provider who gets a notice and they can't associate it with the original claim. We hope that this kind of website will make that easier. Providers will be able to look up information to see OK, this letter, what exact claim numbers is it associated with? And the last one is the validation process. That's what I talked earlier about. Having a contractor look over the shoulder of the RACs to make sure that they are making accurate determinations. We had an optional program that varied by state until the very end of the RAC demonstration program, and going forward, it will be a mandatory program and it will be uniform.

So again, just to recap, the goal is to move from 5 states to 50 states, by 2010 and to do it gradually. The procurement process is underway and we anticipate announcing the four permanent RACs in the spring of '08. CMS is dedicated to making more RAC information available on websites sooner. We think that the kind of information that you guys are asking for—these specific examples—are important, and need to be provided rather than once a year in a report. They need to be available on a website, at least quarterly. And I think we'd like to get to the place where we could make them available on a monthly basis. I anticipate that it will be 4 separate websites, one for each RAC. But I will work very closely with them to coordinate them and make sure that they are presented in a similar way, and that similar data is presented so that people can make sense of it.

We encourage providers who are contacted by a RAC to name a point of contact that helps to minimize the documentation denials and sometimes we have calls with provider organizations or individual providers, and it allows them an opportunity to participate in those calls. In addition, we really encourage each provider to use the RAC information, look at the denials that they're getting back and figure out where they're making mistakes and where they can submit claims more correctly going forward.

And here is Connie Leonard's address. Isn't it nice that I get to come and talk, but she gets all the follow up email and questions. Any further questions on the RAC program?

Dr. O'Shea: I wanted to know where Alaska was located, and I'm going back to slide 20. Alaska and Hawaii got put together there and I didn't know if it's C or D.

1 Ms. Combs: I am pretty sure that Alaska and Hawaii are both in region D. And Alaska is the dark
2 color that will start in January 2009 or later, and Hawaii—is that striped? They're both in D, is it striped?
3 Yes. Hawaii is striped. So it will go October '08 or later.
4 Dr. Azocar: Once the permanent RACs are implemented, will that process of all the carriers to the
5 present, will that continue?
6 Ms. Combs: I'm sorry, will what continue?
7 Dr. Azocar: The regular carriers do, some of the—
8 Ms. Combs: Yes, all of the—the RACs are not going to be replacing the Medicare claims
9 processing contractors. The regular Medicare claims processing contractors will continue to be in place.
10 The carriers, the FIs the MACs. It is true that the MAC strategy, the Medicare Administrative Contractor
11 strategy, is to replace all the carriers and FIs over the next few years with MACs, Medicare Administrative
12 Contractors. But that is totally separate than the RAC program. The RACs do not receive claims from
13 providers. They don't process claims and issue payments to providers. They don't do provider education.
14 They don't do enrollment stuff. They don't process appeals. That's all the stuff that our carriers, FIs, and
15 MACs do.
16 Dr. Siff: Back to the issue of the improper inpatient hospital payments, I concur with what Dr.
17 Bufalino said, however, the issue is not just should they stay or should they go? The issue becomes the
18 issue that observation admissions are considered outpatient treatment whereas an admission is an inpatient
19 treatment, and the decision under rule, for billing, is that the provider with the patient has to make that
20 decision. In many community hospitals, that may be the physician who's going to take care of him. Dr.
21 Bufalino may come in and see his patient and make the decision. In many academic centers and larger
22 hospitals, however, that physician's not there, the emergency physician will admit to their service, and we
23 have to make a judgement, and if I knew everything Dr. Bufalino did about chest inpatient, I wouldn't need
24 him. I'd be a cardiologist. So I have to make an estimation based on my clinical experience and my clinical
25 knowledge of what that status should be. And we can have a much longer discussion off line, but this is a

1 huge problem for both hospitals and emergency physicians, in determining the status, dealing with the
2 numerous regulations and rules that go around determining should it be an inpatient admission or should it
3 be an observation admission, in other words, outpatient? The confusion of just the terminology alone is
4 enough to flummox many providers. And then the rule of who needs to make that decision is also very
5 confusing, and I can explain it to you in much more detail off line.
6 Ms. Combs: Thank you. I hope that you will drop your card off with me, and we'll have a
7 conversation so that I can make sure I completely understand that issue. And CMS is always open to if
8 there are places where our policies are unclear or where providers need to be reminded of our policies,
9 where I will certainly take it back to the right people at CMS and see—I know that observation has been an
10 issue for a number of years, the QIOs have talked about that as a problem. They have struggled with it over
11 the years, and so it's certainly one that I would love to get any information that I can about how to solve
12 that problem.
13 Dr. Senagore: Thank you Ms. Combs. Any recommendations based on this? Dr. Sprang?
14 Dr. Sprang: I'm kind of, it's been repeated a couple of times, but especially when somebody's in
15 the ER or has a different issue as to whether they get admitted, it's been said but it bears repeating, if we
16 could actually have significant torte reform and takes the pressure off physicians, you could probably save
17 about 20% of the healthcare dollar, both for Medicare for everybody else, and I know only Congress can do
18 that, and I know it's a major issue, but recognizing the actual money that could be saved, would be very,
19 very impressive. You mentioned you were at the AMA a couple of times, you're using them for coding.
20 You know, there's also some letters being looked at as far as letter that would go out to physicians,
21 requesting information. Is that being bounced off the medical community through the AMA as well?
22 Ms. Combs: Yes, and the AMA has been really good at making themselves available when we
23 have questions, when we don't understand something in the CPT codes, and we really appreciate their
24 being available as a resource to us. I'm sure that our reliance on them will increase as we go from 30 states
25 to 50 states. I'm sure there's going to be a big increase in the number of issues that we need to take to them,

1 but we really do appreciate their involvement. In addition, they were very helpful at reviewing some of the
2 letters that the RACs had planned on issuing, and making sure that we had those worded in a way that
3 would make most sense to physicians.
4 Dr. Sprang: Yes. I was going to make a recommendation to that affect, but you're already doing
5 that, so that's not an issue. You mentioned putting some things on line. I wasn't sure exactly what
6 information you were talking about putting on line.
7 Ms. Combs: We want to put on line a list of the issues that the RAC is reviewing. I'll call them
8 audit areas or vulnerabilities; places where they are finding improper payments. Obviously we don't need
9 to know about the $10 problems, but when it gets to half a million dollars or a million dollars, that's
10 something that we need to let people know about and so we would like to list those on the website and
11 where possible have a link to the Medicare rule or the manual or the LCD, the citation for why that, what a
12 provider can do to prevent those improper payments or what the Medicare contractor needs to do
13 differently. In addition, we would like to put individual cases. Every single time a request for a medical
14 record goes out to a provider, they should be able to go look on the website and see the status. Did they
15 receive my medical record? When did they receive my medical record? Have they reviewed my medical
16 record? What was their determination on my medical record? I don't think that is going to be up overnight,
17 but that is the goal, to have in place by 2010.
18 Dr. Sprang: OK. Clearly, as pointed out if you can educate physicians, prevention is the best step
19 here and if physicians had access to an easily understandable format of up to date issues, it would help both
20 transparency, and obviously their education and make your job easier.
21 Ms. Combs: I agree. Thank you.
22 Dr. Senagore: If nothing more, I have a couple recommendations. And if anyone else does, we can
23 get those and take a quick break, thank you Ms. Combs. First one is that PPAC recommends that CMS
24 make available the specific rules for evaluating E&M codes for subsequent RAC audits, with specific

1 attention to definitions of the components of history, physical exam, and medical decision making, and
2 whether the 95 and/or 97 rules will apply.
3 [seconds]
4 Dr. Senagore: Did you get all that Dana? OK. I tried to go slow. Dr. Ouzounian seconded. Any
5 discussion?
6 Dr. Sprang: I guess the only question is my understanding at least from the AMA is right now you
7 can use 95 or 97, do you want to say either?
8 Dr. Senagore: I said and, I believe I said and/or because we should know which ones should be in
9 play. I just want a definition of it's both either—neither.
10 Dr. Sprang: Hopefully either one of them will be accepted.
11 Dr. Senagore: I think that was consistent with that I asked, but it would be helpful to define that
12 for use. All in favor, say Ay.
13 [Ays]
14 Dr. Senagore: All against? Then the second one is, PPAC recommends that CMS report back to
15 this Council with a reasonably detailed analysis of data regarding the RAC audits and the RAC
16 performance to refine claim identification, based upon unique and specific practice patterns, and to provide
17 educational materials to improve physician documentation and coding, to improve the accuracy of claims
18 submission.
19 [second]
20 Dr. Senagore: There's a second. Any discussion? All in favor say Ay.
21 [Ays]
22 Dr. Senagore: All against? Thank you and we will stand adjourned until 11:15. Thank you.
23 Break
24 Dr. Senagore: We have most of the folks back? We're missing a few people. It looks like we have
25 a quorum. I'd like to welcome Dr. Michael Rapp back, who is our presenter regarding the Hospital

Measure, Physician Quality Reporting. He is the Director of the Quality Measurement and Health Assessment Group at the Centers for Medicare and Medicaid Services. Dr. Rapp is an emergency physician and was an active clinical practice until taking this position with CMS. Folks, we're going to go ahead and start if I could, thank you. Dr. Ross. Until recently he was a member of the George Washington University Medical Faculty Associates. Welcome, Dr. Rapp.

Hospital Measures, Physician & Quality

Dr. Rapp: Thank you, Dr. Senagore. I'm going to address a couple of things today. First of all, I'm going to talk about the Physician Quality Reporting Initiative and where we are, and I know that the last time there were some questions about the Outpatient Prospective Payment System measures and how those were emergency department measures and where they might fit in. So I'll try to talk about both of those today. So just by way of background in general, of course the PQRI is part of the value-based purchasing initiative of the agency, trying to move Medicare from a passive payer to an active purchaser and focusing on value. The paying for better quality is one of the Secretary's four cornerstones of the healthcare system. So financial incentives for better quality, public reporting of quality and cost information, and interoperable health IT, all of those you'll find part of the PQRI.

So just by way of background and to update you, the Physician Quality Reporting Initiative derives from the TRSHA statute passed by Congress in December of 2006. Before that, we had a voluntary reporting program, the Physician Voluntary Reporting Program for which there was no incentive payment to submit quality data, but in December of 2006, Congress passed the Tax Relief and Health Care Act and provided for a incentive payment of 1.5% for a 6-month period for part B physician services, and other nonphysician professionals and therapists. And so in 2007, we went from 16 measures in the voluntary program to some 74 measures. These measures are consensus developed, or endorsed. They apply to specialty categories that cover over 95% of physician part B services. They are applicable to the services rendered; they're not specialty specific measures, so depending on whether the measures apply to a physician will depend on what services they give, and the measures are all posted at the

1 CMS.HHS.GOV/PQRI website. You'll find a lot of information there about the PQRI program, including
2 the statute, the regulations, information, detail specification of the measures, and a lot of other supporting
3 information. So I would urge you if you are interested in some of the details, you'll find probably more
4 than you're interested in there, but we try to put everything there about the program.
5 So, that was 2007. Recently, we released some information about the participation rate in the
6 PQRI for 2007 that people are interested in, which is preliminary information and the rough figures are
7 about 16% of physicians submitted at least one quality data code as part of the program. And you might
8 say, well, what does that mean, 16%? Well, it is certainly not 100%, but it is a substantial number of
9 physicians that sought to participate in it. If we look back to other incentives, such as participating
10 physicians in the Medicare program itself, early on, that's the kind of figure that we were talking about. But
11 today we have 95% of physicians that are participating physicians for payment purposes in the Medicare
12 program. So it is a substantial participation rate. Obviously, we're interested in increasing that for the
13 future. So let's now go to PQRI for 2008. There were the 2007 measures were incorporated by reference in
14 the statute itself. So CMS is part of the Physician Voluntary Reporting Program, had posted a number of
15 measures for 2007, for a voluntary program, but Congress, seeing that, and deciding that they wanted to
16 incentivized participation, went ahead and incorporated by reference, those measures and those were what
17 were used for 2007. But in 2008, we were required to go through a rule making or regulatory process to
18 propose those measures give an opportunity for public feedback and comment on the measures. As long as
19 these measures did meet certain specifications, and then based upon the feedback that we got, then we
20 finalized a set of measures. So the statutory requirements for the measures are first that they have to be
21 adopted or endorsed by a consensus organization such as the AQA Alliance or the National Qualify Forum,
22 so what that means to physicians is that these are not measures that CMS just decides this is what doctors
23 should be doing. They are part of a consensus process that physicians are actively engaged in and only if
24 they are adopted by the AQA or endorsed by the National Quality Forum, are we authorized by statute to

