PPAC Meeting Transcription – May 2004

CENTERS FOR MEDICARE AND MEDICAID SERVICES
PRACTICING PHYSICIANS ADVISORY COUNCIL

Hubert H. Humphrey Building
Room 705
Washington, DC

Monday, May 17, 2004
8:30 a.m.

Council Members

DR. MICHAEL T. RAPP, JD, *CHAIRMAN*
DR. JOSÉ AZOCAR
DR. JAMES BERGERON
DR. RONALD CASTELLANOS
DR. REBECCA GAUGHAN
DR. PETER GRIMM
DR. CARLOS HAMILTON
DR. DENNIS IGLAR
DR. JOE W. JOHNSON
DR. CHRISTOPHER LEGGETT
DR. BARBARA L. MCANENY
DR. ANGELYN MOULTRIE-LIZANA
DR. GERALDINE O'SHEA
DR. LAURA POWERS
DR. ANTHONY SENAGORE
DR. ROBERT URATA

CMS Staff Present

DAVID C. CLARK, RPH, Director
Office of Professional Relations,
Center for Medicare Management

THOMAS GUSTAFSON, Ph.D., Acting Director
Center for Medicare Management

HERB KUHN, Director
Center for Medicare Management

JOHN LANIGAN, Designated Federal Official
Health Insurance Specialist
Center for Medicare Management

MARK B. MCCLELLAN, M.D., Ph.D., Administrator
Center for Medicare & Medicaid Services

KEN SIMON, M.D.
Executive Director, PPAC
Center for Medicare Management

Public Witnesses

JOHN FEORE
Emergency Department Practice Management Association

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DANA TREVAS, Rapporteur

A G E N D A

Morning

Afternoon

Dr. Rapp: Good morning. My name's Michael Rapp. I'm chairman of the Practicing Physicians Advisory Council. I'd like to call the meeting to order, as I think most of you know we have a number of changes of personnel, so you'll have one of the things that we'll be doing is swearing in some new members. Apologize for the short delay in the opening of the meeting. We had some technical difficulties in getting the meeting room together. I would like to thank all the staff for the work in getting things together, because I know it's a lot of work. We get here on Monday morning, but they've been here all weekend trying to get things together, so meetings like this don't seem like they require much preparation, but they certainly do. So I thank, first of all, John Lanigan. He is our new support staff member. He has a long history with PPAC, going back many years, including when it originated, I believe, so he is taking over from Cheryl Slay, who has, since our last meeting, left the agency. So thank you, John for your work. David Clark and Ken Simon for their advance efforts. We'll introduce our new members. We have Anthony Senagore. He is from Cleveland. We have Peter Grimm. He's from Seattle. And we also have Geraldine O'Shea. She is from California. We have a surgeon, an internist, and a radiation oncologist, and so thank you for joining the Council. I'm sure you'll be very productive and helpful members. I don't have anything else preliminarily. I'll turn the meeting at this point over to Tom Gustafson, who's the Deputy Director for the Center for Medicare Management.

Mr. Gustafson: Thank you very much, Dr. At our last meeting, I was here in my capacity as the acting director of the Center for Medicare Management. Tom Grissom had departed in December and I was carrying the torch forward during that period. I'm very pleased to tell you all that I'm no longer in that situation. So I have reverted to my prior role as the Deputy Director of the Center. And I'm here this morning, at least in part, to participate in the deliberations and hear your advice and all that, but to introduce my new boss, who is sitting over here. You'll notice the handsome smiling face, and this is Herb Kuhn. I think he's been around and shaking hands with a number of members at the committee already. But just by brief word of introduction, we reached into the midland of the country to acquire Herb. He comes from Kansas originally, has a degree in accounting from Emporia State University. And started his career in Washington back in the early '80s working for a Congressman from Kansas. He went from there to the American Hospital Association, where he served for 13 years and ended up as a vice president for federal relations and then moved to Premiere, which is a major hospital chain, where he was the vice president in charge of their Washington office for another four years because we had the good luck to grab him

in March. So he's still just getting here, but already firmly in command of the center. And I'd like you to welcome Herb and see if he has any remarks.

Mr. Kuhn: Good morning. Gus, thank you for those very kind remarks. I did get a chance to meet several members of the committee before the meeting starting, and I hope to get a chance to say hello to the rest of you when we get a break here, shortly, but welcome all of you. And thank you for this time that you're taking away from your busy schedules to come and participate in this committee and this effort. As Gus said, my background is a lot in terms of trade association work with hospitals, at least for the last 17 years. And one of the things that I came away from those kind of deliberations and discussions with those kind of groups is the value of boards, board level committees, other advisory committees, policy committees, and the real value proposition they bring to the deliberation of any organization. And I think particularly here, at CMS, I think this group in particular is absolutely essential to us in the work that we have. When I arrived here, and started doing my orientation, I heard a lot of good things about PPAC and the work of the group, the quality of the people that sat on the panel, but the real counsel and advice that these folks brought because it really you bring, like I said, a real value proposition to the solid policy discussions that we have and we certainly have many of them. And committees like this are absolutely essential to make that happen. And as you look at what's happened to the agency over the last three or four years in terms of opening up the agency, I think this is just part of that process. Under Tom Scully, there was an enormous effort to try to open it up through the open door forums to the town hall meetings, and I think that has done nothing but add real value to the discussions here. One of the things that I discovered when I first arrived and a new initiative that the agency's undertaking that I think is really going to enhance our ability, is the creation of a new preceptorship program out of the Center for Medicare Management. For years, when I was in the hospital world, I kept thinking over and over again, why can't we get these policy folks out of Baltimore—why can't we get them out in the field where they can sit down at a hospital and sit down at an outpatient department and see how they code. Sit down with physicians in their office and understand the real difficulty they have with E&M coding. And look at this real, the nuance here and understand it as closely as possible. Get it away from sitting around with the folks in the C Suite, but really get in with the folks that are actually doing the work so they can understand it and that new preceptorship program has been launched and it's moving forward. And I think that, too, is just going to make us stronger and better. So I think when you bring things like PPAC and the value that you folks have, the open door forums that

town hall meetings, and now, ultimately, the preceptorship program, I think it's just going to make us better. And we need to get better in that regard. And so I'm excited about that.

Another nice addition, and obviously, he'll be joining us soon, is Dr. Mark McClellan, our new administrator. Dr. McClellan I think has been on board now for five weeks and I think he is the second physician to head CMS, formerly HCFA, and the first in a decade and a half. And you can already see that differentiation to have a clinical leader at the head of this organization and some of the different things that he's bringing in the discussions, not only externally, with outside groups, but internally, and I think that is really nice to have. And a nice change as well. As I've talked to some of you even before this meeting, but as I've thought about this meeting, I've looked at the agenda. And I've thought about my past experience with boards and committees etc., and how agendas are put together and how we move forward, part of it obviously is reporting to you; things that are ongoing, things that we're doing, queries that you made in the past and reports we can bring you. But also a big part of this is trying to get things to you early in the process. Not only early for your opportunity to study to bring us things that you can talk to your colleagues or different folks about, but also early in the process in terms of our policy making apparatus. And I think if you look at the agenda today, you find some of that. Some of the discussions about graduate medical education, some of the discussion today about care for illegal aliens are things that are on our plate now that we're struggling with some of the policy discussions now, and your input today is going to be most valuable to us. At the same time, there are things that are reports here, like the pay code system, like things in HIPAA, that are kind of updates where we are, and actions that have occurred, so we can go forward. So I think a mix of those kind of agendas are helpful. Need your help in terms of thinking about agendas of topics, etc., and I know you from what I've heard, you're not shy about bringing those things forward, but I think a good mix like that is helpful. I think it makes for a more robust and I think it adds to the richness of the discussion here. And that's certainly what we're after. Because, at the end of the day, it's to write good policy, good policy that works not only for you, and I consider you all our business partners, because we really want this customer intimacy with you all, but also ultimately for the beneficiaries that these programs serve. One final thing, and I know Dr. Rapp already kind of mentioned about it was John Lanigan. John, as he said, has a good long history with PPAC and its earliest inception. John is coming back to do a lot of the administrative work that's going to help us make the board work. And so many of you will be in touch with John on a number of occasions, so I just wanted to make sure to reinforce that. So

with that, I don't have any more observations. So thanks, Dr. Rapp, for the time and I look forward to a good day. Thank you all.

Dr. Rapp: Thank you, Mr. Kuhn, and I want to emphasize how much we appreciate your being here. I know you've got a lot of areas of responsibility, but the fact that you will devote the time to listen to our deliberations, rather than just see a report is I think very helpful and a real vote of confidence in the PPAC. We have another individual who has joined us. I believe Dr. Azocar. He's one of our new members. He's from Springfield, Massachusetts. And he's an internist, I believe. So welcome. So the next item is to really have the swearing in of the members in two minutes and five seconds. I don't know if Dr. McClellan is going to be here—or should we just go on with the first item? OK. So the next item on the agenda will be Dr. Ken Simon. He's the Executive Director for PPAC and he will give us an update on our February recommendations and prior recommendations that we made. Ken?

Dr. Simon: Good morning. The first item, item D-1, the Council requested CMS to provide at the next PPAC meeting a timeline for the implementation of the various regulatory release divisions in the Medicare Prescription Drug Improvement and Modernization Act. And of course we adopted that recommendation, and the Council has received two time lines; one that indicated the activities, and where we are with the Medicare Modernization Act as well as the accomplishments in timelines. And those should be contained within the packet. So it will list where we are with each of the provisions within MMA.

Mr. Kuhn: Ken, did everybody find those? I see people still flipping through. You might kind of direct them where they are in their packets.

Dr. Rapp: I think it's under Tab E, isn't it?

Dr. Simon: The first states Medicare Modernization Act and the second is the Medicare Modernization Act Accomplishments and Projections. And it provides an update for where we are with each section of the Act. It's also available on the CMS website as well. For D-2, the Council recommended CMS use its discretionary authority to remove drugs from the SGR calculation. During the recent confirmation hearings, Dr. McClellan, the CMS administrator, indicated that he would review the system used to update Medicare payments for physicians' services, including examination of areas of administrative authority. If there is administrative authority, he indicated that CMS would give serious consideration to removing drugs from the SGR. Agenda item D-3, the Council requests CMS report on the effect of its current policy of including physician-administered drugs in the calculation of the

SGR. In essence, how the SGR would be affected if these drugs were omitted from the calculation. We adopted the recommendation. Medicare spending for physician-administered drugs has been growing rapidly since 1998. However, drugs currently account for less than 9% of spending included in the SGR. Physician Fee Schedule services account for 84% of the target. While spending for Physician Fee Schedule services has grown more slowly than drugs, it has also grown at higher rates and is contributing to the rate reductions that occur under the SGR system. If drugs were to continue their rapid growth, it is possible that removing them from the SGR would make an increase to Physician Fee Schedule rate more likely at some point in the future. Item D-4. The Council requests CMS provide assurance that CMS does not intend to include in the SGR the cost of prescription drugs included in the new MMA prescription drug benefit. The recommendation was adopted. The statutory definition of physicians' services for the SGR includes items or services that are commonly furnished by a physician or in a physician's office. Because prescription drugs (other than drugs not usually self-administered by the patient that are already covered) are not commonly furnished by a physician or in a physician's office, they do not meet the statutory criteria for inclusion in the SGR. Item D-5, the Council recommends that for the purposes of calculating SGR targets, CMS consider and account for the direct and indirect cost of all of the provisions of MMA that would increase the amount of services provided by physicians. The recommendation was adopted. The statute specifically requires that the Secretary include an allowance in the SGR for spending growth attributed to new laws and regulations. As part of this statutory obligation, we will estimate the effect of each MMA provision on spending for Medicare services, and adjust the SGR accordingly. The statute further requires us to revise our spending estimates included in the SGR once a year, and to assure that it's complete, and reflect that actual spending may be different from earlier estimates. D-6. The Council recommends CMS study the effect of new regulations on infusion and chemotherapy services, specifically whether the new regulations affect access to care, cost, and patient satisfaction. The recommendation was adopted. On January 7th of 2004, in the Final Rule, CMS provided an analysis showing that decreases in payments for drugs would be offset by increases in payment for drug administration in 2004. We have spoken with organizations representing oncologists and office-based cancer clinics that have agreed with our assessments. There will be further changes in payment for drugs and drug administration in 2005. We believe that these changes were designed to pay for drugs at or above the price they are purchased by physicians, and retain most of the large increase in payment for drug administration that were required by the statute. Nevertheless, we recognize there is a concern about access to office-based cancer care services under the new law. As part of our ongoing activities to

monitor patient access, we will pay special attention to the cancer issue. Our ongoing activities include development of a monitoring system to track utilization of infusion and chemotherapy services across the various clinical settings. The monitoring system will help CMS determine whether utilization rates and the site of care have changed in response to the payment changes. We would further note that the statute requires the Office of the Inspector General to provide a report on the adequacy of payment under the new drug payment methodology by October 1 of 2005. The Medicare Payment Advisory Commission is also required to study payment issues made under the statute, and report to Congress by January 1 of 2006. Other efforts to study access are being made by the cancer community itself. CMS recently discussed an effort being undertaken by the American Society of Clinical Oncology with a representative of that organization as well. Further, CMS participated in a meeting of the Global Access Project. The Global Access Project has broad-based representation from a number or organizations involved in providing cancer care and is also undertaking steps to monitor access to care. Item D-7. The Council recommends that CMS evaluate the impact of shifting professional liability adjustment of the RVUs to more fairly recognize the physician burden of increased risk and psychological stress in the physician work component of the service. This requires that no negative adjustment be made to the physician work component and that the entire adjustment should be made to the practice expense component of the Physician Fee Schedule. This recommendation was not adopted. CMS adjusted the work practice expense and malpractice RVUs to match the rebased MEI weights. These adjustments increased the malpractice RVUs by nearly 21% and reduced the work RVUs by 0.15% and the practice expense RVUs by 1.3%. The PPAC recommendation would require us to make no adjustment to the physician work RVUs and further reduce the practice expense RVUs. The adjustments we made are intended to pay physicians for work, practice expense, and malpractice in the same proportion that they incur these expenses, as represented by the MEI. If we adopted PPAC's recommendation, the proportion of Medicare payments for work, practice expense, and malpractice would not reflect the latest information we have on physician expenses for these items. Further, we believe such an adjustment would reduce payment for services with higher practice expense RVUs without an apparent policy justification. Item D-8. The Council recommends CMS include in the MEI all factors that more accurately account for the cost of practicing medicine, including, but not limited to, one, staffing changes, two, compliance with government imposed regulatory requirements related to such matters as fraud and abuse, billing errors, quality monitoring and improvement, patient safety, and interpretive services for patients with limited English proficiency, and three, any other costs currently incurred by physician practices that were not included in the MEI when it was

developed in 1973. This recommendation was not adopted. We have always worked to insure that the MEI accurately reflects the price changes of inputs used by physicians in providing services. As such, we have defined the MEI as a fixed weight price index, which means it can answer the question of how much a fixed basket of goods will cost in the future period relative to a base period. The cost weights in the MEI reflect the distribution of costs of the inputs purchased by physicians in the base year, currently calendar year 2000. Therefore, the MEI cost weights do reflect all costs facing physicians in calendar year 2000, including those based on staffing changes, compliance with government imposed regulatory requirements, and other costs that were not included in the original MEI developed in 1973. The cost proxies used in the MEI, however, appropriately hold constant changes in cost that are caused by non-cost price factors. For instance, the MEI captures changes in wages for fixed occupational distribution, but not changes in wages caused by changes in that occupational distribution. Volume or intensity effects such as this are accounted for in other parts of the physician update formula and appropriately, not by the MEI. We will continue to put forth our best effort to ensure that the MEI accurately reflects the price changes associated with the goods and services purchased by physicians. Item D-9. The Council recommends CMS ensure that the physician community is provided early notification of the average sales price for all impacted drugs as well as an opportunity on the appropriateness of the average sales price. This recommendation was adopted. CMS expects to publish a final rule with comment in early April, providing specifications to drug manufacturers on how to report average sales price. There would be a 60-day public comment period on this Final Rule with publication of a Final Rule later in the year. Further, we will use manufacturer reported average sales price data to simulate the impact of the new payment methodology in the Physician Fee Schedule proposed rule. We expect to publish the Physician Fee Schedule proposed rule in late June. It will also have a 60-day public comment period. We will address comments on the Physician Fee Schedule proposed rule in the Final Rule published on or about November 1 of this year. Agenda Item E-1. The Council recommends that CMS program integrity staff be actively engaged in the process of established CPT guidelines with the CPT evaluation and management work group. The recommendation was adopted. Program Integrity continues to engage in dialog with the AMA regarding E&M guidelines to explore ways to simplify and reduce the burden of documentation. Agenda Item E-2, the Council requests that any pilot project for assessing new evaluation and management guidelines be designed to hold voluntary participants harmless during the course of the project so that variations in coding are not used as a basis for further investigation. At this point, the AMA task force has not devised any project which has been presented to

Program Integrity. Therefore, there is no further response at this time. For Agenda Item F-1, the Council recommends that CMS ensure early involvement of the physician community, including the Council, the Relative Value Update Committee, and the CPT panel in the process of developing codes and related relative values for the Medicare preventive services mandated by MMA, the Medicare Modernization Act. In cases in which a CPT code already exists, and is used by Medicaid or private payers by payment, the Council recommends CMS use the existing code or at least use it as a crosswalk for the new Medicare covered services. This recommendation was adopted. CMS appreciates the input of the medical community and to the extent possible, always attempts to work with the CPT Editorial Panel, the Relative Value Update Committee, and the physician community in the establishment of new codes. However, as has been previously state in rulemaking, there may be programmatic needs related to changes in legislation, regulation, coverage, and/or payment policy that may make it necessary to create G codes. Agenda Item G-1. The Council recommends CMS continue working with the Renal Physicians Association and other pertinent groups to continue to monitor access to rural dialysis clinics and home dialysis programs in light of the new dialysis codes. This recommendation was adopted. CMS has reached out to relevant stakeholders to ensure ESRD beneficiaries have access to care in light of the recent changes to the monthly capitation payment. In March of 2004, CMS representatives gave a presentation on the Department's quality agenda for ESRD as well as the MCP changes at the RPA's annual meeting and extended their Q&A session for an additional hour in order to explain CMS policy and listen to community input. In March of 2004, CMS representatives attended a meeting sponsored by the American Society for Nephrology and the National Kidney Foundation on improving quality in ESRD where the MCP was discussed. In April of 2004, CMS representatives gave a presentation on the Department's quality agenda for ESRD as well as the MCP changes at the American Nephrology Nursing Association's annual meeting, and extended the Q&A session for an additional hour in order to explain CMS policy and listen to community input. Additionally, CMS has had regular discussions with these organizations as well as the ESRD networks, and the American Association of Kidney Patients, and asked them to let us know immediately if there are any access issues for ESRD beneficiaries because of this change. Agenda Item H-1. The Council recommends that in the event there is a delay in processing reenrollment of physicians due to problems in the PECOS system, CMS institute a contingency plan to ensure payment of claims to providers whose enrollment has been delayed. This recommendation was adopted. The answer to this which you, which Bob Loyal will address later today, is that we are not going to require reenrollment until a web-enabled physician friendly enrollment process is

available on line. And that, and Mr. Loyal will go into further detail later this afternoon in that regard. Agenda Item K-1. The Council recommends CMS authorize the patient's primary care physician to order a power-operated vehicle for the patient. The chronic care component of the Center for Medicare Management and Program Integrity have been forwarded the recommendations by the Council for their consideration and review. And with that, Chairman, that concludes my report.

Dr. Rapp: Thank you, Dr. Simon. Is a copy of that available to the Council?

Dr. Simon: It typically is not available. We can make copies and make them available to the Council.

Dr. Rapp: OK, Dr. Gaughan?

Dr. Gaughan: I would suggest the grid format, which we had done before, and although it was an excellent report, I got a little lost and I'm quite aware of some of these things. I'm sorry, Dr. Simon, I kind of phased out here and lost some things, and I think these are very important issues and that Medicare responded positively for several issues and we'd like to get those out. So I would suggest having either the grid, what it was, yes, no, adopted, and then the bullets. I realize this will be in the minutes, but I think I would have to take the minutes and then spend my time doing all that so I would appreciate if, as other stated, we either went back to the old grid, or if that's not going to work for you, then just some kind of, this was the resolution, it was adopted, it wasn't adopted, otherwise, we don't know what to come back and fight for again.

Dr. Simon: We'll be happy to work with you to figure out a format.

Dr. Gaughan: All right. And I also want to thank you for the adopted. Thank you.

Dr. Rapp: Dr. Urata?

Dr. Urata: I have a similar request. As I recall, we had something in the last meeting about what was accepted and what wasn't accepted.

Dr. Rapp: Well, we've had that at every meeting. It's just the issue is just getting it down on paper, or just getting a copy of the report. So will that be available to us? OK. So I think with regard to the grid concept, I believe it should be self explanatory once you get the copy. Dr. McAneny?

Dr. McAneny: Two questions. One is can you give me a little more in detail about the MEI proxies that I, I got lost. I don't type that fast in terms of trying to figure out the rationale of not including the other new updates, the requirements for HIPAA, the increased cost of staff, etc., so I didn't understand that. And the second part of the question is we had also discussed carrier evaluations. We had heard testimony at previous meetings that said that a

lot of the information that people receive from their carriers was either inaccurate or inadequate to answer the question and so one of our recommendations was that CMS start developing a way to evaluate that more and I was curious whether that was acted upon.

Dr. Simon: I didn't have any comments in regard to your last response. However, there is a provision within the MMA that addresses that particular issue in that in the event that a carrier provides information that is inaccurate to a clinician, that the clinician would not be held accountable in carrying out that information. And as a second piece to that, in MMA there's also provision for creation of ombudsman group that will look at the concerns that are provided, not only by physicians but also by beneficiaries, with the intent of trying to be more responsive to the needs of both groups of individuals.

Mr. G**ustafson**: If I could jump here for just a moment. Our provider communication group is actively working the provider communication staff at our carriers and also at our fiscal intermediaries, to try to develop a way of assuring accuracy of responses that folks get when they call and ask questions, so that when billing staffs of physicians, for instance, call the carriers. Almost all the questions that are answered by those staffs are comparatively routine. It's a lot of stuff about claim status and eligibility. Some of them are very complex and go into a great detail about specific billing issues and so forth. Some of those take a fair amount of time to resolve if they're to be resolved correctly. We note that there is concern that the answers that are given out on those lines are not always as accurate as they should be, and we're developing a corrective action plan to move toward improved accuracy in that area.

Dr. Rapp: Thank you. Are there any questions? Dr. Gaughan?

Dr. Gaughan: Yes, I had a question. I believe in the last year or so we had a report on the percent of errors, I don't know if it was like 85% of the questions were answered wrong. But there was a report done by government agency, and I'm blanking on what it was. OIG. Do you know if there's any plan for government studies to do another report, or is CMS considering, since you're going to be making all of these improvements, doing another follow up survey to access how—I don't want to spend all this money, but I do think it's important that such a major problem was identified that we do look at it again and get the numbers and make sure that there is improvement or maybe I missed it at the last meeting. I apologize.

Mr. Gustafson: We are, in fact, the answer to all of the above is yes. The agency that studied it is in fact doing an additional survey in this area. They've been working back and forth with us on that and I guess results are

expected out later this year. We have been doing our own monitoring of calls to see what information we could gather there. We have been working in a strategic way with the representatives of the call centers to try to wrestle with this problem. So we regard the assessment of the accuracy of those questions not at all as a waste of money, but indeed as an absolutely critical part of our cycle of improving how this sort of thing goes on.

Dr. Gaughan: Along those same lines, do you have a time frame when you'd be willing to report back to PPAC? When you have the data in, you could report back to us? Is there a time you could give us? A year?

Mr. Gustafson: Well, I think less than that, but let me consult with staff and see what would make sense. I understand the eagerness for an early report. Let's see when we can get something that fruitful.

Dr. Rapp: Dr. McAneny?

Dr. McAneny: I still don't understand the MEI part, but we also at that last meeting discussed the chronic care improvement project, and there was a recommendation to have AAFP and other interested groups look at the pilot projects that are there for the chronic care improvement programs to see if that was going to be something that small groups of physicians or small practices would be able to participate in, with the idea that that would be reported back at this meeting. And it's not on this agenda, so I was wondering, is that going to happen? Are they going to be on the next agenda?

Dr. Simon: That topic will be discussed on the next agenda. However, I spoke to Dr. Urata this morning. I think that for the specialty organization, the American Academy of Family Physicians, we probably will plan to meet with them offline so that they can meet with the Office of Research and Development where I think that venue is probably a more appropriate venue than through this council. And we can update the council on the activities, but going through that particular venue that I just mentioned probably is a more appropriate approach.

Mr. Gustafson: Actually, Ken, there are updates in this area. The agency has been organizing around this project and regard it as a major initiative. And the administrator as recently decided that the administration of this particular project will be in the hands not of the Office of Research, Development and Information, changed its name slightly when none of us were looking, but will in fact be within our center. So it will be part of the provider billing group, directed by Stuart Streimer, who I think some of you have had a chance to meet, and we have recently hired a director for that activity, Sandra Foot, who is a well-known health policy analyst, and obviously an executive in a preferred provider organization that originated out on the west coast. So we're building a team there, and now

have a well-defined center of activity on this, so that I think we'll be in a better position to do the sort of interaction that you were speaking of.

Dr. McAneny: Are there links that you can send us so that we can be better prepared for the next discussion? So that we know what the pilot projects are and can find them in there?

Mr. Gustafson: Well, we can certainly provide you information about the current state of the project. Exactly what the projects are is open for a competitive arrangement at the moment. We had a bidders' conference, for instance, Thursday or Friday at the building, that absolutely busted the cafeteria and the auditorium, just the number of people arriving in the building looking to find out more about this project. So we've had some open door forums on this subject, bidder conference and so forth. There was a request for proposals that was put out about a month ago. And there's a substantial degree of interest from across this board, from very small operations such as the physician practices that you may be concerned about, to major corporations who have been engaged in this kind of activity in the managed care sector.

Mr. Kuhn: What we can do here, is we do have a dedicated spot on our website for all the activities around this project. Likewise at that spot, we will be populating with FAQs and things like that. So follow-up to this meeting, we'll get you that link, so you can go to it and look at that information.

Dr. Rapp: Any other questions for Dr. Simon?

Dr. McAneny: You still didn't explain the MEI question.

Dr. Rapp: Do you have anything further on that?

Dr. Simon: I'll defer to Dr. Gustafson on that.

Dr. Rapp: Why don't you restate the question.

Dr. McAneny: We had last time felt that the MEI needed to include all of the factors that were not in existence in 1973 when it was set up, and particularly the government regulations and the staffing changes. And you said that you thought that the proxy indicators in that took that into account. But the proxy indicators in the MEI are looking at average salaries, etc., and non office rents in the area, which doesn't really take that into account because when we're recruiting, say, nurses, that's a nationwide market, etc., so the Council felt that some of those needed to be updated to reflect what goes on in 2003, 2004, etc., and so I didn't quite understand why the CMS felt that the proxies of 1973 were still applicable.

Mr. Gustafson: This is a matter which is under the aegis of the Office of the Actuary. We in our center are simply consumers of the information that they provide. They are consummate professionals in their field, and without knowing the details, exactly, what they're up to, I believe their view is that the proxy measures they use have been reflecting the underlying economic forces, even within the sector that you're speaking of. But I think to give you a more detailed answer on that, we would have to get some more input from them, and we will see what we can do to arrange that as quickly as possible.

Dr. Rapp: Any other questions for Dr. Simon? Dr. Bergeron?

Dr. Bergeron: Basically we whitewashed this Medicare carrier positions. I can remember specifically if we had a problem we'd call the Medicare carrier's office, get a field representative in. There was an educational informative rather than adversary. Presently, our carrier, the first time a practicing physician is aware of any infractions or lack of education or ill coding, is when we receive a certified later stating they want 20 of our charts out of the clear blue sky. And 95 to 97% of the time, we're vindicated. Wouldn't it be more cost effective, more friendly between the providers and the Medicare carriers, if we would institute again the field officers coming in at our request, not a certified letter, not a punitive, humiliating, intimidating letter through the mail, I would venture to say that by the time we get these 20, 30, 40 charts, you have all kind of staff members in the Medicare carriers' office, it would be much more costly. Then you have an adversarial relationship between the provider and the Medicaid carrier, rather than an educational. I got audited recently, and the only thing I got from my carrier, subsequently was, Thank you, Dr. Bergeron, for adhering to the educational recommendation, which was two sentences. By the time my staff gathered all the charts, by the time all the communications were done, certified letters, notarizing, I can assure you I was educated—self-educated rather than educated by my carrier. So I would highly recommend that if you want some friendly relationships between your carriers and your providers, educating your providers, it would be much less costly than getting certified letters, humiliation, intimidation, rather than education. I do not view a certified letter requesting that I get 20 charts in the mail, punitive damages, FBI, OGI, and whatever else you want to call. I really specifically would say, if you want to educate the providers, why don't we recommend the carriers institute their field officers that are available? Thank you.

Dr. Rapp: Is there anything else for Dr. Simon? If not, the next item on the agenda, I believe Dr. McClellan will be here momentarily, so we may have to interrupt this next one, but the next item on the agenda is

Dr. Rogers, who will get us a PRIT update. He's the Director of the Physicians Regulatory Issues Team and Medical Officer to the Administrator.

