

CENTERS FOR MEDICARE AND MEDICAID SERVICES

**PRACTICING PHYSICIANS ADVISORY COUNCIL**

Hubert H. Humphrey Building  
Room 505A  
Centers for Medicare & Medicaid Services  
200 Independence Avenue  
Washington, D.C. 20201

Monday, December 8, 2008  
8:30 a.m.

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**PPAC Meeting Transcription – December 2008**

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DR. TOM VALUCK  
Medical Officer & Senior Advisor, Center for Medicare Management

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**PPAC Meeting Transcription – December 2008**

Public Witnesses

William A. Dolan, M.D.  
American Medical Association

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MS. DANA TREVAS, Rapporteur  
Magnificent Publications, Inc.

# PPAC Meeting Transcription – December 2008

## A G E N D A

	<u>Page</u>
<b>Open Meeting</b> .....	5
Dr. Vincent Bufalino	
<b>Welcome</b> .....	5
Dr. Jeffrey Rich	
<b>PPAC Update</b> .....	7
Dr. Kenneth Simon	
<b>PRIT Update</b> .....	16
Dr. William Rogers	
<b>Medicare Physician Fee Schedule Final Rule</b> .....	21
Ms. Cassandra Black	
<b>PECOS Update</b> .....	29
Mr. Jim Bossenmeyer	
<b>OPPS/ASC Fee Schedule and Final Rule</b> .....	31
Dr. Carol Bazell	
<b>STARK Reform</b> .....	48
Ms. Lisa Ohrin	
<b>Value-based Purchasing Efficiency Measures</b> .....	62
Dr. Thomas Valuck and Ms. Lisa Grabert	
<b>Physician Quality and Cost Measures Update</b> .....	86
Dr. Michael Rapp	
<b>Recovery Audit Contractor Update</b> .....	106
Ms. Melanie Combs and Lt. Terrence Lew	
<b>Medically Unlikely Edits Update</b> .....	123
Ms. Brenda Thew	
<b>Public Testimony: American Medical Association</b> .....	127
Dr. Dolan	
<b>Wrap Up and Review of Recommendations</b> .....	131
<b>Adjourn Meeting</b> .....	133

## PPAC Meeting Transcription – December 2008

### 1 Open Meeting

2 Dr. Bufalino: Good morning. Welcome to everyone, to the 66<sup>th</sup> Annual Meeting of the Practicing  
3 Physicians Advisory Council so we welcome everyone to Washington. I want to thank all my colleagues  
4 and co-conspirators here for taking the time out of your practices to spend a day here in Washington. Thank  
5 you for that effort. We have as usual, an opportunity to provide our insight into a number of the issues that  
6 are going to be reviewed by the staff from CMS today. And as many of you know, by looking at the  
7 agenda, we have a reasonably full day today. So we're covering a number of the usual topics, but  
8 particularly interested in seeing the conversations over Value-based Purchasing, and the RAC and the  
9 PQRI. So those will probably be areas of focus for us to spend a fair amount of time on, in terms of  
10 discussion. So we thank all of you for, again, taking that time to spend the day with us. I'd like to begin the  
11 morning by asking Dr. Jeff Rich, who's kind enough to join us. Dr. Rich is the Director for the Center of  
12 Medicare Management, and he is representing the leadership here at CMS. Hopefully, we will have Liz  
13 Richter joining us from Baltimore. She's not on phone yet, but she will be joining us. There's an important  
14 meeting in Baltimore today at CMS Headquarters, and so she'll be coming in by phone. But let me begin  
15 by asking Dr. Rich to open the morning with a few comments.

### 16 Welcome

17 Dr. Rich: Right. Thanks, Vince. Good morning and welcome to all the members of PPAC, and to  
18 the audience, the trade associations, and societies and other guests that we may have here, and of course all  
19 of my colleagues that are in the room, and maybe by phone. I don't think Liz has joined us. Liz is the  
20 Deputy who works with me and she is obligated to be in Baltimore at meetings, so she was hoping to join  
21 us by teleconference. I hope we can get through to her. It's been my privilege to work with you over the  
22 past year. I understand the important work that you do. I've gained a better appreciation for that. Through  
23 the years I've learned what my responsibilities are at CMM in particular for the Medicare Fee for Service  
24 program. It's an extraordinarily complex program. The payment structures and payment systems are very  
25 complicated and at least on the physician side, your work is tremendously appreciated because we do take  
26 it into account. We listen very intently to physicians and the physician communities, and try and make  
27 Physician Payment Fee Schedule a fair and equitable as best we can under the statutory obligations that we  
28 have. In the coming months, we're going to continue to focus on healthcare reform, if you would. And that

1 really translates into high quality, low-cost care, or value-based purchasing. As you know, MIPPA  
2 mandated or authorized us to move ahead with a physician value-based purchasing, not initiative, but report  
3 to Congress, due in May 2010. We have already convened an internal work group. We developed an issues  
4 paper, which is posted, and there is a listening session tomorrow. And I'm not sure if any of you have  
5 signed up to join that listening session. But we're taking the input from the physician community, and over  
6 the course of the next several months, we'll be crafting an interim report, or actually a letter to Congress, to  
7 give them an update on our progress. And then have a formal report in May 2010. We think it's important  
8 to get it right, and it's important to empower the incoming Congress and other legislators with, at least, the  
9 physician community's idea of what value-based purchasing should look at, and I would say that SGR  
10 discussions will likely happen this year, with this Congress, and we hope that having this report, at least  
11 this interim report in their hands will help them, and guide them with at least some ideas that may be  
12 incorporated into that. So we find it, I think it's extraordinarily important and the physician VBP, I think,  
13 really if done right, can change the face of healthcare, because it's much more complicated than the  
14 hospital VBP, which is the single site. We have VBP programs in nursing homes. We have home health  
15 VBP programs. The physician VBP program is going to cross all those sites by the physician community,  
16 and I think, done well, it can really accelerate change for the healthcare system. So I hope you all would  
17 give us your thoughts and agree to participate in that. I can't overstate how much we appreciate your  
18 coming here, taking time out of your practice. I know how that feels over the years, and this year as well,  
19 having just come off a weekend call, and done two emergency operations—thank you, Vince, and your  
20 colleagues.

21 Dr. Bufalino: You're welcome.

22 Dr. Rich: But we really do appreciate it, and we do take your advice into serious consideration.  
23 We have a big agenda today, a challenging one, but some interesting and exciting things. So rather than  
24 prolong this anymore, we should move forward. And I should have said up front that's Herb's not able to  
25 join. He really does like to be at these meetings, but he has competing interests, and it's getting to be quite  
26 an interesting period in the transition with a lot of competing interests, a lot of meetings that are popping up  
27 suddenly. So he sends his apologies, but regards. Thanks Vince.

## PPAC Meeting Transcription – December 2008

1 Dr. Bufalino: Thank you. One fast question just around what raised. A number of us just really got  
2 the comments that are being requested for tomorrow in terms of the listening period. Do you know if  
3 there'll be a second opportunity? Because I think it caught a number of people a little short because it was a  
4 relatively short notice in terms of that. And having read the document myself, on the way here, it's pretty  
5 comprehensive, and it is extremely detailed in terms of the kinds of questions being asked for guidance. So  
6 I guess the only question we had was do you think there'll be any other opportunities aside from this?  
7 Because the listening is the 9<sup>th</sup> and the comment period ends the 16<sup>th</sup>, from what I understand.

8 Dr. Rich: Right, and if you can't be in on the listening session, I realize it was short notice, but  
9 your comments would be appreciated in writing. We'll take those into consideration in writing. And then  
10 there'll be another session as well, once we crystallize all those comments and come forward with some  
11 initial thoughts on that.

12 Dr. Bufalino: Good. So could, do you think by the end of the day we could get at least an email  
13 address of where we should send the comments to? Because I think a number of people would be glad to  
14 put those together. And hopefully, we can get that to them. So if we could just get that to the Council  
15 before we leave today, that would be great.

16 Dr. Rich: Not a problem.

17 Dr. Bufalino: Thank you. Thanks for your comments. Moving right along, we will next move to  
18 Dr. Ken Simon. As you know, Dr. Simon is the Executive Director of the PPAC and a medical officer here  
19 at CMS, and we are glad to have him present to us the responses from CMS from our recommendations  
20 from the August 18 meeting.

### 21 PPAC Update

22 Dr. Simon: Good morning Council members. Reviewing the PPAC Response Report from the  
23 August 18, 2008 meeting, the first agenda item is agenda item E, under the PRIT Update. Agenda item  
24 65E-1: PPAC recommends that CMS provide the 2007 PQRI dataset files to the AMA and other interested  
25 healthcare professionals, so that all can better understand possible barriers and stimulate a physician  
26 reporting in assisting, and increasing the number of physicians who successfully participate in PQRI. The  
27 response: To ensure the privacy and appropriate use of Medicare data, there is a standard process for

## PPAC Meeting Transcription – December 2008

1 requesting Medicare data files. The Research Data Assistance Center can assist anyone seeking Medicaid  
2 data and in the response report, we've added the URL address for the data center.

3       Agenda Item 65E-2: PPAC recommends that CMS work with the physician community to  
4 evaluate and address continued barriers to participation in the PQRI program. The response: CMS is  
5 evaluating the 2007 Physician Quality Reporting Initiative program to identify and address potential  
6 barriers to participation. Since 2007, CMS has significantly expanded PQRI reporting options, including  
7 registry-based reporting and reporting on measures groups. We are currently testing and evaluating PQRI  
8 data submission using electronic health records, and anticipate introducing this reporting option in the  
9 future. As required by the Medicare Improvements for Patients and Providers Act of 2008, commonly  
10 called the MIPPA, for this legislation, we plan to introduce group level reporting in 2010. We intend to  
11 actively engage the physician community in considering expanded options for participating in the PQRI  
12 program.

13       Agenda Item 65E-3: PPAC recommends that CMS provide, in the Final Rule, a thorough  
14 explanation of why some measures proposed by the AMA Physician Consortium for Performance  
15 Improvement were not included in the 2009 PQRI Measures Set. The response: The Medicare Physician  
16 Fee Schedule Final Rule was published November 19, 2008, and we refer the Council to that document for  
17 a discussion of the measures that were adopted. We will continue to seek and consider suggestions from  
18 physician organizations and other stakeholders regarding physician performance measures.

19       Agenda Item 65E-4: PPAC recommends that CMS provide more comprehensive guidelines and  
20 instructions to provide, as regarding national provider identifiers, and other identification numbers to  
21 prevent rejection and delay of claims and require that carriers provide liaisons to assist providers in  
22 submitting claims. The response: While we recognize that some providers and suppliers experienced claims  
23 processing difficulties at the national provider identifier compliance date, on May 23, 2008, and shortly  
24 thereafter, we believe that the majority of these billing issues have been resolved. CMS is committed to  
25 educating all enrolled providers and suppliers about the correct way to submit claims to the Medicare  
26 program and will continue to provide targeted education to those providers and suppliers with specific  
27 billing concerns.



## PPAC Meeting Transcription – December 2008

1           Agenda Item F: The Physician Fee Schedule Update. 65F-1: PPAC recommends that rather than  
2 extend the inpatient hospital acquired conditions, commonly called the HACs, policy to other settings, such  
3 as physician offices, CMS focus its efforts on encouraging compliance with evidence-based guidelines  
4 developed by healthcare professionals. The response: CMS is focusing on enhancing the value of services  
5 provided to Medicare beneficiaries using tools under the Medicare statutory authority, including payment  
6 incentives. The primary goal of the Hospital Acquired Conditions Payment provision is to enhance quality  
7 of care for Medicare beneficiaries, by providing financial incentives to promote compliance with evidence-  
8 based guidelines developed by healthcare professionals. We believe that not paying more for selected  
9 complications will encourage evidence-based practice in Medicare payment settings beyond the Inpatient  
10 Prospective Payment System hospitals. We discussed expansion of the principles behind the Hospital  
11 Acquired Conditions payment provision to the physician office setting in the calendar year 2009, Medicare  
12 Physician Fee Schedule Rulemaking document that was published in the summer of this year. We will be  
13 evaluating the experience and the Inpatient Prospective Payment System setting to inform potential  
14 expansion of the Hospital Acquired Conditions policy to other Medicare payment systems, which would  
15 likely occur through Notice and Comment Rulemaking.

16           Agenda Item 65F-2: PPAC recommends that CMS reexamine the HACS policy in the hospital  
17 setting, to focus on evidence-based data that does or does not support recommendations for nonpayment of  
18 certain conditions. The response: CMS in partnership with the Centers for Disease Control and Prevention  
19 undertook a rigorous process to evaluate candidate conditions for the Hospital Acquired Condition Payment  
20 provision. That process included a day-long public listening session, and three rounds of public comment  
21 through Inpatient Prospective Payment System Rulemaking. The statutory selection criteria required that  
22 the selected conditions be considered reasonably preventable through the application of evidence-based  
23 guidelines. In light of the public comments, we considered and selected the conditions to meet the statutory  
24 criteria.

25           Agenda Item 65F-3: PPAC recommends that CMS not adopt the proposed changes to retroactive  
26 billing, and instead keep the current Act to allow retroactive billing for 27 months. The response: CMS  
27 published the calendar year 2009 Medicare Physician Fee Schedule Final Rule on November 19, 2008. As  
28 part of this Final Rule, we establish an effective date of billing for physicians, certain nonphysician

1 practitioners and physician and nonphysician practitioner organizations as the latter of 1) the filing of a  
2 Medicare enrollment application that was subsequently approved by a Medicare contractor; or 2) the date  
3 an enrolled physician or nurse practitioner first started furnishing services at a new practice location. This  
4 rule also permits physicians and nurse practitioners to retrospectively bill for services rendered up to 30  
5 days prior to the effective date if the physician or nurse practitioner meets all program requirements. In  
6 addition, it permits physicians and nurse practitioners to retrospectively bill patients for services furnished  
7 up to 90 days prior when there is a Presidentially declared disaster, under the Robert T. Stafford Disaster  
8 Relief & Emergency Assistance Act. We are not changing the current retrospective billing practice for  
9 enrolled providers. We are limiting retrospective billing to 30 days (90 days when a disaster is declared  
10 under the Stafford Act), prior to submitting an enrollment application for newly enrolled physicians, nurse  
11 practitioners, or physician or nurse practitioner organizations. Or to 30 days (90 days when a disaster is  
12 declared under the Stafford Act), prior to the date an enrolled physician or nurse practitioner first started  
13 furnishing services at a new practice location.

14         Agenda Item 65F-4: PPAC recommends that CMS abandon its proposal to treat physician offices  
15 as independent diagnostic testing facilities and instead, focus on ensuring smooth implementation of new  
16 accreditation procedures, mandated by Congress. The response: We appreciate the Council's  
17 recommendation. Physicians, nonphysician practitioners, and physician or nonphysician practitioner  
18 organizations will not be required to enroll as an independent diagnostic testing facility and meet the IDTF  
19 performance standards, when providing diagnostic testing within their practice settings. Based upon the  
20 provisions of the calendar year 2009 Medicare Physician Fee Schedule, with the enactment of § 135 of  
21 MIPPA, and after careful review and consideration of public comments, we deferred the implementation of  
22 this proposal, while we continued to review the public comments received on this provision and we will  
23 consider finalization the provision in a future rulemaking effort, if deemed necessary.

24         Section 135 of the MIPPA legislation requires that the Secretary establish an accreditation process  
25 for those entities furnishing advanced diagnostic testing procedures, which include diagnostic Magnetic  
26 Resonance Imaging, Computer Tomography, and Nuclear Medicine, include PET scans and other  
27 diagnostic testing procedures described in the Medicare Act by January 1, 2012. Accordingly, we are not  
28 adopting our proposal to require physicians and nonphysician practitioners to meet certain quality and

## PPAC Meeting Transcription – December 2008

1 performance standards, when providing diagnostic testing services, except mammography services within  
2 their medical practice setting and have removed the paperwork burden in regulatory impact analysis  
3 associated with this provision in the Final Rule with Comment Period.

4       Agenda Item J: The Recovery Audit Contractor Update. Agenda Item 65J-1: PPAC recommends  
5 that CMS require RACs to provide data on overpayments collected for durable medical equipment claims,  
6 and differentiate between physicians and commercial suppliers of durable medical equipment. The  
7 response: CMS appreciate this recommendation and understands the need to be as specific as possible when  
8 reporting data, so we can implement effective corrective actions. We are currently exploring what steps are  
9 necessary to differentiate between overpayment collected on durable medical equipment claims from  
10 physicians and commercial suppliers. We anticipate that this may take at least a year to implement and  
11 begin reporting.

12       Agenda Item L: The DME Update. Agenda Item 65L-1: PPAC recommends that 1) the Secretary  
13 of Health & Human Services, and CMS immediately halt the durable medical equipment, prosthetics and  
14 orthotics supplies accreditation requirement for physicians and licensed healthcare professionals, and 2) the  
15 Secretary of HHS and CMS exercise this newly expanded authority to exempt physicians and license  
16 healthcare professionals from quality standards and accreditation requirements, considering the licensing,  
17 accreditation and other quality requirements that physicians and licensed healthcare professionals must  
18 meet. The response: CMS provided guidance at a special Open Door Forum on September 3, 2008, related  
19 to exempted professionals and other persons as defined in § 154(b) of the MIPPA Legislation. A slightly  
20 revised version of this guidance document is available on the CMS website and the URL address is  
21 provided. All related information is listed on the DME POS accreditation web page.

22       Agenda Item P: Wrap Up & Recommendations. Agenda Item 65P-1: PPAC recommends that  
23 CMS (1) prohibit any contractor from auditing physicians on consultations until a clear policy is in effect,  
24 and (2) continue an open dialog on concerns raised by the AMA on medical consultation reimbursement.  
25 The response: In order to reduce Medicare's improper claim payment rate, CMS believe it is important to  
26 not prohibit contractors from auditing physicians' consultation services. However, CMS will conduct  
27 oversight to ensure that each contractor who chooses to audit physician consultation services, is doing so

## PPAC Meeting Transcription – December 2008

1 consistent with the Medicare consultation policies. In addition, CMS will continue an open dialog with all  
2 interested parties on the Medicare policies for consultation services.

3         Agenda Item 65P-2: PPAC recommends that if possible, CMS provide data on trends of providers  
4 who are showing decreasing trends in beneficiary care. The response: CMS tends to monitor beneficiary  
5 reported experiences on their ability to access needed care. Using longitudinal data from the Consumer  
6 Assessment of Health Plan Survey, commonly called the CAPS, we will be able to examine and monitor at  
7 the state level whether beneficiaries are reporting changes in their access to care. In addition, over the next  
8 year, CMS expects to design and implement a new claims-based monitoring system to track physician visit  
9 rates for new and established patients by geographic area and specialty. This claims-based monitoring  
10 system can be used as a signal of underlying access issues.

11         Agenda Item 65P-3: PPAC recommends that CMS not expand the Hospital Acquired Conditions  
12 Nonpayment Policy from inpatient hospital settings until the hospital policy has been evaluated and  
13 analyzed, in particular, determining the impact of the policy regarding the following issues: (1) Quality of  
14 care delivered to patients, especially in proportion to the additional cost to the Medicare Program to comply  
15 with the HAC requirements; (2) the need for appropriate risk adjustment techniques; (3) how attribution  
16 issues will be determined with respect to when, where, and why a condition occurred; and (4) reasonable  
17 number of expected incidences in which these conditions will occur in individual hospitals, especially with  
18 regard to high risk patients, when evidence based guidelines are followed. The response: CMS has  
19 expressed interest in various payment rules in expanding the Hospital Acquired Conditions concept of not  
20 paying for selected complications that are not present on the patient hospital admission. Discussion pieces,  
21 addressing various issues for consideration by stakeholders, were included in the calendar year 2009,  
22 Outpatient Prospective Payment System and Physician Fee Schedule Final Rules. CMS will discuss its  
23 analysis of the inpatient policy during the fiscal year 2010, Inpatient Prospective Payment System  
24 Rulemaking process. Issues related to quality, cost, risk adjustment, attribution, and reasonable  
25 preventability, were discussed during the fiscal year 2009 IPPS Rulemaking process. And we anticipate  
26 that these topics will be discussed again during the fiscal year 2010 IPPS Rulemaking process. All  
27 stakeholders, including physicians and physician associations, are invited to attend a listening session,

**PPAC Meeting Transcription – December 2008**

1 regarding inpatient and outpatient hospital acquired conditions to be held on December 18, 2008 of this  
2 year.

3 And that, Mr. Chairperson, concludes the Response Report from the August 18, 2008 meeting.

4 Dr. Bufalino: Thank you, Dr. Simon. Any comments, questions, or clarifications for Dr. Simon,  
5 from the Council. Greg? I'm sorry, Karen?

6 Dr. Williams: Ken, during that listening session, does that mean that data will be presented during  
7 that session regarding all those issues that you just discussed in your last point?

8 Dr. Simon: I'm not sure whether data will be presented, but I think I'm sure that an overview of  
9 the HACS policy and its concepts will be presented and provide an opportunity for the public to provide  
10 input on the thoughts of how that program should evolve.

11 Dr. Williams: And where will that discussion take place?

12 Dr. Simon: It's posted on the CMS website. It will occur at CMS Headquarters in Baltimore on  
13 December 18 and I believe it's from 10 to 4 pm.

14 Dr. Przyblski: I wanted to express my continued frustration and disappointment with respect to the  
15 Hospital Acquired Conditions, specifically the comments on 65F-2. We've had this discussion in this  
16 forum, as well as other forums. If the statute really requests that conditions need to be reasonably  
17 preventable, I think we should follow that. I don't think that there's a single physician at this table, and if  
18 there is, please speak up, that seriously thinks that a surgical site infection is reasonably preventable. The  
19 only way that it is, is by not operating. I don't believe that there is any study that says you can reduce the  
20 risk to zero. I think that's the same with catheter acquired infections, ventilatory acquired infections; you  
21 can reduce them, but you cannot eliminate them. And to say that the scientific community has looked at  
22 this and agrees that these are reasonably preventable just does not make sense to me personally, and I  
23 suspect to others as well.

24 Dr. Simon: I think we'll have an opportunity to have further discussions on this issue this  
25 afternoon at 1:00 when the presenters come in to discuss Value-based Purchasing.

26 Dr. Przyblski: Thank you.

27 Dr. Ross: Dr. Simon, the response on the RAC recommendation, dealing with overpayment  
28 collected for durable medical equipment; why such a long time when it looked as if the data was there

**PPAC Meeting Transcription – December 2008**

1 according the RAC Report, that day, on their pie chart? They had a specific 1 percent for physicians, if I  
2 recollect correctly, and I think 1 percent for the commercial suppliers. So I would imagine that they do  
3 probably have this data and could it be reported within at least the next one or two sessions that PPAC  
4 comes back here to Washington?

5 Dr. Simon: I will share your comments with the RAC group. Currently the RAC Program is on  
6 hold, so Ms. Dyers will come today to update the Council on the RAC Program and it will be an  
7 opportunity for her to perhaps address your comments at that time.

8 Dr. Ross: Okay, thank you.

9 Dr. Ouzounian: Just a simple request if we could get the responses forwarded to the Council  
10 electronically for our records in the future, that would be helpful, the ones you read today, if you could  
11 send them to us, so we could just save them electronically.

12 Dr. Simon: They were sent...

13 Dr. Ouzounian: They were?

14 Dr. Simon: So we'll make sure that all the Council members have it. But we did send it out to  
15 everyone.

16 Dr. Bufalino: Other questions? Leroy?

17 Dr. Sprang: [off mike then restates on request] Ken on 65U-1, PPAC recommending PQRI data  
18 set be available. The point is just clearly we're trying to help make it strong, trying to make more  
19 physicians be able to use it. Clearly a lot of physicians, and I'll say this for the physicians in my area, still  
20 kind of don't fully understand it, and the more information that's out there, they would be more likely that  
21 the program would be successful and more physicians would successfully complete it. The answer says that  
22 Medicare data is available through the data systems center. From a positive point of view, obviously trying  
23 to make it better, how likely is it that they will actually get, if somebody wants, whether it be the AMA or  
24 any other professional organization, actually get enough of the data to be useful to work toward making it  
25 more successful?

26 Dr. Simon: Well, if they go through the data center, they certainly will have access and receive the  
27 information. How they choose to use it, to incorporate comments to make the program more successful, I'm  
28 not sure I can respond to that.

**PPAC Meeting Transcription – December 2008**

1 Dr. Sprang: My question really is whether they actually get enough data? I just don't know how  
2 much data is actually available. Simplistically, I just don't know, so I'm asking you how much of this  
3 information will actually be available to them so that they can work toward helping doctors and the system  
4 be more successful?

5 Dr. Simon: Well, we can find that out—to date, I've not heard anyone express concerns to our  
6 forum indicating that they've received insufficient information or not been able to receive information.

7 Dr. Sprang: Okay.

8 Dr. Simon: But we can find out, I can find out what people have generally inquired, and whether  
9 they've been able to receive what they've asked.

10 Dr. Sprang: The information I'm hearing is that they didn't feel they got enough information about  
11 the process, so they could really be helpful going forward.

12 Dr. Rich: You might mention that we did an exhaustive analysis of the PQRI Program. We met  
13 with the AMA and a number of medical societies on Thursday afternoon, and at 4:00 it was posted on our  
14 website. It's probably a 30-page analysis. And it has exhaustive tables that you may be interested in about  
15 each measure and where each measure either was reasonably reported, or where the failures were. Probably  
16 that analysis is what you're really looking for, to get the raw data for you to do that would be an enormous  
17 task.

