CENTERS FOR MEDICARE AND MEDICAID SERVICES

PRACTICING PHYSICIANS ADVISORY COUNCIL

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Room 505A
Washington, DC

Monday, August 30, 2004
8:30 a.m.

Council Members

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DR. JAMES BERGERON
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DR. WILLIAM ROGERS, Director
Physicians Regulatory Issues Team
Medical Officer to the Administrator
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DR. KENNETH SIMON, Executive Director
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MR. DON THOMPSON, Director
Division of Ambulatory Services
Center for Medicare Management

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Public Witnesses

DR. JOESEPH BAILES
American Society of Clinical Oncology

DR. JEROME CONNELLY
American Academy of Family Physicians

DR. J. EDWARD HILL
American Medical Association

DR. GEORGE TALER
American Academy of Home Care Physicians

DR. DANIEL WALDMANN
AdvaMed

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MS. DANA TREVAS, Rapporteur

A G E N D A

Morning

Afternoon

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Open Meeting

Dr. Rapp: Good morning. I am Dr. Michael Rapp. I'm Chairman of the Practicing Physicians Advisory Council. So I'd like to welcome you all to what is our 49th meeting of the Council, and I'm happy that all the members of the Council have been able to make it. We did our best to give you some decent weather here in Washington. I hope the rain doesn't bother you too much. But, any rate, thank you all for coming and we're looking forward to a very productive session of our meeting, as we discuss the issues related to the Medicare Program. These are, of course, very exciting and challenging times for the health care system, and, as practicing physicians, we are pleased to be able to participate in that, in trying to address the various issues. You have the agenda. And there are no changes to that. I do want to thank the staff for their assistance in preparing for this meeting. The first item on the agenda here is to welcome Mr. Herb Kuhn, who is the Director of the Center for Medicare Management Centers for Medicare and Medicaid Services. Welcome, and thank you for being here with us.

Mr. Kuhn: Dr. Rapp, thank you so much and I, too, want to extend my welcome, not only to the members of the panel but also those in the audience. We're grateful that you're here. I'm also so grateful to see that so many of you have agreed later this afternoon to present testimony. I think last time we had the meeting, we had two or three presenters. This time, we have at least double that amount, if not more, and so the meeting is flexed so that we can accommodate those public comments and we're grateful that we'll have those and we appreciate that very much. I'd also say that much has happened since we last convened PPAC. The final Inpatient Rule has been published. The Proposed Physician Rule, the Proposed Outpatient Rule is out there now, so we have plenty to talk about. Plus, Titles I and II are out there right now of the MMA, dealing with the drug card and the new Medicare Advantage Program. And then, finally, the Section 1011, that is the program within MMA that allows us to provide assistance to both physicians, ambulance companies and hospitals, for EMTALA-related services for those individuals that are undocumented aliens. Many of these issues are issues that PPAC opined for us during the last meeting. And we were grateful for that assistance and that input. Hopefully some of those things were

reflected in the proposed reg., if not, we hope we'll be able to hear more about it at this meeting. And furthermore, in the final comments as groups provide those. So we were grateful for those discussions last time and as I said, many things have happened since then, so we'll have plenty to talk about this meeting. Also, you might notice a few changes in this meeting, short of the venue that we have a different room this time. But we've also tried to listen to not only the members of PPAC, but also those in the audience; how we can make this a more meaningful experience for you all during the day that we have, because we only have one day together. So we're trying to do some improvements here, I think, not only in the presentations, both visually, as well as the presentations, but also how we focus the Q&A at the end. The series of questions of things that we're interested in hearing on. Obviously, we don't want to limit the commission members to just those questions, but if there's other things that you want to talk about, by all means. But at least give us some more focus so we can take the information that we need, here at CMS and HHS, ultimately, to move forward.

So we hope that will help in terms of the discussion today. We hope to make some improvements. If members of the commission, or if those of the audience see even further ways that we can make improvements, please let us know, because we want to make this as good an experience for you all, because you are volunteering your time as practicing physicians to help us be better policy makers. But if there's ways that we can do improvements in that, we want to make those. So by all means, please share those with me, or any of the other staff. So, with that, we've got a long agenda, I'll turn it back to Dr. Rapp. But thank you all. Look forward to working with you all today.

Dr. Rapp: Thank you, Mr. Kuhn. The next person on our agenda is our Executive Director, Dr. Ken Simon. He will update us on the response of CMS to our recommendations from our May 17th meeting.

Dr. Simon: Good morning to members of the Council and guests, provide an update from the prior meeting. From the last meeting, agenda item E-1, the Council recommended that CMS require the Office of the Actuary to report to the Council on the assumption that the Medicare Economic Index

Calculations developed in the 1970s reflect the current costs of practice in 2000. [chatter] The response is provided by Steve Heffler, of the Office of the Actuary, who will also be a speaker later this morning. The law requires the Secretary to develop an index to be used in the updating of physician payments. Since its development in the '70s, the responsibility for the index, the Medicare Economic Index, has remained in the Office of the Actuary at the Centers for Medicare Services. While the index was originally developed in the '70s, the Office of the Actuary periodically revises and re-bases the MEI to reflect recent costs and practice patterns. We recently made two changes to the MEI, to ensure that it reflects the current costs of practice, as appropriately as possible. First, we made a methodological change in MEI by applying multi-factor productivity to all cost categories in place of labor productivity, applied only to the labor portions of the index. This change was made for the 2003 update, as published in the December 31st, 2002, *Federal Register*. Secondly, the index was re-based to a 2000 base year for the 2004 update, details of which can be found in the November 7, 2003 *Federal Register*. The main source of data for the latest re-basing came from the Patient Care Physician Survey, published by the AMA. The re-basing was completed using the most current data available from the AMA at the time of re-basing, calendar year 2000 data. Therefore, CMS and the Office of the Actuary feel that the cost weights do reflect the distributions in 2000. As has been our policy, we will continue to monitor the MEI to ensure it adequately reflects the cost of practice faced by physicians.

Agenda Item F1, from Dr. Bill Rogers, Director of the PRIT Program, PPAC recommends PRIT further investigate the burden on physicians of the Limited English Proficiency requirement, concentrating on institutions instead of individual physicians. CMS response is that we will continue to communicate with groups such as the American Hospital Association and the medical community at large to identify any problems related to Limited English Proficiency. We have not received any comments or complaints from hospitals or clinicians at this time.

Agenda Item F2, the Council recommends the Director of PRIT facilitate an update to the Council on the Medicare Modernization Act provisions regarding evaluation and management

documentation guidelines. CMS response is that the AMA efforts to revise CPT documentation guidelines have been suspended at this time. There are no immediate plans to revisit the project at this particular time.

Item F3, the Council recommends that it receives an update at its next meeting on the recommendations from a previous meeting that primary care providers be given the authority to prescribe power wheelchairs. CMS has proposed recommendations through the regulatory process that will give physicians of any specialty the authority to order power operated vehicles and power wheelchairs.

Agenda Item G1, as part of the oversight of the Skilled Nursing Facility Consolidated Billing System, PPAC recommends CMS address the concerns of the physicians community, that this billing system results in inefficient and inequitable billing and payment for both patients and physicians, which threatens the quality of, access to, and continuity of care for patients. The response from CMS that was given by Sheila Lambowitz, the Deputy Director of the Division of Post-Acute Care, indicates that CMS has been working informally with physicians and other stakeholder groups to improve communication within the nursing home community. We agree that it is crucial to clarify the consolidated billing provisions to ensure that beneficiaries have access to high quality care. We have developed ten education articles pertaining to consolidated billing that are currently publishing on the CMS MedLearn Matters website. This information was announced at the SNF open door forum in August, and copies of the articles will be sent to the various trade organizations. It should be mentioned that this information has been provided through the SNF open door forum, over the course of the last year, as this issue has been a recurring issue through that venue. CMS established a separate SNF consolidated billing website recently that contains the educational articles as well as other relevant material pertaining to SNF consolidated program. We think that the information will help stakeholders better understand their responsibilities under this program.

Agenda Item G2, PPAC recommends CMS direct Skilled Nursing Facilities that approve referral of patients for consultation to be responsible for expenses associated with the consultation unless

specifically prohibited in advance of referral (in a manner analogous to the current advance beneficiary notice process used by Medicare beneficiaries). Well, CMS has new program sample notices between SNFs and physicians that are currently undergoing internal review. We anticipate that these notices will be used to alert physicians that services provided during the office visit may be subject to consolidated billing. The sample notices will be posted on the website probably over the course of the next four to six weeks and will be available for public comment and the agency seeks public comment on the sample notices.

Agenda Item G3, PPAC recommends CMS continue to request legislative changes to the list of codes excluded from consolidated billing. CMS has worked with Congressional committees on consolidated billing issues in the past and monitors the program carefully to consider areas where it would be possible to advance recommendations for change. CMS regularly updates the coding lists for services excluded from consolidated billing, under the BBRA, and recommends changes to address advances in medical practice.

Agenda Item G4, the Council recommends CMS explicitly clarify that Part B denial of a claim is not required before a physician can seek his or her share of payment for a service bundled into a Skilled Nursing Facility's Medicare reimbursement. CMS is in agreement with the recommendation. A Part B denial is not required before a physician can request payment for services rendered. CMS has already released detailed instructions relating to services that are bundled into the SNF per diem rate. Since it has been clearly stated that the technical component of these physician services are the responsibility of the SNF, there is no need for a Medical Part B Denial Notice.

Agenda Item G5, the Council recommends CMS evaluate internal methodologies of payment to Skilled Nursing Facilities, such as provider agreements to allow coverage for services not adequately covered in current methodologies, such as the technical component of fees for services provided and incident to medications. CMS has been conducting research to identify ways to redefine the SNF PPS system. One of the primary areas of research is ensuring adequate payment for non-therapy ancillary

services. However, this research does not focus specifically on payment, for the technical component of physician services, or of physician incident to services. Reimbursement of these services is specified in statute, and would require a Congressional action to modify.

Agenda Item I, with regard to payment for medical care for undocumented aliens, Section 1011 of the MMA, PPAC recommends no changes be implemented with regard to collecting patient information and no new questions be added to the hospital registration forms. The lack of a social security number and insurance coverage may serve as a stand-in to identify an undocumented alien. CMS responded that CMS considers a number of alternatives regarding the amount of non-medical documentation needed to support a Section 1011 claim, including the one offered by PPAC. On July 22, 2004, CMS posted our draft implementation approach and the options we considered regarding non-medical documentation. CMS also held a special open-door forum on the implementation of Section 1011 on August 2, 2004, to solicit additional comments. The public had an opportunity to review CMS's proposed approach for documenting the eligibility of individuals described in this provision. CMS accepted public comments through August 16, 2004, and considered public input in its final implementation approach. CMS will issue a proposed packaged.

Agenda Item I2, with regard to Section 1011, PPAC recommends CMS consider the California system for reimbursement for indigent care. Specifically, the following three components: 1. funds are allocated by formula into three separate pools—hospitals, physicians, and other providers; 2. payments are made quarterly, with funds remaining at the close of the fiscal year paid out as an additional distribution; 3. providers seeking payment complete a one-page statement certifying they are eligible for the program. CMS has considered several options with regards to Section 1011. The first, we are proposing that distinct funding pools not be used, but rather a single state funding allocation be used. CMS is soliciting comments through the proposed implementation approach. Agenda Item 2, CMS proposed implementation approach includes PPAC's recommendation to include quarterly payments, with funds remaining at the close of the fiscal year paid out as an additional distribution. And 3, CMS

proposed a number of payment options, including the one offered by PPAC. However, the proposed implementation approach requests comments on a plain specific billing approach.

Agenda Item I3, with regard to Section 1011, PPAC recommends CMS require that if a hospital likes to receive payment of both hospital costs and the physicians' reimbursement, the hospital will be required to remit the physicians' reimbursement funds to the physician. As we stated in our July 22nd implementation approach, Section 1011 does not delegate legislative rulemaking authority to the Secretary. And without rulemaking authority, CMS is not able to require hospitals to remit physician reimbursement within a specified time period. However, our proposed implementation approach does encourage hospitals to reimburse physicians in a prompt manner after receiving Section 1011 reimbursement.

And the last item under Section I, I4, with regard to Section 1011, PPAC recommends information obtained on undocumented aliens not be made available to the Immigration and Naturalization Service. The CMS response: CMS does not have the legal authority to deny the Immigration and Naturalization Service access to citizenship information obtained during the financial screening process. Our proposed implementation strategy requires providers to maintain the information in their files rather than submitting it as part of the payment process.

Agenda Item J, PPAC recommends CMS prohibit the health care industry from accessing National Provider Identifier Information for marketing or research purposes, unless an approval process for obtaining such information is created. The CMS response: The strategy for releasing data from the National Provider Service that specifically identifies a health provider, who as an individual will ensure that requesters identify the purpose or use of the data before approval is given before the release. Research is a routine use for the NPS data, but requesters of individually identifiable NPS data would have to describe the type of research they wish to conduct as part of the data release approval process.

Agenda Item K, PPAC recommends that before CMS implements a competitive bidding system, the following issues be addressed: 1. patients unable to pay their co-pays; 2. protection of physicians from

increased inventory cost; 3. handling of physicians' administrative costs; 4. quality control of drugs; 5. responsibility for shipping when the wrong drugs are shipped, the quality if inferior, or the prescription is changed at the last minute; 6. responsibility for the accuracy of patient information, and lastly, handling of programs that supply drugs to indigent patients. Our response: CMS is committed to implementing the Drug Competitive Acquisition Program, consistent with the statute. And with the quality of care and administrative ease being to of the foremost design parameters. We intend to continue our dialog with the physician community in gathering input on this new payment system, and we will proceed through our notice and comment rulemaking process.

Agenda Item M1, PPAC recommends CMS use reasonable, available means of communication to solicit information concerning individuals experiencing excessive delays in approval of provider enrollment. CMS has formed a senior leadership team in the February of this year to specifically address the problems related to PECOS. This team has had 14 site visits with carriers since February and anticipates 2 to 3 more site visits over the next few weeks. There were 104,000 applications backlogged in February 2004, and as of July 1 of this year, it had been reduced to 81,000 applications. CMS initially processed 22,000 applications in February of this year, 37,000 applications in April of this year, and 53,000 applications in June of this year. CMS is stating in various venues including the open-door forums that providers whose applications have not been processed and who are experiencing financial hardships, should contact the division of provider and supplier enrollment. Allan Gillespie, who can be reached via email, AGillespie@CMS.HHS.GOV has been designated as the contact person to facilitate physicians in this matter.

Agenda Item M2, PPAC recommends CMS strongly support and recommend to the Office of Financial Management that interest on reimbursement be paid to all physicians whose Medicare Provider Number was delayed more than sixty days. Interest should be paid on all bills submitted after the 60-day Provider Enrollment Process was to have been completed, according to the CMS standard. The CMS response: CMS is required to pay interest on clean claims (in essence, claims received for processing) that

are paid more than 30 days after receipt. CMS will pay interest on all these claims, regardless of the reason for the delay. There is no provision in the statute for the payment of interest on claims that have not been filed regardless of the reason. We are currently surveying the carriers to determine the extent and nature of the problem, and will discuss this issue in more detail at the next PPAC meeting.

Agenda Item O, PPAC recommends the Council receive an update at its next meeting on the recommendations from a previous meeting that primary care providers be given the authority to prescribe power wheelchairs. And, as indicated, I responded to that earlier in Agenda Item F3, which was related to Dr. Bill Rogers's response.

I would also indicate that we are currently changing our process as Mr. Herb Kuhn mentioned earlier, and anticipate that for the meeting we will continue to project not only the update, via PowerPoint presentation, but also make it available in hard copy to all the members as well.

Mr. Kuhn: Let me just expand on that. I think at the last meeting, you all requested that PPAC members that we give this information to you in writing in advance of the meeting and I thought that was a reasonable request. Heretofore, I guess we had not. We processed that through, but we weren't quite ready, so we were able to project the questions up there. Ken, as he has in the past, read the responses. The responses in their entirety will be part of the minutes of this meeting that will ultimately be on the CMS website, but for members of the commission, we will email those to you specifically so you will have those. But at the next meeting, we will everything to you in advance, as we process this particular part of the agenda through. So I just wanted to let you know.

Dr. Rapp: Does that complete your report?

Dr. Simon: The only other information I'd like to share with the Council and the public is that the July 23rd *Federal Register* notice requested input from the public for nominations to the Council, beginning in February 2004 so that we would refer Council members to the July 23rd *Federal Register* notice, which should be in the packet, where we are seeking applications for new PPAC Council members for next year.

Dr. Rapp: Are there any questions of Dr. Simon at this point regarding his report? Dr. Gaughan?

Dr. Gaughan: I had a question on M2, if you could put that up. And that involves the interest on enrollment. I didn't quite understand that, because we have new Medicare physicians who are waiting to submit a claim because they don't have a number. Are those applications not going through, are they going to get interest? I didn't understand it.

Dr. Simon: By statute, there is no provision in the statute for payment of interest on claims that have not been filed. So if those claims have been filed, then they would be eligible for interest payment.

Dr. Gaughan: And, is there a way that new people can file the claim without actually being enrolled?

Dr. Simon: They will have to be enrolled.

Dr. Gaughan: You know I'm a new doctor. I put my application in. I've got for instance in Kansas, 2,376 claims over 60 days for new doctors. So those doctors, it's my understanding, can't submit their claims yet, but they've got them stacked up and ready to go. Will they be getting interest, or is there a way those doctors can submit their claims even though they're not enrolled?

Dr. Simon: From my conversations with the group that handles PECOS, each of the carrier sites have received—there have been several issues to address this problem. First is that the agency has pumped several million dollars into the budget for the carrier so that it will enable them to hire additional temporary as well as permanent workers to address the backlog of applications, and recognizing that there are new providers that are providing new services and do not have a number but have claims available, it was with that intent where the agency has developed the contact person, in this case, Allan Gillespie, who is responsible for helping those physicians who are experiencing delays in getting their applications processed so that they can receive reimbursement for the services that are rendered. And that's a change that had not been in place.

Dr. Gaughan: Because it's interesting. Our numbers have increased since August 3, in Kansas, and although your giving more money to the carriers, we wrote a letter to Dr. Rogers, the Kansas Medical

Society. We had concern that it was poor implementation of PECOS by CMS that did this, and so you're saying they're going to pour some more money into it, do some more education, and we expect these claims to be paid, when?

Dr. Simon: There has been more money placed into the system, which enabled the agency to increase the number of applications that have been processed on a monthly basis. That actually began back in February of this year. I think there was an issue of infusion of over five million dollars pumped into the system so that both permanent and temporary employees could be hired. And as a result of that, which was the numbers that I reflected when they, in February, when it was noticed that this was a major problem and we spoke about it at our February meeting, the agency had the capacity of only processing 22,000 applications a month. By April, that increased to 37,000, and by June, it had increased to 53,000 and that was largely as a result of being able to employ more employees to process those applications so that the claims could be submitted and filed.

Dr. Rapp: Mr. Kuhn?

Mr. Kuhn: If I could just [?] briefly to you. I think, this afternoon at 2:15, we're going to have an update on the PECOS systems, so maybe we want to suspend some of these comments 'til then, would be fine with me, and if it would be OK with you. But importantly, I think you raise a good point. Number one, as Dr. Simon said, we're in a position that we have no authority to pay interest on overdue claims that do not yet have a billing number or for claims that are lengthy, so we just don't have the authority. We looked at it. You all raised the issue at the last meeting, we just don't have that authority to do that. But what we do have an obligation to do, and that is to process these new enrollments in a timely, fast, and appropriate way, and the PECOS system in the process just hasn't gotten us where we need to be just yet. I think we've done a lot of mitigation strategies to try to deal with that, as Dr. Simon said, in terms of putting additional resources, allowance for hiring the temporary help, etc., to help catch up on the backlog. We'll get an update on that this afternoon. I think we've done a good job of moving further, but we're not good enough yet, and I'll tell you up front, we've got to do better in that in terms of catching

up. Some states are really moved aggressively, and I think have gotten some of the carriers have done a terrific job of getting us where we need to be. Some still need a little bit more work. So we've got some additional mitigation strategies we can talk about this afternoon to try to get us there and get this right and get it fixed, because it is not appropriate that physicians should be waiting more than 60 days to get their billing numbers period. And that's a milestone we need to achieve here as an agency and we're going to strive to try to be a better business partner to make that happen.

Dr. Gaughan: Thank you for the clarification. I'll be happy to discuss this this afternoon.

Mr. Kuhn: That'd be great. Thanks.

Dr. Rapp: Are there any other questions for Dr. Simon? Dr. Bergeron?

Dr. Bergeron: [?] happen in our offices. Specifically, the patient has some debilities and needed and required for dermatological care bathing. And said, well, Dr. Bergeron, where can I get a little apparatus that I can get from my chair into the tub, except I'm still not clear on who has authority, what health care providers have the authority to assess, evaluate and then prescribe, equipment—wheelchairs, walkers, etc.? Is there a brochure, is there a protocol, something that we can readily refer to saying, yes, physical therapy evaluation is needed. Physical medicine is needed, all the data has to be satisfied, and then you send them to the place. Is there something available? Because I'm on the PPAC and I said, well, you know, I don't know, do I have to send a patient to be evaluated by physical therapy, physical medicine? Is there something, guidelines, that's readily available for the practicing physician in their offices? Who is eligible, what protocol we have to go through? What consultations for prescribing the wheelchair, durable medical equipment?

Dr. Simon: Yes, that information is available on the CMS website under the DME webpage, however, we can make that information available to the Council members.

Dr. Bergeron: Because I'm wondering if myself, multiply that by many practitioners throughout the country. I mean here we're in a quandary about it. I don't know, and here I'm on this Council. I know we discussed, but something that I can—yes, wheelchair, you go to physical therapy, you need a walker

to get in and out of the bathtub, yes, you go here. Am I eligible as a dermatologist, making a dermatological diagnosis that this individual needs this particular apparatus, therefore write a prescription.

Dr. Simon: One of the, yes, and the request that the Council made in this regard, a few months past has led to discussions internally within the agency, both in the Program Integrity section of [?] as well as the Chronic Care section of the agency. And at least at this point, as it related to power wheelchairs, there were specific specialties that were restricted—

Dr. Bergeron: I remember that, but I mean, are other pieces of equipment needed?

Dr. Simon: For most of the other pieces of equipment, a licensed physician or clinical provider—

Dr. Bergeron: In other words, I could have prescribed that walker for that particular patient?

Dr. Simon: That's correct. And that information is available in terms of who would be able to provide so on our website under the DME Billing. There is a Q&A section of the website where—

Dr. Bergeron: Could I get that before I leave today?

Dr. Simon: Yes, we'll get that page to you.

Dr. Rapp: Dr. McAneny?

Dr. McAneny: There's been a lot of interest about the undocumented aliens. And in our discussion last time, after hearing about the fact that the Skilled Nursing Facilities were not willing to receive the money that they received from Medicare with physicians, I'm curious what the decision that CMS has made to not put the money into distinct pots, therefore setting us up for the same sort of problem when an undocumented alien comes to, if you do it simply by states, then the money goes to the hospital. And again, we were hoping for more of a stick from CMS to make the hospitals actually share the money with the treating physician, not simply be encouraged to do so. So I'm wondering if you would expand on your comments that CMS has decided to just do it as a statewide pot. I'm also concerned that the money will run out in February and that any undocumented alien who is treated in October, that provider is just out of luck.

Dr. Rapp: Don Thompson apparently is the designated. He's the Director of the Division for Ambulatory services. He's going to be talking to us a bit later, as well.

Mr. Thompson: Acting Deputy Director, but thank you for the promotion.

Dr. Rapp: Oh, you're not the director?

Mr. Thompson: No, Liz Richeter. But I think we've gathered a lot of public input, as was mentioned earlier on 1011 and I think this issue about the separate pools, one of the key factors to keep in mind is that we're actually going to wait, one of the options here is to wait a period of time past the close of the quarter in order to calculate what the payments would be, so that essentially you don't have a situation where you would be paying more to hospitals, more to physicians, more to ambulance, what are the correct percentages? It'll essentially be for the care that's provided, and for the information that's submitted to us for payment, we'll then look. And that will essentially establish the pools. So it's not like first in, first out. It'll just be the physicians will submit all their information; the hospitals will submit their information; the ambulance companies will submit their information, and then if we allow a sufficient period of time for that information to be collected by CMS, to a certain extent, the pools will self-create, if you will. So it won't be a disadvantage or advantage to any particular group there of the three. They will all have an opportunity to get the information in and we'll look back and that will be the determining factor in how much physicians get and how much hospitals get, and how much ambulance companies get. We felt that was kind of a more appropriate approach than to try to estimate or guess what percent should go to physicians, what percent should go to hospitals, what percent should go to ambulance companies? Just look at the care that's actually been provided and let that be the determining factor.

Dr. Rapp: Thank you very much. Is there any other questions for Dr. Simon? If not, let's move on to the next item, which is the Update on the Physician Fee Schedule, Section 941 E&M Coding. Steve Phillips, Mark Hartstein, and Don Thompson, as well. I'll let you tell me what your titles are so I won't get them too wrong.

Mr. Phillips: I will start. I'm Steve Phillips. I'm the Director of the Division of Practitioner Services.

Mr. Hartstein: I'm Mark Hartstein. I'm a senior technical advisor in the Hospital and Ambulatory Policy Group.

Mr. Thompson: Don Thompson. Acting Deputy Director of the Hospital Ambulatory Policy Group.

Dr. Rapp: Acting Deputy Director. All right, thank you. Go ahead.

Mr. Phillips: All right, thank you and good morning. As I said I'm the Director of the Division of Practitioner Services and I was going to talk about the two issues to start off here, the summary of the proposed Physician Fee Schedule for 2005, and hopefully we'll have some slides up here in just a moment. And the second topic is Section 941 of the Medicare Modernization Act, dealing with implementation of changes to the Evaluation & Management Development Guidelines. Moving on to the next slide here, the topics more specifically, the Physician Fee Schedule. The proposed rule was published August 5th of 2004, and the comment period runs through September 24th, 2004, so I guess this is a time to point out that while we're certainly open to your questions, comments and suggestions, since we are in an official comment period, that the official way to get those communicated to us and responded to in the *Federal Register* is to submit written comments, and the regulation, the first page of the regulation specifies how to submit those comments. The second topic, as I said, is that I will discuss the Section 941 of the MMA. The Physician Fee Schedule—and again, I'm working under the assumption that Council members at least had some exposure to what is in the proposed rule, so I'm not going to go into it in extensive detail, just hit on some of the primary topics that we want to bring to your attention, and the slide here indicates that the new preventive benefits is one of the topics that we'll be going over. Also the payment update of 1 and a half percent and then a few of the other proposed changes. OK, with this slide here—can you back up one? There are three specific benefits that were included in the MMA and the first one is commonly referred to as the Welcome to Medicare Benefit, and this is discussed in the

rule as far as our proposed plan to implement this consistent with statutory requirement to be effective January 1 of 2004. A couple of the key features is available for new beneficiaries within the first 6 months after their effective date of their Part B coverage. It would include a comprehensive examination, as well as education, counseling, and referral to other preventive services, and the proposed rule would establish a payment equivalent to a new patient office visit, plus an electro-cardiogram, which is included in the initial benefit package. The next benefit that we did include in the proposed rule is the MMA benefit to expand coverage to cardio-vascular screening tests. And as you see here, there includes tests for total cholesterol, high density liver protein, and triglycerides. Test is permitted once every five years under the proposed rule and Medicare would pay for the test under the clinical lab fee schedule. The third new preventive benefit is the diabetes screening test, and under the statute, this would include a fasting plasma glucose test and post glucose challenge test. It is permitted, the statute specifies for beneficiaries at risk of diabetes and the proposed rule as you'd see here in the second bullet would spell out how beneficiaries who are diagnosed with pre-diabetes would be identified based on a fasting glucose level specified in the level. And again, Medicare would pay for these tests under the Clinical Laboratory Fee Schedule. OK, so then moving on to the update proposed in the rules, actually as a result of MMA is set in statute to be no less than one and a half percent increase and as I'm sure everyone is aware, the Office of the Actuary is currently forecasting payment reductions under the sustainable growth rate for 2006 and later years, when the statutory floor on the update goes away, and although there was minimal mention of the SGR in the proposed rule, as we have in past years, there will be complete discussion of the calculation in the final rule. OK, as I said, I'm really just giving you a quick run through. These are some other proposed changes that were included. We have updated proposed updates to the Geographic Cost Indices for Physician Work & Malpractice. I'm sorry, that should be Physician Work & Practice Expense. Malpractice was updated last year. And so the impacts by GPCI locality are included in the tables in the rule and in accordance with the statute, they are phased in over 2 years. We are also proposing revised payment rules for low osmolar contrast media. This is actually removing some restrictions on when

Medicare will pay for the use of LOCM consistent, we indicate in the rule, we believe this is consistent with current general medical practice. We are also proposing to update the malpractice RVUs with more recent premium data. Also we are proposing to revise requirements for supervision of therapy assistance and therapists in private practice currently are required to provide personal supervision of therapy assistance and we would amend that requirement to be personal supervision essentially indicates that the therapist must be in the room supervising the therapy assistant. We would amend that requirement to a direct level of supervision, which essentially means that the therapist must be in the office suite when the therapy assistant is providing the treatment. And finally under the other proposed changes to mention is the addition of ESRD services to a list of Medicare TeleHealth Services. This is a kind of a follow up to a change that we made last year in establishing new G-Codes for the monthly capitated amount for care of dialysis patients. And part of that requirement was to pay higher rates for additional services provided during the month for the additional visits and included in that was complete assessment of the patient, so the proposal in response to the concerns and a request to add ESRD services to the list of TeleHealth Services would allow for the provision using telecommunication equipment of visits by the physician or practitioner, subsequent to complete assessment. The complete assessment of the patient under the proposal would have to be provided face to face. OK, these are just some websites of interest. The proposed rule is on the Government Printing Office website at that address. Also, this year we have begun to accept comment on our rules submitted electronically and that is the website to do that, to submit your comments electronically. And then the third website contains supplemental data and information as far as some of the data bases used in developing the rule as well as past rules.