Dr. Rogers: Nice to meet new faces, although I'll miss the old faces that we lost on this committee. I think this is my 3,247th presentation to the PPAC and I have great affection for this committee, since it represents, I think, very well, the practicing physicians and concerns that they have with the Medicare program. For those of you who don't know, I am a practicing emergency physician. I've got a pretty full day today because I'm the Chairman of the Emergency Department at the hospital in Washington, D.C., that I work at in my spare time, and we've got an executive committee meeting tonight, and the executive committee meetings in greater Southeast go on all night long. They do feed us, and the food's pretty good. This [slide] didn't come through quite clearly, but everybody will meet Mark soon. I think this is an exciting time for us to have a health care economist in terms of the Medicare program. Some of the statistics I've got up here I find pretty terrifying the fact that our spending on health care is increasing as fast as it is, and I think at an unsustainable rate, and I'm very exciting to hear Mark's sort of innovative ideas about how we're going to start to get a handle on these exploding health care expenditures so that we can continue to provide this service, 10, 15, 20 years from now, maybe even 30 years from now when I qualify, since I'm only 35 right now. I always start out talking about the PRIT website. I'm sure we're getting 9,000 hits a month, so I'm sure you've all visited the website. We have all of the contact numbers on the website so that people can contact us for their issues, and our primary goal is to represent the concerns of the providers at the Medicare program, and to fix things that need to be fixed centrally that can't be fixed locally. And I'm going to go through our list of issues in some detail so that you'll get a sense of how we work these things through and what we're working on right now, and then I would welcome issues from your colleagues when you've returned to your home states. A bunch of it is from anesthesiologists. And the first one here is security of anesthesia carts. It seems that our guidelines about security of these carts, and these aren't carts that contain narcotics, they just contain anesthetic agents and emergent agents, that our guidelines are different than the guidelines that the Joint Commission has and also the states, and that kind of inconsistency only adds to the bureaucratic hassles of the physicians and the hospitals, so it's something that we're going to try and bring some consistency to. An old issue, actually the first issue, I'm embarrassed to say, when I took over the PRIT was this issue of history and physicals by podiatrists. This would be allowing the podiatrists to do a history and physical on a patient that they were operating on in a hospital, and this is going to be addressed in the hospital conditions of participation that should be released soon. And I think

the final solution is going to be favorable to the podiatrist. This sort of goes back to the Medicare's decision to sort of step back from the decision about who does what, and leave that to state regulators and leave that to hospitals for the most part. Database of CMD answers very exciting. There's a lot of talk about consistency. We're going to sit down with the carrier medical directors at the national meeting, which is this week, to talk about ways to further sort of integrate their work into a data base that they'll be able to access so that we can A, not duplicate work, and B, benefit from each other's scholarship. There's a lot of really impressive work that goes on at the CMD level, as I'm sure many of you are aware and it's just a shame that there's not a better vehicle for sharing that between CMDs. So I'm very excited about that. Reenrollment, Ken mentioned, I think that was a good logical, common sense decision, provider enrollment—we've been very pleased at the aggressive response that our central office staff has been making on this issue now that everyone's aware of what a serious issue it is. And we're going to make a full report on that. Bob Loyal's going to be here this afternoon, and we'll talk about that. But probably the most important thing going on right now, except for the oncologists, here at the Medicare program. Changing patient status after admission. This was an issue that patient comes in to the Emergency Department, decision's made to admit the patient to an inpatient bed, and then the utilization review person comes by an hour later, and says, doctor, that patient will never meet criteria, that patient should be admitted to observation. Then the provider is there with an order sheet, wondering whether he or she is going to go to jail if they cross out Admit and replace it with Admit to Observation. And for doctors, and providers, this is a big deal, because we worry a lot about doing something which is prohibited and so it's been important that we've been able to communicate with our central office staff how important this is to providers and we've got a draft of clear guidance on when it is no longer appropriate to change where you're admitting someone. And that should be out pretty soon. It's in Internal Clearance right now. We were also approached at a meeting, and I do a lot of time on the road, by a woman who works with a house call service. And she said we would like to get paid house call rates when we go to retirement facilities—not skilled nursing homes, but retirement facilities, and they would be paid the higher rate. So we're looking at that. We've gotten statistics about it. I'm a little concerned myself, having had a nursing home practice. It's really very cumbersome and very time consuming to make a house call. You got to drive to the house, you see only one patient, you have no staff to help you, and higher payment reflects that increased cost, but when you go to places like retirement homes where you might see six or seven patients, and although they don't have the kind of dedicated nursing staff that skilled nursing facilities have, they still have some staff. It may be an overpayment to pay at the house call rate for

those kinds of visits. But we're looking at the statistics and we're going to make a decision here. Mental health treatment limitation has been a really troubling issue. This limitation is required to be applied when the primary purpose of the visit is for psychotherapy. But it was also being applied to patients who had Alzheimer's Disease and other dementias, and particularly for patients who are poor, the reduction by 50% represented a real access barrier for these patients with physicians. These patients who had Alzheimer's and other dementias. So we actually have clarified that in the proposed Physician Rule, which should be out, as you heard from Ken, in June. Use of macros, we're just waiting for Ken Simon to sign off on a proposal on that. Ken, I got you on the spot now. [laughter] He's going to kill me after the meeting. Nobody here realized how important Ken Simon is. We don't do anything unless he signs off on it. How long can an ASC monitor a patient? We have guidance which seemed to say at midnight, even if you had a fully staffed ASC with a fully staffed recovery room, at midnight the Medicare beneficiaries' carriage would turn into a pumpkin, and they'd need to be transported to a hospital to finish their recovery if they weren't quite woken up. And we've clarified the guidance. It certainly should not be routine that Medicare beneficiaries are in the ASC recovering over night, but if it's an isolated case, that's now acceptable. We don't prohibit it. Post anesthesia reports, old issue, this was in the Secretary's Advisory Committee for Regulatory Reform and I'll mention that later, but this is going to be fixed in the Conditions for Participation that comes out, as will Verbal Orders, another old issue. Verbal orders actually is fixed. If you go to the website, there's a link to a letter which covers you until the Conditions of Participation come out. Vaccination codes. Those pesky primary care physicians—pediatricians and family physicians. We got them their special pediatric codes, and so that they could be paid more—and I'm being facetious, I think it's great that they're being paid more because it is more complicated to give vaccinations to kids than it is to adults, but because the multi-component vaccines require more work, they believe that the values need to be reconsidered. And so we're supporting them in that and that will be of course, up to the RUC. Anesthesia billing issue. This is an issue about how you would bill if the case starts with an anesthetist and finishes with an anesthesiologist. And we actually have gotten the nurse anesthetists and the anesthesiologists to talk to each other, and we've come up with a solution to that billing problem. Chemotherapy Code issues. This was the issue of is it appropriate that we say we'll only pay for the complex codes if the disease is cancer. I think as more and more of these drugs are coming out, which are very toxic, but used for other diseases, it's probably appropriate that we drop that sort of arbitrary line, and we were all set to do that, and then the MMA addressed in the statute, and MMA said we need to do it using existing mechanisms, so therefore, committee's been put together of the CPT

Editorial Committee which has had their first meeting to discuss exactly how to refine the descriptions of the codes so that we can pay appropriately for these services. The last issue is a brand new one. We were told in Wisconsin, that this one code, 96400, which is I think intra-muscular chemotherapy, was being bundled in part A of a SNF stay, so we're actually investigating that. That just came up there. And we put these issues up on the website as soon as we get them just so that people know that we're serious about addressing their concerns. Just to give you an idea, I took a picture in the ER. The paramedic said, Oh, he's just drunk. And it turned out he was in hepatic coma and if you can see those bruises on his forearm. And I showed this picture to a nonmedical person who works for me, he says, He's yellow. So not everybody's as affected as others. The boat's already sold, I made this slide last week. [laughter] It wouldn't be a Rogers talk if we didn't have at least one cartoon. One of the Secretary's issues is the issue of simplifying and communicating better with doctors. And I would commend to you to get on this Quarterly Provider Update list serve. This has been great for me. You get an email anytime there's an update, and this and the MedLearn Matters are just incredible tools, which I think go a long way to address that issue. It was just chance that I put this cartoon up before I talk about the Secretary's regulatory review committee. As you well now, there are a lot of issues. A lot of them have been fixed. And a lot of them are in the MMA, which is appropriate. And they're being fixed because we have to fix them, but Jack Emory had come up with 12 issues the last meeting that he felt sort of didn't fall into one or the other of those two categories. So what I did was stole his list, and I'm just going to go through those. First, recommendation 22 was about the EMTALA interpretive guidelines. And those actually have been written. They're very good. They were supposed to be released I think last Thursday. I forgot to check to see if they've been released, but they should be out. And we also sent trainers out to all of the regions to make sure that everybody was singing from the same sheet of music on EMTALA on the new guidelines. It's too bad Doug Wood's not here. Funding web services. You know, I, in going around, and in talking to physicians, all over the United States almost every week, I haven't had any doctors come up to me troubled about the limited English proficiency guidelines. I've read them. I think they're pretty reasonable. They recognize that not every practice has very many patients who have limited English proficiency, so the idea of pulling money from other places in the physician payments to pay for translation services bothers me a little bit, and unless doctors out in the states start complaining about it, I think we're probably not going to want to do anything about that. Recommendation 142, I just talked a little bit about the Quarterly Provider Update and the Med Learn Matters. There's just a lot going on now, and it's not difficult to sort of wade through, as so many websites are. This is sort of automatic stuff that can

come to you when there's a change and the Med Learn Matters articles are very readable. The little red light, yellow light, green light might start to drive you nuts, but the text is great. It's just exactly at the appropriate level for the providers. Consistent interpretation. I've got a couple things listed up here and then the carrier medical database I'm going to be talking about on Wednesday in Baltimore. But I think this is a very very valid recommendation and I think something we need to work on very hard. We don't tell the CMDs what to do, but they're all interested in consistency and they communicate all the time and it's pretty impressive, so I don't think this is going to be hard to improve on. Early involvement of the profession in policy development process—in addition to PPAC if you look at the way that the defibrillator policy was written, there was a lot of physician input into that. There have been multiple examples with implementing the MMA, with meetings, and open doors, and all sorts of different initiatives to try and bring the providers' concerns to the forefront. The last of Jack's recommendations had to do with CLIA, which I don't know too much about, so we asked our CLIA people. And it turns out that we published the final lab regs in January of 2003 and have interpretive guidelines, which are the ones that you and I can read on the web. And apparently, the CDC's also working with the National Lab Training Network to develop educational programs for physicians who are doing wave tests. And I also want to mention Arty Ballonoff. He's on the right there. That's Lambert VanDerwald, our market expert, in front of Greater Southeast Community Hospital. He's our regional medical officer in Kansas, and he really wanted to come to Washington, D.C., to spend a month with us, and I thought he just wanted to sightsee. But he has been incredibly effective and has helped us on a whole lot of different things. And then the other great benefit has been that he's spent quite a bit of time up in Baltimore, so he's met the policy specialists, and the different divisions up there, which is going to make him much more effective when he goes back to Kansas City, and I'm excited about this dialog that we're developing and improving with the regional medical officers and the carrier medical directors, so I'm hoping that other regional medical officers will also do a similar thing. I spent a week out in Oregon with Peter, with the regional medical officer there in Seattle, and that was also a great opportunity for us to get to know each other better and how to get a hold of each other easier. And that's it, so Mr. Chairman, thank you for the opportunity to make my report.

Dr. Rapp: Thank you, Dr. Rogers. Do we have any questions for him? Becky?

Dr. Gaughan: I had a comment and a question. Being from the Kansas City area and recommending Dr. Ballonoff, I just want to say that I applaud CMS for having the idea of a physician liaison with the community whose job is to work with physicians as someone you can call to educate who understand physicians. And I think

it's one of the best things they've ever done in our area and would highly recommend it to other carrier medical directors. My question for Dr. Rogers is to make sure he gets put on the spot—the limited English Proficiency not being a problem, not that I want my funding taken away, but I know in some of the testimony that we have heard before, the major universities for instance at KU, I don't know. There's like 40 dialects and I'd like to know what's going on—did you want to say something about major universities?

Dr. Senagore: Yeah, I understand it is in larger urban areas where there are greater nationalities represented there. In terms of availability of specific language skills, we have people from all parts of the institution; housekeeping, whatever, we have people working with second and third languages, so you can imagine a small mideastern country or something like that, that is not well represented in the U.S., it could be difficult.

Dr. Gaughan: I know the cost to the Ear, Nose and Throat Department at Kansas University was $40,000 last year for limited English proficiency. This is not for the deaf interpreters. I think that, to one small department, is a burden.

Dr. Rapp: Dr. Powers?

Dr. Powers: On the same issue, your comment, if I understood correctly, why would you want to take this out of the physicians' fund? Our intention with our recommendation was that this not come from the physicians' fund at all, because that's where it's coming from right now if we have to pay for it, then it comes from someplace else. Because it was an unfunded mandate.

Dr. Gaughan: Correct, thank you.

Dr. Rapp: Bill, do we have a copy of your slides?

Dr. Rogers: I can print a copy for you.

Dr. Rapp: If you could that would just help—

Dr. Gaughan: I have a nice copy that you used in I think Kansas two weeks ago that were very good. I just print those.

Dr. Rogers: The cartoons are better in Kansas.

Dr. Gaughan: The cartoons were better.

Dr. Rapp: One other thing on limited English proficiency as I recall the presentation we had, it said that if a physician solely takes Part B Medicare, it's not considered whatever's the requirement for the limited English proficiency rules to apply. However, Medicare is considered a program or something. In other words, the

assumption that you'd have to take it from a Part B pool to pay for it, I just wonder how that fits in with the idea that if you only take Part B, and you don't participate in Medicaid, that is, you do not have to comply with these rules, according to what we learned. But if you participate in Medicaid, you do. So Medicaid really doesn't come from Part B, and if we're talking about English proficiency requirements, that's probably more of an issue, since all refugees are automatically eligible for Medicaid. And it's probably really less of an issue for Part B Medicare since you get eligible for that by being part of the Social Security Program.

Dr. Rogers: Yeah, I was really hiding behind my doctor's office role when I said it hasn't been a huge issue. For hospitals and for emergency departments, and things like that, it can be a much bigger issue.

Dr. Rapp: Well, I would say that you know, on the Medicaid in the doctor's office, to me, that would be the biggest problem. If I have a lot of non English speaking people come into me with Medicaid for which I get very little anyway, and now I have to on top of it, fund to pay for language interpreter to come, I think the reason you haven't heard that much about it is many doctors probably ignore the rule. The suggestion was that you should affirmatively ask somebody—do they want to have an interpreter? Even though they have their family members here with them. I think probably in the real world, doctors kind of ignore the rule rather than comply with it and pay four times as much as they're going to get in the fee to deal with that. I think it's an issue as the rules are written. Dr. Castellanos, Dr. Johnson, and then Dr. Gaughan.

Dr. Castellanos: Bill, I think what we really skirting around the issue on limited English proficiency whether it's HIPAA or not, is all the things called unfunded mandates. All that money's coming out of physician pool. And I think if they're going to make us, or ask us to do things, they ought to put more money in the pool.

Dr. Rapp: Dr. Johnson?

Dr. Johnson: If I remember correctly, when the Office of Civil Rights was here and testified before the Council, they related that as far as the complaints that they had received, it was single digit, if I remember correctly. Two, three, maybe four. Could be wrong on the number. But you say you haven't had a physician complain about it and whenever I probed the question to them, and I remember I was astounded at the low number. So when you say it's not a big issue, at least the complaints that the Office of Civil Rights has had have been not on the radar.

Dr. Rapp: Dr. Gaughan?

Dr. Gaughan: Just to add to Dr. Johnson's comment, I think one of the problems is that major universities, just understand, the Office of Civil Rights are going to tell you that's the law, and nobody wants to come across

against Civil Rights. So it would be very hard for a university to call and say, we don't want to follow Civil Rights, we don't believe in civil rights. So I think that's one of the problems. It's under Civil Rights. What we're seeing in Kansas, we already had a problem with physicians taking Medicaid, as you can imagine, so what we're seeing in the Metropolitan areas is no one takes Medicaid except the university. And the rural areas, since there is a lot of Medicaid in you just have to stick with it, we're just losing physicians. And that's why you're seeing so many new enrollments in Kansas physicians. Because they're all leaving and we're trying to get new ones there. But it's kind of hard to get new ones there when the laws are so crazy. And you wouldn't think that Kansas would have a problem with multi-lingual people, but guess what? We do. And so if Kansas does, I am assured that the East Coast, the North and bigger city areas and rural areas must be having a lot more problems. If it's happening in Kansas, it's got to be worse across the country.

Dr. Rapp: OK, Dr. McAneny?

Dr. McAneny: I think we should conduct the next meeting in Navajo. [laughter] But you glossed over the E&M documentation guidelines, that project is being abandoned? So I'm sort of surprised at that.

Dr. Rogers: ... Part B news report of that, I think, last week.

Dr. McAneny: So, does that mean we're sticking with the bullet points and counting up how many review systems and that whole project that Doug and everybody was working on was just no more?

Dr. Rapp: Dr. Simon?

Dr. Simon: Actually, I think the AMA was the one who approached the agency about developing the guidelines, and so I'm not sure what their present plans will be. I think they're trying to huddle up at this point and figure out what they want to do and how they want to do whatever it is they plan to do. But to our knowledge, I think that it's come to their understanding from their constituency that the guideline project that they proposed probably would not be feasible, and I think a lot of physicians, as we heard, indicated that the current system is not perfect, but they understand it quite well, and had some concerns about what would be proposed and whether that would perhaps be more problematic than what currently exists.

Dr. Rapp: OK, anything else for Dr. Rogers? If not, thank you Bill. It would be helpful, I think, if we had the slides so we can further comment on the different issues if we. . . It is 10:00, would you like to take a ten minute biological break?

[BREAK 10:26 am]

Dr. Rapp: I'd like to call the meeting back to order and the next item on the agenda is Skilled Nursing Facility Consolidated Billing. Sheila Lambowitz, Deputy Director of the Division of Institutional Post Acute Care, Chronic Care Policy Group from Center for Medicare Management—is that correct?

Ms. Lambowitz: It is yes, thank you very much. And thank you for inviting me. I'm hear to talk to you about consolidated billing, everyone's favorite program, and what I'm going to do—

Dr. Rapp: We've got some that are almost on the same plane [laughter]

Ms. Lambowitz: Well, I'm sure you do, but this one seems to be giving every other program a run for its money. And what I'm here to do is talk about what we found and what we plan to do to get it out of the top ten. So most of you probably know that consolidated billing was a program that was initiated as part of the SNF PPS reimbursement system. So in 1998, when we introduced the PPS, we changed not only the way we reimburse SNFs, but we made significant changes in the way SNFs have to contract with suppliers to provide all of the services needed by people in a Part A stay. In effect, we eliminated the provision that Part B suppliers could bill Medicare directly. We used our claims data to determine how much money we had been paying for Part B services, and we incorporated it into the SNF rate, and we gave the nursing homes a global payment, and said that they needed to be responsible for furnishing all necessary services to their beneficiaries. Now, contrary to popular opinion, that was not to ruin the lives of every supplier and practitioner in the country. What we faced when SNF PPS went into effect, is a rapidly increasing ancillary service cost. It looked like prices were rising, utilization was rising, it was not clear how much control the nursing homes were exercising over services provided to their patients. And one of the reasons for putting the reimbursement money in the SNF pot was to try to encourage them to be more prudent purchasers, to look for better rates, not just to accept any price, and to make sure that services were needed before they were ordered and furnished. So I believe that the thought was good. What we found though is that there was a lot of confusion as you would expect for the introduction of any new program. And we had some start up problems. If you remember the millennium, where we had to do so much computer work to get ready for the year 2000, this occurred during the same period we would normally have been building our edits for consolidated billing, and then, of course we were in line with all of the other things that had been put on hold from '98 to 2000. The result was our edits did not go into effect until 2002. These edits are the most sophisticated ones that CMS had developed up to that point because we actually were cross checking between the Part A and the Part B databases. So they took a while to develop, and then they went into effect in 2002. Well that means there were 4 years that people were going ahead

and they were billing the way they thought they should bill, or they were certainly billing anything that they got paid for and all of the sudden we have edits in the system, and claims are being denied. We found that there was a lot of confusion concerning who was supposed to be doing billing, what was supposed to be billed directly, what was supposed to go to the SNF, and we've had a lot of dealings with different associations in clearing up particular problems, and you heard from Bill, we're checking to see if a particular code has been bundled correctly or incorrectly. That kind of thing's been going on for a couple of years. But what we realized is that most of the educational material that went out about consolidated billing went out in '99, 2000, 2001. Nobody's memory is that good. So we have a situation where people are a little lost. They're billing the way they always did, but they get denials. They're not sure who to bill. Sometimes the SNF isn't sure what its responsibilities are, and may not think they're supposed to pay either, and I know that on the practitioners' side, that's caused a lot of friction. So what we're doing is basically starting a national education or reeducation campaign. Within the next week or so, you're going to see our first piece, which is a revision to our manual, our SNF manual, that instructs SNFs on how they are supposed to be working with their contractors. And it also outlines the types of contractual agreements we expect both SNFs and suppliers to adopt so that they can be assured of accurate communication of Part A status and can be assured of payment. So we're going to start with that. We've asked our provider education group to start working on a series of Med Learn articles. And one thing you'll be seeing over the next month or so are articles focusing in on specific problems that may have occurred related to different specialties for practitioners, related to different supplier groups, such as lab and X-ray so that we can really fine tune the material going out. One of the things I'm going to be asking from you is any suggestions you have. Clearly, there have been problems on the practitioners' side as well, and what we'd like to do is get some feedback from you on the kind of questions you have and the kind of information you need and your SNFs need to improve the situation. And what I'll do is I'll ask John Lanigan to act as kind of a referral source. If you could go through this group. And John always knows where to find me. He'll get your comments back to me. And what we'll try to do is develop some Q&As and some educational material to minimize at the very least some of the problems you're having. One of the ways we're going to communicate this new information as we develop it is a website. We're in the process of developing a new dedicated website for consolidated billing, that will include information for all supplier groups and practitioners. And in addition, we have been collecting sample documentation so that we are going to put up some best practices protocols and some suggested documents to show how nursing homes and their contractors and practitioners can communicate with each

other and what we're hoping is that across the country, we'll be able to initiate some of these practices and improve the situation. I've already talked to the nursing home associations and to several other practitioner and supplier associations, and they've agreed to publicize these educational materials through their newsletters and their websites as well. So we're going to be blanketing the country as much as we can with information on the basic procedures—who should be doing what, how should the relationships work? What we can't do, of course, is mandate the terms of the contract, or an agreement, but we can certainly suggest types of agreements that may work better. And that's what we plan to do. You'll be seeing this over the next month or so. In addition, we have been developing a computer system that will allow Part B suppliers to actually go in and check eligibility for beneficiaries to determine whether they're in Part A or Part B stays. That's not as big an issue for your group, because generally, you probably know who is in a Part A stay, particularly if you're the one signing the certification. But it will be available and we'll have more information on that as well. So we are going to be working on education systems development, and we are going to be starting within the next few months, our analysis of the HCPCS codes to determine any coding changes for next January that may change the services that are considered separately billable under consolidated billing, rather than those that are bundled, and we expect to have a manual update, should go out probably around November, to make sure that everybody knows what codes are separately billable. And I deliberately cut the presentation fairly short, because I thought there might be some questions.

Dr. Rapp: Dr. Gaughan?

Dr. Gaughan: I apologize for my ignorance, but I had to ask Dave Clark here what SNF was—skilled nursing facility. So I'm just putting nursing home down, because "SNF" to me, is actually a sinusitis society. [laughter] I'm sitting here with my cold, and going sniff, sniff. She's making me drip. But to give better input, I understand what Part A and Part B and I understand now, that the nursing home—I'm going to call them nursing homes, not SNF, pays the supplier directly. My question is, who pays the nursing home? And also what supplies are we talking about and how does this impact on physicians—and of course a lot of you may know, but maybe you could give a brief summary for some of us who are not in the nursing home business.

Ms. Lambowitz: I'm sorry, this is my first presentation here, so I—

Dr. Gaughan: Well, you probably thought we were all smart!

Ms. Lambowitz: I know you're all smart. Knowing consolidated billing is not an intelligence test. Maybe a test of stamina, but not intelligence [laughter]. What happened under BBA, we initiated the SNF consolidated billing

program. And only a small number of services were considered separately billable at that point. Physician services are included in the separately billable section. But there are some problems because diagnostic tests, even if performed by a physician, are not considered separately billable. So you have a situation where the physician component is separately billable, but the technical component is not. In addition, you have the incident-to services, that are normally provided in a physician's office. The physician office visit is separately billable, but the incident-to services are not. And what—

Dr. Rapp: Such as?

Ms. Lambowitz: Such as lab, X-ray, therapy, any kind of maybe nutritional consult or other service provided by the physician's staff is not separately billable and needs to be billed back to the nursing home.

Dr. Rapp: And you said something about Part A versus Part B nursing homes?

Ms. Lambowitz: Part A, if someone is in a Part A stay, which means that we're covering their room and board, as well as all the ancillary services, and that's the post hospital benefit for a maximum of 100 days per spell of illness. Part B covers some ancillary services, but does not cover room and board. Under Part B, the only thing that is bundled back to the nursing home is therapy. Everything else is just like it used to be before PPS so that you are billing exactly the way you do for an ambulatory care patient.

Dr. Rapp: Therapy meaning physical therapy?

Ms. Lambowitz: Physical, speech, and occupational.

Dr. Rapp: Are you done with your basic overview?

Ms. Lambowitz: I'm sure that I'll have more questions—

Dr. Rapp: You are going to get some more, but I just wanted to make sure you were, OK, so we'll start with Dr. Castellanos, Dr. Bergeron, Dr. McAneny, and Dr. Powers.

Dr. Castellanos: We appreciate your being here and I really appreciate the openness that you have about the feedback that you want between physicians and, because there are a lot of issues. I'm a urologist, and urology there's a lot of issues. Some of the J codes for the 96400 codes specifically for chemotherapy incident-to drugs, that is not covered in a patient who's in a skilled nursing facility. And that makes it very awkward, because I'm seeing the patient, I'm directing the care, I'm responsible for the care, yet I don't have the ability to give that drug to make sure it's been given correctly, the right dosage, etc. And there have been mistakes. Another really big issue is X-rays. I'm a urologist. I deal with stone disease. And often, sometimes, these patients are treated with stone disease.

These patients come to my office by structure, and I'm unable to do an X-ray. I can do an X-ray but I have, excuse my expression, I have to eat the cost on that. Because it's not reimbursed as a technical cost, or I have to send the person to an X-ray unit by ambulance, and then bring it back to my office. The same with urodynamics ... 50% of the people in nursing homes, if you read surveys, are incontinent of urine. And they come to my office for that evaluation and yet I'm unable to do the technical component. So I welcome this opportunity to be able to exchange these ideas through the PPAC committee, because we're here to take care of patients.

Ms. Lambowitz: Absolutely.

Dr. Castellanos: That's the most important thing, and we want to do it the best technique we can, giving them the best service with the least interruption.

Ms. Lambowitz: OK, hopefully I'll remember all of the points you made, but if I don't, remind me. The codes you mentioned, the J codes? That is a special problem because in the original BBA Legislation, very few services were considered to be separately billable at all. Congress went back under BBRA and added some exclusions specifically for chemotherapy agents and for chemotherapy administration, but they added the services not a blanket chemotherapy—they added specific codes and codes that were not within the assigned ranges are still bundled back to the SNF. Now, I did get a letter from your group, and I left a message with Robin from your association last week. I'd be glad to talk to you at the next break about the codes your association suggested adding, but this is a legislative problem. It's not a CMS regulatory or administrative problem. In terms of the codes, we have very limited flexibility to add chemotherapy agents. If there is a new code within the range that BBRA stipulated, we can add them. If there's a coding change that a drug that was on the list now has a new code, we can change it. But we can't add new ranges or totally new codes. And that creates some real problems with chemotherapy because not only are all the codes separately billable for the agent, but other portions of the chemotherapy treatment, are also bundled back to the SNF. And that requires split billing and it requires billing everything back to the SNF. So it's not that it's not paid, but you need to go back to the nursing home for the money, and I think there's been a lot of confusion. Where the nursing home looks at it and says, well, chemotherapy's supposed to be separately billable. Why are you billing us? And that's one of the things we're going to need to really stress. That there are portions of services that cannot be billed directly to Medicare and the same thing applies when you have to do an X-ray, because if you are doing an X-ray and it's needed and it's something that you have to do in that visit, then presumable you should have an agreement with the nursing home so that you can do that X-ray and you can bill

them for the charge. One of the things that we've heard about is that there are problems where the nursing home does X-rays, but doesn't send the X-ray with the patient, so you get the person into your office, and you don't have the material you need to treat. Hopefully, we can do some work to make sure that the nursing homes send you the right information. And we will talk more about any ways you think it might help. But you shouldn't be eating the bill. We are expecting that those claims will be paid, it just may take a little work.

Dr. Rapp: What is the remedy if they're not?

Ms. Lambowitz: Well, one of the things we are urging all contractors and practitioners to have some kind of agreement with the nursing home, particularly if they treat a number of patients so that it stipulates how you're going to be paid and what can be billed, and kind of terms of payment.

Dr. Rapp: And that's necessary? You have to have—if they send the person to Dr. Castellanos's office, he does an X-ray, and they don't have a prior agreement, then he does not get paid?

Ms. Lambowitz: Not necessarily. But I would assume the patient comes to the office; you do your office treatment and if you provide any of the services that are separately billable, you bill those. And then you go back and bill the nursing home. The question comes in whether the nursing home knew you were also ordering some extra X-rays, or you needed some lab tests, and they may be giving you some trouble, saying well, I could have done that for you. And the problem is communication. So even without a formal agreement, they should be paying you for most things. But the difficulties you get into are when you're doing the incident-to services, and they don't understand why you did that in your office. That's part of the education we have to go through now. It's gotten amazingly confused in the last few years.

Dr. Rapp: Dr. Bergeron?

Dr. Bergeron: It may take a Fed Ex truck for what I'm going to ask you to deliver to me. [laughter] I'm a dermatologist, and needless to say, the demands of the elderly on dermatological care are insatiable. I've actually had patients say, Well, Dr. Bergeron this is a *skilled* nursing facility. My mama is in a *nursing* facility. Are these people not skilled? That actually has come up. Write orders, and this and that, and the nursing supervisor on the floor if there's one will call up and say, We're not allowed to administer these particular cures. So is there a little synopsis, not Encyclopedia Britannica, not a Fed Ex truck delivered to my house, do you have a little synopsis to educate me and the panel if you will, what's a skilled nursing facility—what are the parameters, what are the factors, what qualifies, what's a nursing home, what's semi-retirement, retirement center, etc., etc.? It gets a little confusing

as to what does that facility provide. We'll write ten pages of orders, and they'll come back and say we're not allowed. We don't have a registered nurse. We don't have this and that. So I have a great deal of difficulty differentiating what's a skilled nursing facility, non-skilled nursing home, retirement center, semi-retirement. Thank you.

Ms. Lambowitz: I definitely will try to get you some of that information. One of the things that might help short term. I assume that many of your patients are going into a nursing home after a hospital stay. And if it is a hospital stay, the hospital discharge planners will know how the nursing home is certified.

Dr. Bergeron: That's another point—extended care facility?

Ms. Lambowitz: Right.