18 Dr. Sprang: I don't mean for me personally. I mean for obviously professional organizations.

19 Dr. Rich: Right, no. There were 14 million QDC, quality data code claims submitted. So if you  
20 want 14 million QDC data codes to look at, that's fine, but we did a huge analysis. You should look there  
21 first to see if that satisfies everyone's needs.

22 Dr. Ross: Dr. Simon, again in the last 65P, the reporting on the data for providers who are  
23 showing decreased trends in the beneficiary care, some time ago, we asked in that form of a resolution,  
24 looking at if physicians and providers who are delisting. Now the question is are the numbers of those  
25 claims decreasing, and can CMS track those numbers, versus looking at the consumer assessment of health  
26 plan survey? So is the data there that we can show that physicians' numbers are decreasing? Or staying the  
27 same? Or where the changes are taking place? And can we track that just as easily as asking the consumers  
28 for their assessments?

**PPAC Meeting Transcription – December 2008**

1 Dr. Simon: I don't know that that data process is in place. But as when we spoke with our Office  
2 of Research & Development, that's the, they will use with their new monitoring system the ability to track  
3 beneficiaries directly.

4 Dr. Ross: If so, how long will that take to report, and can we get a report on that within the next  
5 couple of meetings as well?

6 Dr. Simon: I can report back to you. That process is not in place, as the response indicates, so it's  
7 unlikely that you would get a report back in two meetings, since the system is not currently in place, but I  
8 can give you, I will speak with them to find out when they envision starting the system.

9 Dr. Ross: I think that's an important part of what's taking place in terms of trends, so I would  
10 think that this committee would really like to see that information so we can make further  
11 recommendations.

12 Dr. Bufalino: Other comments? Hearing none, thank you Dr. Simon. Let's move to the next level,  
13 ask Dr. Bill Rogers to come to the table. Dr. Rogers is the Director of PRIT in the Office of External  
14 Affairs and here to talk about some of the regulatory things and share some of his typical cartoons.

15 PRIT Update

16 Dr. Rogers: Actually, I've innovated my cartoon at the beginning of this presentation. A couple of  
17 you might recognize it. But it's our bible, of course, Title 18 of the Social Security Act. And I use that  
18 picture a lot when I'm talking to graduate students about healthcare spending and why Medicare operates  
19 the way Medicare operates. That explains a lot.

20 We were so busy, the past quarter, with enrollment problems in California, and issues about PQRI,  
21 that frankly, the kinds of things that I think we use our time most productively in, which is the sort of down  
22 in the weeds billing, process issues, we weren't able to do as effectively as we'd like to have. But the PQRI  
23 program I think has made huge strides and we're on the right path in California, thanks to Mr. Weems's  
24 engagement on that. He's been a very, very powerful advocate for physicians on both of those issues and I  
25 think that's caused a lot of energy to be exerted to get both of those problems solved, and I think we're on  
26 the way to solving them although there's been a lot of people who suffered in California, particularly  
27 physicians because of the enrollment problems that we've had there, but we're working hard to get that  
28 fixed. But that having been said, it caused an enormous amount of phone calls and case work and things



1 like that, which really prevented us from doing the kinds of things that we think that we're best equipped to  
2 do.

3 Couple of things though, that we had been involved in: Outreach about ePrescribing, I have heard  
4 over and over and over again physicians' skepticism about the success of PQRI has led them to believe that  
5 ePrescribing might suffer from the same problems and so we've been very busy making sure a) that there  
6 was no reason for concern, and b) making sure that physicians were reassured that this program was going  
7 to operate smoothly. We had a national meeting in Boston and invited experts from across the country, and  
8 that was sort of a kick off for an outreach program that's been very active in trying to persuade physicians  
9 that this is a great way to add 2 percent to the bottom line of their practice.

10 MAC transition issues, primarily California and other areas that hasn't been as much of a problem,  
11 but we have been trying to help to make those transitions go more smoothly. Finally, HASC initiatives, I  
12 was very pleased on November 13, we had HASC is the Healthcare Administrative Simplification  
13 Coalition. It's an organization that I've been a member of since the inception, AAFP, ACP, MGMA,  
14 Healthcare Billing Management Association, number of specialty societies are members, and HASC  
15 focuses on the same sorts of things the PRIT focuses on, which is the sort of down in the weeds  
16 administrative processes that cost physicians money and make their practices less efficient. And Charlene  
17 Fizarra, who's the Chief Operating Officer for CMS, came to that meeting, and she's very smart. She's  
18 been around for a long time, and I think she learned a lot from the meeting. And she's now very engaged on  
19 helping the HASC to promote some of the things that the HASC thinks would be helpful, like allowing  
20 CAQH data to be used for Medicare enrollment, to work on eligibility verification, although Medicare does  
21 a better job of that than most commercial payers, prior authorization and some simplification of the  
22 ePrescribing rules.

23 The last thing I wanted to mention, which didn't make it onto the slide, but an issue that we just  
24 got involved with, MGMA came to us and said you know a couple of our members have gotten checks  
25 from some of the local MA plans, saying that these are PQRI checks, and since they didn't report quality  
26 data to the MA plans, these are noncontracted physicians, they were surprised to get checks. There weren't  
27 large checks, but we looked into it and actually our policy is that noncontracted physicians were deemed  
28 physicians with prior Fee-for-Service plans and are paid for whatever services they deliver to MA

1 beneficiaries. Those are usually patients that they take on an emergency basis, because they're not  
2 contracted physicians. And that's a good policy and we sort of implemented it without bragging about it  
3 very much, but I think it was the right thing to do and we were able to make sure that that policy was  
4 announced to the physicians since I think it's something we should be proud of.

5 January and December are pretty quiet months for meetings. I just spoke to MGMA in Baltimore  
6 Friday and got a couple of trips coming up in January, but it starts picking up again in February. And of  
7 course I've got to get one cartoon in. This is Dr. Rich on Sunday at Norfolk General Hospital. Just had to  
8 get that little tease in. Thank you.

9 Dr. Bufalino: Thank you, Dr. Rogers. Questions and comments. Let me open up with a question  
10 for starters. Would you discuss for a moment the roll out of ePrescribing? Obviously there's been some  
11 concerns about how the PQRI's been calculated and the difficulty in trying to discern what qualifies and  
12 what doesn't qualify. Will it be easier to determine that you met the ePrescribing standards in order to earn  
13 the bonus than we've had on the PQRI experience?

14 Dr. Rogers: Well, I think we learned a lot from PQRI, and we're not going to make the mistakes  
15 again that we made last year with PQRI in terms of measures being stripped or in terms of people not  
16 understanding exactly how to report. So I believe that it'll be pretty easy to do, and I believe that it'll go a  
17 lot more smoothly because of those lessons learned with PQRI. Probably the biggest stumbling block right  
18 now as we say, you will be paid if you're using a qualified ePrescribing system, but we don't really have a  
19 mechanism in place for definitively deciding which are qualified and which are not qualified. And that's  
20 just because as it happens so frequently, we're given a very short deadline to implement a program by  
21 Congress and frankly, a lot of the groundwork had not been done when we were told this had to be  
22 implemented. But we're going to be, I think, try to be really good partners on this and make sure that  
23 physicians make a good faith effort to participate. Get their money.

24 Dr. Bufalino: I sit on the CCHIT subgroup and no one's touching ePrescribing there, I mean  
25 everyone's looking at big systems, so we're trying to figure out so who's going to certify which systems are  
26 okay.

27 Dr. Rogers: Right. And CCHIT probably will end up looking at standalones at some point, but  
28 they just weren't ready to wrestle with that on such short notice.

**PPAC Meeting Transcription – December 2008**

1 Dr. Smith: I actually have not seen anything to “help me” figure out to do ePrescribing. You said  
2 there’s been a lot of outreach. I haven’t seen a single thing. So that’s one. However you’re reaching out, it  
3 isn’t getting to some of us. The estimates I’ve seen are that it will cost about \$8,000 per provider to  
4 implement it and \$3,000 to \$4,000 per provider per year to maintain it. If I don’t know who is going to be  
5 considered a certified provider in your system, if it’s going to cost me that kind of money, why would I  
6 even think about wasting my time looking at it if I’m only going to earn a \$2,000 bonus, which is one-  
7 quarter of my upfront costs that I may not get. I didn’t get it for the PQRI after an enormous amount of  
8 effort, so what is my incentive or the incentive of any other physician to even look at the question?

9 Dr. Rogers: Well, I’d have to take you back to slide one, Title 18 of the Social Security Act. A lot  
10 of this was in statute. I was being a little facetious. But a lot of this is in statute and we didn’t really have the  
11 authority to decide what we thought was an appropriate payment to incentive physicians to do the  
12 ePrescribing. I believe that there will be benefits to your patients from doing it, too, and if the 2 percent  
13 incentive only makes it a non-coster for your practice, it’s probably worth doing on that basis. Now as to  
14 the issue of the outreach, there is a lot of information, which I think is pretty understandable on the CMS  
15 website now, about the PQRI incentive program. And that would be a good place to start. The vendors, of  
16 course, for the ePrescribing systems, are also very interested in telling you about their programs and how  
17 you can implement them if you’re interested in talking to a vendor.

18 Dr. Smith: No, I understand that, but what I’m saying, you said there was a lot of outreach. I  
19 haven’t seen anything coming to me. I have to search it out. And why would I waste the time trying to  
20 search it out when it is going to cost me four times what it might generate? And there may be some benefit  
21 to my practice and my patients, but I haven’t seen anything that convinces me of that to that kind of  
22 financial investment when things are pretty fragile financially.

23 Dr. Rogers: Right. It’s definitely an economic analysis every practice is going to have to perform  
24 individually. But a lot of that was, a lot of those basics were beyond our control to alter.

25 Dr. Przyblski: Two issues; one if you could briefly give us a follow-up on the military physicians  
26 issue, because I was used to hearing that every quarter for several years now, and was surprised not to see  
27 it. And second, on the ePrescribing thing, are there issues with Schedule 2 drugs and what’s the status of

**PPAC Meeting Transcription – December 2008**

1 handling that? Because a lot of what we do in our practice already is done electronically except for  
2 Schedule 2 drugs.

3 Dr. Rogers: Greg, I thought you were my friend.

4 Dr. Przyblski: I'm sorry, but we didn't have a chance to talk before hand.

5 Dr. Rogers: Okay, well, on the military physician, the attorney who was assigned to help us come  
6 up with a resolution to that problem, I should have given this more thought, how I would cover this.

7 [laughter] How about if we talk after the meeting? Right now, I think that we're going to have to wait for a  
8 couple of months, and then I plan on once again trying to make some progress on that issue. And if you  
9 detect frustration in my voice, that's only because I had too much coffee this morning. On the other  
10 question, of course that really is a DEA issue, rather than a CMS issue, but until the final version of those  
11 regulations is released, I guess we'll have to keep our fingers crossed. There is, as you know, a measure  
12 which allows you to successfully report, without using your ePrescribing system if the DEA regulations  
13 make it impossible to use the ePrescribing for a Schedule 2. But hopefully the DEA regulations will be  
14 flexible enough that we'll be able to use our ePrescribing systems for all of the drugs that we prescribe.

15 Dr. Przyblski: Thank you.

16 Dr. Snow: You mentioned that PQRI, you've learned a lot from it, you've solved a lot of  
17 problems. Could you be a little more specific, what the problems were and how some of these problems  
18 were solved? [laughter]

19 Dr. Rogers: Do you mind if I defer to my ex-boss, Mike [unintelligible]? [laughter]

20 Dr. Snow: That's fine. I was going to ask the same question about the MAC transition issues.  
21 What specifically are some of the problems that you've run into there?

22 Dr. Rogers: Well, in California what happened is the new MAC contractor walked into a  
23 warehouse of 25,000 partially completed enrollment applications. It was an unexpected challenge for them.  
24 They were staffed up appropriately to handle the number of enrollment applications which they expected,  
25 and they found far more than they'd expected. They have added a lot of staff, which required training of  
26 course, and they're now digging through that backlog. That hasn't happened anywhere else to the extent  
27 that it happened in California. And that's why we haven't had the same degree of problems in other places,  
28 but I think one of the things that we've learned is that this is something that has to be analyzed before the

## PPAC Meeting Transcription – December 2008

1 transition occurs so that the new contractor is prepared. Like a lot of the things that we've done, like NPI,  
2 like PECOS, you know we have a painful year or two and then once we get past it, those who have  
3 survived can return back to business as usual. So we don't have, we have three more transitions to go, I  
4 think, and because of the California experience, I think all three of those will be prepared.

5 Dr. Snow: So that enrollment backlog is the only real problem you've seen with the—

6 Dr. Rogers: It really has been, all others have paled in significance. I think that they've gotten  
7 good medical directors. Most of the feedback I've gotten from physicians have been that the claims  
8 processing has been working pretty smoothly. There really haven't been an enormous number of problems,  
9 other than this enrollment backlog. We had a little bit of problem with New York and Virginia, but we have  
10 just had a big, big problem in California. Did you want to say something else, Dr. Rich?

11 Dr. Rich: Yes, one very specific issue relates that is the crossover. We had a process for your  
12 physicians who had PCANs. You have multiple PCANs and now you're going to a single NPI. We had an  
13 automated system to do that crossover but with physicians with a larger number of PCANs, we had to do a  
14 forced crosswalk which was done on software that wasn't translated into the new operating system, so we  
15 lost about 600 physicians in the crosswalk drop, and that was our fault, we recognize that, and it's now  
16 fixed. But that was one very specific IT problem that we addressed, but as Bill said, the biggest problem  
17 was the backlog of provider enrollment applications that arrived on the doorstep of Palmetto when they  
18 opened for business. And it's due to be completed by the end of this year, December 31<sup>st</sup>. They made a  
19 commitment to getting all those backlogged enrollment applications done by December 31<sup>st</sup>.

20 Dr. Rogers: We even had a former PPAC member who was caught up in that.

21 Dr. Bufalino: Questions? Comments? Thank you, Dr. Rogers. Pleasure. Move to the next topic, on  
22 Physician Fee Schedule Final Rule. It's my pleasure to welcome back Ms. Cassandra Black. Ms. Black is  
23 the Director of the Division of Practitioner Services here at CMS and she and her staff are responsible for  
24 comments and publishing the Final Rule. We're anxious to hear your comments, Ms. Black.

### Physician Fee Schedule Final Rule

25  
26 Ms. Black: Good morning. I'm glad to be with all of you on this chilly morning. As mentioned,  
27 I'm going to be addressing items that were in the Physician Fee Schedule Final Rule. As usual, there are a  
28 whole variety of topics in there. The first of course was the updates to the Physician Fee Schedule. Also

1 items related to Part B drug payment, ESRD payments, independent diagnostic testing facility standards,  
2 enrollment issues, physician self-referral and anti-markup issues, the Physician Quality Reporting  
3 Initiative, the ePrescribing exemption, some issues related to comprehensive outpatient rehabilitation  
4 facilities, and implementation of certain provisions from MIPPA, and other items. So today, I'll be talking  
5 to you about some of these issues and then other speakers will be addressing some of the others.

6       The Physician Fee Schedule related issues in the rule, involve a variety of topics. The first one, I'd  
7 like to discuss, is potentially misvalued codes. In the NPRM, we identified methods that the AMA RUC  
8 could undertake to assist CMS in identifying potentially misvalued services. In the Final Rule, we accepted  
9 RUC recommendations on 204 codes, with site of service anomalies and high intra-service work per unit  
10 time. We also received many positive comments on a proposal to work cooperatively with the RUC and we  
11 stated that we looked forward to continuing to work with the RUC and the special societies and receive  
12 ideas on ways to identify potentially misvalued services. In the proposed rule, we had proposed a process  
13 for updating high cost supplies, those over \$150 every two years. In the Final Rule, we said we weren't  
14 ready to finalize this process at this point, but we would come back in next year's rule and make a proposal.  
15 We are in year three of a transition to a new practice expense methodology, so that's moving along. We  
16 also addressed items related to the geographic practice cost indices updates. We are in the third year of the  
17 transition to the new GPCIs. We also, in the Final Rule, we addressed the interim report that we posted to  
18 our website in August, on some potential options for reconfiguring our payment localities and we discussed  
19 some of the comments that we'd received in response to what was in the NPRM. Since that time, the  
20 comment period has closed. That was in November. We now have about 200 comments in house and we're  
21 in the process of sifting through those. But generally, the commenters have been favorable that were taking  
22 a look at this issue. So we expect to come back in a future rulemaking document and analyze and describe  
23 all the comments received. We received a fair number from California. I don't think any other areas of the  
24 country were really represented as much as California. But you'll be hearing more about this in the future,  
25 and before, of course, we would propose any change, we would have extensive opportunities for public  
26 comment and we would comment out for a proposal in a proposed rule.

27       In the Final Rule, we also carried on with our proposal to, and said that as part of our work, to  
28 update the malpractice RVUs in calendar year 2010, we would instruct our contractor to research available

## PPAC Meeting Transcription – December 2008

1 data sources for the malpractice cost of the technical component of certain radiologic codes. If a contractor  
2 is able to find data sources, this would be something that we would implement as update the malpractice  
3 RVUs in 2010. We also made some coding changes in the rule. We discontinued payment for the IVIG  
4 preadministration fee. We added new procedures to the multiple procedure payment reduction list and we  
5 adopted G-codes for prostate saturation biopsy. We adopted new and revised CPT-codes for calendar year  
6 2009. We added inpatient consultations to the Telehealth, or follow up inpatient consultations to the  
7 Telehealth list and in addition we implemented a number of MIPPA provisions. Several of them are listed  
8 there on the board. The first one was that we implemented the physician update, and changed to the  
9 conversion factor. MIPPA provides for an average increase in Physician Fee Schedule rates between 2008  
10 and 2009 of 1.1 percent. However, the changes in the payment for any individual service can be more or  
11 less the 1.1 percent, because MIPPA also required us to move the budget neutrality factor from one part of  
12 the Medicare weight, which is the physician work value, to the entire rate, or the conversion factor. And  
13 this change causes a differential change in rates for individual services. Services such as emergency  
14 hospital care or initial hospital visits that have a higher than average proportion of its total payments  
15 accounted for by physician work will see their payments increase as a result of this and conversely, services  
16 such as heart imaging, where physician work accounts for lower than average portion of total payments,  
17 we'll see their payments decrease. We also adopted the changes to the GPCI floor. MIPPA extended the 1.0  
18 floor on work adjustments through December 31 of 2009, and it created a permanent 1.5 work geographic  
19 adjustment in Alaska, that takes effect on January 1, 2009. MIPPA extended separate payment of the  
20 technical component for service physician pathology services, through December 31, 2009. It extended the  
21 therapy cap exceptions process through December 31, 2009. The therapy cap for this year is \$1840 for PT  
22 and SLP combined, and it's \$1840 for occupational therapy separately. And MIPPA also authorized us to  
23 create some new Telehealth originating sites effective for services on or after January 1 of 2009, and these  
24 are hospital-based or a [CA?]-based renal dialysis center, a community mental health center and a skilled  
25 nursing facility. MIPPA authorizes CMS to enroll speech-language pathologists as suppliers of services,  
26 effective for services on or after July 1, 2009, and it made changes to the initial preventive physical exam  
27 or the IPPE. It waives the deductible, it adds some new services, and it creates a longer eligibility period, so  
28 it's gone from six months to 12 months. And these changes take effect on January 1, 2009.

**PPAC Meeting Transcription – December 2008**

1 Other related issues in the Final Rule. The changes that we made to the ASP Program, we updated  
2 our regulations on volume weighting the ASP calculation. This was something that was required by  
3 MIMSE. We made conforming changes to our regulations on the special payment rule for certain single  
4 source drugs or biologicals that are treated as multiple source drugs, and we set the threshold at 5 percent  
5 for 2009 for disregarding the ASP for part B drugs or biologicals that exceed the WAMP or the AMP.

6 Changes with the Competitive Acquisition Program. We held off on implementing the items that  
7 we had proposed for 2009. This point, we're taking feedback from physicians and other interested parties  
8 on the CAP program, and we plan to come back and propose changes next year.

9 ESRD payments in the Final Rule, we updated the wage index and transition, and implemented a  
10 zero percent update to the drug add-on payment. MIPPA requires a 1 percent increase effective January 1,  
11 2009. This change makes the drug add-on adjustment 15.2 percent for calendar year 2009. Independent  
12 diagnostic testing facility changes, in the Final Rule, we finalized a requirement that mobile IDTFs enroll  
13 and bill for the services furnished by the mobile IDTF. Note, we did not finalize proposals related to quality  
14 and performance standards for diagnostic tests provided in physicians' offices.

15 Enrollment issues in the rule. In the Final Rule, we limited retrospective payments to physicians  
16 and nonphysician practitioners. We prohibited physicians and nonphysician practitioners and their  
17 representatives from attaining additional billing privileges if their current billing privileges are suspended  
18 or an overpayment is pending. We required all providers and supplies to maintain ordering and referring  
19 documentation for seven years rather than the ten years that was in the NPRM, from the date of service. We  
20 require physicians and nonphysician practitioners and IDTFs to submit all outstanding claims within 60  
21 days of a revocation date, and we required physicians and nonphysician practitioners to notify their  
22 Medicare contractor of a change of ownership, adverse legal action, or change of location that impacts the  
23 payment amount within 30 days.

24 And then there'll be people here to address other items that were in the Final Rule, so I won't go  
25 into those at this point. So that concludes my presentation. I think I listed in my slides contact information  
26 where you can obtain fact sheets on the items that were in the rule, as well as what the site, if you want to  
27 access the rule. Did you have any questions?

28 Dr. Bufalino: Thank you, Ms. Black. Questions?



1 Dr. Kirsch: I'd like to discuss a little bit the review of the locality configurations. Pretty much  
2 when you go into the website, most of the testimony is from California, and their discussions are that there  
3 are areas that are moving from more rural to urban, that there's more urban spread into those areas, which  
4 is affecting their costs. And when you look at the practice expense GPCIs, 28 percent of it is based on  
5 apartment rentals. We're not looking at office rentals, we're looking at apartment rentals and it's at 28  
6 percent. Within most practices, the cost is typically a rental costs are about 10 percent. It's not necessarily  
7 an adequate reflection of what true practice expense is. And I know when you start reviewing the  
8 testimony, you're going to be receiving some information from the medical society, basically stating that  
9 the GPCIs do not truly reflect what practice expenses are. And I commend CMS for adjusting the issues  
10 that really seem to pertain to California, but you're really not addressing the issues of states like Iowa, and  
11 at the AMA, we recently, they recently passed a resolution to examine what the practice expenses are.  
12 They're going to be reviewing the physician practice information survey and trying to extract actual  
13 practice expense data. It may take a little while before we get that, but I would urge CMS to really take a  
14 look at what practice expenses truly are throughout the country.

15 Ms. Black: Right. And I believe that is one of the comments we received, to take a look at the  
16 underlying data and what's being used, so that's something we will be taking a look at. Thanks.

17 Dr. Bufalino: Thank you. Other questions? Greg.

18 Dr. Przyblski: Since this is a topic near and dear to my heart, I've got a little bit of a list. First  
19 some thanks. I wanted to thank Congress and CMS for making the change of budget neutrality from the  
20 work RVU to the conversion factor. It's something that at the RUC we had advocated for several years ago  
21 and it's nice to see that that finally has happened. I also want to thank Dr. Simon, Ms. Bassano, and all of  
22 the rest of the CMS folks that met with some of the RUC folks on the PLI work group, I believe it was last  
23 month, to talk about the TC issue in PLI, which has been something that the PLI work group has been  
24 sharing with CMS for several years now and it's delightful to see that some progress may be made to  
25 conclusion by 2010. I would caution that you made a comment about if the contractor finds data sources.  
26 Our suspicion is they will not find data sources, and I hope CMS's conclusion is therefore they do not exist,  
27 as opposed to up until now, which is we can't change things unless there is data to prove we should change

1 things. We are fearful that you will not find any because there is no professional liability paid for other than  
2 rare examples like physicists that were brought up in our discussions.

3 In terms of the potentially misvalued codes that the RUC's looking at, if one looks at the screens  
4 that have been shared, they do imply that what is being looked for is overvalued codes, and there is a  
5 sentiment I believe, among different parties that this process is to reduce values of many codes. And CMS,  
6 the RUC need to be prepared that some codes may be undervalued and some codes may be correctly  
7 valued, and the process should be fair, rather than an a priori assumption that things are automatically  
8 overvalued because they've passed through some screen. Some of the screens have included site of service,  
9 just because the site of service changes from the hospital to the outpatient doesn't mean that the types of  
10 services are going to be differently valued. There may be more outpatient services provided now in  
11 exchange for the inpatient services to balance that out. So people have to be prepared for that concept.

12 And then, finally, something that's more of a question to be acted on, although we're thankful that  
13 CMS has accepted as they often do, most of the RUC recommendations for new codes, some were not, and  
14 the question that I have is my understanding is that the refinement process for those is not schedule 'til late  
15 in the year, i.e., September, which seems like a long time if comments are going to be received at the end of  
16 this calendar year to suggest that maybe the rationale was inaccurate, why is the process take so long, and is  
17 there something that could be done to deal with that earlier?

18 Ms. Black: I believe that is our typical timeframe, if we received comments, we come out with a  
19 Final Rule, we make recommendations, I think we typically come back and deal with those issues in the  
20 Final Rule next year. Ken, did you have anything to add on that?