Dr. Rapp: Can I just ask you a couple questions about this portion of it? I did go to the website and I looked at the regulations and so forth, and couples things came to my mind. On this new Welcome to Medicare physical, or examination. First of all, there's a lot of very detailed description in the regulation about what is supposed to be done. Is that statutory or is that regulatory?

Mr. Phillips: Well, it is, it's not completely statutory as far as the detailed level of description. The statute specifies an initial visit and we in the proposed rule described what is entailed within that visit and solicit comments on what's included in there.

Dr. Rapp: How did you decide to go into such detail rather than just leave it to the physician as to what might be appropriate for an initial comprehensive evaluation, since that's quite uniquely medical in terms of the decisions as to what is appropriate.

Mr. Phillips: Actually, our Office of Clinical Standards & Quality developed the detailed clinical information that is in the proposal, based on the statutory language in terms of what they would included as covered under the benefit.

Dr. Rapp: And then, how did you arrive at a level three would be the appropriate charge for that type of visit?

Mr. Phillips: That was based on evaluating the types of services that were included within the covered benefit at a comparable level and E&M does that.

Dr. Rapp: And then finally, you made a comment that the only way that you would be able to consider our comments would be if we submitted them in an official format. Is it your understanding that even though PPAC is an advisory body to CMS that should we make a specific recommendation that you would not be able to take that into account unless we went through this additional process?

Mr. Phillips: I didn't want to suggest that we would disregard anything that the Council said, but as far as responses in the *Federal Register*, we do need to have, for example, if we proposed something, and then would take a different course, that under the Administrative Procedures Act, that would have to be based on a comment, a written comment submitted on the proposed rule. Certainly, though, any input that we would receive today or otherwise, relevant to the rule, we would take into consideration. It's just that if we were to change policy, we would have to have a written comment.

Dr. Rapp: And then finally, there, I believe the rule also addresses the power wheelchair and other durable medical equipment and what is necessary to get those approved? The face to face visits? Is that not in this rule as well.

Mr. Phillips: Yes, it addresses—

Dr. Rapp: So I think I had a question about one of the items I saw in there, and that is a specifically, that limitation, even though, it says it for basically every medical supply, appliance, device, every item of durable medical equipment, it requires a face to face examination. Did I get that right? And then furthermore, it says the limitation—Medicare does not pay for a face to face examination for the sole purpose of the beneficiary's obtaining the physician's or prescribing practitioner's order for the durable medical equipment. So if the person goes to get a power wheelchair or something else, a nebulizer, or I guess practically anything—crutches, I don't know what's all included in that, but if that's something that person comes specifically to the doctor to get, according to this, Medicare won't pay for it, even though Medicare requires that you have to do that and have to go to the doctor. So either the doctor does it for free, or what, I don't know. It seems a little inconsistent.

Mr. Kuhn: One of the things that the agency was most concerned about, particularly after launched Operation Wheeler Dealer last year is what we saw in the Houston areas and other areas around the country, were certain suppliers in this area were loading up a number of individuals in a van, taking them to a community, they'd walk in, see a physician and he'd sign off on power wheelchairs, one after the other. I mean it was fraud for all intents and purposes, what was going on here and we're prosecuting those where we can. What we were looking for here is kind of continuity of care. If a person had a relationship with a physician and they had seen that physician over a period of time and the physician knew that they were ultimately going to need a power wheelchair, they could make that prescription and move forward. What we're concerned about, and we'd love for people to give us comments on it—we were trying to deal with this issue of fraud, where people were coming and seeing a physician they'd never had a relationship with before. They'd walk in, they'd sign off on a power wheelchair and off

they'd go. So we're trying to kind of come to a happy medium here, where we create a situation where patients do have relationships with physicians; we have good medical evidence that they need this, to try to avoid this situation of people popping in one time, getting the power wheelchair, and moving on. So you can kind of see what we're driving at. Whether we elegantly fashioned it or not in the proposed rule is another matter. And people can give us comments on that. But that's what we were trying to address at that time. Don, anything else?

Mr. Thompson: Eloquently put. That's exactly the way, it's the continuum of care issue. And again, this is open for comment. I mean all of these issues. It's the purpose of notice and comment rulemaking, so we can go in and get additional input. So this is the type of thing we're out there and exactly as Herb said, that is the thought process is how to address the fraud issue. Yet, we don't want to also create an unnecessary burden for physicians. So this would be a type of thing you can comment on in the context of the proposed rule.

Mr. Kuhn: I mean I can see a scenario where someone moves to a new community and they see the doctor for the first time and this physician says, "You need a power wheelchair." I mean there are unique situations that we'd like to be able to hear from and understand how we can deal with those.

Dr. Rapp: Well, or as Dr. Bergeron, was sort of talking about, it might require, that might be an extensive evaluation whether they need a power wheelchair or not, especially if we're supposed to fine tune it a little bit as opposed to just sign it. But Dr. Bergeron was asking about possibly sending them for a physical therapy assessment, would that not be paid for either? Or is it the physical therapy paid for, but not the doctor visit? In other words, they go to Dr. Bergeron. He's a dermatologist. He says, "I don't really know that much about power wheelchairs or walking or anything else, but your skin looks pretty good. But I'll tell you what, I'll send you to the physical therapist. And while I'm at it, I'm going to send you to Dr. Powers, because she's a neurologist and she knows a lot more about that than I do." And so Dr. Powers has never seen Dr. Bergeron's patient, but she does know a lot about that. She does a total evaluation and can't bill for it. And the physical therapist, how about, she says well, since I can't bill for

it, I'll send you to the physical therapist. Now does the physical therapist get paid for it? Or whoever hires the physical therapist?

Mr. Hartstein: I want to be careful about responding to that question just because the policy was developed in our Office of Clinical Standards & Quality, so I want to only speak where I have some certainty. But it seems to me a complete evaluation would constitute a visit, and then it would be payable, and it probably weren't suggesting that we not pay for something so limited, but it perhaps requires some clarification and comment.

Dr. Rapp: Well, that's what it says here, though. It says Medicare does not pay for face to face examination for the sole purpose of the beneficiary's obtaining the physicians or prescribing practitioner's order for the durable medical equipment.

Mr. Thompson: I think in the context there, sole purpose, was more to the point of as Herb was mentioning—somebody coming in and just kind of saying, "OK, here's a list of patients," you know, signing off on all the power wheelchairs. I don't sole purpose was necessarily being put in the context you just described. So maybe one comment you could make on the rule is for us to clarify what sole purpose means. And that would be a legitimate comment, to say you put up the scenario you just mentioned. And say, does this constitute sole purpose? What does CMS mean by "sole purpose" in this context?

Dr. Rapp: And then, I guess, the other thing I'm personally concerned about is power wheelchairs are one thing, but durable medical equipment—I don't even know what it all includes, or all these appliances, but it sounds like there's a lot of stuff that could be involved here. And patients come in for a lot of minimal—I mean, they may come in just for that. They're not coming in for anything—well, I think I need this, Doctor. At any rate, Dr. Powers, Dr. McAneny, Dr. Urata, and then Dr. Castellanos.

Dr. Powers: I'm a little confused. I don't see how a face to face visit is fraud because you have people who are set up in an office and the patient may come in. They may not do anything and may not get paid for it, but it's a face to face visit and they sign off on the chair, I don't see how that's going to keep people from committing fraud. There needs to be a lot of clarification about what that face to face

visit means. Does that mean that if I've taken care of a stroke patient in a hospital and they leave the hospital walking with a walker or in a wheelchair, whatever, and I sign for that day and maybe they progress to a cane, and then I need to sign for that, do they have to come back to the office at the time they progress to a cane, which could occur momentarily. I can't fit someone in my office that quickly just so I can sign for their DME. But the fact that I've seen the patient and I know that they're probably ready for that because that's a natural progression of their improvement, just because I've seen them before, is that not good enough for me to sign for their DME?

Mr. Thompson: I think maybe addressing those in two pieces. In terms of the face to face visit actually preventing fraud, I think it's virtually impossible to completely prevent fraud, so the question here is are you doing something that helps you prevent fraud, I think is the thought here. It's not necessarily that we believe the face to face visit is going to completely eliminate any fraud in the system, I don't think that's the case, but does this take us one step closer? And then with respect to whether or not you know the patient, you've been treating the patient and whether or not that constitutes, all the sudden you think OK this is logical, you don't need to see them again, in my mind, that seems to be part of the continuum of care issue. So a comment you might want to make on the rules, is again, exactly that scenario, just say, could you clarify for me. This is my patient. I know that this patient—I don't need to see this patient for this. This is OK. That would be the type of comment you could put in the rule and then we would respond to in the final. Again, going to that clarification issue about the continuum of care versus the fraud.

Mr. Kuhn: If I may, just to share with you just an observation on the issue of fraud, moving forward, we have a much more robust offering in this area than just this particular issue. In the spring we announced kind of a three-prong effort to deal with the issue of power wheelchair. One was supplier certification. We need to make sure that those suppliers that are out there providing these products, there needs to be an accreditation process and better certification in that area and we found that out the hard way down in the Houston area, and we're making those changes. The second has to do with coding. It's

been a long time since we've updated the coding and as I think most people know, the K-11 code is where 95% of the chairs go into—but yet you have differentiation of pricing from $1500 to well over $6,000 all fitting into that one code, and we need to do much better area in the coding, and we've got a major initiative going forward on that and a meeting in Baltimore on Wednesday, June 1, to start that process. And finally is the benefit definition, and what we're talking about here is a little bit dealing with that definition, going forward. So we're looking at it in a much more expansive way, but this is just one part.

Dr. Rapp: Dr. McAneny?

Dr. McAneny: I wanted to move back to the Welcome to Medicare visit. I did read the CMS 1429 and as I look at the several pages that list what is required for this benefit, and I think about what it would require for a primary care provider to document that they evaluated all the things that you list on these pages and then I look at the level three reimbursement that I would get for that, were I a primary care physician, I would say, "I hope someone else does the Welcome to Medicare benefit, because I don't want to spend an hour of my time, which is what I think it would take at a minimum, get paid a level three visit, for doing all these things, probably get it denied because I forgot to document whether or not I assessed their functional capability at home or their depression, and go through all of this particular coming up with a care plan that's needed to set up their immunization schedules, etc. It seems to me that this is a well-intentioned idea of getting people into a system and setting up a plan for prevention, but that we have taken it through these comments and through the documentation that you're requiring on that and making it a large battleship to try to get anything done with. So I think that go into the level of detail that CMS chose to go into will defeat the entire purpose of doing this, and I suspect most primary care physicians will do one or two, figure out they can't afford to do this in their practice, and that they don't have time. You also look at the estimated million people entering Medicare every year, and that means a million hours of primary care time that you're going to need to come up with to do this and document all this stuff. A million hours of primary care time is a lot of time and we don't have that much. We don't have the capacity to absorb that into the system. So my comment would be it's great to have a Welcome

to Medicare physical. It doesn't fit in with what the US Preventative Services Task Force has ever suggested is truly beneficial in providing good health care, but to make it this burdensome in terms of documentation and requirements will defeat any good purpose it started out with. I think it needs to be streamlined and revamped and paid for, if you truly intend to do it.

Mr. Thompson: Sure, and I guess, two pieces. One would be the level of documentation and the other would be the reimbursement. Obviously those two are inter-related. I think to the extent that people look at the scope of what's in the preventive visit and they say to themselves, as you said, well this much too much detail. I think that would be a valid comment and a constructive comment would be how you think it should look. So if one were to look at this and say how would I structure this differently, what would be the minimum standards that we would need to put in place? If the public thinks that we have, that the standards that we have in there are too burdensome, well, what's the alternative? What are the standards that you'd like us to use? I think that would be a very constructive comment on the rule. And then the second one in terms of level of payment, even if one were to accept what has been delineated out for the visit, the question becomes is the payment level that we have associated with that adequate or inadequate? And again, the payment level is also something that's open for comment. So not only the content but also the payment level we crosswalked it to is something we can take comment on. And if in fact, your comment is, well, this is an hour, an hour and a half of documentation over and above what you'd normally see in a 99203, that would the type of comment we could look at and why, you know, why is it—how does this compare if you look at the 99203 in a normal documentation requirements for 99203, how does this compare to that and then why is this in excess of that? And again, that goes to the heart of notice and comment rulemaking.

Dr. Rapp: Well, sort of a simple answer to that is first of all, it's described as a comprehensive evaluation, which the CPT already have, which is a level 5. And doctors know how to do a comprehensive evaluation and that's basically all you need. It's sort of the E&M coding guidelines gone wild here. If this was the case on every service, the federal regulations would be like to the 10th or

whatever power. But anyway, that would be the simple way to do it and it would put back in the hands of doctors that they know how to do evaluations. I think one of the things that annoys me personally about the E&M coding guidelines is you don't go to medical school anymore to figure out how to do a physical exam, or do a history, you go to the Code of Federal Regulations. Actually, I went to medical school before that was in there, but so I learned two different methods. But the first one isn't of much utility anymore. Sort of a sarcastic comment. I apologize. Dr. Urata?

Dr. Urata: I wanted to comment on the DME issue. I applaud you for considering that continuity of care is important to take care of these patients particularly with chronic problems, and like Dr. Powers said, sometimes they progress in their disability and as a continuity physician, you might be able to write prescription for more equipment that might benefit them without necessarily seeing them face to face, or you could refer them to a physical therapy, have them fitted for a wheelchair or something like that if they digressed from a walker or something like that. I have a patient that I follow with chronic venous disease and gets ulcers all the time and I understand there's somebody got a comment on wound care. And when they get a bad ulcer, their nurse calls me and tells me they get a bad ulcer, so I refer them to the physical therapist and follow up on that later, so I don't see them face to face. Or get an appointment necessarily right away because I don't have enough time for that and so isn't it possible that under, when you write a prescription for DME or something along that line that your code gets placed in some kind of computer somewhere that you can actually see if you've been following the patient or not? Is that a way of dealing with this when you write a prescription, you can see if you're the continuity provider for a patient?

Mr. Thompson: That's something we can explore. I actually don't know enough about the systems operationally, our system's limitations to be able to answer in an intelligent fashion. But it does sound like an interesting idea for us to explore. Is there any way, using our existing technology and the data bases we have, is there any way to kind of look at this? It's a good point.

Dr. Urata: Because that would be one way of in terms of trying to have patients being seen by their continuity physician rather than somebody at a storefront selling power wheelchairs. Or however they set that up.

Dr. Rapp: Dr. Castellanos?

Dr. Castellanos: I'd like to go back to the comment you made on Malpractice Relative Value data and you're going to try to get more recent premium data. I did read the revisions to the medical payment policies under Fee Schedule for 2005. Specifically one of the issues you've talked about risk classes, and you said to ensure consistency, we use the risk classes of St. Paul Company, one of the largest and oldest malpractice carriers. For your information, St. Paul has been out of that business for three years and you're using their data. I don't think that's correct. I think you need to use current data and one of the things I have about this is that you haven't been able to do that. You say that there's no recent data available; you're unable to collect any national available representative samples. Let me read you something because I went up from $23,000 to $120,000 last year. A 380% increase. And I read a lot about malpractice. And there's a medical liability monitor 2004 rates. This survey has been completed every year since 1991. It's used by professional groups, government agencies and lawmakers and in a report to Congress the General Accounting Office said that the medical liability monitor survey is the only source of data available on medical malpractice insurance. And based its recommendations to Congress on this analysis in rates. Now, if the General Accounting Office feels that that's good, I would hope that CMS would look at this data also. You also mentioned things about office rent, and just for laughs, again you're using, as you well know, we've talked about it, you're using data on apartments, and for whatever reasons that you said, is that physicians frequently locate their office in areas that are in residential rather than commercial. So perhaps the residential rates may in fact be a better measure. I would suggest that you go out in the community and see where the doctors' offices are. They're not in residential areas. They're in office space areas. They're in commercial areas. So if you're basing your studies and your rates on this information, I think you're not getting the most current information. My criticism isn't what you're doing.

My criticism is I would hope that you would look at all sources, post-government and private to get your data.

Mr. Phillips: I think those are good comments. Just on the point about the residential data, I mean, we have received that comment previously in terms of the statement that that's where physicians' offices tend to primarily be located. I think frankly that's a carryover from prior updates that we've done in the *Federal Register*, so I think maybe the bigger point there is whether there are national available data bases on office rents that could substitute for that and that's something that we need to explore, perhaps further, as well, if people are familiar with something that would be a useable substitute, that again would be an excellent point for comment.

Mr. Thompson: Just to follow up what Steve was saying, my understanding of this is that the other alternative that we had for data was kind of huge large retail space. So it's to a certain extent if your options are to use a huge, large retail office space number or to use the number that we used, which one is a better proxy. If we had, obviously, national representative data on office rent per physicians, I can't imagine we wouldn't use that. But I guess, given the data sources that we had, this is as close as we'd have come. But that's not to say that moving forward, we couldn't, if someone had a suggestion about another data source we could use here that was available to us, again, nationally representative, that we wouldn't examine it.

Dr. Rapp: Let me see the hands again? Dr. Senagore, Dr. Azucar, Dr. McAneny, and Dr. Grimm. Just timing wise, we are at 10:00 now. They've got a few more points to make about the E&M coding section of the MMA and then we're supposed to take a break. But maybe we can have Mr. Thompson stay and talk about the O5MMA activity, since he's supposed to be up for that. And but anyway, so just bear the timing in mind. Dr. Senagore?

Dr. Senagore: Just a follow up on the malpractice issue. I wonder if we might be able to get a little more feedback on the methodology behind that. Two specialties I noticed that went down in this current plan actually doubled I rates in Northeast Ohio—neurosurgery and orthopedic surgery. So it

would be interesting to know what methodology was used; was a dominant specialty approach used at all? But to get some clarification on those impacts because those seem incongruous with real life experience.

Mr. Phillips: OK, the issue of whether dominant specialty was used for establishing the amounts is discussed in the *Federal Register* as far as that as an option. Basically it would base the RVUs on the dominant, on the data for the dominant specialty, being the procedure, exclusively, and that was not the option we proposed. It was based on the weighted average of all specialties performing the procedure and as far as the impacts on specific specialties, probably safe to say the rates for all specialties are increasing again. These are relative values which in the end reflect where the costs are for each specialty relative to the national average. And so some may not have increased as much as others even though at an absolute value they may be much higher. Again that's with specifically neurosurgery comment that we have already received and are looking at. But our analysis at this point indicates that that's the case that some of the other specialties actually increase at a higher rate nationally.

Dr. Rapp: Dr. Azocar?

Dr. Azocar: I welcome the part where all the proposed changes. There is a section about updated [?] practice, because I think that's very interesting, and I assume that's something for the future that's being studied now? Or something that has been already done?

Mr. Phillips: Yeah, there actually in the proposed rule for 2005, it's the first of a 2-year phase in of 2000 Census data in the GPCIs, the practice cost index, geographic practice cost index. So that's actually in the proposal for next year.

Dr. Azocar: OK and that's, you can actually go to the website? You can find that information at the website? I'll have some comments for that.

Dr. Rapp: Dr. Grimm?

Dr. Grimm: I have a follow-up on Dr. Powers's comments about durable medical equipment. It would seem to me that each disability that a durable medical equipment is going to address has certain

criteria in which it establishes its need. And as a minimum, if you want to create a deterrent, you make those who are responsible to them sign something that attests to the fact that they have this disability. It would seem to be a very easy thing to do to create—and I'm against forms or anything like that—paperwork. But simply have checklist of minimum requirements for the approval of durable medical equipment and that would make both the patient and the physician responsible for it once they've signed that, which would be a reasonable deterrent.

Mr. Hartstein: Again, these are all very good comments and comments CMS will definitely take into account. One thing that wasn't mentioned—I do want to say that there is a statutory provision that required, this was initiated because of a statutory provision, one of the features of the statutory provision was the face to face visit requirement but clearly there's some flexibility within the statutory provision that CMS can exercise and so to the extent that we have these comments, we can look at where we have authority and where we have flexibility to be able to respond to some of the concerns about the proposal.

Dr. Rapp: Dr. McAneny?

Dr. McAneny: I'll go back a little bit to the comments about using apartment rents and other proxies. The OIG is very good at figuring out whether or not a subsidy that a hospital might give to someone coming to town to set up a practice is truly fair market value. So I would suspect that the OIG might actually have some data on what it costs to have an office space. I think when you go to a given community and you also say, "I want to set up a medical office," the realtors groan because not only do they have to provide you office space, but wheelchair accessible bathrooms and all of the things that fit in with the ADA and other laws that require that we come up with office space that meets multiple regulatory requirements. In most poor communities, such as ours, you can rent an apartment for $400 a month. There is no way that any physician could get an office that would meet any of the regulatory requirements for that amount. I think we are going to discuss this later in more detail when we talk about the MEI and the proxy indicators, but given the fact that we're about to fall off a major cliff in 2006 with a 5% per year decrease unless this is fixed, I think this is probably the most important topic that we're

going to discuss over this meeting and probably the next couple of them. So I do not have at my fingertips, and I suspect nobody on the panel of practicing physicians has at theirs, exactly where the OIG organizations, or the Board of Realtors gets their information as to what a fair market value is for providing office space, but those parameters are used in judging us if we're kickback law, so it seems to me that the two agencies might actually be able to talk together a little bit and come up with what a fair market value is for an office rate and then put that into the MEI.

Mr. Hartstein: Yeah, and when we've considered alternative data sources, one of the things that we have to have is it has to be comprehensive nationwide and detailed enough for us to be able to calculate the geographic practice cost indices, and so to the extent that we don't have that data specifically for a physician office let's say, then we would have to go to a proxy. And even though the proxy may not be ideal, because it is a proxy, it is trying to measure geographic variation to the extent that it's comprehensive in the geographic variation and that cost item is similar to the cost item that it's a proxy for such as physician office rent or some item of physician practice expense. And to the extent that it measures that variation correctly, then it's a reasonable proxy. The extent that it doesn't then of course that gives it some limitation. But it does have to be a comprehensive data source, and we are using it in all areas and even though it may not measure apartment rents in one area, in an absolute sense, if in a relative sense, it does. It's very much like the malpractice insurance premiums and we're trying to measure relative cost difference in a budget neutral system, so we do the best we can with the most comprehensive data sources and it's like as Don said before, that doesn't mean that we're not going to try to find better alternative data sources to the extent that there are any. We certainly will look at them, but they do have to be comprehensive and detailed enough for us to make these indexed calculations.

Dr. Rapp: I'd like to move on to let you finish up on the E&M coding, spend a couple minutes on that and then go on to the next item.

Mr. Phillips: OK, thank you. We just wanted to go through and the slides pretty much follow the statutory language, but just to have some brief discussion of MMA Section 941 and as it reads, "The

Secretary may not implement any new or modified documentation guidelines, which for purposes of this section includes clinical examples for Evaluation & Management Physician Services under Title 18 of the Social Security Act on or after the date of enactment of this Act, unless the Secretary…" and I won't read through all of these, but essentially develops guidelines in collaboration with practicing physicians, establishes a plan with goals, conducts pilot projects, and then based on those pilot projects, finds that the objectives described in Subsection C will be met, and then implements an education program, real quickly, Subsection C, the goals to be met, based on the evaluation pilot projects, would be that the any proposed new guidelines would identify clinically relevant documentation, decreased non-clinically pertinent and burdensome documentation, increase accuracy by reviewers and educate both physicians and reviewers and then Section D of the MMA directs the Secretary to carry out a study of developing simpler alternative system of requirements for documentation. Consider systems other than current coding and documentation requirements. To do this in consultation with practicing physicians and to report to Congress by October 1 of 2005 on the results.

Dr. Rapp: What's the status of that study?

Mr. Phillips: At this point, we are assessing the recently, as you know AMA has had a task force that has looked at the potential for revising the documentation guidelines. There's a handout in your packet I believe that gives a summary of the status of that effort, and so our plan at this point is just to continue to work in close collaboration with the AMA and the industry to asses where next steps may, what direction to go from here and the study, will really just kind of assess where we determine, I guess a summary of where we are at this point as well as likely steps for further development. But I don't think at this we have plans for a very specific approach going forward for changes.

Dr. Rapp: You don't plan on an independent study group, or more to follow what the profession might be doing on this?

Mr. Thompson: Well, I think at this point, the key bullet in this entire section is that anything that we would do would be in collaboration with the practicing physicians. I know in the back there, the AMA

has provided an excellent summary of kind of what their activities have been. And I think if you look at this to a certain extent as a nice synopsis of how we got here and where we are, I think the question becomes for us and for the clinical community to try to determine what is the most appropriate steps going forward and I think what Steve was saying as we sit here today, we don't have the report written, so I think as we look at as we work through next year, again, working closely with the practicing physicians, and any comments this group would have, and working closely with the AMA to determine what is the right path going forward.

Dr. Rapp: Great, OK, I'd like to then move on, keep you here, excuse the other two gentlemen unless they're part of your presentation as well, let's do the O5 MMA Activities & Issues and then we'll take a break at that point.

Mr. Thompson: I think Steve and Mark will stay a little bit. We're going to do a little discussion of practice expense, but we'll obviously be mindful of the time. I think that when you look at 2005 and the MMA and other payment policy activities, one of the largest ones on the plate for our payment policy area is the drug competitive bidding; the new payment system for drugs, so maybe talk a little bit about that. I think as was mentioned earlier, 1011, the implementation will be this year. But as we move forward, I think there will be opportunities for discussion and education, provider education on our part and maybe we could schedule another session with the Council on 1011 specifically. And I think obviously, the elephant in the back of the room is the update to the Physician Fee Schedule. And so obviously that's of major concern. I think we're expressed our willingness to work with Congress on that, on what are the, what steps should we take and can be taken moving forward on the Physician Fee Schedule Update? There's been a lot of discussion as you well know, the Council well knows, the update is primarily statutorily driven, especially in the short term. It's not clear any administrative action on the part of CMS and that's it. It's not clear in looking at the analysis that's been done here. There's not short-term solution that can be achieved administratively. But we stand ready to work with Congress. We understand what's happening after 2005, so that would be an activity, in 2005 and as well, looking at the

2006 update. And then a little bit of discussion is more may be just of an initial opening discussion we can have this more in future meetings about the practice expense payment methodology. And as that is matured, where is that headed going forward? Now that we've kind of completed some activities with respect to checking on the data and some of the surveys. So that's what I wanted to hit. I can talk a little bit on the drugs competitive bidding, and we're going to talk more about drug administration and drug pricing for 2005 in a later presentation, but for the drug competitive bidding, which is due to be implemented 2006, getting kind of a quick background: MMA overhauled the payment system for Medicare Part B drugs not paid on a cost or perspective payment basis. The majority of those drugs are drugs administered in physicians' offices. And what it did was replace the old 95% of AWP methodology in three phases. The first phase was for 2004 where the payments were locked into a certain percentage of the AWP, locked in at the April 1st, 2003, levels. So that is obviously ongoing this year. And we're very thankful, we've done some monitoring activities and it does not appear we have any access issues in 2004, and we hope that will be the case moving forward. In 2005, it then replaces that locked in AWP system with a system based on average sales prices, where we'll be paying 106% of the average sales price of the drugs, and again, we'll talk about that again a little later. But that's 2005. And in 2006, we go to a hybrid system. And in the hybrid system, physicians can continue to buy and build the drugs and be paid at 106% of ASP or get the drugs from competitive vendors that we select in a process and that's really the focus of the 2005 activities, will be the development of that process, that competitive bidding process. How will vendors bid to us? What geographic areas will we select? What drugs will we select? I think this is another probably area ripe for future discussions with the Council as well as we move through the rulemaking process. What we've done to date since I was here last and updating the Council, was we've actually selected a design contractor, and that is RTI. And they are currently working on some design parameters in helping us to design the competitive bidding program so that we can go through that rulemaking process in 2005 and we expect their report will be back to us late this year, early next. So that's probably the major, I would think, milestone of significance since last we spoke, is that design

contract was let. And we're definitely looking forward to reading that report. There are multiple stages to their task. But stage one, they're kind of going out and building on some of the activities that we've done to date in terms of some of the open door forum and taking comments on the proposed system. They are building on that and actually going out and interviewing different stakeholders in this issue; the oncology community, and others working through trying to gather input directly from them and they'll be summarizing that for us, and then kind of building on that, giving us some design parameters that we can work around and go through that rulemaking process in the spring.