1 use them. We then propose them as I mentioned, through the rulemaking process, and get feedback, and so
2 based upon the comments, then we include them or don't include them in the list of measures.
3 The statute required that the measures have to include those submitted by a physician specialty
4 and so we made note of that in our rulemaking, but most of the measures that we included in the PQRI for
5 2008 were actually developed by the AMA Physician Consortium; not all of them, but most of them, and as
6 you know how that works, there are specialty organizations which form the work group for various
7 measures, depending on what the consortium is working on. The measures have to have been developed
8 through a consensus based process, which we interpreted to mean they have to have gotten to the point of
9 endorsement or adoption by the AQA or NQF, and we were required to include structural measures, such as
10 the use of electronic health records, or eprescribing technology, and we did include and I'll talk a little bit
11 more about that, later on, in detail, we did include two structural measures on those two points. And then
12 finally, Congress was very interested in registry-based reporting. And said that we must address registry-
13 based reporting. And I'll get to that a little bit more in detail, but just in general, the philosophy here is that,
14 and what we had to do with PQRI and as you know, it's a claims based submission process. When we were
15 trying to figure out how it would be that we could get physicians to report quality data, there were some
16 options. One option would be EHRs, but of course most physicians don't have EHRs. Another possibility
17 would be chart abstracted data. That's what we require the hospitals to do. They have people go through the
18 medical records and mine the data there and then submit that to us. That would be very burdensome to the
19 physicians we felt. So we were basically left with a claims based submission method which I think does
20 work pretty well. And are based upon CPT 2 codes and physicians can just submit those codes along with
21 their bills. So it does work pretty well, but on the other hand, there are some definite negatives to that. One
22 of course, is it's just Medicare only data. And in all of our other quality reporting programs, we seek to
23 have the overall practice of that particular provider. So for hospitals for example, the hospital compare,
24 that's all patient data. It's not just Medicare patients. And the home health, and the nursing home, all of
25 those are like that, but in our PQRI just because it's claims based process, then of course it can only be a

Medicare data. So how do you deal with that? Well the registry based reporting is potentially a way of doing that, plus physicians submit data for a lot of purposes so Congress is definitely very interested in this and put in the statute right at the beginning that we were to address that, and so many physicians, for example, the Society for Thoracic Surgery has a registry, and if the physicians are already submitting to that, or some other registry, if we take it from the registry, then we don't cause them to duplicate work. So we're very enthusiastic about registries in general, and we were to address that, which I'll talk about.

So for PQRI for 2008, first of all the reporting period if different. It's January 1 to December 31st, 2008. So for 2007, it was just a 6-month reporting period, and the reporting period is important for 2 reasons; one it tells you when you need to deal with the data submission, but secondly, it's the period of time for which the services that you're going to get the incentive applies. So for 2007, there's only 6 months reporting period, but the 1.5% incentive only applied for 6 months of services. For 2008, there's a year long reporting period, but the incentive applies for the whole year. For 2008, we have 119 measures as I mentioned, including 2 structural and over 95% of Medicare part B spending applies to it. So going to the structural measures, I think these are important for a couple of reasons. One, they encourage the use of these electronic modalities, the EHR the first one, we see listed here, what the parameters there are. You see reference to the CCHIT certification, or CCHIT certified EMR, which is the commission that does that. Currently, not large numbers of such systems are certified especially for specialties, and so we did not require to comply with this measure that you have an EHR that's actually CCHIT certified. If it's not, however, it had to be capable of doing several things; generating medication lists, generating a problem list, entering laboratory tests as discreet searchable data elements. But this is a structural measure and it has the same status as any other of the clinical measures and the thing to remember here is sometimes the doctors say well, I don't have any measures that apply to me. If that's true, if the clinical measures, if there are none that apply to you, the structural measures have general applicability. And EHR of course, probably 1.5% is not going to be sufficient to get a physician to get an EHR because of the cost, but if you have one, it'll do a couple of things; one it will help you to qualify for the incentive payment, and as I'll discuss in a

1 moment, in the near future, it would be a mechanism whereby you could submit your measures as well. The
2 second structural measure was eprescribing, and again, on the eprescribing side, this is a little different than
3 the EHR which is quite costly to put in your office, but eprescribing, on the other hand, I understand that
4 there are actually free systems that you could take advantage of, so the cost, incremental cost to a physician
5 of adopting eprescribing is not great. And in this case, there are some particularities as to what the
6 eprescribing has to do, including generation medication list, selecting medications, printing prescriptions,
7 or transmitting them, sometimes DEA prescriptions require narcotics numbers—there can't be eprescribing,
8 and conducting safety checks. So again, if you are in a situation where none of the clinical measures apply
9 to you, this would be, and you report on this particular measure, that would be sufficient to get the 1.5%
10 incentive payment. If on the other hand, there are measures that apply to you then you would need to report
11 those. There's a requirement to report 3 measures, but some physicians, we do have a few, that perhaps
12 they wouldn't have a measure that applies to them.
13 And then moving on to the registry based reporting, the way we addressed registry based reporting
14 is we indicated that we would test 2 mechanisms of registry based reporting, and have the registries report
15 the data to a clinical warehouse, and then we also indicated that we were going to test electronic health
16 record based reporting. So there are 5 measures specifically. There are 3 diabetes measures, coronary artery
17 disease measure, and another one, a 5th measure that we've posted specifications for electronic health
18 record based reporting, so we did that at the end of last year, actually. So this is going to be tested this year.
19 So these are primary care, chronic care kind of conditions so for your average office-based internist or
20 family doctor or others that deal with these chronic conditions, diabetes in particular, that would be enough,
21 if you have an E HR system that you could report enough measures to qualify for the incentive payment,
22 without having to deal with the claims based system, that I once we implement that. So that's not
23 implemented for 2008. It's something we're testing, but we would anticipate implementing that in 2009.
24 So I indicated the two options that we're going to test for the registries. There are the two that
25 we're going to test is one, where the registry would submit the basic data and we would calculate the

1 performance results. And the second option that we're going to test is where the registry calculates the
2 performance results and just submits them to us. So that's one of course, involves a lot more infrastructure
3 on the part of CMS, which is if we get the data and we calculate it, that's a big infrastructure. If we, on the
4 other hand, take the performance results directly from the registry, then it's less burdensome to our
5 infrastructure, and takes advantage of what the registry is doing anyway. So we'll test both of those, see
6 how they work. Matter of fact, today, there's a meeting going on in Baltimore, where the registries that
7 have been selected and we do have those registries posted on our website, who's participating in that, and
8 also for E HR. But there's a meeting going on in Baltimore, where they have come together to start with the
9 details of this testing process. So we're going to do that during the course of this year. But Congress is even
10 more interested in the registries than they indicated in the first TRSHA statute. And I'll talk about that in a
11 second here, but in the Medicare and Medicaid SCHP Extension Act, signed in December of 2007, there
12 made some modifications to the PQRI program; one, the measure cap was eliminated. So you may
13 remember that before you got 1.5% up to a cap, and there was a calculation of a certain amount of money
14 per measure. That was a little hard to figure out for doctors I think, in first place, and second of all, the
15 1.5% wouldn't be expected to be that much anyway, so Congress eliminated that per measure cap, so you
16 don't have to be concerned about that in particular for 2008. But in addition, Congress gave us some
17 additional authorities and not only, authority is one way to put it, but I would say instruction would be
18 another way to put it. And that has to do with 2 things. One is groups of measures and registry based
19 reporting and Congress required us during 2008, to establish alternative criteria for satisfactory reporting,
20 and establish alternative reporting periods for both groups of measures and registry based reporting. So you
21 heard me just talk about how for 2007, we were to address registry based reporting and we did by saying
22 we would test it. But now, Congress came to us in December and said not only test, that's fine that you're
23 going to test it, but also establish alternative criteria for satisfactory reporting and establish alternative
24 reporting periods for 2008, and 2009. So that means that in the not too distant future, we're going to need to
25 set forth what that will mean. In other words, so alternative reporting periods means that it could be

1 something other than January 1 to December 31st. Alternative criteria could mean something different than
2 3 measures or 80% of 3 measures, for example. So we have to figure out what exactly we're going to do. I
3 mean we have some definite ideas, but we haven't set forth what that's going to be but you'll, it won't be
4 through a rulemaking process, because it wouldn't be possible to really work through that, so we're just
5 going to have to establish through program instruction what that would mean. But the bottom line is that
6 sometime during this year, we're going to need to provide that physicians can submit and get their
7 incentive payment for registry based reporting. The second issue that Congress put in here was regarding
8 groups of measures. So what that would mean would be for example, and we have some possible measures
9 groups listed here, diabetes. We have several measures that deal with diabetes. We have several measures
10 that deal with preventive care, chronic kidney disease, and end stage renal disease, so these are conditions
11 that we could bring together a group of measures and the physician would report just on that group of
12 measures, but perhaps have a different method of reporting. For example, NCQA has a system where they
13 have physicians report on a certain number of consecutive patients. And so that would be a possibility that
14 we could establish that for a group of measures, that would be alternate reporting criteria; physicians could
15 report on a consecutive number of patients that have diabetes; report on all the measures for the diabetes
16 and once they've done that then they would qualify for their payment. So these are again, possible
17 measures groups that are under consideration, which would be a way of implementing what Congress said
18 we need to implement in 2008, which is reporting on groups of measures.
19 So reporting on groups of measures could be done either through the claims based process or
20 through the registry based process as well. So again in summary, for 2007, PQRI used a claims based
21 submission process with broad participation and we had significant expansion of measures from 74 to 119
22 for 2008, plus the addition of the structural measures. For 2008 as I've just discussed, we're required to
23 initiate measures, groups, as a reporting, registry based reporting. We are interested of course in expanding
24 PQRI participation, even though it was a very substantial participation, obviously the goal would be to have
25 broader participation and we will have to engage in 2008 through another rulemaking process, just like we

1 did last year for new measures. Now one of the things that I wanted to address was how the rulemaking
2 process works.
3 When the statute says we have to propose the measures by August 15, 2008, which is what it
4 required last year, but the way the rulemaking process works, you have to get, if you have to propose
5 something on August 15th, especially if you're going to actually propose it on July 1st, which is the way we
6 did last year, which was part of the physician payment rule, you have to get busy and have it ready to go
7 and go through quite a variety of clearance processes before it actually gets posted. So we did put a notice
8 on our website to indicate, and sometimes people get the idea well, we'll wait until that's proposed and
9 suggest a totally different measure, and that's not how the notice and comment rulemaking works. We
10 propose the measures, and then you comment on the ones that we have suggested. So we would encourage
11 interested parties to suggest measures to us that they would like us to use, and we've invited and have that
12 notice on our website for you to submit any measures that you would be interested in us using and
13 considering for proposal for 2009, in our 2008 rulemaking and get that to us by the 21st of March. That
14 sounds early but that gives you an indication of when we have to have things for us to really fully consider
15 them for inclusion in the rule. So I know there are a lot of people that have some ideas about measures.
16 They do have to meet the basic requirements that I've mentioned, which they have to be NQF endorsed or
17 AQA adopted, so it can't be just a measure that it doesn't rise to that level of consensus, but there are quite
18 a number of measures out there that might be available for inclusion in the 2009 program.
19 So finally, I did put a few issues for PPAC consideration; which is one, the basic goal, as I
20 mentioned, of expanding participation in PQRI, I'd be interested in what your thoughts might be and how
21 we might be able to expand that; what are the impediments to participation by the physicians? I'd like, be
22 interested in what your feedback is on the registry based reporting. As I mentioned, Congress is pretty
23 enthusiastic about that, as an alternative to claims based reporting, as are we, but I'd be interested in the
24 feedback of the Council, and finally measures, groups, one of the things about the requirements currently is
25 the physicians have to only report 3 measures and 80% of the time. But there's no consistency or pattern to