21 Dr. Simon: Yes, I was going to say that there typically is a 60-day comment period for the Final  
22 Rule so that the comments for the Final Rule, CMS would be accepting and anticipating receiving any  
23 comments, written comments up until the first of the year. For those specialty societies that have questions  
24 pertaining to the valuation of their services, those specialty societies will write CMS in which case then  
25 CMS then has a process where through the course of the summer, the refinement panel is organized, and  
26 those topics of services that specialty societies have questions about would then be put on the agenda for  
27 the refinement panel. And the refinement panel typically meets at the end of the summer, usually at the end  
28 of August or first part of September in anticipation of if there are changes in the valuation of those services,

**PPAC Meeting Transcription – December 2008**

1 that it would be then be amenable for inclusion into the Final Rule for the upcoming fiscal year. That's the  
2 process that has taken place, and for those individuals that are not familiar for the full refinement panel, it  
3 usually consists of a panel that has four CMDs on it, usually a member of AFP, ACP, and the specialty  
4 society that's in question is also a member and they usually would also have a specialty society that also  
5 performs that service and is familiar with that service. The requester would then have an opportunity to  
6 present the service before the refinement panel. Each of those members that I've identified will listen to  
7 those comments and independently create a valuation for that service. Those values are then aggregated and  
8 undergo as linear aggression analysis and other statistical analyses to kick out the outliers and whatever  
9 number turns up in that final valuation is the number that everyone lives with and accepts. And that's the  
10 process for the refinement panel, so for those individuals that may have, or specialty societies that may  
11 have questions or concerns in regards to the valuation of their services, the process for submitting a code or  
12 codes to the refinement process is contained in the Physician Fee Schedule Final Rule so you can refer, I  
13 refer you back to the Final Rule in order to obtain the information relating to how to go about having  
14 service reviewed by the refinement process.

15 Dr. Przyblski: So the summary conclusion, Dr. Simon, is that these are interim values for the  
16 entire calendar year of '09, with potential change in 2010, depending on what comes out of the  
17 refinement—

18 Dr. Simon: That's correct.

19 Dr. Bufalino: Thank you. Other comments, questions? Thank you, Ms. Black. Let's pause for a  
20 minute and just take the first two presentations, the PRIT and the Physician Fee Schedule and ask whether  
21 or not you have any recommendations for consideration for CMS. Janice?

22 Dr. Kirsch: Okay. PPAC recommends CMS expand its review of the practice expense GPCI  
23 beyond taking testimony on geographic localities; and in addition, PPAC recommends CMS reevaluate

24 Ms. Trevas: Excuse me—are these two separate recommendations?

25 Dr. Kirsch: I think they kind of tie together or...

26 Dr. Bufalino: We could just separate them, let's do one at a time. You want to read the first one  
27 again? I'm sorry.

**PPAC Meeting Transcription – December 2008**

1 Dr. Kirsch: Yes. PPAC recommends CMS expand its review of the practice expense GPCI beyond  
2 taking testimony on geographic localities.

3 Dr. Bufalino: Okay, do we have a second—

4 [Second]

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

6 Dr. Simon: I would just comment from the panel's benefit that in the Final Rule and certainly if  
7 you would like to receive an electronic copy I can give you the URL address for it, but I think there was a  
8 rather robust discussion of the whole GPCI concept and the agency was seeking input from the public in  
9 terms of how it could better address reallocation of RVUs and funding for GPCIs throughout the country,  
10 so I just share that for council members who may not be privy to the fact that CMS did request input from  
11 the medical community at large to comment and provide substantive comments on how it could better  
12 improve the system.

13 Dr. Bufalino: Would you like to vote on the motion? All in favor?

14 [Ayes]

15 Dr. Bufalino: Opposed? Thank you. Again?

16 Dr. Kirsch: PPAC recommends CMS reevaluate the formula for the practice expense GPCI and to  
17 use actual practice expense data in making its determinations, and report back to PPAC next meeting.

18 [Second]

19 Dr. Bufalino: Thank you. Dana, you okay? Thank you. Any discussion?

20 Dr. Przyblski: I'm not sure that the time table is sufficient. As CMS has been strapped somewhat  
21 on PE data sets because there has been no newer data other than things that they get from the Bureau of  
22 Labor and Statistics, etc., the AMA's fantastic effort at collecting contemporary PE data is only being  
23 collated and looked at in March so I don't know if the time table of next meeting might be a little bit too  
24 early for a useful response.

25 Dr. Bufalino: Friendly amendment?

26 Dr. Kirsch: Friendly amendment's fine.

27 Dr. Bufalino: Okay, two meetings?

28 Dr. Kirsch: Two meetings?

**PPAC Meeting Transcription – December 2008**

1 Dr. Bufalino: Yes.

2 Dr. Kirsch: Okay.

3 Dr. Bufalino: Okay? All in favor?

4 [Ayes]

5 Dr. Bufalino: Thank you. Any other recommendations? Okay, hearing none, we'll move on. This  
6 is not included in your agenda. We have an add-on for the morning. Happy to welcome Jim Bossenmeyer  
7 back. He has provided us an update on Provider Enrollment and the Chain Ownership System, PECOS.  
8 You will recall that Jim has addressed this Council several times concerning NPI and other enrollment  
9 issues. CMS has mandated a fiscal intermediaries, carriers, and national supplier clearinghouse for use of  
10 the CMS form 855 to capture, verify information relating to Medicare provider supplier enrollment.  
11 PECOS is a vehicle for collecting and relating and storing provider enrollment information on a national  
12 data base. Thank you for joining us, Jim. Please.

13 PECOS Update

14 Mr. Bossenmeyer: The Provider Enrollment Chain Ownership System, PECOS, serves as a  
15 national repository of Medicare enrollment data. On Thursday of last week, CMS announced the  
16 availability of an Internet-based PECOS for physicians and nonphysician practitioners in 15 states and the  
17 District of Columbia. CMS will phase in Internet-based PECOS for physicians and nonphysician  
18 practitioners over the next two months. The new enrollment process will allow physicians and  
19 nonphysician practitioners, except for DMEPOS suppliers the option of enrolling, either using the paper-  
20 based enrollment form or the electronic enrollment application. We expect to implement Internet-based  
21 PECOS for organizations, so group practices, hospitals, other organizational other than DMEPOS suppliers  
22 early next year, and we'll be bringing DMEPOS suppliers online with PECOS in early 2010. The  
23 objectives of the new enrollment process are to reduce the time necessary for physicians and nonphysician  
24 practitioners to enroll and make a change in the enrollment, reassign their benefits, to a new practice. We  
25 believe that this will increase, reduce the time necessary to go through the enrollment process by about 50  
26 percent because there's a lot of back and forth right now between the physician or the physician's office  
27 and contractor, so this will streamline the enrollment process for physicians and nonphysician practitioners  
28 and allow them to make their changes more timely than in the past. It will also reduce the administrative

## PPAC Meeting Transcription – December 2008

1   burden for the Medicare contractor and free them up to look at other issues from an enrollment perspective.  
2   We issued a list serve announcement on December 4. We have information regarding Internet-based  
3   PECOS on our provider enrollment website which is on the next slide, so it's available for you and it's the  
4   left hand side of our screen. There's several downloads, which are available. Talks about security, privacy,  
5   the process of getting started guide, there's frequently asked questions, we will be scheduling an Open  
6   Door Forum most likely in January so that we can discuss Internet-based PECOS with the public. We've  
7   established an external users help desk, which is able to assist an individual if they're encountering a  
8   problem with navigating the system, or if they have an access problem. Internet-based PECOS is set up as a  
9   scenario-driven process, so you will only see those screens that are necessary to be complete to process the  
10   action that you would like to process. So if you think in terms of Turbo Tax or TaxCut or some other type  
11   of software that is a scenario-driven product, if you have no farm income, you never see all of the questions  
12   related to farm income. Today, with the paper-based application, the 855I, there's information on it for both  
13   physicians and nonphysician practitioners. This can cause some confusion. There's telephone numbers and  
14   email addresses for the EUS and the National Provider Identifier, the enumerator, can also help you reset  
15   passwords, we'll be using the password for physicians and nonphysicians will use the password that they  
16   currently have assigned through NPES and they won't be using the existing IAX user IDs and passwords to  
17   access Internet-based PECOS. So I'm happy to answer any questions.

18           Dr. Bufalino: Thank you, Mr. Bossenmeyer. Questions? Comments? Seeing none, thank you for  
19   the report. We're due for a break. Is Carol here? Do you want to cover one more area? Let's do that. Let's  
20   take a 10-minute break back at 10:00 and we'll keep ourselves ahead of schedule. Thank you.

### Break

22           Dr. Bufalino: Let me introduce our next speaker. Our next speaker is Dr. Carol Bezel, she's here  
23   to provide an overview of the 2009 Outpatient Prospective Payment System, Ambulatory Surgical Center  
24   Payment System, the Final Rule went on display at the end of October and was published on November  
25   18<sup>th</sup> of this year. Medicare provides payment to more than 4,000 hospitals and community health centers  
26   and more than 5100 Ambulatory Surgical Centers. Dr. Bazell's the Director of the Division of Outpatient  
27   Care and the Hospital and Ambulatory Policy Group here at CMS and responsible for both of these areas.  
28   Just to alert the Council, Dr. Bazell asked for us to consider a couple questions and let me give you those so

1 that you have those kind of circulating in your head as she presents her information this morning. So three  
2 areas: First, for the Hospital Outpatient Department services, who determines what specific services,  
3 devices, drugs, etc. that are available to the patients? Are physicians influential in these decisions, and if so,  
4 how do they provide input? Second question is: What factors affect the choices of physicians and their  
5 patients regarding the setting for a surgical procedure? And third, under the revised ASC system  
6 implemented in 2008, are the ASCs changing their portfolios of services? If so, what factors affect ASCs'  
7 decisions to offer certain services? So those are a couple of things for you to be thoughtful of, and we'd ask  
8 Carol for her comments. Thank you.

9 Outpatient Prospective Payment System/Ambulatory Surgical Center Fee Schedule and Final Rule

10 Dr. Bazell: All right, I'm getting seasick, we'll just wait 'til it gets to the beginning. All right,  
11 there we are. Good morning, thank you for having me speak to you today. I'm here to talk as was  
12 mentioned, about the Hospital Outpatient Prospective Payment System. That's how Medicare, under the  
13 Fee-for-Service payment system pays hospitals for their outpatient hospital services, and also regarding  
14 Ambulatory Surgical Center payment for 2009, and that's how Medicare pays Medicare Certified ASCs for  
15 their surgical services and other ancillary services. As was mentioned, the rule was issued on October 30<sup>th</sup>  
16 and published in the *Federal Register* on November 18. We are still in the public comment period for that  
17 rule. That comment period closes December 29, 2008. There are a number of issues that are open for  
18 comment, including the new codes for 2009, which have interim assignments under the OPPS and ASC  
19 payment systems, as well as some other areas including some questions we had on drug payment, and we  
20 welcome public on those and look forward to receiving them. The websites are up here where you can find  
21 both those rules as well as a number of supporting data files that give more information regarding the data  
22 that were used to construct the payments for 2008. I'm going to cover the policies areas outlined here.  
23 These are basically the high points. There are a lot of other areas in the rule and that would include cost  
24 estimation, quality reporting, healthcare associated conditions, payment for partial hospitalization services,  
25 type B emergency department visit payment, composite APCs, drugs and biologicals,  
26 radiopharmaceuticals, brachytherapy sources, drug administration services, and then finally ASC payment.

27 By way of background, as a reminder, the OPPS rates are based on relative payment weights  
28 calculated for groups of services. Those are called Ambulatory Payment Classifications, or APCs, where

## PPAC Meeting Transcription – December 2008

1 the services in these groups are similar in terms of clinical characteristics and resources costs. We annually  
2 update those groups and their weights using the most recent claims data, Medicare cost reports from  
3 hospitals and the wage indices. For 2009, the annual inflation update for the OPPS is the hospital market  
4 basket, and that was 3.6 percent Overall, we estimate that hospitals will receive approximately \$30.1 billion  
5 in calendar year 2009 for hospital outpatient services. That's up from \$28.5 billion in 2008. And  
6 beneficiary copayments are on a slide down to 20 percent, and they're projected to fall in aggregate from  
7 25 percent of total payments to 23 percent for calendar year 2009, with an estimated decrease in beneficiary  
8 liability of approximately \$62 million.

9 We discussed cost estimations significantly in both the proposed and Final Rules this year for the  
10 OPPS and in fact, for the IPPS. Fiscal Year 2009 proposed and Final Rules. In particular, we had a  
11 significant discussion of charge compression and that's the practice that's reflected in hospitals' often  
12 assigning lower markup to high cost items and higher mark up to low cost items within one cost center. We  
13 contracted with RTI to evaluate the impact on the IPPS and OPPS cost-based payment weights of hospitals'  
14 charging practices. And the RTI recommended both short and long-term accounting changes and short-term  
15 statistical adjustments, and that report is available at the website you'll see above.

16 We note that in the Final Rule, we're going to focus on long-term solutions to improve cost  
17 estimation and to address charge compression. In the fiscal 2009, IPPS Final Rule, there were separate cost  
18 centers created for implantable devices and other medical supplies and these will be utilized under the  
19 OPPS as well. Of note, we did not create separate cost centers for drugs with high and low pharmacy  
20 overhead costs for 2009 as we had proposed, because hospitals and other commenter expressed significant  
21 concerns about the administrative burden of two drug cost centers. And all the cost center changes we'll be  
22 adopting will affect both the IPPS and the OPPS, relative weights.

23 Moving on to Quality Reporting. The Quality Reporting Initiative that are discussed in the OPPS  
24 Final Rule build on efforts across Medicare to strengthen the connection between the quality of care and  
25 Medicare payment. By law, hospitals that fail to report in 2008, there were seven quality measures, on  
26 emergency department and perioperative surgical care, will receive a 2 percentage point reduction to their  
27 calendar year 2009 payment. That reduction also applies to beneficiary copayments. The final policy for  
28 2009, this would affect the 2010 update for hospitals, requires hospitals to report eleven quality measures



1 for their full payment in 2010. These include the seven measures that were required in 2008, plus four new  
2 imaging efficiency measures, which are claims-based measures. There also will be starting a voluntary test  
3 validation program, beginning with January 2009 encounters, and we will validate reported data by  
4 reviewing 50 or fewer records from 800 randomly selected hospitals. This is our first foray into validation  
5 in the outpatient reporting program.

6       Next I want to talk a little bit about what we're calling HOP-HACs. Those are Hospital  
7 Outpatient Healthcare Associated Conditions. In the 2009 Final Rule, we announced plans to extend the  
8 IPPS hospital-acquired condition payment reduction policy to the OPSS. As many of you may know, that's  
9 a policy under the IPPS, where Medicare doesn't pay more for the care delivered to patients when they  
10 acquire certain conditions in the hospital that could have been reasonably preventable. And that's been  
11 discussed and finalized those policies for 2009 in the IPPS Final Rule. While we didn't adopt a policy for  
12 the OPSS in 2009, we certainly signaled our intent to move in that direction. We have a commitment value-  
13 based purchasing across the continuum of care. Many medical and surgical diagnostic procedures are  
14 performed in both inpatients and outpatients, and beneficiaries often initiate their hospital encounter in the  
15 hospital outpatient department. We will pursue any HOP-HAC proposal through the annual OPSS notice  
16 and comment rulemaking cycle and I'll note that we're having an IPPS/OPSS HAC/HOP-HAC listening  
17 session on December 18, 2008, jointly sponsored with the CDC and later on in the slides, I'll provide some  
18 more information on if you'd like to register to listen to that and location in the website where you can find  
19 more information on that listening session that's upcoming actually shortly.

20       With respect to partial hospitalization program services, these are basically an outpatient day of  
21 service for mental health services. We considered them to be the most intensive outpatient mental health  
22 services provided to patients. For 2009, we created two separate groups for partial hospitalization program  
23 services. There's one group for days in which three services are furnished. That per diem rate is  
24 approximately \$157. That's basically pretty much a half a day of care for patients. And there's one APC for  
25 days in which four or more services are furnished, with a per diem rate of \$200.

26       Moving on to type B emergency department visits. For purposes of the OPSS, we have  
27 distinguished two types of emergency departments. The first are what you might classically think of as an  
28 emergency department, see emergency patients, open 24 hours a day, 7 days a week. Those are type A

1 emergency departments. They have an EMTALA obligation. The second type of emergency department  
2 that we've identified are what we call type B emergency department visits. These are also emergency  
3 departments that see emergency patients. They have an EMTALA obligation, yet they are open less than 24  
4 hours a day, 7 days a week. While the vast majority of hospital emergency departments are type A  
5 emergency departments, there also are a number of the type B variety. These type B ED visits have been  
6 paid at the same rates as clinic visits, prior to calendar year 2009. Our claims data showed that most of  
7 these visits are more costly than clinic visits, but less costly than the type A emergency department visits.  
8 So for 2009, we created four new APC groups for type B emergency department visits, where payment is  
9 based on the cost derived from type B emergency department claims data, and since the cost for the most  
10 intensive, that's the level 5 type B and type A ED visits are very comparable, that payment for those visits  
11 is the same as for all level 5 visits. There aren't distinguished payments for type A versus type B  
12 emergency department visits.

13         Now moving on to composite APCs. We are seeking to encourage efficiencies by making a  
14 comprehensive payment for several major services, a single one, that may be reported with multiple  
15 HCPCS codes. For 2009, we're continuing four composite APCs that we created for 2008. Those include a  
16 composite APC for low-dose rate prostate brachytherapy and for cardiac electro physiologic evaluation and  
17 ablation services. For 2009, however, we've created some new APCs for multiple imaging services. These  
18 composites apply when there's a second and/or subsequent imaging procedures provided during the same  
19 session within three imaging families. Those families, for purposes of OPPS payment are ultrasound,  
20 computed tomography and computed topographic angiography without contrast, CT and CTA with  
21 contrast, magnetic resonance imaging and magnetic resonance angiography without contrast, and MRI and  
22 MRA with contrast. The law requires us to pay through separate groups for services with and without  
23 contrast. That's why the three turn into five, in particular for the CT and MRI composites. So again, under  
24 the OPPS, when a hospital provides two or more services in one of those imaging families, there's a single  
25 payment rate that will be provided to the hospital for that encounter and that rate has been derived from  
26 claims data that reflect those circumstances that hospitals cost under those circumstances. When a hospital  
27 provides only one service, they'll continued to be paid a single APC rate that was established by single  
28 claims for single service from historical hospital claims data.

**PPAC Meeting Transcription – December 2008**

1 Another area which received significant public comment in the OPPI rule was payment for drugs  
2 and biologicals. The Medicare Modernization Act requires payment based on hospital average acquisition  
3 cost, which can include an adjustment for pharmacy overhead costs. Our current 2008 policy is to pay at  
4 the average sales price, plus 5 percent with drugs with per day costs over \$60. Our 2009 proposal was to  
5 pay at ASP plus 4 percent for drugs with a cost of over \$60 per day. We updated that packaging threshold  
6 of \$60 and we used for the proposed rule hospital claims data to calculate the mean drug cost, including  
7 acquisition and pharmacy handling costs.

8 Our final policy for 2009 is to pay at ASP plus 4 percent for drugs over \$60 per day. This is as we  
9 proposed. We note that our actual hospital drug cost that we observed in Final Rule claims data was ASP  
10 plus 2 percent, however, we finalized a rate of ASP plus 4 percent consistent with our proposal as well as  
11 consistent with a transitional rate that would be a blend of our 2008 rate and the 2009 claims data. We  
12 sought comment on a number of areas in seeking comment during this public comment period, in particular  
13 related to refining our drug payment methodology in the future, including affects of hospitals' participation  
14 in the 340B drug pricing program. That was a comment that was brought up to us by multiple commenters  
15 that the costs of those hospitals are different for drugs and we have about 10 or 11 questions we ask the  
16 public to comment on in the Final Rule as we further explore that issue over the upcoming year. So  
17 hospitals will continue to include handling and pharmacy overhead costs in their drug charges and report  
18 these in a single cost center.

19 For radiopharmaceuticals, the Medicare Improvements for Patients and Providers Act of 2008,  
20 requires payment for therapeutic radiopharmaceuticals at hospitals' charges adjusted to cost through the  
21 end of 2009, so we'll be providing based on that payment methodology our payment to hospital outpatient  
22 departments. We're also continuing to package payment for diagnostic radiopharmaceuticals in 2009. So  
23 when we provide an OPPI payment for a nuclear medicine procedure, it contains payment for the  
24 radiopharmaceutical that's used and that is not paid separately.

25 Brachytherapy sources are also required to be paid at hospital's charges adjusted to cost by  
26 MIPPA, and I'll note that they're not eligible for outlier payments or the rural adjustment while they're  
27 paid at cost.

**PPAC Meeting Transcription – December 2008**

1 Moving on to drug administration services. Our 2008 policy had a six-level structure, reflective of  
2 the CPT coding that was available from 2006 claims. In 2009, we've restructured the APCs to provide five  
3 levels of APCs to more closely align payment to cost as shown in our claims data, and we'll note that we're  
4 no longer providing a separate payment for IVIG preadministration related services in 2009. We're  
5 packaging its payment into drug administration services just like we do for other drugs under the OPSS.  
6 Last, to briefly touch on ASC payment, beginning in 2008 the revised ASC payment system rates are based  
7 on the OPSS payment weights and payment policies. So the ASC rates reflect the same relativity of  
8 resource use as under the OPSS, while recognizing the lower ASC costs. So for 2009, we've revised a  
9 system to maintain budget neutrality, updating it in synch with the OPSS update and the OPSS payment  
10 weights. We used a budget neutral ASC-specific conversion factor to determine ASC payments and we  
11 expect to make payments of almost \$3.9 billion in 2009 to more than 5100 ASCs, compared with \$3.5  
12 billion in calendar year 2008. I'll note that the inflation update by law for ASCs was zero for 2009. That's  
13 the last year that Congress has provided, at least currently, a statutory update of zero. 2009 is year two of  
14 our four-year transition to the revised payment system, so the rates in 2009 are based on a 50-50 blend of  
15 calendar year 2007 ASC rates. That was the last year of the predecessor payment system, and the calendar  
16 year 2009 rates are calculated according the standard ASC methodology. We've added procedures to the  
17 list, thirty surgical procedures in particular, and we've added eight procedures to the list of office-based  
18 procedures and those are procedures where payment is made at the lesser of the Medicare Physician Fee  
19 Schedule office practice expense amount or the standard ASC rate.

20 Key websites are indicated here. The OPSS website, again, where I mentioned you'll find a lot of  
21 supporting files, the ASC website, and the RTI report on cost estimation. Information on the listening  
22 session, on healthcare associated and hospital-acquired conditions, December 18, you may register up  
23 through December 11, and we're accepted written comments until December 31, 2008. And if you're  
24 interested, we'd really appreciate your participation. And there's more information available on the CMS  
25 website at the site located on the slide. And that concludes my overview. Thank you for your attention.

26 Dr. Bufalino: Thank you, Dr. Bazell, you know, just a comment. That's the most impressive  
27 mentioning of acronyms all together without taking a breath. [laughter] IPPS, OPSS, HAC, HOP-HACs, I  
28 think I can't do it. But that was very impressive.

**PPAC Meeting Transcription – December 2008**

1 Dr. Bazell: It had to fit on the slide.

2 Dr. Bufalino: Kidding aside, again, I'd address the Council questions for your comments, and of  
3 course open this for open discussion and questions.

4 Dr. Standaert: I have a couple of comments. You covered a lot of territory. I've got a few  
5 questions here. Two questions. One is fairly straightforward. On the issues of more measures going for the  
6 hospitals and going up from seven with four additional. Our hospital has been having trouble just getting  
7 information on abdominal CT measures and what it is we're supposed to be reporting and commenting on  
8 and they're kind of curious how with more, so they can't even respond to one of the measures that's out  
9 and they're wondering where they can get more information on specifications for some of the measures that  
10 are already there, and how they comment if they can't get that.

11 Dr. Bazell: I'm sorry. So you were, how do they comment?

12 Dr. Standaert: See they're trying to comment—the call for comments, and they're having trouble  
13 finding information on the specifications for abdominal CT is particularly what they're after. It's a trauma  
14 hospital. And so they're having trouble getting that information, but they're being called for comment and  
15 more measures are coming, and they're sort of going, we can't even comment on the measures we have,  
16 much less get ready for me.

17 Dr. Bazell: I think that was, I think a point that a number of commenters made to the proposed rule  
18 this year. There were four new measures proposed for comment, for actual reporting in 2009 imaging  
19 efficiency measures. And there were about 30 others that were mentioned for the future and I think there  
20 were a number of public comments that where folks really were of the opinion that it was hard to fully  
21 comment because they didn't have enough information about the specifications of the measure, so certainly  
22 moving forward, I think that's something we've heard very seriously and we'll take into consideration for  
23 future rulemaking. In terms of the information on those measures were adopted. And are they having  
24 trouble right now?

25 Dr. Standaert: They are, yes.

26 Dr. Bazell: Figuring out what they're going to need to do?

27 Dr. Standaert: Right.

1 Dr. Bazell: I'll take that back and we'll talk to our colleagues in OCSQ about the timing and  
2 availability of more information on the newly adopted measures.