So that's on the drug competitive bidding where we are right now. Again, working through the operational issues, taking input, continuing to take input and will continue to take input from the physician community. And the design contractor is also helping us work through some of those parameters. I think in terms of—did you want to stop here? Any questions?

Dr. Rapp: Why don't you go through it.

Mr. Thompson: OK. 1011 as we mentioned, activities that were summarized earlier, we have our proposed implementation out there. We received a number of very informative comments that we've taken to heart and hopefully at the next meeting we'll be able to discuss in a little more detail exactly how we've responded to those comments and any changes that have been made. In terms of the other activity for 2005, obviously it would be the Evaluation & Management Guidelines, and we've already covered that on 941 in our activities, and the last one on the Physician Fee Schedule, what I wanted to touch on was in the practice expense portion—actually there are three portion to the payments for physicians. There's the work RVUs, the practice expense RVUs, and the malpractice. Over the last couple of years, we've done a lot of work on the practice expense portion of those payments. We have developed a resource based system that has primarily two components to it. One is a listing of all of the direct inputs that go into any physician service. So you have clinical staff time, equipment, and supplies—all those direct inputs that are involved in any physician service or procedure. And that data base started being developed in the late '90s, has gone through an exhaustive review process and we think is much more

robust now that that kind of activity's been completed, obviously, for new procedures and new codes, there'll be activities around the appropriate direct inputs that are involved with those, but at least, I think for the bulk of the services, we've gotten to a point where I think we in the physician community are comfortable at least with those direct inputs. And the other piece is surveys. And the surveys address two components. One is the indirect cost. Obviously there's the direct cost of providing the services, but we need information on what the appropriate indirects were, and the surveys, the socioeconomic survey was the basis and that's been supplemented over time by surveys done by physician specialties, and that's given us kind of a good insight into the indirects and then in addition those surveys help us to a certain extent, quality control if you will, on some of the direct cost inputs. Where we look if you survey a physician practice, and here's your direct cost and here's your indirect costs, one would hope that the direct costs you get from the survey would correlate to a certain extent with the direct price inputs that you're using. And so all this has over the last few years developed. And the question is where do we go from here? Right now, we're in a situation with the methodology because of the way it's constructed and it looks it kind of aggregate practice costs in those surveys, the RVUs can change year to year. There's not a lot of RVU stability, or not as much RVU stability in the practice expense as you see in the work RVUs and we know that that was a concern to the physician community with the work RVUs; they want to see year to year stability, and the question for us is is that now a good goal for us moving forward and how do we achieve that? Are we at the point now with the practice expense methodology where maybe we don't have to necessarily rerun it every year? We've got the relatives where we think they need to be, and maybe we move to something more like a 5-year review like we do on the work relative values. So that's something again, very preliminary discussion and hopefully will be back with the Council. Just wanted to put a place holder if you will for 2005 activities that we're starting to think about that, where is the practice expense methodology going? Obviously there are some ongoing surveys that we wouldn't want to do anything without taking that information into account, but at least start thinking about what's the next phase for practice expense? So in summary, it's the drug competitive bidding, obviously a large

one, a little bit of practice expense, and 1011, and the E&M Guidelines. So we see that in terms of the physician payments, some of the larger activities that will be going through from a policy making perspective.

Dr. Rapp: Thank you. I think that is helpful for the Council to at least anticipate the issues that we're going to be involved in. Dr. McAneny?

Dr. McAneny: Two questions. The first was, did I hear you correctly that you're considering just looking at practice expense RVUs updates every five years, like we do physician work?

Mr. Thompson: No, I think what—I apologize if that was the message that came across. I think what I was trying to say is the question becomes what is the next phase of practice expense? And it wouldn't be the case where we necessarily would say, it's locked in, it's done, we're not touching it every five years, but somewhere between a complete lock down, which probably would not be appropriate, and what we have now where we're essentially rerunning the methodology every year from scratch. Imagine redoing your RB RBS for work from the Harvard Study every single year and that's kind of the other extreme. And I think what we're trying to decide is and look for input from the community is where do we take this on the practice expense side? And how do we approach the methodology in general and I was not specifically referring to drug administration. That is obviously an issue where you have new codes from the AMA and those will be evaluated by the RUC and we're looking forward to that, but I think in the context in looking in general across the entire fee schedule for practice expense, the question is what's the most appropriate path moving forward?

Dr. McAneny: Well, I hope that as you consider that that you will also find a way to make all of our suppliers hold their prices stable for those years as well so if there's no update on this side, that we can also not have to pay more for any of the widgets that we require. Previously, my other question was that we had a very specific list in our May recommendations of our concerns about the competitive bidding process. And in the previous answer, we got, gee, we're going to look at this and we'll keep this in mind and we'll talk to the providers and see how things are going. So I would like to hear a little bit

more specifics about how you see the competitive bidding process going and whether or not the company that you have hired to start designing this process is going to look at those levels of concerns.

Mr. Thompson: Yes, and I think that one of their tasks, obviously, is the input of the Council that we received last time and it's not to say that because I don't have definitive answers on where CMS and how the system will look on a point by point basis for all those recommendations that they won't be taken into account. I mean in the intervening three months, we haven't developed the whole system, so I think that where we are now is obviously taking that input and the other input from the community, moving forward yes. We have given to RTI, who's the design contractor, all the information, including the Council's recommendation that we've received to date and any future recommendations the Council would make, we would bring to RTI in terms of that report being written. So I think yes, that is, all those issues that you brought up last time with respect to physician administration burden, quality of drugs, patient burden, co-pays, all that will be given and worked through not only in design contract, but through formal notice of comment rulemaking, but I don't necessarily have, because the system is not finalized, I don't have a decision if you will on each one of those particular recommendations at this time.

Dr. Rapp: Dr. Castellanos?

Dr. Castellanos: On competitive bidding, again, we're faced with ASP plus 6% this year and really the final rules aren't going to be available until November 1st and impacts 37% of my revenue from Medicare's that drugs. And it's well over 85% for oncology. With competitive billing, we need that data early so we can make business decisions. We need to have some kind of a time table. I'm not going to put it in cement but for us to make business decisions on how we're going to practice, what we're going to do to make these things, it has to be available with comment period to the physician community early, not late, and I applaud you if you could please try to think of us as business people. I know you need to make your business decisions, but believe it or not we have to also.

Dr. Rapp: Thank you. Dr. Bergeron?

Dr. Bergeron: This is a point of information if you will. Dermatologists, we're virginal as far as getting into the realm of prescribing and administering medications in our offices. We're getting in a lot of biologicals. I'm going to use a specific diagnostic entity such as psoriasis. About 14 million people in this country have psoriasis. When the biologicals now, we're getting to administer these particular medications in our office, so therefore we have to have all kind of things set up and what I'm getting at is this. A lot of third parties file a Medicare protocol on oncology and stuff. We get $6 reimbursed for an injection and $5 for drawing lab, so in actuality, we lose a lot of money per psoriatic visit when we get biologicals in our office. We talk to the pharmaceutical reps that come in, say, "Well, throw out a figure you can charge this, you can charge this." No, I said, "Give us a reasonable fee" and he said, "Well, check with your oncologist." I was appalled to learn that only 20% of dermatologists in this country administer systemic medications to psoriatics because of the complexities involved. Of that, less than 5% or maybe 7% will be administering biologicals. So here we are denying the cutting edge therapy for psoriasis, that has an impact of billions of dollars on Americans in this country, like I said, 14 million in this country, whether it's psoriatic arthritis, the infirmatism, the debilities, so what I'm getting at is here I'm looking for a recipe. I'm looking for something readily able to be followed—does Medicare, or can dermatologists or any discipline of physicians administer medicine in their office, whether it be biologicals, chemotherapeutic agents—can we use the same protocol? Can we use the same competitive billing? Can we use the same E&Ms in getting reimbursed? In other words, I'm crying for some help for some guidance, and maybe Medicare can give that to me and we can extrapolate that into third parties down the line. Or should we just go to the oncologist and say, "Give me your recipe and we'll extrapolate it and utilize it as what we dermatologists need." Am I making myself clear?

Mr. Thompson: I think there are a couple components to that. To the extent in terms of payment for the drug administration, obviously the CPT has just made some recommendations. And they also make recommendations with respect to the values for those codes, the extent those are provided by your specialty. To the extent the current coding does not accurately reflect what dermatologists do, and maybe

those codes need to be relooked at again. I'm not sure if the Academy of Dermatology, if you've gone to CPT and asked to have those codes reevaluated if they're not appropriate for the type of work that's being done now, this cutting edge material, with the biologics. And then in terms of the drug price itself, I guess the question, the ASP plus 6% is kind of statutory for all the drugs and the biologicals so there's no discretion that CMS would have in terms of altering the drug price specifically for biologics versus nonbiologics. The law doesn't provide any discretion in that area, but I will say in terms of competitive bidding, that would be a comment or a recommendation that the Council may make or you might make, or the dermatologist might make to include those drugs in competitive bidding. The Secretary has discretion in terms phasing in the drug competitive bidding and if you felt that the dermatological biologicals needed to be included that would be a comment that you could make to us. So I'm not sure I necessarily addressed all aspects of that, but I think the key to remember here is that we want to pay appropriately. Our goal is to pay appropriately for the drugs and the drug administration as the statute directs and the statute directs ASP plus 6, it directs the competitive bidding program, and we have certain processes that we use for drug administration and to the extent any of those are lacking and it's not a statutory issue, we stand ready to work with you in terms of kind of concrete proposals you might want to make in terms of where does the drug or drug administration need a coding or payment not work for dermatology, and then we can examine that and see what it is we can do from regulatory standpoint.

Dr. Rapp: Thank you, Mr. Thompson. And—

Mr. Hartstein: Dr. Rapp, I just want to amplify a comment that Don made on practice expense RVUs. A particularly about the stability, because I know this has been a subject of tremendous interest to physicians. We've been refining the practice expense methodology since 1999, and there are literally tens of thousands of data points that are in that methodology through the recommendations from the practice expense advisory committee, and so that has been an extraordinarily helpful process, and we've now gotten to the point where we've actually looked at all the direct cost inputs for probably thousands of services, accounting to about 95% of Medicare allowed charges. So I think really where we want to get to

is a point where we have more stability, even though expenses could change for individual items, from year to year, it is a budget neutral system, each individual item could have very little impact on the final practice expense RVU. So that's why we think just getting to a point now that we've had this exhaustive effort on the resource inputs that getting to a point where we have more stability, because the methodology is very complex. It's sometimes it's hard to explain its impacts and its effects, and so we think there would be some advantages to getting to that point and then just trying to update it on a periodic basis and this is certainly something that has been conveyed to us by many in the physician community since we're at the end of this very very lengthy exhaustive review process.

Dr. Rapp: Well, thank you for that amplification and thank you Mr. Hartstein, and thank you Mr. Phillips and we'll now take a 10-minute break.

BREAK

Dr. Rapp: OK, I'd like to reconvene the meeting and the next item is on the Medical Economic Index and Proxy Indicators. We have Steve Heffler here, who is the Director of the National Statistics Group of the Office of the Actuary for the Centers for Medicare and Medicaid Services. Mr. Heffler?

Mr. Heffler: Thank you very much for inviting me here to talk about the MEI today and hopefully the presentation will be informative in giving you some background information on the index and then I would be glad to answer any questions that you have regarding the index. What I'm going to focus on today is a little bit of background information on the MEI, specifically what the MEI is intended to measure as well as a brief history on how the index has evolved over the past 20 years or so. And then I'm going to move on and explain specifically the most recent revision that we made to the index involving updating the base year and making some methodological changes to the MEI.

A little bit of economics here and I apologize for this, and even though I am in the Office of the Actuary, I am not an actuary, I'm an economist, and so I can't help myself but to do this to you. And so a little bit of background on what the index is intended to measure because it helps set the table for how we approach the data that we use and what the index ultimately ends up being. The MEI is a fixed weight

price index, and by that it answers the question of how much a fixed basket of goods will cost in a future period relative to the base period and the key here, so a fixed weight price index, a fixed basket of goods. So how do we fix that basket of goods? Well, there are two major components to a fixed weight price index. The first are the cost weights or this sort of fixed basket of goods. In the case of the MEI, those are inputs in providing physician services; things like the physicians' time, practice expenses, professional liability, products that are purchased, like prescription drugs. We talked earlier about rents as well as other types of expenses. The way the index works is we chose a base year and fix the distribution of the inputs that are used to provide those physician services for that base year, and use cost data to fix that distribution. This methodology is similar to the methodology that's used by other government agencies when they're producing price indexes. I'm going to talk some more about other price indexes that are available for the Bureau of Labor Statistics. But the methodology is similar to those other agencies, as well as this methodology is exactly similar to the methodology we use for the other price indexes that are used to update Medicare payments for other providers, hospitals, home health agencies, Skilled Nursing Facilities. So while this index is specific to updating the Physician Fee Schedule, the theory behind it, the structure, how we put the index together, is actually consistent with other government agencies as well as the other indexes that we produce for the Medicare System. So that's the first component, is the cost weights in this distribution. And the second important piece is how those costs move over time. And the way we capture that in the index is by choosing a price series for each one of those costs and measuring the price change associated with that cost. We call that a price proxy. It measures not just the change or the level in a base year, what the proxy measures is the change over time up to and through the current period and then we also project those price increases to include in the proposed rule as well as in other exercises, budget exercises and so forth. So the important point here is that the price proxy measures the price change between the base period and the current period. The weights themselves stay fixed in the base period. Price proxies pick up the change between that base period and the current period. A little bit more on the price proxies, and this again gets back at the idea of keeping the basket of goods fixed and

measuring what the cost of that basket of goods will be in the base period versus the current period, because you want to use price proxies that hold constant changes and costs that are caused by non price factors and that's an important key to how we structure our price indexes because what we do not what our price indexes, our price proxies to reflect are changes in cost caused by intensity changes or quantity changes. We do not want the price proxies to reflect those. I think a very good example of this, I get this question a lot on the hospital end is in our hospital market basket, we would have our drug component of that index going up four or five percent and the hospitals would say but wait a minute, my costs are going up, you know, ten or fifteen percent, why isn't the price going up that much? And the answer is because the price isn't going up that much. The price for that given set of drugs is only going up five percent. It's the fact that either more drugs are used or it's a change in the mix of drugs that are being used, or there's brand new drugs coming on that are being used that are causing the cost increase, and so when we're talking about an index where we're focusing specifically on price and what we're not reflecting is cost. And so that's why when we describe our indexes, we describe them as fixed weight price indexes and we sometimes use the term input price indexes is because we do not want to reflect cost increases associated with non-price factors. The price proxies that we use in the MEI other than one particular category are indexes that are produced by the Bureau of Labor Statistics, part of the Department of Labor. There's some acronyms up there. We've got a list of acronyms in the back of the presentation to refer back to, but the BLS produces a number of indexes, employment cost indexes, producer price indexes, consumer price indexes, average [?] earnings, we generally use indexes that are publicly available, timely, and relevant and representative for what we're trying to proxy and those are some examples. So that's enough of the theory behind an index and a little bit on sort of how the MEI has evolved over time.

The MEI itself became effective in 1975, some form of the MEI. And it has changed since then. That was based off of legislation in 1973 that they required an index to be developed. There was a lot of research that went into the initial development of that index. There was some changes between '75 and '92 to the index. I didn't highlight this here, because I thought the more important thing would be to focus

on the Fee Schedule forward. In 1992, and the years in the presentation are the years that we did the work, so they would be applied to calendar year of the following year, so '92 for the '93 update. The index was rebased to reflect the cost distribution of physicians' costs in 1989. The productivity adjustment in the MEI, which I believe I talked to the Council before about, but has been detailed in regulation over the past few years was revised at that time, and that was based off of an expert panel that had been convened in the late '80s to discuss alternatives, both for the index as well as that particular adjustment. In 1998, for the 1999 update, the index was rebased again to reflect the cost distribution for 1996. In 2002, for the 2003 update, we adjusted, we made a methodological change to the productivity adjustment in the MEI based off of about a year's worth of research. We convened an expert panel again, where we brought together the industry folks in the academic world as well as in the government statistical world to look at productivity estimates in the physician sector as well as the current measures of productivity that are available through the US Government statistics. After that research, we proposed and then actually made the methodological revision to the MEI for the 2003 update. It actually increased the MEI by .7 percentage points in the 2003 update, based on that revision. And then last year, for the 2004 update, we rebased the MEI again to reflect 2000 cost data, which at that time was the most current comprehensive cost data that we had, and that was used for the calendar year 2004 update. And so just getting into some specifics about that rebasing effort. When we rebased the index, we explored all the alternative data sources that were available to us. We chose 2000 as the base year as I mentioned because that was the year where we had the most comprehensive data. It had been our policy over the prior developments of the index to use the AMA data from their socio-economic survey. 1998 was the last year of data from that survey. They did do a special survey for the year 2000. The 2003 patient care physician survey, that had data for 2000. And so we used that data to help us structure the index and update the base year from 1996. The important to remember here, because I know this is specifically where part of the recommendation from the Council came from the last meeting is that in 2000, that data represents all costs to physicians. The survey in that year did not have nearly the detail that prior AMA surveys had, so we were only able

to use that survey to come up with the total and to split it up into the physicians' work portion, the practice expense, and the malpractice pieces. Those were the only three pieces we could get from that survey. But the survey does capture all the costs in that year, in that given calendar year. We then supplemented that survey from a number of different sources to try to fill out the rest of the index structure. We used data from BLS's Employment Cost Index. We used data from the Bureau of Census's current population survey, we used data from Bureau of Economic [?] Input Output Table as well as some of the prior AMA surveys. We detailed all that in the regulation last year and compiled it all together and produced the cost structure for the 2000-based index. As far as the impact of that change, the major cost weights and the detail, there was not a lot of revision in the cost weights. And I say not a lot. We look at a lot of numbers, so maybe that's a relative term. I think the physician work portion went down about 2 percentage points and likewise the practice piece went up by two percentage points, the malpractice went up by about .7 or .8 percentage points, which is a significant change. One methodological revision we made to the index was we actually were able to get some data to specifically break out pharmaceuticals from medical materials and supplies. In the past we did not have that detail, so we lumped them all together, so we broke that out that actually resulted in a pharmaceutical weight that was larger than it would have been if we had used the prior methodology, and we also made two changes to our price proxies in the index, although they are not dramatic changes. The first is that the Bureau of Labor Statistics in the pharmaceutical index that they developed, they actually stopped publishing that index. But they started publishing a special index to get at pharmaceutical price changes, so what we did was we had to splice those series together based on data we got from BLS to produce a consistent prescription drug series over time that we could use in the index, and we did the same for our other indexes as well, the hospital index and the SNF index. The other thing that we did and I'm sure there'll be some questions on this on the professional liability side and I did talk to the Council at some point I think last year about our efforts here was we really did a sort of a full-blown look out there for professional liability data and much like GAO found, found that there's not that much good data out there. Unfortunately, and it's not

easy to get. It's generally not all that representative and for the most part, it's generally not that timely and so what we did was, we actually went back and we redoubled our efforts on our own collection, data collection effort for this particular price proxy, we reevaluated the carriers that we are picking up in our sample, and we tried to go out and get carriers that had a pretty large market share nationally, as well as in some of the larger states, again. This index is an aggregate national index. We're not as concerned with the geographic distribution that the folks that have to put the GPCIs together would be concerned with. So we wanted to get something that was capturing the price changes in the larger states as well as the carriers that had picked up a lot of the market share, that say, St. Paul's had when they left the business. So we went out and we did that. It's not an easy thing to do. It takes time. We did get more carriers in than we had before. We did I think get a little more representative cut of what the whole US looks like and we incorporated that into the index for the 2004 update and are in the process of doing the same for the 2005 update.

The impact of rebasing the index and making these revisions both to the proxies as well as the different data sources we use was relatively minimal, but there was an impact. The index was one-tenth higher than it would have been if we had not rebased and revised the index, and a significant proportion of that has to do with what's going on in the professional liability side. And when we do the price updates for the fee schedule year, so for calendar year '05 update, we actually use historical data that's available to us at the time that we have to set the update. For the '04 update, we were able to use historical data through the second quarter of 2003. And the statute requires us to use historical data in updating the calendar year. And the rest of the presentation has just got some websites on market baskets and links as well as the *Federal Register* and contact information. Just in closing, the goal of the MEI is to as best we can adequately reflect the current price changes facing physicians in providing services. It's not meant to pick up and account for in the system any non-price factors. It's also not meant to pick up and account for any distributional factors, whether they be by diagnosis or service, or by geographic area. It's a national level index, intended to reflect the national level price change, and that's its sole focus and that's the

intent of it and that's how we've designed it. So, with that I'd be glad to address any questions that you might have.

Dr. Rapp: OK, thank you. I think the members of the Council will recall is that the reason we're discussing this is at the request of the Council at the last meeting that we get more information on this. But maybe you can help me make sure I understand it. Let's say the average cost of malpractice insurance for physicians goes up 30% one year. And then how would that impact the MEI?

Mr. Heffler: What we do is we would go out and collect data from commercial carriers for a constant level of coverage by specialty, by state.

Dr. Rapp: Let's say that's 30%.

Mr. Heffler: Say that the average nationwide is 30%. That 30% would be incorporated into the index. A 30% increase would be and this is a little bit of a shortcut, but to simplify, would be multiplied by the weight that malpractice carries in the index.

Dr. Rapp: The weight that that is of the overall expenses?

Mr. Heffler: Of the overall expenses, which is a little bit under 4%, it's like 3.8, 3.9% and the cumulative affect of all the pieces in the index; the changes times their weights, produces the aggregate level percent change in the MEI.

Dr. Rapp: And then, what happens with that?

Mr. Heffler: With the aggregate percentage?

Dr. Rapp: What happens with the MEI in terms of the—

Mr. Heffler: Well, the MEI is one of the factors in the statutorily required formula as part of the update, as part of the SGR. It's the price piece of the formula. So the MEI itself is actually used to update the conversion factor. One of the factors used to update the conversion factor.

Dr. Rapp: But unlike where it's part of the payment for a given code, where the malpractice is also reflected, that's a total amount that if the malpractice goes up, it's affects some—it's a zero based system. It doesn't go up. But this, if the malpractice is found to go up, that would raise the payment level.

Mr. Heffler: Correct.

Dr. Rapp: All right. Dr. McAneny?

Dr. McAneny: I think the basic problem that most physicians have with the MEI if they think about that very much at all is the disconnect between what we see in terms of reality and what our expenses are doing in our offices year by year, and the factors that are ascribed to it by CMS. For example, February a year ago, the AMA presented some data on medical inflation, on the costs that went up and showed that it went from 9 to 11% yet the MEI doesn't seem to reflect this, and therefore that makes us wonder about the credibility of the entire process. And so I don't understand how you can adjust the various weights that pertain to the malpractice issue, where this is given a weight of 3.9%, yet most physicians find that their malpractice premiums have a far more significant weight than 3.9% in their true practice expense that they pay out every year in their office. So the weights do not seem to reflect what reality reflects. And the major problem that most of us have with this is we look at the hospitals, who are assigned a market basket, who get to look at what it actually costs to hire a nurse, for example, rather than just the labor index that we get, yet when we hire a nurse, we're in competition with the hospitals and we're also in a nationwide competition for that same nurse, who since there's a shortage, can move any place he or she wishes to go and get a competitive salary anywhere. So I don't understand several things. One thing I don't understand is why do physicians get an MEI, when hospitals get on the Part A side get a market basket? And secondly, how do you assign these weights to the various pieces of it, and how do you change those weights when they no longer reflect reality?

Mr. Heffler: The first part of the question—the MEI versus the market basket. My shop does the MEI as well as all the other market baskets, hospital, SNF, home health, and from our standpoint, there's really no difference in theory about with regards to the different indexes. They all attempt to capture the same thing. They all have a base year distribution that's reflective of the costs associated with providing care by those providers. For the hospitals, I talked here about physicians using the AMA data from 2000, actual data that came right from a survey that the AMA did that basically said that roughly 4% of

physicians' cost were associated with professional liability in 2000. For the hospital market basket, we also have a professional liability component in there. That data comes directly from the hospital cost reports. Physicians don't submit cost reports to the agency like hospitals, home health agencies, SNFs do, so therefore we have to go and use an alternative data source. But the approach is exactly similar with regards to the MEI versus the market baskets for the other providers. The differences are the inputs that are used are different, the distribution of those inputs can be very different and the price change associated with those inputs can be very different. And we think appropriately all three of those should be measured differently. And therefore we develop a hospital market basket that attempts to adequately reflect the price changes that hospitals are facing whereas we approach the physician developing an index that's more specific to reflecting the conditions that physicians are facing. With regard to that first comment, I think there is a lot of parallel between the hospital market basket and the MEI. It's just the inputs that go into producing those indexes are different because the two sets are different. The distributions are different and the price changes associated and facing the two groups are very different.

Dr. McAneny: Does the market basket increase parallel the MEI? You said earlier that the two were basically equivalent, and therefore my question is why would you have to if they're equivalent. Why not just give the hospitals our MEI and--

Mr. Heffler: They're equivalent in the develop—in the theory of developing an index. They are developed exactly the same. They are not equivalent in the outcome of taking all the inputs that we use in developing an index and producing the percent change, and they shouldn't be. And they shouldn't be because the rate of increase that hospitals are facing on a professional liability side is different than the rate of increase the physicians are facing on the professional liability side, and the weight of professional liability on the physician is three to four times larger than it is in hospital. So they shouldn't be the same percentage increase. Because they—

Dr. McAneny: No, I wasn't talking about just professional liability, I was talking about the entire market basket increase.

Mr. Heffler: Right, and what I'm saying is if you go down in every component, and in every component you have the same set of issues, in that the distribution of the costs is different in a physician's setting than it is in a hospital setting. And it's different in a SNF setting and it's different in a home health setting, so the distribution of cost, how you weight those series together, and the rate of change of those series is going to produce a different result in the end, and so the rate of increase will indeed be different. On the second comment about whether the weights reflect the actual experience. As I mentioned, we do use, as a current of surveys as we can use and with a fixed weight index, using a 2000-base year off of the animated data. It's not 2004 data. But there's not 2004 data available. It is the most current data that we use and from an index point of view, as long as that cost distribution is not changing much over time, whether you would fix the distribution in 2000 or '92 or '73, if the distribution was exactly the same in all of those years, it wouldn't matter what your base year is. The reality is, those distributions do change over time. And that's why we've attempted to update the index on a periodic basis to try to reflect the current conditions facing physicians. We just did that last year with 2000 data, which is recent as we have. We're always monitoring the index to see whether it's reflecting current conditions and whether we should either update the base year or make any methodological changes to the index to ensure that it accurately reflects the price changes facing physicians as we did in 2002 with the productivity adjustment.

Dr. Rapp: On that point, malpractice insurance premiums were relatively stable until 2000. And it was at that point that the malpractice premiums took off. And so maybe that's part of it. It was attributed to 911 and this and that and the re-insurance market and so on and so forth, but whatever the reason, the premiums went up tremendously at the end of 2001 into 2002 and impacted the physicians to the tune of 30 to 50, to Dr. Castellanos will tell you the excruciating details of this, but isn't that right in terms of the timing of these changes? So that's one thing that perhaps it's necessary to or would be helpful in terms of being accurate at least, to be more aggressive at getting more recent data because we're talking about 4 years now, almost five years. Secondly, the AMA surveys, although they're helpful, I know for example in emergency medicine, when it had to do with practice expense, I think the data was based on about 60

doctors in the entire country, and therefore, I'm not sure, although the AMA data is very useful, I'm not sure it's designed to be statistically significant and really be—it's informative, but it's not things that perhaps should be totally relied upon and if they're not current, or if they're not doing them as actively for one reason or another, maybe there needs to be some other source of getting this information. Because this is pretty critical. If it's the only way to raise our prices and we've got a zero-based gain we're dealing with here, which we are, through the SGR formula, and everything's got to be budget neutral, this is the only way to really reflect what is going on out there, and perhaps CMS should seek its own data, rather than rely on something that's just meant to be kind of informative that the AMA does.

Mr. Heffler: I think the search for better data should always continue and this is an area where I think across the agency, there is some concern about the currency of the data and the reliability of the data. And I know that there's been a lot of discussions with different groups about whether it be professional liability data, practice expense data, whatever it might be about getting information and to help us appropriately determine these payments rates, whether it's on the MEI which is just one piece of a much larger system or other parts of the system, and so any data sources that you are all aware of, any efforts to help us better collect data, get data in to uncover data sources that we haven't uncovered, even though we've tried, I think would be greatly appreciated. Any time a data source goes away, or isn't produced regularly, is always troublesome for us. This happens to be an area where there, at least from our research, that there is not a lot of easily accessible, publicly available, statistically valid data on the distribution of costs and physician's offices. And so information to that end that you would all have would be extremely helpful.

Dr. Rapp: Dr. McAneny?