Dr. Bergeron: What's extended care? 1 day, 2 days, 100 days? 1000 years? Very confusing.

Ms. Lambowitz: You have two types of nursing homes that are certified by Medicare and Medicaid. You have a variety of other facilities that are state licensed and the requirements for those facilities in terms of their medical staffing, their RN supervision, you know the mixture of their staff is very very different. And it can range from having an RN only one shift a day to maybe just having assisted, to aid staff basically in an assisted living facility. I'll see what I can get for you, but a lot of it may be state-specific licensure.

Dr. Rapp: Dr. McAneny?

Dr. McAneny: I have a letter from an orthopedist who sent this via a resolution to the AMA about SNF billing and the tech fee problem that Dr. Castellanos is talking about. What often happens if somebody has a fracture in a SNF is that they end up being sent sometimes with an inappropriate X-ray that doesn't particularly help. They go to the orthopedist's office. They get another X-ray. The tech fees are eaten by that orthopedist because the SNF says, well, we took an X-ray, or the person gets sent to the emergency room where they get the X-ray and then go to the office and it's not the views that they want to see if they've got the alignment proper, the second X-ray is written up. So there's a lot of folks who are just refusing to see patients from SNFs because of this cost. The cost of doing the X-ray, the cost of not collecting those tech fees on the services that you provide cost you more than you're going to get in your E&M doctor visit by a long shot. We see this particularly in radiation oncology. It would be very helpful to be able to park a patient from out of town who needs some rehab in an SNF. That's the ideal use of an institution like that. They don't really need acute care hospital, but they can't function without some medical supervision. But the radiation tech fees far outstrip the amount of money that the SNF is going to get on their per

diem, and I think that that and other radiation and lab tech fees should be put on that list of things that can be billed separately. The other problem is it's not just communication with the SNF. You can communicate with the SNF all you want, and we do, and they still don't pay us. You can send them the bill and you get the endless bureaucratic runaround—you should submit this to Medicare when you get your Medicare denial, bring it back to us and we'll reconsider it, and then you go on and on and on, and by that time, it's gone 6 months, you can't bill your secondary. So if you see a SNF patient in the office, and you do anything more than an E&M code, you lose money in the process and so you just can't do this. So I would be very curious to hear what new things are going to be put on the list of excluded services that can be billed separately to Medicare, and I would hope that things like radiation and radiology tech fees will appear on that list. Can you give any information?

Ms. Lambowitz: Well, I wish I could say great idea, we'll do it. I think it probably is a valid point. Whether or not we can do it, I'm not sure because the legislation is so limited in terms of the flexibility it's given CMS that we may not be able to do this. It may be a question of requiring a legislative remedy, but I would really like to get a list of some of the services you think need to be considered separately and some of the examples you've just given of what happens when you have the patients and you need additional work. We can look at it. I can't make any promises. What I can say is that we are not assuming that the nursing homes are administering this program correctly. And that if they are not paying for things they're supposed to pay for then we need to make that clear, and the educational material needs to go out and give that information to nursing homes as well.

Dr. Rapp: What about this general idea of before you bill the skilled nursing facility, you have to bill Medicare first and get a denial and then send it off to them? Is that the way Medicare expects to be done?

Ms. Lambowitz: That is not a requirement that we have initiated. We actually spend a great deal of time providing a list of the services that are separately billable on the assumption that everything else is bundled back to the SNF and it doesn't seem that we really need the Medicare denial.

Dr. Rapp: So maybe that needs to be made clear to the SNFs that that's not appropriate. And then on that same thing, you've got 1998 to 2002 where apparently Medicare was paying a lot of non-separately billable services and they're kind of out there but those are ones that really the SNF was supposed to be paying for. Is there some big recoupment program?

Ms. Lambowitz: No. [laughter] Short answer.

Dr. Rapp: Just trying to give you a little immunization here.

Ms. Lambowitz: And it's a good question, because the way the law is written, the SNF is the appropriate payee, so that everyone else who has gotten paid has gotten a duplicate payment. And there has been fear that we're going to go back and say, oh, well, you know, this program was in effect since 1998. I'd like to get all our money back. We have looked at this very carefully, and we have made a conscious decision that in the absence of any enforcement mechanism or edits to alert people to the problem, that it would not be equitable to go back at this late date and recover money—

Dr. Rapp: From the SNF.

Ms. Lambowitz: Well, no actually, the problem is the law says it would be recovered from the Part B supplier or practitioner who got the money. But we're not doing that. Don't spread rumors.

Dr. Rapp: I'm glad. I think it's much better to hear what you're not doing. [laughter] So we're glad to hear that. Dr. Powers, Dr. Senagore then Dr. Leggett, and then Dr. Iglar.

Dr. Powers: I have two questions. I'm a neurologist and I see a lot of patients who are in nursing homes, and even if I personally know a patient who has been discharged from the hospital and within 100 days, I'm not sure that they're skilled, because they can be skilled or not skilled depending on the nursing home that determines that. So when they come to my office, it's hard for me to identify them because many times I get an order sheet, and I get an MAR, which is a list of medications. I may or may not get a face sheet, and even on the face sheet it's kind of hard to find if they're skilled or not skilled at that time. So the identification part is difficult for us to know. We do neuro-diagnostic testing, and obviously that falls into technical component issue. And I can see us with this knowledge going out and having to make contracts with maybe 15 or 20 nursing homes. Are they aware that they are obliged to make those contracts with us, and do I understand correctly that you'll have sample contracts for the nursing homes?

Ms. Lambowitz: Right, we do have something that, barring complications, is supposed to be released next Friday, that talks about the need to have contractual agreements between the SNF and suppliers. And that could include practitioners. We are not recommending 40-page contracts. We don't need to give the entire legal industry a 20% raise this year, but we do need to make sure that you have a way of knowing which patients are in Part A and when you have to bill back to the SNF and some agreement on how they're going to pay you. So we are going to put some sample agreements on the website so that you can use those and depending on how closely you work with nursing homes, there may be some nursing homes that refer a number of patients to you, and it may be simpler to get

an agreement than others. But we will have some samples for you, and we realize, particularly for specialty physicians, that you are not the primary care doctor signing the certification. You need to have this information.

Dr. Rapp: Dr. Senagore?

Dr. Senagore: Just a follow-up. I enjoyed your presentation. I think this is a huge educational issue for everybody. SNFs don't understand it, I think most practicing physicians don't understand that you need to go out and have these types of contractual relationships, and what do you do for the onesy twosies? You may have several that you do lots of business with, and then what do you do for the isolated exposure? Do you proactively have a contract ready to send before the patient comes. I think it can be a very confusing issue, as you just saw from around the table, most folks are not familiar with the process. I think you have a definite job.

Ms. Lambowitz: Oh, I agree. And I've talked to some nursing home people and they at least appeared willing to send a notice with the patient on the way to the office visit stating that this is a Part A patient, remember what the rules are. We'd like some input from you. What information would your office staff need as their setting up that appointment as they're getting the chart ready for the appointment so that you'll have that information? And there's something I wanted to ask. I know that a lot of HMOs require the physician office to call before certain services are provided. And if you have any ideas you could share with me on how some of those protocols might be adapted so that if you think an X-ray is needed, or you need to do a test that you hadn't expected, that you can alert the nursing home so that it doesn't come as a surprise to them when they get a bill, and that may be some of the information we can put on websites.

Dr. Senagore: I think that would be good to add to the contractual language, because a lot of HMOs will have a box to check—consult only, consult & treat, and give you some degree of latitude for what you think is medically necessary. I think to give guidance to physicians of what they can build into that contractual language would be helpful.

Dr. Rapp: Although perhaps most doctors would not like to graft onto anything HMO practices. [laughter]

Ms. Lambowitz: I really hesitated to mention that, but I couldn't think of any other example where you might have some kind of communications—

Dr. Rapp: But personally, I think that's the problem with this. You've got the SNF set up effectively as an HMO. They're being given global payment. It's their job to farm out the business. They can use any factor that they want to in that, and then when you don't have some kind of arrangement with them, they can say, well, you know,

you didn't follow the rules so we're not going to pay. So to me, and I'm not involved in this, it seems like the worst solution to it to expect doctors' offices to have to, OK, now you're going to get an X-ray and so forth.

Ms. Lambowitz: Well, and I'm not suggesting that that's the way we go. What I'm suggesting is to look at practices you have in place in doctors' offices for other payers. Is there anything that would help you working with SNFs that we can adapt. So I don't want to make the nursing homes another HMO and create another type of bureaucracy, but if there's anything that you have in a physician's office that might also work for SNFs, I think we should try it. Because I can't change the law, but I can try to help with the regulations.

Dr. Rapp: Dr. Leggett?

Dr. Leggett: I just think that this one breakdown is that the strategy that you have now works great for you, not you being you, but you being you, actually. [laughter] Because the bundling concept makes it simple as you distribute it to the SNF. But frankly, after it gets there, it's terribly convoluted and it simply doesn't work. Number one, there's no mechanism in place for the SNFs to enter into agreements with doctors' offices, and frankly, if I were a SNF, I would avoid it. Because I would have agreements with potentially 100 different people, and if my issue is, which it is, economics, and dollar retention, then there would be no incentive for me to have these agreements. Secondly, there does not appear to be any mechanism in place that would actually force the SNFs to make these agreements. I mean you can send out this sort of uniform legal document that suggests what the relationship should be, but if you don't make them enter it, it's just additional paperwork that they have in their offices that frankly doesn't achieve anything. So and I think the last issue is really the issue of the diagnostic part of the evaluation. I mean frankly most of the individuals in the SNF organization are probably unqualified to be working these patients up. So when you send information to the doctors' offices and the orthopedic example that was given earlier, the information is worthless. So now you've got to rework the patient up, and then you have to decide at that point, you'll be conflicted, frankly. Should I work this patient up, knowing that I'm not going to get paid for it? Or should I just send them to the hospital, or just get them out of my office all together? Because that's what you're creating. You're creating a sort of an interaction between the doctors' offices and the SNF that's dysfunctional, that does not work, and there's no apparent solution for that. So now the patient is caught in the middle because they're not getting properly evaluated because economics is a real issue and you cannot continue to work these individuals up and get into some protracted attempt to get your money from the SNF. I mean that's ridiculous.

Dr. Rapp: Dr. Iglar?

Dr. Iglar: Many of our elderly patients undergo total joint replacement and from the acute setting they'll end up in a rehab center, quote. Some will go home, and some will go on to an acute skilled nursing facility. Are those looked at truly differently? The acute rehab that's, I think it's kind of an intermediary kind of thing? Or how are they treated or is that the same set of rules?

Ms. Lambowitz: It really is the same set of rules if a person has been to a rehab center and is transferred to a nursing home and they're still receiving therapy. That therapy is evaluated according to the same rules as someone who came directly from a hospital to the nursing home. As long as it meets the guidelines for skilled care, they are eligible for the SNF benefits.

Dr. Iglar: So all the bundling and everything is essentially the same?

Ms. Lambowitz: The bundling would be the same that in that case, the therapy has to be, the SNF needs to pay the therapist, and that's true even if the person is in a non-covered stay, because anyone in any kind of nursing home, a SNF or a NF, which is considered a Medicaid certified stay, may have the bundling requirement for therapy.

Dr. Rapp: Dr. Urata?

Dr. Urata: Does this cover Medicaid also, or is Medicaid separate?

Ms. Lambowitz: Medicaid is separate, so that they SNF consolidated billing applies totally to Medicare. One of the reasons you may have heard this, well, you have to get the Medicare denial, is that's a procedure that used to be required in the crossover between the Medicare and the Medicaid payments. It's not a consolidated billing issue. But once somebody is on Medicaid, none of these requirements apply.

Dr. Urata: Are there any plans to follow up on quality of care under this program?

Ms. Lambowitz: We have a number of initiatives that are talking about quality of care. If you're talking about quality related to the problems identified in consolidated billing, we don't have anything formal, but I think that with the input that we're going to be getting from you and from other groups it's going to give us an idea of where the most severe problem areas are.

Dr. Urata: Because I think that quality of care will possibly go down.

Ms. Lambowitz: Well, what I'm hearing now—I'm very concerned about some of the comments about we may not be able to treat these patients; the patients are caught in the middle, and that's something we definitely need to be working on.

Dr. Urata: I think there will be access problems and things of that sort.

Dr. Rapp: Dr. McAneny?

Dr. McAneny: The patients actually do get care, they just get it in the more expensive setting. They get sent back to the emergency room, or in the case of the radiation oncology patients, we just keep them in the acute care hospital longer, so that doesn't help Medicare at all. I agree with Mike's comments about beware of asking for the HMO utilization review process. You may get what you asked for, which means that I pay someone in my office a salary which wasn't originally conceived of in the MEI of the 1970s to argue with trained denial personnel who are working for the nursing home, or in this case, the SNF. And they never turn you down, but you have to pay somebody and they have to pay somebody to bicker about it for a while before you can get the thing. My real question is the agency willing to request legislation to expand the list of separately billable services. And you also had requested that we send you information, yet your email is not on your handout.

Ms. Lambowitz: Oh. Well, I will give you my email. I'll start with that. It's SLambowitz@CMS.HHS.gov and I do want to hear from you. And the second thing I'll say is I'm so sorry I mentioned HMO. [laughter] I was not suggesting the HMO utilization review procedure. I was hoping that somewhere in the country, there might be an HMO procedure that works. And if there is, if you find one, could we also use it with SNFs. Your other question in terms of legislation. We have already sent reports through out office of legislation to Congressional staffs pointing out some problems with consolidated billing and suggested some changes. We did not get a positive response at the last Congress. Clearly, the Congressional Committees are very afraid that any change to consolidated billing is going to open the spigot again, and that we'll start increasing Medicare expenditures. And that they are very hesitant to address changes in consolidated billing. But I think that that is the avenue that needs to be pursued, because we are pretty much at the limit of our flexibilities as an agency to expand the list of billable services.

Dr. Rapp: Could Medicare bill a SNF? Could the doctors send it to them and they could send it back?

Ms. Lambowitz: You're not the first person who's asked. Actually we did even check with our legal people, and no, the law specifically written that the appropriate payer is the SNF and that everybody else is getting reimbursed incorrectly, so when the problems occur, we can't go back to the SNF for the money.

Dr. Rapp: Dr. Senagore?

Dr. Senagore: What you have is a very immature economic relationship, where neither side has figured out what the issues are, and you've de facto made the SNF an insurer, because they control the pot of dollars. And they

have every motivation to control access to care. As long as they can get free care, they're more than happy to provide it. But it is an issue that it's going to come out as both sides become more sophisticated, you will have an issue in whatever be the time, 18 months, 12 months, as each side starts to understand the relationship better.

Ms. Lambowitz: I don't think it was our intention to make SNFs the insurers, but well, there is a point in that. I just wanted to mention that we do monitor the quality of care in SNFs through our survey process, and one of the things we specifically look for is under utilization of services, because they are controlling the money, and there is that risk that services, certain needs will not be met. So we are aware of it. It is a problem. No doubt.

Dr. Senagore: The one problem though with the quality of care issue, as a surgeon, if they are exposed to something that is going to be an expense to them, I have a contract with them. It'll be an easier default position for them since going to an acute care hospital looks like a premature readmission on my part, so it becomes my quality care issue, not their quality issue. And I think we just need to be aware as we build this relationship with the different components that we try to do the right thing for the beneficiary and the right care for the overall system.

Ms. Lambowitz: I agree.

Dr. Rapp: Dr. Powers, I think was next, then Dr. Urata, then Dr. Gaughan.

Dr. Powers: I am sitting here trying to be a little constructive about this and rather than send out 50 contracts to all the homes in the area that might send us one patient who needs one test a year, I'm thinking OK, they'll all go to the hospital where I have a contract with the hospital for the professional component; let the hospital work out the technical component with all these individual nursing homes and let it not be my problem. But then I realized that that's fine for me if my neuro-diagnostic testing can be done in hospital as an outpatient, but not so good for people who do things in their office. And it just seems that there ought to be some kind of pressure on the nursing homes that on a relatively quick basis, that they can just, if they want someone to come to your office for something, that you ought to be able to get a contractual, something signed from them on the spot, that says they're going to pay the technical component. It has to be done right then instead of fighting them for it for months on ends for this legal document that you get that says they're going to pay you for something.

Ms. Lambowitz: I think that's a great idea. I don't think we want to get into these enormous complicated legal agreements if we can do something simple.

Dr. Powers: But the pressure has to come from CMS, it can't—we can't put the pressure on them because they'll just—

Ms. Lambowitz: Well the first article that I've mentioned that's going out does say that if you don't establish agreements with your contractors and practitioners, that you're out of compliance with your provider agreement. So that there is some pressure to stay in compliance with your provider agreement. But what you're saying I think is that we need to be giving this message on an ongoing basis, and I agree with that.

Dr. Powers: It has to be done quickly. We can't wait a month for a contract to come back before we can agree to see someone for a test.

Ms. Lambowitz: I agree.

Dr. Rapp: Dr. Urata?

Dr. Urata: I'll pass.

Dr. Rapp: Dr. Gaughan?

Dr. Gaughan: I just wanted to make a positive comment to Ms. Lambowitz. To the best of my recall ability, this is the first time at PPAC I have heard such a direct answer to a PPAC member's question. I applaud you for your earlier two-letter answer, no. Thank you. [laughter]

Ms. Lambowitz: Thank you.

Dr. Rapp: Dr. Senagore?

Dr. Senagore: To follow up on Dr. Power's comments, could the agency think about using something similar to the ABN format. That the sending facility could sign the ABN when the patient comes. That could be a good vehicle.

Ms. Lambowitz: OK.

Dr. Rapp: Dr. Grimm?

Dr. Grimm: Thank you. This is just a basic question entertaining the dynamics of the financial relationship with the SNF and Medicare in terms of per diem payment. It seems to me that there is a variability of cost for every patient that goes into a skilled nursing facility. Is there some, do they get a fixed amount, or is it an adjustable amount depending on the services that patient requires?

Ms. Lambowitz: It's an adjustable amount depending on the acuity level of the patient. We have a system that basically separates acuity levels into 44 different groups, based primarily on nursing resource needs in the nursing home. We add to that ancillary payments so that even the ancillary amounts are adjusted by the acuity level, so there is definitely a difference in payment for somebody with a more serious condition.

Dr. Grimm: Let me give you an example of a person that's undergoing radiation that's in a skilled nursing facility. Obviously radiation daily expensive treatment everyday, or chemotherapy. Is that then reflected in what the skilled nursing home receives as a payment?

Ms. Lambowitz: It is reflected. Whether it is totally reflected or not is a question we're looking at. We've been doing what we call refinements research for the past couple of years and we expect to have a report to Congress in January. One of the things we're looking at is ancillary costs because you're right. If somebody is getting an expensive treatment everyday, there's a question how completely our ancillary payments will cover that, and if it's not fully reimbursed, what do we have to do about it? So we are working on the issue, but I don't have an answer.

Dr. Grimm: It seemed to me that it would make a lot of sense that if the skilled nursing home gets a certain amount of money for having this sort of complexity of treatment, then that's already built into the system, that's already built into the contract, that really, they're not out anything for sending him over to radiation, for example. And that's the way it should be.

Ms. Lambowitz: It's built into the system, but one of the difficulties is how completely is it built into the system? Because if you are taking the average ancillary expense per patient, even if you case mix adjust it, you may not be totally reimbursing for the very highest acuity patient. And the question is, how do you identify that very top segment of the nursing home population? That's what we're trying to do now.

Dr. Rapp: Just out of curiosity, where do ambulance rides from the SNF to the doctor's office fit in here?

Ms. Lambowitz: If you will remember that this is Congressional and not me, I will tell you. [laughter] There are certain services where in the statutes ambulance service is considered separately billable. And that includes the initial trip from the hospital to the nursing home and from the nursing home upon discharge. It includes ambulance trips for dialysis service. Administratively, we have made certain hospital level services separately billable by saying that services provided in a hospital are usually beyond the scope of a nursing home. That includes ER services, it includes outpatient surgery in the outpatient hospital department. And it includes CAT scans, MRIs and radiation therapy. And the ambulance for those services is also separately billable. Ambulance services between two nursing homes—if somebody is transferring from one nursing home to another, the responsibility of the nursing home that is transferring the patient. Ambulance trips to a physician's office or an ambulatory surgical center or an imaging center, are the responsibility of the nursing home. Clear as mud, isn't it.

Dr. Rapp: You did a good job, there. It's curious, I'd say.

Ms. Lambowitz: And it's another instance of legislation being built upon legislation, trying to correct problems and not quite hitting the mark.

Dr. Rapp: OK. Dr. Senagore?

Dr. Senagore: So is it anachronistic now that if I get a form for a nursing home patient to sign the transport form, do I really need to sign that form, or is it their responsibility? Nursing home patient comes to my office and then goes back.

Dr. Rapp: It was medically necessary to do the ambulance.

Ms. Lambowitz: Technically, the nursing home needs to pay that. Regardless of whether you signed the form or not. But truthfully, there may be other reasons for signing the form that I wouldn't be aware of so I'll check.

Dr. Bergeron: I think it's just a verification. Certain time they arrive, certain time they leave, how many patients went out there. So basically, it's a verification and therefore I don't think there's anything we have to sign.

Dr. Rapp: Thank you very much. I appreciate your being here. All right, it is 11:23. We could spend probably seven minutes on recommendations or we could go eat lunch or we could... We're going to go eat lunch. [laughter] I'm advised. So we're eating lunch a half hour early, so we will start a half an hour early. We'll resume at 12:30.

[LUNCH]

[RESUME 12:34]

Dr. Rapp: There's been a change in the agenda in that the person who was going to present for us will not be able to do that on medical education payment and so that we will have to defer until our next meeting. And so the next item on the agenda is medical care for undocumented aliens, James Bossenmeyer is here, who is Program Manager for Hospital and Ambulatory Policy Group at the Center for Medicare Management. Welcome, thank you.

Mr. Bossenmeyer: [off mike] about reimbursement of emergency health care services furnished to undocumented aliens. This is section 1011 of the Medicare Modernization Act. This section appropriates $250 million for each year beginning in 2005 through the period of 2008. That money's going to be divided into two large buckets. The first bucket, $167 million or 2/3 of the $250 million, is going to be allocated to all 50 states and the District of Columbia, based on the relative percentages of the total number of undocumented aliens. And we'll be using the 2000 Census data on to calculate that portion of the payment amount. An additional $83 million, or 1/3

will be provided to six states based on the highest number of undocumented alien apprehensions. And we'll be using information based on the four quarters preceding the beginning of the fiscal year to calculate that amount. The combination of these two funds will be how the state allocation will be set up. While the funds will be allocated on a state level, we will be paying providers directly as required by the statute. This is in contrast to the 1997 BBA Law in which we pay $25 million to individual states. There were 12 states that received funds from 1998 to 2001 and the money was paid to states, not directly to providers. Under this provision, money will be paid directly to providers. The providers that are eligible to receive funding are hospitals, physicians, ambulance providers, as well as Indian health service and tribal organizations. From a coverage standpoint, the payments are going to be available for the otherwise unreimbursed cost of providing emergency EMTALA services and related in-patient and out-patient services. The individuals that will be eligible for which payment will be paid for will be there are three groups of aliens as defined in the statute: The first is an undocumented alien, the second is an alien paroled into the US port of entry for the purposes of receiving emergency services, and the third is a Mexican citizen permitted temporary entry into the United States on what is called an laser visa, so it's a 72-hour pass to get medical services. From a payment approach, there's a couple different things that the statute requires. First, it requires that we make payments quarterly, which doesn't indicate how often payments will be submitted or payment requests will be submitted into CMS, but it does require that we make payments on a quarterly basis. The statute allows us to make payments prospectively, but does not require that we do so. It allows us to establish different payment methodologies for hospitals, physicians, and ambulance providers. Something that will probably be of interest to you is that also it requires that the hospital make an election to receive a payment. The payment can be one of two types of payments; one, the hospital cost plus the physician services, or the hospital cost and a portion of the on-call payments for physicians. But if the hospital does elect to take both the hospital and physician payments, then they need to pass that along to the physicians without any additional costs, so there will be no administrative fee being passed on if they take that type of payment. Payments are going to be made from based on the allotments of where the provider renders service. So in the case of a physician with multiple practices in different states, they would be able to request payments, and have different payments based on the different states in which they're operating. Provider payments are also subject to what is referred to as a pro rata reduction. This is very different than the way payments are set up today. Essentially, we have a $250 million a year pot. If we take a state, we'll just say, the state of Maryland has a $100,000 for example. That means that we can't pay more than $100,000 for providers in the state of Maryland. So

if we receive payment requests that greatly exceed that $100,000 or exceed that amount, $400,000 in payment requests, then we're going to have to reduce the payment amounts down to $100,000, essentially giving providers one quarter of their total payment request. The statute requires that we set up a process by September 1st of this year. And we're working towards that goal now. That's a quick overview of the provision. We've also had an open door meeting back in March, March 29th, I believe, and during that open door forum, we received a lot of information and certainly we're going to get some feedback from you today about your thoughts in us implementing this provision. During that first open door session, we heard from a number of individuals and associations that wanted us to ensure that the process that we laid out was administratively simple. And we received different thoughts on what could be done; everything from establishing a proxy method to paying providers, specifically hospitals, to other ways which we could reduce the cost both on the provider submitting a bill and CMS effectuating that payment. We were also asked to consider establishing defined payment amounts or pools for each state. So that providers would get, hospitals would get X percentage of the amount available, physicians so much, and ambulance providers a third amount. Concerns were raised about documenting this population; documenting the undocumented. And most people thought that that was somewhat of a paradox and it is going to be a unique challenge as we move forward. We are also from the coverage standpoint, as we mentioned earlier, this covers EMTALA services and related in-patient and out-patient services. And some people are asking well, what does that coverage criteria mean? And where would we expand the coverage to allow additional services to be covered for this and that's something that we're looking at as we develop the policy around this provision. Finally, some people asked if we could establish a minimum payment threshold so that a provider that has, say $75 worth of charges for a month that they be excluded. These were all recommendations. We're looking at those recommendations as we consider the policy and how we develop the operational implementation plan for this. Clearly, much like every other provision that we implement in CMS, there is the policy component, but as we develop that policy, it cannot be devoid of the operational realities of making the payments. And this particular provision is going to be a unique challenge, because the individuals for which we will be paying services for are not Medicare beneficiaries, are not Medicaid beneficiaries, and in fact they will not have a social security number or a HIC number, so we have to as we design the systems to make these payments, we have to be cognizant of that. So I was hoping to take a few moments and maybe get your thoughts, comments on a couple of different items. The first being the payment process and how the physician community would look at, what would be the administratively simple approach of your submitting a bill, or a payment request,

and maybe we can have some dialog about that, and then also, like to get your thoughts maybe on the coverage aspect of where you think the coverage line should be drawn, and then finally the issue of documenting this population, and how it would work best between hospitals and the physician community in providing documentation.

Dr. Rapp: Yes, Dr. Hamilton?

Dr. Hamilton: Have the data been collected that will allow you to determine how much will actually be distributed to the states of that 2/3 of the $250 million?

Mr. Bossenmeyer: We have some preliminary numbers. And we're working with the Department of Homeland Security. The language in the statute needs to be, we're working with Office of General Counsel to make sure we have correct interpretation of that, especially for the 1/3 amount of money, and the 6/8 pool, as soon as, so we're working on that right now.

Dr. Hamilton: When will you have some idea as to what those figures are going to be like?

Mr. Bossenmeyer: Well, the first set of numbers, the $167 million, we probably are pretty close right now, depending upon how Office of General Counsel helps define how that $83 will be divided up, or can be divided up because the language isn't exactly clear.

Dr. Hamilton: That's divided among the six states with the highest percentage of undocumented aliens?

Mr. Bossenmeyer: Yes, sir.

Dr. Hamilton: And that is based on what figure? How are you going to determine?

Mr. Bossenmeyer: That's based on the information that comes from the Department of Homeland Security and so they provide us that. And it's really based on the four quarters preceding the years that we're waiting—we're working to get that information now, but we probably won't have that until little bit later in the year.

Dr. Hamilton: Well, the hospitals and the providers in Texas are rather interested in this because we have probably as many if anybody has more, it'd be hard to imagine. But it's been estimated that in Texas alone, the cost to the health care system is something like $600 million a year. So this is obviously not going to be a major factor, but every little bit helps. We were just curious as to how much they might expect to give.

Dr. Rapp: Dr. McAneny?

Dr. McAneny: I'm wondering whether or not patients who are not admitted through the emergency room are still going to be eligible for these. For example, through the emergency room we were sent a young man with

Hodgkin's Disease, which means that if I spend about $30,000 worth of drugs for him, his chances of living to be 90 years old are good. If I don't choose to do that and he goes back to Mexico as an undocumented alien, as a citizen there, his chances of getting treatment are very very slim. He has no money. There's no safety net there for him. So, we are currently treating this young man, hard-working father of three who just happens to be a Mexican national instead of eligible for help in the US. Is a patient like that going to be eligible for your, for this program?

Mr. Bossenmeyer: Well, I think the first part will be, we're in the process of developing the policy about what will be covered and what won't be covered. But we'll have to fall back onto the definition of the statute that says it's an EMTALA service. So it's going to be an emergency service and related in-patient, out-patient. So if you're, so we'll have to look at that, and as we find that policy, that'll, those decisions I think will become a little clearer.

Dr. McAneny: I was asked to relay from nephrologists, that one of the frequent events that occurs because the dialysis program south of the border are also somewhat few and far between, is that patients will come up, go to a local emergency room, be dialyzed until they're stable by some of our hospitals, and you might be surprised to discover which ones, it's not the for-profit ones, and then being turned out on the street. You're stable, your potassium is back down It's not seven, anymore, it's back down to 4 and a half, good luck, with no arrangements being made. Whereas, the dialysis companies have to spend about the cost of a year of dialysis is estimated to be about $3200 a year for the Medicare payment for dialysis, plus there's about an extra $2400, not quite that much. $32,000 per year for the dialysis and $2400 a year for the physician for this. And if that patient is on a dialysis program, obviously they live, and they avoid an emergency, and they avoid an EMTALA admission. If they are thrown off of their dialysis program, then within about 96 hours they go to the emergency room and are an EMTALA problem because they're in a life-threatening situation. So the question I was asked to relay is will ongoing maintenance of things like dialysis treatment for life-threatening illnesses be included in this? And I think that was the idea with the chemotherapy issue as well. If you provide the service, the patient lives. If you don't provide the service, the patient dies. And I'm hoping that you're going to tell me that that will be taken into consideration as you formulate what is an EMTALA related emergency.