3 Dr. Standaert: And my second question in this was the transfer of the concept of hospital-acquired  
4 problems into the outpatient setting. I guess you can see a lot of difficulty implementing that. Say you have  
5 a patient who develops a pressure ulcer at one hospital, gets transferred over to a hospital like mine, which  
6 is more of a tertiary sort of place and that means ongoing management as an outpatient. Who's  
7 responsible—and if Medicare isn't going to pay for that, then who's responsible for paying for the hospital  
8 care? The hospital that is treating the condition that was acquired somewhere else? How does that work, is  
9 that the intent, or what?

10 Dr. Bazell: I think we didn't actually make a, just to remind folks, we didn't make a specific  
11 proposal for 2009 for healthcare associated conditions for outpatient payment. We had a sizable discussion  
12 and in the Final Rule we have an extensive discussion and we asked people, we asked for comments in the  
13 area of conditions to consider, how to deal with what's present when the patient comes to the hospital,  
14 that's been a significant challenge on the IPPS side, certainly as on the OPPI side, the whole issue of  
15 reasonable preventability, and attribution which is partly what you're referencing. So these are all  
16 important issues I think, while we're committed to movement in this area, we, people made a lot of  
17 comments about that and we've given them a lot to think about. We expect that we'll have significant  
18 discussion of this area as well at the listening session because we're very interested in people's thoughts  
19 about how to move forward in this area, recognizing again that our desire to not pay more for care that  
20 happens is required, because conditions are occur in the hospital that could have been reasonably  
21 prevented. But that there are a lot of issues of attribution and obviously in the outpatient department in  
22 particular, you have a less captive patient than the inpatient setting.

23 Dr. Standaert: And those conditions will need to be cared for. And my question is then who is  
24 liable for payment and then how do you track that and how do you follow that through the extended  
25 healthcare system, because it can be an extensive amount of care down the road in an outpatient setting.

26 Dr. Bazell: Certainly, take your point, I think we heard that point from many and we expect to  
27 have a lot more conversation about this over the upcoming months.

28 Dr. Bufalino: Jeff had a comment.

1 Dr. Rich: Just the process of how or the way that we pay or don't pay for it. Say you're admitting  
2 a patient with congestive heart failure to the hospital from a SNF, and that patient has a pressure ulcer. The  
3 DRG payment's preadjusted for the presence of the pressure ulcer based on historically claims data and  
4 costs, involving caring for a patient with a pressure ulcer with congestive heart failure. So let's say if it was  
5 \$5,000 for the DRG for heart failure, but it's \$5,900 for something for a DRG for a heart failure with  
6 pressure ulcer already present on admission. I think that's what you were asking.

7 Dr. Standaert: [crosstalk] getting into sort of any outpatient setting then, you transfer this to an  
8 outpatient setting, the pressure ulcer still needs care. If it's not a hospitalized, institutionalized patient,  
9 they're getting care for that pressure ulcer on an outpatient basis and the pressure ulcer was deemed sort of  
10 a hospital-acquired condition that shouldn't be paid for. Somebody still has to pay for the outpatient care,  
11 wherever it's being delivered. So that was my question, how that conceptually flows.

12 Dr. Rich: Once a patient's discharged from the hospital, the outpatient care is paid for in the  
13 similar fashion.

14 Dr. Standaert: Currently, yes.

15 Dr. Rich: It's not eliminated.

16 Dr. Bazell: I think he's just concerned about if we move forward, how are we going to deal with  
17 all these issues of sites and patients moving around and coming in with conditions that could be hospital-  
18 acquired but they already have and definitely an area that we received a lot of comment on and we'll be  
19 continuing to discuss.

20 Dr. Ross: I wanted to bring up a case in point, and I brought this up in the past anecdotally, but  
21 once again it's worth repeating. I had a patient that I went to see who had been admitted for, I think it was a  
22 fractured knee, and he had been in rehabilitation for a period of time, and I had clearly written on the orders  
23 to wear fleece heel protectors to prevent a decubitous heel ulcer. Lo and behold, he was in dialysis. I went  
24 down to dialysis to check up on him to see how this other ulcer was doing and lo and behold, there was the  
25 hematoma on his heel. So now a hospital-acquired condition and even, not only preventable, but was even  
26 in the order sheet attempted to be prevented, and nonetheless still developed. So the question is, what  
27 happens now in terms of my care. I have to do this IND of this hematoma, I now am responsible for this  
28 now new decubitous ulceration, what happens in this scenario? It's a perfect case in point where we're

1 going the extra mile to try to prevent this from happening. I've been predicting this for a long time. We've  
2 gone the extra mile and it still happens. Now what happens to us?

3 Dr. Rich: The hospital-acquired condition policy does not apply to physician services. You still  
4 get paid for your care. We're talking about the hospital not being able to use that acquired condition to get a  
5 higher DIG payment for that particular patient.

6 Unidentified speaker: But your physician services are still paid the same way.

7 Dr. Ross: I guess really what I'm also trying to say is, and I think I mentioned this even in the last  
8 occasion when I introduced a resolution—how do we educate? How do we prevent these things from  
9 happening? It's not just nursing care. It's perception. And we can prevent them, many of these “side  
10 complications” from occurring in the first place, not just in the SNF unit setting, but even in the acute  
11 setting as well as in the long-term setting.

12 Dr. Williams: If I can add to that, there are a lot of studies in the anesthesia community, in the  
13 operating room, where we have peripheral nerve injuries, where the patients are positioned on the OR table,  
14 appropriately padded, and protected and they still get a peripheral nerve injury. So even though the  
15 physician may get paid, if the hospital doesn't get paid in view of all of the evidence-based studies that  
16 have been done on this, I mean I think it sort of adds to your question of what happens with the hospital in  
17 that case? I mean no matter, sometimes no matter what you do, the person still has an injury.

18 Dr. Bazell: Certainly that gets to, I think, the issue we've talked about at length under both the  
19 IPPS of reasonable preventability and also the limitations. Right now, the current methodology which is  
20 basically a case-by-case assessment, because of a number of commenters have brought up to us that  
21 reasonable preventability may not mean 100 percent preventable and that there may be some rate of  
22 complications that is expected and predicted no matter what measures you take and certainly again a topic  
23 that we've had substantial discussion about and we'll continue to have discussion about as we think about  
24 adopting conditions and moving forward with the same methodology and/or alternative methodologies. It  
25 might begin to contemplate the issue of rates rather than just a case-by-case assessment.

26 Dr. Howard: There's some confusion, and I just wondered if you could clarify it. Where is the  
27 policy that extends the statutory authority from the hospital-acquired inpatient site to the outpatient site?  
28 Could you direct us to that for some clarification?



**PPAC Meeting Transcription – December 2008**

1 Dr. Bazell: Right, there's no explicit statutory authority for a hospital-acquired conditions policy  
2 like there is under the IPPS. Under the OPPTS, there is a broad statutory authority that allows for equitable  
3 adjustments to payment under certain circumstances. And what we've said is we would consider that  
4 authority among others were to actually proceed with proposing a policy. Again, we made no specific  
5 proposal this year, but feel like we have currently under existing statutory authority, the ability to make a  
6 proposal, albeit there aren't explicit parameters that are outlined, like there are for the IPPS under certain  
7 circumstances. That similar, the first policy we adopted for the quality payment reporting and the reduction  
8 of the conversion factor, we actually adopted and finalized a policy prior to the statute which now requires  
9 us to utilize such a policy. So we used the equitable adjustment authority in that case to propose and to  
10 finalize that policy, and then Congress came along and put that specific policy in the law.

11 Dr. Howard: So in order to go back and do an outpatient side to this would you have to then go  
12 back to the same process and get Congress to approve that or are you just...? [crosstalk]

13 Dr. Bazell: They didn't have to do that. They chose to do that. I think it's our belief that we have  
14 existing statutory authority that would permit us to make a proposal in this area and that it wouldn't require  
15 statute, although certainly we would of course abide by whatever laws existed at the time or came into  
16 being, but it worked in the reverse order when we did the quality reporting proposal and policy. But one of  
17 the advantages of not having a specific statute that governs this is some of the specifics that indicate what  
18 the IPPS must do are not, don't exist for the OPPTS, so you may have the ability to consider a broader type  
19 of policy, taking other things into consideration rather than being strictly bound by the precision of the  
20 statute in some cases.

21 Dr. Howard: Can you direct us to where we can find that information if we wanted to look over  
22 your, just to read it or is there...

23 Dr. Bazell: Sure, I can certainly provide afterward the section of the final, the most extensive  
24 discussion of this for the outpatient is the section of the final rule that went on display October 30, and I  
25 can certainly provide that to Ken or whoever and he can circulate that reference.

26 Dr. Bufalino: Other comments? Greg?

27 Dr. Przybelski: Addressing your second question, what factors affect the choices of physicians in  
28 doing things in certain settings versus others? Just speaking personally, a lot of what I try to do as a spine

1 surgeon, is in the outpatient hospital setting and most of what I do is there. But the hospital has come back  
2 on certain things that I do to say that we can't effectively pay for some of the implants, for example,  
3 through that payment system versus inpatient and so there seems to be a disconnect whereas services  
4 provided in a theoretically cheaper setting but they can't capture the costs in that setting, and therefore try  
5 to encourage it to be done in a more expensive setting, which doesn't make global sense. And so I guess I  
6 would ask how can one influence what is included in the APC, for example, I was just quickly looking  
7 through a database, looking at some spine procedures and a lot of decompression procedures are included  
8 in that list, but fusion procedures are not. And some decompression and fusions are done at the same time  
9 in the same patient and can be done in an outpatient setting. So how does one influence the choices of those  
10 APC groups?

11 Dr. Bazell: Most of the work in terms of the configuration of the APC groups goes on through the  
12 proposed and Final Rule making cycle for the OPPI. We have a technical advisory committee, the APC  
13 Panel, that advises us, it's a FACA committee, that advises us and typically has a meeting in the winter,  
14 prior to the proposed rule and then during the common period. I'm not sure exactly what's going on in the  
15 spinal procedures, but so those, we structure those APC groups based on assessment of the clinical  
16 considerations of the procedures and the costs from hospital claims data. The Panel may provide us advice  
17 there as well as the comments when we make a proposal. Under the OPPI, though, we also have a policy  
18 which there are certain procedures we consider to be inpatient procedures for which we don't provide a  
19 payment in the outpatient setting, and that process to change that list, also goes on through the rulemaking  
20 cycle. So it might be that some of the fusion procedures you mentioned are not payable under the OPPI at  
21 all, because they're on what we would call the inpatient only list. And we rely upon commenters  
22 throughout the year to give us information about those procedures. We're interested in information to show  
23 that they are safely done in the outpatient department on a typical Medicare beneficiary, and we revise that  
24 list through the rulemaking process. So we would welcome your suggestions or either people or their  
25 societies about procedures that they feel we have on the inpatient only list for which we don't make OPPI  
26 payment that folks believe have moved along in the current medical practice environment, are appropriately  
27 done in the hospital outpatient setting, because we're interested in seeing that all safe settings for care,  
28 Medicare provides payment in those settings.

1 Dr. Przyblski: One of my follow-up questions is the example that I'm thinking of is an anterior  
2 cervical discectomy infusion, they're often done together, and the fusion procedure's not in an APC group.  
3 When I look at the Medicare database, 7 percent of them are done in the outpatient setting, similar to the  
4 cervical discectomy, so I would think the technical advisory group would sort of notice such a thing and  
5 say this is a disparity that doesn't make sense.

6 Dr. Bazell: We definitely look at data. We typically look at physician data because it gives us a  
7 sense of all sites of service for these procedures, and we bring topics to the panel, but again, I would say  
8 that we regularly get comments from interested folks and/or interested professional societies, who are  
9 making a case about their specific procedures and patterns of care. So would certainly welcome your  
10 comments if you have them, so we can consider that for 2010.

11 Dr. Przyblski: Thanks.

12 Dr. Simon: I was going to say, too, that it's not uncommon for both the outpatient setting and in  
13 the ambulatory surgical setting for the specialty societies to request services to be approved in those  
14 settings, and when we look at some of the data, we'll hear from physician groups saying that a service may  
15 require, typically require, three days of an inpatient stay. And then they also want to have that done in an  
16 ambulatory surgical setting that requires less than 12 hours of care, which is kind of incongruent because if  
17 it's stated that for typical payment for physician payment purposes it's a three-day hospital day, which  
18 requires three days of inpatient services, then we struggle with how to sort out how that service can be  
19 provided in a setting that is less than one day that doesn't reflect the typical patient. So it's those kinds of  
20 incongruencies that we usually will appeal to the specialty societies to help clarify and further delineate.

21 Dr. Przyblski: Thank you.

22 Dr. Williams: Well I was going to add to that the degree of co-morbidities, I guess. Initially when  
23 surgery center started, as you know, we didn't do very high risk patients in an outpatient basis. Maybe  
24 some of this has to do with a degree of co-morbidities the patient has. Is that partly influencing your  
25 decisions?

26 Dr. Bazell: We think about typical Medicare beneficiaries. Now we don't necessarily think that the  
27 most severely ill beneficiaries, but we certainly take that in consideration because we are making our  
28 decisions for the Medicare program, even though sometimes people say our decisions drive others'

1 decisions, we really feel like for the Medicare program that's an appropriate decision. So most Medicare  
2 beneficiaries are 65 and older and a number of them have co-morbidities and so we are very interested in  
3 only providing payment for those procedures that we don't think would be a significant risk to beneficiary  
4 safety in there and we have to make a clinical assessment there of that with advice. But again, one of the  
5 things we often do is have discussions in our proposed rule about a given area, so we can seek broader  
6 public comment on perspectives on the types of patients and what the complications might be and what the  
7 co-morbidities might be of those patients in order to inform our assessment.

8 Dr. Ross: Back to your first question on the Final Rule seeking our advice on the following topics,  
9 in particular the second topic of what factors affect the choices for physicians and their patients regarding  
10 the setting for surgical procedure. Are you going to be polling this group or are you going to be polling  
11 physicians to determine what procedures should be done in an ambulatory setting versus an inpatient  
12 hospital setting? How are you going to go about getting that data, that information?

13 Dr. Bazell: Right now we have a set of services that we pay for in the outpatient setting that are  
14 open for comment and in the Ambulatory Surgical Center setting. We don't typically poll physicians. What  
15 we do is deal with this through our annual rulemaking process where you make a proposal to pay for  
16 certain procedures at certain rates and to add procedures for example, usually to add, we're not typically  
17 taking them off of a list, although we have done that occasionally, and that's the way we solicit input from  
18 the community in general, the public in general and that would include physicians.

19 Dr. Ross: But what I'm asking is if for instance, we see that if it's more a hassle to perform that  
20 procedure in the hospital versus doing it in an ambulatory setting, if it's not been approved yet, how will it  
21 become approved so that it can be reimbursable?

22 Dr. Bazell: Again what we would typically have you do is you could write to me and we take  
23 those under consideration all year long. People do write to us about cases all the time. And/or you could  
24 comment to a proposal we make for 2010, where we didn't propose to pay for a certain set of procedures  
25 and you think we should.

26 Dr. Ross: Will you seek the advice, counsel of our specialty societies rather than just individually  
27 writing you?

1 Dr. Bazell: We typically are interested in input from everyone. We typically don't, we have not  
2 gone to individual societies, although many comment to us on our proposed rule. That's the way we seek  
3 broad public comment and we certainly have many professional societies over this last rulemaking cycle  
4 that came in and one that actually I think maybe talked to the APC Panel about some services that they  
5 thought should be paid in the hospital outpatient department that weren't, and commented in the  
6 rulemaking cycle and that's typically where we would interface with the societies. And we're very  
7 interested in what they think and what the public in general thinks about appropriate procedures for the  
8 ambulatory setting.

9 Dr. Bufalino: One other thing I'd just add on to your first question, you asked whether or not  
10 physicians play a role in the outpatient side. At least in my practice, we are involved in eight cath labs in  
11 suburban Chicago, and frankly the services, the catheters, the drugs are really typically dictated by the  
12 physicians. We actually provide a fair amount of input and are listened to in terms of how, what services  
13 we actually try to accomplish outpatient cath lab settings, along with what devices we use to get that job  
14 done. So it's typically physician-driven, as opposed to hospital-driven. Now the hospitals love to congeal  
15 us and get us to be using two or three vendors instead of eight vendors for purposes of them being able to  
16 control costs for obvious reasons when they can have two vendors exclusively providing all of that  
17 equipment to that setting. They're able to get better pricing, obviously, than they are in other settings. And  
18 if it's reasonable and they're comprehensive vendors, then that tends to be something that folks go along  
19 with.

20 Dr. Sprang: Consistent with what Vince just said, clearly in most hospitals, the physicians actually  
21 decide what needs to be done there and usually the hospitals go along with that. Patients and physician,  
22 convenience, safety, less anxiety. What factors choose the physician to pick one or the other of the things I  
23 just said, but I wanted to kind of just take it a step further, because especially in GYNY and I don't know as  
24 much for the other specialties, there's more and more articles being written on doing more in the office  
25 setting, not the outpatient hospital setting. In my hospital anyway, if I just even walk into the hospital to do  
26 a procedure, it's \$5,000 to start with. In my office, there's no cost. So I think from an overall cost savings  
27 point of view, it's extremely intelligent to do, patients like it, it's much more convenient for everybody, and  
28 assuming obviously you're picking safe procedures—it may be even safer because you don't have the

1 hospital-acquired bacteria and MRSA, etc., as much in the office. Specifically in GYNY, there are  
2 numerous articles now and I will say what we're doing in our office. Adrenal PAP smear, we do  
3 colposcopy, and biopsies in the office. If there's a dysplasia in the cervix, we do the cervical conization in  
4 the office. If a person has post menopausal bleeding, which is [unintelligible], often apply to Medicare  
5 patients as well, we do the endometrial biopsies. If we think we need more with the new medications, any  
6 of the medication help dilate the cervix. Probably in the last couple years, I've done 50 office DNCs. And  
7 most of the patients are pretty comfortable. We give them a lot of medications ahead of time. Hysteroscopy  
8 which again, used to be just hospital procedure. We do those in the office. Less so probably for Medicare  
9 patients, but I got a Medicare patient now who's pregnant who I'm taking care of, and Medicare patients  
10 sometimes obviously are younger. We're doing endometrial ablations, if people have extremely heavy  
11 periods and they may have ended up in the past with a hysterectomy, obviously the cost involved in that  
12 being very, very significant, we do endometrial ablations in the office. I'll say the more enlightened third  
13 party payers, Blue Cross in our state, will actually pay us \$4,000 for doing the endometrial ablation in the  
14 office and \$500 for doing it in the hospital, because we're saving them all kinds of money. Because in the  
15 hospital they're paying \$10,000 or more at least for the OR, so it is evolving very dramatically. We're  
16 doing more and more not only in outpatient hospitals but in the office, and it does make good sense from  
17 the patient's point of view, from the physician's point of view, and obviously from the overall cost of  
18 healthcare. I'll throw one more out there, which people in the room are going to cringe a little bit, but we  
19 do tubal ligations in the office. You can actually with the medications, you can do hysteroscopy, look in the  
20 uterus, see where the tubes come into the uterus and put a little spring in each one, three months later we do  
21 a hysto sonogram to make sure the tubes are blocked and then say, you're sterilized. Now that won't apply  
22 to a lot of Medicare patients, but it does to some and that's the direction medicine is going in I think for the  
23 right reasons, including overall cost savings in right care, right time, right setting. And insurance companies  
24 are actually paying us more to do it in the more cost effective setting.

25 Dr. Standaert: I'm also, I agree somewhat with both of you said about physicians and driving what  
26 devices and everything else. I have one question I want to clear up on the multiple imaging APCs. I was  
27 trying to understand the rules so I get both for my own patients and also understand the relative incentives  
28 or disincentives for the hospitals or imaging facilities. Does this mean that if people come in and they get

1 an MRI with and without contrasting in one setting, it's paid for under one price, if they come back for  
2 MRI with contrast the second day, it's two separate charges? What does it mean if they get MRI of their  
3 spine, plus their pelvis, plus their knee all in one day, it's all in one charge? What does that mean exactly,  
4 just so I understand what my—

5 Dr. Bazell: Sure, it's basically when a service would be reported with more than one CPT-code.  
6 So if the CPT-code says CT with and without contrast, a single CPT-code, that's one payment. So when we  
7 talk about multiples, we mean more than one CPT-code reported for it, so CT of the chest and abdomen or  
8 MRI of the brain and the orbit, there's a single payment for that. But there's always been a single payment  
9 for services provided with a single CPT-Code that reflect with and without contrast.

10 Dr. Standaert: So what they're saying here is again multiple body parts will now be lumped  
11 together? Is that what I'm—

12 Dr. Bazell: Right. Basically if you go in and you get a CT or CTA reported with more than one  
13 CPT-code, the hospital will get one payment for that as opposed to a payment for every CPT-code they  
14 reported.

15 Dr. Standaert: So this low back pain and knee pain, I got a back MRI and a knee MRI, that's two  
16 codes, that's two codes.

17 Dr. Bazell: They'll get a single payment.

18 Dr. Standaert: But it's low back pain and you get back and pelvis, that's one payment? If you get,  
19 sacral pain and you get lumbar spine and pelvic MRI that's one payment or that's two payments?

20 Dr. Bazell: Is that two CPT-codes?

21 Dr. Standaert: If it's sacral pain then MRI it crosses body parts—

22 Dr. Bazell: Right, so the body part is not, the Physician Fee Schedule has a conception of  
23 contiguous body parts that affect their families and their payment reduction. You can consider this just  
24 modality basically. So if you had an MRI in one session of the head and the knee, not very likely, you  
25 would receive a single payment for that, for your MRI encounter. If there was contrast provided in that, that  
26 would be a with contrast payment and if there wasn't contrast it would be a without contrast payment.

27 Dr. Standaert: So head and knee there's two different problems, would be one payment?

28 Dr. Bazell: Correct.

**PPAC Meeting Transcription – December 2008**

1 Dr. Standaert: So if it's, again headache and knee pain, and acute knee pain and they just happen  
2 to be bringing someone for two MRIs in one day, that's one payment for the hospital, not two.

3 Dr. Bazell: It's one payment for the hospital—

4 Dr. Standaert: They come back the next day to get the knee, it would be two payments.

5 Dr. Bazell: It would be two payments.

6 Dr. Bufalino: Any other questions? Thank you, Dr. Bazell.

7 Dr. Bazell: Thank you.

8 Dr. Bufalino: We'll take a second presentation and then we'll cover any recommendations for both  
9 of these, so the next is STARK Reform. Generally as you know, Mr. Don Romano joins us for this update.  
10 Mr. Romano has actually left CMS and entered the private sector, and so we're pleased to introduce Ms.  
11 Lisa Ohrin, did I get that right?

12 Ms. Ohrin: Ohrin. Yes.

13 Dr. Bufalino: Thank you, and Lisa has practiced healthcare law for 14 years in a variety of settings  
14 and is currently the Acting Director of the Division of Technical Payment Policy within CMS and as you  
15 know, CMS is responsible for the policy and regulatory issues related to physician self-referral and anti-  
16 markup limitations, including the advisory opinions regarding the same. So Medicare's approved transplant  
17 centers and handling a variety of statutory and regulatory Medicare payment issues. Lisa is one of the  
18 principle drafters of the STARK Phase III Regulations and the revisions to the STARK III that were in the  
19 2009 Hospital Inpatient Final Rule. So we'd ask you to welcome you and await your comments. Thank  
20 you.

21 STARK Reform

22 Ms. Ohrin: Thank you. I apologize for being a little stuffy. I had surgery on my nose so it's a little  
23 crazy, so if you can't hear me just let me know. I'm going to cover two things today that were in the fee  
24 schedule. We had some physician self-referral provisions that we had proposed but didn't finalize, and we  
25 also had some anti-markup provisions that were finalized and this is my first time here so I apologize if I  
26 start too far in the beginning and just go back to the basics of the physician self-referral rule, but just to  
27 make sure we're all on the same page, I wanted to do that.



1           As you probably know, the Physician Self-Referral Prohibition is a statutory prohibition that  
2 essentially says if there is a compensation relationship or an ownership interest that a physician has with an  
3 entity that provides designated health services, the physician cannot refer to that entity for designated  
4 health services, unless there's an exception that's met. With respect to ownership there are only a handful  
5 of exceptions and with respect to compensation, there are eight statutory exceptions, and about 20 or so  
6 regulatory exceptions that we have finalized. So once you have that exception, the physician can go ahead  
7 and refer for services to the DHS entity that it has the relationship with.

8           A lot of different compensation arrangements implicate the Physician Self-referral Statute,  
9 including what is commonly known as gain sharing. We have never had an exception specific to gain  
10 sharing. The arrangements between hospitals and physicians, whereby hospitals share with physicians some  
11 portion of the cost savings that they achieve by the changes in the physician's clinical and administrative  
12 practices. The OIG has a similar statute that they enforce, the Anti-Kickback Statute and they don't have a  
13 safe harbor either, but they have been able to write advisory opinions that say we see your arrangement, we  
14 do think it implicates the Anti-Kickback Statute, but we're going to use our discretion and not prosecute  
15 because we don't think there's any risk here. On our side, on the Physician Self-referral side, we don't have  
16 the authority to waive violations or to waive the statute when it does apply. There has to be an exception  
17 and if there is no exception, then the arrangement itself would be prohibited and any referrals that result  
18 between the two parties will be prohibited.