1 that. If you think about a program where you're trying to measure quality and especially if you're thinking
2 about trying to compare quality among providers, that sort of, if you have 20 measures that might apply to
3 primary care physicians or physicians doing chronic care, then one takes one measure, one set of three, and
4 one takes another set of three. There's no rhyme or reason to that and it's hard to do anything more than to
5 say well we've got the doctors to submit some measures. And to get where one wants to go, with value
6 based purchasing, you have to not only have people submitting measures, but you have to have measures
7 that you can compare, measures that you can then incentivized, over time and of course public reporting is
8 something that's always part and parcel of that as well. So the measures groups by having doctors perhaps
9 only submit measures for diabetes, at least if the doctor picked out diabetes as a particular condition that
10 they were focused on and they reported a set of measures dealing with diabetes, rather than one diabetes
11 measure and one heart failure measure, and one coronary artery disease measure, it does seem that that
12 might be something that would promote where we'd want to get to. But I'd be interested in your comments
13 and feedback there. And but before we get to that, I do want to just address an issue that was brought up, I
14 think at the last PPAC meeting, and that has to do with outpatient measures. I don't have any slides on
15 these, but the Outpatient Prospective Payment Program, as I mentioned, we have a hospital inpatient
16 quality reporting program that's gone for several years, but last year, we initiated the outpatient hospital
17 reporting program. And Congress put that in as part of the TRSHA statute so there was a great need to
18 move rapidly to be able to get that implemented in less than a year, which we were able to do and there are
19 a 7 outpatient measures that we included in there. Five of them have to do with emergency department and
20 having to do with patients that are transferred from the emergency department. And then two additional
21 outpatient measures are the surgical care infection prevention measures, prophylactic antibiotics that are
22 done, used for surgery in the outpatient setting. So it's the same basic measures for the inpatient setting for
23 surgery that's done in the outpatient setting. So with regard to the five emergency department transfer
24 measures, they do overlap in 3 instances with the inpatient measures, which are fibrinolitic therapy within
25 30 minutes of ED arrival, median time to transfer for primary PCI, and aspirin at arrival in the emergency

department. The only difference between those measures in the outpatient setting and the inpatient setting is an exclusion for patients that are transferred as removed from the inpatient measure. So it's designed to capture care rendered by hospitals that don't necessarily admit them for those kind of conditions. Rural hospitals, in particular, if they're going to transfer them for PCI, the time to transfer is pertinent. Aspirin is still pertinent, and the fibrinolitic therapy within 30 minutes of arrival, and so it just removes the exclusion for transferred patients. So for the inpatients, there's an exclusion for that. And then there are 2 other measures that are just for the outpatient setting; the median time to fibrinollize and the median time to the ECG. So I just wanted to kind of go over those briefly. I know that there was some question last time. I'm not quite sure what the issue was but I wanted at least to go over those. It is an example of how we try to have overlap of measures in all the various quality measurement settings, so for example, the aspirin on arrival to the emergency department we have as an outpatient measures, we have an inpatient measure, and we have it in the PQRI program as well rather than just have measures that are in only particular settings. So any rate, I wanted to cover that. And so now I'll leave it to you to pose any questions you might have, or comments, criticisms, feedback.

Dr. Senagore: Are there questions for Dr. Rapp? Dr. Jordon?

Dr. Jordon: I participated in the process last year, and I'm reporting on the vision codes, which were glaucoma, diabetes, diabetic retinopathy, communication with other providers, cataracts, macular edema, and measure of axial length. Now, as of January 1, a few of these got deleted, and more were added in, so all the sudden it's a relearning process, and being that I'm involved on this committee, and at the level I am on my national association, I feel pretty darn comfortable knowing what is going on; what's changing and how to actually code these. Now I did get a hold of the preliminary report on the PQRIs, and if I'm reading my state right, I'm from Wyoming, very, very rural, I'm going to throw you some numbers out, see what you guys think. There was a possible of 1100 plus providers who were eligible for file. 112 filed. Of those 112, 12 were successful. Now my office, there are 4 of us in it, and I educated my other three partners, I thought, quite well. So if this is correct, I could possibly be 1/3 of all successful

practitioners in the state of Wyoming, which is really very, very unfortunate. I know of what you guys are trying to do. [laughter] Now I'm going to comment on EHRs a little bit later on when that comes up, but we are putting into place EHRs, which the way our software works, and I'm sure most of them do, I think that may make it a little bit easier for an office to maybe comply by using the EHRs and having the CPT 2 codes already there. But looking as I've traveled the state and talked a little bit too, with some of the other practitioners in my profession, which is optometry, I mean there's an apathy there, first of all. There's a second of I think total uncertainty and ignorance of what the process is and even how to do it, and this year, with the addition of extra codes, especially that we can deal with as far as our profession, I think there's total. They don't know what to do, how to do it, and on who to do it. And so that's as far as the participation level, I think it's how much time, how much complication is involved, and all the sudden you're changing again, quickly. We had 6 months of OK, let's learn how to do it, all the sudden we're into another year, and it's redone again, and then next year does it get redone? Next then, would be as far as the state, the people that were the 112 that did file, thinking oh, I was successful, I'll be getting my check come this summer, and they're also filing this year, too, come the summer, and nothing happens, do those other 90 say I tried, I'm done, and again, the participation level even goes down more. So there's, I think a lot of scenarios here that need to be addressed and I don't know if you have any just rough, rough summary of the, I know it was only through November, but I was just kind of looking at, and if I read mine right, I'm hoping the rest of the country wasn't quite as bad as the state of Wyoming was.

Dr. Rapp: Well I wouldn't want to say the state of Wyoming is bad in any way, but the overall participation as I mentioned was about 16%, so some of the issues that you raised I think are certainly legitimate. I can understand with regard to the measures that you're talking about, there was a rapid development of quality measures. The kind of gold standard for consensus is NQF endorsement. The AQA is another consensus mechanism but it is not as strict and not as rigorous a process as the NQF, so the position that we adopted was if a measure is specifically considered by NQF, and turned down for endorsement, then we don't include it thereafter, even though we previously did it based upon AQA

adoption, so that's what you're running into with some of those measures. But the part about having stability in the measures; obviously, that's important. And stability in the program itself. I think when it first start, it was 6 months, and there was no necessary assumption that it would continue. So now at least Congress went back and sort of reiterated its support for the program for 2008 and 2009, and I would expect them in assuming that there's some more Medicare legislation that they might address this more definitively. But I think that's definitely an important fact. And I'm encouraged what you say about the E HR and hopefully that will be a way of making things easier. But I am hopeful that you'll continue to encourage your colleagues to participate because I think that is a big part of it. CMS can do a certain amount to encourage participation, the things we can do is make the program stable, make it easy to submit information and give you information about the program, and I think you'll find on the website there's a tremendous amount of information, but basically right now, the physicians or other practitioners just have to pick 3 measures. So they don't have to submit all of them. They just have to pick 3, and that's generally what we saw the participating physicians did seek to submit information, they submitted on about 3 measures. So even though they might have 10 that applied to them, they picked 3 and just consistently do that. So if you're going to give some advice to your fellow practitioners, that would be it: Pick the 3 measures that you want to deal with and submit those.

Dr. Senagore: I'd like to speak to the construct of data bases. I think that if you look at quality improvement projects in industry, they rely far more on that kind of detailed information about outcomes rather than process. They obviously alter processes based on the outcomes, and I think in this country, STS probably has the most robust, Nisquip is trying to catch up, but if you look at some of the specific process measures, it's unclear if they are at least neutral, let alone negative in terms of patient outcome and just to say a couple of examples; the core measure of 4 hours to antibiotics for pneumonia, current data in this country is 35% of people who receive antibiotics in 4 hours don't actually have pneumonia. So now you have a rate of C. Difficile colitus for one shot exposure to antibiotics. And it's not clear that 4 hours is different than 5 hours in terms of mortality from pneumonia. You look at the recent paper in JAMA about

1 administration of epo medication for anemia in oncology patients; 10% increase in mortality from their
2 tumor, even though that's one of the reported core measures for correction of anemia. I would submit that
3 that's not beneficial to patient outcome. So the access to data like robust data bases and STS to their credit
4 took a huge financial risk to develop this data up front, to provide the information, will provide far more
5 robust guidance on how to practice, rather than these isolated independent process measures that have
6 never been vetted in ongoing trials. I think that there's significant risk; the recent study that was terminated,
7 the Accord Trial, for hyperglycemic management in Diabetics. They had looked at 7.5 versus 6 for
8 hemoglobin A1C, dramatically increased cardiac mortality in the more aggressively treated group. Begs the
9 question, do we even understand what the risk is in diabetes? So I think that my fear is that if these process
10 measures get fixed, it will strip out innovation, and we will only recognize adverse outcome much later in
11 the process, so if I could speak to anything as an individual, it's to try to have CMS get behind the construct
12 of these larger outcome based data bases that specialties could provide, so we have some real data to
13 develop, alterations in care that help patients.
14 Dr. Rapp: So what you're talking about has a lot to do with a registry based submission.
15 Dr. Senagore: Correct.
16 Dr. Rapp: So in registries, you could submit process measures or you could deal with outcome.
17 Now obviously outcome is more—
18 Dr. Senagore: Well the advantage of a registry is that you get both.
19 Dr. Rapp: Right.
20 Dr. Senagore: You get reported process measures with the backdrop of outcomes. So you can
21 actually now start to statistically manipulate the data, and say which things truly correlate with outcome,
22 and we've looked right now with some data with collectomy and it appears that using standard patient
23 based data; gender, age, co-morbidities actually matters less in predicting outcome than using a minimally
24 invasive versus an open technique, and using a standardized enhanced recovery program. Those two things
25 matter far more in patient morbidity and mortality than the standard things that we usually look at, which is

status of tumor and heart disease and diabetes. So I'm afraid that because we're relatively new as a profession internationally, at looking at these kinds of outcomes, that unless we test these with some scientific rigor, we may make some very bad decisions about things that we think are very good.

Dr. Rapp: Right, well I think you make some important points. You're of course discussing more, when you talk about the core measures you're in the hospital, as opposed to the PQR, but that's a very important thing, because in the hospital arena, all those measures do come down to the physicians. Because the physician's there practicing, and if the hospital says well, CMS's joint commission says we got to do these things, then they're going to come to the physicians and expect them to do that. So there's a rulemaking process that takes place with regard to the hospital inpatient prospective payment system, which you're talking about, so I would encourage PPAC members and others, to look at that because the same issues that you're talking about and the same issues that come up with PQRI registries and all that sort of thing, there are issues there, and we did indicate in last year's inpatient prospective payment rule, that we would, we were focused on increasing the number of outcome measures and measures of complications, rather than process measures for a lot of the reasons that you talk about.

Dr. Senagore: Dr. Sprang?

Dr. Sprang: Just similar to what Tony's saying, and the physician's I've practiced with in the hospital I practice at, part of the reasons they're not as interested in some of the quality measures is because they don't really feel there's enough data that doing those is actually going to improve patient health and patient care, and to do a lot of work for something that you're not convinced is going to increase quality of care isn't going to make a lot of sense. So I think it's what Tony's saying is having better data that the things we're looking at and the things we're asking doctors to do are going to make a significant difference in care, to justify their time effort and energy. You might get them to put more time into it if they obviously paid more, too, but then they're doing it because they're getting paid more not because it's increasing quality of care, in their opinion and so it's not really serving the purpose as we want it to. So just I think it's better measures that it's more data, that they really do make a difference.

Dr. Senagore: Yes, I think the program in the UK, the NICE, National Institute of Clinical Effectiveness, has been a far more robust approach to try to improve quality, not only at individual system levels, but actually down to the provider level, because it allows one to measure the appropriate implementation of a process and its over completion, so not only do you get credit for starting it, but you get credit for effectively completing the entire course and use that effective protocol versus something that may be less effective. Dr. O'Shea hiding in the corner?

Dr. O'Shea: Dr. Rapp, thank you very much for your presentation. I think that we're again a little bit in the dark here, and I think some of what you're saying is administration of this tool and I think that you've been doing some great work on the tool, but I think that this Council wanted more specific information, so when you say that you had about 16%, I actually have some raw numbers of all those NPI eligible to submit, there was attempting submission, 15.7%, but those that did report 1 plus measures was actually only 10%, and again that's just the raw data and you did try to address that. I found interesting the measures that were on here that actually didn't have enough submissions at all, if you're looking at that, and then again, as you said, the ones that were submitted, what made it easier for the doctor? And that might be very, very, very basic, because I think Mike, you're also, and we all have outcomes that we'd like to see, but at first we're just trying to make it easier to submit and then see if those are the ones that actually eventually did have a better outcome when you can go and compare them against one another. I think it would be a good idea, maybe with primary care, to do a little bit of limiting now in rural settings. Maybe they have a wider scope of practice, but if you could limit if you want to compare apples and apples and oranges and oranges, I think it would be, and make more sense to the doctors that are doing it. When you say, go to the website, I don't see anything on your presentation that has the website on it that you'd like us to address to, unless I don't have it.

Dr. Rapp: Yes, it's on one of the slides, it's CMS.HHS.GOV/PQRI

Dr. O'Shea: Got it, and this was presented actually in the National Register, I think that you did publish your data November 15th.

Dr. Rapp: Federal Register, do you mean?

Dr. O'Shea: The Federal Register, excuse me. The Federal Register is where this was actually published.

Dr. Rapp: Yes, we publish, as part of the rulemaking process, we publish in the Federal Register, so where all of the list of measures that we would use are published there. The detailed specifications are found on the website. They're not in the Federal Register.