Mr. Bossenmeyer: Well, certainly, it's something to be considered. But I think one of the things that we'll have to look at is certainly the number of dollars this gentleman mentioned over here, that there's $600 million worth of cost in Texas alone. And we have $250 million for all fifty states, plus the District of Columbia. So as we

defined, we know what, we have a definition of the EMTALA service right now and it's in the regulation and I think it was published in November of last year. So we'll look to that regulation. We'll also look to the statute and define the coverage policy. But certainly the issues that you raised about people needing ongoing care, and even situations where there's a persistent need, we're cognizant of those. Whether or not we can address that in this provision we'll have to see as we go forward.

Dr. McAneny: One final point. Your question about how you can figure out who is eligible for this. Most of us in our practices will make a significant attempt to collect, but if someone has no social security number and no insurance as ACEP suggested in their document, and you've made a reasonable effort to collect payment, that should probably be sufficient. Because we're not going to spend as practitioners a whole lot of administrative time collecting documentation on something that we have a small chance of being paid for. It just doesn't pay me to pay a clerk to do that.

Dr. Rapp: Dr. O'Shea?

Dr. O'Shea: California's also very interested in this program. We also serve a lot of undocumented aliens. I had some questions though on your referral to Maryland, that pay down, if I got it right, I know there's a finite amount of money. The first quarter, are you going to be paying 100% of what was suggested or reimbursed or requested for, and then as the pot declines it's going to be less of a percentage?

Mr. Bossenmeyer: Well, that decision is being made right now as we speak and we're working on to get those decision. But the pro rata reduction requires that that, at the end of the year, there's going to be a reduction. So it's not going to be a first-come, first-served, if that's your question.

Dr. O'Shea: That's how it sounded. If you get your request in early, you'll be paid, but as a pot decreases then a ratio is going to come in.

Mr. Bossenmeyer: No, there will be—it's not going to be a first-come, first-served proposal.

Dr. O'Shea: OK, so then, if it's finite, then the payments will stop until the next year, when it's funded again.

Mr. Bossenmeyer: I think we are looking at a couple of different ways to make sure that the money is available to a provider that has a service in let's just say, June, that they are eligible to receive some type of a payment, versus a provider who only has a service provided in October. So we're looking at a couple different payment approaches to addressing providers that have spikes throughout the year, versus an evening out those

payment flows and as we lay out our policy, we'll be looking forward to receiving comments on the specific approach that we're going to recommend.

Dr. Rapp: On the issue of what is actually covered, CMS in their recent EMTALA revisions excluded in-patient services from EMTALA service. In other words, once they're admitted to the hospital, then EMTALA no longer applies. So my question is, is this and related hospital in-patient out-patient ambulance services something in addition to EMTALA services, or do you contemplate that it's only EMTALA service? In other words, not in-patient services would be covered. I'm not sure they had defined this when, maybe they had.

Mr. Bossenmeyer: No, it's not defined in the statute, so we have some latitude as we develop the policy. Some individuals have suggested that we limit this to just treat and release. Clearly that's something that as we develop the policy that's something that we can consider. But there's the piece that you mentioned also about "and related in-patient, out-patient services." So we're in the process of developing several different options of what would be the best coverage policy around this provision, and so we're working on it to come up with that answer right now. And as we listen to the public, or give this to the public for comment, we'll be certainly looking forward to getting comments on that. That decision just hasn't been made yet.

Dr. Rapp: OK. And with regard to the payment through the hospital, were you saying that the hospitals will determine whether the doctors are paid directly for their services?

Mr. Bossenmeyer: The hospital can make an election to receive both the hospital and physician payment or the hospital payment and a portion of the on-call payment. If the hospital elects to receive both the hospital payment and the physician service payment, then when the hospital goes to pay the physician, they can't add on an administrative fee to transfer the money back over to the physician.

Dr. Rapp: Will they be required to transfer the money? [laughter] I'm a little concerned about the SNF discussion we had today, which is, they get the money, but the doctors don't end up seeing it.

Mr. Bossenmeyer: That's something we'll need to address as well.

Dr. Rapp: That could be something you could include in there to require them to actually pay the money. And then, as far as the documentation of who's an undocumented alien, paradoxical there, but you said something about a Census? Does the 2000 Census tell us how many undocumented aliens we have?

Mr. Bossenmeyer: Yes, it does. I believe it's around seven million undocumented aliens. But when we look at that, that number may be high or low, but that's going to be the number that we use to divide the money up for the

$167 million. So we'll be using that Census information for that. The documenting of individual cases and how we go about that is a separate issue.

Dr. Rapp: I see, so the amount of money that's going to go to each state and the border states are the ones; that's going to be based upon the 2000 Census?

Mr. Bossenmeyer: In part, and then the second part being the number of apprehensions. So there's two pieces to the funding formula—the first being the number of undocumented aliens, based on 2000 Census percentage wise, and then the second part of it would be for those six states with the highest number of apprehensions, they would then receive a second portion of money. Those two combined would total for the state allocation.

Dr. Rapp: And so then, the next segment after that would be the people that actually provide the services; the hospital and the doctors would then submit some kind of claim potentially? Is that what you contemplate, that they will require independent claim for an identified individual that is supposedly an undocumented alien?

Mr. Bossenmeyer: I think we've been given a number of different recommendations. Clearly, the one that's probably, that most everybody is familiar with is the submission of a claim. There are different approaches that we could take. The statute allows us to do something prospectively. If we chose to. Clearly we have several things that we need to look at as we develop the payment policy. One, we want to avoid overpayments. We don't want to get into a pay and chase approach on this. This is money not out of the Medicare Trust Fund, this is money out of the General Fund, so it's something slightly different. But we don't want to pay providers and then have to take the money back. But we also want to make sure that we have the appropriate program safeguards in effect so that whatever we're paying out, we're paying appropriately.

Dr. Rapp: But the part about an example of a way to identify an undocumented alien is what they don't have. Would you suggest—how are you going to identify what they do have? Are you going to require their name, for example?

Mr. Bossenmeyer: I don't think decision's been made yet. We're in the middle of the policy making process. But we want to keep it as administratively simple and close to the types of things and types of information that are being collected today. So we're not adding a lot of burden onto providers, so we're looking at what's being done today, and today's practice, and if there needs to be an incremental change—

Dr. Rapp: That's not a administrative issue—that's an issue of the undocumented ...they don't normally want to be identified and to what extent does this put the hospital and the physicians in the business of sort of identifying undocumented aliens for the government.

Mr. Bossenmeyer: As we look at implementing this provision, we have to ensure at some level that we're paying for the services that the provision requires us to and that clearly there's a number of uninsured, underinsured individuals that are U.S. citizens that come into emergency rooms everyday, for which money is written off as uncompensated cost. That is not the population that this money is designed to assist or to provide reimbursement to providers. There is Medicaid that is available to a large number of people, both US citizens as well as in some cases, foreign, undocumented aliens. So making sure that there are payment vehicles other payment vehicles that are appropriate, with Medicaid being the primary example. If the hospital was able to tap in or use that funding source, that'll be the primary funding source. This will be the payer of last resort.

Dr. Rapp: How does that work? The Medicaid, how does one get reimbursed under—I did see that in the law a few years ago, but I never saw any evidence that it was actually done. How is that done?

Mr. Bossenmeyer: It's in the hospital's best interest to seek the payer that's going to pay them the most and in this case, Medicaid would pay a higher percentage than the funding from this—

Dr. Rapp: But are you familiar with the mechanism under which Medicaid—how a physician or hospital identifies somebody as an undocumented alien and gets paid for those services?

Mr. Bossenmeyer: Well, currently, they're probably not being paid for those services. For the undocumented alien.

Dr. Rapp: But there's some provision in the law to allow for that under Medicaid?

Mr. Bossenmeyer: No. Not that I'm aware of. Medicaid will pay for those individuals that are covered for eligible Medicaid services and as I understand it, if a person is not eligible for Medicaid, and has no other payer, and is not a self-pay individual, those costs are written off as bad debt or uncompensated care.

Dr. Rapp: I may have been mistaken, but I thought I had read someplace that there was a provision for Medicaid to cover undocumented aliens for emergency services.

Mr. Bossenmeyer: There may be for emergency services, but that would be covered—

Dr. Rapp: I never saw any evidence that anybody got anything. I was just curious whether they did. OK, so the issues that Mr. Bossenmeyer asked us to comment on would be the payment process itself, the coverage, and documenting the population. So does the Council have any suggestions on that? Yes?

Dr. Castellanos: I just really want to emphasize what was said to you earlier. It's similar to the SNF. If that money goes to the hospital and you expect the hospital to divide that money equitably, it's not going to happen. In our community, if there's an automobile accident, and there's a $10,000 sum that's paid to that person, that money is used in the first three minutes in the emergency room. And there's nothing left over for the physician. And by state law, they're able to do that. Now I have a real problem. In my community, most of these undocumented aliens are being treated by myself, and I don't bill them, because it costs me too much money to spend money to try to collect money that's not available, and it's a lot easier for me just to provide that service gratis, say thank you, hope you're doing well, and not continue to turn that bill over to somebody or go through some kind of a billing process. So I really want to try to emphasize that when this money is distributed, that it is distributed perhaps by law that a certain percentage of that goes to the physician care.

Dr. Rapp: And the other thing I think about that is that all of the physician services provided in the emergency department are not necessarily emergency physicians working there, but they're all the on-call physicians, and Dr. Castellanos and so forth that come in to provide services as well. Dr. Hamilton and Dr. Grimm?

Dr. Hamilton: I just want to go back to this business of how you determine the numbers of undocumented individuals that are going to be credited towards this amount of revenue. You know it's one thing to count the number of people that come into the emergency room that have no social security number and insurance. One, one, one. It's another thing to compensate the law enforcement industry as it were to see how many undocumented people they can round up in some sort of a dragnet operation. Now this does not just apply to border states, although it would affect them more, but there are major industries in this country if you were to do that. If you show up a construction site and arrest everybody that's an undocumented worker, you're going to shut down major construction operations in this country. You're also going to shut down a lot of agricultural operations in this country, so you know, it's one thing to give a state or an agency or somebody credit for having apprehended undocumented workers. It's another thing to count people that actually show up in the emergency room that are sick and need to be treated. The latter is vastly preferable. I mean it really is. You're going to have major dislocations of

economic activity if you start compensating entities for just rounding up undocumented workers, whether they're sick or not.

Dr. Grimm: I'd like to reinforce that notion. I think that you'll have to use some sort of methodology other than just the Census to determine the number of undocumented aliens requiring these kinds of services other than what you're doing, and on an ongoing basis, so that you can equitably distribute funds to these various states. The other issue I have a concern about is this whole issue about having bundled money because, as indicated before, we're going to blow through that in the first few minutes of this program. $250 million is going to go like that. And you're not going to have anything for October, November, and December. And I would suggest that the agency work out some sort of system where it is done parceled out over a period of time so that the funds are available all throughout the year. Everybody's only going to get 20 cents on the dollar on this program anyway, but there shouldn't be an incentive for everybody to try to grab as much in the first few months.

Dr. Senagore: Just speaking to the process itself. It should be fairly simple – a 1500 form or something like that; a simple invoice to a specific location for payment, as much as we talked about the quarterly allotment or whatever it ends up being, should be the process. Should be fairly simple to submit the bill and not worry about having tracking in our current format of submitting insurance bills.

Dr. McAneny: In terms of the amount of money, I figure if you've got 70 million documented undocumenteds, and maybe one percent of them go to the emergency room for treatment, that $350 per person, which doesn't buy you a whole lot in the emergency room, or anyplace else. And also, as you're looking at these forms, for $350, if I see a patient, I do not want to be part of the INS. I do not want to have to report that person's address or any other way that they could be contacted by the INS, because a lot of these folks, as Carlos mentioned, are in a situation where they are the support of their families, both here and in another country, and I do not want to be responsible; your choice is you get healthcare and then get deported. So please do not make physicians be part of the INS. And please consider out-patient life-threatening nature of care, and I would hope that as you are reimbursing people for care for undocumented aliens, that you would consider the severity of the illness. Those that are threatening to life and limb should be above those who come to the emergency room because they have a cold. Not too many undocumented aliens come in until they are at death's door, but occasionally they do.

Dr. Rapp: Dr. Urata?

Dr. Urata: It seems to me that if it's not too hard, that it may be better to distribute the money not according to what the Census bureau says, but according to who's taking care of these patients in terms of emergency room census, and hospital census and even clinic census. I don't know if that's possible, but that might be a better, equitable way of doing it, of distributing the money, than using the Census indicator.

Dr. Rapp: It talks about paying for otherwise unreimbursed costs, so that would imply that there would have to be some effort on the part of the individuals to get reimbursed? Is that what you contemplate or not that wouldn't be necessary?

Mr. Bossenmeyer: Yes that would be what we'd contemplate. That if there is another payer, whether the person—assuming the person comes in the door, they're, you're not allowed to ask about their insurance status under EMTALA until after the person has been stabilized. So at the point of stabilization, you start to ask about the financial payment issues, the billing information. The questions may first come up—is the person a Medicare person? Are they a Medicaid patient? You may not know that this person's an undocumented individual. They could be a U.S. citizen that has Medicare or Medicaid and the normal course of action from a billing perspective would follow through. Once you've made a determination that there is no third party payer, the person does not have the financial resources to pay you, then this payment may be applicable.

Dr. Rapp: So in California, they have a system where there's an EMS fund I believe, and after a certain period of time that goes by that there's no payment, then the individual I think physicians are allowed to bill that fund, but what they have to show is that there was no payment for certain period of time. In other words, I guess one issue is whether unreimbursed cost, presumable the undocumented alien, could pay, too. They could just pay cash. And so I guess the issue that you're really discussing there is whether they just have to say, I don't have any financial resources, period, and then you could bill this? Or you have to wait a period of time and bill them under the usual billing things. And whether I think in California, too, it's required that there be no payment, period. And after a certain period of time and no payment, then you can go ahead and seek money from this fund. As opposed to a situation well I got 95 dollars on a hundred, but I didn't get that last 5. So I think that might be a factor to consider, just the magnitude of it. And then with regard to the in-patient and out-patient services, in-patient services are much more in terms of the dollar amount, potentially, since the primary thing is EMTALA services, not necessarily in-patient services, the EMTALA issue that's what the statute addressed, I guess the question is how you potentially allocate that money. Because if it's just allocated on, there was ten billion dollars worth of related in-patient

services, and six hundred million of out-patient services, it's possible that the in-patient services dwarfs anything for out-patient services, or the true EMTALA services, as defined by CMS most recently. Dr. Leggett, and then Dr. Bergeron.

Dr. Leggett: The situation is so terribly naïve in not having their insurance status on the front end and that you're going to walk in and sort of cerebrally be aware of what their insurance status is. But that's just now how it is, and this whole reimbursement issue has to be better worked out, because it's going to get exhausted. I mean it's almost like throwing a solution at a problem, where you know up front it's not even a solution. I mean the dollars are terribly inadequate to address this issue, and we're still addressing the issue, which is you've got a sick patient in front of you. And knowing on some level that the reimbursement for that, whether it be on a hospital basis or a physician basis, is just not going to happen.

Dr. Rapp: Dr. Bergeron?

Dr. Bergeron: This is going to sound so far-fetched, I'm going to be on Mars. Number one, an undocumented alien is a foreigner. Have you looked at any other sources of revenues to fund this program of yours? We're getting foreigners, how about foreign aid? [laughter] We know where the dollars going, we document it, they're healthier workers, they contribute to our economy, they become citizens, their children are well developed mentally, physically contribute to our great nation. Have you ever looked at foreign aid?

Dr. Bossenmeyer: [off mike] the reason the Congress and the President signed back in December [laughter]

Dr. Rapp: Is there anything else—with regard to the inadequacy of the funds, it would seem to that that is an issue for additional funding, but what we're trying to deal with right now is can they get the mechanism right to distribute any funds, and then if it works, potentially more money could be put in that pot. And the spigots would work. But right now, we're trying to get the spigots to work. Dr. Iglar, and then Dr. Urata.

Dr. Iglar: Are there any provisions for identifying abuse by either the provider or the recipients. Say somebody comes in that really does have some type of funding and their employer may tell them to say they don't, or a provider is saying that he provided this service, that service, that he didn't.

Mr. Bossenmeyer: [off mike] inappropriate payments, successive payments, fraudulent payments. We'll be working to try to establish a framework where we can capture that. If not on the front end, then during an auditing process.

Dr. Rapp: Dr. Urata?

Dr. Urata: Do you know when this plan is going to be completed?

Mr. Bossenmeyer: We're required to complete the process by September 1st of this year. We're hoping to be able to make some announcements a little bit later in the summer. So you'll get an opportunity to comment on the proposal.

Dr. Urata: Sometimes it's easier to critique the proposal once it's in place.

Dr. Rapp: That's true, but at this stage, you have some real opportunity to give them what the proposal should be, as opposed to once it's already pretty much in draft form it's a lot harder to budget than it is right now. OK. Anything else? If not, thank you very much for your presentation. And the next item is an update on HIPAA. Gary Kavanagh who is the Director of Business Standards and Systems Operation Group, the Office of Information Services, Centers for Medicare and Medicaid Services. And Patricia Peyton, who is a Health Insurance Specialist, with the office of HIPAA Standards at CMS.

Ms. Peyton: Hi, I'm Patricia Peyton from the Office of HIPAA Standards in CMS, and I think one of the handouts is 28 slides about the National Provider Identifier, which is what I'm going to be talking about. The National Provider Identifier is a new identifier. It's the standard unique health identifier for Health Care Providers. It was mandated by the HIPAA legislation. And it is to be used by covered entities in the HIPAA Standard transactions. Covered entities are health plans, health care clearing houses, and any health care provider that transmits electronically in connection with a transaction for which we would offer the standard, a HIPAA standard. The Final Rule was published January 23, 2004. It has an effective date of May 23, 2005, which is 16 months after its publication date. This gives us time to complete the development of the system that will actually enumerate providers and test that system before providers can begin applying for NPIs. They can begin applying on May 23, 2005, a year from now. The compliance dates for all covered entities except small health plans, the compliance date, excuse me is May 23, 2007, and then small health plans have an additional year, until May 23, 2008 before they need to comply. The NPI will be a lasting identifier. Once a provider is assigned its NPI, it won't ever get an additional one. It won't get a changed or revised one. Eventually in the standard transactions, the NPI will replace the use of the legacy identifiers, which are those numbers that health plans have assigned to providers over the years. It will simplify transactions and we do believe it will save covered entities money in the long term. Some will have to work a little harder than others, and some won't see the benefits as quickly as others. The NPI will not guarantee that a provider will be reimbursed by a health plan. It won't enroll a provider in a health plan. That's a separate

process that health plans will continue to do. Getting an NPI doesn't make a provider a covered entity. If a provider obtains an NPI, it doesn't mean it has to start conducting electronic transactions, and having an NPI, or using an NPI does not replace the need to sometimes use the tax payer identifying number on standard transactions, or the DEA number when that's needed in a transaction. Those are needed to identify taxpayers and prescribers of controlled substances, and the NPI is just to identify a provider as a provider. And by the way, when I use the word "provider," I do mean health care provider, just cause sometimes I might slip and leave out the health care part. The NPI is ten positions in length. It's all numeric. It doesn't convey any information about the provider it identifies. It means you can't look at an NPI and understand that it belongs to a physician, a hospital, or what part of the country the provider's located in. It's compatible with the health insurance card issuer standard, should at some point a health care provider need to be a health insurance card issuer. Any entity that meets our definition of health care provider in our regulations of section 160.103 is eligible for an NPI. You don't have to be a covered provider that conducts electronic transactions in order to get an NPI, but you do have to be a health care provider. And I say this because some health plans, primarily Medicaid, reimburse for services that are performed by entities that aren't health care providers like taxi services and language interpreters. Those types of entities and people would not be eligible for NPIs. We also allow NPIs to be assigned to some subparts of certain types of organization providers. This subpart concept is explained in the Final Rule. It doesn't apply to individuals, meaning doctors, nurses, etc. They can't have subparts, and they aren't considered subparts. Briefly, a covered provider, any covered entity has to be a legal entity. There are some organization providers that have parts of themselves that function as health care providers and might even conduct electronic transactions, but those subpart aren't legal entities themselves. The Final Rule allows the covered organization provider to obtain an NPI for each subpart that it feels should have one. For example, it may bill health plans, a subpart might. It would need a number to do that. It could be federal regulations, like some of the Medicare enrollment regs that require of some of the entities who are subparts to have billing numbers, so of course they would need an NPI eventually to do that. The subpart concept does not necessarily correlate to the health care component discussion and the privacy rule. Organized health care arrangements also may or may not consist of subparts, there's no relationship between the two. A covered organization provider is responsible for determining if it has subparts and if those subparts should have NPIs. If they should, then the covered organization provider is responsible for either obtaining the NPIs for the subparts, or instructing the subparts to get their own NPIs and the covered organization provider is responsible for insuring any subparts with NPIs comply with the requirements of

the Final Rule. The health care provider will complete an application for an NPI. It will be able to do this either over the Internet or on paper. The application will then go to the National Provider System for processing. This is where each provider does get uniquely identified. Some of the data are edited, some are validated, and the NPI is assigned. There is no charge to a provider to have an NPI. The information that we collect on the application will ensure the uniqueness of the provider or the subpart. We won't be assigning NPIs if we can't uniquely identify the provider. We're collecting the minimum amount of information necessary to uniquely identify a provider. Money was always a factor in this. The HIPAA law didn't give additional money for this enumeration function, so we had to make sure that we were only going to ask for information that we needed to have and we try not to duplicate the information that health plans collect and validate for their member providers. The NPI application will be filled out by individuals or organizations. There are the two categories of providers that will exist in the national provider system. Individuals of course are doctors, nurses, pharmacists and others. And the organizations are the hospitals, group practices, skilled nursing facilities, etc. A lot of the same information will be required from each type of provider, but of course, it does vary. Slides 11 and 12 sort of list the information that will be collected from each type of provider. And this is spelled out in more detail in the Final Rule. Note that we do require the taxonomy code to be supplied on an application for an NPI. And this taxonomy code is the provider's classification or specialty. It's a ten position number that ends in an X and I think the application will have a link to the website [break] I don't know if anyone here has read the system of records notice that we published in 1998 for the National Provider System, but that did list the routine uses and the routine users of the data in the system and that notice will be along the lines of that notice. The enumerator. This is going to be a second contract that CMS will let, and this will be with the entity that will operate the National Provider System and actually interface with the providers and the health plans and others. That's who providers will call if they have problems with their application and that's who will call the providers if there's problem with the application. And the enumerator will handle requests for data from the system and resolve all sorts of problems. On May 23, 2005, all existing health care providers may begin applying for NPIs. They can't do anything before then because the application and the system aren't up yet. There will be a heavy work load on the system at that time, we're aware of that. That's why it's going to go through a lot of testing. And also the data requests. The health plans are going to need to know what the NPIs are for their member providers. Non-covered providers may apply for NPIs as I mentioned before. And again, just because they get an NPI, doesn't meant they're suddenly a covered entity. There are situations where providers who aren't covered entities should be

identified in standard transactions so we encourage them to apply for NPIs and use them even though our Final Rule can't require them to do so. A couple of other words about what the National Provider System will not do. It won't be credentialing providers, meaning when a provider submits its application for NPI, it will have to attest that the information is correct that I'm an MD or whatever, but we're not going to go and check that. That's something that health plans do. Group Practices. A group practice is an organization provider, certainly entitled to an NPI. The NPS will not be assigning an NPI to every location of a group practice, those are just multiple addresses. The NPS will not be linking a member of a group practice to that group practice. It won't be capturing the names of doctors or other practitioners who are in a group practice. These are all things that health plans do. The NPS wouldn't be able to do this nationally. It would just be bogged down in all that work, and in all the changes. The data dissemination strategy. There will be three levels of users. The first level is HHS, which includes of course CMS and the enumerator. They'll have access to all the information in the system. The second level of users is the health industry. These are health plans and others that need NPIs in order to conduct standard transactions. They may be entitled to some data that's protected by the Privacy Act, such as an individual's address and other types of information. They would have to be approved users before they could get that information. The public is the third level. And they would not be entitled to any Privacy Act protected data. Again, the system of records notice was published. That does contain a lot of information about data dissemination in the system and again, we'll publish our strategy in the Federal Register. The Final Rule adopts the NPI, it states its required use, which is on standard transactions, and it does permit other lawful uses of that number. It defines a covered healthcare provider. This is not really a new definition, but we decided to include it in the Final Rule, because we are talking about providers. It sets the compliance dates for covered entities. It lists the functions of the National Provider System, and it places requirements on covered entities. I've already talked about some of the requirements of covered providers. They also have to disclose their NPI if anyone requests their NPI in order to conduct a standard transaction. And if a covered provider uses a business associate to perhaps send electronic claims to a health plan, it is required to make sure its business associate uses all NPIs appropriately in the transactions that it does for that provider. And then, as I think I did mention, an organization with subparts needs to make sure that those subparts comply with everything that a covered provider has to do. Health plans and health care clearing houses of course, have to use NPIs in standard transactions to identify health care providers and health plans can't require providers that has an NPI to obtain an additional NPI. At this time, covered entities should be becoming very familiar with the NPI. They should

educate their staff. I get a lot of phone calls from people in doctors' offices who think that getting an NPI completely eliminates the Medicare enrollment process, for example. Covered entities need to look at all the processes and systems they conduct. All their operations to see where the NPI will impact it and then they need to start talking with their trading partners and their business associates to determine how to implement the NPI and when. The effect on providers of course is that upon the compliance date, they'll use only their NPI to identify themselves in these transactions. They won't have to use all those other identifiers they've been using over the years. It will certainly simplify their billing, and it should speed up the COB payments. The effect on health plans. They'll have a lot of work to do to implement the NPI. They have to get used to just seeing one number per provider. Not intelligence in that number. They will be able to get rid of a lot of the enumeration systems that they use internally if they want to. That's up to them. This Final Rule doesn't impact internal process. This should facilitate utilization review and program integrity efforts of health plans. I have several other slides on the effect on health plans. I really wasn't going to take our time to go over all those. I mean basically it's everything that I've just said. Health care clearing houses have the same types of things to consider as health plans, although I'm sure they'll be busier just getting entities NPIs than they will be in changing their systems. The effect on the X12 N transactions. There's been a lot of talk about the implementation guides, how they read right now, and how they'll have to read on the compliance date. Those guides will be changed during the implementation period, which is the time from May 23 of next year to the compliance dates. Health plans might be asking providers to a variety of things on these standard transactions. Some might want to capture the NPI plus a legacy number for a while during the implementation period. So if you hear that somebody's doing that. As long as it's compatible with the guide, it's certainly not impossible. Two things I should say though, the EIN may still be needed to be reported if it's needed for tax purposes, which the guides clearly indicate it is, then it is needed for that purpose. The electronic transaction information number, the ETIN, the trading partners use to identify each other in EDI, the Final Rule doesn't require that the NPI be used for that. That's between trading partners. They can decide yes or no on that one. We in my office continue to provide guidance on implementing the NPI. Your last slide does have our CMS HIPAA website on it. That's where we have questions and answers about the NPI, some of which we're fine tuning right now. It does have the check digit algorithm and a summary of the Final Rule along with a link to the entire Final Rule. We continue our speaking engagements to try to educate as many people as we can about the NPI and we're still hosting

the round tables. We had one last week. We will be participating, continuing to participate with the designated standards maintenance organizations, and WEDIs and others to get the word out about the NPI and help implement.

Dr. Rapp: Thank you very much. Does anybody have any questions for Ms. Peyton? Dr. Johnson? Dr. Hamilton?

Dr. Johnson: Has CMS chosen the numerator? Will there be contracted with one, will it be multiple, will it be regional contracts?

Ms. Peyton: It'll just be one contract.

Dr. Johnson: That'll handle it for the entire nation?

Ms. Peyton: That's right. We haven't done that yet. This summer we expect to award that contract.

Dr. Rapp: Dr. Hamilton?

Dr. Hamilton: Does this replace the UPIN and if so, what's the difference?

Ms. Peyton: Well the UPIN isn't assigned to every health care provider. It primarily was developed for the Medicare Program for physicians and certain other practitioners and groups. On standard transactions, it will replace the UPIN on the compliance data, it will only be the NPI that's used. But are Medicare's going to continue the UPIN process and when, is a decision that's being worked on now. There's a lot of conversations going on in CMS about what may or may not fall by the wayside and when.

Dr. Hamilton: I was just curious. I can only remember so many numbers. [laughter]

Ms. Peyton: Well you only have to remember one.

Mr. Kavanagh: I mean it does replace the UPIN in the sense that it's the only number you're going to have to report is this ID. You will not have to report the UPIN in the future, once this is effective.

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

Dr. McAneny: [off mike] I would also like to have you work toward having it replace the DEA number and replace the health plans assigning us other numbers. I think as long as we're doing this, let's simplify it as much as possible. But I had one concern, and from the look on your face, there's some problem with that. I'll be interested to hear—

Ms. Peyton: No, I was just going to say that it does replace those health plan assigned identifiers. That's what—

Dr. McAneny: So they can't assign us those anymore?

Ms. Peyton: No. Well, they can assign them, but you don't have to use them in standard transactions.

Dr. McAneny: And then they don't have to pay you right, when you don't have to use them? [laughter] That's the way they usually work. But the other fear that I would have with this is as you get the health industry level of user, I really don't want my address and office phone or home phone or any of those numbers being given to people who want to detail me with drugs, sell me products, sell me insurance, offer me tips in the stock market, any of that stuff. I really want to make sure that all of the data that you collect on us will remain with HHS and with the various payers we use and will not ever be sold to industry as a marketing tool.

Ms. Peyton: I agree completely and it won't be.

Dr. Rapp: Dr. Urata?

Dr. Urata: So if I'm a graduate from a medical school or from a residency and I want to go out into practice, how long will it take me to get my NPI number?

Ms. Peyton: It's my understanding that if you apply on line, and there's nothing wrong with your application, you would have it within ten days. That might sound a little long, but they, we didn't want—

Dr. Urata: That's really good compared to the UPIN number which can take up to six months. Are you serious when you say 10 days? Because that's hard for me to believe? So this is a number I will need to use to bill Medicare?

Ms. Peyton: That's correct.

Dr. Urata: So ten days?

Ms. Peyton: That's right.

Mr. Kavanagh: That's right about this number, now let me explain this, because it's not all that perfect. You are still going to have to enroll in Medicare. It isn't that you just get this number.