19           So we have been hearing anecdotally from people that they would like to see an exception that  
20 made it far more clear that gain sharing was in fact acceptable under the Physician Self-referral Statute. In  
21 the IPPS proposed rule, we actually put out a solicitation of comments, to see if we needed such an  
22 exception. And overwhelmingly they were positive and said yes, it would be great to have an exception, not  
23 just for gain sharing, but for other types of incentive payment programs; Pay for Performance programs,  
24 and not the type where the insurance company pays but the type where the hospital itself would incentivize  
25 physicians to change administrative and clinical practices to achieve quality measures. So in the fee  
26 schedule, we did propose a single exception for incentive payment and shared savings programs. And if we  
27 had finalized that exception, if you did comply and designed your program like the proposed exception,  
28 then we would have said that's fine. There's no risk of program or patient abuse, and the physician self-

1 referral law is not going to be violated. The exception itself was very narrow. We're very concerned that  
2 we didn't have enough information and that we needed to get more information, but what we knew we  
3 could go out with, that wouldn't risk program or patient abuse, was narrow and we did admit that. We  
4 realized and put it right in the preamble. We can't put out an exception, we can't make up an exception,  
5 essentially, that risks any program or patient abuse. That's the statutory mandate.

6 We've really very closely tracked what the OIG has looked at and approved in its advisory  
7 opinions. In response to that, we got comments on two sides of the camp. A lot of the comments said yes,  
8 we're very much in favor of an exception, just not this one. We don't like this one and then on the other  
9 side, no, you shouldn't do it, and those were generally from the device industry. And so I'm going to talk  
10 about each set of those comments real quickly and where we went.

11 Most of the people that were in favor said, like I said, we like the idea, we need the exception,  
12 we'd feel better if there was a clearer exception or maybe two, one for incentive payment programs and one  
13 for shared savings programs, but we don't like the one that you've proposed. Nobody wants to design a  
14 program like this and if they did, it has very little utility because it is so strict. The particular areas of  
15 concern that people had, specifically we had required, or said we would require, independent medical  
16 review of the program. A lot of people have supported that, but we're worried about the cost of that, where  
17 these independent medical reviewers would come from, what type of review that had to be. We also said  
18 that if you were going to have a quality payment, a payment for achieving quality measures, the measures  
19 needed to come off of a particular list, the CMS specification manual for the National Hospital Quality  
20 Measurements. Others said that's great, we like that list and some people said well can we use other lists?  
21 How else can we do this? Can you expand that? We had a number of requirements for how physicians  
22 would be able to participate in the program, particularly in pools of five or more and that caused a little  
23 consternation as well. The reason for that was because we felt that it diffused the risk; that a payment  
24 would be directly related to a particular physician's referrals to the hospital that was making the payment.  
25 But we are certainly open to comments on all of these areas. And what we did realize from the comments  
26 was that they raised more questions than we had realized we should have been trying to answer to begin  
27 with. And so instead of finalizing exception, that we didn't think anyone would want, we decided to reopen  
28 the comment period. But we also took a look at the commenters that were opposed to the exception. And as

**PPAC Meeting Transcription – December 2008**

1 I said, that was generally the device manufacturing industry. And they had a couple of legal arguments as  
2 well as some policy arguments for us saying that the civil monetary penalty statute would be violated. And  
3 that is a statute that is enforced by the Office of Inspector General, and that statute says that any time you  
4 make a payment that reduces or limits services to Medicare beneficiaries in any way, it's per se illegal. You  
5 can't do that, and so the argument was there would be payments made to adjust services, to reduce or limit  
6 them in some way, therefore, all gain sharing must violate the CMP Statute, and in fact, that is the position  
7 of the OIG. So that's fine, but then they went a step further and said well if you do that, then you must be  
8 risking fraud and abuse, program abuse, patient abuse. So that was the main gist of the comments in  
9 opposition to our exception. They didn't like the patient notification procedures either; thought they were  
10 too, not strong enough I guess, and on the other side, the people that liked the idea of the exception thought  
11 that patient notification was too stringent. But we decided ultimately not to finalize the exception in the  
12 form that we proposed. Instead, we've reopened the comment period for 90 days and we have a lot more  
13 ideas about the information that we wanted to get and most of that was provided through the comments that  
14 we already received, but we went out with a new solicitation for more comments and in a reopened  
15 comment period, and I think it's about 55 specific questions that we've asked, and asked people to think  
16 about grouping them together because it's sort of like the balloon full of air, if you want to be a little bit  
17 more flexible in one area, you've got to squeeze the balloon so something else has to give and we're going  
18 to need more protection in another area. So the comments seek sort of a holistic approach to how we can do  
19 this, stay within our statutory mandate of no risk of program or patient abuse, and yet still have a really  
20 useful and flexible exception that would allow a pretty full range of nonabusive incentive payment and  
21 shared savings programs. I would suspect that we're going to get comments back that are so different from  
22 what we proposed or provide so much more information that ultimately we would need to propose some  
23 new exceptions, instead of working from what we started with. I think the comments, just even that we got  
24 took us far enough away that we might be outside of the ability to finalize that exception, even revised, so  
25 it's more likely in the future, you probably see new exceptions proposed for incentive payment and shared  
26 savings programs. And we were very clear in our comments that we did not believe that the naysayers were  
27 correct, that we could not go out with an exception. And we were also very clear because we don't want to  
28 have a chilling effect on beneficial gain sharing and beneficial incentive payment programs, that there are

1 exceptions to the Physician Self-referral Statute now that can be used and that we believe people are using  
2 and using appropriately, and we did in fact list those exceptions. So we think that a properly structured  
3 program is already capable of meeting an exception, but we have also felt that in tracking the OIG's  
4 advisory opinions, and the fact that this is such a priority in the department, that a separate exception for  
5 this particular type of compensation arrangement would be appropriate. So that's where we stand with that  
6 exception. That was the only physician self-referral issue we had in the fee schedule this year, unlike last  
7 year where we had plenty. So I can either take questions if there are any on that, or I can wait until the end,  
8 but I mean I shift gears and go to anti-markup next, and they're very different, so if you have questions,  
9 you might want to ask them. Yes?

10 Dr. Przyblski: Sure, let me throw out an example I'm familiar with, and this is probably why  
11 device manufacturers got upset. As we heard a little bit earlier, physicians often drive what device or drug  
12 might be used in any particular setting, and unfortunately, they don't tend to compete on price when they  
13 do on things unless forced to do so, so in the spinal setting as an example, I may have an exceedingly  
14 similar device that can have a tenfold difference in price, and the hospital essentially eats the cost if the  
15 physicians choose the more expensive device rather than the cheaper device, and so one of the gain sharing  
16 proposals I've seen was can you get a group of physicians together to agree to single vendor, that is cheaper  
17 and then reduce the price and then share the savings. Well, I could see as vendor X, the nonchosen vendor  
18 to say you're restricting the Medicare population from getting my device, yet that device is no different  
19 than the device they are getting and how do you potentially look at solving that issue?

20 Ms. Ohrin: Well, actually that came up when we were talking and planning the proposed  
21 exception. In fact, we had something to address that and said essentially, you can have this product  
22 standardization in your program, but in order to not risk program or patient abuse, and in this case, I think  
23 we're talking more of patient abuse necessarily, you would have to at least keep everything available to the  
24 physician if they wanted it. And maybe they wouldn't get a payment under this gain sharing or under the  
25 Incentive Payment program, but the other devices would need to be available if a physician felt it was  
26 appropriate medically. And if you didn't have that in your program then your program wasn't going to be  
27 protected. You didn't have to pay the physician for choosing the other thing. So and that is in fact the  
28 situation, now, in product standardization, a lot of hospitals have this already, you just can't pay a physician

1 to choose within the three. You can make them choose three, say this hospital only stocks three. But you  
2 can't pay them, and as long as you don't pay them, you don't violate the CMP statute, so that's how people  
3 are doing it now anyway. We did address that.

4 Dr. Przyblski: Thanks.

5 Dr. Bufalino: Ms. Ohrin, when you anticipate the exception will be finalized so that this can be  
6 clarified going forward?

7 Ms. Ohrin: Well, if we get the comments that are, we would really need to talk to the Office of  
8 General Counsel to see how the comments come in and if it is a logical outgrowth under the Administrative  
9 Procedure Act. If we've diverged too far from what we've proposed, we can't finalize off of the proposal  
10 that we have. And that's just a legal issue with the Office of General Counsel. We have to comply with that  
11 statute. And if we have to repropose something, I suspect you'd probably see it in the next vehicle for us,  
12 which might be the fee schedule next year, hopefully, I would hope, the fee schedule.

13 Dr. Bufalino: Other comments? Questions? You could proceed.

14 Ms. Ohrin: Okay. The Anti-markup Payment Limitation. This is something that we've been  
15 working on for a couple of years, revisions to this and I'll go back and start again at the beginning. This is a  
16 statutory requirement in the Social Security Act that says if there is a diagnostic test that is ordered by a  
17 physician or a physician practice, and it is performed by somebody who doesn't share that practice, you  
18 can't mark it up. You can't get a test for \$40, pay someone outside for \$40 and then bill Medicare the full  
19 fee schedule amount for \$100 because that person didn't share a practice with you. If they do, it's fine. And  
20 so that's a statutory requirement. We implement that through the regulations in 42CFR 41450. And up until  
21 this past year, in fact this goes into effect on January 1, but we had done some changes last year that would  
22 have gone into effect January 1, 2008 and we delayed them. So up until January 1, 2008, that applied only  
23 to the technical component of purchased diagnostic tests. And this is all about diagnostic tests by the way,  
24 nothing else. We, last year, took a look at that and had been proposing, we see that there is a great potential  
25 for group practices, physician practices to be profiting from purchasing diagnostic tests from people who  
26 have nothing to do with their practice and then billing the program for the full fee schedule amount. It's not  
27 necessarily an overutilization fear, but it is a fairness issues and obviously Congress thought to address it as  
28 well, so we were looking at the regulations and realized we needed to kind of address what was really

1 going on out there and particularly in the area of POD labs. This has kind of all started with the POD labs,  
2 and I'm suspecting everyone knows what that is, but I'll go back and talk about that. That's essentially say  
3 you have a group practice in Texas that sends all of its anatomic pathology to a POD lab, to a lab in  
4 Florida. And a POD lab essentially looks like, the best way to describe it is sort of mini storage, like cubicle  
5 after cubicle after cubicle, and it might have one microscope in there and whatever is the minimal amount  
6 of equipment necessary and a physician, a pathologist, is hired by the manager of that self-storage mini  
7 storage POD lab, and the physician goes from lab to lab, so for the 15 minutes he's in lab A, he is working  
8 with Group Practice A in Texas. For the 20 minutes he spends in POD B, he is part of a group practice in  
9 Georgia. [laughter] Group practice B, so those groups then get to bill the full fee schedule amount for his  
10 services, even though they're not paying him that much. They're purchasing the tests and the person really  
11 has no other real connection to those other group practices. That's a typical POD lab arrangement. That  
12 concerned us. Obviously. The physician self-referral rules go very far to make sure there's a proper nexus  
13 between the physicians and the group practices that bill for their services, but the anti-markup rules are  
14 really what address this particular issue. So last year, we had proposed and finalized some changes  
15 regarding the anti-markup rules and those were with respect to the technical component of diagnostic tests  
16 as well as the professional component. We ultimately delayed the application of that because we were  
17 concerned that there were some new terms that we started to use; office of the billing physician, or other  
18 supplier, net charge. People complained that we, that they really didn't understand these new terms and  
19 they kept looking back to the physician self-referral rules, which are separate rules, and so we weren't  
20 pulling the same terminology, because they are a different set of rules that addressed different problems. So  
21 we did delay last year that, except with respect to anatomic pathology, diagnostic testing services, so we  
22 did actually get to address this POD lab issue that was of great concern to us. And then, but the rest has  
23 been delay. And in the meantime, we repropose some ideas on how to be more clear about the anti-  
24 markup provisions and also to really target what it is that was our greatest concern about when a physician  
25 shares a practice with the billing group closely enough that it's okay that the billing group bill us the full  
26 fee schedule amount and not just what they paid that physician. So this year, we ultimately finalized two  
27 ways to deal with the anti-markup payment limitation. Essentially, the payment is limited. On the slide,  
28 you'll see, when a physician or other supplier bills for the TC or PC of a diagnostic test and they had

1 ordered that test, and the test is performed by a physician who doesn't share a practice with the billing  
2 physician or other supplier. We have two ways to determine when that payment limitation will actually not  
3 apply. It's a blanket limitation unless, is the way this rule reads, and the first one is what we call the share  
4 practice, or substantially all tests and the second is the site of service test.

5 When the payment limitation applies, the payments going to be limited to the performing supplier,  
6 that is, the physician who's not sharing the practice or isn't on site. With respect to the TC, the performing  
7 supplier is the physician who supervised it and with respect to the professional component, is the physician  
8 who actually did the PC, the professional component. So the limitation will be the net charge, what it is that  
9 the performing supplier charged the billing group, the actual charge that the billing group charged the  
10 patient, or the insurance company, or the fee schedule amount, whichever is lower. Usually that's going to  
11 be the net charge. And that is why net charge has become kind of a complicated issue. We have not defined  
12 net charge exactly in our regulations, and there's a reason for that because we think that people come at it  
13 in a lot of different ways. And as long as you have a reasonable methodology for determining that net  
14 charge, what did the performing supplier charge you for that test? We're going to be okay with that. We  
15 didn't want to be too prescriptive. Essentially, you can't include overhead, so the fact that the billing group  
16 maintains a lab and they have equipment costs and space costs, you can't pass those on to Medicare if all  
17 you did was pay for the TC or the PC part from the, and remember that's the part that's supervised or  
18 performed by the physician. You're only getting to charge us for what the physician charged you. And the  
19 physician didn't charge you for the space and equipment. And no tricky leasing the space and equipment  
20 back to the physician and then having him charge it back to you. That's also taken out of the equation. So  
21 usually it's going to end up being a salary benefits type thing, if the person is your employee, or it's going  
22 to be a per test amount. They charge you \$40 per read of the diagnostic test, and that's what you can bill  
23 Medicare. And again, you can determine that in any reasonable manner. We're not going to get to  
24 prescriptive about that. And that's how the anti-markup payment limitation works.

25 Now, the way to get out of it what this regulation is really all about. And again, there are two tests.  
26 The first test, and we think this is going to cover a lot of the concerns that we heard and a lot of the  
27 situations that are out there and that is the substantially all or at least 75 percent test, and what we mean to  
28 say is remember Congress said you can't mark it up if the physician that you got it from didn't share a

1 practice with you. So how do we determine what sharing a practice is? Well, we think if that physician  
2 furnishes at least 75 percent of their services, from you, then they share a practice with you, so substantially  
3 or 75 percent of their services will get you over the hump and the anti-markup payment's not going to  
4 apply to any of the services that that physician performs for you and that you bill Medicare for. How do  
5 you determine 75 percent? You obviously could do it looking at the billings, but you don't know what  
6 they're doing in the other 25 percent of their time, necessarily, so you just have to have a reasonable belief  
7 when you submit the claim, if you're the billing group, the group practice, that for the last 12 months, or for  
8 the next 12 months, this physician really is going to perform 75 percent of their services with you, and if  
9 that's the case, then you can bill the full fee schedule amount for those physician services.

10 We don't require exclusivity. The person can do a lot of other things outside your group practice.  
11 They can work for another practice. They could staff outreach centers, they can work part time somewhere  
12 else. They can do on call or moonlighting, locum tenens, as long as 75 percent of their services are  
13 furnished through the group that wants to bill for their services, for their diagnostic testing services. We  
14 don't care if they're employed by you. We don't care if they're an independent contractor, or an owner. It  
15 really doesn't matter and one of the biggest concerns we had heard from people was that our original rules  
16 last year would have precluded what everyone was telling us. They were calling hub and spoke  
17 arrangements, where there was one centralized testing facility and for or five practices around the area and  
18 they all used—I'm sorry, four or five offices for the same group practice and they all used that centralized  
19 diagnostic testing facility. This rule addresses that, and so I have four hypothetical kind of slides and I want  
20 to go through them with the Substantially All test, and then I'll talk about the Site of Service test and we'll  
21 go through the same slides and see how they apply.

22 I teach law, so I can't help myself with the little diagrams, I'm sorry! So here this would be if a  
23 physician is in, say the physician organization building three, and they order the test from building three.  
24 The patient comes to building three, order the test there, send the patient to the centralized diagnostic  
25 testing facility. Would there be an anti-markup payment limitation on the TC? Well, as long as the  
26 physician A who ordered the test shares a practice by furnishing substantially all, at least 75 percent of their  
27 services for the group that is billing for it, there's no problem. It doesn't matter that the test is performed  
28 somewhere else from where it was ordered as long as that person furnishes at least 75 percent of their



1 services with the group, it's fine. No anti-markup payment limitation. And in the next slide, we have a  
2 basic locum tenens arrangement, and here we have physician A has gone on vacation and physician B is  
3 filling in for physician A and as a locum tenens, billing in physician A's name. So we have the ordering  
4 physician, who's doctor O and she's going to order it—everyone's in the same building here. Orders the  
5 test in the building, the TC's conducted in the building, and it's supervised in the building. So does the anti-  
6 markup limitation apply? Well, that all depends on physician A. If physician A, who's out on vacation right  
7 now, furnishes at least 75 percent of her services through the group practice, physician B, who's essentially  
8 standing in her shoes while she's on vacation as a locum tenens, then anything physician B does is okay,  
9 too, as long as physician A shares a practice by doing substantially all of her services there. So even though  
10 physician B is physically the physician, we really look at physician A in this situation and see what her  
11 status is. So no anti-markup payment limitation, as long as she furnishes substantially all of her service  
12 normally through that group practice. Then in the next slide, a little bit different. Now we have two offices.  
13 And again, we have physician ordering in one building, patient getting the diagnostic test in that building,  
14 but this time the service is being supervised in a different building, and a lot of our payment rules allow for  
15 that, that you can supervise from far away and when the diagnostic test is not right there, being done under  
16 your nose. Same analysis though because physician A, we're worried about whether or not she shares a  
17 practice by performing substantially of her services through the group. As long as she does that at least 75  
18 percent of the time, then this is a perfectly fine arrangement as well. The anti-markup payment limitation's  
19 not going to apply and you can bill the full fee schedule amount. And then the last one, this has come up  
20 quite frequently since the rule came out. People keep asking us about what happens when the diagnostic  
21 test is ordered by a physician who's rounding in the hospital or in the middle of surgery in the hospital?  
22 They're not ordering it from their office. They're not performing it in their office. Same analysis here. This  
23 is a very easy analysis. This is why we think it covers the majority of situations. If the physician who orders  
24 the test and performs it at the hospital shares the practice with the billing group by furnishing at least 75  
25 percent of his services through that group, there's no anti-markup payment limitation. It's not going to be a  
26 problem. In this little hypo, the hospital's billing for the TC, so that's, that takes away altogether because  
27 the thing you have to have right at the beginning is an ordering group that is the same as the billing group,  
28 but someone else performing. Here, the ordering group isn't the billing group, so the anti-markup payment

1 limitation wouldn't even apply to that TC. So that's how our first alternative way to figure out if you can  
2 get out of the anti-markup payment limitation works. And generally, it's very easy to apply.

3         The next one is a Site of Service test and we expect that there will be some situations where a  
4 physician just simply doesn't furnish at least 75 percent of their services through the billing group. Perhaps  
5 they work 50 percent for each of two groups and then they're out. Neither group can say that the physician  
6 shares a practice with them in that sense. So we also put in a site of service test. And this is another way to  
7 say this physician, who's either supervising this TC or performing this PC really does share a practice with  
8 the billing group and we think that's a physical location alternative. If you are physically located in a  
9 particular place, a site of service, we think that of course you're sharing the practice, you're in the office of  
10 the billing group. So even if it's on a test by test basis, for that test, you're sharing the practice. So in this  
11 test, the performing physician is deemed to share the practice. If they are an owner, employer, independent  
12 contractor of the billing group, and the TC is conducted and supervised in the office of the billing  
13 physician, and the PC is performed in the office of the billing physician. So essentially, everything has to  
14 take place in the office of the billing group, and if that's the case, even if this person walked in for one test,  
15 with respect to that test, we think they were sharing a practice at that time.

16         So we need to know what some of the terms mean because this is the important thing. What is the  
17 office, the billing physician or other supplier? And that is an office, its office base in which the ordering  
18 physician regularly furnishes patient care, so they have to regularly furnish patient care there. We have a  
19 concept in the physician self-referral prohibition called The Same Building. And essentially we have  
20 incorporated that here. It is the same building. Same building means at the same U.S. postal address where  
21 the billing group resides. So if you have your multi-building office complex. And group practice is in, is at  
22 2200 Suite 1, and they have a testing facility across the parking lot at 2205. That's not the same building,  
23 even if they're connected by a breezeway because they have different U.S. postal service addresses. That's  
24 how we define same building, but as long as it's anywhere in the same building, the office could be on the  
25 eighth floor, the testing facility could be in the basement, that's the same building for us and it doesn't  
26 include a mobile unit. So if there is a mobile unit that pulls up and connects to a loading dock or to some  
27 type of part of the building, that's not the same building, even when they're connected. And it doesn't  
28 include a centralized building that is somewhere else. And those are physician self-referral concepts, but we

1 did incorporate them here, partially because people asked us to, it as an easier concept to understand, and  
2 we think that it's appropriate, that it really is the same building, and that would constitute the office. And  
3 when you're talking about a group practice, if the billing supplier's a physician organization, which is  
4 another physician self-referral term, the office is space in which the ordering physician provides  
5 substantially the full range of patient care services that he or she provides generally. So the reason for that  
6 is again to show that tight nexus, and we don't want to say the group practice has seven offices. The  
7 ordering physician only ever works in office one, but as long as he was stopping by office two one day and  
8 ordered a test, that's okay. That's not going to work under Site of Service. So if you're looking at the Site  
9 of Service test, it really needs to focus on where the ordering physician normally provides the full range of  
10 services that they provide, where the test was ordered, and where it was performed.

11 So it doesn't take away shared space arrangements. We know those are pretty popular and the  
12 anti-markup provisions will still, you can still avoid them, even if you're using shared space, and again as I  
13 said, the mobile vehicle's not part of this and the centralized building is not part of this concept either. It  
14 has to be a same building. And so we could go back to the next set of hypos. It's the same pictures, but  
15 we'll go through them with this particular test.

16 So on the first one, the hub and spoke configuration. So here we have the diagnostic test is ordered  
17 by physician A in building 3, and the TC is conducted and supervised in the centralized diagnostic testing  
18 facility so the question is would the anti-markup payment limitation apply? And it would apply to the TC  
19 because this time, we're going to assume the physician doesn't spend 75 percent of their time. The ordering  
20 physician does not spend 75 percent of their time—I'm sorry, the supervising physician doesn't spend 75  
21 percent of their time with the group practice. So we're not going to even look at the shares a practice idea.  
22 But here, the supervising physician, it wasn't conducted in the building where it was ordered, so therefore,  
23 the anti-markup's going to apply, unless you could argue that the ordering physician actually generally  
24 provides the full range of services that he or she normally supplies in that diagnostic testing facility. My  
25 guess is it's not office space, it's just a diagnostic testing facility. So in this case, if you can't get the first  
26 test, the shares a practice 75 percent test, you're going to have the anti market payment limitation apply  
27 here and that the most you can charge Medicare for the TC of that test is what you actually paid for it. What

1 did that physician who's supervising it, charge you for that, or what did the, if you had it done by a  
2 management company, what did they charge you for that particular test?

3 So the next one is the basic locum tenens arrangement and here we have again, the ordering  
4 physician, the supervising physician, and the patient are all in the same building, and everything was done  
5 where the ordering physician was, the ordering group is, the billing group is, everything is in the same  
6 building. So even if physician A does not furnish 75 percent of her services through the group, the anti-  
7 markup payment limitation would not apply here, because we satisfy site of service, because the test was  
8 performed, the TC was conducted and supervised and the PC was performed in the same building where it  
9 was ordered. And if you're going to do that, we say, yes, you sure do share a practice, so we're not going to  
10 make the payment limitation apply. So this is fine, too, under the Site of Service test.

11 The next one gets a little trickier because no longer are you conducting and supervising the test in  
12 building one and the PC is performed not where it was ordered, so the anti-markup provision would in fact  
13 apply here unless and this is the question we've been asked, and we've been answering lately, is what if  
14 physician O, what if it's just general supervision and physician O orders it and supervises it right there in  
15 that office, in which case that's fine. And a lot of tests only require general supervision so that it doesn't  
16 have to be physician B supervising that test. Any physician who's available in building one, if they were  
17 going to supervise, then at least the TC would not be subject to the anti-markup provision. So it's all about  
18 where the test was ordered and where it was performed and it needs to be in the same place. And if that's  
19 the case, then you're okay. If physician B truly is the one supervising the TC, and conducting the PC, the  
20 anti-markup is going to apply to this situation. But if you let physician O supervise it, at least the TC  
21 wouldn't be subject to the anti-markup.