Dr. O'Shea: Again, if at the next meeting we could have a little bit more meat on the bones, would be really good for us to give you better and better feedback, because we really are keenly interested.

Dr. Rapp: OK, so you would like some more, the information that you have about the preliminary participation is just something that was released last week, so I wasn't prepared to really go into detail about that, but I could do that at a future meeting.

Dr. Senagore: Yes, we could develop a more specific recommendation for you.

Dr. Sprang: As a follow up to that, said about 16% made some attempt, and had at least one 1quality measure. What percent of physicians in the United States actually followed the process well enough to actually get the 1.5%?

Dr. Rapp: Well, we don't actually know that until, because it was just last week that the physicians had to submit their claims, so we can't tell you that, but it looks like at least over half of the ones that attempted to submit at least with the preliminary data, would get the incentive payment.

Dr. Senagore: Would it be reasonable to say that you might have data by May or as we make our recommendation so we don't unfairly burden you, to report your process measures.

Dr. Rapp: We could give you a lot more detailed information.

Dr. Bufalino: For the '07 year, when do you anticipate actually finishing the data and mailing the checks?

Dr. Rapp: Mid-year.

Dr. Senagore: Any other questions or comments? Seeing none, we will adjourn for lunch. And we will return at 1:15 to begin promptly. Thank you.

Lunch

Dr. Senagore: I think we'll go ahead and get started with the afternoon, if folks can get their seats. So we'll begin the afternoon with our new guests Debora Terkay and Bob Connelly. Debora is a nurse consultant in the Division of Ambulatory and Post Acute Care, Quality Measurement and Health Assessment Group in the Office of Clinical Standards and Quality. Debora's worked in the home health industry since 1989 in a variety of leadership roles, and has experience both as a hospital-based registered nurse, and then a visiting nurse, and then with the Oasis/OBQI implementation, Complication/Regulation staff education, Coding & Quality Improvement activities, and prior to CMS, Bob worked for 14 years in hospital social work clinical care, and administration at Union Memorial Hospital, and Johns Hopkins Oncology Center in Baltimore, and the Children's Hospital & Medical Center in Oakland California. He is currently the project officer for the Minimum Data Set Conversion, 3.0, validation contract, and is a member of the CMS team developing the Continuity Assessment Record Evaluation, Post Acute Care instrument focusing on health information technology, and standards and organizational issues, including coordinating efforts with the National Library of Medicine. Welcome to our Council, and I guess they have several questions they would like to pose to us as you listen to their presentation. What do you see as the most important capabilities for practicing physicians? What rates and topics will be most useful to communities? And what information would you most want to have for office records, both items and trends? And welcome both of you, thank you.

Update on Health Assessment Tools

Mr. Connelly: Thank you very much. I'm Bob Connelly and I'm very pleased to talk to you about post acute care, and specifically where I've been working, which is nursing home assessment instruments. Although many of you do not work in nursing homes, I think we all have a vested interest in quality of long term care as well as acute care. We need to improve the quality of care and quality of life. Reasons many of

1 your patients are living longer, we're all living longer, and may need to have nursing homes. Baby boomers
2 will be needing nursing home care in larger numbers, and we'll really need an improved service delivery
3 than we have today. Each of us has experience with a family member, a friend, our community, our church,
4 of someone in a nursing home and often you hear the worst stories, not the best stories, and we're trying at
5 a national level to look at this. Further, there's lots of interest in the validation that we're doing right now.
6 We had over 3,000 people tune in to an open door forum that Dr. Deb Soliba, our principle investigator did,
7 because it really affects payment quality and survey. And as Dr. Rapp, who's our boss and please be nice to
8 us in front of him [laughter] said, that we're moving towards more electronics, and how can electronics
9 help the bedside staff. So we're in the Office of Clinical Standards. We're part of long term care, skilled
10 nursing facility, and we're going to talk to you about that in the post acute care payment reform
11 demonstration. But there are other areas we're involved in; hospice, ESRD, home health, which Debbie
12 will talk about, and we have compare sites.
13 So in 1987, there was a National Omnibus Reconciliation Act that really said nursing home care is
14 not standardized. At that time, HCFA needs to do something about it and at that point, the minimum data
15 set, the resonant assessment manual in a more standardized approach to care assessment was born. The key
16 dates that we're working from are in 1995, we implemented the minimum data set so that all 16,000
17 nursing homes that are Medicare and Medicaid certified use this instrument. In 1998, they began reporting,
18 so we now have electronic data, and in October of 2009, we plan to implement the MDS 3.0. As I said,
19 there are many uses for it. Medicaid uses it for case mix facility and survey, care planning at the bedside
20 staff, quality improvement through our QIO program, policy and public reporting.
21 So the nursing home is basically your assessment process of where you assess, you look if more
22 critical areas are needed and you do a resident assessment protocol, you care plan, you implement your care
23 plan, and then you reevaluate. So in 1998, we came up with the SNF prospective payment system. It's a
24 case mix adjusted per diem. It's payment based on intensity of care and services provided and the
25 automation of MDS submission became mandatory, so every nursing home in the country submits to us.

Some of them, we've given them only computer though, so but we are getting electronic data in a timely manner. The resource utilization groups; there's 53 utilization groups. They're broken down into rehab, extensive service, special care, clinically complex, this is time study data that we've used to figure out how to pay on a prospective payment system, and I want to say that although we're going to report to you on validation on the MDS 3.0, there's currently a study underway to update these [rugs? 05:45] groups and look at our payment items. And 27 states use our minimum data set for payment. In terms of nursing home quality initiative, we have quality measures out there that are being used on nursing home compare, and we want to indicated that MedPAC has really recommended that we revise pain, pressure, ulcer, and delirium measures currently reported. And you'll find in our validation study we're going to have better information. The website is there. Nursing home compare.

This is our time line that kind of shows you that we start out with town hall meeting. We had the VA partner with us on research. We then had review and national testing and now we've completed data analysis and are making final revisions. So it's been a process that started in 2003. The Veterans Administration has really been an excellent partner. As you know, they have some of the leaders in research including some of yourselves. So they really did two things that really helped with us. One was, can we move to interview patients? Right now staff do observation. So they were able to test in VA facilities, to find that for depression, pain, and activities of daily living that we could really interview patients even with cognitive impairment. We then asked them to look at standardized tools, both for our validation where we would compare PHQ9 for depression, to Cornell or a BIMS brief interview, to many mental. But they found that we could use the BIMS, the confusion assessment method for delirium and the PHQ9 for depression. So all of the sudden, we go from collecting data that's been defined by CMS and HCFA to data that can be compared more broadly with strong instrumentation.

These are the 8 states and 71 facilities that participated in our study. We really looked at validity and we used gold standard nurses, which compared short tests with established tests as I said, examples below. And looked at reliability, gold standard nurses to a test retest, and gold standard to a facility nurses

who are completing the new MDS 3.0 instrument. So I'll just briefly report on some of what we think are really strong indicators of this instrument.

Using the BIMS, we found a strong correlation with gold standard measure, 0.91, whereas on the old MDS 2.0, it was only 0.74. There was excellent reliability in terms of capa score of 0.95, where the capa score range is from 5 to 10. So we're way up on a capa score. Better explanatory power, and the acceptance rates were high, even for residents who are cognitively impaired, which you hear figures that that could be 40 to 60%. Eighty-five percent were able to answer these questions on recall and other issues in the BIMS.

The PHQ9 is developed by Kurt Kronke, and it's sponsored by Pfizer, and we're getting a licensure to use this. It uses a resident interview and assesses mood and it uses standardized questions. We also have used the PHQ9 0.v which uses observation, and we've added an irritability item on that, and again, it's a very strong standardized tool.

So we ask nursing staff the over 100 that completed it, 88% that the PHQ9 interview was better than our MDS 2.0, the current instrument, 72% found that the observation was better. Excellent reliability, again 0.94, for resident mood, and 0.93 for staff observation and again, acceptance rates were really the rubber meets the road. The bedside nurse and staff felt that it was helpful and the residents could complete it. Behavior items, we had all behavior items that had items that were considered somewhat negative by our advocate groups, and we worked with various groups to change the labels to make them clearer. As far as customary and routine, this is where we used to ask a resident when they came in whether they wanted a bath or a shower when they wanted to eat, those kinds of questions. We've now got them done over time so we can get at more quality of life. And we had a huge quality of life study in 2005 by Bob and Rosalie Cane that really gave us some items that we're using. So we're trying to be evidence based where we can.

Pain is another area that we worked on and we found that the pain items showed a poor correspondence with independent pain assessment. Clinicians, beneficiaries, and families were frustrated.

We used multi-dimensional items. Resident interview again was used on this and the section was expanded to capture effect on function.

Again the pain items results 91 to 97% of nurses felt it was improved. Ninety percent felt that all residents who responded understood. Ninety percent felt detection in communication about mood would improve if staff learned to watch for these. So pain treatment had a high capa, and staff assessment, 92 and 97, and again we were able to have 85% of non comatose residents use this, so we're doing patient-centered care, which we know is a departmental focus. The other areas we changed were pressure ulcer, and I'll have a slide on this. We eliminated reverse staging, which was in there. We're able to now determine hospital, whether the pressure ulcer came before the nursing home or at the nursing home, because the question of it always seems to be in the ambulance comes up. We worked on balance items, we've worked on falls, and we've improved bowel and bladder. We had an item where catheter rate was considered continent, and we've changed that. And especially with pressure ulcer, and immunization, we're trying to look across settings and we know that for pressure ulcers, hospitals are going to be looking at this, home health agencies, and this is what we're able to determine. We found in a study that Joanne Linn had led that if we combine pressure stages 1, 2, 3, and 4 all in one quality measure, that we really couldn't show improvement. So now, we're able to separate them out by stage in [inaudible 13:28 hub un-stageable] we're looking at stage 2, not healed within a month. We're actually asking the staff, which hadn't been done before, to measure length and width and to follow up on unstageable. We're working with national organizations on wound care to really be consistent with what the current science is showing.

So the main advances in MDS 3.0 are to give the resident voice, and this really improves accuracy, feasibility and efficiency, increases clarity of questions, and reduces time to complete. We found with the MDS 3.0, it took about 62 minutes. The MDS 2.0, 112 minutes. The other thing, and I mentioned before, the staff time, resources and intensity verification study is going on now. It won't be completed until the end of this year, but basically they've done data collection, looking at nursing, therapy and ancillary staff to look at the time values in our [rugs? 14:35]. They use PDAs, personal digital assistants, and they're looking

at time, and they're really going to hopefully in 205 facilities in 15 states and 9700 residents, have a better payment system than we have today. So MDS 3.0 can't be completed until we get this study, which won't be until the end of the year.

So our implementation plans, as we have this open door forum on January 24, we're going to have specifications draft in November of this year and final because there's a whole industry out there. There's vendors, there's consultants, there's nursing homes, there's all kinds of groups that are relying on this information. Our rule will come out in February 2010, that will look at the Strive Study and will make final changes, and we plan to implement MDS 3.0 in October 2009.

Ms. Terkay: That's where I come in. I'm going to talk to you very, very briefly as part of the post acute settings. Home health is one of those and the Care instrument as well. Quality and payment reform, obviously in the long term care industry has happened at least a decade ago, where these instruments were replacing Fee for Service reimbursement with prospective payment systems and actual data collection was mandated that we collected on long term care industry first, and then home health followed suit. The Balanced Budget Act of 1997 was passed and with that was some changes to the payment structure for home health. There was an IPS aggregate spending cap for a 3-year interim period, from 1997 to 2000, the actual data collection instrument was mandated in 1999, and then in 2000, the payment items were selected, end of payment transferred from a pay per visit system, to a fixed price 60-day episode of care for those admitted to the home health services. The quality reporting became in 2003. the OASIS instrument is greater than 70 data items that measures the patient's home health care outcomes and it does involve an adjustment for risk factors. Currently home health agencies collect 41 quality measures, and of those 41, 30 are risk adjusted, and in addition, they collect what are called 13 adverse events.