Ms. Peyton: You can bill with this number, but whether—it doesn't guarantee payment. That's where the provider enrollment comes in [laughter]

[Chatter]

Dr. Urata: It's not really going to replace a UPIN number then.

Ms. Peyton: Well, it will on the electronic claim, and the other standard transactions, you use your NPI period. It can't require you—

Dr. Urata: But you won't get paid.

Ms. Peyton: You will be paid, assuming you're enrolled.

Mr. Kavanagh: It will replace the reporting of it on every claim. You won't have to report the UPIN on claims. You still have to be registered, in fact, we'll still have to have some kind of Medicare enrollment data base, so we'll know for Medicare you're enrolled, as well. And every other third payer is going to have to have something similar.

Ms. Peyton: Like they probably do now. But you'd still only use your NPI, no matter who you send your claim to.

Dr. Rapp: It identifies you, it doesn't qualify you. Anything else on this? If not, we are going to back up here to Gary Kavanagh who's going to talk about a little different aspect of HIPAA.

Mr. Kavanagh: Thank you. I think at the last meeting, you asked for an update on how Medicare was doing with HIPAA implementation. And that was what I was going to provide this afternoon. We get statistics from our contractors on a weekly basis on HIPAA implementation. And we're actually doing quite well in terms of the incoming claim, that's the claim that providers send to us, physicians send to us, or submitters send to us, and we've gone up significantly since we're supposed to be in compliance with HIPAA on October 16, 2003. We've gone from 33% to now 83% of all incoming claims are now in the HIPAA format when they come to Medicare. And there's really not that much of a difference between the institutional claims and the physician and the supplier claims. On the intermediary side, it's now about 88% of claims are received in the HIPAA compliant format. And on the carrier side, it's about 82%. So we're doing quite well on both institutional providers as well as physicians and suppliers. The electronic remittance advice is another transaction that many of you physicians deal with. And we're not doing quite as well, but we are making progress as we move forward and I think providers are a little bit reticent to adopt the electronic, the HIPAA electronic advice because they're concerned about its accuracy and some issues with it. But and they're also concentrating on getting their claims compliance, so I think as we move closer toward 100% for the incoming claim, you're going to see the number of electronic remittances go up significantly as well, approaching the 100%. You can see from the number here, about 75,000 entities use electronic remittance, and about 55,000 of those are either physicians or suppliers. Maybe a little over a third of those are compliant at the moment, so you can see there's a ways to go there, but we are making progress. We're also instituting a new process as we move closer to the end of our contingency plan because that is our goal here; to end the contingency plan for Medicare at some point in the future. And we're trying to collect data by provider type. Not just by intermediary and

carrier, which we do today. And we do get data today on the number of electronic claims that are processed, the number that are HIPAA compliant, and non HIPAA compliant; the number that are carrier and intermediary. But we want to get data but in a little bit more specificity than we get today. And we're breaking it down into the categories that we usually receive data from intermediaries and carriers in terms of workload and as you can see on page 5, we're going to be collecting data in the next month or so by physician, LLP, non physician, therapy provider, diagnostic lab, clinical lab, and ambulatory surgery center. So we're going to have some level of finer granularity of data about how we're doing on HIPAA in the next month or so coming in from our carriers. We're not going to get that on a weekly basis. But on a monthly basis. So what are we going to do with this data? I think one important thing that we're going to do with this data is we're going to be able to better focus our outreach on the people that are not compliant yet. We always think that it's the small rural provider or the home health agency or the ambulatory surgery center or the smaller providers that aren't complying. But that may not be the case at this point, so we're trying to better target who it is that we need to reach out to and encourage them to become compliant. And it's also going to help us evaluate better when we can actually turn off our contingency plan for Medicare, at least for incoming claims, because we are reaching a point now where that's in the realm of consideration. I mean it's something that we really need to think about when we're going to do. As you probably know, in February we changed the terms of our contingency plan for Medicare. And what we're requiring as of July 1st is that if you submit us a non HIPAA compliant claim, a claim that's not compliant, that we're going to change the payment timeliness of that claim. Today we would pay a claim, any claim, after the 13th day. You might not get paid on the 14th day, but you're going to get paid sometime between the 14th day and probably the 20th day on a claim that got through the system without any manual processing. We're going to move that for a non HIPAA electronic claim to after the 27th day. The same time frame that we pay today for a paper claim. The reason we're doing that is really it's an incentive. It's to get people moving to get on the format, to get on the process and become HIPAA compliant. We're now 7 months beyond the time frame that was in the law. We certainly recognize the need for contingency plan, but we're taking what we think is another measured step toward ending the contingency plan, at least for incoming claim. So we think it's appropriate to do so. So we have heard from some physician groups that some of the groups believe that we're unfairly burdening providers with this change in the contingency plan; that we're not really penalizing anyone else for not becoming HIPAA compliant. But the facts are that providers are the covered entity under HIPAA. And the provider is the entity that is responsible for the actions if they have vendors, if they

have clearing houses for them becoming compliant, and we believe this step, in terms of changing the payment timeliness doesn't end the contingency plan. It's still going to continue payments, but we think it's a measured step toward eventually ending the contingency plan. And we think it will make sense to have such an incentive in place, starting on July 1. Something else is happening on July 1. I'll say this twice. It really doesn't affect physician and supplier claims, but it does affect institutional claims. Medicare is changing some of our billing requirements for claims that are coming into the system, starting July 1, and why are we doing that? As we got into the HIPAA requirements, or the HIPAA compliancy period, we started crossing over claims to third party payers. And we cross over a lot of Medicare claims to third party payers, little more than half of our claims, about 550 million claims, we send from the Medicare carrier and the intermediary, once it's processed onto a third party payer or Medigap policy, or Medicare secondary payer, and for them to be able to process that claim. And that claim to them works like an incoming claim to them. And what was happening is that Medicare was making a determination when we accepted a claim that we only needed certain data to process a claim, like an admission source code and admitting diagnosis, things like that. And this is again, only on an institutional claim. And we realize that in order for that third party payer to accept our claim, we were going to have to edit for those particular data elements. So starting in July, we're going to require that those certain lists of data elements, and it's all laid out in a number of places and Medicare Matters, articles, our website, and done a lot of outreach and education on this. Reaching out to institutional providers to make sure that they know how to bill appropriately, starting in July, so that those claims not only will get the Medicare and get paid by Medicare, but can be electronically crossed over in the HIPAA format to third party payers. And again, this only affects institutional providers, it doesn't affect physicians, suppliers. What we're really concentrating on with the physician supplier community is getting to 100% so that we really can turn off the HIPAA contingency plan for incoming claims as soon as we possibly can, and then working on the other transaction as well, remittance advice, because we want to get to that point as well. So we can really start to see some real savings in HIPAA going through this—what we all expected, probably some didn't expect it as much as others, but a significant learning period as we transition to these new transactions. We haven't experienced the train wreck that we could have experienced last October. We've tried to do it in a measured way, but we've got to keep moving forward to reach true HIPAA compliancy.

Dr. Rapp: Are there any questions for Mr. Kavanagh? If not, thank you very much. OK, we're a bit ahead of schedule. We haven't so far entertained any recommendations, but we might spend a little bit of time if there are

recommendations first of all that you want to make right now, we'll do this again at the end, but on the skilled nursing facility consolidated billing? Dr. Castellanos?

Dr. Castellanos: As part of the oversight of the Skilled Nursing Facility, consolidated billing system, CMS should address the concerns of the physician community that this billing system results in inefficiency and inequitable, and payment for both patients and physicians, which threatens quality access and to the continued care for the patient. In other words, what I'm saying here is that, CMS needs to address these concerns of the physician community.

Dr. Rapp: OK, is there a second to that?

[seconds]

Ms. Trevas: will you read it again?

Dr. Castellanos: I can give that to you if you like.

Dr. Rapp: If you've got it on paper, why don't you hand it to her. Do you have anything more specific on what they should do? In addressing those concerns?

Dr. Castellanos: I think I wrote it down. I want to make sure we get exactly what I wrote down.

Ms. Trevas: As part of the oversight of the skilled nursing facilities consolidated billing system, CMS should address concerns of the physician community that this billing system results in inefficient and inequitable billing and payment for both patients and physicians which threatens quality, access to, and continuity of care for patients.

Dr. Rapp: Any discussion on that?

Dr. Hamilton: Are we going to suggest some specific way that this can be monitored or something in a more concrete way?

Dr. Rapp: If I was given that myself, I'd have to, it doesn't give me very specific guidance on what exactly to do.

Dr. Castellanos: Well, I think there was some discussion that we're going to, nothing's in the Final Rule right now, that we want CMS to have some oversight to prevent these problems as they can potentially exist, both to the physician community and to the patient.

Dr. Rapp: Dr. Urata, then Dr. Senagore.

Dr. Urata: It says in the AMA report that House of Delegates are going to address these concerns next month at their annual meeting, then they'll later update the Council. Perhaps another report on this by the lady that presented it might be in order for the next meeting.

Dr. Rapp: Dr. Senagore?

Dr. Senagore: Would it be worthwhile an amendment, some of the specifics that we discussed during our discussion, for example, an ABN equivalent for sending institutions that could sign off if they would agree to pay, rather than requiring a contract for each and every patient, if we already understood that there were some guidelines in terms of contractual issues that were going to be put out by CMS as guidelines for these relationships, to give a little more direction to the recommendation.

Dr. Rapp: OK, what do you mean by that ABN equivalent?

Dr. Senagore: If you're a Medicare beneficiary, and you're not sure if a service will be covered, your current statute, you can sign a form saying that if this ends up being an uncovered benefit, that I agree to pay for the service. That would be the equivalent of the sending institution signing off that if this is my responsibility, the SNFs responsibility to pay for it, and if it's not covered in some other fashion, they would by definition, agree to pay for that service when they send the patient.

Dr. Rapp: OK, so you're suggesting that CMS should make such a regulation?

Dr. Senagore: Right.

Dr. Rapp: All right, that's sort of discussion, but that'll be the next thing. We won't add it to Dr. Castellanos's thing.

Dr. McAneny: I would be concerned with that that if they sent the patients over—

Dr. Rapp: Why don't you if it's not to Dr. Castellanos's motion, let's not get a second motion—he's going to make that motion in a second, and then you can discuss it. Address Dr. Castellanos's motion or we'll vote on it. OK. Is everybody aware of what it is? OK read it back one more time.

Ms. Trevas: As part of the oversight of the skilled nursing facilities consolidated billing system, CMS should address concerns of the physician community that this billing system results in inefficient and inequitable billing and payment for both patients and physicians which threatens quality, access to, and continuity of care for patients.

Dr. Rapp: OK, is there any further discussion on that? All in favor?

[Ayes]

Dr. Rapp: Anybody opposed? OK. Yes.

Dr. O'Shea: Do you have a quorum here without them sworn in?

Dr. Rapp: We have a quorum unless somebody votes No. Unless somebody talks about. I don't know what a quorum is, but I think we're OK, unless somebody says different. Dr. Senagore, let's see, I guess you theoretically can't make the motion just yet. But you have a good idea. Dr. Hamilton has a good idea here.

Dr. Hamilton: Let me see if I can paraphrase what you're saying. Resolve that the CMS direct skilled nursing facilities that approve of the referral of patients for consultation that the skilled nursing facilities will be responsible for associated expenses unless specifically prohibited in advance ...

Dr. Senagore: I'd like to say analogous to the current ABN process used for Medicare beneficiaries, if I can do it.

Ms. Trevas: [unintelligible] the last half of the sentence. That SNFs will be responsible for associated expenses unless specifically prohibited in advance of the referral. Does that include your. . .

Dr. Rapp: No, he wants to add—

Dr. Hamilton: So you want to add this other?

Dr. Senagore: I would just say, comma, analogous to the current ABN process used by Medicare beneficiaries.

Dr. Rapp: OK, so start them off with PPAC recommends that, as opposed to resolve or whatever it is. Start all of the motions off the same way.

Dr. McAneny: I have some concerns on the ABN idea because I think if you had the SNF send over an ABN, they'd sort of wash their hands of any responsibilities pay for it themselves and say, OK, go after the patient. And the patients often don't have any money. And the patients who are SNF appropriate often are not able to go after the SNFs to make them pay for it, so I don't quite understand how that would work.

Dr. Senagore: It would be their version of an ABN. They're the beneficiary. They're basically signing off. If this is an uncovered benefit or not, they know the Medicare format, they agree to be legally responsible for the payment.

Dr. McAneny: So the SNF is signing the ABN, not the patient. Ah! Sorry, I'm slow.

Dr. Hamilton: Is that clear the way you have it written down there?

Ms. Trevas: That's crucial, to have it clear.

Dr. Hamilton: The skilled nursing facility is responsible for the cost, unless they specifically say that they're not in advance.

Dr. Rapp: All right. Any further discussion on that? OK, Read it back one more time so everybody knows what they're voting on.

Ms. Trevas: PPAC recommends that CMS direct skilled nursing facilities that approve referral of patients to be responsible for associated expenses unless specifically prohibited in advance of referral, analogous to the current ABN process used by Medicare beneficiaries.

Dr. Rapp: Any further discussion? All in favor? Yes, Dr. Leggett?

Dr. Leggett: [off mike] the only problem I have with it is that I kind of see the SNFs basically not signing off on saying you do whatever you think is appropriate, because that opens them up to costs that frankly they don't know what the cap is. And I think the block for that will be basically not ever, sort of checking that box, unless there's some other way that you can capsulize it. Because pretty much it'll say you do what you think is appropriate and we'll pay for it and if were the SNF, I would never say that.

Dr. Senagore: Then, you as the provider would know that they are in agreement to pay. I mean you have that discussion with the patient, say, I'm not sure what set of services we can provide, and it would be the equivalent of having that discussion for any uncovered benefit that you would have on a Medicare beneficiary now.

Dr. Rapp: Although that's a covered benefit. It's not uncovered, is it? It's covered, it's just supposed to be paid for by the skilled nursing facility.

Dr. Senagore: No, but it would be the equivalent of uncovered functionally, because it's already been paid in another venue. It's been paid to the SNF.

Dr. Rapp: But an uncovered benefit, you can bill the patient. You can't bill the patient on this.

Dr. Leggett: I think on some level, what you would want to do is basically lock the SNF in and exclude the patient and create a statement that locks them in to paying for what you have to do in your office without you having to go after the patient and them agreeing to it within their mind believing there's some cost containment.

Dr. Senagore: Right, I guess what I would be looking at this recommendation to be is for the odd patient that you get, one a year from SNF-ettes; if you have high volume from a given SNF, that's the contractual language that we talked about earlier. You would need a specific contract to address what you're saying. I'm the SNF, I'm

always going to send all of my patients to you for cardiac rehab, here's what I agree to cover, here's how I agree to pay for it, here are the stop gaps in our relationship. That's going to be a much different discussion than the one patient I send to you every three years. You don't want to go through all that contractual language for that.

Dr. Leggett: I think that that would be fine if you could separate them out like that.

Dr. Rapp: OK, any further discussion? If not, all in favor?

[Ayes]

Dr. Rapp: Anybody opposed? The motion is adopted. Yes?

Dr. McAneny: I would like to have PPAC recommend that CMS continue to request legislative changes to the lists of the codes excluded from combined billing and that CMS include in the provider agreement mechanisms to ensure that physicians are paid the technical fees for services provided for the incident-to medications.

Dr. Rapp: Is there a second to that?

Dr. Gaughan: Second.

Dr. Rapp: Let's here that again.

Ms. Trevas: I'm sorry, the second part.

Dr. McAneny: OK, the first part was that CMS continue to request legislative changes to the lists of coded excluded from combined billing. That was the first part. And the second part is and that CMS include in the provider agreements mechanisms to ensure that physicians are paid the technical fees for services provided and for incident-to medications.

Dr. Rapp: OK, is that's two different things. One's certain legislation, the other's do something with—how about if we break that down? How about if we stop with the legislative support?

[Unidentified]: My next one is the—let's just restrict this to the legislative.

Dr. Rapp: So stop with Dr. McAneny's comma, and make that a period. And could you read that back then please?

Ms. Trevas: Yes. PPAC recommends CMS continue to request legislative changes to the list of codes excluded from combined billing.

Dr. Rapp: Is that it? Is there a second to that modified motion?

Dr. Gaughan: Second

Dr. Rapp: And is there discussion on that? If not, all in favor?

[Ayes]

Dr. Rapp: Anybody opposed. That motion is adopted. Dr. Grimm?

Dr. Grimm: [off mike with Dr. McAneny]

Dr. Rapp: Let me ask you a question. One, this issue of some skilled nursing facilities apparently require or suggest that this should be submitted to Medicare and that a denial be obtained before they'll consider payment. Would the Council think it would be good to recommend that CMS be explicit in stating that such a denial is not required?

[yeses]

Dr. Rapp: PPAC recommends that CMS make explicit that a Part B denial is not required in the context of a physician seeking payment from the SNF for services covered in their bundled payment.

[chatter]

Dr. Simon: Does that read CMS make it explicit that a Part B denial is not required in the context of a physician seeking payment for services that are within the SNF bundled payment?

Dr. Rapp: Yes, that's sounds pretty good. Is there a second to that?

[Seconds]

Dr. Rapp: Do we have discussion on that? If not, all in favor, say Aye.

[Ayes]

Dr. Rapp: Anybody opposed? That motion is adopted. Dr. McAneny?

Dr. McAneny: PPAC recommends that CMS should evaluate internal methodologies, such as the provider agreements, to allow coverage for services not adequately covered in current methodologies, such as technical components and incident-to medications.

Dr. Rapp: Before I ask for a second, can you explain that a little bit?

Dr. McAneny: Well, they said during their presentation that one of the sticks that CMS has over the SNFs is the provider agreements; that they can require certain things as part of the provider agreements with the SNFs. So they could, theoretically find that or other mechanisms that we don't know about to make sure that they do pay physicians for technical fees, the X-ray fees, for the orthopod fixing a broken arm, etc., as part of their payment. Because that's the issue. Currently, they're just denying those parts and not paying them. So I'm trying to be as specific as possible.

Dr. Rapp: All right, Dr. Grimm?

Dr. Grimm: The other issue on that is if there are mechanisms within CMS that allow for changing the scale of these payment systems, SNFs based on the needs for the patients, then they should explore that as well as the legislative aspect of it. Does that make sense?

Dr. Rapp: Yeah, it makes sense, I'm just reflecting on the entire system. It just seems like one sort of doomed to, it puts the SNF in the coverage business, but they're not required to cover everything that Medicare would be required to cover, because they can pick and choose how they do it, they can decide what they want to pay, they can decide they don't want it to happen, you name it. But somebody else advised me during the break that sometimes the SNF doesn't have anything to do with it, that the family members arrange some doctor visit for some patient and pack him up and haul him off to the doctor visit and whatever's done is done, but the SNF doesn't really have anything to do with it, it's not a referral in the sense that we were talking about before, it's just, OK, I come to take mama to the doctor. OK, well, go ahead, let us know when she's back. It's just like something we didn't set up, and even CMS didn't set up. The legislature set it up, and now I'm trying to deal with this mess, is kind of difficult, but at any rate. Restate your motion, please. If you got it The other thing, sort of opposite what I was talking about before, where to state clearly that you don't have to send in a Part B, don't have to get a Part B denial, I was talking about somebody at the break as well, is the possibility of a system whereby in so far as a Part B payment is denied on the basis it's part of a Part A SNF bundled payment, that the explanation of benefits, the EOB, is copied both to the individual who submitted the payment request, and the SNF, advising the SNF that it was denied on the basis that it's their responsibility, so that when the doctor goes back and says, wait a minute, now I want payment, they will have already heard from Medicare that they're responsible and that's why it was denied. In other words, Medicare wouldn't be billing them, but Medicare would be advising them, and that would put the heat—it would probably make it much more likely that the physician could then send them a bill and they'd pay it.

Dr. McAneny: Can I reread what I've word-smithed, here?

Dr. Rapp: Yes.

Dr. McAneny: OK. PPAC recommends that CMS should evaluate internal methodologies of payment to SNFs such as the provider agreements, to allow coverage for services not adequately covered in the current methodologies, such as the technical fees for services provided and for incident-to medications.

Dr. Rapp: So what would this provider agreement do? Oh, is there a second?

[Second]

Dr. McAneny: So they could say in the provider agreement that if you send a patient from the SNF with a broken arm over to the orthopedist, you have to pay the fees of the X-ray must provide incident to his treatment of the patient, or any physician who is seeing somebody and currently, you know, you have to get a lab test, or you have to get something else in order to properly evaluate and treat the patient. Your E&M code is currently the only thing that's covered, so people are sending these people to the emergency room, because they aren't covered to get various other things that you would ordinarily do for a Medicare beneficiary when you're taking care of a patient. When they show up from a SNF, you can't do any of that, because you eat the cost of it.

Dr. Rapp: I'm just wondering if that's getting too detailed and maybe it's a more general principle that they are responsible for a variety of things that are included in their bundled payment, and it includes not only the technical component for a diagnostic X-ray but laboratory studies and this and that and then the other thing, and in so far as they don't make arrangements for these things, it's their obligation to pay as if they were stepping into the shoes of the Medicare program.

Dr. Gaughan: I'd like to call the question.

Dr. Rapp: Yeah.

Dr. McAneny: It seems to me that if we put this forward to CMS, then if that's more detailed than they want, they'll tell us, and if it's not and they think it's a useful idea of a way to make sure that physicians continue to treat Medicare beneficiaries who happen to be residing in the SNFs with the same level of quality of care that they've treated beneficiaries who happens to be residing at home and shows up in your office with a broken arm, that they can comment back to us, and whether they accept the recommendation or throw it out.

Dr. Rapp: All right, anything else on this? All in favor of the motion?

[Ayes]

Dr. Rapp: Anybody opposed? All right, that motion is adopted. Anything else on the SNF?

Dr. Gaughan: Is there a reason we skipped PRIT, or are we not allowed to make recommendations?

Dr. Rapp: Sure, you can make a recommendation.

Dr. Gaughan: Well, no, this is just PRIT update.

Dr. Rapp: No, I just saw that as the first substantive item, but sure, what do you have to recommend?

Dr. Gaughan: I'm not sure Dr. Rogers, if this is [unintelligible] to you I apologize if I make it official, but I think it would be nice to know, at least for you, that the whole group agrees on this, hopefully. Number one, I have three of them. That PRIT further investigate the physician burden of LEP, concentrating its efforts on universities. That's the motion.

Dr. Rapp: Is there a second to that?

[Seconds]

Dr. Rapp: Do you want to talk more about that?

Dr. McAneny: Why are you limiting it to university?

Dr. Gaughan: Because Dr. Rogers had said that they [unintelligible] but I'd be happy to take a friendly amendment. If you would like it to say further investigate ... I just want to make sure, Dr. Rogers, that you look at all areas. Is it clear without universities?

Dr. Rogers: Yeah, I confess that I focus on doctors' office and practitioners rather than institutions.

Dr. McAneny: Let's just change it to institutions.

Dr. Gaughan: OK, further investigate the physician burden of LEP concentrating on institutions.

[second]

Dr. Rapp: OK, could you read that back please?

Ms. Trevas: PPAC recommends that PRIT further investigate the physician burdens of the limited English proficiency reimbursement requirement concentrating on institutions.

Dr. Rapp: Anything in particular that you want him to focus on in that subject matter?

Dr. Gaughan: I think if he has any questions we can talk later, but I think it's pretty clear.

Dr. Rogers: Where's the money? [laughter]

Dr. Gaughan: I don't have it, but don't take any more from me.

Dr. Rapp: OK, all in favor of that motion.

[Ayes]

Dr. Rapp: Anybody opposed to that? If not, that motion carries. Did you have something else on the PRIT.

Dr. Gaughan: Yes. That PRIT give us a report at the next PPAC meeting on the reasons for the failure of the previous E&M task force [and] suggestions that we obtain information from Dr. Wood, the AMA, etc. I am not asking for confidential information that cannot be shared, but I know that you were concerned that Dr. Wood was

not here today. So basically give us a report at next PPAC meeting on the reasons for failure of the previous E&M task force.

Dr. Simon: Mr. Chairman?

Dr. Rapp: Yes, Dr. Simon?

Dr. Simon: I think it would probably be appropriate for the Chairman of the E&M Task Force, Dr. Wood, to submit a report to the Council in lieu of the PRIT.

Dr. Gaughan: Very good. I take that as a friendly amendment.

Dr. Rapp: Why don't we just write him a letter and ask him to tell us about it?

Dr. Gaughan: As long as you make it a recommendation from us, I'm happy. Whatever you'd like to do with it.

Dr. Rapp: It wasn't a CMS initiative. It's an AMA initiative, and Dr. Wood was reporting to us periodically on what they were doing.

Dr. Gaughan: So, you'll get it done?

Dr. Rapp: Why don't I just write Dr. Wood a letter and ask him to—

Dr. Gaughan: OK, then I withdraw the motion. You're going to take care of it.

Dr. Rapp: Mr. Lanigan, can you write that down so you remind me to do that?

Mr. Lanigan: Consider it done.

Dr. Gaughan: Now, you're going to tell me this is AMA. That PRIT—

Dr. Rapp: That's the AMA. [laughter]

Dr. Gaughan: If it is, that's fine, but now we have Dr. Rogers in the room. That PRIT continue to investigate revision of E&M documentation guidelines as this is still a major national physician concern. And I think this does affect Medicare, since it does affect payment. Continue to investigate revision of E&M documentation guidelines, as this is still a major national physician concern.

Dr. Rapp: There's something in the Medicare Modernization Act about that, isn't there? How the agency should approach E&M Guidelines?

Mr. Gustafson: [off mike]

Dr. Gaughan: I'm just asking keep it on the front burner, because it sounds like after this task force went away, we were all just sitting here going, OK, what's next? And if there's anything that PPAC can do to prod a little

bit, that's fine. And if it takes us to write a letter also to the AMA that's fine, but I think this is still a very important physician national concern. As Dr. McAneny said, we're still tired of bullet counting and we also fear federal prison. [laughter]

Dr. Rapp: OK, so let's hear what that motion was again.

Ms. Trevas: PPAC recommends PRIT continue to investigate revision of the E&M documentation guidelines as they remain a major concern among physicians nationally.

Dr. Rapp: Is there a second to that?

[seconds]

Dr. Rapp: Do we have some discussion on that? Dr. Simon?

Dr. Simon: Just as a point of information to the Council, it should be recognized that the Academy of Family Physicians and the American Society of Internal Medicine suggested to the AMA, CPT E&M Task Force that they were satisfied with the current status of the coding methodology and actually made suggestions to the AMA to abandon the project. So I just make the Council aware. That they were satisfied with the present system, and that though it was not perfect, they had considerable trepidation about establishing and embarking upon a new system.

Dr. Gaughan: Well, what we could do, then, since I'm going to, I'm sure a lot of us, including Barb, who's on the Council, are AMA delegates, is if you would prefer, thinking that this is not a national issue. I disagree. I know there's a lot of family doctors out there, but I guarantee you there's a lot of other kinds of doctors out there and we are not happy with it.

Dr. Simon: I wasn't commenting on whether it was a national—I'm just stating a fact.

Dr. Gaughan: I'm just saying I would like PRIT to continue to do this, and then in addition, I would be happy, and I'm sure Barb would, too, and I'm sure anybody else, I'm sure not all family doctors agree with us. We got a big meeting coming up pretty soon in June and I have a feeling that there will be quite a few E&M guideline resolutions, but I would still like PRIT to keep this on the front burner, because obviously we're still having speakers coming to talk about the OIG, we're still worried about it. Unless something has changed in the last year, and you all are all taking Valium, I think we're still worried about it.

Dr. Rapp: All right. I guess the issue is what to do about it. Because the AMA has spent the last 4 or 5 years thinking about it, and Dr. Wood did present to us a rather extensive report about what had hoped to be done, namely to come up with essentially vignettes, and he was going to keep us up to date.

Dr. Gaughan: Well, I'm hoping that Dr. Rogers is smarter than us and he's going to help us out.

Dr. Rapp: The ball would seem to be somewhat in their court, but in any event, Dr. McAneny?

Dr. McAneny: Maybe as a friendly amendment, we could say PPAC recommends that PRIT continue to monitor any changes for revision of E&M documentation guidelines so we at least know what's going on and PRIT seems to be the logical group to watching that.

Dr. Rapp: Stop with that—

Dr. McAneny: Oh, I was talking. I have a problem with that.

Dr. Rapp: That's what I figured. [laughter] So do you accept that as a friendly substitute amendment?

Dr. Gaughan: I thought she was just talking. [laughter] I would like Dr. Rogers's comment before I comment on whether I like what Dr. McAneny said.

Dr. Rogers: Just like [off mike] breakdown of the AMA. There's a provision that says the Secretary will study simpler alternative systems of documentation for physician claims and systems other than current coding and documentation requirements. That's section 941. So maybe what we could do is just report on what has been done to comply with section 941 and then we can get the person at the Secretary's level, who's going to be working with us, or whoever's working with us, to make a report the next time around. It sounds like that's what a lot of the energy will be focused on.

Dr. Gaughan: So what would my motion be, Dr. Rogers?

Dr. Rogers: I'm happy to help to make sure that this happens, that we make sure we have the right person here to report to you.

Dr. Rapp: I think the motion is to ask that Dr. Rogers facilitate update on the MMA Provisions on the E&M Guidelines.

Dr. Gaughan: Is that it, Dr. McAneny?

Dr. McAneny: Yeah.

Dr. Gaughan: I accept her amendment or whatever.

Dr. Rapp: OK. Does our reporter have that down?

Ms. Trevas: Yes. PPAC recommends that Dr. Rogers facilitate the update to the committee on the MMA provisions on E&M guidelines.

Dr. Rapp: Is that it? OK. All in favor of that?

[Ayes]

Dr. Rapp: Anybody opposed? That motion carries. Welcome Dr. McClellan. So as you can see, we have a visit from Mark McClellan, MD, PhD, who's the new administrator for CMS. We're very pleased to have you here. And welcome to the PPAC meeting and if you have any comments. I know you're here to swear in the new members. I know you probably don't have a lot of time, but we're always interested in speaking with the Administrator and seeing what you have to swirl up around the agency.