22 And then our last slide is back at the hospital, and here we have the physician who ordered the test  
23 also performed it. And we're only talking about the PC here, and the physician organization wants to bill.  
24 So here we have, where was the test ordered? Was it ordered in the office of the billing physician or other  
25 supplier? Well the hospital's not really the office of the billing physician or other supplier and this is an  
26 issue that's still outstanding for us. We normally think of the anti-markup applying in ambulatory setting,  
27 where the test is ordered in a physician office. Here, it's ordered in the hospital, so we are still working on  
28 this issue and whether or not the fact that the physician was in the hospital when they ordered the test,

**PPAC Meeting Transcription – December 2008**

1 would the anti-markup have to apply to the PC? And all logic would tell you that it shouldn't apply because  
2 the physician ordered it, performed it, and billed for it. So there's certainly ways around the situation. If the  
3 physician billed individually, bill the full fee schedule amount, but as the anti-markup provisions are  
4 written, it does appear that they would apply to the PC, because it wasn't ordered in the office of the billing  
5 physician or other supplier and it was performed outside the office of the billing physician or other  
6 supplier, but we are considering how to address that issue as well. And that's how the anti-markup works as  
7 our Final Rule. Any questions on that?

8 Dr. Bufalino: Thank you. Very technical discussion.

9 Ms. Ohrin: I know. I'm sorry. It does get everybody ready for lunch though.

10 Dr. Bufalino: Very well described. Thank you for the detail. Anyone have any issues in terms of  
11 either of these two concerns? It looks like you're scot free. Thank you for being here.

12 Ms. Ohrin: You're welcome.

13 Dr. Bufalino: Before we break, I think we'll cover one more agenda item and we'll jump to  
14 Medically Unlikely Edits and ask Brenda Thew, who's the presenter. Ms. Thew, along with Kim Brandt,  
15 the Director of the Program Integrity Group, provided us a thorough account of MUEs. [off-mike remarks]  
16 Okay, sorry I said that. We'll break for lunch. So we're at 11:30 and we'll try to start back at 12:30 if we  
17 can make that happen. So two announcements, go ahead.

18 Dr. Simon: PPAC will meet the following dates. March 9<sup>th</sup>, June 1<sup>st</sup>, August 31<sup>st</sup> and December  
19 7<sup>th</sup>. That will be March 9<sup>th</sup>, June 1<sup>st</sup>, August 31<sup>st</sup>, and June 7<sup>th</sup>. Each Council member also has—

20 Dr. Bufalino: One more time because I think they were writing.

21 Dr. Simon: March 9<sup>th</sup>, I will repeat it. Have your pen. March 9<sup>th</sup>, June 1<sup>st</sup>, August 31<sup>st</sup>, and  
22 December 7<sup>th</sup>. Each Council member also has a copy of the transmittal, the federal notice regarding value-  
23 based purchasing. Where written comments can be submitted is on the back of page 2 at the bottom of page  
24 2. It lists both the address as well as the fax number.

25 Dr. Bufalino: Actually, before we break, let me ask one last thing, I'm sorry. Any  
26 recommendations from the Council on the last two presentations which were the OPPTS and the STARK  
27 Reform? Any recommendations from anyone? Seeing none, enjoy your lunch. 12:30 we'll start.

## PPAC Meeting Transcription – December 2008

1 Afternoon

2 Dr. Bufalino: Thank you for rejoining us for the afternoon session. Welcome everyone back. Our  
3 next presentation is surrounding value-based purchasing. A number of speakers have covered it this  
4 morning and we're looking forward to the discussion this afternoon. Tom Valuck is joining us again, along  
5 with Lisa Grabert. Tom, as you know is a Medical Officer and Senior Advisor to CMS and has been here a  
6 number of times and is clearly the resident expert in this area, and I already warned him that we're here to  
7 pick his brain today and we are also going to hear from Lisa Grabert. Lisa has been with CMS three and a  
8 half years. Her current role supports Strategic and Operational Implementation of the value-based  
9 purchasing initiatives along with the hospital-acquired conditions. So we look forward to both of your  
10 comments and without further ado, please.

11 Value-based Purchasing Efficiency Measures

12 Dr. Valuck: Thank you, Mr. Chairman. Good to be back in front to the group this quarter to talk  
13 about a particular initiative that we have under Value-based Purchasing that we're terming Physician  
14 Resource Use Measurement and Reporting. You see in the presentation overview that we've divided the  
15 presentation into two sections. My portion is to bring everyone back up to speed on where we've been with  
16 Physician Resource Use Measurement and Reporting in the context of our broader Value-based Purchasing  
17 Initiative or Initiatives, depending on how you think about it, and then, my colleague, Lisa Grabert, who is  
18 the coordinator of this particular project and the project officer for a contract that we have to pursue this  
19 work with Mathematica Policy Research is going to be covering the second half on our specific, almost  
20 step-by-step approach. And we'll both be able then to discuss who we're looking to engage the physician  
21 community in the best approach to measuring and reporting Physician Resource Use.

22 The next slide then takes us up to the 50,000-foot level where we begin our discussion about  
23 value-based purchasing. A reminder that CMS has a document called the Quality Improvement Roadmap  
24 that all of this work that's looking to link some measure of performance to our payment systems and to  
25 public reporting for accountability and for information for various audiences, that's all under our Quality  
26 Improvement Roadmap and you see the vision here and the six dimensions of quality represented as a part  
27 of that vision. These are consistent with the Institute of Medicine's vision for healthcare in America and  
28 that's what we're trying to enforce.

1 I think the takeaway from the slide, and you'll hear me say this repeatedly in this presentation,  
2 because we are focused on resource use today, is that efficiency, which you see as the second to last bullet  
3 there, is a dimension of quality. And so we're looking to bring the cost picture into the quality equation.  
4 The next slide then is the five strategies of the Quality Improvement Roadmap that are under the vision.  
5 Value-based purchasing is one of those and there are four other strategies. Working through partnerships is  
6 important to this initiative because we're going to be working with the physician community on resource  
7 use measure development and how to report that in the most meaningful way. We are measuring quality  
8 and reporting comparative results as a part of all of these value-based purchasing initiatives, and then other  
9 important strategies include encouraging the adoption of effective health information technology, using our  
10 incentives, our financial incentives, also using health information technology to collect information and to  
11 feedback information to improve the quality of care and the efficient delivery of care, and promoting  
12 innovation by using the data that we gather for building the evidence base for the most effective uses of  
13 technology.

14 The next slide then are the goals. So we've had the vision, the strategies. The goals flow from the  
15 vision and strategies and you see that they are reflection of the six key dimensions of quality. I'm not going  
16 to read through them all, I'm just going to point to the fourth bullet there, in context, that even though our  
17 discussion is about cost, remember it's in the context of clinical quality, reducing adverse events,  
18 enhancing patient-centeredness and so on. So that's the context.

19 So the next slide then is the bottom line on value-based purchasing. We can talk about the formal  
20 documents in terms of the vision, the strategies, and the goals, but what does it really mean? Well, it means  
21 that we're transforming the Medicare Program from simply being a passive payer to an active purchaser of  
22 higher quality, more efficient care, using the tools that are within our statutory authority. You see them  
23 listed there; measurement, payment incentives, public reporting, also our Conditions of Participation for  
24 institutions, our coverage policies—what we will and won't pay for is a value-based decision. And the QIO  
25 Program, which provides direct provider support. And those tools then are used in various combinations to  
26 inform the initiatives that you see there. Pay for Reporting, which, as you know, we have for physicians,  
27 hospitals, and home health agencies. For physicians, it's the PQRI program, which is the next topic for  
28 discussion. But we're moving toward true performance-based payment. We have a plan that was submitted

1 to Congress a year ago for the hospital setting, which is still getting a lot of attention on Capital Hill, and  
2 we've just begin work on a physician value-based purchasing, or Pay for Performance plan. We've got a lot  
3 of demonstration projects going on to look at; gain sharing, competitive bidding, bundled payment, etc., so  
4 that's what we're really pursuing here. And this might be an appropriate point in time to note that during  
5 the transition in looking at and following the blueprint for health reform that's come out from the President  
6 Elect's advisors, in looking at the Baucus whitepaper. Baucus will continue to be the Chairman for the  
7 Senate Finance Committee. These kinds of initiatives and tools are seen throughout those future oriented  
8 documents. So we can expect more attention, potentially acceleration, as we look at healthcare reform and  
9 Medicare reform in the next administration.

10 The next slide then, making the case for Value-based Purchasing. And I don't need to dwell on the  
11 next set of slides, because you all as both care delivery and quality experts, are very familiar that we have a  
12 big opportunity for quality improvement, but the takeaway here is we also recognize that the Medicare  
13 payment systems that we currently have in place, such as the Physician Fee Schedule, do have financial  
14 incentives. The incentives are toward resource consumption and quantity of care delivered, not quality or  
15 avoiding unnecessary costs. So this value-based purchasing overlay for our, over our current payment  
16 systems is an attempt to better align the system's incentives with what we would like to get out of the  
17 systems, the vision, strategies and goals that I mentioned before, the idea of higher quality and more  
18 efficiency.

19 The next two slides then are a couple of maps that show the variation in care across the country,  
20 both from the perspective of cost, which is this first map. The more darkly shaded regions are the higher  
21 cost areas per Medicare enrollee, and then in the second map then, we see the lower quality regions actually  
22 are more correlated with the higher cost area, so we know we have a cost quality disconnect. This is not a  
23 comment on what happens in any particular area of the country, as there's a lot behind these maps, but the  
24 point is that we should be and are using the tools that we have within the statutory authority of the  
25 Medicare Program, in order to try to address the factors that are keeping us from getting the most value for  
26 the Medicare dollar.

27 The next slide then is the breadth and depth of support for value-based purchasing. I've already  
28 mentioned that we anticipate through the documents that we've seen, the value-based purchasing



1 continuing into the next administration so I would suspect that it would say President's Budget FY2010 and  
2 so on and Congressional interest, that list there, that alphabet soup from the early part of this decade, from  
3 BIPPA all the way through MIPPA, we would expect that that would continue to be extended. MedPac and  
4 the Institute of Medicine are very expert and well-respected advisors for both the Congress and the  
5 Administration, have encouraged us forward in value-based purchasing. In fact, they've probably been  
6 some of the strongest advocates, and then we're learning from what's happening in the private sector and  
7 vice versa. The private plan medical directors call me and say we really appreciate you opening the door on  
8 something like our hospital-acquired conditions provision or potentially resource use and similarly, we can  
9 learn, in the Medicare program, from various pockets of activity that are happening out there in the private  
10 sector, through the private health plans. And then the employer coalitions are encouraging both the private  
11 sector and Medicare to figure out how to get more value from our healthcare spending.

12 The next couple of slides just are a quick reflection on our current value-based purchasing  
13 demonstrations and pilots. Anything that we're doing that has a component of performance measurement,  
14 whether that's clinical effectiveness or patient safety or cost of care, or patient-centeredness, that is tied to  
15 some form of payment, even if it's just Pay for Reporting at this point and a transparency or public  
16 reporting component, you'll see those then throughout our demonstrations and pilots. So we've got in the  
17 second slide then, the cross-patient care setting demonstrations. In the previous slide, you see the  
18 demonstrations that are within settings, so we've got for the hospital setting premiere, we've got the PGP  
19 demo, and MCMP demo within the physician payment setting, nursing home, home health, and then across  
20 the payment settings on the second slide, then we've got care coordination, disease management, gain  
21 sharing, between institutions and physician practices, the acute care episode demonstration, ACE, which is  
22 about bundled payment, our data aggregation pilots, the BQI pilots, tying incentives to the adoption of  
23 effective health information technology and using that technology to report quality information and then  
24 the idea of the medical home, where there's payment for performing certain care coordination type  
25 functions. So those are all value-based purchasing demonstrations, and then in the next slide, then, we have  
26 the ongoing authorities. So unlike the demonstrations, which have a specific endpoint, we have ongoing  
27 authorities for these programs, or initiatives. In the hospital setting, which is sort of leading here, because  
28 it's a little bit easier to get your arms around 4 or 5,000 facilities than it is 850,000 physician practices in

1 various forms, so we've got hospitals leading on Pay for Reporting and also the first setting to have the  
2 value-based purchasing plan and report to Congress. Also we have our nonpayment for complications in  
3 the hospital-acquired conditions provision.

4 And then in the next three bullets you see parallel activities on the physician payment system side.  
5 Our PQRI, the Physician Resource Use Reporting, which we're going to be talking about here at the  
6 moment, and then the next item, which is the Physician Value-based Purchasing Plan and Report to  
7 Congress, which I suspect Ken will have us on the next agenda to discuss, because we'll be well along the  
8 way in planning to approach to performance-based payment for physicians. In fact, we have a listening  
9 session tomorrow on an issues paper that we've published on this topic. And Dr. Rich is leading our work  
10 group. Then we also have home health Pay for Reporting, ESRD, Pay for Performance in the latest  
11 Medicare Bill and then Medicaid. But the point of all of this is to show where the specific initiative, the  
12 Physician Resource Use Reporting fits in, generally, with our value-based purchasing goals and the  
13 ongoing programs.

14 So let's turn to that more specifically. The next slide shows our statutory authority for this work,  
15 which comes out of the recent MIPPA legislation passed on July 15 of this year, as an override to  
16 Presidential Veto, and requires the Secretary, which has been delegated to CMS, to establish a physician  
17 feedback program, under which we would use claims data to provide confidential reports to physicians on  
18 their resource use. And so that's at base what we're about here. Just as a reminder in the next slide, this  
19 approach to looking at cost of care, is under the quality umbrella. The idea that efficiency, looking at cost  
20 and quality together, is really what we're after, taking waste out of the system, overuse, misuse and errors.  
21 Our goals for this particular project are to construct measures and populate reports with the data from those  
22 measures that are meaningful, actionable, and fair. So we've set a high standard and we don't want to just  
23 be spending a lot of Medicare dollars disseminating information that may not be considered meaningful and  
24 actionable and certainly if we're going to be using this data for things like payment, like public reporting,  
25 we need to pay attention to the perception of its fairness as well. We would, as a goal, provide the data and  
26 confidential reports to begin, potentially at different levels, individuals, groups, and then in that reporting  
27 compare actual to expected resource use, so you'll see in Lisa's discussion of the reports, how we would  
28 anticipate doing that. And then, very important, that last bullet to link the measures of cost of care, resource

1 use, to measures of quality for an overall assessment. So we don't want to be looking at cost without  
2 considering the impact of cost savings on quality. Otherwise, we lose sight of the value equation, so we  
3 want to look at both together. So in the next slide, then we have the measurement challenges. And this is  
4 my last slide here but I wanted to just point out that we recognize that this is not easy to do. To meet our  
5 standard of providing reports of physician resource use that are meaningful, actionable, and fair, we need to  
6 find tools that will allow us to group claims in meaningful ways, like the episode grouper tool, which we've  
7 been exploring in some depth. We need to figure out how to attribute the costs in a way that makes sense to  
8 individual physicians, physicians groups, teams of physicians who are caring for patients in various  
9 settings. We need to figure out how to make meaningful comparisons. It's not going to work to compare all  
10 cardiologists when some might be having a more invasive practice, some might be more community-  
11 oriented, and everything in between. We need to be able to figure out how to make meaningful  
12 comparisons.

13 Risk adjustment. Always an issue when we're looking at measurement of costs or outcomes of  
14 care, and so that's an important piece to get to our fairness standard. Small numbers, a big issue when we  
15 start looking at specific episodes of care, measuring the costs for specific condition-oriented measures.  
16 Very quickly we get into small numbers problems that lead to reliability issues. And then we want the  
17 reports to be designed in such a way that they can be used to improve the efficiency of the practice. So high  
18 standard, lots of challenges along the way, but we've also made some progress in addressing those  
19 challenges and so at this point, I'll let Lisa tell you about that progress.

20 Ms. Grabert: For implementation of the Physician Resource Use Program, we're implementing it  
21 on a phased approach, so I'm going to be talking to you today about what we've done for what we call  
22 phase one of the program and what we will be doing in early 2009 for the program. MIPPA laid out several  
23 different options for us to use as we implement the program. The resource use measures can be used to  
24 capture an episode of care, a per capita or total cost, or use both of those approaches from an analytic  
25 standpoint. The resource uses can be measured through claims-based methods or through other data sources  
26 and the focus can be on physicians by specialty, on certain conditions, various different benchmarks of  
27 geography. We can focus on high cost outliers and define if we want to, a minimum number of cases. CMS  
28 can make certain adjustments to the claims data. As Tom mentioned, we will be doing levels of risk

1 adjustment, and also adjustments for price standardization across different settings of care and the resource  
2 use measures can be applied to either individuals or at a higher group practice level. This slide sort of lays  
3 out the overall framework for the phase one approach and that the first step is to prepare Medicare Fee for  
4 Service claims data and to standardize prices. And then we grouped claims into episodes of care, or we  
5 look at total cost expenditures for a single beneficiary for any given year of service. Then we risk adjust the  
6 cost of each episode or each beneficiary. We attribute each episode to physicians and we have several  
7 methods for attribution that we're testing within the first phase of the program. We calculate a physician's  
8 average score for cost across all the episodes or patients and then we compare that score to a benchmark,  
9 and there are several different benchmarks that I'll highlight as well. And finally, we produce, test, and  
10 distribute resource use reports based on all this information.

11 Phase one of the program is using both the episode of care and per capita analysis. As I mentioned  
12 before, per capita is total cost for part A and part B services for beneficiary. And the two episode products  
13 that we're using to do the episode of care analysis are the ETGs or the episode treatment groups, and the  
14 MEGs or the medical episode treatment groups, and they've both commercially available episode grouper  
15 products. We will be assessing several different approaches for risk adjustment, different methodologies for  
16 attribution and looking at several different benchmarks as well. And we'll be producing alternative resource  
17 use report designs. We have already tested on a one on one individual physician basis with small samples  
18 of physicians, different designs of the reports. We've sat down with about approximately 70 physicians for  
19 60 minutes each and gone through in depth, the design of the reports to make sure in the early phases we  
20 are getting the design, the look and feel of the report right, before we go into a larger distribution of reports.  
21 And then also at the beginning 2009 and in the spring, we'll be mailing out reports to a larger sample of  
22 physicians.

23 Phase one of the program has concentrated on eight conditions; four acute including community-  
24 acquired pneumonia, urinary tract infection, hip fracture, and colistitis, and for chronic conditions,  
25 congestive heart failure, COPD, prostate cancer, and coronary artery disease also looking at flare ups of  
26 acute myocardial infarction. So as I mentioned, phase one focuses on processing Medicare Fee for Service  
27 claims data with each grouper. When we show the reports to physicians, we're only focusing on one  
28 design, but we're testing different designs. We populate the IURs or the resource use reports, with relative

1 cost performance scores from either grouper and this evaluation is not to look at which grouper is better  
2 than the other, rather we're using both groupers when we take reports out to physicians.

3 So the next thing I'm going to do is in several slides, highlight the different steps that we've used  
4 for phase one of the program. And the first step is really to standardize use unit prices, because an episode  
5 of care encompasses all settings of care that the physician may provide services in. So we remove payment  
6 variation across all those different settings, and remove factors like graduate medical education, which is an  
7 adjustment done to inpatient claims and disproportionate share payments. Also look at the differences in  
8 how hospitals are paid, critical access on a cost base or inpatient acute care, which is based on a prospective  
9 payment system. And then we also removed geographic variations that are applied to payments. Examples  
10 include GPCI pricing for physician services. We adjust for wage index for several services, and then we  
11 also adjust for variation and carrier price services. So we adjust for price across the board so we're looking  
12 at true resource use of services.

13 We are standardizing payments to include payments made by the Medicare program, payments  
14 made by beneficiaries, in terms of deductibles and co-insurance, and payments made by third-party  
15 insurers, so all of those aspects play into what we're looking at for resource use and in order to increase the  
16 fairness of medical cost comparisons, when we look at benchmarks for comparison, which is one of the  
17 further steps I'll talk about, we're looking at both the national and state comparison.

18 So the second step in the process is to adjust for risk. The first three rounds that we did in terms of  
19 the look and feel of the design of the reports that I'll talk about in a little more depth, we didn't actually risk  
20 adjust what we've done so far with physicians because it's really early phases in testing what the reports  
21 look like. For the reports that we'll be mailing out at the beginning of the year in 2009, they will be risk-  
22 adjusted when they go to the physicians, and we'll be testing different alternatives for how one can risk  
23 adjust the cost data. We'll be looking at patient characteristics, such as age, sex, disability status, and what  
24 their status was in the prior 12-month period, using CMS's HCC or hierarch categories of conditions. We'll  
25 be looking at case mix, in terms of the different complications and co-morbidities, surgical procedures, and  
26 death as a factor for risk when we look at patients. And then also looking at local area characteristics, such  
27 as physician supply, income, and racial and ethnic demographic of patients.

1 Step three is to attribute or to assign cost to physicians within an episode of care, or for the per  
2 capita approach. As I mentioned, we're testing several different methodologies for attribution. Really, the  
3 different rules that you could test for attribution are endless. The ones that we're using in the phase one  
4 approach are E&M, or evaluation and management service base attribution methods. And just to highlight  
5 some of what we're testing and what we're looking at, you can assign total cost of an episode to one  
6 physician or to several physicians, and we're testing those methods out. You can assign total episode cost  
7 to one physician or you can assign portions of that episode cost to several different physicians. You can  
8 look at E&M based on whoever provides the first E&M visit to a patient, or the managing physician for the  
9 first encounter for the episode. Or you can again, look at a proportion of E&M visits across the episode.  
10 And the evaluation and management visits that we use to assign attribution include the office visit, hospital  
11 visit, emergency room, home health or nursing visit, specialist visit, and consultation E&M services. So  
12 there's a whole range of different services that we're using for attribution. When we assign cost to  
13 physicians, we're currently using a 10 percent minimum for E&M services for billing purposes, but you  
14 could use a higher threshold than 10 percent or you could have no minimum as well. There are various  
15 different options and how you can assign cost. And the types of cost that we are assigning to physicians is  
16 something else that we're asking physicians in these one on one type of interviews. So should the cost of  
17 services to include everything inpatient, outpatient, office visit, post-acute care be included and assigned to  
18 a physician. That's also one of the questions that we asked in the Physician Fee Schedule comment period  
19 when the Final Rule went out. That's the current approach that we're looking at. You can also look at cost  
20 of physician services, and only referrals as specialists, so only concentrating on what the physician is  
21 directly in control of, whereas some of the other downstream things, they may not necessarily be in control  
22 of. And then we can look at the differentiation and assignment by physician specialty as well.

23 Step three in the process is to look at different benchmarks for peer comparison. You can compare  
24 a physician's cost performance to other physicians in performance. [off-mike consultation]

25 Unidentified speaker: You said Step three. You meant step four?

26 Ms. Grabert: Oh sorry! One more. And there are several different ways that we've been looking at  
27 benchmarking in terms of the resource use reports. There are benchmarks for performance, where we look  
28 at low, median, and high cost providers. Low providers signify the lowest 10 percentile of cost. Median is

1 at the fiftieth percentile, and high cost looks at the ninetieth percentile for cost. We also can look at  
2 geographic benchmarks. We're looking at a national level comparison, also including state level  
3 comparison, and local service area, which is just the hospital service area that physicians and the  
4 benchmark typically refer to in terms of inpatient services. And then we're also looking at specific provider  
5 specialties. We're looking at the same medical specialty, broader, to include their board specialty so  
6 comparing to all primary care physicians, and then physicians treating just the same health condition, is  
7 what the episode of care basis does.

8 Step five is to look at drill down statistics, which tend to be more actionable in terms of the  
9 information that you can capture. We are looking at professional E&M services that the attributed  
10 physician applies for their patients, and then looking at all of the E&M services other physicians also  
11 provide for their patients. So it gives the physician a perspective of both what he or she does, and what all  
12 other physicians treating the patient as handling in terms of E&M as well. It also shows the major  
13 procedure codes by broad specialty, so it allows the individual physician to see the procedures that are  
14 happening to their patients, and also for ancillary services such as labs, inpatient hospital cost, outpatient  
15 hospital cost, and post acute care, so it really provides a full spectrum of what you can see for patients.

16 Further down in our drill down statistics, we're capturing a couple of statistics for utilization  
17 purposes for the patient, allowing the physician to see the sheer number of emergency room visits their  
18 patients typically have on average, the number of hospital admissions their patients have, the length of stay  
19 for hospitalization for their patients, and then ambulatory sensitive hospitalizations as well. We're also  
20 showing cost measures for all beneficiaries versus for the breakdown of beneficiaries that are still alive at  
21 the end of the episode, taking death out as a perspective to show as well, and then beneficiaries age 65 or  
22 older, so if there's a difference in case mix between 65 and over, we're showing what the patients look like  
23 under 65 that they're treating as well.

24 Step six talks in this process as field testing or formative testing of reports and as I mentioned, we  
25 had three rounds of one on one individual interviews with physicians to really get down the look and feel of  
26 the reports before we go into a wider distribution. We asked them to evaluate the alternatives for the things  
27 that I've already covered. We've completed sessions in Baltimore, Maryland, Boston, Massachusetts, and

1 Indianapolis, Indiana, and as we move forward in 2009, we'll be expanding to 12 different sites in which  
2 we're distributing research use reports.

3 The last step is to test the dissemination and the logistics of the actual program. As I mentioned in  
4 2009, we'll be targeting 12 different pilot sites distributing through the mail probably approximately 400  
5 reports. The first wave of reports that we send out will be both per capita and episode of care base. The  
6 January distribution will be based on the MEG grouper only and then wave two that we're planning April  
7 of 2009 will be based on the ETG grouper only. We will be risk adjusting the costs of those reports and  
8 we'll be conducting a provider evaluation via a 1800 number and providing an email source for the  
9 participants to give us feedback on the reports, and we'll be following up with a logistic call with a small  
10 sample of providers, to see if they received the report, if they were able to understand the reports and  
11 testing. Some of the logistics we would test if we were to in fact, do a national dissemination of reports.  
12 And then based on that feedback we received from that phased implementation, we will be revising the  
13 reports for future phases of the program.