Again, these instruments serve multiple purposes over the year, they're clinical assessment, they're used for survey and certification, Conditions of Participation, Medicare payment, public reporting, QIO projects. Other payers have begun to adopt these instruments as well, using them to develop their own payment systems, and they're used for policy analysis and care planning. The areas of assessment, we'll

1 just kind of skip over that. It's probably more detailed than you need to know. Just a little bit about the
2 actual quality measures; it was really visionary for its time. The outcome based quality monitoring and the
3 OBQI outcome based quality improvement, became available in 2001. And what this provides at the
4 agency level are incident rates for their untoward events. And it provides benchmarking, home health
5 agency to home health agency, the outcome quality based measure measures stabilization improvement,
6 decline, and utilization, and the publicly reported measures—there are currently 12 and those are just a
7 subset of the ones that they collect. Each agency is provided with a case mix report, which also tells them
8 the characteristics of their particular patients.
9 This is an example of a item that would be measured, and that would be an outcome for
10 improvement in lower body dressing. And first you'll see the agency's number of patients. You'll see the
11 agency's incident rate, the reference incident rate, and if it was a statistically significant different. So on the
12 41 measures that they submit, they actually get a report back that kind of defines for them things that they
13 may need to consider for quality improvement at an internal level.
14 So the next steps in the PPS was the Deficit Deduction Act of 2005, and that became effective for
15 data collected June '06 through '07. And that is that if quality measures were not reported, there would be a
16 2% reduction in payment to the home health agency taken from their market basket adjustment. Of the
17 9,000 agencies, this past year, there were 61 who had their 2% withheld, so it's obviously a pretty
18 compliant group. Two point seven five percent of the base payment rate went into effect for 2008. Where
19 there's a base rate reduction, for this year and the next 2 years, and they developed a whole new payment
20 algorithm, again it's been almost a decade, and there were some high percentage margins of profit, for
21 home health agencies that needed addressed and their payment method went from 80 resource groups to
22 153 and again they're experiencing a percentage in their payment rate over the next three years. In addition,
23 there's a Home Health Pay for Performance Demonstration going on and that's basing agencies that
24 volunteer and can stay in the top 20th percentile of the quality measures that are publicly reported right now.
25 We're also revising the instrument and there will be a new version with revised items in 2009.

1 So there was a B1, effective January 1, and Oasis C is going into testing, and we send our
2 measurements for refinements and what we can report publicly to the NQF and then we plan to implement
3 next October as well. This year, there were 2 additional public measures that were added to the home health
4 ones, and those were wounds, and that was of particular interest to physicians. There was surgical wound
5 improvement as an outcome, and a wound deterioration resulting in going back to the emergency room or
6 the hospital for it. The new instrument add process measures, so we started out with outcome measures, and
7 we're not adding process measures, but for key prevention and other relevant health issues that need
8 addressed in the home health setting, flu and pneumonia vaccination is going to be actually unduly
9 collected item in the home health industry, and I've been on the NQF forum for the global harmonization of
10 the vaccination measures, and that's where they're going to try to measure it universally across all settings.
11 Fall prevention is very much an issue in the home health industry and obviously a very costly issue when
12 they have to go back to the hospital for fractures and whatnot. CHF intervention, CHF, we see a lot of
13 chronic type disease patients in the home health setting, and there were some interventions added specific
14 to certain diseases and one of the things that they were going to measure was actual communication with
15 the physician, that they're notifying the physician appropriately of any signs of decline. The refinements
16 were based on industry feedback, a technical expert panel, and MedPAC recommendations.
17 So moving on to the next stage, which is the post acute care demonstration, and I believe this
18 group has heard a presentation on this in the past, but just a quick overview. As we were mandated by
19 Congress to have an instrument available by January of 2008, and that it should be a patient assessment
20 instrument, a web based electronic reporting system, and that it could be used for a payment reform
21 demonstration. So the post acute payment reform demonstration came as part of the Deficit Reduction Act,
22 and it's a standardized assessment instrument that built on the insights of all the current instruments, so
23 Bob reported on MDS 2.0 and leading up to 3.0, I reported on B1 leading up to C. These are multiple
24 versions. They use numbers. We use alphabet letters, and there's also an instrument for inpatient rehab
25 facilities that's been mandated. So all of these instruments have their own way of measuring, their own

1 measuring scales, their own terminology, and they're really been developed in silos and so the goal is to
2 have something that's equal in definition and measurement so that you can actually measure across time
3 and across settings. And it will be an internet platform, to help meet the IOM goals, grounded in scientific
4 evidence and flexible for accommodation of clinical and technological advances. Right now, it's kind of a
5 painful process to go through revalidating items and testing and all these silo settings and again this is
6 hoping to be more flexible and responsive to the changes. The assessment toll should combine new
7 instrument development methodologies, modify existing assessment instruments, it should guide clinical
8 decisions, monitor health and functional status, assess service needs, evaluate treatment outcomes, guide
9 payment policy and improve seamless transitions. And that particular goal was added by CMS because it
10 serves to function as an electronic health record that can resolve perhaps some communication issues at
11 times of hand off and hand over to from hospital to post acute.
12 The tools application is going to be at the acute hospital discharge. It will be at the admission
13 discharge and interim times for cases that use long term care hospitals, inpatient rehab facilities, skill
14 nursing facilities, and home health agencies. The vision of CMS is that this instrument will replace all
15 Legacy instruments.
16 The goal being measuring patients across the continuum of care and all of the acronyms and the
17 freestanding place where we currently have measurements, and places where we don't have any tools to
18 measure, long term care hospitals don't have a tool, acute care hospitals don't have a tool, and our current
19 existing data element aren't congruent with each other.
20 So again, questions for consideration, what do you see as the most important capabilities for
21 practicing physicians? We hope to some day make this available to physicians with some upload and
22 download carry forward and tailored questions. What rates and topics would be useful to communities,
23 again, looking at completely redevising the quality measurement system, as we can actually then start to
24 collect pressure ulcer items for the city of Cleveland or per beneficiary. How did they look from this point
25 in their life to this point in their life, as they went through the whole long term care community and what

1 information would you want to most have for office records, both items and trends? And we're looking to
2 have them be able to provide summaries. So those are things that we'd like you to consider. Ask any
3 questions that you have.
4 Dr. Senagore: Dr. Ross?
5 Dr. Ross: I have a question and then I have a possible recommendation. You know we all see
6 pressure ulcers all the time when we go into both the nursing homes, the SNF units, even the hospitals, and
7 there's nothing worse than seeing a patient who's been under long term care who developed a decubitus
8 ulcer, whether it's sacral, or foot, and then if it is a little extremity ulcer that could have been prevented,
9 now we're dealing with a possible amputation, increased care, increased cost. It's very discouraging when
10 you go in for an initial visit and you see that situation arise. So having said that and I'm sure you're going
11 through all this, I would like to make a recommendation to try to help this situation out, because I been
12 dealing with this for year. And my recommendation would be that as your unit or your department, that
13 CMS provide to hospitals, skilled nursing facilities, nursing homes, hospice and all of the long term care
14 facilities, recommendations on the prevention of decubitus, or pressure ulcerations, how to assess these
15 patients who are at risk for developing these pressure ulcerations, and the proper early intervention
16 treatment of such entities.
17 Ms. Terkay: Thank you, that's actually in the instruments themselves that are coming out next
18 October, the Risk Assessment of pressure ulcers is going to be rated in both MDS and Home Health Oasis.
19 Dr. Ross: So when the patient's admitted to the facility, an assessment will be performed which
20 will show that risk?
21 Ms. Terkay: Yes, yes. Were they at risk for pressure ulcers? What was done about it?
22 Dr. Ross: Right, what was done preventatively, whether its fleece hill protectors, whether it was a
23 special air bed, whatever, in order to prevent this from occurring. Still would go along with the
24 recommendation though.
25 Dr. Senagore: Is there a second?

[Second]

Dr. Senagore: Comments discussions? All in favor?

[ays]

Dr. Senagore: Against? Motion passes. Dr. O'Shea.

Dr. O'Shea: Another comment for you. I think that nice presentation for all of us that do the SNF and chronic care. There's a new vaccine out there that I think is being under utilized, so this is just to throw it out there, but the new Zostavax, if you're talking about wound and also chronic care, and I don't see it on here, but I don't know if you're exactly the right people to talk about it but definitely on the horizon and something that should be now doesn't even have to have a doctor's order for it, so I'd like to encourage both home health and the SNF units, any of the units to have their providers, whoever they may be, using this vaccine also. I think we're talking about skin breakdowns and definitely increasing pain and debilitation in the elderly so I don't know if that needs to be a recommendation from us, but I'd like you to consider it.

Dr. Ross: I'll take that back.

Dr. Bufalino: Question. Do you segment out in the skilled nursing facilities? There's an increasing demand, at least in our world up for higher tech beds where you can have people that get sort of a higher level of service, higher level of care, you know, in my world of post open heart surgery, who needs another week of more intensive monitoring or some drugs, versus the typical skilled nursing facility folks that are there for chronic problems. Do you discriminate between those two groups and measure them differently, this group of people that need more intensive services, is there a difference?

Dr. Connelly: We kind of leave that to the facility in their care plan. We provide them through our quality measures, information, and don't think there's really anything in the—

Ms. Terkay: No, in the instrument, the instrument itself is designed to collect level of acuity, so there's a higher level of acuity attached to a certain patient based on the types of skilled needs that they have, which affects their payment. But on our quality measures, I believe there is some differentiation

between short term patients and long term chronic care patients, if I think that might be what you were asking.

Dr. Bufalino: Just, I mean most of the hospitals in our community have gone out of this business because it was no longer profitable for them to have these skilled nursing facilities. So we're all in search of facilities who can handle this higher level of patient, that sicker patient with higher medical needs that are just not there for PT, they're there for a higher delivery of service. And we've been trying to encourage the facilities in our community to develop those units, provide better nursing, provide better oversight, etc, and just didn't know what's happening on your side, but it seems at least in our community, that's a trend. I don't really know what else is going on around the country. But I'd be curious to hear what Art has because he's very involved.

Dr. Snow: As a matter of fact, we've had problems at our community hospital where the open hearts are having a number of deep sterna infections, and they routinely kept them in the hospital for a period of time, transferred to a rehabilitation hospital, continued to have those problems. They're going to start sending to our skilled nursing facility now, so ask me again in 6, 9 months whether it works out, but it certainly can be done, if there's interest. I think the payment mechanism is there. Otherwise, I can assure you my facility wouldn't be doing it, so I'm sure they get some extra for it.

Dr. Senagore: Any other comments? Thank you very much. We'll move on to our next presentation, Health Information Technology Issues, and for that we are joined by Dr. David Hunt, Chief Medical Officer for the Office of Health Information Technology Adoption in the Office of the National Coordinator for Health Information Technology, in the Department of Health & Human Services. Dr. Hunt's work centers on developing health information technology, adoption strategies and providing technical support for standards development. Dr. Hunt would like the Council to consider the following questions as he does his presentation: 1) What is the proper role for CMS payment policy in advancing electronic medical record adoption? 2) What are the expectations for quality reporting in an electronic medical record environment? Thank you Dr. Hunt.

1 Office of the National Coordinator for Health Information Technology (ONCHIT]

2 Dr. Hunt: Thank you all very much. I'm really very pleased to have been asked to present today.
3 The timing of this opportunity is especially fortunate, given the public focus on our current national
4 healthcare challenges. There is general consensus that all possible paths moving forward will require a
5 larger role for information technology in all aspects of healthcare delivery. So for the next 15 to 20
6 minutes, I'll outline some of the major issues regarding health information technology. Electronic health
7 records, and personal health records. To do this, I'll highlight four areas: utilization, cost, quality, and
8 standards. Now by way of a disclaimer, I must point out that any one of these topics could easily consume
9 one full hour of our discussion; that is of course because they each resonate with a very difficult and
10 fundamental question in our national health care system. In general CMS is at the center for all of these
11 questions, so in other words, I'd like to say that each of these areas has immediate relevance, to you absent
12 any consideration of health information technology. We live and practice in a very, very different world
13 than physicians at the turn of the 19th Century, as Cero Chantler pointed out, the tradeoff for the simplicity
14 of days gone by of the late 19th Century is a complexity that is at times effective. Now, recognizing this,
15 nearly everyone is calling on modern technology as sort of a savior, if you will. Computer, and information
16 technology, are the ways out and an unqualified way out. But I do worry, I do worry because some have
17 elevated this call by describing health IT as the panacea. They then sit back and wait for some uber-geek if
18 you will, with a killer application to ride into the rescue. [laughter] This type of expectation, which vacates
19 any realistic acknowledgment of our circumstances seems to make the case that if we just wait for the folks
20 who gave us Google or Ebay, everything'll work out just fine. We really have to resist this desire to
21 become Vladimir in Samuel Becket's *Waiting for Godot*. Early on, in my medical informatics training, I
22 was taught a cardinal rule, and that rule was namely that information technology has never been the sole
23 solution to any problem of substance. While we do have significant technical challenges around bits and
24 bytes, our greatest issues are actually cultural, which is why advisory committees, such as PPAC, are so
25 critical to moving forward. As I said, our immediate problem is not about bandwidth or gigabytes, or

processor strength. The questions that we must answer to overcome the current inertia we have have more to do with the structure of payment policy; the growing consumer empowerment movement, and a clinical establishment that is somewhat schizophrenic, bouncing between loyal allegiance to anecdotal practice phenomenon and randomized clinical control trials. So really the open question is, can we use information technology as a vehicle to change our culture and in turn our methods in 21st Century health care? Now I phrase that question very specifically because I have to reiterate. Our problems in health care will not vanish on the morning of that great getting' up day, when there's a computer next to every stethoscope. And anyone who thinks that they will really has misinterpreted the profound societal changes that we've recently witnessed that are coincident with the Internet revolution.