Dr. McAneny: I'm wondering whether or not, you do any, and I'm sure you do, and I'd love to hear about it, some internal validation of the data. For example, we discussed rents earlier and we were told that the purpose of looking at apartment rents was that you could compare the apartment rents across the country and therefore use as an index to compare office rents across the country because you can get

apartment rents and you can't get office rents. And I understand that. However, I've never seen any data that says office rents correlate at all with apartment rents. And so I'm wondering, do you ever go and do sort of a biopsy of various practices across the country and find out do the apartment rates in a given area actually correlate at all with the office rents in a varying area? Because if you're basing your GPCI on something and your index on something that really has no bearing on reality, then neither does your index. And it seems to me that it really wouldn't be that difficult for CMS to do a survey to see what office rents are in varying areas. I suggested the OIG as data for that. You could also look at for example what nursing salaries are in varying areas because they use the Department of Labor Statistics as our way to look at what we pay for labor. Yet, when you look at what the hospitals get in the market basket, they actually look at the skilled labor, at nursing costs, and tech costs, but when we are in our offices we are hiring nurses and techs. We are not hiring burger flippers and I think that you can't go with a very specific labor market there. You need to go with what physicians actually do. And I would love to see some correlations, either somewhere, if we don't want to do that, PPAC, I'm happy to go read it someplace, that shows me the data that says that the indexes that you're using actually reflect true physician practice and are not just a convenient index that you can use because it's there. I mean, for us, as we approach this cliff we're going to fall off of in 2006, if we don't have an accurate way to express the true costs of physicians doing business, that cliff will be even larger than you're currently projecting.

Mr. Heffler: I think the idea of internally validating the indexes or externally validating the indexes and presenting information on how the price proxies we choose move over time relative to other indexes is extremely important. It is something that we do every time that we pick an index. There's only so much information out there. We try to get our hands on it. We try to compare it. Earlier, Mark had mentioned, Mark or Don, had mentioned looking at the rents and looking in different areas and seeing, not the absolute levels of the rents, but the relative levels of the rents, because it's going to proxy what the differences are. Likewise—

Dr. McAneny: Is that approximately what offices are, or is that just the assumption?

Mr. Heffler: That's their shop, but likewise on the price change side, we may not have a specific measure that exactly gets at what physicians office rents increase by the price associated with that because there's not information out there like that, but what we can do is to hopefully pick a proxy that reflects that trend, and we may compare it to office rents in general, or residential rents in general. Or different kinds of indicators about how things move over time, to hopefully validate the choice that we make in the choice proxy. So that validation point is a very important, it is something that we do, even though on the surface when you look at the end result the index, you might say that specific price index that's used isn't physician specific. We do internally analyze the data and how it moves to hopefully proxy what's going on in the industry.

Dr. Rapp: OK, we're going to have to draw this to a close. We'll let the closing question or comment by Dr. Bergeron, then we'll move on to the next item.

Dr. Bergeron: Yes, I've been politically incorrect occasionally. And a couple of years ago, I said, would you get the blood draw in here and come on in and draw your blood. Well, she was a registered clerk. Check with the insurance clerk. What insurance clerk. I'm a registered codifier. Oh, OK. And the next one. The records clerk. I'm the custodian of records. Let's see what these titles entail. Well, these titles entail significant increases in salaries, because you're competing with the hospitals and other health entities if you will. Now because of HIPAA and no HIPAA, etc., etc., we have someone who is the custodian of our sharp instrument containers. And I said, "Well, what am I the custodian of, when I'm picking up paper in the hall and stuff like that? I guess I'm a custodian, too." So you are, I say, you all, y'all, if you will, you're not putting into context of what the skilled laborers like my colleague from New Mexico. Honey, let me show you how to draw blood. Two seconds. No, no, you got to go register, you got to have continued medical education. We supply these costs for that. So there is labor intensified, and I appreciate my colleague from Florida with his malpractice crisis and stuff. We do have it in Louisiana also to an extent, but we've been pretty politically stooped because we've capped it since 1977. So you need to look in that. Look in all these letters behind these people's names we hire in the office, and that,

to me, has not been addressed, because we have our accountants. They put all this stuff in—where are spending? Labor. Codifiers, custodian of records, HIPAA qualified, etc. etc., that's where it's a tremendous cost, because we as dermatologists, 50% of the day, we have some body fluids being exuded somewhere in the office. Thank you.

Dr. Rapp: Thank you very much, Dr. Bergeron. I take it that's somewhat of a rhetorical question. Thank you Mr. Heffler and we'll now move on to the Update on the Average Sales Price. Mr. Thompson and his panel will come back. So we have again, Steven Phillips, Mark Hartstein, and Don Thompson.

Mr. Thompson: We find it safer to travel in a group.

Dr. Rapp: I don't blame you. I brought 13 people with me.

Mr. Thompson: Earlier, we had discussed many of the changes on the Physician Fee Schedule and some of the 05 activities, but we thought it appropriate to break out the Part B Drug and Drug Administration payments, which we discussed a little but need a little more detail here in order to give these kind of a full airing, being one of the more highlighted aspects of the Physician Fee Schedule proposed rule. And there is obviously two parts to this that we'll be talking about. One is the actual payment for the drug itself and the average sales price methodology and the information that we had in the proposed rule. What's occurred since then and then a preview of 05 and the final rule and then also the Physician Fee Schedule itself will talk about drug administration, codes and payments, and some of the activities that the AMA has been engaged in over the last few months. For the drugs itself, as I mentioned, there's a statutory methodology for paying for Part B drugs, not paid on a cost or perspective payment basis and that methodology is 106% of the average sales price. That average sales price data is reported to us quarterly. The first reports were due to us April 30th of this year. And they were based on the average sales price from the first quarter of 2004. We recently, at the end of July, early part of August, received a second bath of data and that was for the second quarter of 2004. Our contractor, we have a contractor who takes the data, which comes in at the national drug code level, comes in at the [?] level, takes that, and then maps that over to the HCPCS code, because we as you all know, pay for drugs at the

HCPCS level, for drugs administered in a physician's office and they also go through and do some quality control on that data and we expect to have that back to us in the coming weeks and that will be based on the second quarter. And that will be the data that informs the impact analyses for the Physician Fee Schedule final rule. So for the proposed rule, we had data from the first submission, and for the final rule, we will have data from the second submission. However, for the actual 2005 payment rates, because we want to use the most up-to-date data as possible, we'll actually using data from the third submission, so from the third quarter of 2004. So the point I want to make here is that in terms of data availability, because the third submission is not due to use until October 30th and because the Physician Fee Schedule final rule has to be published by November 1st, one could see there's a difficulty there in actually using the third quarter submission to do the final rule. So we'll be using the second quarter for the final rule, but the actual payment for 2005, the payments in the first quarter of 2005, will be based on that third quarterly submission, and the approach we've taken here is to try to compress that time frame as much as possible in terms of what the data reporting period is and when we implement the price change based on that data. And that's about as tight as we can get it. And so they'll report to us October 30th, we'll turn that around, and hopefully have those actual 2005 payment rates to our contractors, our goal is by December 1st. And then moving forward on a quarterly basis after that, it'll be kind of that same time period, and we'll update those rates quarterly in 2005. In terms of the data that went into the proposed rule, because if you look at the drug expenditures, the Part B drug expenditures for the Medicare Program, they tend to be concentrated in a relatively few number of drugs in order to inform the impact analysis for the proposed rule, we focused on those top drugs, and because it was the initial reporting period, we tried to work very closely with the manufacturers, and make sure that the data we did put out was reflective of that first quarter. Obviously, we don't know what the data will look like for the third quarterly submission. There may be price changes that occur between now and then, but at least for the data that we got, we concentrate on those top drugs and make sure that we had the best data that we could put out there for the proposed rule in those top drugs. Now in the final rule, now that we have the second

quarter data, our goal is to kind of work through that, scrub that as much as we can, make sure we have exactly what the statute requires us to get from the manufacturers. The manufacturers are clear on what they're reporting and we think we've made great strides in those areas since the first report, and the manufacturer that has been an excellent dialog, an excellent process, us working through, clarifying exactly how the calculation works, what is it you're actually asking for and Congress in its wisdom, actually gave us two dry runs so to speak to get that right before we go to the 2005 payments. So working through those, taking that second quarter data, and making sure that data is accurate and then using that for the final rule and then obviously going and doing the 2005 rates based on that third quarterly submission, so that's kind of where we are from a drug pricing standpoint with respect to 2005 rates. Again, it's the statutory methodology. The data submissions will come in. We'll use that for the final rule, the second quarter, and then the third quarter will be the one that we pay on for January 1, 2005.

On Physician Fee Schedule, I think Mark's going to talk a little bit about what the CPT's been up to.

Mr. Hartstein: OK, drug administration. That's the other major piece of our payments in the changes under Sections 303 and 304 of the Medicare Modernization Act. In the January 7th 2004 final rule, we implemented major provisions of the Medicare Modernization Act with respect to drugs and drug administration, in particular with drug administration, we were required to use a survey of practice expense that was supplied to us by the American Society of Clinical Oncology. We were required to establish work Relative Value Units for specific drug administration codes, and we were required to reflect the higher costs of some nursing personnel in the drug administration services and then, in addition to that, we were required to increase the payments by an additional 32%. So there were some permanent changes related to the survey, the work RVUs and so forth, that increased payments for drug administration by about 110% on average across all of the drug administration services. These are infusions, injections, and chemotherapy administration. So that's a permanent increase of about 110% in the services described under those categories. Then in addition to that, there was an additional 32% that

applied to 2004 only in an additional 3%--the 32% will go down to 3% for 2005 only. So the payment for drug administration between 2004 and 2005 will go down and it will go down again less significantly between 2005 and 2006. However, when this transition is over, the payments will still be more than 110% higher in 2006 than in 2003, and that's if we made no further changes to the drug administration codes and payment amounts. The statute, in addition to requiring us to make these permanent changes in these two years of temporary changes to the drug administration codes, required us to consider the coding and payment for drug administration promptly consider the coding and payment for drug administration and use existing processes to make changes. I'm sure some of you may think for us to do something promptly using existing processes may be an oxymoron, but we really are working very hard in 2005 to try to meet that statutory guidance. In particular, we think the focus on existing processes that the statute was really directing us to use, the process that we normally use to make coding and RVU changes, and that is working through the CPT Editorial Panel. We were very grateful to the CPT Editorial Panel that they established a work group on drug administration earlier this year. That group has met several times via teleconference, has had a open meeting in June of 2004 where a number of people from the physician community were able to come and make presentations and raise concerns about coding payments for drug administration and the types of service they think need to be incorporated into the codes that are not specifically incorporated now. The CPT Editorial Panel met again in August, where this drug administration work group was able to report to it, and now the next step in the process is that the Relative Value Update Committee, which makes recommendations to CMS on relative value units, is expected to meet later in September. And they will be making their recommendations to us. So we illustrated the potential for changes in drug codes and the drug administration codes based on how they're currently configured in the proposed rule. However, the one thing that we do not know is how the changes in coding and payment will come to us in the recommendations from the CPT Editorial Panel and the Relative Value Update Committee. So the changes that we illustrated in the proposed rule are not final changes. There could be some additional changes as a result of the CPT process. We won't know what

those are until for another few weeks. And then we will incorporate those changes. We will review all of those recommendations and incorporate those changes into the Physician Fee Schedule Final Rule. One thing that we do know is that the CPT book for 2005 is currently closed and no additional changes can be made to that. There needs to be some lead time before the year begins the publication of that book is complete. So what our plan is, is once we review the recommendations of the CPT and RUC is to try to incorporate any of those changes where we are in agreement into the Physician Fee Schedule final rule through the use of temporary G codes, and then continue to work with the CPT panel to try to establish permanent codes through the CPT process. But because there is a directive to us to work promptly, we will try our best to make all of the changes by January 1, 2005 and announce them by November 1st in the Physician Fee Schedule final rule.

Mr. Thompson: I think with that, if there's any questions you want to take, either on the drug payment side or the drug administration. Comments?

Dr. Rapp: Dr. McAneny, Dr. Castellanos.

Dr. McAneny: This question goes to Mark, first. You keep talking about 110% increase so clearly I'm missing something. My understanding that the admin fees for 2004 were the 2003 admin fees plus 32% and that in 2005, they go to the 2003 admin fees plus 3.5%. Is that not right?

Mr. Hartstein: No. That's correct. That's not correct. The payment—

Dr. McAneny: Maybe I understand why I'm confused!

Dr. Rapp: That's Washington talk.

Mr. Hartstein: Just to give you an idea. 96410, chemotherapy infusion code, I'm sure you're familiar with. Its 2003 payment was $59.22, national average, so the payment could be somewhat different in New Mexico. Its 2004 payment is $217.35. And what that would reflect is the permanent increase to the Relative Value Unit, and then an additional 32% increase on top of the 32%. Then for 2005, under the current coding and structure in Relative Value Units, the payment's going to go down to $171.75 and then it's going to go to $166.75 in 2006. So that would be for this particular code 182%

increase between 2003 and 2006. When I talk about the 110%, that's an average across all of the drug administration codes that got these increases.

Dr. McAneny: I just wondered how you were getting the 110 because we weren't seeing that number anywhere where we calculate any of the data that we looked at. But the issue that we've had all along is that admin codes were very very very low and we made it up on drug margin, which is no longer there. There was a comment earlier about the fact that you haven't seen any access issues for 2004 and from talking to oncologists around the country, as well as urologists, neurologists, rheumatologists, people who are infusing this, there is for 2004 because of that 32% on top increase that we didn't lose a huge amount of money and we ran all of the drugs you published and looked at how much we've actually lost per dose per drug for the drugs that you listed, and then we look at the changes in 2005 and I think you will see some access issues because oncologists across the country are already saying that particularly people who do not have a Medi-gap policy or who are the duel eligibles, you can't afford to lose 20% of both the admin codes and the drug reimbursement codes and continue to treat these poorest of the poor. So for 2004, most oncologists have made the business decision that we would continue taking care of Medicare patients, because it's our goal to continue to take care of Medicare patients as much as it is your goal to do that. But for 2005, the numbers don't look too good. There's one drug that I'm in the black on when I give it to a Medicare patient who has a Medi-gap insurance. So without the change in the administration codes to reflect the reality of what it costs to administer the drug, which the 2003 were not, then we're in some serious trouble. And across the country, we're hearing from oncologists as well that the hospitals are not prepared to take this into account. That while it will go into the Part A pot, sometimes, because people will be admitted for things that they're currently doing as an outpatient, what we're looking at and what most oncologists are looking at in survival techniques, is what are the services that I can stop giving to Medicare patients in order to cut down the variable costs that occur when I add another patient to my practice, who's a Medicare patient? If I can make my fixed cost on the HMOs and the others, then adding in the variable costs of that additional patient, do I not have them have access to

the social worker or to the nutritionist? Do, if they call in and they say, gee, I wanted to get a prescription for X, Y, and Z, do I make them come into the office now and do another E&M code to provide that service instead of just treating their bladder infection over the phone? If they come in and they have [?] sepsis—we're treating a lot of that in the out-patient setting now. I can't do that in the out-patient setting when I will lose on each Nupagen injection $38.22 per injection per day. Do I stop using Procit? And just put these patients in for transfusions? What we're finding is that the ethical issues of how can I afford to take care of these patients? How can I do it? And how can you deny a certain service to a given patient versus the financial implications if I give them Epo, I lose $108 per injection. Can't do that very long.

Mr. Thompson: I think that, obviously access is a major concern and although we haven't seen any systemic access problems in 2004, we're going to stay diligent in 2005. We've implemented our Office of Research demonstrations and information has implemented some activities and environmental scanning activities so we can stay on top of this issue. The one thing I would say, though, with respect to 2005 is that the book isn't closed. It's difficult to know without seeing what the CPT panel comes up with in terms of their recommendation exactly what 2005 will look like, so in terms of saying whether you'll be making or losing money in 2005, I think that's a difficult projection to make given that the data that we have and you have right now, I think that picture will become clearer once we get the recommendations from the CPT panel on the drug administration codes. But I think it's a difficult projection to make right now based on the information we have.

Dr. Rapp: Dr. Castellanos?

Dr. Castellanos: February PPAC meeting one of the PPAC recommendations was for CMS to ensure that the physician community was provided in an early notification of the average sale price for all impacted drugs, as well as an opportunity to respond. And that this was in a May meeting, CMS adopted that. And they said they would hope that there would be a scheduled proposed rule in late June with about a 60-day comment period. Well, in August 3rd, you gave us a list of about 30 drugs, of which only three are urology drugs. We still don't have a complete list. CMS is in my specialty of urology, hasn't

addressed an issue of bladder cancer. And right now I can show you the data. My purchase price for Mitomycin and my payment, I purchase the drug for $787 for the 40-miligram vial, and I get $255 as my reimbursement. I don't know how you can expect us as small businessmen to be able to plan ahead, to budget. I'm going to have to lay off staff. I'm going to have to close satellite offices. I'm going to have to stop giving treatments, because I can't afford to give patients medications when I lose money. I have a lot of people that just have Medicare and no other insurance. No Medigap. No. My area was hit by Hurricane Charley. They were struggling to live then. They don't have anything now. I lost my house. We closed our office for a week. Our area is desperate and you're asking me now to continue to provide this care to patients. I'm losing money already on my bladder cancer treatments. These patients in some of these trailer parks don't even have a roof on their head. They don't have the 20% to pay. Where are they going to get the care? Are they going to go to the hospital? Hospital's going to be a higher co-pay. Three of our hospitals in one community, they're gone. Two of the hospitals in my community are gone. The hospitals aren't going to be able to afford this. Do I have a legal responsibility to continue giving these patients the care that I'm giving, where I'm eating it now and I have been eating it. Why? Because we've been able to cost shift from the overpayment that we were getting. I don't know where this is all going. I really don't know. I do know that if you expect the physicians—the urologists, the oncologists, or whatever, you need to provide us with the data that you said you were going to provide in June. It's 2 months later. We still don't have the complete list that we asked for. You have got to give us that data so we can make some business decisions so we can plan, too. Now I understand the frustration you have in getting it out. But you have to understand, you're going to give it to me November 1st, and I'm going to have 2 months to decide which office I'm going to close, which employees are going to be gone, what services I'm going to provide. I'm the only Medicaid provider for a 5-county area. I'm the only pediatric provider for the whole area for Medicaid. I lose on that. Why do I lose? Why do I do it? Because I'm making money up on cost shifting. I can't do that anymore. I'm a small business man. I have expenses and I need to have a budget that I can work with. I need to be able to plan ahead. I need to be able to know how to order stock. I need

to know how to cover my bad debt. And I don't have that data and it is so important if you expect me to stay in business and provide the care that we have been providing that we get this data available to us.

Mr. Thompson: Obviously the devastation of the hurricane impacted a great deal your area. And I don't think in terms of any payment policies that we were addressing in the proposed rule, the final rule, I don't think we were necessarily taking into account the devastation of the hurricane. I'm not sure how we would have done that. I understand from an operational standpoint the devastation that must have occurred down there. I'm just not sure from speaking from our little tiny island here in terms of the Medicare Payment Policy, how we might have addressed that in that context, although obviously there's been a lot of activity in the federal government down there trying to help the people down there in the devastation. With respect to the planning issues, we have heard that we are cognizant of the fact that we did not publish all 450 drugs. Our goal here was to balance a number of things. We wanted to, for the purposes of the impact analysis to hopefully be able to provide people with an indication and physician's indication of what the changes might look like for 2005. It appears for your particular practice, we failed to do that. We didn't capture all the drugs that were necessary for you to be able to make those determinations. One of the questions that I would have for you is, do you know what of the drugs that we did publish what percent of your drug revenue that represents?

Dr. Castellanos: A very large percentage.

Mr. Thompson: And that was kind of our goal, and not that that to a certain extent alleviates it if you given the data we did give you, if that wasn't enough for you to look at the scope of your business and make a decision, I understand that frustration. We also had a situation where we didn't want to raise alarm bells in the sense that it was the first submission. I think Congress was wise not to have us on pay based on the first submission. Obviously there's some kind of as you can imagine working through the reporting process. So on the flip side, suppose we had published something based on the first quarter that was in fact inaccurate or misleading, and then you made business decisions based on that data. I understand in an ideal world, sure we would have published all 450 drugs. We would have been entirely

confident we would have worked out all the reporting issues with the manufacturers. This thing would have been up and running and ready to go this entirely new reporting requirement on the manufacturers that never existed before. It would have been ready to go. We would have had all 450 drugs up and we would have had them up June 1st. The reality of the situation was that in the time frame we had, from the passage of the MMA that didn't happen. We just weren't to the point where all 450 drugs were ready to go prime time; that we were confident in the manufacturers who had given us this data were confident in what that data looked like. So it's true that the prices aren't there for those drugs, but when you compare that to the potential for putting out inaccurate prices, which is not the case where we felt on the top 30 and we had worked through with the manufacturers on some of the reporting issues, that degree of confidence wasn't there on the tail. So I guess the question was, again, understanding ideally would have given you the drug prices, all 450 and they would have been exactly perfect and recorded well, but given that wasn't the case, which is the lesser evil, to provide data that might be misleading to the public in terms of what the 2005 rates are going to look like? Or to say you know, we're going to wait for the second quarterly submission and see what that data looks like. But I completely understand the bind that puts you in from a small business perspective in terms of planning. And the only thing I can hope for is that the data that we were able to provide and scrub, hopefully gives you some indication of what '05 would look like. I know we did manage to get a few of the high volume urology drugs in there. And hopefully that's enough. And maybe it wasn't.

Dr. Rapp: Any other questions or comments? If not, believe it or not, we're on time. It's time for lunch. We'll see you back here. We're scheduled to reconvene at 1:15.

Lunch Break

Resume

Dr. Rapp: I would like to call the meeting again to order. The first item on the afternoon agenda is our esteemed director of the Physicians Regulatory Issues Team, Medical Officer to the Administrator, Dr. William Rogers. Is that you, Bill?

Dr. Rogers: That is me. Thanks Mike. PRIT's pleased to give our report to our friends on the PPAC and also to the public here. And I ask you please not to flip forward in the handout because really the only good thing about my presentation is the cartoons and that'll destroy the whole shock value of the cartoon. This cartoon is just to remind us that malpractice is an issue for physicians. I had three issues that were assigned to us at the last PPAC meeting. And Ken sort of stole my thunder by giving them in his report. But we'll talk about them a little bit. The first is LEP compliance in the institutions in the facilities, the second is the E&M Guideline Revisions, and the last one is prescribing POVs. Fortunately, in the report, Ken didn't steal my cartoons, so they're still there. Dr. Gaughan asked us to look at the issue about how burdensome LEP compliance, Limited English Proficiency compliance was for facilities. And we had an intern for a month last month from Lincoln, Nebraska and she had a great time in Washington, D.C., but we also made her work. And one of the things she had to do, she had to call a bunch of facilities and states where we thought there probably would be a pretty high level of immigrants, and basically I've sort of scrubbed the spreadsheet there for identifying features, but what she found by talking to people mostly in the social services departments was that the facilities didn't seem to think they were spending an awful lot of money to comply with the Limited English Proficiency. So we would be interested if you want us to look at it more, or if there are other ways that you'd like us to research this, we're happy to look at it more. But it seems that this is not a huge problem for facilities.

The next one is 941 and this has been covered pretty well in previous testimony. I guess I would only say that as long we continue to look at the medical record as the metric for the value of the service provided, we're going to have a hard time simplifying the documentation guidelines as the next slide shows, the AMA has recognized now that some specialties support CMS documentation guidelines as an objective means to document and protect against audits. So it's back to the old problem that if the medical record's going to be the measure of the intensity of the service, then it's going to be complicated and we're going to have to have some pretty rigid guidelines to use when a person's audited. Prescribing of POVs, I think we'll come to a good resolution of this with our proposal to allow licensed physicians of

any specialty to prescribe the POV and that's in the final approval process now. I should say though that this has been difficult to deal with because as was mentioned, it's been a huge arena for fraud in some areas, and if you look at the increase in spending on POVs, and Senator Grassley and others' interest in this whole issue, it really wasn't the best time to be broadening the number of specialties that could do it, but it is the right thing to do and that's why we're moving forward on doing it. This slide just show you, we worked very hard to push the issues forward that the PRIT's working on other than in addition to the issues that the PPAC gave us and we also work very hard to keep our website updated so that people who are interested, for instance, in reenrollment or chemotherapy codes can look at the website and find out that we are working on it and where the issue is. I'm going to go quickly through the issues that the PRIT has. Just so that you know the sorts of things we're looking at and then at the end I'd like to ask for any issues that the committee would like us to work on. The first one was ordering of POVs, which I mentioned. The next one, an issue near and dear to the heart of emergency physicians, payment for services provided under contractual arrangement. Staffing companies have been very interested in being able to bill for physicians who work for them as independent contractors and this has been problematic for them until recently we changed our regulations to allow them to do that, but we've also made it very clear that physicians have to have access to the collections and billings that have been done on their behalf and that's awfully important because the physicians obviously are liable if there is an audit or an accusation of fraud, so the physicians have to know what's being billed on their behalf and we've been very clear that that kind of information has to be available to the physicians. The next one is SNF consolidated billing and this is a huge issue, I know. There's been a lot of recent great work by Provider Education and there's now actually a website, Consolidated Billing website, with a lot of useful information on it. We haven't done anything though in terms of changing regulations or imposing new requirements on the Nursing Homes and we'd be interested in input from the provider community about if that's necessary or reasonable, but I think the provider education initiative has been very helpful and I want to make sure that physicians knew that that information was available. People wonder by bariatric

ambulance service is on here. As you know from reading the National Enquirer and other important news media, there have been a lot of problems recently with very large patients needing to be moved to hospitals and other venues for care and it presents a bit of a logistic challenge for the ambulance companies and their special equipment and special vehicles and things like that and so the ambulance companies and providers have asked us to look at whether Medicare should be paying additionally for moving these people since it requires extra staff and extra equipment and to the extent that these services aren't available in some communities, this might be an issue that providers are concerned about. So we're working on finding out just how big an issue of access it is. Cardiac rehab supervision. We talked about the last report. This has been a real problem for some rural hospitals, the requirement that a physician be present and supervising. But we can't do anything until the OIG Report is released and we're hoping that that will be released next month and once that's out, we'll be able to move forward on this. Security of anesthesia carts—there's a discrepancy between the Medicare standards and joint commission and some state laws and we're going to bring these requirements in to consistency. It's not fair to expect providers to have to deal with those kinds of inconsistencies. Probably the oldest issue for the PRIT, history and physicals by podiatrists. It's in the Hospital Condition of Participation when it's released. Reenrollment as I said, during the last report, we're not going to require reenrollment until PECOS is fixed and until we have an online user friendly mechanism for doing it. This is enrollment issue and I think as Herb said so well, we're not where we need to be. We made a lot of progress. And actually we just did a projection of the curve for new provider numbers and we're actually going to be back at baseline in a few weeks. Which is great. We're not doing quite as well in reenrollment and we're very focused on getting this problem fixed because we recognize it's impossible to run a business this way. I say it's like opening your store and finding out your cash register's not going to be delivered for six months. Changing patient status after admission. Pretty straight forward issue—people wanted to know at what point in the admission process it was legal for a physician to change the patient for instance from inpatient to observation. And all we need to do is tell you. It's one hour after the patient arrives at the emergency

department, or it's before the bill is submitted or whatever. We just need to tell you what the rule is. And so we have in final review, a manual revision which will make that clear. This point of service code issue has to do with home service codes. And there's a change request which is on our website which clarifies that you can only use home service in the home. Mental health treatment limitation—we've got a manual revision which is currently in internal review. This is the issue about applying the mental health treatment limitation to CPT code 90862. In the law, it says that that shouldn't be imposed, that treatment limitation, if the patient suffers from Alzheimer or other forms of dementia and we just have to make sure that our regulations are consistent with that. Some macros in teaching documentation. Dr. [Boffie?] and I just had a conversation about this probably an hour ago. And we're working to make sure that AAMC is comfortable with the decisions that we make about this. But as EHRs are sort of becoming almost universal, it's an issue that we have to look up and we have to come up with a clear policy on. Post-anesthesia reports and verbal reporters are both in the Conditions of Participation which hopefully will be out soon. Anesthesia billing issue is exciting. We got the nurse anesthetists and the anesthesiologists sat down and told us what they wanted to do and so we're working at turning that into our policy. That's the best way to solve a problem is to have everyone who has a dog in the fight to sit down and tell us what works best for them. So I'm excited about that. And then the chemotherapy code issues. We had a report about that. Mark Hartstein stole my thunder on that one and I'm pleased that the AMA's recommendations are really excellent. This is an old New Yorker cartoon. It probably was funnier 15 years ago than it is now, since we've all gotten used to Medicare. These are just some key websites, and I'd just like to thank you for the honor of addressing the PPAC again and would welcome any comments, or recommendations, or issues.

Dr. Rapp: Dr. Urata?

Dr. Urata: I just want to voice my support for a lot of flexibility in the cardiac rehab supervision issue. I come from a rural hospital and it would really affect our cardiac rehab program that we've worked so hard to get going.

Dr. Rogers: What would you recommend as a policy.

Dr. Urata: Well, that ER physicians, can, since they're the only physicians on the campus of the hospital, be allowed to supervise. Basically, I've evaluated the patient and sometimes the patient has gone to Seattle for an evaluation, and when they come back, we start cardiac rehab. And I can't be in the campus of the hospital and leave my practice, which is located miles away, to watch my patient go through cardiac rehab. So the only physician available would be the ER physician in the emergency room. Next door.

Dr. Rogers: Yeah, I appreciate that. That makes a lot of sense. I'm not sure that you ought to pay the emergency physician if they're not providing direct supervision, but I think to allow that—

Dr. Urata: No, he doesn't—I don't get paid, he doesn't get paid, but the hospital gets paid because they're the one who's doing the service. Right, and the emergency room physicians are OK with it.