14 The second to last slide just talks a bit about the outreach in coordination we have had through  
15 development of phase one of the program. We've had several presentations to and have had conversations  
16 with stakeholder groups that include a wider range of stakeholders, including providers, consensus-based  
17 organizations, such as the Quality Alliance Steering Committee, consumers, payers and purchasers, we've  
18 had many interviews with private health plans and how they're using resource use reports to educate  
19 members within their plans and then also accreditation and standards organizations. Just to talk a little bit  
20 about sort of where we're looking towards the future, a potential next phase, or phase two of the program  
21 likely would begin to look at combining efficiency measures with existing quality measures to provide a  
22 true score of efficiency, also to possible develop and test some composite measures, so what types of  
23 conditions when we're looking at episodes look like they lend themselves to composite measures? Also to  
24 continue to improve the validity, the usability, and the fairness of the resource use reports, based on  
25 physician feedback, and to scale up beyond just the 12 sites that we're looking at, to possibly a regional, a  
26 national dissemination.

27 Dr. Valuck: So before we go to questions, I would just point that in addition to some of these  
28 outreach and coordination activities that Lisa mentioned, in terms of our engagement with the physician



1 community, just as Mike has, I have regular meetings with the AMA staff and the DC representatives of the  
2 medical specialty societies. We typically do it in the AMA board room about every six to eight weeks, and  
3 as this phased implementation that Lisa describes plays out, we'll bring the various pieces forward to those  
4 groups and then we count on them to bring input from the practicing physician community. The other point  
5 that I'd make is that like most of our ongoing Medicare programs, we are doing our implementation  
6 through rulemaking, so in this year's calendar year 2009 Final Rule, we actually issued a Final Rule with  
7 comment because of the timing with when the statute passed. So we're in a comment period right now, to  
8 get comments on our initial implementation, these first steps that you've seen here, and then in next year's  
9 rulemaking for the Physician Fee Schedule, we'll be going through subsequent phases of how this project  
10 will unfold. So I would encourage you to watch rulemaking as well.

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

12 Dr. Siff: I appreciate your presentation to the Council today. Your slide of measurement  
13 challenges makes clear the many challenges in implementing this program. I noticed that several of your  
14 phase one conditions, such as community-acquired pneumonia and hip fractures, are conditions where the  
15 episode of care is commonly initiated in the emergency department. While emergency department visits  
16 were included in your list of E&Ms to be considered, emergency physicians are not on the list of providers  
17 mentioned in the full program. I'd appreciate if you could reconcile that for me. Also on the attributions  
18 slide, you mentioned that the cost for the episode may be attributed to either the most or the first E&M.  
19 Given that emergency physicians have no ability to influence or control what happens to a patient post-  
20 discharge or with an admission, I'd appreciate an explanation of how you plan to address [inaudible]  
21 emergency medicine and cost attribution.

22 Dr. Valuck: Yes. Difficult challenge and I suspect that each of you, from the perspective of each  
23 of your specialties and the type of setting that you practice and the size of the group that you practice in and  
24 how you interact with other providers could raise all kinds of additional scenarios, many of which we have  
25 tried to think through, but I suspect that we haven't gotten to all of them. So I appreciate the magnitude  
26 maybe, the exclamation point that you're putting on our point about attribution being a challenge. There  
27 will be, of course, specialties that will be more or less amenable to this kind of measurement. So think, for  
28 example, about the pathologists or the radiologist and how you would ever figure out how to attribute a

1 portion of the patient's costs, or whether you would even want to, but I can tell you that there are some  
2 folks who are looking at that and thinking about the role of folks you don't typically think of as managing  
3 patient care. And then there are those who you would think of as definitely, primary care, they control a lot  
4 of what happens with the coordination of the care for the patient, on down to referrals and even the  
5 institutional services that are provided often. So that tends to make more sense and then there's a lot in the  
6 middle. The role, for example, of the emergency physician and how does that play in? I've had a lot of  
7 discussions about this actually, with Dr. Rich, and he and I are of the mind, he can comment on this if I get  
8 it wrong, Jeff, that we really want to be promoting the idea of a patient care team, and joint accountability,  
9 where there is an attempt to coordinate handoffs among the care team as well as between institutions. So  
10 thinking about the emergency department physician's role in that, I think is an important consideration. But  
11 whether you would make that emergency department physician the primary person responsible for a chunk  
12 of services beyond what's happening in that particular setting of care does raise a number of questions. In  
13 terms of the attribution rule specifically, the first E&M visit is an interesting one. I'm not sure it makes a  
14 lot of sense in most instances, and we do have some early experience with evaluation of some of these  
15 attribution rules, and I'm going to ask Lisa just to briefly comment on where we're headed in our thinking,  
16 as we try to narrow down these various options to the ones that really make the most sense.

17 Ms. Grabert: Sure, when we first started testing the universe of attribution rules that we had in our  
18 early testing, in fact, we did fine. And got a lot of pushback on particularly the first E&M service type of  
19 methodology. As we move forward in January and April, we'll be testing two different attribution rules, the  
20 first is looking at multiple E&M assignment to physicians, so the number of E&M services will signify  
21 what the proportion of cost is within the episode or for the per capita analysis that will be assigned amongst  
22 all of the physicians that treat that patient. That's the first rule that we'll be looking at. The other rule that  
23 we'll be looking at for that implementation is a rule that looks at the highest number of E&M services and  
24 then therefore, whoever provides the most evaluation and management services will be assigned all of the  
25 costs within the episode and for the per capita approach, because that's look at as the managing physician  
26 for that individual patient.

27 Dr. Valuck: It's not perfect science, but we're going to get some experience with it to assess the  
28 imperfections.

1 Dr. Smith: I have a number of questions here. I guess one of my concerns is that you say you're  
2 going to be looking at risk adjusting costs and if I understood you correctly, you're mostly going to be  
3 gathering this from claims data. And I think everyone, every physician, and probably lots of other people  
4 are very aware of the limitations of the four diagnoses on the claims. I'm a rheumatologist. If I have a  
5 rheumatoid arthritis patient or a scleroderma patient, or a lupus patient, I'm probably working with  
6 anywhere from 10 to 15, 17, 20 diagnoses, all of which I have to juggle at any given time. You don't have  
7 access to that to tell you that these are very complex patients as opposed to a patient with four diagnoses  
8 who can be complex, but, and the same thing is going to apply in asthma and congestive heart failure and  
9 everything else. So I'm not sure how we can trust your sources by which you're looking at severity of  
10 cases, when you don't have all of the data that we have to juggle. I'm concerned when you say that one  
11 thing you're considering is comparing diagnoses across all providers. And I'll use again, the diagnosis of  
12 lupus. The primary care physician may code lupus as a diagnosis because it was the reason for the visit, but  
13 what he did with the visit was to refer to the rheumatologist, and then the rheumatologist, almost by  
14 definition is going to have a far more complex situation to deal with because the primary care physician  
15 referred the patient for the complexity of the problem. And so if you take a diagnosis for comparison,  
16 you're going to get skewed data very much so. Dr. Howard probably has similar things in her field,  
17 everybody else. You can't just use a diagnosis and assume that the complexity is the same for everybody  
18 seeing the patient for that diagnosis. So I don't think you can make a valid comparison. On the logistics,  
19 you commented that you're going to look at a large sample of physicians and look at 400 physicians. And I  
20 had heard I think one of you say earlier that there are 850,000 physicians in the United States. I don't see  
21 400 as a large sample, as a valid sample from which to draw representative conclusions. I'm not a  
22 statistician at all, but it just sounds to me like it's not very many when you're trying to test something like  
23 this. And then the last question I didn't hear is what do you propose to do with these reports? Are you  
24 simply sharing them with the physicians who are involved? Are you proposing to put them on some kind of  
25 public information website, which would be very scary indeed in a testing phase?

26 Dr. Valuck: So to the first of your three comments about risk adjustment. Yes, we agree that it's a  
27 challenge and I can tell you that our methodologists, our contractor Mathematica Policy Research and  
28 others around the country frankly, are having a lot of fun with the topic and in thinking about how to help

1 us work through that. We have certain tools that are already in use in various ways for Medicare's various  
2 purposes, but I would say as we're addressing some of these challenges, everything that we do in a policy  
3 world is on a continuum. From what we would ideally like in terms of perfection to something that's  
4 absolutely useless and I think we could all look at these challenges and throw up our hands and say well,  
5 let's just not do this because it isn't going to be perfect, especially in our early rounds, but I think that  
6 policy makers have determined, and in fact Congress has given us a mandate to move forward here because  
7 there is a general belief that using this information, and this goes to your last point, for confidential  
8 feedback reports to physicians at this point, because we don't have experience with the level of precision  
9 yet, that you would want for other uses like payment or the public reporting for transparency that you  
10 mentioned, that we'll continue to work in that direction. We'll continue to work on the improvement of  
11 these tools, if not the perfection. In terms of the sample, a sample of 400 to comment on the design of the  
12 report, we think is more than adequate and we're really looking forward that feedback from the various  
13 specialties that are involved in our early work. Lisa, you may want to comment further on what we're doing  
14 in our initial phases of risk adjustment in light of the particular question or in the sample size issue.

15 Ms. Grabert: Just on the topic of risk adjustment, yes it is true that there is a limited number of  
16 diagnoses that you would submit for a patient for a physician claim. There's quite a larger number that you  
17 would submit for that same patient for an inpatient claim, and inpatient post-acute care, all of those services  
18 get encompassed into an individual episode. So there's a lot of information that's available through our  
19 claims data that go well beyond what's available through just physician claims only, just as a point of  
20 clarification.

21 Dr. Valuck: That's helpful, thank you.

22 Dr. Snow: You made the comment regarding the attribution that for instance, primary care  
23 physicians typically would be expected to have more input and be more of a causative factor, so to speak,  
24 on an episode of care. And I would caution you that that, for a lot of reasons, that's not necessarily going to  
25 be true because of patient choice, because of physician choice in how they practice, or because of setting  
26 and location for instance. An asthma patient may choose to never go to their primary care physician, but  
27 only to go to a specialist, whether it's an allergist or a pulmonary doctor for that particular problem that  
28 they perceive that they have. So even though the primary care physician may have many more visits for the

1 multiple other things they see the patient for, they certainly may not have any input at all into the  
2 management, for instance, of the asthma or a whole variety of selected other problems. So I think it's a  
3 much more difficult problem, even for that primary care physician, who theoretically should be able to take  
4 care of everything, but frequently does not.

5 Dr. Valuck: One of the things that we're struggling with in all of our value-based purchasing  
6 initiatives related to physicians is how to determine who's responsible for what, given that under the Fee  
7 for Service scenario, there is no formal relationship or no exclusive relationship between any particular  
8 patient and any particular physician. So we use proxies for that and Lisa described some of the ways that  
9 we're trying to look at that. One of the, Mike reminds me of this, but one of the attributes of claims-based  
10 reporting, which we've had certain challenges with through the initial implementation of PQRI, but are  
11 certainly making progress with is that if it's on the claim, that physician did it. I mean they're basically  
12 attesting to the fact they did it, so there's a very clear line of attribution in claims-based reporting, because  
13 if they didn't do it, they wouldn't be reporting it or at least didn't know of that piece of data. They wouldn't  
14 be reporting it on the claim, so similarly, when we receive information, via the claims, of services that were  
15 provided, we know that those can be attributed to that individual physician. Now when you start looking  
16 beyond that at hospital services or other institutional services or labs or things provided by other  
17 physicians, other members of the care team in a larger episode, it gets a little bit more difficult, but we hear  
18 what you're saying and we're trying to figure out the best way to go about doing that attribution.

19 Dr. Standaert: Yes, I hear what you're thinking and I admire what you're trying to do. And I think  
20 I get the point of the whole thing. I guess I have a concern that was brought up before, sort of how people  
21 interpret and what is the use of the end result of what you get? If you, I'm not a statistician, so you have to  
22 go with me for a bit. I'm sure you have many statisticians thinking about how to do this because it's very  
23 complicated, but if you think about this, my assumption is the end result of all this you come out with sort  
24 of a number. You have a 20 or you have a 40, and if you assume this is like a zero to 100 scale, most  
25 people when they see a number, they assume it's a linear scale, meaning if you have a 40, that's twice as  
26 good as at 20. The trouble I have though is when you look at this, I look at it as though I'm reviewing this  
27 like a paper for publication. What would I think of the statistic you came up with? You make a large  
28 number of assumptions in here. And for every assumption, you introduce a range of error by adding that

1 assumption in. So when you make multiple assumptions through the sort of statistical analysis of  
2 something, every time you add another assumption the error bar gets sort of bigger and bigger and bigger  
3 and that range of error gets bigger. When you have lots of assumptions, frankly then you try and sort of  
4 find out, you go through a system. You have a lot of assumptions, and then you look at one individual data  
5 point that came out of that and try and look at the significance of that one data point. It's very hard with all  
6 those assumptions. You may be able to find the extreme outliers, but within a large cluster in the middle, to  
7 come up with a number is quite inaccurate, because unless you're giving that number with a large error bar,  
8 or you're giving some range, and people are aware that this is a nonlinear model, because there's nothing in  
9 your assumptions that's going to lead you to some sort of linear model of somebody who's twice as  
10 efficient as somebody else. There's no way you can do that. If you come down with too precise a number  
11 without a big range, without a big error, without some big notification that this is a distance that somebody  
12 may be within, that data point again be taken saying, well it was a 40, but it ranges between a zero and a 90,  
13 and somebody says well he's a 40 and somebody else is a 60 but it ranges between a 10 and 100.  
14 Statistically, they're the same, but nobody will look at a 40 and 60 and say they're the same thing if you  
15 just come down to that number. So my concern is sort of when you come out with all this sort of stuff, are  
16 you accounting for this degree of error and how do you control what happens to this number, this product  
17 you come out with? And is it intended to create a pseudo linear scale where people are ranked, or is it  
18 intended really just to find the extreme outliers and look and see what's different about them. Does that  
19 makes sense?

20 Dr. Valuck: It definitely makes sense. If I didn't know you were a busy practicing physician, I  
21 might think you were a statistician [laughter] Or that you were sitting in on our weekly calls with our  
22 contractors who go around and around about these kinds of things. As I said to previous comment, they're  
23 having a field day with this important and difficult topic, and you're exactly right. To get to the level of  
24 precision we're looking for, we're figuring out how to navigate all the various channels to make the  
25 decisions that minimize the level of imprecision and that will ultimately match the uses of the information  
26 with the level of precision of the information, so we don't want to overdrive the headlights here. So we're  
27 talking about confidential feedback reporting. We would certainly have experience with that before we  
28 would use the information for other purposes at this point. But I think when we get the opportunity to be

1 invited back to address you in future quarters, when we can show you reports, we can show you ranges  
2 with confidence intervals and all this stuff, I think you're going to be interested in that, but I would again,  
3 encourage you to think not at the level of precision for example, of a randomized control clinical trial.  
4 What we're talking about here is information that we're going to have to assess for the purposes of its use.  
5 And the use of the initial phase would be confidential feedback reporting. In terms of one thing you  
6 mentioned, which is looking at outliers, that's an obvious place to go, and we've already talked about that.  
7 Our government accountability office came out with a report, I think it's about a year and a half ago now,  
8 that actually recommended that we look primarily at outliers and that would be a place to start for the uses  
9 of the data. But I think you're jumping ahead of this idea of the confidential feedback report.

10 Dr. Standaert: No, I understand the confidential. My concern is for the genie in the bottle issue  
11 that you may be uncorking something you don't intend and that if you create something that you know isn't  
12 linear, you know has a certain error bar, you know has all these sorts of things, you know more than most  
13 people, and if you sort of uncork that and list it out and you follow the progression of where this goes, five,  
14 10 years from now, this is into Pay for Performance, this has come up with a ranking, with a value, this is  
15 what you get paid based upon, and people are going to be looking for a number to decide that. And if  
16 they're using your model to come up with that number to do it, you have to be extremely careful with what  
17 happens to this genie and what you let out of that bottle is extremely important, because what's done with it  
18 isn't going to be within your control once it ultimately becomes not confidential. And as we found with the  
19 PQRI stuff, some things that people thought might have been confidential, suddenly they said well they're  
20 going to go on a website. That was never the intention when people submitted their data. And so the whole  
21 idea of sort of unintended consequences of your actions is important to consider. Is my point.

22 Dr. Valuck: I think it's an excellent point. I hear you.

23 Dr. Arradondo: I wanted to follow up on something that Dr. Smith said and Dr. Snow kind of  
24 touched upon. But Dr. Valuck, I agree with you. Chris's statistics are good enough for me. [laughter] As a  
25 person trained in epidemiology, your statistics are very good, particularly the error that the public would  
26 commit by looking at two numbers as if they were on a linear scale, when in fact they kind of show  
27 tendencies that might not be any, sometimes even parallel, and that's something I guess you've been

1 wrestling with and will continue to wrestle with. I just hope that Chris gets satisfied a bit more the next  
2 time he raises it at the next meeting of Dr. Valuck, when I'm sure you will return.

3 Lisa referenced on the quality side having the hospital data that would give more than the  
4 traditional super bill four diagnoses reported. Yet, part of the question that Dr. Smith was raising gets at  
5 how do you value a diagnosis and she didn't say this, but she said to us internally, when it's one of four.  
6 And when the number five, six, and seven diagnosis that's not listed would impact the one or two of the  
7 four that are picked up. I could see a scenario very easily occurs often enough, so that's the reason I can see  
8 it, of a person coming in with we don't like to report symptoms but sometimes we're reduced to that, with  
9 dysnia that wasn't there before, beyond what we say is chronic bronchitis with exacerbation, legitimate  
10 code, on top of their COPD, another legitimate code, alongside or on top of their tobacco dependency, all  
11 of which might be related, except that diagnosis number five isn't listed—hypertension, which might be  
12 throwing them into heart failure, which could in fact be the cause of the dysnia, not the bronchitis, not the  
13 COPD, that scenario. So that some resource gets expended and gets counted for or against the provider, but  
14 ultimately maybe three visits later, the dysnia comes in on top of not COPD, acute bronchitis, or chronic  
15 with exacerbation and tobacco dependency, but comes in on top of chronic heart failure by then, maybe,  
16 hypertension, whatever else might be related to that, say diabetes. My question is, how often have you, and  
17 I'm sure you have, you look at this fairly comprehensively from my perspective, how often have you  
18 looked at the additional diagnoses? You mentioned the hospital setting, but particularly on the ambulatory  
19 side, the additional diagnoses that would further inform you about the quality relevance of that one  
20 diagnosis that you're working on. I think Dr. Smith used arthritis, I think. I heard her say that and point out  
21 that different people might use—that might mean different things to different people, simply because one  
22 might be a primary approach, the other might be a secondary or tertiary approach. How often have you  
23 looked at those additional diagnoses and my other question that relates to that, to what extent would you be  
24 amenable to doing some sort of study or maybe not a serious research study, but certainly an evaluation for  
25 further planning study to see what difference diagnosis five through eight might make in informing you  
26 about the quality of the services delivered, in particular in the ambulatory care basis, because ultimately all  
27 these things we're doing are going to affect ambulatory care providers who so often are by themselves or in  
28 small groups and don't always get the attention that the large money users or resource user providers get,



1 i.e. hospitals, or other fixed facilities? I'm, four diagnoses versus eight. Where does that play in your  
2 thinking in what you've done and what you might do?

3 Dr. Valuck: Excellent point. I'm going to let Lisa talk about past work and current work and  
4 potentially future work, because that is how you look at the adequacy for example, of the risk adjustment  
5 model or even these episode groupers and how they take information and use it in different ways. But I just  
6 wanted to make a higher level point, which is the language of coding, and billing, and claims processing  
7 that we're talking about here as the basis of this, that language, we're finding as we're doing these value-  
8 based purchasing things for performance measurement, doesn't translate what's happening in the clinical  
9 setting very well to our initiatives. So if we can't capture it through coding and through claims or other  
10 sources that we have for information sources, at some aggregate level, because otherwise, we're having to  
11 all deal with very, very detailed level, and just means coding burden on you, and it means more analytics  
12 on us, if we can't capture it at some meaningful level, then we've got to relook at how we're getting  
13 information and what information we're getting. So this raises lots of questions about the adequacy for  
14 example, of administrative data in this case, for doing something like measuring the efficiency of the  
15 services, so not to put you on the spot Lisa, but have we done some comparisons that were being proposed?

16 Ms. Grabert: I can comment on, to a certain extent, how we use the HCCs as a risk adjustment  
17 methodology. It looks at the 12 months prior to the year that you're looking at for measuring resource use  
18 for a beneficiary in that a beneficiary's given a score. And that score is used to adjust risk for the next year,  
19 so within the previous year, we look at every service the beneficiary has had. For purposes of a physician  
20 claim, you may only see four diagnosis codes, but for purposes of an inpatient stay that that patient may  
21 have had, you can see up to 10 diagnoses codes.

22 Dr. Valuck: And different physicians may have billed different diagnoses, so you're not just  
23 limited to the four—

24 Mr. Grabert: So you're seeing a wide range of diagnoses for that patient and how you can account  
25 for what the risk may be as you look at future services. But I do, your point to the problems that we do have  
26 with what we can see through claims data and things that we can look at sort, for example, on the hospital  
27 side, when we look at the quality of care measures that are medically abstracted, we can see much more  
28 robust data than what we can see if we look at clinically based data. So as we move forward in programs

1 like PQRI, we move into registry-based reporting, we look at other data elements that will give us much  
2 more robust information that we can use moving forward.

3 Dr. Arradondo: Just a small follow-up. Would that mean, I'm a family physician, and typically,  
4 say if I were reporting diabetes, and I didn't know anything about coding, I would just report 250.02 maybe  
5 if it's out of control, a 00, if it's not, the type 2. That's pretty good, five digits, but if I knew a little bit  
6 about diabetes, I would know that most of the people with type 2 who come for the first time and are not  
7 just accidentally diagnosed but come for symptoms, will have one or more of the complications;  
8 nephropathy, neuropathy, peripheral circulation, not to mention cardiopathy, enteropathy, all the others.  
9 One or two of those we look for, the others we typically don't. So would it make a difference in informing  
10 your risk factor for the patient for the following year, on the one hand. On the other hand, my involvement  
11 in Quality of Care, if each time I reported, I would report not 250.02 for uncontrolled diabetes, but 250.42,  
12 say, for uncontrolled diabetes with nephropathy, or .62 for neuropathy, or .72 for peripheral circulation  
13 problems. Would that put that patient on a higher list for the next year, or let you know that I had a clue that  
14 they were having problems and maybe I, because if I don't send that person to the nephrologist or to the  
15 neurologist, or to the peripheral vascular person during the course of that year, or if they don't go on their  
16 own, that number might not get listed. Would it do any good for me to list that?

17 Dr. Valuck: General rule is that the most precise code that can be used is the right code for that  
18 patient and I think that would feed into the risk adjustment model, but even then, and I think this has been  
19 raised, you aren't necessarily going to capture everything that's going on one claim. It helps to look at the  
20 whole range of claims over a time period for different types of providers and so, but it still raises the  
21 question as to the ultimate utility of the administrative data. I don't know if you wanted to comment on.  
22 Okay. Good points. You, all have careers at Mathematica Policy Research, by the way, if you get tired of  
23 practicing clinical medicine [laughter] you can bring your expertise to—[chat/laughter]

24 Dr. Kirsch: I just have a quick follow up on the Medical Home demonstration. My understanding  
25 is that with the demonstration project that the reimbursement does not have geographic variation. Is that  
26 true? And is the plan to continue that when it moves forward?

27 Dr. Valuck: I'm sorry. We're not experts on that particular project. You were asking about the  
28 Medical Home demonstration?

1 Dr. Kirsch: Right.

2 Dr. Valuck: We don't know the methodology. Sorry.

3 Dr. Przyblski: Just real quick, I understand looking at variations of E&M to try to target how to  
4 attribute. How are you going to handle that among surgeons where perhaps you'll do a consultation and  
5 then E&M services disappear and are hidden in the global period? What were your thoughts about that?

6 Dr. Valuck: Well we had that conversation just last week about how to handle surgeons. It's  
7 likely, well, yes, it's a long discussion. [chat/laughter] Carefully. Involved several articles that have come  
8 out recently in the newspaper, but the idea is that we may have to use different attribution rules for different  
9 specialties to ultimately get at this, which then creates a question as to how you deal with overlaps and  
10 whether that's the right thing to do to hold folks jointly accountable, or whether you end up double  
11 counting and it looks like folks need to be controlling things that they don't really have control over. So  
12 that is an important question. I suspect that we'll do some sort of assignment to surgeons that have to do  
13 with the total cost of the care for the patient as opposed to the number of visits or the number of E&M  
14 services because of the way that the global fee plays out and then do a different attribution for the same  
15 patient to kind of see what the two medical physician, to kind of see how that plays out. But we haven't  
16 gone down that road yet. We're starting with those who can be assigned the E&M services at the moment.

17 Dr. Rich: But to follow up on that, your global fee has a certain number of E&M visits built into it  
18 so to do a crosswalk would be quite simple for us. To say all right, your neurosurgical procedure has 5.1  
19 E&M visits built into it. So then you would be attributed that many E&M visits.