Now that I've been a bit of a killjoy, [laughter] I'll say that there is a great deal of hope, because change is underway. These are the forces that can transform American health care, with the lever of health information technology as a means to create better health care value, and remember that is really the goal; increasing health care value. In that context, these assets, electronic health records, personal health records, will improve individual quality and care and support our public health information system, using interoperable standards. I'm going to get back to that word in just a minute. Over secure networks. In a nutshell, this is really the reason for my office's existence, ONC. Why we were initiated by executive order. But now, how do we get there? Well, I often like to say that the answer was old when the Phoenicians invented money. And Michael Saylor summed it up pretty wonderfully: In the course of losing $4 billion on the day that the Internet bubble burst, he learned a profoundly painful lesson, that the new economy is no different than the old, in its fundamental requirement that products and services must make an unqualified value proposition to those who would use it. And to date, we really have not make a convincing value proposition to physicians in general. Here, we can see that even using very liberal definitions, only 25% of practices have an electronic medical record. Now, when you limit the question to those IT solutions, that are required with 4 essential functions or elements to make a true electronic record, which is the electronic notes, for progress notes, the ability to order labs or medications on line, and the

capacity to retrieve those lab results, we can see that only 14.8% of practices are using an electronic medical record. The good news is that this does represent a 50% increase from 2005.

And still we can see that in small practices, where over half of the care in America's rendered, we're not seeing a strong voice of confidence. As you can see here, at this point, adoption is still very heavily weighted to large practices. And when we look at hospitals, the picture isn't really much rosier. E HR use is heavily skewed to larger hospitals, and thus we really see that those greater than 500 beds have a much higher adoption rate of EHRs than those less than 50 beds, and I think that really reflects that fact that we haven't made a convincing value proposition to those small practices, those small hospitals, that are working on a very tight margin. I can actually go through these relatively quickly. These are just some graphics that I used in my old days in biochemistry to try to illustrate what we're trying to do in the office of the National Coordinator. If you think of health information technology adoption as a chemical reaction, we have the substrates over on the left, and the actual end result is what we need to have on the right. And this is just the old-fashioned energy of activation reaction that many of us are familiar with and this is what I've tried to make into a metaphor here of what our value at ONC is. Hopefully we are the catalyst that will help lower the energy of activation and achieve health information technology adoption on a larger scale. Just so you know, our goals is having 50% of Americans with some form of electronic medical record by the year 2014.

So actually this really is just a graphic many of you have seen in different types of consumer journals on what is high cost, high features. When you start to look at features and functions, versus costs, up in the upper left hand column is low cost and high features and typically we talk about that as a value. Down in the lower left hand corner is low cost low features, that's usually what we talk as cheap, or not worth very much. High cost and low features, that's in my old neighborhood, that was always a gyp. [laughter] In high cost, high features, that space is actually the space my daughter lives in most of the time [laughter] but we're trying to get away from that, and see right now EHRs have been all over the map, but right now we have pretty good consensus that they're settling right about that point in terms of the value

1 proposition, and our real goal is to move them up to that left upper quadrant. So really let's get back to the
2 question of a value proposition to physicians. By any realistic measure, electronic records are expensive,
3 they're expensive to acquire, they're expensive to use, they take significant training for staff to use. There's
4 no guarantee that market forces by outs and failures, won't leave buyers orphaned when a particular
5 company goes belly up, and finally, there are a host of legal concerns that electronic records open up. So
6 with all of these issues, there's no question that in our office, particularly, we have a tremendous amount of
7 work to do, and we've started that work. We've started to change the landscape. We've established an
8 electronic medical record certification process, which means that data elements are interchangeable
9 between systems and will work with any other certified electronic medical record. This means that you
10 can't really be orphaned regardless of any market vagaries, short analogy would be that you won't lose
11 your files even when you switch from WordPerfect to Word. You'll still have the data that you need.
12 We've been able to relax anti-kick back provisions in the Stark, which allow hospitals to partner with
13 physicians around the question of electronic medical records and we're actually able to talk to malpractice
14 carriers about an EMR dividend. Those discussions are early, but they haven't closed the door, and we're
15 somewhat encouraged that there will be some form of EMR credits that may be possible. HRSA or the
16 Health Resources and Services Administration, is actually providing a number of grants to help safety net
17 practices, those who work in the most disadvantaged populations, actually acquire and use HIT and the
18 DEA has actually announced a notice of proposed rulemaking to consider a change in current rules that
19 preclude prescribing schedule 2 narcotics electronically. That's an obvious barrier to the adoption of
20 electronic prescriptions, because nobody's going to have two systems to write a prescription. You're either
21 going to do it one way or the other and right now, unfortunately, it's difficult to, you can't, it's not just
22 difficult, you can't prescribe schedule 2 narcotics electronically. And we're hoping that we're going to get
23 some movement on that topic, on change with this notice of proposed rulemaking. And finally, Medicare
24 will begin testing and providing incentives with about 1200 small practices, beginning this summer, in what
25 we call an EMR demo, which we're actually going to provide incentives for the adoption and then the use

of electronic medical records, specially targeting that group that we see as the most recalcitrant. The group of small practices, anywhere from 2 to 4 or solo practitioners that really we need to be able to make that convincing value proposition. And it is really in Medicare's interest to partner with physicians to make this happen. Under the Secretary's leadership, CMS is stepping to the plate with a number of common sense initiatives that understand that although doctors may be altruistic, supermarkets and college bursars and malpractice carriers aren't. So every hour of the physician's time has to add value to his or her bottom line, and no one has a greater incentive than Medicare to make common sense moves now as you can see, we have the gerification of America occurring. Because of that, I often like to point to an article that was written by Michael Porter. Out of many of the proposed changes that have come and gone around what to do about the larger cultural issue of health information technology, and health care value, he's written a wonderful piece in JAMA and I recommend it to every medical student, every resident, every practicing physician that I ever meet in the country. And basically it says that physicians have to step up to the plate and put more value into the health care system, but they have to be supported in practical policies in doing so. This was a profound article, again, and I highly recommend anyone grabbing that JAMA article and reading it. Michael Porter is an authority, a world renown authority in market competition.

And now just briefly to that final component of standards. I lumped a lot into this category, but there is universal agreement that privacy, confidentiality and security must lead this whole discussion. This triad is fertile soil that will allow all of this to grow if we get it right. Sometimes I hear that we use the words interchangeably, so I'd really like just to review briefly the distinctions. Privacy means it is, privacy actually comes from the Latin *privitus* means belonging to oneself, not to the state. It is in effect, a right. Confidentiality means a trust, and security means to be free from care. It is a state of being. Now assuming that each of these 3 can be achieved and they're each somewhat distinct and require separate and distinct policies around health information technology, assuming each of these 3 can be achieved and maintained, the American health information community, also known as AHIC, which like this group is a federal advisory committee to Secretary Leavitt, has outlined a set of priorities.

The process of transforming this list of priorities into a set of standards that IT professionals can then create products for, involves an intermediary step. And that's the large piece of the work that we're doing currently in the Office of the National Coordinator. We call that work developing use cases. Use cases are actually a term of IT and are of no use beyond this discussion for most of you. They were first formally described way back in the Stone Age days of computer science in 1987 by an Erickson engineer called Ivar Jacobsen, and they were to facilitate software development. But briefly, a use case documents tell the story of what you want the software to do at a very high level. Tech types in general and software developers in particular, are a distinctly different species from your standard homosapien. [laughter] Anyone who's installed a computer or a high def TV knows that communication between these two groups is often very difficult at best. Use case documents in effect are cave drawings from those who need to get something done, to those who know how to make computers do things. They come in the form of descriptive scenarios. And the scenarios outline the actions and use actions of users and their functions of a computer system to achieve a desired result. These documents are really the first step to what we call functional requirements and in our world, and particularly in our world of ONC, what we're trying to do is making functional requirements that go beyond any particular brand of software products, and these are what we use then to certify these products saying that all of the software in this particular area has this functionality and meets these standards. I often give the example of a use case for say an ATM machine that would describe the goal of getting of $20 out of the machine. The scenario would identify, would detail the identification of the proper account followed by a debit, based on the user's request. It would go on to describe dispensing the funds, and finally documenting the transaction. For our purposes, after public feedback, this narrative of events is then sent to the health information standards panel, also known as HITSP, and these are translated into specific standards, all products can then be held accountable to. Effectively, regardless of what city you go to, or which ATM vendor you use, you all expect to be able to get cash out of the system, and that's a basic level of service. And that's what we're trying to describe with the use cases. This process has actually been very successful to date, creating standards that can be used to

test and certify health information technology products. In many respects, we've seen more success in the last 3 years than we have in the previous 20. So basically I can recap, privacy and security are the soil; standards a network backbone, and certification are enabling policies from the federal government and they represent the roots. Sprouting from all this is a governing structure which is really AHIC, the American Health Information Community, and they're going to actually be transitioning from the current body that we have now, which is a federal advisory committee into a public-private partnership. We describe it right now for lack of a better term, as AHIC 2.0, in which we have stakeholders and a group of members in the federal government working to achieve essentially the same functions. What the Secretary did which is actually very prescient, he's trying to take the discussion of HIT governances out of the realm of being a political football, particularly during the transition, to make sure that we're able to keep this work going at a regular pace, because the thing the industry needs least of all, is uncertainty. They have the term called the business cycle, which means sometimes things go up, sometimes things go down and all of that can be accounted for and dealt with in a pretty reasonable way. The thing that kills business more than anything is uncertainty, and that was really the goal of moving to AHIC 2.0. When you have this governance structure in all of the things that rely on it down below, you can really see that we can get some fruit out of health information technology. In today's world of sort of instantaneous market, internet downloads and spiral CTs that take seconds, the expectation of a 10-year transformation must really seem like 100 years to those who need something right now. We know that. We really do know that, given our current acute circumstance that this time scale may seem interminable, which is why I have as my prolog slide, with John Kennedy pointed out, is that that's all the more reason that we need to get started on this work today. With that, I'll stop and take any questions. Thank you.

Dr. Senagore: Thank you, Dr. Hunt. Any questions?

Dr. Przyblski: First of all, I want to congratulate you. That was a brilliant presentation.

Dr. Hunt: Thank you.

[applause]

1 Dr. Przyblski: One of the most cogent presentations I've heard in the 4 years I've been here in
2 terms of understanding overall in the specifics of the issues.
3 Dr. Hunt: I'll let my mom know the check is in the mail.
4 Dr. Przyblski: You may not have a future in government, but the issue of the four corners that you
5 put in terms of value and cost, and your particular I think was interesting was your emphasis on what is the
6 value and cost to the person who you're provider, versus the perception of value and cost to CMS. They are
7 two distinctly different perceptions.
8 Dr. Hunt: Absolutely.
9 Dr. Przyblski: And that in order for this to implement, they both have to be incongruence.
10 Dr. Hunt: Well, you know it's interesting, when you look at the whole subject, and I'm sure many
11 of you have heard other presentations, or descriptions or seen things on line, all the wonderful things that
12 will happen when health information technology is ubiquitous. We see that records are instantaneously
13 available. We can transfer information. You have a heart attack in California, and your primary medical
14 doc is in Baltimore, you're able to shift that information over. You're able to have some continuity among
15 care, you decrease the amount of drug-drug interactions because you have a consolidated medication
16 record. All those are wonderful things, but the fact of the matter is, for that information to get into the
17 system, somebody has to do it, and it's got to represent a value to the person who actually does it. When I
18 go to the hospitals that I work in that actually have CPOE, I got to admit I'm sometimes frustrated. I can in
19 between cases go up on the wards and write for a dose of Anseph, a lot faster than it takes me to log into a
20 computer, find the patient, find the drug, make sure that I clear all of the dialog boxes that pop up that say
21 that this patient is allergic to penicillin but I know that they're really not and all of those things that go on it
22 just takes too long. It's not really a value to me, particularly when the OR is calling me—where are you? I
23 expected you right back down, right now. So one thing that we've got to do is really make that value
24 proposition to the end user in the physician's office, these tools are wonderful, but you have to completely
25 change how you practice. You've got to completely change how your staff interacts with your patients. The

work flow actually can be quite wonderful and it moves along very well, but it's not a minor overlay on the way you do business. It's a complete revamping of your practice patterns. And everything changes from the fact that, how do you know that a patient is in room 2? Usually because there's a chart up on the door. The chart won't be there on the door. How do you know someone's not going to wait for hours and hours—there are a number of considerations that have to be made and we see groups throughout the country that are starting to understand this and make changes in the work flow and design work flows and processes that actually take advantage of this and you start to get that dividend to the end users, it's got to be that value. And we're starting to see that. The value to public health is immediately obvious. I can tell everyone who's automatically, who's had their influenza vaccine almost instantaneously. We can make queries across a system and identify quality issues and issues of a process that can be improved upon, but not of that's really going to make a difference until we have the people on a day to day basis that are going to be using this, and that's the physician and the patient and unfortunately, or I should say unfortunately, fortunately, you can't insinuate too many things in between that relationship. That's a fundamental relationship, and we've got to add value to that equation or else this is all for naught.