Dr. Roger: They're the ones that are going to be resuscitating the patient anyway.

Dr. Urata: They might do a better job than I do—possibly.

Dr. Roger: Thank you.

Dr. Rapp: Dr. McAneny?

Dr. McAneny: I'm wondering if as we move forward with the PECOS system, and we're hopefully going to get a system that people can enroll, are we going to do a pilot trial run on it before we open it up and require that everybody do reenroll? For example, in all of the carrier districts, see if they can enroll 200 people correctly before we tell all of the physicians in the country that they have to be enrolled again?

Dr. Rogers: Sounds like a very good idea.

Dr. McAneny: And the other question was that the verbal orders thing needs to be addressed fairly soon because hospitals are making all kinds of strange policies. One of our hospitals refuses to take a verbal order face to face, but will take one over the phone. So if you stand in the ICU, and you're telling

somebody to do something and they don't want to take it as a verbal order, if you pick up the phone and talk into it, then they will take it as a verbal order. So please issue some guidance on that soon.

Dr. Rogers: Well that might be a different issue. Because and we'd be happy to address it, but the issue that we addressed is the issue of the co-signature, or the counter signing of the verbal order. And it's actually already addressed, because temporarily there's a letter that you can find referenced on our website you can click to until the conditions of participation come out, and probably has something to do with joint commission, too, since there's concerns about air. But I'm not of any Medicare regulation which prevents that.

Dr. McAneny: But they're doing it because of how quickly are you going to sign this thing and just because there's no clear guidance. So they start making up their own very strange rules.

Dr. Rogers: There's clear guidance. On countersigning it, yeah.

Dr. McAneny: It's on the website?

Dr. Rogers: Yeah.

Dr. Rapp: Dr. Castellanos?

Dr. Castellanos: Just asking on the Limited English Proficiency, I think if you had talked to social services, they may or may not be aware of that problem. I think if you went down to the ER, on the floors, you would see that I think there is a problem. Fortunately, most hospitals have a system in check already. I guess where we need some guidance is where, according to the law, at least how I look at it, we're obligated to ask the patient whether they want an interpreter after we've provided with them—is that necessary to do? I guess most people aren't doing that.

Dr. Rogers: I'm sure that everybody's doing it. It gets difficult when you get down to the details about whether family members can translate appropriately and issues about patient confidentiality and as an emergency physician who will be in the ER in about an hour and a half, I'm very aware that the devil's in the details. All we were looking at was the expense of complying. And the hospitals that we spoke to

by and large didn't feel that it was a huge expense. But it really is a challenge in some areas because so many of the patients, particularly in the emergency department, don't speak English at all or very well.

Dr. Castellanos: I think the problem is being solved already. I mean it's been solved in the last five or ten years, but to make added requirements to ask the patient if he or she wants an interpreter is a little onerous.

Dr. Rogers: Well, we don't own those regulations, but I'll go back and take a look at them and see precisely how clear they are.

Dr. Rapp: Dr. Gaughan?

Dr. Gaughan: On the Limited Proficiency, my concern is in physicians' offices. The hospital has a system and the hospital has funding, but then they get followed up after the ER, of course they get sent to our offices and then we have to arrange the translators, and also I know at the AMA meeting there was a resolution for this to be covered by Medicare or by insurance carriers. And that was as I recall, Jack might help me out, almost a unanimous decision of the House of Delegates. I don't think anyone voted no. And so that concerns me because I am very thankful to you for calling hospitals, and I really appreciate the study, and I appreciate your efforts. I'm just concerned if the AMA House of Delegates said that, and I know in private practice, even in Aletha, Kansas, we might have five different languages and I have to provide that. And as we all know, our payments are going down, so it's very hard to do that. And I appreciate you looking at hospitals, but I would question whether maybe some dialog with the AMA on this on or looking at private practitioners or asking the state medical societies to send out a survey. I know it's hard to get data from doctors, but I still see it as a problem for practitioners.

Dr. Rogers: I appreciate that, I think though that since we're only permitted to pay for those services which are reasonable and necessary for the diagnosis or treatment of disease, our hands are probably tied in terms of having an additional payment, unless Congress created it as a benefit category, I think we'd be unable to pay for it.

Dr. Gaughan: And then on another topic on the E&M Guidelines, I just wanted a clarification. On your slide, you said the panel, I assume that's the CPT panel, intends to study the possibility of including broad documentation principles and the clinical task force recommended using specify that services require two out of the three components: history, medical decisions making, and physical exam. And then, I the conclusion of the report, sent to us, they said that CMS expressed significant concern regarding the need to revalue any changed E&M codes, the fiscal impact, blah, blah, blah. So it seems like broader guidelines were suggested. But that wasn't the problem. The problem was the payment; that CMS would be able to pay for things if we changed the E&M codes. And that just, I need clarification on that. I'm just confused.

Dr. Rogers: I'm not sure that I read the report that you're referencing.

Dr. Gaughan: It said [off mike]

Dr. Rogers: This is the AMA CPT Editorial Panel Actions on E&M Documentation Guidelines.

Dr. Gaughan: Right. But the reason they said it failed, was the concern that CMS would not be able to revalue the codes, and I thought that was one of the reasons we were kind of looking at all of the different documentations like whether there should be two or three or four and I don't know what that means. That was sent to us. I assumed everyone got it.

Dr. Rapp: I think Dr. Rogers got this as more of a give us feedback—are you personally involved in this?

Dr. Rogers: No, I think Ken probably knows more about this than I do.

Dr. Rapp: I'm not sure he's the one to address the question to specifically.

Dr. Gaughan: I didn't mean to put you on the spot. It was on your slide, so I thought—

Dr. Rogers: No, I appreciate it.

Dr. Rapp: He doesn't mind being put on the spot, but I think. . .

Dr. Rogers: Ken was at those meetings and. . .

Dr. Rapp: We'll handle this with another speaker. OK, anything else for Dr. Rogers? He takes on every and any assignment. He's the minister with and without portfolios.

Dr. Gaughan: I think Dr. Rogers is doing an excellent job. I really appreciate it.

[applause]

Dr. Rapp: We all do. All right, the next item will be Chronic Care Improvement Program, Sandra Foote. She's the Director for the Division of Chronic Care Improvement Programs for the Centers for Medicare and Medicaid Services.

Ms. Foote: Thank you for having me here today. I understand that you all have not yet had any formal presentation on the Chronic Care Improvement Programs that were authorized under Section 721 of the Medicare Modernization Act. So although what I would really like to do is get input from you on communications with physicians, I think it would be wise to start by framing this and future discussion of the programs by just running through a little bit of background on them. So I'm going to start with an overview of the program briefly and then talk a little bit about the implementation timeline, which is very aggressive, and then a little bit about our communication plans, as they're beginning to shape up. The big picture is of course there's tremendous pressure for change. The Fee for Service Medicare Program, which is 35 million or more beneficiaries day by day and 250 billion in spending annually, treats a population or manages a population that as all of you know all too well, has many many chronic diseases and the prevalence of those is growing and is very different in different parts of the United States. And there are many reports of quality problems as the institute of medicine is reiterating and pounding at these systemic problems. So in the Medicare Modernization Act, they were looking at those and looking at the fact that coming at the program is a population that is early on becoming more and more sick. This is the national population, not the Medicare population, diabetes of course being a precursor to so many of the other problems. And finally, the widespread quality failings being now, already well documented and widespread. So the idea of the first round of Chronic Care Improvement Programs is to look at beneficiaries who have a trigger condition of either diabetes or congestive heart failure, in most of the

populations, or in COPD in some of them, partly because as you'll see there, they represent a tremendous amount of Medicare spending, a disproportionate amount. That is inclusive so these will not be diabetes programs, or CHF programs, or COPD programs, per se, but those will be using, along with risk factor analysis—there's a risk score calculated that looks at the probability that people will have a large amount of expenditures in the following year. And the combination of those is being used to identify populations for Chronic Care Improvement Programs. The goal of the programs is to implement on a large scale some programs that can help reduce risks and improve quality of care for chronically ill beneficiaries to assist physicians and the beneficiaries and their care givers in dealing with the extreme fragmentation of care that we're all aware of, and to create a platform, a contracting platform that is performance based, which is, again, new under traditional Fee for Service Medicare. In phase I, which begins very soon, the law says it needs to begin by December 8th, by this year, we have to have made the first awards, there will be about 20,000 under each of the Chronic Care Improvement Programs in the Intervention group that will actually be getting some services from the organizations that will be awardees in different parts of the country. The target populations as we mentioned are either those two, either or, or possibly in some sites, chronic obstructive pulmonary disease. They will be randomized control trials, and the idea is to look at a wide variety of intervention models and organizational models and see what we can find that we can really rigorously test and see if it works.

The core strategies are to work with beneficiaries, particularly in between doctor office visits to help them with their self-care, make sure they're adhering to their physicians' plans of care, make sure they understand their diseases and their medications and how to take them. A second piece of it, we're hoping these organizations will come with proposals to do a lot of data integration and to find ways to feed that to treating physicians in valuable ways. They also have to be using evidence-based guidelines for any counseling they're doing. That's built into the law, and the goal, which we've made very clear in this solicitation is to enhance the physician-patient relationship. This is a new population-based construct, which I'll talk a little bit more about in a minute. But here's what doesn't change, which I think is

important as what does. What doesn't change is it does not change their access to care, it doesn't change their benefit package. It's entirely voluntary for the beneficiaries and it's integrated into traditional Fee for Service Medicare. They continue going to their normal providers. Those providers continue to be paid as they are for the services they've been providing. The organizations, though, have accountability for outcomes. Specified in the law, that accountability is for clinical outcomes, satisfaction and financial outcomes. The law says it must be budget neutral. The Secretary made it even a little bit more than that. There is risk assumption by the Chronic Care Improvement Programs, but it is not insurance risk. And this is a very important point. They will have fee risk. If they don't meet the target of at least 5% savings, compared to the control group over three years—so they do have time to have the interventions have some impact—they will owe the fees back dollar for dollar until we do have that much savings. So there is some risk. But it is not about looking for particular kinds of patients. The population's assigned to them, and the comparison is to a control group. Both may have their costs go up, but it's a comparison between the two and whether the organizations can help people get better clinical outcomes cost effectively. So we would have a good rationale for whether or not to—and good evidence—as to whether or not to expand it.

There is built into the legislation a trigger to expand it possibly nationally if it is successful on all three of those dimensions of outcomes. The organization of this—just sometimes, people like a graphic better than verbiage, so the thing that's different about this is that CMS will now have an accountable entity to which it will assign a target population. That target population becomes a denominator and you can measure changes over time in that population. That organization has under the law, the right to subcontract with a lot of different organizations Whatever would help them get better outcomes and they can do information exchange with a lot of different organizations and we're hoping that especially that as we add in the drug benefits, we'll have drug data as well as medical data that we can begin merging and feeding back to their physicians and into models that look at what their risks are and what might help them in their self care.

As I mentioned, the statutory requirements are pretty slim. They just talk about care management plans, very individualized clinical decision support tools being used and clinical information data bases being developed. The Secretary, in the solicitation, added a number of additional requirements as he had latitude to do around other things that we would like to see from these organizations and integration with community organizations, collaboration with physicians were among those. And again, integrated information systems to help everyone involved have better support for decision making.

The first star that he hit is what the main focus of the legislation is. But a second one is there in the data base in the tracking of beneficiaries, and in the desire that this should reach not only the beneficiaries, but the caregivers and their providers to support them all. Again, addressing the fragmentation issue. And the third, the medical care support is least well defined, is least well done at this point in the private sector, because there's not much of this going on in such concentration that they're working closely yet with the physicians, but we're hoping that they will play a strong role in improving the data that's available to physicians from all the different physicians these beneficiaries often are dealing with, pulling it together and getting it to them in a timely manner. The initiative is leading toward new strategies for improving chronic care cost effectively. The organizations have a lot of latitude in the way they do that and they can change it over time and refine it. It's also leading to a shift in Medicare funding as the Secretary and the Administrator said in the press conference, from treating acute exacerbations of chronic disease toward preventing them, which is new and very important in Fee for Service Medicare and it's something that Congress has really struggled with because they have looked at from case management, should we fund case management, should be fund care coordination, how should we do it, who should we do it, and in this case, they were less about tactics and more about setting the accountability for defined at risk populations and saying, "Come to us and tell us what you're going to do, what the causal pathway is better outcomes. If we think it's a good idea, and you beat out your competitors, we'll try it."

So we have a very aggressive implementation schedule. We are the closing date for applications was August 6th. We had a tremendous interest in this program, everything from 500 people at the Bidders Conference, and 200 on the line, to a thousand questions on our website, as people were looking at whether they could make creative and innovative and fiscally responsive responses to this. We are now going to be reviewing those applications. We don't talk apparently much about the numbers or the range or any of that, but hopefully soon, by December, we'll have some answers for you along those lines, at least as to the winners. We will possibly be site visited some, depending on what we find in the review. We have large panels of internal and external experts helping us with the reviews. The first awards will be December 8th. We envision implementing as quickly as possible, but this is a very large and complex thing. It involves using Medicare claims in new ways. We'll be then working closely and collaboratively with the awardees and hopefully with you all to try to make this a success, and by 2007, we'll be looking at do we want to expand? So the real reason I was hear today was I wanted to get your input on communications with the physicians in the regions we do pick. You know those can be an MSA—Metropolitan Statistical Area; they might be an entire state, they might be the intersection of two states, you know, for an area, whatever areas we go into, we want to make sure we do a good job of making the physician community and other key local organizations aware that this will be starting well before we then go to the targeted beneficiaries to let them know they can chose to participate if they want to. And then we were looking for ways to have ongoing communication over time with the physicians. A lot of that responsibility and a lot of the creativity in how they go about it will be with the awardees, but CMS's plan is to initially introduce the program. We would certainly want to meet with physician leaders in those regions, to meet with the chiefs of staff of the major hospitals, to talk to the major physician organizations. We'll also run claims data find out which physicians have been treating those beneficiaries and send them letters. The follow-up will mostly be with the awardees, to work with the physicians, but I would love to hear your input about thoughts as to our letter, whatever, we will be drafting it and getting

it moving again before you meet again, but if any of you are interested in volunteering to take a look at it with us, as we draft it, that would be great, too. So questions, suggestions?

Dr. Rapp: OK, so what she's, as you've heard, the description of the program, what she's interested in hearing is what suggestions you have with regard to communications with physicians about the program as it's implemented. Dr. Powers?

Dr. Powers: I don't have any problem with the concept because I think that obviously we spend a lot of money on chronic conditions and it's something that could be managed better and I don't have a problem with it being more of a pilot project, because I think we can learn from something like that. My concern is when I look at this, and as far as your writing a letter to physicians, the first thing I see is more work, more papers to fill out, more data to send in, more work for us. That's probably not going to be something that's a part of our, it'll be folded into the low fees we already get. As far as you having the information as to how the patients are doing. Like if it's diabetes, for instance, how their blood sugars are doing. You get that data from us, you don't get it from the patient. So I think the letter needs to have some reassurance. If it's true that it won't be more work for us, there needs to be some reassurance that it won't be.

Dr. Rapp: In other words, some organization is going to get paid to do this and the doctors are going to have to do all the work for them.

Dr. Powers: Exactly, that's what it sounds like.

Dr. Rapp: Dr. Grimm, Dr. McAneny, then Dr. Iglar.

Dr. Grimm: I have a couple questions. What do you ultimately do you envision the result from these pilot programs—you envision a model for other centers to use? Or what is, what will you learn from these?

Ms. Foote: I hope we will learn what the law says is that we are to look at the components of the program and overall programs. There will be an evaluation of each program on its own merit. We will also be developing a performance monitoring system to look at trends over time. We'll be testing a lot of

hypotheses about how these organizations might be working with beneficiaries and/or providers, depending on the interventions they propose to improve outcomes, an example being, to lower readmissions after congestive heart failure. They're very very high in the Medicare population. And there are some studies that suggest you could lower them drastically if you had better monitoring of weight with those beneficiaries. With diabetics, there is from the private sector, evidence that just simple things like making sure people are getting their flu shots, taking their aspirin, those kinds of things, can in fact lower complications in hospital stays and—

Dr. Grimm: I understand that, but what I'm, my question is really what is going to, once you have a—assume that there's one pilot program that simply superior to everyone else. Then are you going to reward everyone else in the country that adopts that particular program in order to get more people to adopt a particular program? Is that what is going to happen from this?

Ms. Foote: There is no pre-determined endpoint of this? It's at the Secretary's discretion, both what it is that is chosen to be expanded, and how, but there is a mandate to look at it and find ways to scale it. So that, I think, translates to making sure we look now at models that could be replicated but there is no commitment that a particular model goes everywhere. That's not in the law. It's very open. There's a lot of latitude to develop it and learn from it as we go along.

Dr. Rapp: Dr. McAneny?

Dr. McAneny: Disease management is new to Medicare, but it's not new to the managed care market, and we see a fair amount of this already, so we have some experience with it. And there are some cautions. Speaking, I chair my city's emergency medical services authority, and what I find disease management often means is that patients get a letter in the mail which tells them to call this number for questions or problems or whatever, and then the nurse on the other end of that line goes through her list of questions, and if she gets past what she can deal with on the phone, the common denominator is go to the emergency room, and what we're finding is our emergency departments are being overwhelmed with people who, if they had called the office instead, would never have shown up in the emergency

department, wouldn't yell at me after they sat there for eight hours, when I finally show up when I discover that they're there, and it's just completely unsatisfactory for both the patient and the physician. So, in the private sector, when I find a patient gets one of these letters from the disease management company saying call us, I tell them please don't, and I write a letter to the disease management company and tell them that I've instructed that patient to call my office, not to call their nurse. So I worry about the emergency department. I also worry about our nursing shortage. If I were a nurse, and you offered me a job sitting someplace answering the phone or working the nightshift at the county hospital, it wouldn't take me a long time to figure out which job I would rather have, so I'm very concerned that this will exacerbate the nursing shortage that we already have. And my third concern is the budget neutrality. This also occurs in the private sector. When we see a disease management company come to town, they go to the hospital or health plan administrators, and say this is no risk to you. I won't charge you a thing. I will take my fee out of the savings that you get because you won't have to deliver so many services. And what this generally seems to be translating into is that they cut it into the physician reimbursement. Now that maybe cannot happen in Medicare, since the physician reimbursement is set, but it does occur in the way of bringing on more work, or requiring more paper work to be filled out or otherwise being, somehow in the budget neutrality, I suspect it will come out of the physician pocket and I would like to not see that happen. So yes, I think we would be interested in seeing the letter and interested in seeing how this is going to evolve. I would very much like to see at least one of the pilot projects involve getting a group of the primary care physicians who cannot take the kind of risk that you're talking about in the document because they don't have that kind of a deep pocket to take that risk, but instead of doing it with the negative of, "if you can't make this work, we will take away X amount of fees," but doing it in the positive of saying, giving them a management fee and saying, "if you will set up your after hours services so that you have space for acute patients in your office or that you have a system that does not involve the emergency department, or that you will manage these acute patients after hours as well, and provide the certain services, that we will pay you extra. And it may need new money in the system, or it may be a cost

shifting. But I think to put this into a new company, a new layer of bureaucracy, rather than putting it in the primary care physician's office, is maybe the wrong tack to take.

Dr. Rapp: Dr. Iglar?

Dr. Iglar: As a corollary to Dr. Powers on this idea of having more paperwork for the physician, is there is a consideration of this management fee at all to these pilot projects for either individual physicians' offices or groups of physicians? Or is it all based on—

Ms. Foote: Two issues. One is there is no required paperwork by physicians, although I have no questions in my mind that these organizations will in fact definitely want to hear from, work with, and communicate with the physicians—I think it's a very legitimate issue. And the second thing is, it was clear I the solicitation, I don't know yet what we've gotten back, but that they could subcontract whoever the accountable entity is, which can be a health system, can be any of a number of kinds of entities, that they can subcontract with primary care physicians—with others. So there's a lot of flexibility in terms of how it is structured. What's new is Medicare saying you trust fund dollars can flow toward prevention and self-care support and management of these diseases with this accountability caveat so they know it's budget neutral. So there's a lot of room for the kind of model that you've mentioned. Whether they've come in with that kind of proposal for this very first round, I don't know yet.

Dr. Rapp: Dr. Azocar?

Dr. Azocar: I'm very interested and very excited. I think this is a move in the right direction and hopefully has the potential to end up incorporating prevention, which is something that has been difficult to get paid for. And we basically will, means a lot of education and, but I can see also that there will be a need for integration and collaboration eventually, the primary care physician's going to get involved. We work with a lot of patients are primary care providers that have many chronic diseases, and it's frustrating to see how the lack of education and prevention actually doesn't change the outcome. I think you will have no difficulty in getting the final outcome because you eventually, patients end up in the hospital and you will be able to get your numbers. But it will be in need and anticipate of a great collaboration

between the primary care provider, and that may mean some additional time and work collaboration. But you asked at the beginning if somebody would be interested, and I'm one that would be interested in looking more into that.

Ms. Foote: Great, thank you.

Dr. Rapp: Anyone else? Could you just explain to me what it means to be budget neutral or more than budget neutral?

Ms. Foote: What it means, better than budget neutral? What is means is that there will be these intervention groups of 20,000 beneficiaries, there will be a control group of 10 to 20,000 individuals. We'll track their utilization history over the three years and they'll be randomly assigned to those two groups and we will look at the end at the per beneficiary, per month Medicare costs between the two groups on average. And actually the stakes are even a little higher than that for the Chronic Care Improvement Program because they have to also recoup their fees and come out at least 95%, no more than 95% of the cost of the control group on average. It's hard to describe—does that make sense?

Dr. Rapp: For them to get their money?

Ms. Foote: For them to keep the fees that they will be paid per member, per month, it's per beneficiary per month for the duration of the program, which is three years.

Dr. Rapp: They're given a certain amount of money to achieve certain results, not provide any care.

Ms. Foote: Exactly, not provide care. It's mostly self-care support, data integration, communication.

Dr. Rapp: And they don't have the right to approve or disapprove any kind of service.

Ms. Foote: No. And it's not a new benefit. It's not locked in. It's a pilot because there's been very few opportunities to do randomized control trials on a very large scale in the private sector.

Dr. Rapp: Well, I think probably what Dr. Azocar says is right. It has the hope of accomplishing some good things. I'm hopeful though that, I've heard a number of these quality improvement projects

from the chronic disease standpoint that one day one will come in for the solo practitioner, or the small group of three or four or five doctors. Because I think still, although there's been all these efforts to have huge organizations, there's still a lot of medical care delivered in that form and if I look at dentists, one of the good chronic care arrangements that they have is they do have preventive care arrangements, and they send you cards and say come in and get your teeth cleaned and so forth, and I think that perhaps the solo practitioner or group of three or four doctors may have a better hope of accomplishing the kind of things that are being, there's an effort to accomplish with huge structures and organizations and computer this and computer that, that in the old days, the doctors had these little tiny cards of about this much from 20 years of seeing their patients and they knew what happened and they kept tabs on them and all that sort of thing. And if they called up, they knew exactly what was going on with them, I mean, as an emergency physician, sometimes I've been amazed that I call up a doctor and I mention this person, that person, that person, oh yeah, Mrs. So and so, well, she was in—they have all this in their head and that functions as their computer and data base and everything and do a good job with their patients, but I just hopeful that CMS doesn't forget that there is a lot of medical care given this way and to try to, and this won't obviously work for this, but to try to come up with some model or some demonstration project or something because all of them to date have involved some big organization and they don't involve Dr. Urata in Juneau, Alaska and things like that.

Ms. Foote: Yeah, there is a physician group practice one, but it is a group, not so much solo practitioners. But presumably this could evolve to be very supportive of that, depending on how it gets shaped.

Dr. Rapp: Yes, but it still involves some outfit as opposed to just the little bitty operation. Little bitty operations sometimes are the best. Any rate, it's just a plea. Dr. Johnson?

Dr. Johnson: One thing on the little operation, I thought I'd follow your suit with that comment is whatever you evolve, it would probably be good early on to try to do something, at least on the web, to have it accessed for the small provider and so that anyone nationwide could see, and the other thing is to

try to have something that's there for these particular conditions for the consumer, for the beneficiary, so that the beneficiaries that log on out there can look and identify and understandable ways of how they can help to try to do the empowerment that you've given to the web-based learning about more about their condition, how to interact with providers, and save cost and enhance their health. So that would probably be beneficial for those that are web savvy on beneficiaries.

Dr. Rapp: Dr. Powers, then Dr. Urata, Dr. McAneny?

Dr. Powers: Our PRO already did this, I'm pretty sure, with congestive heart failure. I know the hospital had, and I'm pretty sure it came through [?] Foundation that they were, did the CHF project. And they did just the kinds of things that you were talking about and it did not, there wasn't really a middle man, since MidSouth provided it and so the doctors didn't wind up having to carry the burden. Is there not, do you not use models like that? I'm sure that it was a fairly large program, because it was at least statewide. And I'm pretty sure it was successful. I know of patients that seem to do better and weren't in the hospital as often because they had the nurse call them everyday to take their medicine.

Ms. Foote: Again, until we've reviewed them and picked some of the awardees, we won't know which models we're going to move forward with, but we're looking for a variety of models so we'll know, hopefully by end of December—

Dr. Powers: But it's like it's already been done.

Dr. Rapp: Dr. Urata?

Dr. Urata: Yes, I wasn't going to comment on this but since my name was mentioned, you know, I think that emphasis on preventive medicine is really good, but I think the way of going about it is in many ways a mistake. I think the incentive ought to be in the person who's the person with the problem. And that's the patient. And if the patient were educated and learned about the various things that they should have, like I try to teach my patients about hemoglobin A-1C with diabetes, they seem to have more incentive to deal with this and get their diabetes under control. Same with blood pressure. Try to give them a blood pressure cuff and tell them they got to get their blood pressures under—and now it was

a whole new standard because they came out with new blood pressure standards, so it's like a whole new thing going all over again. Congestive heart failure, I think doing weights, watching salt, and things of that sort, and then the call us when they get into trouble and then of course there's the usual regular visits. I find if the patients learn what they need to learn to get well and stay well, because they always have the incentive of wanting to be well, generally speaking, there's a few of those with personality disorders that you have to work with a little bit more. But I think that's where the emphasis ought to be. Not on another layer of bureaucracy. But unfortunately, I guess Congress didn't see that, so we're just left with what you got. Maybe one of the projects ought to be teach the patients, or something like that. Work with the patients with that kind of emphasis rather than somebody else working, another layer of bureaucracy with another layer of expenses working with the patients and the physicians.

Dr. Rapp: Dr. McAneny?

Dr. McAneny: I think the goal to do prevention primary or secondary is admirable, but if I were going to game this system and apply for one of your disease management contracts for that extra hundred mil that you're tossing out there for this, what I would do would be to make sure that I advertised in all the health appropriate journals and get the really motivated people, because they're going to be the ones who are going to do best at keeping their hemoglobin A-1Cs down and exercising and dieting. So I'd make sure if I were going to game the system that I would cherry pick all the patients who are most likely to be compliant and then I would dump all of the people who are noncompliant or have multiple medical problems on the poor primary care DOQ out in his office and then it would be easy to say that my services cost 95% of what his services did, because he'd be taking care of all of the noncompliant folks, so I think you really need to scour your process and make sure that it's divided well. And I would hope also that you would look at some of the big primary care groups—AFP or ACP or some of those, and say, can you come up with an office space program because AFP I know is working on developing information technology systems that would allow them to track when your mammogram is. Pay a DOQ an extra buck if they get the woman to have her mammogram on time. Pay a small amount and you may

discover that they recognize that if my whole practice gets their mammograms on time, I make more money than if they don't, and just give people that kind of incentive. Call it a management fee if you will, but people respond when their own personal best interest is aligned with what you want them to do for the patients. So this system to me looks like it's set up to be easily gamed.

Ms. Foote: Well, let me explain that one more time a little bit more clearly. What we will be doing is identifying the target population in a region. Just arbitrarily say, it's Georgia. Southern half of Georgia. We will look at claims data and identify the people that meet the selection criteria, the trigger diagnosis and—you can't cherry pick. It is a defined target population. We randomly assign with the evaluation contractor between the experimental and the control group. And it's not about marketing to the beneficiaries other than to encourage them to participate. But who is possibly in it is predetermined and then all the measurement of outcomes is across the entire population, whether they participated or not. It's an intent to treat model. Precisely. So that concern, which is a huge and legitimate one, is not real.

Dr. Rapp: Just in terms of that control group—are you going to notify the physicians who are involved in the care of the people of the control group that they're in the control group?

Ms. Foote: They are a passive group. We won't be notifying them. We won't be notifying their physicians. Nothing about their normal care will change and we will not notify anybody about them.

Dr. Rapp: How about the active group?

Ms. Foote: And on the intervention group, what we'll first do is send a letter from CMS telling people about this program—tell them all the things I told you; it's voluntary, they can get in or out any time they want, it doesn't change their benefits and it is at no cost to them, but we will give them a phone number that they can call and say they do not want to be contacted further by anybody.

Dr. Rapp: But they know they're in a group.

Ms. Foote: Well, they will know that then they are not participating.