Dr. McClellan: I'm looking forward to the swearing in because it continues the tradition of this advisory council being an important source of input for us. I was a practicing physician myself until coming into government in 2001, but I don't have time for that anymore with managing the programs here and everything else. So it's very important for me in particular to make sure that our programs do work from the standpoint of the physicians and the patients that they're working with and since you are on the front lines, this is our best way to get systematic input into Medicare and in CMS programs generally as to what we can do as effectively as possible to help you do your jobs well. And this is a process that's been going on for a while, and I think given the fact that you've got a physician running the agency for the first time in quite a while, there's even more opportunities for input in what you all are doing and thinking and advising to have an impact on what we do. I know you've had good discussions this morning already about such topics as SNF consolidated billing and working on the undocumented immigrant issues. These are just two of a long list of subjects that are going to come front and center with the new Medicare legislation. And as I talk about issues related to Medicare around the country, with physicians, I keep coming back to one main point, which is that on the one hand, health care today is more complicated than ever, and our physicians are facing more challenges than ever in keeping up and making sure their patients get high quality care. But on the other hand, thanks to the new law, and some better evidence on what works and some new technological opportunities, we've got the best opportunities ever to make sure that health care not only stays affordable but also stays focused around effective patient physician interactions in what should be an increasingly individualized and personalized health care system as we learn more and more about what can work best for particular patients. So, as you've heard from Herb, we want this group to focus as much as you can on looking forward, not just reacting to

problems after they arise, but helping us anticipate problems and head them off. And you're doing that already on topics like the ones that I mentioned. A few others that I just want you all to make sure you know that we're thinking very hard about—competitive bidding generally, you're having some discussions about that now, but that's going to be a major set of changes in the Medicare program we know in hearing from docs that they do think there are opportunities for us and for our carriers to provide higher quality services, and for us to reward carriers that are providing high quality services even more effectively, but we also don't want to see any disruptions in claims processing while all that is going on, and that's going to be a challenge. We think that by planning ahead, though, we can meet it and deal with it effectively, but we need your input in that. And more generally, there's a recurring theme in Medicare and in CMS generally today, which is trying to move toward paying for performance. That's happening in our competitive bidding for contractor reform. It's starting to happen in our payment systems more fundamentally though as well. Hospitals are getting different updates in the coming year based on whether or not they provided quality information to us. We're starting a number of pilot programs and demonstration programs and more directly involved physicians in providing higher quality care for particularly chronic conditions, and rewarding them when they do more to keep the patients healthy—not only out of the hospital, but in some cases even out of the doctors' offices. That's not the way our payment systems are set up today. And we need to change that, so that we can get more out of the resources that we have and we can make sure that physicians are more appropriately rewarded, not only supported, but rewarded for helping to bring better medical innovations, and better modern technology, and proven approaches to care to our patients so that we can get more for what we're doing. In all of these areas, we need you to help us to look forward and plan ahead, since you all have the best pulse literally on what's actually going on with our patient care today, and we need to make sure that's incorporated in all of our policies. That's the only way that we'll be successful and not just talking about getting more for what we're spending, but actually doing it in a way that reinforces patient physician interactions and patient care. So I'm especially glad to be here at a time when I can swear in some new members to this committee, because I think it reinforces the point that we need your input now more than ever, and as we move forward on implementing the new law, and implementing a bunch of other changes in the program and hold the potential for making easier for patients to work with their physicians to get high quality care, we're going to do that effectively with your advice, including the advice of some new members, and that's why I wanted to be here personally today to thank you for what you're doing, to let you know that I'm going to be paying close attention as are the rest of our staff, the results of this

meeting and meetings like this one to come, to make sure that we're getting ahead in this goal of improving the quality of our services and doing it in a way that puts patient and physician interactions front and center.

Dr. Rapp: I understand you might have a couple minutes for a few questions.

Dr. McClellan: Sure, a few minutes, that's right.

Dr. Rapp: Dr. Leggett?

Dr. Leggett: Hi, I appreciate your coming. I just had sort of a general question that's not related to physician fees etc. If you look at the Institute of Medicine report from 2002 that addressed this national issue of disparity in this country in the health care delivery process, I'm just wondering from a philosophical standpoint, do you see any role that CMS can play in helping to shrink this disparity in care that we see in our country?

Dr. McClellan: Yeah, absolutely. I see a major role, I think in general, we've seen a lot of reports identifying gaps in our health care system where errors are occurring or complications are occurring that could be avoided or might potentially be avoided and I think there are a lot of things that we can do to help with that. And I've talked extensively about things like electronic prescribing and improved quality measures and things of that nature, but these efforts needs to be particularly focused on the populations where we're seeing worse health outcomes. And when we talk about preventable errors, and preventable chronic complications, those are most serious, and the opportunities for improvements are largest in many of our disadvantaged populations. As we've been implementing the new Medicare law, including programs to help Medicare Advantage Programs, which disproportionately serve our minority beneficiaries and implement new things like the drug card which are of disproportionate value to lower income seniors including minority beneficiaries who don't have good drug coverage and are really struggling with their drug costs, we've tried to focus particularly on outreach and education efforts to connect us more closely with providers and patients in communities that have been hard to reach and have been hard to get the word out to about new approaches and new benefits that can help address disparities. Later this week, we're going to be having a meeting with the Agency for Healthcare Research and Quality on new steps that we can take to learn more about which treatments are more effective in particular patient populations. I think there's a lot more that we can do after treatments have been approved and shown to be in general safe and effective, for the population to learn more about when they work best and particular patient groups and when alternative drug therapies or alternative therapeutic approaches might be better. We got a new program we're starting with AARP on that. In all these areas though, talking about disparity is one thing, but actually implementing specific programs to

do something about it is what we're really focusing on now. And we've got more opportunity to do that than ever before, thanks to the new Medicare law and thanks to opportunities for collaborations with groups like AARP that share this goal. So I hope you'll help us identify ways to reach physicians and patients involved in practices where we can have a big impact on disparities, too.

Dr. Rapp: Dr. McAneny, then Dr. Bergeron?

Dr. McAneny: Dr. McClellan, you were one of the few administrators when you were at FDA that I ever saw the AMA give a standing ovation to. And I'm hoping that you'll want to get a standing ovation from every physician in the country by helping to redo the SGR. Is that in your plans?

Dr. McClellan: It is, making sure that we've got effective physician payment is definitely in my plans. And substantial payment reductions year after year is obviously not a way of assuring access to high quality care for our beneficiaries. We've taken some first steps to address that in the new Medicare law. You know without the Medicare law that passed, we'd be in a 6% worse position. 1.5% payment increase this year and next year would have been a 4.5% reduction, so we started to make progress there, and obviously where I've got an ongoing dialogue with many members of Congress who are very interested in this issue who are looking at ways, how can we address the physician payment updates effectively beyond 2005, because we know that's coming. The only other thing that I emphasize though is that when everything else fails is when people turned to the tried and true approach quote unquote to keeping health care costs down, which is cutting provider rates in one form or another. And I think there are a lot of other things that we can be working on together to both have an impact on the overall cost in the Medicare program without reducing quality and without compromising access as provider payment cuts often do. And to find better ways to deliver our benefits. That's why I was emphasizing new steps like seeing if we can work in a pay for performance approach. The physicians can support and reward them for doing things that they're doing now, and if anything, being penalized for, like talking with their patients on the phone, sending emails, things of that nature that you can't bill for now and that may actually keep the patients out of the hospitals, so everybody's better off. Fewer resources, yet our system isn't designed well to recognize that. New approaches in chronic care management. We've got a new pilot program that we're starting right now, that we're, among the performance measures for the chronic care contractors in this program is a set of provider satisfaction measures, including how well they're working with physicians to help them manage the care, manage the disease complications, and educating their patients about when they need to come in for a visit, or what kind of regular screening they could

get. They should get things that many patients just aren't doing today. New sets that we can take with our QIOs to work on everything ranging from how to help physicians' offices approach e-prescribing to finding ways to improve immunization rates. So, yeah, I think there are a lot of things that we need to do to make sure that we don't hit year after year of large reductions in the SGR, but I think it's going to be much more effective in both policy level because we can have an impact on cost and on the perception level with interacting effectively with the public about this, if we're visibly working together with physicians to find ways to get more out of Medicare for the money, and there are plenty of opportunities to do that, and I can't think of a group better situated to assist in it than physicians, since they are most knowledgeable about their patients' problems and in the best position to help us figure out ways to spend our money more wisely.

Dr. Rapp: We'll take one more from Dr. Bergeron and then

Dr. Bergeron: I'm from Shreveport, Louisiana.

Dr. McClellan: Good to see you.

Dr. Bergeron: I'm all for the concept of giving quality care and getting the most bang for your buck. I'm a little concerned about the report card concept; the liabilities that grow open, in other words hospitals can receive an A, B, C, and a bonus. What's the safe stopgaps, what are the parameters we're going to use to the report card? Are you going to reward hospital A and they've done an excellent job, so immediately in the patient's mind, hospital A because they've been rewarded with a nice bonus, they must have better facilities, better trained people. Hospital B will not get that bonus. This is going to be public knowledge, and therefore to me, there's a liability issue somewhere there that I'm a little concerned about. How do you see the stopgaps and safeguards being implemented?

Dr. McClellan: Well, let me say first that I'm very concerned about many of the liability problems that health providers, not just physicians, but all health providers are facing in many parts of this country today. Our liability system just isn't working well. There are a number of proven reforms out there that some states have adopted that have contributed to keeping costs down and have been shown not only not to lead to compromising in quality but actually have improved access to care, physician care, other types of care and improved quality. When I talk with a lot of groups about trying to get e-prescribing system, electronic health systems to work, partly it's to enable health care providers to work better together to avoid problems, but if they're worried about liability and lawsuits, then that actually impedes their putting any useful information into these systems, so we need to keep working on ways to address the liability problems and until they have been addressed, unfortunately, we probably

can't do as much as we'd like in terms of directly focusing on steps to improve quality since the liability system is getting in the way in many states. But fortunately, once again, there are some proven steps that we can take to address it. We're going to keep working with Congress to do that. In the meantime, I do think that by focusing first on coming up with some quality measures that have been validated that do work, that many physician groups have told us can be used effectively is a good place to start. And then before we start paying on a basis of whether someone did better or worse on quality measures, there are some intermediate steps. What we're doing right now for example with hospitals is we're not paying more to a hospital that gets a better rate of use of beta blockers that discharge after an MI, but we are asking them to send us that information so that doctors and patients can use it and potentially making some decisions to provide an added incentive for the hospitals to try to help get it right at discharge. But they don't get a differential payment based on how well exactly they do on the measure, they only get the full update if they send us in the information. So that's kind of an intermediate step toward, perhaps an intermediate toward more direct pay for performance, and we just need to see how well that actually works and make sure it doesn't lead to any fundamental problems of access to care or other undesirable reactions because of liability or other types of concerns. But I do want to make some steady progress in this area and keep an eye open as to what kind of effects we're having. And I have to say from talking with a lot of physician groups around the country, while there continue to be some real concerns about making sure quality measures are developed and used appropriately since they clearly have their limitations and some of my own research before coming into government focused on many of those limitations, I think there's more interest than there has been on physicians recognizing, look, we can't just keep doing what we're doing. We can't just keep paying more for more complications, and more for more visits; that's not the way that we want to deliver care. We need to get to a system that helps us focus on delivering more of what patients really need and give us the flexibility to provide individualized patient doctor interactions and assistance for patience. So, it is going to be a challenge, we are going to approach it carefully. And that's why this group should be focused I think on how we can do pay for performance and how we can use quality measures involving not just physician care, but all types of care effectively so we don't have those undesirable effects so that as we make this steady progress forward, we'll be doing it in a way that that doesn't create new problems, that does actually help us achieve the intended goal of better care at a lower cost and more physician patient control.

Dr. Rapp: Well, we have four new members and here is the document, swear them in. So why don't we have Dr. Azocar, Dr. Grimm, Dr. Senagore, and Dr. O'Shea.

[Swearing In off mike]

[applause]

[chat]

[Break]

[Resume 2:55pm]

Dr. Rapp: OK, we've been a little bit ahead of schedule all day and now we've got behind schedule somehow, but we'll move ahead and the next item on the agenda is Update on Competitive Bidding Efforts, History, MMA, Impact, Chester Robinson, who is the Director of the Division of Community Post Acute Care, Chronic Care Policy Group, for the Center for Medicare Management, and Don Thompson, the Director of the Division of Ambulatory Services. I believe we've seen Mr. Thompson here before. And Mr. Robinson I don't recall seeing you, but welcome. So I know this is an interesting topic and somewhat innovative, so welcome, go ahead.

Mr. Robinson: Thank you. This will be a two-part presentation. I'll be talking about competitive bidding for durable medical equipment and supplies and Don will be talking about competitive bidding program for drugs and biologicals. What I'd like to do is sort of achieve at least four things in this presentation and that is to give you sort of an overview of the competitive bidding provisions that were included in section 302 of the MMA. Second, highlight a couple of those provisions that I think the Council might have special or particular interest in, and perhaps at some future meeting, you might want to give us some feedback or guidance or your thoughts on how we should proceed with consideration of these issues. Third to let you know that the Congress, in setting up the competitive bidding process for durable medical equipment provided for a freeze in current payment levels, as well as some future payment limitations in preparation for competitive bidding between now and full implementation, which would be 2009. And then finally to certainly give you a sense of where we are in terms of the implementation process. Now, competitive bidding for durable medical equipment includes four areas: DME, prosthetics, orthotics that are off the shelf, and medical supplies. The first thing that Congress addressed in the competitive bidding legislation, and we think it provides for high priority or at least emphasizes the level of concern that the Congress had in these areas, but it dealt with quality standards and clinical standards. The Secretary has the authority to establish and implement quality standards for DME suppliers that would take us a long way in terms of addressing

program fraud and abuse. We currently have some standards for the Medicare program, but they've generally been viewed as more generic or across the board and just basically have basic functions that would apply to almost any business to keep it in check. But the Congress clearly envisioned higher levels of standards and asked the Secretary not only to establish and implement these standards, but also to designate and approve at least one independent accrediting organization no later than one year after these standards have been published. And the Congress envisioned that these standards certainly would be no less than any standards that currently would apply to DME suppliers. In terms of clinical conditions for coverage, the Congress saw fit to require that we set up certain categories for face to face examination by a physician to be eligible for and receive durable medical equipment services and supplies. Now we've given it some preliminary thought and we expect to have a proposed regulation published later on this summer. It'll either be published independently, or as part of some other rule that will be proceeding through the department. But this provision is designed for some long standing fraud and abuse problems that we've been having. For example, the proliferation of use of certain items that appears to be unexplained. Or items that are not actually delivered to the beneficiaries, just the paper function. And then other things where there's actually falsification of the documentation itself. So we're thinking that the actual face to face requirement will be a giant step forward in terms of helping us to combat fraud and abuse in this area. Congress chose to make the first item that they would require face to face visit to a physician was motorized wheel chairs. And I suspect, as many of you are already aware of the recent hearing that took place by the Senate Finance Committee on that issue. The program will be phased in between 2007 and 2009, and in 2007, we must have the program implemented, and ten of the largest MSAs. And by 2008, 80 of the largest MSAs, and in 2009, additional areas as the Secretary may determine. Now we could phase this in by various categories or items over this period of time, too, looking at either the highest cost items and services, the highest volume items and services, or the highest savings potential that would be offered by these competitive bidding. So, for example, the Secretary could choose for 2007 to implement the top ten items in terms of reimbursement under the Medicare program. The Congress clearly wanted us to proceed expeditiously because it provided us with the authority to waive federal acquisition regulations if we found those to be overly burdensome in terms of complying with the time frame that the Congress has set forth. The statute provides us with authority to provide exemptions for rural areas, or areas with low population density within an urban area, and also to exempt items from the competitive bidding program that would not necessarily result in significant savings. It leaves in place existing arrangements for the rental of equipment. For example, oxygen

equipment that's on a rental basis now. Those agreements can continue until they have been terminated. They will not be modified or changed under the competitive bidding arrangements. Now, one of the items that I think that we'd like to bring to your attention and perhaps get additional input on is that the Secretary may establish a process to allow a physician to prescribe a particular brand or delivery modality for certain items and services. And we are wondering or we would like to consider under what circumstances would a physician like to prescribe a particular brand or item of modality of treatment for one of your patients. And we've asked, we'll be coming back to that a little bit later. That may be one item that you'll want to consider giving us some feedback on later on. The broad program requirements envisioned by the Congress would call for quality standards that suppliers would have to meet, financial standards that they would have to meet in order to participate in the program. It expects that the payments in the areas that are subject to competitive bidding would be no less than what Medicare currently pays and that access would be maintained for multiple suppliers. So those are sort of the general guiding rules that we'll be using in establishing the competitive bidding program. Certain other little things I'd like to just sort of tick off. Timing implementation. The Congress asked us to, if the quality standards are an oversight committee that it has provided us to give us guidance on, on the implementation of the program, if those items or the committee has not been formed, or has not given us recommendations, the Congress still would like us to proceed with implementation on a timely basis. It would envision re-competing contracts under the competitive bidding arrangements no less than every three years. The government can limit the number of contractors that we would enter into contracts with. It certainly envisions multiple winners that there will be a single payment amount for each item within the competitive bidding area. The second item that I thought that you all might have an interest is, is that there is a provision in the law that says that we can consider the clinical effectiveness and value of specific items that have a great therapeutic advantage in terms of setting a different price for it, or putting it in a separate category. So we'll be giving some thought into exactly what does this mean, and how would we in effect implement this provision. The statute provides for an advisory and oversight committee. We're envisioning now that this committee will probably be around 15 members and will consist of beneficiary consumer representatives, physicians and other health care providers, manufacturers, suppliers, professional standards organizations, financial standards and data manage. Some of these areas are called for in the law. Others we think that will just be good business to deal with. As I mentioned before, there are certain freezes in preparation for competitive bidding. For example, there is a zero percent increase for this year, beginning in January 1, which has already been implemented, and future increases

will be subject to reports by the GAO and as the Secretary determines might be appropriate. So where we are in terms of the implementation of this provision is that we are pursuing a contract which will help us to gather data, do analysis, go out and collect information from the industry, look at different examples of competitive bidding. I'm sure that many of you are already aware that the Medicare program, CMS, had a competitive bidding demonstration project that a lot of these things were based on. But we're also aware that there are other competitive bidding models that are out there. So we want to make sure that we are aware of everything in terms of how we will proceed with implementation of this. So the contractor will help us to sort of gather that type of information. The freeze has already been put in place. One of the first things you'll probably see from us is a solicitation in the Federal Register for nominations for the Advisory Committee. We hope to have that out within the next couple of weeks, and then proceed with establishing the committee first, since we want this committee to be a very active and involved committee and solicit their advice on a regular basis. The award for the contractor, we also expect that to be achieved by certainly no later than the second week in June.

Mr. Thompson: Did you want to do the questions in between, or do you want to wait all till the end?

Dr. Rapp: Are there any DME questions, or do you want to listen to the drugs? We'll listen to the drugs. [laughter] They've been lying in wait.

Mr. Thompson: Always appreciate the opportunity to gather input from the Council. To provide a context for the discussion and briefly talk about how the MMA reformed payments for Medicare Part B drugs, talk a little about some of the activities that we've done together, public input on section 303 D of MMA, which is the drug competitive bidding. And also, essentially, as Chuck did, kind of focus on maybe on some areas that we would be particularly interested in input from the Council. Obviously, any aspect of it, but some particular aspects with respect to vendor quality, and also physician administrative responsibilities. So to start off, as many of you are aware, the MMA completely revised how Medicare Part B drugs are reimbursed, and it did that in three phases. Under the old system, we had 95% of the average whole price, much like the sticker price of the car, didn't really reflect the drug acquisition costs of the physicians. However, it was also pointed out to us we were under paying for the drug administration. So that the overpayment on the drugs was cross-subsidizing the drug administration. So Congress sought to address that by increasing the drug administration, and as I mentioned, reforming the drug payment in three phases. Phase one was in 2004, where they locked in the AWPs from April 1st of 2003 and they paid specific percentages of that locked AWP amount, primarily 85%, but certain high volume drugs were based on

studies that were done by the OIG and GAO. They also provide an exceptions process for manufacturers who felt that those rates were not adequate to come in and essentially request that CMS provide data to us, and request that CMS raise those rates. So that's kind of the ground work for 2004, and in 2005, the Congress indicated that drug manufacturers were to begin to submit data to us on what their average sales prices were. They actually began to submit that data in 2004. The first data submission was April 30th, and what CMS does is compile that data, and we pay 106% of the manufacturer's average sales price. So the 2005 payment system is 106% of manufacturers' average sales prices as they are reported to us by the manufacturers, quarterly. And then in 2006 comes the third phase of the reform which is the subject of this particular discussion, which is the drug competitive bidding. And in 2006, physicians are given a choice. They can continue to buy and bill a drug, and be reimbursed at 106% of the average sales price, or they can choose to acquire the drug from a vendor selected in the competitive process. The physician would not purchase the drug at that point; they would just provide a prescription to the vendor. The vendor would supply the drug, and the vendor is then responsible for billing the program. So those are the kind of three phases in which they did the drug reform. With respect to the competitive bidding, it is simple in concept, challenging in execution. We are as we do when we're faced with difficulties and challenges like this, we always seek public input. And our first step in that direction was to hold an open door listening session. Some of you may have participated or listened in on that. That was held just recently on April 20th. I received a great deal of very valuable input with respect to issues that we need to address, and some suggestions, with respect to how we might go about implementing this program. And if one were to categorize some of the input that we received, I guess at a very broad level would talk about quality of the drugs; quality of the vendors. There was a lot of concern with respect to how CMS was going to ensure that the drugs that the vendors were providing were in fact of high quality and there was no quality issue with respect to how the current situation was operating. So that's kind of one broad category. And then the second category I would say had to do with what would be the physician's administrative responsibilities under this program. I think at a minimum, kind of looking at the law, it provides that the Secretary shall establish a process for physicians to be able to transmit enough information to the drug vendors, so that the vendor can bill the beneficiary for the co-insurance and the deductible. That responsibility is the vendor's, not the physician's. However, since the vendor has no interaction with the patient, that information needs to be provided by the physician and what process are we going to use to try to implement that. And that's a particular area that we'd like input from the Council on what might be the least administratively burdensome way for us to facilitate that

information flow. But going beyond that, that's just obviously one aspect of this, is how are we going to handle the prescribing, the interaction between the drug vendor and physician. How can we structure those in such a way, again from an administrative standpoint, that we reduce any burden that the physician might have. So I guess with that, I was hoping that we could have a little bit of an interactive session on both the quality questions, how do we ensure the quality of the vendor and the quality of the drugs, and then also on the administrative burden. And I guess with respect to the quality, one question I would have for the Council, and actually, we can take whatever questions you might have, but what do you do now, as a physician? Obviously, some of you have practices that are more heavily involved in drug administration than others, but what are the standards that you use now in your own practice in order to ensure that you're dealing with a quality drug vendor? What process do you use? Because one thing that we're looking at is how can we harvest what's going out there right now in the physician community and kind of adopt that best practices from CMS standpoint. And from the administration, again focusing in on how anything you can think of about how you might deal with your drug vendors right, are there any practices there that we might be able to adopt that might kind of reduce any of the administration problems that physicians might encounter when dealing with these vendors? I'm willing to discuss any aspect of this, but in particular wanted to focus on those two areas. In terms of further implementation, again we're at this fact finding stage, very preliminary, so we don't have any kind of firm timelines yet with respect to rule making, but again just seeking input, and the Council's input being very valuable to us as public input.

Dr. Rapp: Dr. McAneny?

Dr. McAneny: I do have some comments. I'm sure that's a great surprise to you. First a little update, so far in 2004, with our increase in administrative fees, the 99211 increase about covers some of the administrative fees, so we lose a few percent, we don't lose our shirts. 2005, when it's 6% markup on whatever ASP turns out to be, whether or not I'm treating Medicare patients in the office is going to depend on whether the ASP markup is sufficient to account for the decrease of administrative fees. Last I checked, Huber needles cost $4.75 and they don't fall out of the sky into my lap. Nor does saline tubing, etc. and I don't have any way to bill for that. With the competitive bidding, first of all when a patient comes into the office, and we give the medicines, we try to collect the co-pay, but we know we can't often collect the co-pay. We have to bill the secondary insurer if they have a Medigap, or the people who don't have it, we accept $5 a month or whatever they can pay for that. And somehow I have difficulty imagining that a vendor is going to be willing to take a patient's word for it, particularly somebody

who may not live very long. That they will indeed pay this 20%. I can imagine that a lot of patients are going to go to their vendor with their prescription, or however you plan to use it, and they're going to say forget it. I want the 20% on the barrel head or you don't get the drug. I'm also exceedingly concerned with the inventory costs that I will incur when a competitive bidder, one of these competitive vendors, is going to send me the drugs for patient X and different drugs for patient Y. The analogy that I have had that is best for this is imagine what would happen to your grocery store's inventory cost, if they had to have a separate freezer, refrigerator and dry shelf for your family as opposed to your neighbor, and your next door neighbor, and your next door neighbor. I do not have a system in place that can keep track of that level of inventory control. Plus, if the drug is shipped to me, now, you ask about current practices. And it's cloudy, or the container is cracked or I suspect from how it's delivered that they can't prove the chain of control that the drug was handled properly on its way from the manufacturer to my office. I have enough rapport with the manufacturers that I can call them up and say, I'm not using this vial. I can pull another vial and they will replace that one. But if that's the one vial for you and you show up in my office and I cannot use that vial, I am not going to maintain an inventory of drugs to account for that because no one is paying me to account for those drugs. Therefore, I will send you, as an elderly Medicare patient, away to wait for them to ship me a new vial. Now the question is, who pays for me to ship that vial back to the manufacturer? And who is going to come in and inspect me to make sure that it truly was a bad vial and I'm not performing fraud and abuse by keeping good drug and using it for somebody else, so there's this whole level there. When the manufacturer ships me these drugs, how am I going to know this isn't diluted Taxol? Happened in Kansas City. How am I going to know this isn't diluted Epo? Happened in Florida. Who's going to take the liability when those drugs get diluted or mishandled or just sat out in the sun on a loading dock for a day and they don't bother to tell me that before I administer them to a patient? The money, these vendors are not going to be interested in setting up a business to distribute drugs for me for no profit. Where is the profit going to come out of this system that sets up their entire company, that's going to want to make money doing this? And furthermore, I get to provide them with the information, so they can track down my patients and bill them properly and bill the secondary properly. And do all this kind of stuff. I'm not the least bit interested in becoming a collection agency for a vendor. I think that there is significant problems. If I break a vial, and that happens. Last I check, we still have humans working on humans. If a vial hits the floor, if the saline is contaminated and I throw it away, you know, we can't afford to eat that kind of price. So—

Dr. Rapp: Barbara, are these directed toward the 106% ASP, or the competitive bidding?

Dr. McAneny: Both. Because they're linked together. My choices are to either take the competitive bidding, and have this company interpose itself between me and the administration of chemotherapy to my patients, and trust them to do all these things properly and be able to set up the administrative nightmare that will be required for that, or to accept 103 I think percent of ASP, whatever that is, with no increase in my administrative fees for 2006. As I understand it, those are my choices.

Dr. Rapp: How does that differ from the current system, as far as these points that you're making?

Dr. McAneny: The current system for 2004, they've increased the administrative fees—

Dr. Rapp: I guess I'm talking about the one with the 95% of the average wholesale price.

Dr. McAneny: What happened with the 95% of the wholesale price, which we all recognized was fiction, but it wasn't our fiction, it was just written for us. The mark-up on the drug was used to pay for the administrative cost because they don't pay for Huber needles at $4.75 apiece.

Dr. Rapp: How about the dropped things and the adulterated medications and all that sort of thing that you were bringing up?

Dr. McAneny: Well, we use that to cost shift. To pay for that. If it is a bad vial of medicine or vial that's cracked because I buy a lot of chemotherapy directly from the manufacture and say, hey I got this vial. They come pick it up and they ship me a new replacement drug. The other thing that they do which I'm going to sorely miss in this new system is that because I buy directly from my vendors in bulk, not patient by patient, with chemotherapy, is that they give me good programs by which I can get free chemotherapy for indigent patients. And I cannot imagine that one of these vendors is going to have the least bit of interest in donating to me any free drugs so I can treat some poor soul who doesn't have any insurance.

Dr. Rapp: OK. Any other members of the Council have some input on the issues, particularly that Mr. Thompson was interested in is how do they approach quality and the administration issues. Dr. Castellanos?

Dr. Castellanos: Barbara's points are well taken. I'm a urologist so I don't deal in her realm as much, but I deal considerably in the chemotherapeutic realm. And my major concern is cost to cost shift. When there was 95%, the people without the 20% still got their drugs and still were treated in my office. Where are these people going to be treated now, except at the hospital setting? I'm going to tell you the hospitals are not going to be able to provide that care to the individual patient. The other issue I have, and again is an issue of fraud and abuse, because we've seen that in urology where there have been cases where the individual urologist has diluted the drug, has used

another drug, and you know, there's really no control over that. And who's going to be liable there? One of the questions you asked right from the beginning is how can we get quality in this system and how can we be assured that the patient is getting the right drug and the physician's getting the right drug. I don't have a good answer under this present system except to send the patient to the hospital. And I think what you're going to find out is that the patients who don't have the co-pay—I get this now with the VA, I get patients bringing in medicines for me to give, and I feel very concerned because these medicines in Florida have been in 100 degree temperatures. I'm not sure if they've been adequately stored by the patient or the VA, yet I'm assuming the liability and I'm insuring the risk and I'm accepting all the liabilities that greatly exist in Florida today, in a very litigious state. I'm not going to have much of a choice except to say, you know, it's not worth 6%, it's probably best that I take care of that patient, bill my level three or level four, give them a piece of paper and say I can't afford this anymore. I think you better go to the hospital and get this drug because I can't do it. And that's the only way I can be really assured that the patient. The only other good thing I can see about the competitive bid, and I really would like your input is my understanding of this takes the drugs out of the SGR.

Mr. Thompson: Separate issues, there, actually. There's no, in section 303 in general, there's no provision that actually removes the drugs from the SGR. So that's kind of a separate issue.

Dr. Castellanos: It's not an incident-to drug anymore.

Mr. Thompson: Oh, you're saying if it's competitive bidding, would it be counted in the target.

Dr. Castellanos: No, the target.

Mr. Thompson: You mean specifically for a competitive bid, to what extent is the existence of the competitive bidding model and the physicians choosing that, how do those expenditures get captured in the SGR, and that I do not have an answer for you, but I have not yet heard that the administration has made it, obviously drugs in the SGR—

Dr. Castellanos: I would really like a good answer from you or from somebody, because my understanding is that would be taken out of the target. But to answer your question, I think, I'm going to take a very serious consideration because of the 6% or going to be 3% profit margin, I will probably send this patient somewhere else to get that drug.