Dr. Senagore: I think one of your comments earlier on was really true. I mean I've held off buying a high end DVD waiting to see who was going to win between Blue Ray and HD. So now that it's pretty clear who won, so I'm good to go, But that really I think in a nutshell is where the issue is for the typical provider. I practice at 4 hospitals. There are 3 different computer systems. I never knew there were 12 kinds of lactate ringers. [laughter] Until I went to one.

Dr. Hunt: And you still don't really want to know that, do you?

Dr. Senagore: No that's more information that I wanted to know about lactated ringers. I can assure you. But that is the problem. And I don't have a way for my H&P to populate each one of those hospitals so I can get the value added of having done that H&P once, and book that case for surgery at every hospital.

Dr. Hunt: Exactly, exactly.

Dr. Senagore: So there is no value for me, from the EMR. I became the transcriptionist, but I didn't get any value back for that process, and I'm sure that 2 of the hospitals are not going to worry a whole lot about whether they accept my H&P electronically.

Dr. Hunt: And that's really the value of interoperable standards. That's the big thing that we have to have. There are a number of E HR and EMR vendors and that's one thing that the industry continues to try to push this, but until the systems just like WordPerfect and Word, until the systems talk with each other seamlessly, no one's going to—I went, and I bought Beta, instead of VHS, because I bought the hype that the quality was better, and it really was, but you know, that's a very little use.

Dr. Senagore: I got one of those, that's why I waited this time! [laughter]

Dr. Hunt: So it really has to be interoperable, and to add value to the system, because we'll be able to squeeze time out in some areas, but some things, quite frankly for the immediate are going to take a little bit longer, but how can we make this more valuable to you? Things, such as being able to report your quality measures directly into CMS or the joint commission or to any other accrediting body, or to automatically tabulate your cases so when you go for your recertification examination you don't have that onerous process of filling out the form. There are a number of opportunities that we can really make. Making the small but noticeable credits to malpractice carriers, will be a little bit more and more to chip away at that value proposition. We always say that there are two things that are important in practice, and actually there's only one thing, time and money. And you know, Benjamin Franklin in his notice to young tradesmen said that time is money. And it really is. We've got to be able to make sure that the time that you spend on an EMR is of real value to you and that you're going to get dividends again and again and again. First is making it safe, and that's what the certification process is meant to do. The next is to make sure that we have interoperable systems, such that when you send it to Hospital Center or Providence or Mayo that you can send the same history and physical and it'll get there. It'll be recognized and things will happen. The real leverage will come when they get that notice of that case, that H&P that they recognize that this patient is a great case for quality measures 1, 2, 3, and 4 and that they automatically flay notices down in

the pharmacy and they get your antibiotics on time, a number of things can happen, but they all start with the end user.

Dr. Senagore: Dr Arradondo, first.

Dr. Arradondo: You reference the HRSA grantees.

Dr. Hunt: Yes.

Dr. Arradondo: Have any of them produced any measurable results yet?

Dr. Hunt: They are, and actually they're starting to come through more and more. There's a lag phase, a startup phase, and these grantees are the safety net practitioners who really practice in some of the most severe and toughest areas in terms challenges. They are starting to come back with some realizable gains, particularly around being able to manage, oh I'm so sorry, usually volume is never a problem. It's always a content issue. Talk to my kids [laughter]. They're really starting to get into being able to see realizable gains, particularly with the safety net practices, and being able to manage their practices more efficiently. And we're starting to see from the HRSA grantees particularly, that some of the advantages are starting to look like those practices that have 11 and 12, those large practices, because they have very, very tight, even tighter than most time constraints, and we're starting to get some value out of that. But picking the right software product, making sure is so much has to do with training, training, training. When your staff, and it's particularly the staff that is trained how to use this. They start to see these efficiencies. One fear that we have is they'll be wonderful standards and you get interoperable systems all around, but no one really spends the time to really train the rank and file staff on how to use these new systems, and universally, if you don't have good training implementation, goes sour, and basically the computer sits over in the corner. So we are starting to see some of those. We're really encouraged about what we hope to see with the CMS EMR demo that's going to start enrolling small practices, 1200 of them, across the country that will be able to see, because that really is the canary in the coal mine if you will. These are regular practices, small solo practitioners or very small groups that we have 2 to 4 folks that can actually begin to use these systems, and implement them, and the onus is really on us, us that is at HHS to begin to show that

1 we can support that activity in the implementation phase, because that's where the real value comes out that
2 we don't abandon the staff to just try to figure this out. Everyone who remembers their first experience,
3 trying to buy something on Amazon.com or use a new piece of software, will tell you it wasn't that much
4 fun. So we've got to train and support them. We have a program called DOCU, which is Doctors Office
5 Quality, I forgotten what the acronym stands for. But effectively, it's an online training course that CMS
6 begun to implement to help support staff around the issue of HIT implementation.
7 Dr. Jordan: Just want to give you guys a scenario what I'm going through at this very moment, in
8 relation to that 20,000 per physician cost. I'm in a group of 4. We are making the paradigm shift as of
9 March 11, which I'm really really looking forward to doing. [laughter] And so we're being proactive in
10 trying to get our office paperless. When you purchase an E HR, obviously you usually have to practice a
11 business management software that will interoperate amongst the two of them, so you got that cost.
12 Because EHRs, you'll usually also, and I know the $20,000 did not include hardware. But hardware
13 upgrades or additional hardware are always associated with this upgrade, so that I think first of all should
14 be included into that. Next, we have paid staff overtime for the last few months to train, and to also input
15 data into the system before we actually go on line, so that's been involved. We also have an in office onsite
16 training, which we were having to close the office completely down, and then, obviously I write the checks
17 to the office, I administrate the office, so I know the dollars, and production, which obviously we have not
18 got there yet, but right now as a rough range, and you can do your own math, for, right now I'm estimating
19 between about a 40 and 50,000 per doc cost to upgrade into this system, which like I say, we're in a very
20 rural situation up in Wyoming. I'm looking forward to 2009, that's what I'm looking forward to financially
21 so.
22 Dr. Hunt: And what we've got to do first of all, God bless you for going through the steps to go
23 through that. And we really need to make that investment very valuable to you and that's the day to day
24 function of the office and that's one thing, one of the big reasons that our office is so important, is that
25 unfortunately, to make the sales the vendor community, they obviously they emphasize the high points, but

didn't necessarily talk about some of the challenges involved, and the frank challenge involved with virtually any new disruptive technology, which is what this is, is that you're going to take a productivity hit. You're going to take a productivity hit, and the question is, are you going to be able to make up for that? And we think that now the answer is yes, particularly with the opportunities to begin to talk about submitting more quality information there, to be able to submit interoperably, records across numbers of hospitals, it's going to come there, but it's not going to be immediate. And that's one of the things that we really need to have a very open and frank discussion with everyone. Because if you don't manage expectations properly, telling everyone that everything will be wonderful, we have failure of adoption rate that is not insignificant, it's not trivial at all. And I think that has to do to a large extent with unrealistic preinstallation discussions.

Dr. Sprang: I practice in a hospital that is actually one of the most wired hospitals in the United States, and we went on 5 years ago, but clearly there are advantages. I can look at my patient information from my office, there's some good things without a doubt, but the time commitment, after I delivery a baby, it takes me half hour to put in three different sets of orders and if that's 3:00 in the morning, it's not exactly what I want to do at that point in time. I go up to the post partum floor, I see every nurse on the floor, sitting in front for computer screen entering data. And I ask them who's taking care of the patients, they say nobody. They're spending 50 to 60% of their time doing data entry and this is 5 years later. We put a system in our office, just started this year, and I didn't go to the same system because control of the records, and when you click into my hospital system, it says everything in the system belongs to the hospital system, do not expect any privacy, etc., etc., etc. And it's just, I have a group of 32 OB/GYNs and I would like access to my own patients' charts. So we went to a different system. It's for my young docs, they're doing great, 3 of the 8 in my office can do it very nicely, the other 5 are still saying do I really want to do this? And staying an extra hour or two each day and they're only putting half their patients in the chart. It is a lot of work. And it's hard to really see the value. We tried, talking about interoperability, obviously all bought systems that are interoperable and am trying to talk to the very administrators at the

hospital to connect our systems. They absolutely do not want to do that because it's ownership. It's in the hospital system in the Chicago area, which is a big market, that will talk to each other because they all want ownership of their charts and their patients and so it's, can it theoretically can it be done? Do the hospitals and the administrators want to do it? No because who owns the chart, owns the patient. And it's just so far, there are a lot of good things about it, but there are a lot of time consuming headaches about it too, and the value at this point certainly isn't worth the $500 grand that we spent already and the hospital probably spent a couple hundred million grand. They have advantages as far as billing because everything that gets ordered, gets billed whether the patient ever sees it or not. So I'm not sure how it's going to decrease cost for anybody. But I'm just saying there's a lot of things, and at least so far and this is after 5 years, not 5 months. So far, the emperor has no clothes.

Dr. Hunt: No I hear you and I would tend to agree. I think some of the issues around not sharing data, our office is putting out within the next few weeks actually a framework to start to discuss privacy, security and confidentiality. Obviously risk managers at hospitals are very risk averse, and they tend to lock things up a lot tighter, until they really get more guidance from a number of entities on how they'll be able to share this information, and I'm hoping that that framework that our office is going to put out is going to be a good guidance for one, Capitol Hill, in beginning to talk about different types of new statutory requirements to make this a little bit more seamless, still provide the protection that we obviously need for confidentiality, for patient privacy and for security, but to allow the free exchange of information, because that is one of the big values to the whole proposition and if we can get that flow going, then it's going to be a problem.

Dr. Sprang: I think unless there's a Congressional mandate, what I'm seeing in Chicago is really ownership of the record, and so it's not that they're worried about risk management, it's really they want the patient in their system.

Dr. Hunt: And see that's going to change also. And the landscape is changing tremendously, primarily from patient empowerment. Now I didn't talk a lot about personal health records, but actually

that is a big piece to the whole equation. When I first heard and understood a little bit more about personal health records, which are basically a record that contains all the patient's information that they can control, and it can be through their own portal. You may have heard the Google and Microsoft with Health Vault are coming out with these products. There are a number of stand alone products, or stand alone companies that are starting to do this, that are basically helping the patient to say hospital A or St. Elsewhere General, you do not own my information. I own my information, and I will control that and that's going to be one lever that I think is going to begin to pry open some of those doors, because the fact of the matter is the one universally accepted individual that owns that data is the patient themselves, and when we get to a point where their personal health record information will be able to flow seamlessly into our office record, into the hospital E HR, then we're going to see a lot more free flow of exchange. And then the hospitals are going to have to change the paradigm and begin to understand, how can we better empower our patients? Because that's how you're going to get market share by showing that you're going to be able to help them manage their own conditions.

Dr. Sprang: I believe it can happen, but it's going to be a lot of work, because a lot of them don't want it to happen, and they're worried about any of their data being corrupted by data from outside. There's just a lot of issues that need to be dealt with.

Dr. Snow: I'm glad you mentioned the assistance for the small and solo providers. Secretary Leavitt was in Kansas City couple weeks ago and laid out that program for the areas there, but I think the biggest problem that we as, I'm a solo practitioner, primary care, and quite frankly, it's finances. The program laid out and we don't need to get into the details of that, but as I saw it there, it does give the solo and small practices some dollars, but it does not cover the cost, and I think as Dr. Jordan has well pointed out, there's a number of costs that I think are not included in there and then you look at a looming 10% pay cut that we've got coming in July, and quite frankly primary care physicians are hovering on the edge right now. There's going to be a reduced productivity permanently for primary care physicians in particular, using these E HR systems, none of them can be as efficient and having talked to a lot of people who have

used them for a number of years, this is true. So to have an additional 10 to 15,000 dollars per physician minimum cut per year, which comes directly out of your take home pay because you still got the same overhead, it's gone up, but we're hopefully covering that through some other methods. It's a start in the right direction, but more needs to be done, primary and solo and small groups are going to have to have significant financial help and assistance in order to get this done.