Dr. Rapp: No, but if they are participating, they know they're going to be participating.

Ms. Foote: If they don't say—

Dr. Rapp: The people who aren't, the control group doesn't know they're being looked at. The group that is being looked at knows they're being looked at.

Ms. Foote: Knows they have the right to participate in this program if they want to.

Dr. Rapp: But I'm just talking in terms of your study, your experiment.

Ms. Foote: What they will be told is that they are welcome to participate in this program if they want to, that's all they'll be told.

Dr. Rapp: I'm just curious of what effect that would have if you told another group that ...another 10,000 that they're a control group and they know they're a control group because that Hawthorne type effect can be significant—

Ms. Foote: We won't be telling either one that will be telling them that they have the opportunity to participate in the program. That's it.

Dr. Rapp: Dr. Senagore?

Dr. Senagore: I think this is a great project in terms of the ability to accumulate a large amount of data in a population based study. I worry about where you go to the next level, though, because if you are truly going to pay for performance from there, and I'm a primary care doctor, you're going to control my stroke rate to someone else's stroke rate. Well, how do I know I didn't just draw a bad lot or my practice is smaller so I had one stroke, that was ten percent. I think that what I worry about is how does this project really fit in ultimately to the current payment structure that Medicare uses? The savings to Medicare and the benefit to the population is huge if you decrease death rate from congestive heart failure, huge benefits to the individual and to the health care system. But it's difficult to say how do you address the burdens then on the provider for that care?

Ms. Foote: Actually, that's one of the reasons that the population in each site is so large, is to do a power calculation and to actually get statistically significant results. Because the cost curves are so wide on these people, you actually need a very large cohort to come up with statistically significant results. So I don't think the individual physician level that's one of the problems. It's very difficult at the individual

level, you can't do it. So the evaluation will be across the entire population; the intervention group compared to the entire population of the control group.

Dr. Senagore: No, from a study perspective it's an outstanding opportunity.

Ms. Foote: I do think we'll learn a lot descriptively. I mean, for example, we've asked them in the solicitation about screening for depression, as a co-morbid condition. I think we'll learn an awful lot.

Dr. Senagore: But if we take diabetes or congestive heart failure, the person who's most integral to the success of this outpatient management is the patient with the disease, if I don't go out and have a gallon of ice cream, maybe my diabetes will be under a little better control. And so I wonder. It's good to focus this way to get the data. But ultimately, isn't the beneficiary, who should be at risk for poor performance? If you were really going to try to drive the appropriate motivation, and I understand that has nothing to do with the way we currently finance it, but the one who can most mitigate the actual events is that individual more than any doctor in this room, they can change the outcome. Once they know the best practice.

Ms. Foote. Yeah. Nancy Johnson talks a lot about the beneficiary who testified at the press conference and how he said the value of this was learning how to get control of his disease and you're right, it was right back to the self-care and support and motivating them to do it.

Dr. Rapp: That's why I wondered if you had a third control group where you told them they were a control group. And you don't do anything. You just tell them you're a control group and we're going to compare you against a group that doesn't know they're being a control group and a group that's being actively worked on at the highest level.

[Dr. Urata, off mike]

Ms. Foote: No, it's a pilot program that's part of the Center for Medicare Management. It's a part of Medicare rolling this out. It's not, we're just using a control group to compare to. We're not doing it as research.

Dr. Rapp: You're not doing research?

Ms. Foote: We're doing it as research. We put it in the Center for Medicare Management.

Dr. Urata: It's operations research.

Dr. Rapp: Operations research. OK, Dr. Azocar.

Dr. Azocar: I just have a comment. It's from the ethical point of view, because everybody knows that the group that does adhere to the recommendation is going to have a better outcome. Now is there any higher authority that reviews the study because you are going to have a group that you are going to have an ethical issue, you are going to obtain a trial, and you are going to intervene in one group, and the other one, know in the outcome, what could be. Just a comment.

Ms. Foote: You want the, well, it depends on the—a lot of things change as you manage an insurance plan that you try things to make it better and you don't do it as research. It's—

Dr. Rapp: This is Congressional research.

Ms. Foote: All the time, as you're managing an insurance plan, you keep trying to find ways to improve the outcomes of the population. You don't assume that what you have now is better.

Dr. Azocar: I agree. It's just a concern as somebody who does research that you're going to have an outcome that supposed to be better in the group that you intervene. So you know, it's an issue that...

Dr. Rapp: Dr. Gaughn?

Dr. Gaughan: I'm a specialist but I read the testimony from the American College of Physicians and the testimony from the American Academy of Family Practice, and it looks like they both are very concerned about this organization management and both are asking for a pilot that utilizes practicing physicians as leaders of the management team. And both societies actually have some excellent points on why the primary care physician or internist whatever, should be at the forefront of this—one would be physicians buying into this, two is that adding another layer, three is when you look at this, everyone's concerned about what's going to happen in the future and I think what we're all thinking is that these organizations are going to take the patient-doctor relationship in primary care will be over. So I'm just wondering, since both of these organizations suggested a pilot study using practicing physicians, as

leaders of the care team, is that being considered and then compare it of course to this organizational. I can see why you're doing it as an organization because it's easier in the beginning to do it with established groups, but I guess what both these societies are saying is, are you going to do this with practicing physicians? Is this going to destroy the patient-physician relationship? Or is this going to benefit it. I'm just concerned about that. I'm a specialist, but I can read, and it looks like both these organizations which represent a lot of physicians are concerned.

Ms. Foote: I have to be very careful because we're in the review process, but I think I can say that before I even took over this current position, I'd been in a lot of discussions with them and a lot of brainstorming about how they might be very much involved in this kind of thing. And also in the private sector, what is the most frequent, although not always the outcome, is that the number of physician visits goes up because much of what happens is encouraging people to go get the routine care. So the experience is the hospitalization goes down; drug cost, drug compliance, medication compliance goes up, and office visits go up. So that's actually, if you were going to hypothesize the outcomes, I would expect to see, I would expect that, and I would expect to see a little bit higher rate of referrals to hospice.

Dr. Rapp: OK, I think in terms of trying to summarize what you've asked for is what doctors, what your communications should have. I think the things that I've heard were said were one, that you should somehow make it clear that this should not be, that is should not be additional work per se for the physicians, so that there's additional money being provided to certain organizations to do these services that it's hopeful that this will be a benefit and aid the doctors who are taking care of these patients, in providing the care through additional information and so forth, and you might also, what you mentioned is that the organizations have the ability to subcontract with individual or groups of doctors, so make it clear that if they found out that they would be saddled with a bunch of extra work that it should be apparent to them that they could request some kind of remuneration for that, since they can subcontract and then, I think that's primarily what I—and Dr. Hamilton?

Dr. Hamilton: As I understand it, these entities that will do this management under contract with you—will they be able to develop their own strategies for this management? So you're not going to necessarily have guidelines for how the management ought to proceed or what they ought to do?

Ms. Foote: Not much beyond what is in the law that it must be evident space, that they must use clinical decisions support tools, that they have to individualize what they do. We added a lot about special needs, language, working evidence of working collaborative over the physicians in the community, those kinds of things, but still very general. So in other words, they can do more patient education and support for people who are not in crisis, they could do more full-fledged coordination of care for people who were in acute care, or crisis or post acute care or whatever. They can individualize their interventions with beneficiaries and providers, based on what the providers and the beneficiaries want.

Dr. Rapp: And then the final thing I was going to mention is you might make it clear that they don't, based upon Dr. McAneny's comment about HMOs, they don't have the authority to approve or disapprove any of the physician's services. In your communications make that clear. To the doctors.

Ms. Foote: Right.

Dr. Rapp: OK, if there's nothing else, thank you Ms. Foote for presenting that and taking our suggestions. The next item on the agenda, we will hear from Ms. Debra Robinson, who's the Acting Director of the Division of Provider & Supplier Enrollment, Office of Financial Management for Centers for Medicare & Medicaid Services and she is going to give us an update on Provider Enrollment and the chain ownership system, better known as PECOS and she'll share with us a couple of important development on that. Thank you, Ms. Robinson.

Ms. Robinson: Thank you. I thought that I would start out today by talking about the status of the PECOS enrollment system and give you an idea of where we are with that and then go on to a little bit of what's happening with the PECOS web application, which is in the development stage as well as the national provider identifier, which is also in the design and development stage. So I'll start with what's probably uppermost on people's minds, which is the status of PECOS. I'll start with some numbers.

What I've been doing over the last couple of weeks, is I've gone out to the carriers and I've asked them to provide us with what I'm calling a target rate, which would be the number of pending actions that they could have on an ongoing basis and still be able to meet our timeliness requirements, which is processing initial applications within 60, 90% within 60 days of receipt, and 99% within 120 days, and with changes in reassignments, 90% within 45 days, and 99% within 60 days. So as a result of that, I started getting in numbers last week, and I think I have most of them in. And the national target rate we have, which would kind of be what we would expect to see on a recurring basis over a period of time would be around 51,300 actions pending at any given time nationally. Our current national pending rate as of the end of last week was 67,196. So for my purposes I'm kind of looking at it that we have a backlog right now of around close to 16,000 cases that still need to be processed, what I would call our backlog. Just to give you a sense of perspective, in April of this year, we had a total of 98,458 actions pending, and so in the course of the last 3 months, we've processed around 31,200 applications. Sixteen of the thirty carriers at this point are already at or they are very closet o meeting those target rates across all three categories. What we have been doing over the last couple of weeks also is looking at the carriers, their pending workloads and their timeliness activities to identify those carriers, where we, CMS, needs to focus our attention more directly and for those who seem to be doing OK, who have got their pending levels down, who seem to be meeting timeliness requirements pretty well, we can kind of shift our focus away from them and do more concentrated activity and attention on those who we think need it most. The other thing that we have been doing is asking those who seem to be struggling a little bit more is developing a strategy for getting their numbers down and also addressing their aging applications within the next month. The target was that they would be at their targets by the end of this fiscal year, so that in October, everybody kind of starts from a point where they can make their timeliness requirements and were in a more stable situation. I think that from a systems perspective, we are certainly in a more stable situation than we were a few months ago. We have not had any issues with the system not being accessible problems with access, those kinds of things, for the last 2 months. That's a result of a couple of

different things. One is that, in terms of the data flowing through the CMS system, and the CMS data center and those kinds of things, we've reached a level of stability where there really just isn't that much of an issue when we do have problems, they're identified immediately. We had a problem last week. It identified immediately the night that it happened. It was with the batch processing and the next day, it was fixed and the problem was identified and the data center was looking on what actually caused the problem and monitoring the jobs that were coming through during the evening so that the PECOS load was not interrupted, essentially. We also increased the number of users who could access the system simultaneously. It's now up to 450 users who can get into the system, use it simultaneously, and there's no real affect on their ability to access and process. The other thing that I've done, well let me go back for a second. We also, the last two months, we implemented the transitory data base, which, if you're not familiar with that, what we did we went to the carriers, we identified certain fills that we could move into the PECOS system so that the carriers did not have to directly enter that data themselves, so that in processing, for example, reassignments and changes, it became faster and easier, because the contractor could just pick up that information and move it into the PECOS system without having to do data entry. As a result of that, we're seeing the reassignment workload go down fairly significantly across the carriers because they're able to move data instead of typing it in. The other thing that we have done and it was done long before I got there, but we're continuing it is that we're having CMS is having daily and/or weekly calls with the contractors who, well, initially it was with all the contractors, so every week or every day we would be in contact with them to see how they were doing to identify specific problems where CMS could intervene and be helpful either from a systems perspective or from a how does the PECOS data need to be entered perspective. And the other thing that we've done and this is what I've mentioned earlier, is that we are starting to focus our attention on the carriers with the largest workloads and those that have the most pending and need to do the most amount of work to address those. In terms of what the carriers have done, a larger number of them, well, almost all of them, actually, have been working overtime and weekends to get the workloads down. They've hired temporary staff, and as I said,

a number of the carriers who are kind of at their target rates, they're in a good enough position where they've let some of that temporary staff go. They've also shifted work to more experienced staff so that if they have staff who are new, who need to be trained, they're going ahead and bringing in experienced staff to work on the PECOS load while they're training the new staff. The other thing that some of the contractors have done is shifted some of their work load to other contractors. For example, NHIC New England, has shifted some of their workload to NHIC California. The one thing that I wanted to say and I think that I've tried to say it at all the open door forums as well, is that if there are providers and if you are aware of any, and you guys could help us get this message out, if there are providers who have applications that have not been processed and they're outside our 60-day timeliness standard, and who are experiencing cash flow or other hardship issues, we would like for you to let us know, and central office, the contact person up there, I've just changed it, because I've reorganized the office a little bit, and I'm concerned that Allan would not get to these email messages quickly. And so the person to contact is actually Sharon Chester and it's Schester@CMS.HHS.GOV and we can certainly be in touch with the carriers to expedite those applications and find out if there are problems and what they are.

Dr. Rapp: Have you, is that posted on the website?

Ms. Robinson: Yes it is. If you go to the Provider Enrollment website, which is—

Dr. Rapp: And it says something to the effect if you're having serious problems—

Ms. Robinson: Yes, it says pretty much exactly what that says, but if you go to the provider enrollment website, which is in your slides at the end, there's a sidebar that has a list of topics. And one of them is hardship. So if you click on hardship, it gives you that contact information.

Dr. Rapp: That was a suggestion we made at the last meeting, so thank you for doing that.

Ms. Robinson: Yes. So with that, I'll go onto some discussion about the PECOS web application.

Dr. Rapp: Let me just ask you, what did you say it's down to, the backlog? From 98,000 to what?

Ms. Robinson: The backlog is down to if you use my numbers and assume that we have a certain level of actions that are always going to be pending, the backlog is down to around 16,000.

Dr. Rapp: And do you have an aging of that? Like people do accounts receivable? Aging 30 days, 60 days, 90 days over 240?

Ms. Robinson: Yes, I did. But I don't have a national aggregate number on that. So what I ask the carriers to do is provide those numbers to me on a carrier basis about every month. So is that what you're asking me?

Dr. Rapp: Where is your outer space limit?

Ms. Robinson: Well on the weekly calls, what I really concentrate on are the cases that are over 120 days and most carriers don't have any. We have a, Empire New York has an issue with aging and to a more limited extent, First Coast Florida and a few of the others. But for the most part. . .I check before I came with some of the larger carriers. For example, and I get this information in different ways, so for example, I'll just give Empire as an example. Empire currently has a total of 6,445 applications actions pending, so that's initial applications, that's reassignments and changes. Of that 6,445, 2900 of them are less than 60 days old. So 45% are less than 60. 1,418 are in the 60 to 120 day range, so that's 22%. And 2,127 are over 120 days. So that's 33%. My assessment at this point is that for the aging—

Dr. Rapp: That's four months.

Ms. Robinson: Yes, so what we have done with Empire naturally, they're coming in at the end of the month—

Dr. Rapp: Does your aging go beyond 4 months?

Ms. Robinson: It does, but I do ask them, when they are sending in their specific data, I ask them for over 120 days, over 200 and then—

Dr. Rapp: Do you let out a loud screech if they go over 200?

Ms. Robinson: Yes, actually I do. And I say give me, I want to know what the cases are that are at this point and what we need to do to like work them, just do it. So, yes, if that's a screech. Yes. Let me just talk a little bit about Empire because I know there's some concern about it. Empire is going to come out at the end of, sometime in September, I've asked them to come in and present a strategy to us where

they would give us some comfort level that they are in fact processing not just the initials that continuing to come in so that they don't get old, but that they are working down the aging simultaneously. I can tell you a little bit about what they've done already, which is that the new applications that are coming in now are all going to Empire, New Jersey. Empire New York is concentrating their efforts in working the reassignment cases, as well as the aging that they already have and they're also using some of the staff at Syracuse, which is their Part A. So the Syracuse staff is also helping them. The other thing is that Empire New Jersey is moving the information from the transitory data base for Empire New York, into PECOS for them so that as they're processing the reassignments, it's happening faster. Empire doesn't have to even move the transferred data base information.

Dr. Rapp: Thank you.

Ms. Robinson: In terms of the PECOS web application, I didn't know if there had been any conversation with this group about it before, but I thought I'd let you know kind of what's going on. We are at this point in the fairly early stages, but we meet every week to discuss systems design and business requirements. So we're in the development stage of PECOS web, the early development stages. I'd like to thank Jackie Marine AMA because they helped us early on with providing some volunteers who we could talk to and I'm sure we're going to be doing more of that as we get to a point where it would make some sense. The strategy for PECOS web is that providers and entities would of course have the ability to enroll and make changes via the web. It would be interactive, set up something like Turbo Tax, so when you go into the website, you won't see the 855 I or R, you would have a series of questions. You would answer the questions, and then behind the answering to your questions, your 855 would be completed. Tentative implementation for PECOS web is the fall of 2005. That may slip a little bit depending on some of the issues that we are starting to struggle with now between the N-P-PEZ, the NPI system and the PECOS interface, and the other important thing that I thought you would care about in terms of PECOS web is that revalidation will not begin until the PECOS web application is up and it is stable. There will be testing prior to of course live implementation of PECOS web and how we're going to go about that,

we haven't decided, and it's one of my questions for you. For maybe you to think about how we could engage your other groups, other physician groups and other provider groups in terms of testing that application before we actually turn it on in productions. The issues around PECOS web include access, security, electronic signatures, the interface with N-P-PEZ, which is the system that's associated with the National Provider Identifier and form revision. Just a couple of things about access and security. We're working really hard and it's a fairly complicated process, but we're working hard to balance a couple of things, those two things. We have a need and an obligation to protect CMS records and CMS data. This is really the first application where the outside world comes in directly to CMS in this way. We also have an obligation to protect you and your information and your records from unauthorized access and use so we're trying to find a way so that access is not too onerous but at the same time we have appropriate security to protect the data and protect you. In terms of electronic signatures, we're as interested in that as I'm sure you are, that's not however, that would be an enhancement down the road. Because we would need to follow departmental and CMS policy and procedures once we implement the electronic signatures so we would be behind whatever the department decides and whatever CMS decides to implement electronic signatures. The interface with N-P-PEZ is something that we just started to talk about. The concept behind it is that if you were to come in and say you want to enroll in Medicare and at the same time you need to get a national provider identifier, you could do all of that at one time. So you come in, you enroll in Medicare, you've got your on the web, the question would be, do you also need and NPI? And that would be part of that process and you would be issued an NPI and Medicare Provider Number at the same time or as part of the same process. Form revision is tied both to implementation of the national provider identifier and PECOS web, because as we design the PECOS web application, we would need to have an updated and appropriate form, and in order to do that, and if we're going to ask you about do you need an NPI and get those few data elements that we would need that we don't currently collect for you to enroll in Medicare, it would have to be part of that process. We're hoping to have the form revisions by the spring, so that that part of the design for PECOS web would be done in time for a fall implementation

date, and that means OMB approval and all those kinds of things. The national provider identifier, again, in terms of status, we are in the midst of systems design, developing the business requirements, and also soliciting bids for the enumerator function and I'll get to the enumerator in just a second. The strategy, in terms of the national provider identifier is that we will offer both a web and a paper process. The web process would be a situation where once again, you would access through a website, the application, you'd be able to complete your information through the web as well as through the paper process. The paper process is just what it says. There's an application that's very short. Not like the Medicare enrollment application. Very short. And we have an enumerator, the contractor for the enumerator, there is only one, would be processing those paper applications. The second item there is bulk loads for groups and I did this a couple of weeks ago and we've since had more conversations about how this would work. So let me define some terms here. We have been talking about doing what we've been calling bulk loads. Bulk loads are now defined as groups or entities who want to submit to us their entire provider list for the purpose of populating the system. At this point, if we do this, it would be pre-production, and production, we're scheduled to go live with this in May of 2003. So the bulk loads would occur prior to actual production and that would give us time to work those lists, eliminate duplicates, and do the kind of the behind the scenes things that need to happen. In addition to bulk load, as defined by pre-production, we're also talking about an electronic data interface which would be also accomplished through agreements with entities and groups where they would electronically submit to us after production and on a regular and recurring basis, information on their providers so that we could update the information if you've changed you address, if you've changed your specialties, you know, if there are any changers that occur, we could do that through this electronic data interface process. We're in the early early stages of conversations about this, so right now it's kind of a gleam in the eye and conversations about how it would work, again, how we would ensure against duplication and how we would protect the individual providers as well as that data file. The enumerator, and there will be one contractor who will be providing this function, would handle the day to day operations of the national provider identifier program. They

would process the paper applications. They would be responsible for providing customer support and at this point, we estimating between 4 million providers and 3 million health plans would be enumerated through this process, paper or web. As I mentioned earlier, the tentative time, actually our plan at this point is that we will be up and running on the 23rd of May. It's a statutory regulatory requirement. We will be able to accept paper and web applications on that date. We're anticipating that on that date we will be accepting web applications from individuals or individual entities. We would not be ready at that point to accept either the electronic data interfaces and those larger applications. There would be testing prior to that May 23rd date, for all of those things. And between May of 05 and July of 05, we would be testing in a different environment. The electronic data interfaces that I just talked about, and again, since we've changed our kind of definitions and how we were approaching this, the electronic data interchanges we were expecting will be available in the July-August time frame. Same issues with this system for the most part as with PECOS web, access and security, provider industry communications, and this in particular in terms of what it means to the provider community, what you need to do, different ways that you can go about doing it, and of course, the interface with the PECOS Medicare Enrollment System. And one other issue is data dissemination. It wasn't on there, but we do have a responsibility to disseminate data and we need to come up with a strategy for that. Questions for the Council are things like, how could you assist us with testing for the PECOS web application to make sure that we're ready to go live? How could you help with educating physicians on the NPI and its significance to them? And different ways that physicians could go about getting themselves enumerated? And the last thing is, it's actually PECOS and enumeration. The name, the social security number, and your date of birth has to be consistent within certain parameters, with SSA information for enrollment and NPI actions to process. It is the first edit that we do when an action starts through the system. We hit up against the SSN file to make sure that we have the right person and that you are who you say you are and all those kinds of things. And so it's important that that information be consistent, otherwise there's going to be an exception and it takes time to work those exceptions and we do require the carriers to work them. So the question is how can we better inform

the community, how can you help us inform the community. But this important, particularly when we start doing the national provider identifier and you're going to get that unique number. That is yours and that's going to be the only way we have of identifying you as you. And that's pretty much it. Key websites again, the ones that I have listed, the first one is the provider enrollment website. That last one in the NPI website. And if you're interested in going to the NPI website, once you get there, you should go to Administrative Simplifications and if you click on that, there's places there where you can find NPI information and also frequently asked questions.

Dr. Rapp: On the web-based system, is that intended to give you an instant number or does that take a 60 to however many day process?

Ms. Robinson: At the PECOS? No, it will not give you an instant number. Are you talking about the PECOS web application? It's still the 60 and 120-day time frames because the process behind processing that enrollment still occurs. All those validations, all those checks, all the verification that the carriers have to do with that information still has to occur.

Dr. Rapp: OK, so it really won't do that much?

Ms. Robinson: It could but we have not at this point chosen to reduce the timeliness requirements.

Dr. Rapp: It just means the doctors have to fill out the form, I mean have to, it doesn't seem like it's going to do that much if there's no automated process to it. It's just fill it out on the web as opposed to fill it out and fax it?

Ms. Robinson: Right. Or mail it. It should be, the hope is that it will be easier and the hope is that it will be faster because what will happen what we're building in as part of the web application is you would not even be able to submit. For example, the web application would not even go to the carrier, if there's a piece of information that they have to have in order to process that isn't there. So it wouldn't even go forward. You would be told oops, you don't have this filled out and you have to do it otherwise we can't process it. So we're expecting that it will ultimately save time. The same thing with the SSN

validation. That will happen while you're in the process of completing that application on the web. If it doesn't match, you're going to get an exception from SSA. It will come back to you and say we're not getting a match on Social Security Number, date of birth, and name. We won't tell you which one, because we don't want people, we don't want to do a tutoring session for how to get into your record. But we'll tell you that it's not matching, so you need to resolve it. Maybe you transposed a number or something.

Dr. Rapp: Is this going to be optional or mandatory?

Ms. Robinson: Which?

Dr. Rapp: Use of the web.

Ms. Robinson: It's optional.

Dr. Rapp: Dr. Senagore?

Dr. Senagore: First just a comment given the fact that most physicians don't know that there's 95 and 97 guidelines for E&M coding, I'm not sure, I think you have a significant hurdle getting over the fact that this NPI is going to be essential in about 9 months, 10 months from now?

Ms. Robinson: Actually, May of 2007 is when it's required, and small groups is May of 2008.

Dr. Senagore: Then a comment about training and testing the web-based system. It may be helpful to select a group of people at random to run through it and test it and test the feasibility, i.e., if you get to a spot that you don't know the data input, can you stop and come back at a later date to pull up the form etc., like a lot of electronic filing systems allow you to do. And then finally given the issue we just talked about at the beginning of your presentation, is there a grace period for continued payment if the glitch is on the processing side. You've submitted your data, it's clean. But for some reason, you're in the 200+ day category. Do you still get to be paid under the old system, or are you in Limbo now that you've committed to the new filing process?

Dr. Rapp: Dr. Urata?

Dr. Urata: I've just a suggestion for testing PECOS, I would recommend that you use that Empire group in New York and if they can do it, then probably anybody can do it.

Dr. Rapp: He lives far from New York. Dr. Hamilton?

Dr. Hamilton: Yeah, I assume most people know when they're born and what their social security numbers are. So obviously there must be some glitches in this validation process that are quite onerous. What sort of things in the validation process are so hard? I mean what do you have to do to—

Ms. Robinson: Well, first of all, there are some things that, it doesn't appear to be onerous, but I will give you an example. We had a person—we kept getting exception reports. The person swore that they had a name, that was the name that they used and that they always used. Well, when we went to SSA validation, that was not the case. The person also swore that they knew their birthdate. They were five years off. I mean these things happen. So the more obvious and the more probably typical things is that you may have been going by Bob and your practice is set up in the name of Bob but Social Security has you listed as Robert. That will create an exception. And that's why it's important for providers who are coming into the system to at least have some idea of how Social Security has them listed with Social Security. If you don't like that, you can always, you're Bob, Social Security has you as Robert because that's what your parents gave to Social Security when you were born, I mean Social Security I think would change you from Robert to Bob if that's what you wanted, but you have to go to them first, get it changed, to keep an exception report from occurring for us. Now, we go back, if that happens, it's not like we just leave it. The contractor goes back to the individual and says, "We have a problem here" and again, we won't necessarily tell you because we want to make sure that we're not giving somebody your information so that they can go in and do it the right way, for wrong reasons. That is what happens. And it just takes a little bit of time to get it straight.

Dr. Rapp: Dr. McAneny?

Dr. McAneny: I think I'm being a little dense today, but I'm sure that we currently have an electronic data base of physicians. And in all the process of trying to figure out how to get people into

PECOS in a timely manner, I've lost track of what it is we're going to have once we have everyone in PECOS that we didn't have before. What is going to be the difference between—I'm sure we currently have an electronic database of physicians' names, addresses, Social Security Numbers, and now we're going to have this new database of physicians' names, addresses, and Social Security Numbers. So other than the NPI, what are we going to have now that we didn't have before? Why are we doing all this?

Ms. Robinson: What we will have, and we have and what we will have now is a national data base of physicians and providers. As opposed to carrier specific data bases of physicians and providers. We did not have that before. We did not have a national system. The only national system that we had was the UPIN registry, which was the registry that by law we had to use in order to enumerate physicians and then it extended out to other provider groups. And that's the referral. The UPIN number is your referral number if you have to refer for DME or other services, but we did not have a national system.

Dr. Hamilton: What is the difference between this and the UPIN number? Because that's the first thing people are going to ask me when I tell them they really need to get on the stick.

Ms. Robinson: The UPIN number is not a billing number. The claims processing folks do not need your UPIN number in order to bill, what is used to bill is your PIN or your performing PIN number, which is assigned by the carriers and that was, that's the information that has been contained in the carrier specific data bases that were never part of a national system, and frankly, part of the implementation issues with PECOS flow from carriers each had individual enrollment systems. They had individual ways of enumerating you and some of that came to light as part of the implementation of the national system.

Dr. Rapp: Dr. Iglar, then Dr. Castellanos, then Dr. Sencore.

Dr. Iglar: Your last questions, how can PPAC help to inform the community? We all go through state licensing every 2 years, one, two, three years perhaps. Perhaps in addition to an addendum to our state licensing, something informing the physician community that this is going to be necessary at a certain date and well, we all come up at different times, I think. So that might be a thought.

Dr. Rapp: Dr. Castellanos?

Dr. Castellanos: I guess I just have a hard time understanding what takes 120 days? I don't understand why it takes this system up to 120 days when this information is given to you or is available to you.

Ms. Robinson: Well, let me back up for a second. The 60 and 120 days is not necessarily associated with the PECOS system per se. Those were timeliness standards that were in effect prior to PECOS so it is part of the, and remember, it's 99%. So the expectation is that 90% of the initials will be processed within 60 days. There are a number of activities that the carrier has to do before they can process that action. And not all of it is necessarily enrollment activities. If you notice on your enrollment form, we're also collecting payment and claims processing information from you, so that once you're enrolled, we can automatically roll it into claims processing. But the first thing, as I said, is the SSN validation. From there, we do a number of other validations through contracts that we have through various folks, like address verification, we make sure that the addresses that are provided are actually for example for a medical building as opposed to a 7-11. If there are things that don't look right to us, then the carriers have to develop those—

Dr. Castellanos: So in a sense, this is against fraud and abuse.