Mr. Thompson: Just to clarify a little bit on this—that 3%, where that's coming from?

Dr. McAneny: [off mike] 3% is the administrative fee increase for 2005.

Mr. Thompson: Right, it's ASP plus 6.

Dr. Castellanos: Plus 6. It's going to be 6%, but it's going to be 3% in addition to that in 2006. My understanding.

??: That's for the administration side.

Mr. Thompson: Right. This ASP plus 6% is the payment for the drug, and then there's the drug administration, which is a separate issue.

Dr. Castellanos: Right, but not until 2006.

Mr. Thompson: The drug administration is being phased in. There was a transition period, as Dr. McAneny—

Dr. Castellanos: But just for oncologists next year, not for anybody else.

Mr. Thompson: Right. The drug administration issue as being distinct from the payment issue, so when you were saying a 3% margin, there'll be a 6% margin above the average sales price for the drug.

Dr. Castellanos: There'll be a 6% margin to buy the drug. I'll make a profit of 6%, that's correct.

Mr. Thompson: Right, if you were buying the drug at the average sales price.

Dr. Castellanos: But that doesn't include my risk of storage, my risk of breakage, inventory—

Mr. Thompson: That's correct, that's under

Dr. Castellanos:. . . that I have to pay. I mean it's probably not going to cover those expenses.

Dr. Rapp: Dr. McAneny?

Dr. McAneny: In several areas, where it is perhaps a little more rural, like New Mexico, we may have a difficult time getting any competitive into the competitive vendors. If there's just one in an area, then they could price fix. They could charge me and then you whatever it is that they want, and we are both stuck with it, so there won't be any cost savings with that. And I don't know with ASP what I've read in the Federal Register about the determinations of ASP, if everyone submits their price, and CMS collects all of these prices and looks at them as average, does that not mean that the half of the curve that is above average is immediately paying more for that drug than Medicare is going to reimburse, and therefore half of the people in the country who are purchasing that drug are already in the hole from the get go? And then if you look at it again, the next update, you eliminate that upper half, because they're gone. They're not going to purchase the drug anymore, so you've eliminated that half of the bell-

shaped curve of direct prices, so now you're looking at this? And then you eliminate that half until we end up as a single drug pricer. But in the meantime, you've pushed a lot of people out of the ability to purchase those drugs.

Mr. Thompson: I guess there's two pieces to that. One is that the statute is very explicit on the drug price, so to the extent that we wanted to vary from ASP plus 6, that would require legislative change. And the second one is dealing with the issue of price compression. Which is to what extent, what is the distribution now around the mean and to my knowledge nobody has that data. To the extent that that is a narrow corridor right now, it may be in fact the case that ASP plus 6 will cover the majority of physicians. We've heard a lot of input from both arguing both sides of this issues about are physicians getting the best prices or not. So if physicians are getting the best prices, then in fact that price compression will really occur on the nonphysician entities that have been purchasing the drugs, whether those be hospitals, for example.

Dr. McAneny: No, my understanding is that hospitals get an entire different price list than I am ever even allowed to see or supposed to know exists. And that their price list is significantly less than what is offered to any physician for use in the office. So are those prices, those hospital prices that don't exist for me, are those going to be factored into the ASP?

Mr. Thompson: I gather, again, I'm saying we've had input from both sides on this. Your understanding would be that the hospitals are in fact getting much lower prices than the physicians, but that has not been uniform public opinion. In fact, some people say that physicians are actually getting, hospitals for example would say that physicians are getting better prices than hospitals are. So in the absence of somebody actually having data on what the acquisition costs are for all these areas, as I said, one might envision, to the extent you have an ASP plus 6 model, you might see price compression in that, could envision a response to an ASP plus 6 price methodology, might be a reduction in that variance around the mean.

Dr. Rapp: All right. Dr. Grimm?

Dr. Grimm: Pardon me for being a bit confused about all of this. And I am just entering into this to understand the process what's happening here and what you're trying to ultimately do is reduce the cost of Medicare for drugs, correct?

Mr. Thompson: I think the goal here was not necessarily, not cost reduction necessarily. I believe that the goal of the legislation was really to kind of pay appropriately for the drugs and pay appropriately for the administration, so as an overall goal, you had this cross subsidy going on, where the profit on the drugs, the spread

on the drugs, was cross subsidizing the administration, which is not really a great system to be under. So I guess I would kind of say that the goal of the legislation was to pay appropriately for the administration and for the drug, and not have one cross subsidize the other.

Dr. Grimm: The other issue is that for me when I look at this issue, this would only apply to drugs that have equal effectiveness. Is that correct? Because if you're competing against, if one company builds a better drug, they come out with a better drug, and you're compelled as a physician to prescribe that, then there's really no competition at all because you're compelled as a physician to give the best to your patient. So there's no competition there at all. There's only for generic drugs in which three or four companies can produce, which we'd have a competitive bidding situation anyway. Is that true? It's going to be a limited number of drugs that's going to actually apply.

Mr. Thompson: What the statute envisions; there is a section of the law that speaks to when you have multiple products brand of generic equivalents within the same billing code, so within the HCPCScode. That the vendor is required to provide at least one of the drugs within that code. So that's the scenario you just discussed, which is, you could envision competition within a HCPCScode where you have drugs with generic equivalents. On the other issue, the individual codes themselves, like a unique drug that would still be under patent, manufacturer, the drug vendor would give us a price for that, and at that point, most of the competition, you would envision, would come from one of two sources; either they're more efficient at being able to reduce the cost of getting the drug from the manufacturer to the physician, so that distribution cost, it would compete on that for a branded drug. Or, in fact, if they have they can predict sufficient volume, they can go to the manufacturer in that particular situation and try to get a price cut that way. So the vendors would be competing for essentially two things; one is to reduce the drug distribution cost, and the second is to try to get a better deal from the manufacturer for volume.

Dr. Rapp: I think I'd like to draw this to a close, since we have the PECOS system, which I know is an important issue. I think it's an important one, we've got a law that says that this is what they're going to pay. Right? 6%. So it's, we can argue about well that's not enough, or we should have a different law, but what Mr. Thompson is asking is this the law, this is what's going to be implemented. There are legitimate issues with regard to maintaining quality and so forth, so to the extent that we can give some input on that, I think that would be helpful. If we simply just say, well, that's a bad law, whatever, I'm not sure we're going to give him that much helpful information. I would like to draw this to a close with Dr. Urata's question or whatever, and then I'm sure we'll have some recommendations on this, and when we do that, we can do that after we get done with the PECOS system.

Dr. Urata: I thought you had a question about how things are done now, about how we get our drugs? We buy our drugs from the— and this is a small family practice clinic in Alaska, we buy our drugs from a purchasing group, down in the continental United States, and we find that we used to buy it from the local pharmacy, but with the purchasing group, it's much cheaper for us. We don't use very many, mostly just some anti-biotics, and Toradol for pain. We used to have narcotics, but we got broken into by people who were looking for narcotics, so we've eliminated narcotics and valium except for emergencies. And since we have a crash cart, so we fill that with medications from the hospital. It's pretty expensive getting it, but it's like one vial of this and one vial of that.

Dr. Thompson: And do you know what criteria your purchasing group uses, when they determine where they're going to get their drugs from, do you know what criteria they use?

Dr. Urata: I'm sorry. My administrator does. But I can give you his name if you want to talk to him about that.

Mr. Thompson: Sure, absolutely.

Dr. Urata: And you had another question about how would we be able to get information to a vendor for things, and we make a copy of our face sheet, which has address and insurance information on it, but I'm sure some vendors would probably send us a form and we just have the patient fill it out and send it back. Now we have NPI.

Dr. Rapp: Thank you very much, gentlemen. I know this is an ongoing topic and project and I appreciate the—

Mr. Thompson: I'm sure I'll be back.

Dr. Rapp: The next item on the agenda is enrollment in the PECOS systems, Dr. Rogers, I believe, had to go, but Mr. Loyal, good afternoon, you're back. Director of Division of Provider & Supplier Enrollment for the Office of Financial Management. Thank you for coming. And what good news do you have for us?

Mr. Loyal: Dr. Rapp, I like to think I have some good news for each of you. We think we're making some significant strides with regard to correcting the situation that each of you find somewhat unsettling. As you're aware, each of the carriers had accumulated substantial backlogs. And we've been attempting to alleviate that process. We're going to take a number of steps to try to bring some order to the process. Ironically, one of the things that we learned from this process is that many of the individuals at our carrier sites did not truly understand provider enrollment. So we've undertaken a significant effort to see that the message gets out with regard to the content of provider enrollment manual chapter. But additionally, what we've done is to make some adjustments in our PECOS

system. Provider chain ownership system that we have, which essentially is an electronic data base system, which house all of our provider records—which is intended to house all of our provider records eventually. Additionally, our carriers, as I implied have gone through what we consider a substantial learning curve, not only with respect to provider enrollment, but understanding how PECOS can work for them, each of them. It's been a struggle. We've obviously identified some things that we probably could have done a little better as far as implementing PECOS in November of last year on the Part B side. Things went very well on the Part A side, but the Part A side as you know is not the same volume in terms of enrollment activity. We've also sent inter-disciplinary teams out to each of the carrier sites to look at what they were doing and how they're doing provider enrollment. And we've had to correct a number of abhorrent performances, and a number of redundant type activities to bring about the improvements we're now seeing in the area of provider enrollment. Subsequent to that, we have formed what we call Carrier Response Teams, which means that each carrier now has a team of central, regional and contractor personnel working directly with them on a daily basis to address any concerns, questions, etc., relevant to either PECOS or the provider enrollment process, or applications that they have pending. We want to eliminate some of what we see as overdevelopment by Medicare carriers and a number of instances, which obviously creates a burden on the health care community, when the carriers are asking for more information than is required by our existing instructions. These carrier response teams report to upper management weekly and we're beginning to see some substantial improvement. Of the past couple of months, we've noticed gradual decrease in the backlogs at the carrier sites. During the 3-week period ending May 7th, the backlog was decreased by 8,000 applications and we expect to see greater decreases during the coming days and weeks. During the next 3 days, the 19th through, the 18th through the 20th, we're holding a 3-day provider enrollment training session for all carrier personnel involved in provider enrollment and our regional office staff and does involve Central Office people here in Baltimore, I mean in Baltimore. This session is designated as a training session. We expect that as a result of this, individuals who come in from the carriers will be able to go back and make further improvements in the way they do business and to facilitate the processing activities that currently exist at their respective sites. The administration has approved for each of the carriers supplemental budget funding. So contractors have been hiring additional staff to help them deal with their respective backlogs of applications. We expect to see a continuing trend of the decrease in the backlog. We've also commissioned the establishment of what we call a transitory database. What the contractors have told us is if we could find a way to reduce the keystrokes that they are saddled with regard to entering data into PECOS

system, it would further facilitate their ability to process provider enrollment applications. So what we have done is to identify all the key fields that are essential for getting provider enrollment information into the PECOS system, and we designate what we call a transitory data base. This information will be keyed in by the additional personnel that the contractors are hiring so that when an applicant comes in; for example, a group practice, the group will already be in the transitory database and can be downloaded into PECOS electronically and this should facilitate the ability for the carrier to link up a provider coming or a physician coming in who is reassigning his or her payments to a group in a more expeditious manner. With regard to suggestions made by PPAC relevant to seeking ways to potentially pay interest on claims involved in delay, I can only say at this point that our Office of Financial Management is presently looking at those situations in which physicians already in the program are making changes with respect to their enrollment activities and have claims in the system, the administration is looking at what can be done in those specific situations to address the concern of potential interest. I don't have any concrete information which way that's going, that study is not being done in my division obviously, but I want you to know that that phase of it is being considered. With respect to individuals already in the system who are making changes and the changes have not been processed by the carriers, to the extent that we learn of those situations and they represent what could be considered hardships, we are asking the carriers to take expeditious action to process those applications. Contrary to something I read, I don't recall if it was in the PPAC material, someone indicated that a carrier said it had instructions to delay processing new applications until the backlog was cleared up. And that is not a CMS instruction. What we've told contractors, both in our onsite visits and our daily communications with them that they should be processing both sets, new and pending applications. They should find a way to devote their staff to handling both, because setting aside the new applications is only going to create another problem down the road. So we want them to devote attention to both parts of that workload activity. Some contractors are doing a better job than others. Of course, those contractors went through the learning curve a lot better than others for some reason, but at this time, we believe that we're making great strides and we hope to see substantial improvement the next few weeks.

Dr. Rapp: Dr. Castellanos?

Dr. Castellanos: I didn't raise my hand, but I'd like to make a comment. [laughter] I think you're right. Things are getting better. I can tell you they're still not perfect, and the real problem now is the reassignment, person who's changing a group and they have four to five months' backlog of fees, where these people are not going out, at

least in my community, and going to a bank, borrowing money to pay their expenses, they're small businesses. But I think in Florida, and I did talk to this carrier medical director that he is making strides. It's been a learning curve for you and it's been a learning curve for them, and it's been unfortunately a financial burden for the physician. But I think you are making progress at least with our carrier.

Mr. Loyal: Yes, and we apologize for the burden that's been experienced by the health care community. We'll try to make it up to you.

Dr. Gaughan: Mr. Loyal, I do hope you're just the messenger, so I don't have to shoot you [laughter], but I have several comments. One, I came prepared to speak about a letter that we sent to our senator in Kansas and I'm going to summarize that and then ask three hard questions. But in listening to your presentation, I couldn't help but think of some questions, and one, I will say we have something called preventive medicine. I find it hard to believe that CMS does not have some preventive program and should have predicted way before hand training of providers. You said what, that providers didn't understand. Well why? Why weren't they trained? Why wasn't this done ahead of time? Who pays for it? The physician. You said that there was a learning curve. Well you know do some pilot projects, get some people out, train them, then switch—these are just future suggestions, and I hope you didn't think of this plan. Again, you work on it, get the people going. We just got a new computer system in our office, and we didn't just say here's one day of training. OK, everybody, do the billing, or I wouldn't make any money for a year. We have had extensive training. We looked into all the things we needed to do. We planned ahead. Sure there's a few glitches, but certainly not six months delay and if I ran my business the way CMS ran this enrollment program, I wouldn't be here today. You also stated, and again, it's just you you you, I'm sorry.

Mr. Loyal: That's all right.

Dr. Gaughan: I understand that you're a messenger and I do not have any weapons. I know this is a federal building [laughter], seriously I don't, not even a nail file because I flew here. Interdisciplinary team sites that you're doing to go out. You know, that's wonderful, I don't think Blue Cross—now, just so you know, Blue Cross Blue Shield of Kansas City which has Arnie Barlonoff, that covers the Kansas City area, I'm speaking for the state of Kansas, which is Blue Cross Blue Shield of Kansas, I personally have been down to their office. I know their carrier medical directors, and I do not think they're a bunch of stupid ignorant people, and I do think that they have the ability to learn, so these interdisciplinary teams site visits I think are a great idea, but you know, they should have been done way in advance. Having a problem, delaying payment, costing money to physicians, and then saying you

may pay interest only to those doctors that are re-enrolling is not fair to those doctors that are the new doctors which we'll get into in Kansas is the problem. I guess I could just go one and on. It's great that you've got 8,000 decrease, too bad they're not in the state of Kansas. And also, I'm glad you're doing some three-day training, but again, should have been done a long time ago. And I do think that this is no way to run a business. I think you need to plan ahead. I think if other businesses ran this way, they would not be here today. As you can tell, I feel very strong about this issue. I've done a lot of research into this issue, because this is not only an issue in Kansas, but in rural states, and I have been getting 50 emails a week on this issue, I guess physicians knew I was interested and I opened my mouth once too many times. So now that I have thoroughly, sorry, it was not personal. But I'm just saying that in the future when we look at plans, it's just like Dr. Rapp said before we have the things to look at and to try to make suggestions before hand, before these things go into effect. If you had a planning group that looked into this, I seriously would consider having them change their job. I just think that this is sad and I'm not going to say anymore because I'm obviously getting too emotional on this. This issue, it's the end of the day, because I've had enough time to sit here and get hot. So now I'll go into something that's going to make Dr. Rapp very happy. And I'll tell you why. I'm speaking for the Kansas physicians, however, I find it very hard to believe that other states aren't experiencing similar difficulties. I'd like to summarize a letter as briefly as I can, and Dr. Rapp, it was 8 pages written last night and I've gotten it down to 3, thanks to staying up til midnight and not going out to dinner with everybody.

Dr. Rapp: Come to dinner next time.

Dr. Gaughan: Come to dinner. Really, I know.

Dr. Gaughan: I have before me a letter, which I have given to the transcriptionist because I tend to talk fast, written to Senator Pat Roberts from Kansas Medical Society our Executive Director. I don't know if you know Senator Pat Roberts, but he has a lot of rural interests and he also sits on a lot of very important committees right now. I am then going to ask three questions of Medicare. I will tell you that the purpose of the letter was to express Kansas's physicians' concerns not only for ourselves, but more importantly for our patients, since the November 2003 and I'm going to say it, Provider Enrollment Chain and Ownership System, PECOS?

Mr. Loyal: That's it.

Dr. Gaughan: OK, because I hate to use abbreviations that no one knows what we're talking about. The primary concern is the inability of the system to properly enroll Medicare physicians and other providers. Kansas

Medical Society has discussed this concern at length with our medical carriers Blue Cross Blue Shield of Kansas, as well as CMS representatives here. This has been futile. Now I'm going to give you five fun facts from Kansas. And they're in this letter, which if you'd like to be made part of the record, it was sent to Pat Roberts, and I've been given permission for you all to have it if you'd like it. Number one, Kansas Medicare carrier has 2,852 pending applications waiting for processing. This is two and a half times the number that we had since November of 2003 when PECOS went into effect. Now that says something to me. I don't know if it says something to you. Number two, 50% of these pending applications, which is 1,426, are over the 60-day processing request time established by CMS. Number three, the delay in the Medicare provider number creates a significant financial burden for smaller rural physician offices, who have a high percentage of Medicare patients. Number four, Payola, Kansas, and I'm sure you all know where that is, but it's a small community, 40 miles from where I live, is a town that needs physicians. And it added a physician over 6 months ago. And this physician, I will call Dr. Payola out of privacy issues, because I believe in them even without HIPAA applying to this, and he waited and he went through all the channels, and the hospital called for him, couldn't get it. But finally, after no number, no billing Medicare, and no payment, I am pleased to report that he recently got his Medicare number. He obtained this by writing Congressman Ryan, who interceded for him with CMS. So that took I won't say an act of Congress, but we had to go to his Congressman. Fact five, last fun fact from Kansas. Unfortunately, Dr. Payola's enrollment delay problem is not isolated in Kansas. Kansas is a rural state with many medically underserved areas. Obviously, physicians need to be recruited and retained in Kansas to care for Medicare as well as all our other patients. Again, no provider number, no billing Medicare, no payment. Now, in my opinion, I'm going to assume that this leads to no physicians willing to practice in rural Kansas. And that is my assumption, not a fact. Now finally, three hard questions for CMS. Number one, in July of 2004, new residency graduates will be entering the practice of medicine across the country. How can Kansas expect to recruit and hopefully retain much needed new physicians with the serious delay in obtaining a Medicare number? So that's all these new grads getting out. What are we going to do? Because we can't pay them. Number two, since 1,426 Kansas physicians are waiting now for more than 60 days for a number, what is the data from the other states? I know you told us the data of the 8,000, but what is happening in these other states, nationwide? Kansas cannot be the only state having a problem and we don't even have that many people in Kansas. Number three, now you've covered some of this, and you've told me what you're about to do, but it's not quite fast

enough for me. What is CMS doing now to immediately correct the unacceptable, unfair business practice of delays in the Medicare provider enrollment process? Thank you.

Mr. Loyal: OK.

Dr. Gaughan: [chatter] I think this is an issue that is not just in Kansas and I'm very concerned about it.

Dr. Rapp: Well it is important issue and I think that some of the details that you gave are helpful. I don't know if you have any particular response, but. . .

Mr. Loyal: Yes, I do. I appreciate the comments made and we understand that there has been a hardship and there is a continued hardship among a number in the healthcare community. And we are trying to address it. With regard to the new graduates, we have asked contractors to hire additional staff to enable them not only to reduce their respective backlogs, and to try to get those backlogs down during the summer, but also to be able to handle the new graduates coming out of school. So each contractor was asked to submit supplemental budget requests along with some indication as to how they were going to use this to make themselves current during this fiscal year. So we're expecting that the funding in some cases additional funding. In other cases, what the contractors will be doing is shifting monies from other line items that they are not going to use, that they didn't expect to be able to use to the provider enrollment line item, so that they could secure the additional staffing or resources they need in order to handle the provider enrollment applications.

Dr. Gaughan: I was just hoping that wasn't in physician education, because that seemed to be the first thing that went in our state, so when you said using it on things they're not going to use, the only thing I could think of in Kansas was less provider reps, less people coming out to your office.

Mr. Loyal: Well before they shift any funding from any line items, they're going to have to get concurrence from the other areas to make certain that they are not going to cause any either irreparable harm or any problem in the area such as education since that's a concern to your particular contractors, then I'm sure they're not going to be shifting them from that area. Let me make a comment with regard to training. All the contractors in the program now have basically been in the program since its inception. And what we did prior to the implementation of PECOS was to ask each contractor to furnish representatives who would attend training in Northern Virginia in PECOS and these individuals were to be trained trainers. They were to go back to their respective contractors and train the steps. Obviously something happened in that training the trainer that did not retranslate when individuals returned to their respective operations, because we saw in some cases some significance variance in the understanding of how

PECOS worked, what each of their employees should be doing with regard to getting data into PECOS and also processing applications. But as I said earlier, one of the glaring things that came out of it from the conference calls we had with individual contractors to find out what problems you are experiencing as a result of entering PECOS, was that we had assumed that carrier personnel in the provider enrollment area were very knowledgeable in the area of providing enrollment. And that was not the case at each contractor site. We found that a number of employees were either overdeveloping, holding on to practices that the carrier had implemented prior to our implementation of a national enrollment process, which meant that it was no longer necessary. They were doing things that they'd done in the past, which were not necessary. Those actions were only creating additional burden for the health care community by requiring certain signatures in places where we didn't need it, asking for additional documentation where it was not needed, and that slowed up the application process. We received some of the same complaints that you referenced earlier about why contractors were asking for certain information. When we learned of that, we tried to bring that to the attention of the various contractors involved and there were a number of them. So we also found in one contractor situation where employees were duplicating efforts. We found, we sent people on site and we found that a contractor had created a pod of several individuals to review applications and once that pod reviewed that application, it transferred the application to another pod, and that pod reviewed the actions of the first pod, and in that situation, there was a third pod that reviewed the actions of the first two pods. So these were things that should have been picked up by CMS obviously with onsite reviews with a regional office staff, and I'm not casting blame on the regional office staff, but these are things that should have been picked up and so we should have been aware of them so that we could have corrected them. So there was training, the only thing, the two things that I think we could have done better, last year, we canceled plans for having our 3-day provider enrollment training session, which we're having this year. We've had one each year since we've been involved in provider enrollment except for last year. And the reason we canceled it last year was because we wanted to use the money to finance personnel at the contractor and the regional office level attending to PECOS training. We thought that would be money better spent. And so national provider enrollment training last year. This year, obviously, we're having them in three full days. With regard to other states, you are correct. Other carriers are experiencing backlog problems. Presently the backlog is down to, nationally, counting enrollment applications, change requests and reassignments, it's presently at 100,149. That's the national pending.

Dr. Rapp: Does backlog mean more than the 60-days or any?

Mr. Loyal: Well that's what we're trying to get a fix now on, what's the age of the applications in the backlog package in terms of how many are beyond 60 days or a 90-day period—

Dr. Rapp: So you don't have a distribution of the accounts receivable so to speak? The aging of the –

Mr. Loyal: Not at the moment. PECOS is capable of producing certain reports. We have a team of individuals who are trying to who are trying to come up with the kinds of reports that our carriers, so they need for management purposes and also the CMS needs for ongoing operational purposes, so among that will be the age of applications in the system.

Dr. Rapp: Can I ask you about what your reaction is to, I mean it seems to me that this is potentially pretty serious, and I know the Council is kind of concerned about it, and the individual doctors are, and certainly, some of the stuff that Dr. Gaughan had mentioned is kind of alarming, but the American College of Physicians in their statement suggested consider assigning a temporary UPIN number to physicians so there could be some way to, it sounds like kind of an emergency. Since I'm an emergency physician, we like to figure out some immediate action to take as opposed to well, let's see if we can't send them down the road. So that just sort of appeals to me. Is that possible, to assign a temporary UPIN number, especially for people over the Congressman got some immediate action, somehow, something got done. Is there any kind of immediate steps that you think can be taken to deal with these outliers. The ones that are, well Dr. Castellanos was telling me there are people that he talked to down in Florida that were waiting four months, and all they were doing was reorganizing their group to get paid. And it sounds kind of outrageous.

Mr. Loyal: And we're hoping that you can bring those situations to our attention, and we're asking the carriers to expedite those situations. With regard to the assignment of UPIN or a PIN, which will be necessary to the processing of claims, we looked at that subject, meaning CMS, and we looked at the concerns that IG has presented to us etc., and for the moment we're determined that for new applicants the administration is not prepared to assign temporary numbers for new applicants. And where we have parties who are already in the system, who have established a relationships with us, we believe that there should be some kind of relief provided for those individuals, especially where the parties were being paid, and they've made a change in some enrollment data and as a result of submitting the application, the payment process has been abated or they're not able to submit claims now until that action is completed. So we're looking at some way of remedying that kind of situation.

Dr. Rapp: What about a system where CMS solicits doctors' complaints on this issues; that is you have submitted this and you haven't heard in 90 days or something like that, that you tell us and we're going to get on this.

Mr. Loyal: Exactly. That's what I'm saying You have situations like that, we want to know about it.

Dr. Rapp: How about putting it on the website? Encourage, invite people to, if you've got a problem with your carrier, we're concerned about this situation, tell us. And we're going to get after it.

Dr. Gaughan: If you wouldn't mind telling me, I'll call AMA News and ask them to put that in the AMA News.

Dr. Rapp: It's very reassuring what you say in certain respects, but it's alarming in other respects because from some personal experience, well, I know you submitted this—nothing to do with enrollment, I'm not dealing with that, but OK, well it's in the system. Well, is there somebody I can talk to? Well, no, we'll get to it or something like that. And you sort of feel that way. And if CMS sort of was outgoing to the physicians, saying we know we've got a problem with this, we don't like it, we're trying to remedy it and this and that and the other thing, however, for those of you that this is presenting a real problem to, here's how you can contact us. It's really the carriers doing it, but we will basically put the heat on them.

Dr. Gaughan: My comment was that not everybody goes to the website and if there was other ways we could get this out, I know there's [off mike]

Dr. Rapp: And you get that aging report pretty quick that way, too.

Mr. Loyal: Yes, you would.

Dr. Rapp: People, you not only get an aging report but you get an assessment of the degree of urgency that it is creating for people, and so maybe if they're just letting it go, OK, 3 months, 4 months, I'll go to Europe for a while, for people that it's important to facilitate their communication might do a lot to lessen their concern, too.

Mr. Loyal: Yes, and the carrier response teams that I referenced earlier assigned to each individual contractor, when those type cases are brought to our attention, they are given immediately to the carrier response teams, and the carrier response teams are, if you will responsible for seeing that the carrier takes immediate action on those cases.

Dr. Gaughan: Now, would you like me to contact the AMA and have them send you the report, or would you like to contact them?

Mr. Loyal: Whichever you prefer. Whichever is more convenient for you.

Dr. Gaughan: I'd trust you.

Mr. Loyal: OK.

Dr. Gaughan: If you would like to call, I'm sure that, I don't know if Jack Emery's still the—

Mr. Loyal: Jack Emery?

??: 789-74 [inaudible]

Dr. Gaughan: I think Jack Emery would be the one to get it out, who at least knows physicians, and if you all on the committee have other ideas to get it out through your society, you know, I mean we can get this out to all the different specialty societies. And Barb, since you're on the AMA Council thing, you could probably get the AMA to send it to every delegate, yeah, state, and especially society. Because I agree with Dr. Rapp this is key, and I do think my point, which was my third question and thank you for answering the other two honestly, was what immediate action, and just like just maybe you don't know about this, but in hospitals, when you credential people, when you take somebody that just got out of med school or has never been, hasn't been in practice at all or is just getting out of med school, it's clean, their record's clean, they get fast tracked. I mean they've had no time to commit felonies, they haven't had 8 licenses in 7 states and killed 15 people. They're fast tracked, so when I hire a new doctor, that's a fast track credential. OK, so a new doctor actually gets fast tracked. Now, when you've had doctors who've been out a while, who, as we all know, could have been in Iowa and then we get a few from Texas, I'm sure you get Arkansas, because those doctors keep practicing, but I don't know how you do it, but it just seems like you said physicians that have been doing it a long time--

Dr. Rapp: We'll call the question here. Anything else?

Dr. Hamilton: Well, I know this has not been much fun for you obviously you have been sitting here listening to all this. Let me ask you a question. When or will you be able to come up with a definitive date when this problem will be resolved, based on the information and the work that has been going on?

Mr. Loyal: Well, based on the feedback we received from the contractors as part of looking at the supplemental budget requests for this year, it looks like most of the contractors are expecting before the close of this fiscal year, meaning September, to be back to their pre-PECOS levels.

Dr. Hamilton: So by August 31st, this probably basically should be resolved, is that—

Mr. Loyal: Should be close to being resolved.

Dr. Hamilton: And your contracts with this groups out here, are there certain penalties built into these contracts in the event that they don't perform according to whatever the standard might be?

Mr. Loyal: Well, the administration always has at its disposal, as you know, these are cost contracts, which are renewed annually unless the administration decides or the contractor and the administration decide that the contractors won't be extended. The administration looks at a variety of things in determining whether or not to retain a contractor from year to year and then that's been the process since the inception of the program, and so this year like every other year, the administration will be looking at contractor performance to determine whether or not the contracts should be rolled over to the next year. Provider enrollment is only one aspect of the contractor evaluation process.