Dr. Hunt: I agree. One thing that I think we'll see though is that the productivity hit while very, very real should be transient. Now how long is transient? It may be a year or two because you can increase productivity in a number of areas. Great example of that is when you have your patients come in for their routine follow up for say hypertension. You'll also be able to be flagged that oh you know, they need their flu shot. Mrs. Jones hasn't gotten her mammogram and we haven't made sure that we took care of this standard screening tests that are all billable expenses, and we've seen very, very real value in systems that efficiently basically capture all of the guidelines and sort of bundle that, and I feel uncomfortable, and I'm starting to feel the CMS eyes burrow down in me because sometimes you can make sure you're a lot more efficient in capturing all aspects of care that you can, and in time it will increase your productivity. When we start talking about having to report quality measures, which is going to take time, there is no doubt about it. For any incentive bonuses, we're hoping, and again this is still something that has to be realized in real time that these systems will be able to provide that information with virtually no additional work. So you'll start to see some gains back as far as the productivity. But you're absolutely right, you can't sugarcoat it. It's going to be a productivity hit.

Dr. Bufalino: I hesitate to be aligned with you, but [laughter] I see everybody else is on the other side, and Roger you haven't spent the money yet, because when you start to maintaining your system, you'll really learn what it costs. We've been electronic for 10 years. And have invested many hundreds of thousands of dollars each year to maintain that system, but I will tell you that number one, we were clearly more productive, two, frankly I think today we are practicing better medicine today than we were when we started it, three, we each get quality report cards in house every quarter, tells us how well we're doing on

each of the consortium measures and if you asked us before we measured, we would have told you we were really, really good. And then we measured and found out we were really, really bad. [laughter] and realized that we needed to make a lot of difference and so today on the whole consortium measures, we're at nearly 90% now on every measure today, and that's a process, took us some time to get there, but you know, we're delivering better medicine, we have better follow up, and I have to tell you at then end of your office, you're done dictating, you're done documenting, you walk away, I don't have a pile of charts on my desk anymore. I don't have letters to dictate, I don't have people to call after office. I'm finished. I walk away and I'm done and I have to tell you my guys to the man, no one would go back, no one will change. They are addicted, love it that way, and we are totally dependent on the system.

Dr. Hunt: And that's a fantastic measure. Particularly what we see, and again, we see the obvious advantage to large practices, but small practices starting to recoup that also, that's one thing that we're starting to see that people are saying once they get through that horrible pain and you can't sugarcoat it, and I guess we can liken it a little bit to going through medical school, once you get through the medical school, and OK, internship, and OK, residency, and you get through all of that, it's not that bad. It's really actually very good and you can leverage that system to do things that you couldn't do before. I came from CMS actually not that long ago, and I was on the hospital side, particularly around the area of quality measures, if you've heard of the Surgical Care Improvement Project, or SKIP I was largely involved with that. And we see obvious immediate benefits that can be derived through the interaction of good hospital IT systems, to make those quality measures happen and to make them happen reliably, so there is an upside to it, but it takes a while.

Dr. Snow: I appreciate Dr. Bufalino and all the cardiologists in the world who have these systems now, but I want them to start paying my medical record costs, because when my patient comes to see you on their monthly visit, I get 20 pages of material kicked out by the computer. Two lines in there may be different, maybe the first line what they came in for, and the last line what you changed and the intermediate 19 pages and 2 and a half are all the same and after about 12 of those visits, I've certainly got

a chart that's totally unusable from the information that I got. I used to get a nice letter from the cardiologist, to sum it all up [laughter] one page usually and now I get 20 that are totally useless.

Dr. Bufalino: You need to move to Chicago. We'll only send you one page.

Dr. Snow: Very good. Very good.

Dr. Sprang: Vince, in Chicago, from my hospital, every patient that is in a nursing home where he works a lot, when they get a report of a patient that's been in the hospital from my hospital, which is extremely well wired, it's like this. A CBC is on 3 pages because it lists all where the labs are, the data the demographics, and someplace in there it says the hemoglobin. You add a stack like this and it goes to the nursing home, you know what happens to that stack, it just gets dumped. It just gets pushed over to the side. So they've got less information now than they had before because it's useless information the way it's presented. Because it's not electronic electronic. If I copy, when my patient leaves to the hospital and I want to print some of the things, I'll get 3 or 4 copies of everything and I'll have a stack of 30 pages. I go through them, throw away 28 and bring 2 to the office. And that's grossly inefficient.

Dr. Bufalino: Well, I will say to you unequivocally, none of our hospitals connect to us, so we're in 7 different hospitals and we have 17 outpatient locations that are perfectly connected, but we connect to no hospitals today other than some rudimentary connections and most of the time, we actually have a duplicate CRT with their information on a separate computer where we pull it off, so no one is writing those bridges interoperability be damned, sort of no one really cares, because no one's going to pay for the connection and unfortunately what we see is each hospitals wants to own our patients as Leroy said, and so they want to control that database, so we have said no, we're going to keep control ourselves, and for the time being, we've maintained a separate system.

Dr. Senagore: Great. Thank you, Dr. Hunt, let's take 10 and then we'll reconvene and do the picture.

Break

1 Recommendation Review

2 Dr. Senagore: We're having our earlier recommendations being printed for our review. Are there
3 any new ones while we're waiting for those to appear? I think Dr. Ross is working on one.

4 Dr. Ross: Mr. Chairman, going back to, I'd just like to revisit the recommendation from the past
5 meeting of 62P5 and the response 62P5 and would like to make the following recommendation: That PPAC
6 recommends that CMS clarify and define whether physicians who supply DME POS as part of their
7 professional service are subject to all the requirements to the DME POS competitive bidding final rule,
8 compared to physicians who act as commercial suppliers, including a stipulation that they must become
9 accredited.

10 Dr. Senagore: Read that back please, Dana.

11 Dr. Ross: Basically a clarification of the final paragraph and the final sentence which says that
12 physicians who act as commercial suppliers of DME POSs as opposed to furnishing items as part of their
13 professional service, are subject to all the requirements of the Final Rule. The recommendation would be
14 that PPAC recommends that CMS clarify and define whether physicians who supply DME POSs as part of
15 their professional service are subject to all of the requirements of the DME POS competitive bidding Final
16 Rule, compared to physicians who act as commercial suppliers including a stipulation that they must
17 become accredited.

18 Dr. Senagore: Is there a second?

19 [second]

20 Dr. Senagore: Any questions? Comments? I think the construct is assumed to be part of the
21 practice expense of the CPT code or are we able to provide that as an independent item and not be certified.

22 Dr. Ross: That's correct.

23 Dr. Senagore: OK. I'll call the question, all in favor?

24 [Ays]

25 Dr. Senagore: All against? Motion carries. Dr. Snow.

Dr. Snow: Regarding the NPI, I think we had one recommendation on that, but I would like to have PPAC recommend that CMS take immediate steps to ensure practices do not experience cash flow interruptions as a result of the transition to the NPI.

Dr. Senagore: Second?

[Second]

Dr. Senagore: Any comments, questions? All in favor say Ay.

[Ays]

Dr. Senagore: All against? Motion carries. Those are printed sheets as we speak.

Dr. Ross: Can I make a friendly proposal? That we have official photography pictures next time for CMS for a group picture.

Dr. Senagore: I'll leave that to your next chairperson, make that executive decision. So just take a few minutes and read through the recommendations and if there are not changes I think we would stand adjourned at that point.

Dr. Simon: Just make the Council aware, we did receive 2 written testimonial statements from the AMA which you have in your packet and additional copies are available along the walls.

Dr. O'Shea: I just have a question on the first agenda C item that I made the recommendation. Dana I was quite sure that I had actually stipulated November of '07 and yet I will say, Dr. Simons, would you know if that is all the data that will have been collected by May of '08, because I think it's going to go through January, and that's why you were saying that. May I ask that please? Do you know?

Dr. Simon: The raw data that you have goes through November '07.

Dr. O'Shea: And will there be more data available that could be made available to all of PPAC by May of '08.

Dr. Simon: Probably not. That's why we put the August '08 meeting date in the recommendation.

Dr. O'Shea: Well I'm then happy with keeping it November of '07.

Dr. Senagore: Anybody see anything to correct on the printed recommendations?

1 Dr. Bufalino: This will make Dr. Simon's report about [inaudible]

2 Dr. Senagore: Yes, correct. We've done him a favor.

3 [chat/laughter]

4 Dr. Senagore: I'm sure he'll be able to answer questions on the fly from the chairperson at the next

5 meeting. Dr. Snow?

6 Dr. Snow: Could we make additional recommendations?

7 Dr. Senagore: Absolutely, yes.

8 Dr. Snow: Are you ready?

9 Dr. Senagore: Go for it.

10 Dr. Snow: PPAC recommends that CMS require RACs to reimburse physicians for medical

11 records requests associated, not only with underpayments, but with any and all medical records requests.

12 Dr. Senagore: Second?

13 [second]

14 Dr. Senagore: Any comments, questions? All in favor, say Ay.

15 [Ays]

16 Dr. Senagore: All against? Motion carries. Dr. Snow again?

17 Dr. Snow: Again, regarding the RACs, PPAC recommends or urges CMS to revise subsection E9

18 on staff performing complex coverage coding reviews that medical necessity denials within the Medicare

19 program should be reviewed by a physician of the same specialty and licensed in the same state.

20 Dr. Senagore: Second?

21 [Second]

22 Dr. Senagore: Any comments or questions? All in favor?

23 [Ays]

24 Dr. Senagore: All against? Motion carries. Greg?

Dr. Przyblski: Just a question on G last sentence of the first recommendation. Do you mean or both or either in that last line, because I would not think that you would want both applied concurrently.

Dr. Senagore: No, I don't. It should be correct to say whether the 95 and/or 97 E&M Rules will be applied.

Dr. Przyblski: I mean I think the intent is can you use either rule or will it only be one of the rules, but it can't be both of the rules at the same time.

Dr. Senagore: You could try. [laughter] If you had an EMR you could do that.

Ms. Trevas: [off mike]

Dr. Przyblski: Well, they're two different rules. And in theory you could simultaneously ask that both rules be applied, but then it just requires additional documentation that nobody's doing.

Dr. Senagore: Yes, it should just say whether the 95 or 97 E&M rules will be applied. Dr. Snow?

Dr. Snow: PPAC recommends that CMS change the minimum amount—

Dr. Senagore: I'm sorry, Dr. Snow. We have to approve that amendment. You want to make that motion?

Dr. Przyblski: Sure, change it to what we just said. [laughter]

Dr. Senagore: And I'll second that. And all in favor say Ay

[Ays]

Ms. Trevas: [off mike]

Dr. Senagore: Yes, we approved that, yes ma'am.

Dr. Sprang: What does it say now, Tony?

Dr. Senagore: It just takes or.

Dr. Sprang: No I mean with the change, what do we have?

Dr. Senagore: Yes.

Ms. Trevas: Whether the 1995 or 1997 E&M rules will be applied.

Dr. Senagore: Will it be '95 or '97, that's what it says.

Dr. Sprang: I guess because my understanding obviously from being involved with the AMA for a long time, when the 95 issues came out, physicians were in an uproar. The AMA was, the president was going to be hung in effigy, and so that's why they added the 97 rules and the understanding at that point in time was that either set of rules would be acceptable.

Dr. Senagore: We would leave that option open to the RAC to say that.

Dr. Sprang: Well, but do we want to even recommend to the RAC that either, following either set of rules would be acceptable?

Dr. Senagore: How would you prefer to have it worded?

Dr. Sprang: I need to look at it again.

Dr. Senagore: I think that accomplishes what you're saying.

Dr. Sprang: Does it? Because if it accomplishes it fine, I just want to make sure it does that.

Dr. Ouzounian: It's what we want.

Dr. Sprang: As long as it does, fine. [laughter]

Dr. Senagore: OK, Dr. Snow, I'm sorry to have interrupted.

Dr. Snow: No problem. Inasmuch as the RACs may attempt recoupment for claims less than $10, PPAC urges CMS to change the minimum amount to $25 consistent with the minimum amount of debt eligible for referral to the Department of Treasury.

Dr. Senagore: Interesting. I'll second that one. Any comments or questions?

Dr. Bufalino: How the hell did he know that? [laughter]

Dr. Senagore: Without that friendly amendment, I'll move, I'll call the question. All in favor?

[ays]

Dr. Senagore: All against? Motion carries. Anything else? I thought I saw another hand on that side of the room. No? Otherwise I entertain a motion to adjourn the meeting and thank you for everyone's participation. [applause]

<u>Adjourned</u>