Ms. Robinson: Yes, part of it. The other part of it is that we want to make sure that what we're processing for you is actually for you, so that's a fraud and abuse kind of activity. Part of it is making sure that the information that we have in fact is accurate and correct, so we do, there's lots of internal verification processes that occur when you submit that information that's behind the scenes. And if there are exceptions, and edits, they have to be worked. And I won't say anymore than that.

Dr. Rapp: Dr. Senagore?

Dr. Senagore: First a question—the distinction between the UPIN number and the NPI, will I still use the UPIN number for, I see a patient of Dr. Iglar's and consultation I need to file his UPIN number? And then I use my NPI number for billing? That'll replace that number?

Ms. Robinson: I think that you will no longer ultimately you would no longer be using the UPIN number, you would be using the NPI number for billing and for referrals. That would be the only number that you would need.

Dr. Senagore: Then an application question. If I file a clean claim, I'm already in the system now, with Ohio and all of my information remains identical, why would I not get a number instantaneously?

Ms. Robinson: In terms of the—

Dr. Senagore: I fill out the data, you have my UPIN number, my address is the same, my Social Security Number's the same, I happen to remember my birthday, and we went through all that and the system was clean, could the system not be capable of just giving me my NPI number immediately? Mailing address hasn't changed, office practice hasn't changed? I'm simply complying with your need to—

Ms. Robinson: Yes, I would think the time frame for the NPI, at least as it's written right now, is I believe three days.

Dr. Senagore: So I guess what I'm my fear is given what we've heard about the PECOS system, should not the vast majority of these claims be instantaneous then, in the transition. And the 120 days would be the real memory gap.

Ms. Robinson: Yes, and the 120 days is for Medicare enrollment, not for the NPI, so it's, you know—

Dr. Senagore: But even for Medicare enrollment, shouldn't I, if I'm already enrolled now and I fill out all the forms completely, should we have some assurance that that should be processed very expeditiously three, seven days and have no fear of it being longer, only if I misapply. If I have a data field entry that is not consistent with the current data. Because that's really all we're doing. We're taking one current system that works and now having a new number appended to it.

Ms. Robinson: Yes, I think that's a valid assumption.

Dr. Senagore: If you could give that kind of assurance to the physician community that if you fill out the current data correctly that it will be nearly instantaneous to make this transition, it'll take a lot of concern away.

Ms. Robinson: Right, and I think that would be true. And I think the other piece of that is that we're going to make at this point at least, we're planning for the electronic data interfaces, so that if you're part of a large group, if you're a physician with an Aetna, then we'll take Aetna files. Aetna will submit your information, the NPI we haven't figured this out yet, but will go back to Aetna, and we would inform you. This is your NPI.

Dr. Senagore: My fear would be, not that this could ever happen, of course, a fiscal intermediary could take this little gap out of a month or two and use it to their advantage in processing claims, even though the data's clean. I know that would never happen. But hypothetically.

Dr. Rapp: Dr. Gaughan?

Dr. Gaughan: I just had a question. I realize that CMS is delayed the revalidation where we all have to fill out the Medicare application every three years? Is that going to come at the same time as this NPI? I mean it seems if there's been such a mix up with PECOS, then we're doing this NPI, then we're all going to have to revalidate every three years, it just seems like that project is just going to be insurmountable for CMS.

Ms. Robinson: We haven't set up a time frame for the beginning of the revalidation process, and it would not be that everyone would have to revalidate. The thinking is at this point that if we have not heard from you in I can't remember whether it's three or five years, then you would be in the first round of providers who would need to revalidate. If we have heard from you in terms of a change of address, or a change of a pay to, or whatever you came in, you changed your date of birth, if we've heard from you, then you would not be in the initial round and it would be a rolling activity. And again, we would not even start it until we were sure that the PECOS web application was working.

Dr. Gaughan: And you're going to pilot test that.

Ms.Robinson: Yes.

Dr. Urata: With Empire.

Dr. Rapp: Dr. Powers?

Dr. Powers: How many volunteers are you looking for?

Ms. Robinson: I don't know yet, I think we would need—I don't think we need a lot, but I think we need representatives from like individual physicians, small groups, large groups, because we need to work out how we would want to process all of those different kinds of entities that exist. So I'll know more later. We're just starting to talk about this. And I need my systems people to tell me that.

Dr. Rapp: Yeah, probably most of us will volunteer. We'll do this one. OK, anything else? If not, next on the agenda is a short break, we'll take a ten-minute break. And after that, we'll have oral testimony by the groups that have asked to do that and then final recommendations.

[Break]

Dr. Rapp: I would like to reconvene the meeting. The next portion is reserved for those organizations who requested in advance to present oral testimony. Those are the American Academy of Family Physicians, American Academy of Home Care Physicians, the American Medical Association, the American Society of Clinical Oncology, and the Advance Medical Technology Association. And I'll take those in order and we ask the presentations be limited to five minutes. We also acknowledge that we have received written testimony by the following organizations: The American College of Physicians, the Coalition of Wound Care Manufacturers, and the Medical Group Management Association. Those have been received and are by the Council, and provided to them, and so even though they are not specifically mentioned in the deliberations have been considered. I understand there are some other groups that have asked to testify. Unfortunately, our schedule doesn't permit to add any at this point. We'll be happy to distribute any written comments to the Council that those organizations may want to give to Mr. Lanigan. The first presenter will be Jerome Connelly, from the American Academy of Family Physicians. He's Senior Government Relation Representative, I believe, for the Academy.

Dr. Connelly: That's correct, Dr. Rapp. Members of the Council, I'll be very brief, because I listened with interest to your discussion relative to the Chronic Care Improvement Program and I particularly appreciate the comments of many Council members with respect to the role and the value of primary care in the management of patients with chronic disease. There was some discussion around the notion of trying to figure out how to test or demonstrate a program that would compensate primary care physicians for the care coordination activities that the literature demonstrates abundantly are cost effective. And it's interesting to note that Medicare and other insurers reimburse for those procedures and those decision-making processes that physicians and health care practitioners deliver, that are deemed to be of value and of merit and to have efficacy. One of those that is not, however, compensated or reimbursed, but is of merit, of value, and is efficacious is care coordination activities. So this is something I listened to the discussion with great interest because in fact, care coordination activities, in the literature, shown to demonstrate cost-effective measures, reduce hospitalization, and deliver higher quality care. One of the pieces of literature that we have produced at the Academy, you have in front of you now, I believe. And that's called a New Model of Primary Care. And I think you'll find it quite of value and of interest to you and it does in fact have a fairly lengthy bibliography at the end of 58 or so entries that talk about the ecology of medicine. They talk about the usual source of care and how important the usual source of care is, particularly in the elderly. It talks about the importance of care coordination activities, particularly in addressing these patients with comprehensive medical needs. It also illustrates through outcome indicators and health care expenditures through tables where the United States is in standing with the rest of the world when it comes to the delivery of primary care services and how then that translates to the other kids of utilization expenditure situations that we encounter. So I would commend this to your reading and hopefully this could be the subject of future discussion, and around which we could build some discussion about how a care coordination model of compensation, which is of value and importance can be tested or piloted or demonstrated within the Medicare Program.

Dr. Rapp: Thank you very much, sir. Is there anything from the Council? If not, the next testimony will be presented by George Taler, who's Director of Long-Term Care at the Washington Hospital Center in Washington, D.C. and he's speaking for the American Academy of Home Care Physicians.

Dr. Taler: Thank you very much. I've come before the Council to request your support for two initiatives at the American Academy of Home Care Physicians. One is to reevaluate the domiciliary care codes and through both CMS, the CPT Editorial Panel, and the RUC, and the second is some support for what seems to have been an orphaned part of home care, which is travel time. For DOM care, in 1989, when the codes were initially established, domiciliary care was just a wastebasket code that included board and care homes, halfway houses, group homes, and foster homes, and it wasn't expected that those individuals would require much in the way of medical care or that medical care could be delivered very effectively to them. And so those codes were limited to the lower three levels that most of us know at the office setting. Over the past 15 years, domiciliary care has changed dramatically, especially with the advent of Assisted Living. And it's now a very large segment of the population and it represents a very frail group of patients, approximately a million strong. These are individuals who have difficulty accessing health care services, and because of the antiquated reimbursement system, it's made it virtually untenable for physicians to actually provide care in those types of facilities. My own practice, I make approximately 900 housecalls a year and less than 5% of our practice is in DOM care because we find that it's financially untenable for us to provide care in those services.

The second issue is about travel time. In 1989, when the Home Visit Codes were reevaluated, which really reflected a C-change in the ability of physicians to provide point of service care, there was an expansion of the house call codes, from what looked like DOM care codes, to what looked closer to the full spectrum of office codes. So there are five levels of service for the new patient, and four levels for established patient codes. As it turns out, those levels when they were evaluated through the RUC, we were requested by CMS to withhold issues of travel time in anticipation of the practice expense

movement. Unfortunately, when practice expense came into being, there was no provision for travel time. And so, what is obviously a component of home care, which is you have to go from house to house, has no home. We went to the CPT Editorial Panel, requested that they give us some guidance, which they did not. We did find an obscure code that related to travel, requested that that be changed, and the CPT Editorial Panel again refused. Without a lot of explanation. So we have what is clearly considered an integral part of a service that has no ability to be compensated adequately. And so what we request of the PPAC is that if you would support us in having travel time compensated in some way, we're not advocating either for a code or for a modifier, but that it simply be something that is addressed. So it's those two issues that the domiciliary care codes be reevaluated, in compliance with some recommendations with both our organization, the American Geriatric Society, and the American Medical Directors Association, and the travel time be an issue that is brought forth to CMS and to the RUC process.

Dr. Rapp: Dr. Urata?

Dr. Urata: Is not some money in the payment of the CPT code includes travel time?

Dr. Taler: No, it is explicitly not covered, either in work or in practice expense.

Dr. Rapp: Dr. Senagore?

Dr. Senagore: I [off mike] don't remember any discussion or testimony related to the home care codes for advocated for coverage for travel time through that discussion. So if that indeed happened, I guess I don't recall it personally and that would probably be the best vehicle to address this concern would be to petition the RUC to readdress it. There is still a peak subcommittee that will address these issues as codes are looked at again. That may be your best avenue to get an audience.

Dr. Taler: We're more than happy to go through any avenue. What we're asking is the PPAC to support our effort.

Dr. Johnson: With that process, the earliest that you get line to have those come into publication would be 2006, right?

Dr. Taler: Yes.

Dr. Senagore: I don't speak for the RUC, I don't know what the [?] be whether practice expense is going to be opened up again or not, but for an issue that was specific to a code, and someone could look at the minutes to see if this was actually addressed or not. I personally don't recall this discussion ever coming up related to these codes.

Dr. Johnson: Is there a provision that we have for assigning the code for travel, for coverage?

Dr. Rapp: Dr. Simon?

Dr. Simon: There was discussion at one of the recent RUC meetings in the past year in regards to travel time and I think some of the concerns and struggles that the committee had was that the purpose of the RUC is to look at what is the typical service provided to 51% or more of the patients that are involved. And it was difficult in determining travel time. Travel time, just for the sake of discussion here, from Washington to Baltimore, can vary tremendously depending upon the time of day, as opposed to those individuals that travel and perform home visits in a rural setting. And those were some of the topics I think that the RUC Panel got struggled with in terms of how to define an average time of travel that would reflect travel both in an urban and rural setting, geographically across the country, because clearly, traveling from one patient to the next in Alaska is very different than in New York City, or here in Washington, D.C. So I think that because of the struggles that the RUC had, they decided that they would not address it at the time when they met in that regard. In regards to your second question, if this issue were to come up before the RUC, over between now and sometime in February, there would be the possibility that if one could define what would be a travel time that would be acceptable by all of the people that sat at the table, that conceivably, there could be a payment rate assigned for the year 2005. If however, it was deemed that this should undergo the 5-year review, it would be 200—I'm sorry, it would be 2006 if it went through the RUC process. It would be 2007 if it went through the 5-year review process.

Dr. Taler: We're patient, as long as it eventually comes to the surface. Right now, it seems to be an orphaned part of our practice.

Dr. Simon: I should say that the clinical groups that have been interested in travel time, have gone before the appropriate bodies and have undergone the discussion, and made their case, and those bodies have chosen to table the discussions at the conclusion of each of those meetings.

Dr. Rapp: Thank you, Dr. Taler. The next testimony will be presented by J. Edward Hill, MD, who is the President-elect of the American Medical Association.

Dr. Hill: Thank you, Mr. Chairman and members of the Council, and good afternoon. I've enjoyed today very much. I've been here a couple of other times, this is the best day I've been here, so as the Chairman said, I'm Edward Hill, I'm president-elect of AMA and a family doctor from Tupelo, Mississippi. I really do appreciate the opportunity to address you today about our concerns about the proposed rule of the 2005 Physician Fee Schedule. As you've heard already today, the proposed rule implements the 1.5% actually conversion factor payment increase enacted in last year's MMA, and if Congress had not acted, physicians would have received 3.7% cut in the current sustainable growth rate formula. But this year's increase, as far as we're concerned, is a very short reprieve. Now we're faced with pay cuts, as you've also heard today of 5% beginning in 2006, so it's clear, I think that the sustainable growth rate system is just not sustainable. And what concerns us more than anything else of course is the patient-access crisis that is looming because of this. The most helpful thing that CMS could do would be to remove drugs from the SGR. Now in the fee schedule presentation this morning, you would told that there was nothing that CMS could do in the short run that's going to help with the SGR problem. We disagree with that. Over the past five or ten years hundreds of new drugs to treat cancer and infectious disease and other disease have entered the market. These drugs have improved the medical and health care for millions of elderly and disabled Americans. But they're very costly and that has a major impact on Medicare spending. Currently, CMS includes the cost of physician administered drugs when calculated whether physician spending exceeds that SGR target or not. Drugs have continued to consume

a growing share of the SGR dollars. Between 1996 and 2002, that 6-year period of time, spending per patient for the drug products alone, increased 244% compared to only 38% per patient for actual physician services. This lopsided growth of course lowers the SGR target for real physician services and worsens the growing gap between the actual and target spending. So this flawed system cannot continue. Drug products are not a physician service and should have never been included in calculating the SGR. As I recall, CMS admits that it has the authority to remove drugs from the target. And there's widespread support in Congress for such action. Key members of Congress are committed to developing a long-term solution to the SRG formula before cuts began in 2006. But they need to start working on the alternatives very quickly, early next year for sure. Given fiscal realities, the feasibilities of future legislative options will depend largely on what steps the Administration takes this year to lower the cost and we think CMS must signal its intentions right now. So therefore, we urge CMS to announce that it will remove drugs from the sustainable growth rate pool, retroactive to 1996 in the final 2005 Physician Fee Schedule Rule. Medicare Modernization Act has significantly changed the way Medicare pays for physician administered drugs as you've also heard today. While this mostly affects oncologists, hematologists, urologists, gastroenterologists, there are 20 other specialties that are impacted in some way, and you have again heard today that payment for physician administered drugs in 2005 will be based on 106% of the drug manufacturers average sales price. The proposed rule includes projected rates, as you heard for only 32 of the more than 400 Medicare covered drugs, thus it's virtually impossible for the AMA and affected physicians to do a full impact assessment. The preliminary data however, indicates that there will be some substantial cuts that could seriously compromise patients' access to quality care. And I think you heard from Dr. Castellanos this morning that the gaps in information make it very difficult for both physicians and patients to plan ahead to a budget at all. We don't know as physicians, whether we'll be able to buy the drugs at the average sale rates, because we don't know what the final rates will be. Doctors are unsure if they can afford to keep offices open, as you've heard, or satellite clinics open, or if they're going to have to layoff employees and staff. Patients also don't know if they're going to be able to continue their

treatments in their physicians' offices. Patients with cancer and rheumatoid arthritis, infection diseases of course, are among the sickest of all of our Medicare patient population and given the critical nature of these illnesses, CMS must do everything it can to provide accurate and complete information to ensure patients have continued access to physician care. So we urge CMS to proceed with caution in implementing these average sales price rates. CMS should make broad use of any discretionary authority they might have to make exceptions to revisions or delays in the average sales price rates. Now, if CMS does believe it has the authority to delay these changes, until it has complete and reliable data, then it should ask Congress for such authority and we would recommend and request if that's appropriate, to ask Congress for that authority. CMS should also inform physicians of the average sales price for all covered drugs as soon as possible, so that there can be an informed and complete review process. Even then, we urge that the final drug payment rates be considered interim, so that further changes can be made, based on more complete data. And finally, we urge CMS to create a system to monitor how access to drugs are affected by the ASP payment system. My last comment addresses the incentive payments in the health professional shortage areas of the PSAs. The MMA required CMS to publish a list of those physicians, or professional shortage area counties and areas in the Proposed Fee Schedule Rule on its website. Well, as far as we can tell, this has not been done. So we ask that CMS publish a list of these counties immediately, because physicians and state officials and other interested parties desire an opportunity to comment on these counties. If CMS is not able to publish a list of the scarcity areas in time to be included in this comment period, CMS should make the PSA designations also interim and allow an additional comment period. Mr. Chair I want to thank you for the opportunity we have to speak to our concerns relative to the . . .

Dr. Rapp: [off mike] Does anyone have any questions or comments? If not, thank you very much, sir. The next testimony will be presented by Dr. Joseph Bailes, who's presenting on behalf of the American Society of Clinical Oncology.

Dr. Bailes: Thank you very much, Mr. Chairman. As you said, I'm Joe Bailes. I'm the past president of the American Society of Clinical Oncology and I appreciate the opportunity to address the Council about changes in the Physician Fee Schedule that are proposed for 2005. As you've heard earlier, the Medicare Modernization Act made substantial changes in the way the Medicare Program covers cancer services. It addressed the issue of the significant payment for drugs that had subsidized payments for services over the years, but oncologists are particularly affected, and I think most of you know that from earlier discussions today, because oncologists, most of the people we care for have infusional drugs, and injectable drugs. But also, other specialties are affected. Rheumatologists, gastroenterologists, infectious disease, hematologists, urologists. In 2004, the Payment Reform, enacted by MMA is essentially budget neutral so you would not expect to see any significant displacements or access issues in 2004. However, in 2005, there will be a sharp decline in the Medicare revenue available for caring for cancer patients. Drug administration services, by statute, will drop by approximately 21% of January in 2005, and the net funds from Medicare Drug Reimbursement, that is the revenue available after purchasing the drugs, will also drop sharply. And this may not have been what Congress intended. In fact, we've been told originally by Congressional staffers that they thought total payments for 2004 would be the same in 2005. So I think our concern is the situation may threaten access to patient care and to patient's access to cancer therapy. Approximately 80 to 85% of cancer care is delivered in the community setting in the United States. Not in academic centers, not in cancer centers. Chemotherapy and its related services are costly. Without the reimbursement, oncologists may not be able to sustain the infrastructure necessary to care for these patients. Also, most hospitals do not have the capacity to furnish chemotherapy to the patient population in the Medicare setting. Approximately 40 to 50% of any oncologist's practice at any given time is composed of Medicare beneficiaries. We realize Congress needs to address some of these problems. However, there are three things in our view that CMS can do. First, as you've heard, it could provide more information about the data available on average sales price. I personally and others who are intimately involved I the legislation from June to November of last year

and realized the discussions related to ASP etc., however, ASP data from the 3rd quarter of 2004 is what will set the allowables, January 1, 2005. CMS has released only data relating to high volume drugs, essentially, while it is about 70% in CMS's view of the drugs used and the drug revenue available, this limited release actually hampers the ability to identify for an individual practice what this will mean to that practice. Most oncology practices in the United States are still very small. It's by and large a cottage industry, fewer than 6 oncologists. So this is a significant issue. So it makes it very difficult to plan. So that's the first CMS could do is release the ASP data for all drugs. Secondly, CMS could provide more detailed guidance to pharmaceutical manufacturers about how to calculate ASP. Manufacturers have raised questions. I think CMS has provided some general guidance, but specificity is I think very important in the current environment. I think most manufacturers, in the absence of official guidance, we are concerned may be overly conservative, and report frankly low ASP, which put us in, again, a position of trying to define how the ASPs are. Thirdly, CMS should take advantage of the Medicare Modernization Act to create new and revised codes. I have been involved in that process. I think that process has worked, however, there are opportunities in 2005 and 2006 outside of budget neutrality for CMS to create new codes that recognize services that have long standing documentation—I personally have been involved in this issue for 14 years and I think this is an opportunity for CMS to recognize codes that the AMA's CPT process does recommend. So I think that this also will help maintain patient's access to cancer therapy in 2005. Thank you very much for the opportunity.

Dr. Rapp: Any questions? Thank you very much, Dr. Bailes. And the final testimony will be presented by Daniel Waldmann, who's the Director of Federal Affairs and reimbursement for Johnson and Johnson and speaking in behalf of the Advance Medical Technology Association.

Dr. Waldmann: Good afternoon, thank you. I apologize for my voice. If I don't make it through, you have our written statement. I'm Daniel Waldmann, I am the Director of Federal Affairs for Reimbursement at Johnson and Johnson. I chair AdvaMed's committee that deals with Medicare policy relating to durable medical equipment. AdvaMed represents more than 1100 manufacturers of medical

devices, including many who manufacture DMEPOS items. AdvaMed wishes to bring an important issue to the Council's attention regarding provisions in the August 5th proposed rule for the Physician Fee Schedule. Specifically, we are concerned about the proposal to require a face to face examination with a physician for prescribing, determining medical necessity, renewing prescription, repairing and replacing all DMEPOS items. Section 302 of the Medicare Modernization Act requires a face to face visit with the prescribing physician only for power wheelchairs. That mandate was based upon hearings and evidence provided by CMS regarding fraudulent activities, specifically associated with power wheelchairs. For other DMEPOS items, Congress directed CMS to establish clinical conditions for payment including a face to face examination where appropriate. We interpreted this to mean that CMS should examine the evidence relating to specific types of products, before determining whether to impose additional requirements. While AdvaMed supports the concept that patients who required DMEPOS items should see their physicians regularly, we believe that the all-encompassing approach, required in the proposed rule goes far beyond Congressional intent. Requiring a face to face visit to prescribe all DMEPOS items is overly burdensome to the physician and the patient, and may result in reduced access and diminished treatment. Moreover, the proposed rule would impose that burden without analyzing whether it is needed to address fraud or control inappropriate utilization for specific types of DMEPOS items. We are also concerned that in many situations, the proposal may not reflect, except in medical practice. For example, as outlined in written testimony submitted to the Panel by the Coalition of Wound Care Manufacturers, immobile wound care patients, especially those who live in rural areas, are examined by home health agency nurses more frequently than they see their physicians. During these visits, sometimes on a daily basis, home health nurses document both the overall health status of their patients and the condition of the patient's wounds. This information is communicated to the prescribing practitioners who make decisions about the products to be included in the comprehensive wound care plan. If CMS requires these same patients to be seen by the prescribing practitioner before any wound care products can be added to their care plans, the challenge of mobilizing and transporting patients may cause unnecessary delays in

treatment, regression in the condition of the treated wounds, and decline in overall health care status. In comments to the proposed rule, AdvaMed will ask CMS to reconsider the across the board face to face visit requirement. As an alternative, we will propose that CMS set forth criteria for determining which types of items, and in what situations a face to face examination should be required, and to apply those criteria in developing clinical condition policies for specific DMEPOS categories. We hope that the Council and the physician organizations you represent will review CMS's interpretation of Section 302 and urge CMS to seek an alternative to the all-encompassing approach described in the prescribed rule. Thank you.

Dr. Rapp: Thank you. Any questions? If not, I appreciate your testimony. All right, we have not gotten to the final part of the meeting. For proposed recommendations by PPAC. I don't know, Dr. Powers?

Dr. Powers: I have three. I'll do them one at a time.

Dr. Rapp: She's going to read them, but I think she wrote them down for you.

Dr. Powers: Yeah, the first one is the same as the first one on the AMA testimony on page 2, titled inclusion of physician administered drugs in the SGR. And unfortunately, CMS has to hear this every time we come. We just won't shut up about this. The administration should announce its intention in the final 2005 Physician Fee Schedule rule, to use its administrative authority to remove drugs from the SGR pool, retroactive to the SGR base here, April 1, 1996 through March 31, 1997.

Dr. Rapp: Do you have that, Dana? Yep? Go ahead.

Ms. Trevas: PPAC recommends the administration should announce its intention in the final 2005 Physician Fee Schedule rule to use its administrative authority to remove drugs from the SGR pool, retroactive to the SGR base here, April 1, 1996 through March 31st, 1997.

Dr. Rapp: Is there discussion? All in favor? Anybody opposed? We've recommended that same basic thing several times, although not the retroactive part. Next.

Dr. Powers: And I'm willing to invite rewording of any of these others. PPAC recommends that the competitive bidding process should include medications administered in physicians' offices for all specialties—and not just oncology.

[seconds]

Dr. Rapp: Do you have that?

Ms. Trevas: PPAC recommends that the competitive bidding process should include medicines administered in physicians' offices for all specialties, not just oncology.

Dr. Rapp: And why is that?

Dr. Powers: It's what Ron brought up earlier, about whether or not things were included, and were all the urology included, that sort of thing. And rheumatology, neurology.

Dr. Rapp: And what's the system other than that, the competitive bidding process?

Dr. Powers: We just want to make sure that they're all in there. It's not just chemotherapy for oncology.

Dr. McAneny: Remicade is one of the drugs that was just released by that and that's not one that oncologists particularly use. We've used it—

Dr. Rapp: So how will the price be determined for those?

Dr. McAneny: Well, that remains to be determined. But if they're going to do a competitive bidding, I agree. It should affect everybody.

Dr. Rapp: For better or worse.

Dr. McAneny: Hopefully for better, but I doubt it.

Dr. Rapp: You think it'll be better. OK.

Dr. McAneny: I would also like to offer an amendment that CMS involved PPAC in the development process.

Dr. Rapp: Why don't we do that separately? We get too complex. Did you read it back, I think you did, right? Any discussion? All in favor? Anybody opposed? That motion carries. Next.

Dr. Powers: Number three, and this may need to be reworded as well. The face to face required visit required for DME prescriptions under the proposed rule needs further clarification concerning the relationship of the prescriber to the patient and the timing of the face to face visit in relationship to the writing of the prescription. And I'll hand this down to her. It should be clarified that the prescribing physician is either the primary care provider, or the treating physician for that illness. If so, the timing of the prescription may be after a face to face visit for that illness.

Dr. Rapp: Are we opposed to that face to face requirement?

Dr. Urata: Generally. Did anybody second that?

Dr. Johnson: I'll second it.

Dr. Urata: I have one that's kind of broader than that.

Dr. Rapp: Without objection, we'll even though that's been seconded, we'll listen to his as an alternative.

Dr. Urata: In drawing up regulations, it's important for CMS to follow the concept that these regulations should allow flexibility in the way a physician practices. This must be allowed to adapt to the needs of the area and to the patient. One size does not fit all. And chief among that is the face to face evaluation before you fill out a DME prescription of somebody that you're quite familiar with.

Dr. Rapp: OK, is there a second—the only question I have about both these is they're a little complicated. If we say we're not—do we have, somehow we ought to just say we're against the blanket requirement of a face to face meeting for all whatever and the factors that should be considered should be these other things. I mean if we are.

Dr. Urata: My argument is that there is a concept of a regulation, when you're drawing up a regulation not to interfere with the way a physician practices. I think demanding that they do face to face, may interrupt or changes the way a person practices, particularly in a rural area with people who may have to do a home visit on before you can order a DME. And that's the idea of mine. But I think we can do Dr. Powers first.

Dr. Powers: I could reword it entirely.

Dr. Rapp: OK, you want to reword it. Why don't you reword it, we'll work on something else. Both of these are taken under advisement while we go to the next one. Dr. Grimm?

Dr. Grimm: This is regarding average sales price. Recommendation from PPAC is that CMS should publish a complete list of covered drug prices on the CMS website by early September, so that physicians can develop comments before the September 24 deadline for comments on the proposed rule. In addition, drug payment rates published in November rule, should be considered interim so that they will be subject to further refinement as more data is gathered on the payment changes.

Dr. Rapp: Is there a second to that?

Dr. McAneny: Second.

Dr. Rapp: Can we read that back?

Ms. Trevas: PPAC recommends CMS publish the complete list of covered drugs prices on the CMS website by early September, 2004, so that physicians can develop comments before the September 24th, 2004 deadline for comments on the proposed rule. In addition, drug payment rates published in the November rule should be considered interim, so that they will be subject to further refinement as more data is gathered on the payment changes.

Dr. Rapp: That was seconded. Is there discussion on that? All in favor? All opposed? That is carried. Dr. Powers are you back on stage? Dr. Castellanos?

Dr. Castellanos: PPAC recommends that CMS explore all resources available to include both government and private industry to collect most recent up to date accurate data when making geographic practice cost indices relative value determinations.

Dr. Rapp: Is there a second to that? And that relates to what specifically?