Dr. Hamilton: Just in general, when you sign contracts, like somebody's going to paint your house or something, if they do a good job, they get a bonus. If they do a bad job, they don't get paid the last however much. To me that's a pretty good way of doing business. I think most people like to do it that way, I would suggest that might be one you guys consider. But let me ask you something specific. I don't believe I have personally applied for anything under this PECOS system. But we've all of us have applied for many things over our careers. What is it about this system that makes it so much harder to get resolved than all of the other myriad of things that we have applied for over the years. Is there something about it?

Mr. Loyal: From my perspective, I didn't think it was a difficult system. I mean as I envision and saw it unfolding, and we still believe that it's going to be a viable system and be practicable for all involved, but to get to your point, your question. For some reason, individuals found that they either had problems moving from PECOS to the claim system and we, too, found that the interaction between the PECOS system and the established claims system, which was supposed to be a smooth process, didn't work out as smoothly as we had planned it. Additionally PECOS is on the CMS main system. Now, when the CMS main system goes down, or can't handle a certain number of concurrent users, then you're not able to access PECOS, so what had to be done over the past 2 months, is that we had to acquire some additional service, and we also had to make some adjustments in the CMS main system in order that the number of concurrent users from carriers across the country, was one that was sustainable on—

Dr. Hamilton: So this wasn't so much a matter of the information that you were seeking, it was a matter of the system's ability to digest this information.

Mr. Loyal: Well, not just software problems. I mentioned earlier, there was a learning curve to go through, but there was some concern in the systems area that we had to address. We also made a step back and took a look at what we were asking for in terms of provider enrollment actions of the Medicare carrier personnel, and we made some adjustments there, and as you may have noted, we revised our provider enrollment manual to reflect those changes.

Dr. Hamilton: Thank you.

Dr. Rapp: Thank you, Mr. Loyal. We appreciate—do you?

Dr. Gaughan: Yes, I do. And you can't call the question, I'm just further discussion here.

Dr. Rapp: I know but we can end it up, what do you need to—

Dr. Gaughan: I just wanted to clarify a point. I thought you said that you were looking at giving physicians that already had numbers that were switching to other groups interest, but you were not looking at giving interest to the new physicians—

Mr. Loyal: That's my understanding of the review that's currently underway.

Dr. Gaughan: Then I have a recommendation at the end of this, when we're ready for that.

Dr. Rapp: We're going to get to recommendations in a second.

Dr. Gaughan: Thank you, Dr. Rapp.

Dr. Rapp: You're welcome, Dr. Gaughan. If there's nothing else, thank you very much. Keep up the difficult work. We have, I believe we have one person from the EDPMA, Emergency Department of Practice Management Association that wants to give some oral testimony. Yes. This is with reference to the Federal Reimbursement for Emergency Health Service Furnished to undocumented aliens.

Mr. Feore: Correct. I'll keep it brief. My name is John Feore. I thank you for hearing my brief statement. On behalf of Emergency Department Practice Management Association, we represent Emergency Department medical groups, we do billing companies, consultants, and vendors who support ED medical groups. EDPMA members provide patient care and ED management services to approximately 25% of the estimated over 100 million emergency department patients in the U.S. We appreciate that CMS is on a tight timeframe for implementation of section 1011 of MMA. EDPMA believes the intent of this section is that the full range of providers who incur costs providing care to undocumented aliens receive some compensation. We recommend that CMS not rely on states to funnel these funds to the appropriate providers. Instead, CMS should make payments to the entity that typically

bills payers for the emergency services provided to patients. EDPMA participated in an open door policy CMS in March on this issue. In the call, CMS identified challenges to developing a payment methodology in this area including how to insure that the methods and procedures selected to implement this provision do not impose requirements on providers that are inconsistent with their EMTALA obligations. EDPMA believes compliance with EMTALA is critical and we applaud CMS for identifying the importance of EMTALA and the role that EMTALA compliance plays as it considers implementation strategies for Section 1011. As you know, hospitals and physicians are sensitive to asking patients questions unrelated to their medical condition that could be interpreted as discouraging the patient from staying in the emergency department and receiving treatment. EDPMA is concerned that any type of question related to immigration status would be particularly sensitive and could be interpreted by the patient and/or by state surveyor as discouraging the patient from staying in the ED. We believe the registration policies and procedures currently in place have been developed with patient care, EMTALA compliance and payer needs in mind and we urge CMS to not require hospitals or physicians to collect data related to immigration status during their visit to the ED. EDPMA believes that it may be possible to develop criteria to serve as a stand-in for undocumented alien status. For example, if a patient does not have a social security number or insurance, he or she may be an undocumented alien. EDPMA believes that although standing criteria may not be perfect, it may be an appropriate way to determine the patients that are likely to fall into the undocumented alien category. This information is already available and would not require additional burdens on the hospital or physician. EDPMA believes that no changes should be made to the administrative procedures currently in place and that no new questions be added in the patient registration process. Instead, CMS should develop standing criteria from the data typically found in the patient's registration form. EDPMA requests that PPAC recommend that any payment methodology developed in this area not require new questions be added in the patient registration process. EDPMA also requests that PPAC make a recommendation to CMS to model the payment methodology under Section 1011 on California's system for reimbursing providers for indigent care. This program has been in place for over ten years, and although the system is not perfect, it may provide a good starting point for how to think about processing and prioritizing claims. Specifically, CMS may wish to consider the following elements of the California system as a good model for the federal disbursement of funds: one, funds are allocated by formula into three separate pools: hospitals, physicians, other providers, such as EMS; two, payments are made quarterly, with remaining funds at close of fiscal year paid out as an additional distribution; and three, providers seeking payment complete a one-page

statement certifying that they are eligible for the program. At this time, however, we do not believe that in following a California-like model is appropriate to submit individual claims forms. Instead, we support a formula driven approach based on the parameters that identify the amount of uncompensated care associated with the provision of emergency services, to undocumented aliens. This formula could be based on the relevant hospital's bad debt. We're concerned that any submission or review of actual claims could be burdensome for providers and may have implications under the False Claims Act. EDPMA appreciates the complexity of CMS' task in this area and the opportunity to participate in this forum. We hope these preliminary comments are helpful. We thank the Practicing Physicians Advisory Council for considering our request and we look forward to working with CMS and PPAC as it further develops its approach in this area. Thank you.

Dr. Rapp: Just a question, do you really mean that CMS should make the payments to the biller or to the entity that's entitled to the payments?

Mr. Feore: The entity that's entitled to the payments.

Dr. Rapp: OK, any other questions? If not, thank you very much for your testimony.

Mr. Feore: Thank you.

Dr. Rapp: All right, now we have, I think we've got some areas that perhaps members of the Council want to make some additional recommendations on, so the floor's open for that. Dr. Urata?

Dr. Urata: I'd like to make a motion to update PPAC on the next meeting on the primary care providers prescribing power wheelchairs issue that was referred to another committee. So just a simple update.

Dr. Rapp: Update on . . .

Dr. Urata: The recommendation that PPAC made to CMS.

Dr. Rapp: With reference to whether primary care physicians could be the ones that prescribe it. OK, is there a second to that?

[second]

Dr. Rapp: Discussion? Read it please.

Ms. Trevas: PPAC recommends that CMS update the Council on the status of primary care providers prescribing power wheel chairs at the next meeting.

Dr. Rapp: All in favor?

[Ayes]

Dr. Rapp: Anybody opposed? That motion is adopted. Next, Dr. McAneny?

Dr. McAneny: The first one is PPAC request CMS to request that the Office of the Actuary report back to PPAC on why they feel the MEI indicators developed in the 1970s reflect the current costs of practice in 2004.

Dr. Rapp: Is that what they feel?

Dr. McAneny: That's what we were told.

Dr. Rapp: I'm not sure they phrased it quite that way.

??: Isn't that what you said this morning, Ken?

Dr. Simon: 2000.

Dr. McAneny: 2000, that'll do. We request that CMS request the Office of the Actuary report back to PPAC on why they feel the MEI indicators developed in the 1970s reflect the current costs of practice in 2000.

Dr. Rapp: Is there a second to that?

[second]

Dr. Rapp: Is there discussion? OK, all in favor?

[Ayes]

Dr. Rapp: Anybody opposed? All right, that's adopted.

Dr. McAneny: I would like to make some recommendations on the competitive bidding. I've got to find it here for a second. I would like to say that PPAC recommends that before CMS implements the competitive bidding system that the following list of issues be address: patients without co-pays, how they're going to protect physicians from increased inventory costs, how they're going to help physicians with the administrative costs, how they're going to ensure that drugs are appropriately handled, who is going to pay for the shipping for the wrong drugs sent, or for a change in therapy, and who will be responsible for the accuracy of information on the patient given to the vendor, how they are going to handle indigent programs, and how they are going to ensure that vendors pay for the administrative cost of inventory tracking, etc.

Dr. Rapp: Is there a second to that? OK, the only question I have is that it's not giving them any recommendations. I mean I'm sure they're going to come up with regulations. Do you have any idea, it seems to me anyway, it's better to give them ideas rather than just say well tell us how they're going to do it. I'm sure they will, eventually with regulations.

Dr. McAneny: Well the recommendation was that before they implement this competitive billing system that they address those issues with some plan, and not just implement it and then go back and attempt to fix it. We just heard a whole discussion on what happened with PECOS when they implemented it and then tried to go back and fix it and it's a mess. So before they implement this system, I think the following issues should be addressed, and that's why I'm suggesting this.

Dr. Rapp: The last one you said, who will be pay for what?

Dr. McAneny: That vendors for the administrative costs of inventory tracking.

Dr. Rapp: Inventory tracking, so—

Dr. McAneny: And other inventory type costs.

Dr. Rapp: So you're suggesting that vendors pay for that.

Dr. McAneny: Right, that they should pay to track whether they shipped it properly to my office or sent it to someone else's office.

Dr. Rapp: Wouldn't it be better just to recommend that? As opposed to how they're going to figure out how to do it?

Dr. McAneny: Well, I think the vendors need to pay for tracking the inventory and for the shipping and for all the inventory costs since they're the ones that are going to get the mark-up to take care of it.

Dr. Rapp: That's what I'm suggesting. That you actually make that as a recommendation, as opposed to how are they going to do this. They're going to implement, are they not, or maybe Dr. Simon could tell us, or Mr. Kuhn, is not CMS going to implement the competitive bidding process, because the statute requires?

Dr. Simon: That's correct.

Dr. Rapp: So that's going to be done.

Dr. McAneny: Right. And in the process of doing that, I want them to look at how they can ensure the vendors are going to pay for those administrative costs and that they're not going to pass that on to the physicians. I didn't think it was unclear.

Dr. Rapp: OK.

Dr. Senagore: I guess it's not clear—is the system envisioned to be another mechanism for the acquisition of drugs, or is to be a pharmaceutical delivery system for ready to dispense medication? Two very different economic models. One would be just in time transport, if I do it once a month and you do it ten times a day, we get

the same price, it comes ready to go, I just plug it in and deliver it, the other is I'm buying 10 milligrams and you're buying 100 milligrams.

Dr. Rapp: Which do you figure should be the—

Dr. Senagore: I would figure that it's a just in time delivery system for everybody so that I have the same standing in the marketplace as she does.

Dr. Rapp: Maybe we should recommend that and tell them that that's the concern,. Because I think it would be better to tell them what we think they should do rather than....

Dr. Senagore: Because see in the competitive bidding process, we're going to be establishing [off mike] so thoughts like that are helpful.

Dr. McAneny: But I think that if there's a competitive bidding model, then that would allow each physician to decide whether they wanted just in time, because if it's late, and the patient's there, [inaudible] go away and come back the next day when their drug arrives. Or change therapy. I don't agree with that. So I think if there's any advantage to a competitive bidding model, and I frankly see very few, that at least I ought to be able to select those parameters that would be fit in with what I do in my practice. So, but I think those are the issues. What I'm asking in this is that before they just implement this, that they have a list of criteria that they're going to have the vendors offer; that they're going to address these issues so that it's clear to us when we select who we're going to work with as a vendor. Do we want just in time, do we want a month's worth of inventory. You know, we can make some choice.

Dr. Rapp: OK, Mr. Lanigan

Mr. Lanigan: I had the opportunity of working with the competitive bidding staff in the past week. They are developing a council very similar in structure to the Practicing Physician Advisory Council. And I believe that Chester Robinson did talk about that somewhat, about the composition. I wouldn't have released the composition at this time until I had finalized it, but they're going to include suppliers—

Dr. Rapp: But that's the DME, that's—

Mr. Lanigan: and everything to try to identify exactly the issues that you're discussing to get out in front of it, and what they want to do is develop something that's a collaboration that'll have the cooperation of industry working with us in partnership to make the thing work.

Dr. Rapp: He talked about that, but I thought he was talking about the durable medical equipment.

Mr. Lanigan: Durable medical equipment and drugs.

Dr. Rapp: All right, well that's good.

Dr. Simon: Can you give us the list?

Dr. Rapp: Let's read that motion back again.

Dr. McAneny: OK. PPAC recommends that before implementing the competitive bidding system that the following issues be addressed: one, how are patients without co-pays handled, without a Medigap basically, how they're going to prevent physicians from having increased inventory costs, how they're going to help physicians with the administrative items that are unfunded, Huber needles, saline, that stuff, how they're going to quality control for the drugs so we know they aren't diluted or mishandled, who is going to pay for the shipping when the wrong drug is sent, or for a change in therapy at the last minute, how are they going to determine who will be responsible for the accuracy of information on the patient given to the vendor, are they going to have indigent programs, and how they are going to ensure that vendors pay for the administrative cost of inventory tracking, etc.

Dr. Rapp: By indigent, do you mean non-Medicare beneficiaries?

Dr. McAneny: Yeah.

Dr. Rapp: No, she's talking about people that aren't covered by Medicare.

Dr. McAneny: Right, and I recognize that CMS is only interested in people who have Medicare, but they are eliminating a batch of people that we've been taking care of.

Dr. Rapp: OK, could you read that—do you have that all, do you think?

Ms. Trevas: Slightly reworded.

Dr. Rapp: You have it slightly reworded, OK.

Ms. Trevas: PPAC recommends that before CMS implement the competitive bidding system, the following issues be addressed: patients unable to pay their copays, protection of physicians from increased inventory costs, handling of physician administrative costs, quality control of drugs, responsibility for shipping when the wrong drugs are shipped, quality's inferior, or the prescription is changed at the last minute, responsibility for the accuracy of patient information, handling of indigent programs, and assurance that vendors pay for inventory tracking.

Dr. Rapp: So that's been seconded. Is there discussion on that? Just out of curiosity, do you have answers to all of those questions, yourself?

Dr. McAneny: I have ideas on some of them.

Dr. Rapp: OK.

Dr. McAneny: But we don't have time.

Mr. Lanigan: Dr. Rapp, [off mike] I wasn't here when Don was speaking, but that Council that I was speaking of is Chester Robinson's group, which is the durable medical equipment group, so you don't want to give any

Dr. Rapp: So it is just DME. OK. No further discussion, all in favor, say aye.

[Ayes]

Dr. Rapp: Is there anybody opposed? If not, the motion carries. I do think personally that to the extent we gave them specific points on those items, it would be more helpful, but in any event, Dr. Urata?

Dr. Urata: I have a couple from the last presentation about undocumented aliens. And I'd like to make a motion that PPAC recommends no changes should be made in administrative procedures currently in place and that no new questions be added to patient registration process in view of the fact that indicators like no social security number and no insurance coverage would point to an undocumented alien.

Dr. Rapp: Is there a second to that?

[seconds]

Dr. Rapp: Discussion? All in favor?

[Ayes]

Dr. Rapp: All opposed? That motion carries.

Dr. Urata: And I have one more in regards to the same area. PPAC suggests that CMS consider California system for reimbursing providers for indigent care and that would include funds allocated by formula into three separate pools, hospitals, physician, and other providers, such as EMS, two, payments made quarterly with remaining funds at the close of the fiscal year paid out as additional distribution, and three, providers seeking payment complete a one-page statement certifying that they are eligible for the program. That's written down in the Emergency Practice Management Association testimony.

Dr. Rapp: Is there a second to that?

[seconds]

Dr. Rapp: Is there discussion on that? All in favor?

[Ayes]

Dr. Rapp: All opposed? That motion carries. On that subject, there was a question what would people think about a requirement that the hospital if they elect to receive the physician payment be required to remit it to the physicians.

Dr. Urata: The California system has a different—

Dr. Rapp: Well, they may not adopt that recommendation, but they might adopt this. These are all independent recommendations that CMS is free to—

Dr. Urata: OK, I'd be glad to second your motion.

Dr. Rapp: OK. That PPAC recommends that CMS require that if hospitals elect to accept physician payment under this program for undocumented aliens that they be required to remit those funds to the physicians.

Dr. Urata: Maybe we should say something that they shouldn't be allowed to collect—

Dr. Rapp: Well that law apparently allows.

Dr. Urata: Oh, that's a law.

Dr. Rapp: The law allows them to elect to receive the physicians' funds, but it doesn't require them, it requires them not to charge any administrative fees, but it doesn't require them to actually remit the money.

Dr. Urata: OK, second.

Dr. Rapp: I want her to read it back, even though it's mine.

Ms. Trevas: PPAC recommends that CMS require that if hospital elects to accept the physicians' payment under the program, and I'll fill that in, the hospital should be required to remit those funds to the physician.

Dr. Rapp: All in favor?

[Ayes]

Dr. Rapp: All opposed? That motion carries. Dr. McAneny?

Dr. McAneny: I would like to move that PPAC request that CMS make sure that the health care industry cannot get physician NPI information for marketing or research purposes without an approval process. They assured us that this was going to happen in their testimony, but I think that we should be on record approving that so that our names and phone numbers, etc., aren't sold to pharmaceutical companies, stock brokers, realtors.

[seconded]

Dr. Rapp: OK, that's seconded. Could you read that back please?

Ms. Trevas: PPAC requests that CMS ensure that the health care industry does not have access to NPI information for marketing or research purposes without an approval process.

Dr. Rapp: Would like prohibit or something like that? Is that a stronger word.

Dr. McAneny: I'd go with that, I'd consider that a friendly amendment. We'd like to prohibit.

Dr. Rapp: Is there a second to that?

[seconds]

Dr. Rapp: Discussion? All in favor?

[Ayes]

Dr. Rapp: Opposed? That motion carries. I discussed with Mr. Loyal about soliciting CMS soliciting specific information as to individuals who have, I don't know what I said, but to get him to invite people and tell them in instances where they're having long delays and getting enrolled through the PECOS system that's causing hardship.

Dr. Gaughan: I think you asked for him to use [off mike]. You suggested the website, we added to—

Dr. Rapp: Why don't you make a motion to something of this effect.

Dr. Gaughan: OK. I move that CMS use reasonable available means of communication to actively solicit information concerning individual physicians having excessive provider—do you want them over 60 days? Because 60's the requirement correct? I would say 60 just because it's the requirement, but you don't have to agree with me.

[chatter]

Dr. Rapp: Why don't you just say excessive causing hardship. That way, you're saying, look, if this is a—

Dr. Gaughan: Yeah, I agree. Thank you.

Dr. Rapp: Yeah, you don't want 100,000. You want 5,000 that hey, I'm going broke.

[chatter]

Dr. Rapp: Can you read that back?

Ms. Trevas: PPAC recommends use reasonable and available means of communication to solicit information concerning excessive delays in approval of provider enrollment.

Dr. Rapp: Individuals experiencing excessive delays. Not just an abstract general. OK. Any discussion on that? Read it again please.

Ms. Trevas: PPAC recommends CMS use reasonable and available means of communication to solicit information concerning individuals experiencing excessive delays in approval of provider enrollment.

Dr. Rapp: All in favor?

[Ayes]

Dr. Rapp: Opposed? That motion carries. Dr. Grimm?

Dr. Grimm: Just one more. PPAC recommends that information obtained on undocumented aliens be not available to the INS.

Dr. Rapp: Is there a second to that?

[second]

Dr. Rapp: Read it, please.

Ms. Trevas: PPAC recommends that the information obtained on undocumented aliens not be available to the INS.

Dr. Rapp: Is there any discussion on that? All in favor?

[Ayes]

Dr. Rapp: All opposed? That motion carries. Dr. McAneny?

Dr. McAneny: I would also like to move that PPAC request that CMS consider care for out-patient life-threatening illnesses be also considered for payment under this system, the dialysis issue, for example, so they don't keep showing back up in your emergency room needing emergency dialysis thrown on the street, back in, thrown out.

Dr. Rapp: So as it relates to the law, what did it say, that it's EMTALA and related services. Has it got related out-patient services?

Dr. McAneny: It has related out-patient and in-patient services.

Dr. Rapp: OK, so more specifically, you're urging them to interpret that to be a related out-patient service.

Dr. McAneny: Right, that life-threatening medical conditions be considered an EMTALA related out-patient service for purposes of this.

Dr. Rapp: Well, the only problem with that is EMTALA has to do with going to a hospital emergency department. If you don't show up in a hospital emergency department, I'm not sure how you can say it's related.

Dr. McAneny: Well, they do. They go in with a potassium of 7, they get it dialyzed down to 3, they go out into the world, they come back with 7, they get it dialyzed to three.

Dr. Urata: Why don't you just say end-stage renal disease?

Dr. McAneny: Because there's other emergency conditions that may require similar on-going process. And they said in their discussion that they needed to determine what was an EMTALA related out-patient service because they had no definition for this. So what I'm asking them to do is as they're making their decision, am I not correct, as they're making their decision on what is an EMTALA related out-patient service, that they consider other life-threatening conditions.

Mr. Kuhn: So basically you're talking about the definitions that we will be developing here?

Dr. McAneny: Right.

Mr. Kuhn: To include this as a definite—

Dr. Urata: Maybe we should add including end-stage renal disease and is there anything else that you can think of?

Dr. McAneny: For example, end-stage renal disease.

Dr. Urata: Can you think of anything else to add to make it a little bit more specific and give some examples?

Dr. McAneny: To EMTALA?

Dr. Urata: Yeah, I mean because otherwise, it's going to be too vague for them and they'll just discard it.

Dr. McAneny: People with deep venous thromboses on Coumadin are going to end up back in with another PE.

Dr. Urata: Yeah, pulmonary embolism.

Dr. McAneny: My guy with Hodgkin's, he'll end up back in with end-stage Hodgkin's.

Dr. Urata: Cancers.

Dr. Rapp: As far as the EMTALA related services, I would think if they go to the emergency department, they need dialysis. That's related. But not if they just go get dialysis somewhere.

Dr. McAneny: What I'm trying to get, as I understand this whole process, that they have the option of defining EMTALA related out-patient services to include things that are really expanding the original EMTALA. Once you're admitted, or once you're discharged, it's done.

Dr. Rapp: But if you show up some place that's an out-patient dialysis center, they don't have to dialyze you.

Dr. McAneny: Currently, they don't.

Mr. Kuhn: And again, we wouldn't have to, because it's an EMTALA triggered service. So the EMTALA triggering is through the emergency department.

Dr. Rapp: They'd have to go to the emergency department to get the EMTALA—

Dr. McAneny: But once they come to the emergency department.

Dr. Rapp: And once they leave, EMTALA's gone, too.

Dr. McAneny: But could it not be possible to consider in the EMTALA related out-patient services so that you come in, you're an extremist with your potassium of 7. They dialyze you emergently and discharge you, that then the way to keep you out of the emergency room from come back—

Mr. Kuhn: For coming back for subsequents—

Dr. McAneny: Is to set up subsequent dialysis.

Mr. Kuhn: I think that's something that we'd have to sit down with the Office of General Council and read it. But it's something that we could do an assessment with our Council, to see whether the statute. Because again, for the episode of the EMTALA, or is it that plus additional out-patient episodes.

Dr. McAneny: Because what I'm hearing is that they're only limited numbers of acute dialysis nurses who can do this. If they know they're going to be in the emergency room every three days at one in the morning, because the same guys are going to show up, because they know it when they send them home the night before, they can't A, we're incurring those ER fees, and B, there is an increasing difficulty finding these nurses who are willing to do this, and they're quitting, because they don't want to be up at—

Dr. Rapp: But I'm not sure it's set up to be a dialysis program. But in any event, could you read the motion?

Ms. Trevas: For payment of services rendered to undocumented aliens, PPAC requests CMS considere out-patient care for life-threatening medical conditions, such as end-stage renal disease, pulmonary embolism, and end-stage cancer, be considered an out-patient service related to EMTALA.

Dr. Rapp: I'm going to vote against this one, but—

[chatter]

Dr. Rapp: I'm just discussing it to the extent that take the chair hat off. I'm against this. I think it's too remote to EMTALA. I think you've got to go to the emergency department and then be related directly to that.

Dr. Simon: I was trying to consider what kind of patient are we talking about. Those patients that have end-stage renal disease that require dialysis. Are you saying a patient who has already had a conduit put in place that the doctor is abandoning? So they have dialysis access, either graft or temporary catheter, what have you, in place, and they're being abandoned, and they come back three days later for dialysis.

Dr. McAneny: We are seeing this.

Dr. Gaughan: I just have a concern, maybe it's the end of the day, and I think of this because whenever we start requiring more with EMTALA, be careful what you ask you, you may get it. And I personally would like to have more time to think about this; get more information on it and I'm hearing that from my cohorts here. It's not that I'm totally against, I just don't have enough information. I trust my colleagues here that there are enough concerns that maybe we should bring this up next time.

Dr. Rapp: OK.

Dr. Senagore: I guess it would help next time if we had clarification on what the statute actually reads, because I think that's what we're grasping at.

Dr. Rapp: Can you give us some clarification on that next time?

Mr. Kuhn: We can, although the next meeting will put you right around the first of September, and this thing is implemented, will be fully implemented on September 1, according to the statute.

Dr. Rapp: I think we ought to just vote it up or vote it down. I mean we got to either vote it. There's a motion on the floor, so—

Dr. Urata: I'm concerned that it kind of expands the definition of EMTALA or tries to get more patients covered by EMTALA which the law may not have intended. I know that it's covered if you come to the ER, that you're supposed to take care of end-stage renal disease, end-stage Hodgkin's disease, but I'm not so sure that it was really intended to cover these people long term, which is what I think you're trying to get to. Is that correct?

Dr. McAneny: I'm trying to get these kind of conditions that are life-threatening and can be considered some degree of an emergency considered under—

Dr. Urata: Considered an emergency state, so therefore, they're covered by EMTALA, but then, once they get well, they're being discharged from their EMTALA care because they're not being covered so these doctors are discharging them and then they come back to the emergency room with the same thing.

Dr. McAneny: Right, as undocumented aliens. It's the undocumented alien part that I'd like to have—

Dr. Urata: Right, it's a terrible form of medical care, but I'm not so sure that what, I would support your thing, because all they can do is reject it. They could look at it and reject it, you know, but the statement has been made and I think it's a good statement. But I'm not sure that doing it the EMTALA route is the right way. We need to get some sort of long term coverage for these folks.

Dr. Hamilton: The legislation specifically relates to EMTALA.

Dr. Urata: But it's not legislated that way. It just legislated for emergency care.

Dr. Rapp: OK, since there's no further discussion, all in favor of the motion, say aye.

[Ayes]

Dr. Rapp: All opposed?

[Nays]

Dr. Rapp: OK, raise your hand, who's in favor? One, two. Raise your hand who's opposed to it? One, two, three, the motion fails. OK, anything else?

Dr. Gaughan: PPAC recommends that CMS strongly support and recommend to the OFM, that interest be paid to all physicians whose Medicare provider number was delayed greater than 60 days. Interest should be paid on all bills submitted after the provider enrollment process of 60 days was to have been completed for CMS. And I don't know if that is a requirement or, what is it?

Mr. Kuhn: Bob, could you help us out on that one? The 60-day threshold?

Mr. Loyal: 60 day threshold is for 90% of the contractors

Mr. Kuhn: And that is a requirement of ours? Standard?

Mr. Loyal: Yes.

Dr. Gaughan: OK, submitted after provider enrollment past 60 days. Interest should be paid on all bills submitted after the provider enrollment process of 60 days was to have been completed per CMS requirement.

Dr. Rapp: Is there a second to that?

[second]

Dr. Rapp: The 60 days is a standard that they set up for the contractors, that say 90% of the time they should meet this. Is there any current interest payment for Medicare claims?

??: To my knowledge, no.

Dr. Rapp: And this would require legislation or would not?

Dr. McAneny: They said they were paying interest to people who were already in the system, who changed their address or they're thinking of doing that.

Dr. Gaughan: . . . of people who were already in the system, were changing, but they weren't going to do it for new doctors, and my point was, of course,

Dr. Rapp: I'm just trying is the interest something that CMS could just start giving or is there legislation—

Dr. Gaughan: We could recommend to the Office of Financial Management according to Mr. Loyal? You said that the Office of Financial Management was considering the interest?

Mr. Loyal: The Office of Financial Management is considering the situation you described [as to whether or not?] they can [off mike] relations with us, and there have been occasions, some reason of delay and they can't receive payment, for claims already in

Dr. Rapp: Could we read that back?

[chatter]

Ms. Trevas: PPAC recommends that CMS strongly support and recommend to the Office of Financial Management that interest be paid to all physicians whose Medicare provider number was delay more than 60 days. Interest should be paid on all bills submitted after the provider enrollment process of 60 days was to have been completed according to the CMS requirement.

Dr. Rapp: OK, we have a second on that, is there discussion? All in favor?

[Ayes]

Dr. Rapp: All opposed? That motion carries. Thank you very much. It's 5:00. Normally, we have our reporter type all these things up and then we review them. That would require a little bit of time here, or you can let me do it?

??: How about email? Can she do that?

Mr.Lanigan: If you get it to me, I can email it to the PPAC group. Everybody's been getting the emails.

Dr. Rapp: Although I'm a little hesitant to, I don't want to get involved in a change in the motion.

Dr. Gaughan: I think we can all give our opinion and you can overrule us. Why don't we get our opinion and you can make.

Dr. Rapp: It's not a matter of trust, it's a matter of finality. Not trust. So if you'll let me make the final in terms of any, typographical things or whatever. The next meeting is a—is it a two-day or a one-day? And I will tell you this, Mr. Loyal, your estimate that all this will be resolved by August 31st, I'm sure you'll be pleased to know our next meeting is August 30th. So we'll be here talking to you. I'm just kidding you. [laughter]

Mr. Loyal: Actually what I thought I said was the end of the fiscal year. . . [laughter]

Dr. Rapp; And also allow Mr. Kuhn to have the last word here.

Mr. Kuhn: Far be it from me to extend this beyond where we are now. Thank you all, it's been good to meet you.

Dr. Rapp: Thank you. Thank you all for coming and giving of your time and staying until the very end. The next time our dinner will be Indian or Thai.