Dr. Castellanos: I tried to point out this morning that some of the data they're collecting, as with St. Paul Insurance, they've been out of business for three years and they're using that data. I tried to point out the problem with the rent, using the—

Dr. Rapp: They talked about the medical economic index. Was it related to that?

Dr. Castellanos: I think it was more related to the Relative Value determinations on the geographic—

??: It's related to the MEIs—

Dr. Castellanos: It was the MEI. The important thing here is that they collect the accurate data and they try to collect it as up to date as possible, using both government and private industry.

Dr. Rapp: Could you read that back please? And do you mind if we add MEI in?

Dr. Castellanos: Yes.

Ms. Trevas: RVU, GPCI and MEI? OK. PPAC recommends CMS explore all resources available both government and private industry based, to collect the most recent, up to date, and accurate data for making determinations about the RVU, GPCI, and MEI.

Dr. Rapp: All right, any discussion on that? All in favor? All opposed. That carries. Dr. McAneny?

Dr. McAneny: I'd like to move the AMA language, CMS should also establish a system for monitoring—

Dr. Rapp: What page is that on?

Dr. McAneny: Back on ASP. Page 2. I copied and pasted so I don't know. CMS should also establish a system for monitoring access to drugs affected by the new ASP methodology. CMS should continually evaluate whether physicians are able to afford the purchase and administration of drugs that are needed for appropriate treatment of their patients, whether physicians have to lay off medical and/or administrative staff in response to lower drug and administrative payments, physicians have to close satellite offices, or discontinue, or limit the types of treatment they are able to offer, patients have to travel further to get medical treatment if their physicians' offices can no longer afford to provide it; if patients have higher out of pocket cost, at hospital based facilities, and alternative medical facilities, such as hospital out-patient departments have the proper medical infrastructure in place, including drug

inventory, adequate medical staff, and adequate medical equipment and facilities to provide quality medical treatment, especially in rural area, and that these alternative medical facilities are able to absorb the additional patients.

Dr. Rapp: Do you have that?

Ms. Trevas: Do I have to read it?

Dr. Rapp: No, I don't think so. I think it's already written down. Is there a second to that? Is there discussion? If not, all in favor? All opposed? That motion carries. Dr. Powers?

Dr. Powers: Though support of CMS's intent to reduce fraud and abuse in the area of DME, PPAC recommends that the face to face visit required in the proposed rule for prescription of DME be limited to only the prescription of POVs.

??: Second.

Dr. Rapp: Is there discussion on that? All in favor? All opposed? And then you had the other things there—did you want to put something in there if they decide to do that, these are the factors that should be considered or whatever?

Dr. Urata: Sure but this is sort of a request to keep in mind limiting the way a physician practices. It's more of a general concept that should be kept in mind when drawing up regulations. And not really specific to anything, but it seems to come up frequently and fortunately we have some input to this. In drawing up regulations, CMS follow the concept that these regulations should allow flexibility in the way a physician practices. This must be allowed in order to adapt to the needs of the area, or to the patient. One must remember one size does not fit all.

Dr. Rapp: By the time our reporter reads it back, it'll sound like Shakespeare.

Dr. Urata: It's supposed to be a general concept.

Dr. Rapp: Dr. Simon is Shakespearian. He's going to—

Dr. Simon: I was just going to say, Mr. Thompson isn't here, but one of the requests he made was that in an effort for an agency to balance the concerns of fraud and abuse against providing policy that is

physician friendly. He was also seeking input from the Council for its providing advice in that regard. So would the Council like to make any comments in terms of how the agency should address the balance between dealing with the fraud and abuse issues in regards to creating policy that will be user friendly for the physicians that provide those services?

Dr. Urata: Yeah, I think that's a very good question, but there's no good answers and I think it ends up being trial and error and you can make a regulation that plugs all the possible loopholes that one can think of on a particular day and somebody's going to come up with a way to do fraud on that rule. And on the other hand, if you keep that rule in it might limit the fraud, but then it might also limit access to patients and cause havoc in a person's practice. It's a very difficult thing to do, so maybe a general statement like this is not a good thing, but on the other hand, I feel compelled to make it because I'm on the front lines everyday.

Dr. Rapp: Right, well, the other thing is if, at sometimes one tries to envision all sorts of problems when they see one, but the power wheelchair, the reason that came to light is because of the claims data. And when any claims data comes in to CMS and all the sudden, huge amounts of money are going for something previously wasn't going there, or in this case, it was Houston, Texas, wasn't it? Or that huge amounts of power wheelchairs are all of the sudden being prescribed there. That prompts CMS to look at it and prompts them to do something about it. This is like preventive medicine based upon a certain type of abuse that then burdens the physicians and the patients of the country for things where there's no suggestion there's any fraud. So you almost, perhaps, to borrow a legal term, need a little probable cause here before you start putting a lot of penalties in. Because they really are penalties from our perspective.

Dr. Hamilton: Wouldn't the establishment of an ongoing doctor-patient relationship as something that would preclude the necessity for another face to face visit before writing these prescriptions take care of that problem?

Dr. Rapp: Personally, I would think so, but again, I guess my point is we don't assume that every time something is prescribed it's a fraudulent activity. The presumption should be the doctors who are prescribing these things are, they are entrusted with people's lives, they ought to be entrusted to make some prescriptions for a nebulizer or this or that or the other thing and should decide whether they need a face to face meeting to so properly certify, because doctors get handed these things all the time. And sometimes we fill them out, and sometimes we say, hey, we're not going to fill them out. People call you up for prescriptions for medicines. That'd be the next thing. Should we have a face to face meeting when the prescription drug benefit comes along before we can prescribe medicine? Somebody'll think that's a good idea. But that's not the way things should work. Doctors in general should be trusted to be ethical people and only when you have evidence that there's a problem, should you put in Draconian rules. That's my own personal opinion. So this to me seems very over-broad for another problem in trying to solve one that doesn't exist. That's just how I look at it. Dr. Powers?

Dr. Powers: I agree with that. I think that CMS is saying that when they brought to us the problem with the POVs that we were right there with you as far as agreeing that that was a difficult problem and that we were willing to make the restrictions tighter in order for those to be prescribed, but to do it for everything. And I agree that DMEs probably in most of these [?] Medicare, from what I see, I think that it is, and I think that it's partly, the advertising is partly patients feeling that they're entitled to those objects to have in their home. I fought with that every day. But if you have a problem, I think we can be helpful in working out the problem. But I don't know that we can preempt, because I think they'll go from, because if we shut down POVs they'll just go somewhere else.

Dr. Rapp: The other thing, the suggestion that was made is to come up, where there's evidence of a potential problem, come up with criteria for the prescription. It doesn't necessarily have to be a face to face, but if you got to have a power wheelchair, these are the criteria. At least the doctors can just sort of follow the book a little bit. Dr. Castellanos? Then Dr. Urata?

Dr. Castellanos: You talked about the wheelchair issue. I can tell you in South Florida, there's a urologist who's sold his PIN number. There's urologist they're selling PIN numbers. There's a tremendous amount of fraud and abuse and about a half of a percent of physicians in that location in the state of Florida. I've had that discussion with our carrier medical director. So I think you really need to think about—we live in an idea world. Most of us always obey the rules, but there are some that don't and CMS needs to have some authority to be able to prevent and act upon fraud and abuse. I think we need a balance here, not just a rule, cutting everybody and say this or that. But I can say that it does exist and it does exist beside just POV.

Dr. Rapp: Dr. Urata?

Dr. Urata: The thing that I think is a great thing that CMS does is for some of the DME like oxygen, wheelchairs, hospital beds, I filled out a checklist, an actual prescription that I believe is produced by you, but I forgot the number of the form that has to be filled out that asks specific questions about a patient that you would have to know the patient really well in order to fill it out. And maybe an expansion of, I understand it's more paperwork, but it is a prescription which I can fill out and then send to the company that will provide for—

??: [off mike]

Dr. Urata: Yes, there you go. And I think that's an excellent way of doing it and I think you're trying to develop one for the POV and you have to know the patient in order to answer those questions. Sometimes you have to do a specific test, like the blood gas, for the oxygen, and if that was available for the different other things that you provide through DME then that might be helpful too, and help prevent some of the fraud, but—

Dr. Rapp: Dr. McAneny?

Dr. McAneny: I'm a little concerned by the fact that we're taking the role of setting policy or advising CMS to set policy based on a particular episode. Yes, it was a big episode, and it spent a lot of money, but it seems to me that policy should not address all DME because of one particular area. And if

we set specific criteria and have specific forms, then the next thing we know, we're going to have to have a specific form for ordering this X-ray or ordering that mammogram or ordering this drug. It seems to me that that is better the purview of the local CACs. That is they want to set up specific criteria and specific codes for which a payment can be made, then they do that in the LCDs and that I would recommend that rather than doing policy based on one outlier that we had that carrier medical directors look at that outlier and if they find that it's fraudulent, then they have the OIG to come down, or the DOJ or somebody. I know there's folks out there who would love to come down on those folks and send them all to jail. And I think they ought to go but I don't think that we should set policy that affects that. I think that we should leave that to the carrier medical directors and that if areas see this as an ongoing problem, they should write LCDs that set up specific criteria of what Medicare is going to pay for and what requirements and not have us do this from PPAC and not make it a national carrier decision, which is what I see coming from this whole process. So I would let that one drop.

Dr. Rapp: Dr. Johnson?

Dr. Johnson: I echo those comments, and one of the things that come out of this is the system there that you have in place, that identifies the aberrancies worked. Here it singled it out, this was fraud, and here's what was going on. You dealt with that issue and you don't need to rewrite all this policy for the other things because you have your system to identify aberrancies. Then there's appropriate methods of dealing with it and what we look at this example is, it was a great success in identifying and then dealing with the issue.

Dr. Urata: Should I withdraw my recommendation?

Dr. Rapp: That's up to you.

Dr. Urata: Well, there's no second, so I don't have to withdraw. Right?

Dr. Johnson: It just dies on the floor.

Dr. Rapp: How about this—does this reflect how we say, PPAC recommends that in seeking to deal with the potential for fraud, in DMERC, that CMS limit special requirements for prescription of such

items to situations where there is reason to believe there is a significant incidence of fraud. In other words, wait 'til they find some before you put special restrictions.

Mr. Kuhn: Now the way I could read that is we always shut the barn door after the horse has escaped.

Dr. Rapp: No special restrictions. In other words, like these are Draconian. I mean just somehow, we're trying to communicate, I think this seems over broad application.

Dr. Hamilton: Well, what's really at issue is the requirement for a face to face visit before you can write the prescription. Is that not correct?

Dr. Rapp: Yeah, we've already recommended that not be required. So maybe it was sufficient.

Dr. Hamilton: To me it would be OK to require that for a multi-thousand dollar deal like a powered wheelchair, which I've never written anyway. But on the other hand, I do write a lot of prescriptions for diabetic management supplies and to have to see a patient before you write each prescription is unnecessary and should be…but the establishment of fact that there is an ongoing relationship with that patient seems quite appropriate to me.

Dr. Rapp: On the other hand, I do see constant advertisements for those diabetic supplies.

Dr. Hamilton: But the doctor has to write the prescription and you don't have to write it if you've never seen the patient. And you shouldn't.

Dr. Rapp: I know, but I'm just saying when I see all those ads, I get a little nervous and I imagine CMS gets a little nervous.

Dr. Simon: I think that it's important just to solicit input from the Council, recognizing that with this one particular issue, as it was called, one episode, there was a billion dollars worth of fraud committed and that's a tremendous amount of money. And the agency could benefit from the input of the medical community to help the agency determine how to appropriately protect the dollars, while yet not putting undue burden on physicians.

Dr. Rapp: Well, maybe we're not going to be able to solve that problem today. Are you withdrawing your prior thing?

Dr. Urata: Yes, but I have another comment. It occurs to me that this is kind of a confounding problem, is that patients could possibly order diabetic supplies over the internet. I understand that Viagra is available over the internet.

Dr. Rapp: It's only available over the internet.

Dr. Urata: Yeah, and without a doctor's prescription. I thought that that was required.

Dr. Rapp: With the volume of emails I get offering me, it's unbelievable.

Dr. Urata: Yeah, but I thought a written prescription was required for something like that.

Dr. Rapp: Maybe that's how one doctor does it.

Dr. Urata: If we don't require face to face, then these folks will be getting prescriptions over the internet.

Dr. Rapp: Dr. Gaughan?

Dr. Gaughan: In response to Dr. Simon, you identified power wheelchairs as a billion dollar fraud. If at the next meeting you would bring back to PPAC what are the DMEs that are causing all this fraud and abuse, maybe then we could make some recommendations. I don't think we can sit there and cherry pick today, but if there were some major, not diabetic supplies, but you all had some major fraud issue, I think that we would be happy to comment on that. I for one do not know what the major fraud issues are other than the powered wheelchairs that I see on TV.

Dr. Rapp: Dr. McAneny?

Dr. McAneny: Ready to move on, I have some others I'd like to make.

Dr. Rapp: We're ready to move on.

Dr. McAneny: Like Laura, I have a list. One is that PPAC recommends that CMS give serious consideration to the coding and relative value changes for drug administration codes as suggested by the RUC and CPT committee and that these remain exempt from budget neutrality as specified in the MMA.

Dr. Rapp: Do you have that? Is there a second? We have a second.

Ms. Trevas: PPAC recommends that CMS give serious consideration to the coding and relative value changes for drug administration codes as suggested by the RUC and CPT and that these remain exempt from budget neutrality as specified in MMA.

Dr. Rapp: Explain that to me just so I'll explain what it's about.

Dr. McAneny: One of the issues that you hear Dr. Bailes address was the fact that administration codes have been very very very low for a long time because drug codes were too high. And so what's happened is this is a request that is going through, this is a process that's in place and is allowed in MMA for drug administration codes to be provided to cover more accurately the practice expense involved by all specialties in terms of administering incident to drugs. So what's happening now is the CPT committee and the RUC are going to look at this and recommend codes. This puts new dollars into the system because it's exempt from budget neutrality as stated in the MMA.

Dr. Rapp: And what are we recommending CMS do about that?

Dr. McAneny: That they give serious consideration to the coding and RV changes that the RUC brings forth.

Dr. Rapp: That they haven't brought forth yet.

Dr. McAneny: That they will.

Mr. Kuhn: And this is something that when we put out the proposed rate, we said we were looking forward to getting the recommendations.

Dr. Rapp: Is there discussion? All in favor? All opposed? That motion carries. All right.

Dr. McAneny: I would like to move that PPAC recommends that because CMS developed the Welcome to Medicare exam as a comprehensive exam with a requirement for a treatment plan that it reimbursed as a comprehensive visit and that the documentation requirements be kept minimal.

Dr. Rapp: Is there a second to that? Is there discussion?

Dr. Simon: Point of clarification?

Dr. Rapp: Yes.

Dr. Simon: When you say comprehensive, 99204 and 99205 are both refer to comprehensive.

Dr. Rapp: I guess an alternative is to not specifically value that code and allow the physician to bill it based upon the level of service provided. And not conclude that it's worth a this or that or the other thing.

Dr. McAneny: I didn't specifically say the level, but the word comprehensive physical examination and medical history is in the 1429 whatever you call this thing.

Dr. Rapp: I know. Dr. Simon says that's not limited a level 5.

Dr. Simon: I'm saying, the word comprehensive is in more than one CPT code.

Dr. McAneny: Right, but I think that if you let the physician make that determination. If they come in and somebody says yes, I've had my mammogram, my colonoscopy, my flu shots are up to date and I'm fine, that's your Welcome to Medicare exam and you don't need a 215, but if they've never done anything and you have to spend an hour talking them into it, perhaps you do.

Dr. Rapp: So is your recommendation that we leave the procedural code to the physician?

Dr. McAneny: I would just say reimbursed as a comprehensive visit, and then that implies that the physician can pick the four or the five level.

Dr. Rapp: I think Dr. Powers wants to speak against that.

Dr. Powers: I'd like to somehow change the wording to say that to just that the to leave out comprehensive and leave out the 99203 and that the charge would be commensurate with the amount of doc—according to level of service provided.

Dr. McAneny: That is be reimbursed commensurate with the level of service?

Dr. Rapp: Dr. Urata doesn't do more than 01s except on occasion.

Dr. Urata: 01s. Is there a one?

??: Strike that from the record.

Dr. Rapp: Every time he puts it at a level two, he's concerned he's going to go overboard and puts it back to a level one.

Dr. Urata: Come on, come on.

Dr. Rapp: He so testified at a prior meeting.

Dr. Urata: Yeah, that was to the OIG. I told them my name was Michael Rapp.

Dr. Rapp: All right, let's see if we can get that one down. What has our Shakespearian translator come up with?

Ms. Trevas: Because CMS developed the Welcome to Medicare examination with a requirement for a treatment plan, PPAC requests that the visit be reimbursed commensurate with the level of service provided and that documentation required be kept to a minimum.

Dr. McAneny: They developed it as a comprehensive exam, so you want to delete that language?

Dr. Rapp: Yeah.

Dr. Powers: Because I don't think they intended it to be.

[chat]

Dr. Rapp: We're just trying to say that it shouldn't be specified as a level 3 visit but…it's the Urata concept. Start again, and cross off the preliminary "Whereas," and then start with the therefore. PPAC recommends that—

Ms. Trevas: PPAC recommends that the Welcome to Medicare examination be reimbursed commensurate with the level of service provided.

Dr. Rapp: Rather than specified as a level 3, or whatever that code was.

Dr. McAneny: And with the documentation requirements being kept to a minimum?

Dr. Rapp: Why don't we make that a different one? Maybe something to the effect that PPAC recommends that the specifics of the Welcome to Medicare examination be limited to those required in law. I mean there's a lot of definitions that are put in there. There's some that the Welcome to Medicare visit, apparently, the statute says you have to do this and that and the other thing, EKG, right? But in so

far as they don't, but then they paint more definitions, what that means. This means this and that and the other thing. I'm just talking, I'm not making any recommendation. Why don't you just say that the specifics of the examination, except in so far as they're required by statute should be left to the discretion of the physician.

Dr. McAneny: OK, except as required by statute. And that may address, the whole issue of the care plan, too.

Dr. Rapp: All of the specifics that are there.

Dr. McAneny: One of my concerns with the Welcome to Medicare exam was when I read in there that not only did you have to document that you did all these various things as required by law to be eligible to bill for, but it also had this care plan. And I had the vision of what I watch our nursing colleagues and the nephrologists writing out these basically paper heavy meaning short care plans that no one ever looks at again except to submit for the documentation for this. And I was hoping that there might be some way that we could avoid falling into that particular trap.

Dr. Rapp: Well, do you want to make that a recommendation? Or state it?

Dr. McAneny: Well, that's what I was trying to do with the documentation requirements.

Dr. Rapp: But we don't have anything pending to vote on.

Dr. McAneny: OK, so the Welcome to Medicare exam, we've revised it enough times.

Dr. Rapp: No, we passed that one didn't we? It's the accept in so far as required by statute, the specifics of the Welcome to Medicare examination should be left to the discretion of the examining physician. Or other provider.

Dr. McAneny: So that's a whole second thing.

Dr. Rapp: That's a different one.

Dr. McAneny: So as you said it's fine. I'll second that.

Dr. Rapp: I just want to see if she got that.

Ms. Trevas: It doesn't say anything about documentation.

Dr. Rapp: It's about it, but it's a different thing.

Ms. Trevas: PPAC recommends that the specifics of the Welcome to Medicare exam, accept as required by statute, be left to the discretion of the examining provider.

Dr. Rapp: Well, physician or other provider. We like, this is the Practicing Physicians Advisory Council, so we always have to get the plug in for physicians when we can. Because they allow physician's assistant and nurse practitioners and certain others to do those exams, I believe. OK, any other. I think we've pretty much covered the gamut here.

Dr. Gaughan: I've got some.

Dr. Rapp: Except for those that Dr. Gaughan has.

Dr. Gaughan: I moved up here because I was a little lonely down at the other end of the table. Have we addressed the 5% incentive payment to physicians in scarcity areas? Because that's big in a rural state like Kansas. And I gave this to, I already gave this to her. PPAC recommends that CMS publish a list of counties with the 5% incentive payment to physicians in scarcity areas immediately.

Dr. McAneny: Second. I have a question. There were two different kinds of addendums that they could get, the primary care specialty counties and the specialists care scarcity counties. And they are different amounts, you want all of those?

Dr. Gaughan: No, my reading is 5% incentive payment to physicians furnishing services in physician primary care and specialist care scarcity areas, so it was for both.

Dr. Simon: You're speaking of MMA—

Dr. Gaughan: The MMA, Section 413 A.

Dr. Simon: They're actually the same amount.

Dr. Gaughan: 5%.

Dr. Simon: Yes, it's divided into two. Primary care, meaning family medicine, general medicine, internal medicine, pediatrics, and then there's the specialist. And for those, it's actually the, it's aggregate of 15% because it's the 10% that comes through the HPSA, plus the 5% that occurs as a result of MMA

and for those people that actually live within the zip codes that will be designed by CMS and HRSA, that 15% bonus payment for the PC, not the technical component, just the PC, will automatically be added to their reimbursement for the services that they provide. If the zip code is in the area where part of the zip code is in an underserved area, and part is not, then the physicians will have to, for those that have that practice in that area that is underserved in that zip code, they'll have to use a modifier and put that on the claim in order to be eligible to receive the reimbursement.

Dr. Gaughan: So how should this be reworded?

Dr. Simon: Well, I'm giving you the information so that you can sort it how you want to.

Dr. Gaughan: That's complicated. I'll need help on that one.

Dr. McAneny: CMS should immediately publish the list of the counties.

Dr. Gaughan: Yeah, it's basically so that physicians know like if you're deciding where you're going to practice, and you look at some area and say well, I'm never going to be able to survive there and then if you saw Medicare was giving that incentive, I might say, well, maybe I will move there. That's where my family was.

Dr. Simon: I think what was published in the proposed rule was that the list of counties would be published in the final rule.

Dr. Gaughan: Which is?

Dr. Simon: November one.

Dr. Gaughan: So it will be published. So we don't have to have it. It will be published immediately. You're saying it's already going to be done.

Dr. Simon: I'm saying that in the proposed rule, it was indicated that the list of zip codes would be listed in the final rule on November one.

??: And she's asking for it to be put out sooner.

Dr. Gaughan: The reason I want to put it out sooner is because I'm from a rural state that people need to know. If you're saying it's an impossibility because you don't know—

Dr. Simon: I'm saying that it would probably be appropriate for you to make those comments and then that can be—

Dr. Gaughan: So I gave it to her in writing, I don't know if she can read my writing.

Ms. Trevas: Yeah, and I rewritten it a little bit. PPAC recommends CMS publish the list of counties in which the 5% incentive payment is available to physicians in scarcity areas.

Dr. Rapp: Did you say when?

Dr. Gaughan: Immediately.

Ms. Trevas: OK, immediately published. All right. PPAC recommends CMS immediately publish the list of counties in which the 5% incentive payment is available to physicians in scarcity areas.

Dr. Rapp: In order to encourage physicians to go to the—

Dr. Gaughan: Well, you don't need to say that because I think—I mean that's why I'm proposing it.

Dr. Hamilton: Specialties in short supply.

Dr. Gaughan: Well, the scarcity area includes, I thought primary care and specialist care scarcity areas, so if you say scarcity areas, we can just leave it.

Dr. Hamilton: I thought the request was to designate what the scarcities were, not necessarily just where they are, but what they are.

Dr. McAneny: Right, you need to know which specialties.

Dr. Gaughan: That's correct. I see what you're saying. So you'd know if you were a primary care where to go.

Dr. Rapp: And to insert—Dr. Hamilton, put the and what you wanted to say, and—

Dr. Hamilton: And the nature of the shortage.

Dr. Rapp: But you said something else about the specialties?

Dr. Hamilton: It's not only a matter of where the shortages are—

Dr. Rapp: Let's have the language to put in to this thing.

Dr. McAneny: If you just say, publish a list of the primary care scarcity counties and the specialist care scarcity counties, that would solve your question, I think, wouldn't it?

Dr. Rapp: I just want some language to be inserted in this.

Dr. Hamilton: I think you need to specify what the specialties are that are in short supply, are they surgeons, are they rheumatologists—

Dr. Rapp: Specify what the specialties are that are in short supply and what else? The counties affected and where? Read it back please, and pause when you get to the money part.

Ms. Trevas: PPAC recommends CMS immediately publish the list of counties in which the 5% incentive payment is available to physicians in scarcity areas and scarcity—

Dr. Rapp: No, just start again and stop, go slower, and I'll hit you or go like this.

Ms. Trevas: PPAC recommends CMS immediately publish the listed counties in which the 5% incentive payment is available—

Dr. Rapp: comma, and the list of specialties—

Dr. Hamilton: and specify those specialties in shortage

Dr. Rapp: and specify those specialties in short supply.

Dr. Gaughan: And that will include primary care.

Dr. Hamilton: Including primary care.

Dr. Rapp: OK, does that take care of it?

Dr. Hamilton: But I would make an addendum to that that instead of counties, it probably should say geographic areas, because there are lots of counties in Texas that don't have any people at all, and they sure don't have any pediatric orthopedists.

Dr. Gaughan: Is that rule though, 413A

Dr. Simon: The way it's described in MMA, it's going to be by zip codes.

Dr. Rapp: So specify those zip codes. Substitute zip code for county.

Dr. Hamilton: I think geographic area is better terminology.

Dr. Rapp: Yeah, but this is what they're going to be doing.

Dr. Gaughan: You know, if you say a zip code, I mean for me I still have to know where the heck that is. So I mean counties including zip codes. They should publish counties including the zip code because then you'll know where to go.

Dr. Hamilton: I don't think that kind of a break down is going to be very meaningful.

Dr. Gaughan: It says here the statute requires CMS to publish a list of PSA counties, and you're saying that it's a list of zip codes, is what the rule says?

Dr. Simon: That's what is in the proposal.

[Chatter]

Dr. Rapp: Let's just read it back now and make sure we got it.

Ms. Trevas: PPAC recommends CMS immediately publish the list of areas by zip code in which the 5% incentive payment is available and specify those specialties in short supply, including primary care.

Dr. Rapp: That take care of it? OK, that's been seconded. Is there discussion? All in favor? Anybody opposed? That motion carries. Dr. Gaughan?

Dr. Gaughan: OK, this is a little stronger on the ASP rate. PPAC and I've written this down, recommends CMS proceed with caution in implementing the ASP rates. CMS should make broad use of any discretionary authority they might have to make exceptions to revisions of or delays in the ASP rates. If CMS does not believe it has the authority to delay these changes until it has complete and reliable data, then it should ask Congress for such authority. So this is a little stronger, Barb what do you think? Are you going to second it?

Dr. McAneny: I'll second it, but say it again.

Dr. Gaughan: PPAC recommends CMS proceed with caution in implementing the ASP rates. CMS should make broad use of any discretionary authority they might have to make exceptions to, revisions of, or delays in the ASP rates. If CMS does not believe it has the authority to delay these

changes until it has complete and reliable data, then it should ask Congress for such authority. It's a little stronger. Ken loves that one.

Dr. Rapp: You ready?

Ms. Trevas: PPAC recommends CMS proceed with caution in implementing the ASP rates. CMS should make broad use of any discretionary authority it might have to make exceptions to revisions of or delays in the ASP rates. If CMS does not believe it has the authority to delay these changes until it has complete and reliable data, it should ask Congress for such authority.

Dr. Rapp: OK, is there discussion on that motion? If not, all in favor? Is there anybody opposed to that? That motion carries. Seeing no more hands—

Dr. McAneny: Well, actually because we did sort of half of one and one of the simple ones, is that PPAC recommends that CMS involve PPAC in the development of the competitive bidding process. We were going to attach that onto hers and then you said do it as two separate ones. So that's the second half.

Dr. Rapp: Is there a second to that? Did we get that? Read that back again, and tell me about that again.

Dr. McAneny: PPAC recommends that CMS involve PPAC in the development of the competitive bidding process.

Dr. Rapp: In what way?

Dr. McAneny: Just keeping us posted as how they develop it, because first of all they have no idea yet. They're just submitting plans and struggling for ways is what I'm hearing.

Mr. Kuhn: We have a contractor, but I think that's a reasonable ask for the next meeting, we can give you an update on it.

Dr. Rapp: OK. Do you have that Dana?

Ms. Trevas: PPAC recommends CMS involve PPAC in the development of the competitive bidding process.

Dr. Rapp: Discussion? All in favor? Anybody opposed. That motion carries. Seeing no more hands, that will bring the meeting to a close except for the opportunity for me to thank Mr. Kuhn for being here for the entire meeting. He has got a very big job and he's got many many meetings to go to, and so for him to spend this amount of time here is a real demonstration of his commitment to the work of PPAC, and I think him and I know all the members of the Council are very appreciative of this and [applause] I would like to give you an opportunity to make your final comments.

Mr. Kuhn: No, I just want to thank you all for all the comments today and for all the help on all these issues as I said at the outset, we want to improve this process, so meanwhile, if you think of anything more we can do, we will, and if not, we'll see you in November.

Dr. Rapp: Anything else from anybody? If not, thank you.

Dr. McAneny: What we could do to improve this process would be that after we finish a given topic, that might be the better time to make the recommendations.

Dr. Rapp: We'll talk about it.