20 Dr. Howard: I just wanted to ask you guys, we've been telling you what we think, can you give  
21 me you five-year plan, your ten-year plan with this data? Where are you heading with this? Because I think  
22 that's the concern that you're hearing from us we feel like some of these issues that come up we're getting  
23 in on the tail end of them, and then we have no control over what's going to happen to that data, and we're  
24 just here to sit here. So I guess that's the concern, so if you could tell us what your vision is with this—

25 Dr. Valuck: So just very quickly, we would anticipate, ultimately, if and this is a big if, we get to  
26 the level of precision that it makes sense, to use this information in a value-based purchasing model as a  
27 measurement parameter, along with clinical effectiveness, safety, patient experience of care, and so on, cost  
28 of care would be a parameter there. Clearly, we have a lot of questions to answer before the information in

1 my opinion, would be ready for that kind of use. But as was pointed out, sometimes there are things that are  
2 beyond the control of CMS, certainly beyond the control of me, that require us to do certain things and I  
3 know that if you look at the President Elect's advisors' blueprint for health reform, or Senator Baucus's  
4 whitepaper, you see that they're very interested in this kind of information and potentially using it to make  
5 more value-based decisions and to encourage better efficiency in the provision of care.

6 Dr. Bufalino: Two last comments. One, we mentioned earlier this morning, there was some  
7 concern that we really just received, just the day before Thanksgiving, the request for feedback both with  
8 tomorrow's listening session and the December 16<sup>th</sup> deadline and there was a request for you to consider  
9 expanding that a bit or allowing some additional comments. Because I think of the societies and the  
10 physician community has not had an adequate time to digest the document. Having read the document on  
11 the airplane, it's pretty detailed with lots of very tough questions in there. So we just ask you to consider  
12 allowing that to stretch a bit. And we know you're under the gun [crosstalk] to get a report to Congress, but  
13 we feel like this is so important in growing in its stature, that it needs a little digestion.

14 Dr. Valuck: I wouldn't want to cut off that kind of engagement. And here's what I would propose  
15 to the physician community. We will accept any input at any point in time during the planning process. It's  
16 not a formal rulemaking, there's no official cutoff date. If you can't make the comments by December 16,  
17 we are already planning for our next phase of this. So the later that you go after the deadline, the less likely  
18 it is that your comments will be taken into consideration as we're doing the next steps of things. But this is  
19 not a closed or overly structured process. I would say, in fact, give us your higher level, or maybe you  
20 would consider it preliminary comments by the 16<sup>th</sup> and then feel free to follow it up with more detailed or  
21 maybe things that are lower on the priority list. Because this process is moving very quickly.

22 Dr. Bufalino: And the last, just along the same lines, is just to keep PPAC involved. We hope to  
23 continue to have the opportunity, just much like you meet with the specialty societies every six or eight  
24 weeks.

25 Dr. Valuck: Mhmm.

26 Dr. Bufalino: Hopefully you'll stay as a permanent member of the agenda [laughter].

27 Dr. Valuck: My Christmas wishes come true. Thank you, Dr. Bufalino. Such a deal.

28 Dr. Bufalino: Thank you for joining us.

**PPAC Meeting Transcription – December 2008**

1 Dr. Valuck: Great discussion today. Probably some of the best that we've had in these sessions.

2 Dr. Simon: Tom, feel grateful that you didn't have to wait until December 25<sup>th</sup> to get that present.

3 [laughter]

4 Dr. Bufalino: Thank you. So let me go around the room and ask you for some PPAC  
5 recommendations around this because I think it would be important for us to deal with those now. We're a  
6 little bit behind schedule so let's be brief and to the point.

7 Dr. Standaert: I had one off the top of my head about [inaudible] so people may have to help me  
8 with the words here. I'd like to write these out. PPAC recommends that CMS provide us with regular  
9 updates on the planning for the resource use and reporting measures, and the role of their implementation in  
10 management. Did that come out well? I'm trying to say I want them to follow us with, keep on track what  
11 they're doing with the statistics, where this stands, and what they're trying to do with it, because there are a  
12 lot of questions about how they're doing this and what they're going to do with it. I'm trying to get at that.

13 Dr. Bufalino: Okay.

14 Dr. Standaert: I don't know if I got it in my language though.

15 Dr. Bufalino: Want to read it?

16 Ms. Trevas: No. [laughter] I can't reword that appropriately.

17 Dr. Standaert: I'll try one more time. PPAC recommends that CMS provides us with regular  
18 updates on the Resource Use, Measurement and Reporting Program, and I don't know if that's, that just tell  
19 us that—

20 Dr. Bufalino: That's good.

21 Dr. Standaert: That's fine.

22 [Second]

23 Dr. Bufalino: Any discussion? All in favor?

24 [Ayes]

25 Dr. Bufalino: Thank you. Next. Any other recommendations? Jeff.

26 Dr. Ross: Did we go back to an area where I wanted to submit the other recommendation for this  
27 morning that was under the Physician Fee Schedule.

**PPAC Meeting Transcription – December 2008**

1 Dr. Bufalino: Let's do that at the end. Kind of finish this one so that we're kind of focused  
2 around—if you don't mind. We'll go back and kind of accumulate what we've missed. Anyone else on  
3 Value-based purchasing? John?

4 Dr. Arradondo: PPAC recommends that CMS I don't know what I want to say, report, and then  
5 follow up or just keep us abreast, I guess report, and then follow up and its use of downstream diagnoses  
6 that aren't captured among the first four in the claims data base.

7 [Second]

8 Dr. Bufalino: Any discussion?

9 Dr. Arradondo: That includes part of what Lisa was talking about, that's captured on other data  
10 bases, like in hospital, which seems to me a real neat way to capture a lot of stuff, and institutional base, not  
11 just hospital, where a lot of diagnoses get listed, as well as the ambulatory piece that Dr. Smith had raised  
12 when she was first talking. They're probably doing more than we know. We just need to know more so that  
13 we can appreciate and perhaps give better advice, or ask better questions.

14 Dr. Bufalino: Any discussion?

15 Dr. Arradondo: That was my discussion. [laughter]

16 Dr. Bufalino: It was brief and to the point, so we got it. All in favor?

17 [Ayes]

18 Dr. Bufalino: Thank you. Anything else? Okay? Good. Let me take a moment and recognize Mr.  
19 Herb Kuhn who joined us. We missed you this morning. Glad to have you this afternoon. Thank you for  
20 being here. Okay, next up is Dr. Mike Rapp. We're glad to have Mike come back and talk about an issue  
21 that is near and dear to everyone, which is the PQRI. As you know, Dr. Rapp is Director of Quality  
22 Measurement at the Health Assessment Group in the Office of Clinical Standards. Dr. Rapp was a previous  
23 ER doc at George Washington, and previous Chairman of PPAC, so clearly one of our colleagues. Glad to  
24 have you, Mike.

25 Physician Quality and Cost Measure Update

26 Dr. Rapp: Thank you. I'm glad to talk about something much less complicated. [laughter] Very  
27 straight forward. We'll get through a few slides and that'll be that. [laughter/chat] I was asked to update  
28 you on the 2009 PQRI in the Electronic Prescriber Incentive Program. With the PQRI, we're doing always

**PPAC Meeting Transcription – December 2008**

1 three things at once. The 2007 reporting period ended at the end of 2007 and we recently, this summer,  
2 issued the first payments to some 56,000 individual professionals that qualified for the PQRI incentive  
3 program and did feedback reports. Subsequent to that, we got quite a bit of feedback from the physician  
4 community ourselves, which led us to do a more detailed review of the Physician Quality Reporting  
5 Initiative and just last week, the agency made available Physician Quality Reporting Initiative 2007  
6 Reporting Experience Report, which you'll see is quite detailed. I know a number of you have quite a few  
7 questions about how it worked, and so we have in here how it worked well and how it didn't work so well,  
8 and what we're planning to do about it. So that's not the subject of today's presentation, but I wanted to  
9 make it available to you, or make you aware of it, as it is on our PQRI website, which is [cms.hhs.gov/pqri](http://cms.hhs.gov/pqri). I  
10 have a few copies I'll give the chairman one, and a few of the others can get it but, this complete report,  
11 even with the color first page is available on our PQRI website, when you go to that. So I think you'll find  
12 the information interesting and helpful and it tells you specifically what we're going to do about dealing  
13 with 2007 and we came up with a number of issues that were, I think, technical issues in terms of how the  
14 claims reporting system works for quality data. And we find there are some ways that we can make some  
15 adjustments for 2008 that will be beneficial for the physicians in terms of technical business rules in terms  
16 of how the analytics play out for the measures. There's things that we can't fix. In other words, if the  
17 physician simply just reported the wrong quality data for the wrong denominator, we can't fix that, but  
18 there's some technical issues that you'll see are in this report and we're going to apply those for 2008, and  
19 as a matter of fact, for those physicians that didn't qualify for 2007, we're going to go back and rerun the  
20 analytics for them and to see if some of these technical changes will increase the frequency of valid  
21 reporting. We're confident it will in a number of cases. And so it'll be that some of the physicians that  
22 weren't found to qualify during the initial look at this will be found to qualify. And they will get bonus  
23 checks when that's redone. That'll be done in association with the 2008 payment itself, so we provide all  
24 this detailed information here about that, what we're going to do about it, but I think it's good news to the  
25 physician community and we appreciate the feedback and information we got and we spent, as a say, a lot  
26 of time with our contractor going through the details and you'll see that here. So that's 2007.

27 2008 is ongoing. Congress passed two Medicare Bills in the last 12 months. One of them was the  
28 MCIA Statute, where they required us to implement for 2008 alternative reporting periods, and alternative

1 reporting criteria, which we were able to do so physicians during 2008 are continuing to report. There are  
2 traditional or the original claims-based mechanism for three measures, but in addition, physicians currently  
3 can report on measures groups. But in addition, in so far as there's difficulties with the claims process, and  
4 physicians want to use alternative methods, they have the registries that they can use. There are 32  
5 registries that have qualified, including professional organizations, such as the American Board of Family  
6 Physicians. I looked on their website, and they seek to have that correlate with the maintenance of  
7 certification process, and indicate on their website, I haven't talked to them personally, but what's on the  
8 website indicates they'll allow family physicians to report diabetes measures to their registry. And if that  
9 registry then reports on behalf of the physicians to CMS then the physicians won't have to use the claims  
10 process, they will be eligible for 2008 for the 1.5 percent incentive bonus using whatever criteria they use  
11 to report. And the important thing about that is 1) physicians don't have to use the claims process to report,  
12 and 2) registries are retrospective, so one would, could sign up for registry now and submit the data to the  
13 registry, and the registry gets it to us in January. So that's 2007 and 2008 quickly, but again, we're doing  
14 three things at once. And the third thing is 2009, and that's what I'm here to tell you about.

15 So we'll go to the first slide here. [side comments] So for 2009 PQRI, there are program  
16 enhancements. I mentioned the MCIA Statute, which required us to select 2009 PQRI quality measures  
17 through rulemaking and establish alternative reporting criteria and alternative reporting periods for  
18 reporting measures groups and for registry-based reporting. So we did that for 2008 and pursued that in our  
19 initial proposed rule for 2009. At that point, we didn't have the authority to make an incentive payment to  
20 physicians who would report the measure. So all we did when we initially set forth the proposed rule was to  
21 indicate what the measures would be and what the reporting criteria would be. However, MIPPA was  
22 passed, July 15, 2008, which authorized several things. First of all, that for 2009 and 2010, it made it a  
23 permanent program, and authorized an incentive for two years; 2009 and 2010 of 2 percent of the total  
24 estimated allowed charges that a physician would have under Part B for the Medicare program. So that  
25 compares 2 percent compares to 1.5 percent for 2007 which was only for 6 months, compared to 1.5  
26 percent to 2008 which would be 12 months, and now, 2009, 2 percent and in addition authorizing  
27 Electronic Prescriber Incentive program. So physicians can qualify for 2 percent for PQRI and 2 percent for  
28 the Electronic Prescriber Incentive program. And just to get you some kind of quantification of how that



1 might work out, and there's a big distribution, and we talked about statistics and so forth, and the  
2 distribution is skewed quite a bit, but if you took just the average amount of payment for the individual at  
3 the individual level, it was about \$600 under the PQRI for 2007. If you extrapolate that to 2 percent instead  
4 of 1.5 percent and to a full year, instead of for half of a year, you would go from 6 to 8, and then from 8 to  
5 16. So just a average for the individual would be \$1600 for the PQRI and \$1600 for the Incentive Payment  
6 program, but again, that's at the individual level, and physicians frequently practice in groups, so in any  
7 event, the incentive payment was increased substantially under MIPPA. The list of eligible professionals  
8 was expanded to include audiologists, and there was some reference about posting on websites and so forth.  
9 It does require CMS to post on our website names of eligible professionals who satisfactorily report quality  
10 measures for 2009 PQRI. And we dealt with that in the Physician Fee Schedule Rule. So what that means is  
11 that we're required by the Congress, effective for the 2009 program that is for information that's submitted  
12 during 2009 under the PQRI or Electronic Prescriber Program, to post the names of those who successfully  
13 report, satisfactorily report under PQRI or successfully report under the Electronic Prescriber Incentive  
14 program. So for 2009, there were 153 measures under the PQRI program that were finalized in the rule.  
15 That includes 101 measures from the 2008 PQRI program, so those are not new measures, but 52 additional  
16 new measures, and some of them are only reportable through registries. 18 of them, for example, in the  
17 Society for Thoracic Surgery set of measures that deal with cardiac surgery, there are a number of those  
18 that deal with outcomes and so forth. Those wouldn't, they don't lend themselves to claims-based  
19 reporting. Claims-based reporting you report basically what you can, your vantage point at the time of the  
20 patient's, the service to the patient. So it doesn't lend itself to outcome measures or things that require  
21 information over a period of time. Registries, however, can much more readily get that information and  
22 provide it to us, so that's why in some instances we have measures that are not reportable through—that are  
23 only reportable through registries and not claims, and the basic concept is claims is a convenient and good  
24 mechanism for reporting quality data, but it has significant limitations as well.

25       There was an Electronic Prescribing Measure in the 2008 PQRI program, and Congress directed  
26 us to remove that measure and basically establish an entire new incentive program, the Electronic  
27 Prescriber Incentive program, which we did. The measure specifications have to be totally finalized by  
28 December 31, 2008. That doesn't mean that this is going to be just dropped on the physician's lap instantly

1 on New Year's Eve, because, again, 101 measures we already have in the 2008 program, which physicians  
2 are familiar with. Many, 18 of them are only through registries, so they won't have claims-based  
3 specifications at all. And in addition, we plan to post December 15, the claims specifications for those new  
4 measures so physicians will have a chance to get used to them and we're sharing them as well with  
5 professional organizations.

6       There are seven measures groups. The measures groups was a concept that was introduced in the  
7 MCIA legislation, and this concept here is reporting a group of measures, all of the measures pertaining to  
8 a group relating to a particular condition. That way, rather than individual, isolated, random measures so to  
9 speak, you would have all of the measures pertaining to these types of conditions. For example, preventive  
10 care has nine different measures. The back pain has a set of measures. Chronic kidney disease and so forth,  
11 so we added some measures to that, we add some measure groups to that list. Each of them has at least four  
12 measures. Diabetes is supposed to be indented there, those are not all subcategories of diabetes. It's  
13 diabetes is one of the more commonly used measure groups, and I believe that has in it now five measures  
14 instead of four. So a person would report on the way that would work. There are different ways you can  
15 report measures groups, but one of them is consecutive patients. So for, 2008, I'll get to the criteria, but one  
16 can report and qualify by reporting on 30 consecutive different diabetes patients. So a family physician for  
17 example, that has 30 diabetic patients could report the measure on each of those, on 30 consecutive diabetes  
18 patients, and once they do that they will have qualified for the 2 percent incentive payment. And that's the  
19 way it works for all of those measures. Thirty consecutive patients on any of those measures groups would  
20 be one of the reporting criteria. 80 percent is another criteria. So in the 2007 program, there was only one  
21 method that qualify, three measures, 80 percent of the time. For 2008, we gave nine different reporting  
22 options, or nine ways to succeed and we have a similar number for 2008. So there's a variety of different  
23 ways physicians can qualify for the PQRI program, which I think will in addition to the greater familiarity  
24 with the claims-based reporting for individual measures, will lead to the ability for physicians to more  
25 successfully qualify, couple with, of course, the registry-based reporting.

26       We had two alternative reporting periods as was required under MCIA. Four measures groups and  
27 for registry-based reporting of the whole year or half a year. If one reports for a whole year, the 2 percent  
28 would apply for all Part B charges for the whole year. If it's for a half-year then the incentive applies only

1 to a half-year. So one can do either way. It's maybe advantageous in some instances to start only later in  
2 the year when a person is geared up but they can still qualify.

3 Criteria, I talked about for the claims-based is the three measures 80 percent of the time. And then  
4 we have the other reporting options that you'll have in the slides. I won't spend a lot of time going through  
5 the details, but basically four measures groups. One can report on 30 consecutive patients, registries would  
6 permit you to do anything that you can do in the claims-based reporting, and 80 percent of applicable cases  
7 always apply.

8 So at any rate, this just details these options, which again, I won't go through but just from the  
9 point of view of how a physician would look at it. One way to look at it is just to decide do I want to do  
10 claims-based reporting or do I want to do registry-based reporting, kind of make a decision. Don't have to  
11 make it on day one. You can decide right now that you want to use registries to report for 2008, and  
12 proceed to go ahead and do that, even though it's well obviously into 2008. So claims-based reporting,  
13 registry-based reporting, and then decide do you want to report individual measures, or possibly a measure  
14 group, which in many instances is easier if such a group applies to you, and as you saw, we moved from  
15 where it's just all primary care that we have other measures groups even for thoracic surgery, for example.

16 Now I want to move to the Electronic Prescribing Incentive Program, which I think is a very  
17 exciting new area. This does take advantage of the existing PQRI program but it leaves us with some  
18 options for the future which will be extremely easy for physicians and does introduce another concept,  
19 which is that the incentive payment will go for a period of time, after which it'll be phased out, and a  
20 penalty will be phased in. It demonstrates a real commitment on the part of Congress to move toward  
21 Electronic Prescribing and promote it. So under MIPPA, the department was authorized to have a new  
22 incentive program separate from PQRI and to provide an incentive of 2 percent of the total estimated  
23 allowed charges that pertain to 2009, charges for 2009 that are submitted for claims by February 28, 2010  
24 and the incentive payment would come after that. The incentive reporting period, that is for the entire year,  
25 so the incentive payment applies to the entire year. Like for the PQRI, MIPPA does require us to post the  
26 names of those physicians who are successful electronic prescribers on the CMS website. Electronic  
27 prescribing background: This gives you a definition of electronic prescribing and what it is and basically  
28 it's more though than just now we're going to transmit prescriptions electronically as opposed to writing

1 out the prescription. It's more than that. Eprescribing involves as another slide will show, sort of a three-  
2 way communication between the professional, the pharmacy, and the pharmacy benefit manager as the  
3 second point there makes. There are many potential benefits to electronic prescribing, including safety,  
4 efficiency, formula adherence, drug surveillance, and cost savings, but to date, there's been limited  
5 adoption. Under the Medicare Modernization Act, however, Congress indicated a strong interest in electron  
6 prescribing and required that for, under the Part D regulations, that the agency would identify part D  
7 standards for electronic prescription. That is the inter-operability standards for prescribing part D drugs and  
8 the agency has done that. The way electronic prescribing works: Eligible professional decides to order a  
9 prescription, enters it into the program and then the communication occurs in this three-way mechanism,  
10 which is illustrated by this slide. The way the incentive program and disincentive works, 2 percent  
11 incentive for 2009, 2010, and then it goes to 1 percent for 2011 and 12, 0.5 percent 13, and none in 2014. In  
12 2012, a penalty or disincentive starts. It's a penalty for not electronic prescribing. That type of an incentive.  
13 For 2012, it's one percent, 2013 1.5 and 2014 and beyond, there's a 2 percent So I want to make clear 2  
14 percent of what. We're talking about 2 percent of all part B allowed charges. Not only those that have to do  
15 with prescribing events. It works that way for PQRI. You report on diabetes, but you get incentive for all of  
16 your patients. If a cardiac surgeon works in the office and takes care of diabetes patients in part, and reports  
17 on that, they would still get 2 percent on all the cardiac surgery, even if they didn't report on that, and vice  
18 versa if they reported on the cardiac surgery they would get for the additional 10 percent. So that's the way  
19 it works for all physicians so the 2 percent is overall. So that's what makes the incentive I think pretty  
20 significant.

21 Future penalties for not electronically prescribing. The fee reduction is prospective. So the way  
22 PQRI works, you report one year and you get a bonus the next year. That can work for a bonus. But when  
23 you think of a penalty, it wouldn't work. You can't have a retrospective penalty very well, because you'd  
24 have to recoup money later. That has to be really applied prospectively and that's the way Congress set it  
25 up. At some point not before 2010, that's when the reporting period will take place, and it will determine  
26 whether or not you have a penalty apply starting in 2012. So for example, the Secretary could, through  
27 rulemaking identify 2010 as a period of reporting for electronic prescribing and if the physician was not a  
28 successful electronic prescriber in 2010 then there will be a penalty that will apply in 2012, or could use a

1 2011 reporting period, or could use a part thereof. That will be a subject of rulemaking, and rulemaking  
2 means that the agency would, or the Secretary would propose how to carry this out and then the public  
3 would comment on that and based upon that give and take, there would be a Final Rule that would be  
4 developed and I outline that.

5 There is a concern that Congress recognized in terms of well, it may not be appropriate to apply a  
6 penalty to certain physicians on basis of hardship, for example, possibly in a rural area, the pharmacies may  
7 not be able to do electronic prescribing, and to penalize a physician in this case would be a hardship on the  
8 physician, and so there is a vehicle where the Secretary can apply a hardship exemption. How that would  
9 work again, would be the subject of future rulemaking and a give and take with the public before it's  
10 finalized.

11 MIPPA legislation, what is the successful electronic prescriber? It uses the electronic prescribing  
12 measure in the current program, so physicians already have had an opportunity to become familiar with that  
13 measure. It basically is focused on outpatient professional services in the office-based setting, and the  
14 physician is to report on electronic prescribing based upon that set of codes and I'll go through a little bit,  
15 the details of that. But that forms the basis for the 2000 Electronic Prescribing program.

16 So first of all, who is an eligible professional? It's anybody eligible in PQRI, but of course, since  
17 we're talking about electronic prescribing, it contemplates that the person would have prescribing authority.  
18 And you wouldn't be eligible for this, for example, in PQRI a physical therapist is an eligible professional,  
19 but normally doesn't have prescribing authority so wouldn't be eligible for this particular incentive. A  
20 successful reporting of electronic prescribing measure is different than PQRI. It only requires 50 percent of  
21 applicable cases, rather than 80 percent and the details of this are set forth in the 2009 Physician Fee  
22 Schedule Rule.

23 It takes the 2008 measure out, which was reportable at 80 percent and for 2009 PQRI, this will no  
24 longer be in that. So the overall requirement for the electronic prescribing measure I think is important to  
25 make this clear because a lot of times we focus on the measure, but the measure, in terms of what you  
26 report, first thing is that you whenever one reports on this measure, they're always reporting that they have  
27 adopted a qualified electronic prescribing system. So if a physician or other eligible professional for this  
28 measure doesn't have a, has not adopted a qualified electronic prescribing system there is nothing to report.

## PPAC Meeting Transcription – December 2008

1 So the first thing one has to do is get the system. And then report on the use of the system. The way the  
2 measure works, I mentioned 50 percent of reporting on applicable cases, so that's for the whole year. So  
3 that doesn't necessarily mean one has to be going January 1. Theoretically, if you started July 1 and you  
4 had an equally distributed set of patients, you could start July 1 and report 100 percent of the time. So  
5 although one does have to have an electronic prescribing system when they start reporting because of the  
6 50 percent reporting that's required, one doesn't necessarily have to start in January, so we're getting pretty  
7 close to January and that may have caused, that may cause some concern. The electronic prescribing  
8 measure is a PQRI measure. It's got a reporting denominator, which are HCPCS codes, and these are office  
9 visit codes. Now some of the complexity for PQRI had to do with you've got diagnosis in the measures and  
10 you've got age limitations and gender limitations and sometimes multiple diagnoses. So some of those  
11 measures for PQRI are somewhat complex. This was a simple measure. It's only got one set of codes in the  
12 denominator. They're office visit codes. They're codes that you have to put on a claim. So it's not a  
13 complex thing. Once you bill any of these codes in the denominator, which I'll show you what they are,  
14 then the occasion arises to report about the use of electronic prescribing system or not. And I'll go into that.

15 So the reporting numerator is three codes. So again, it's not complex. There's only three set of  
16 codes, and I'll tell you what they are now and repeat it. But basically they are on this office visit, I didn't  
17 write any prescriptions, that's one code. I have a qualified system, but I didn't write any prescriptions, one  
18 possibility. Second possibility, I have a system and I electronically prescribed everything that I prescribed  
19 at this visit. Or the third G code is I have a system. In this case, some or all of my prescriptions were not  
20 electronically prescribed for a good reason; patient request, system wasn't available at the pharmacy, or it's  
21 prohibited by federal or state law, or regulation, or it's a narcotic. We set aside that issue of narcotics and  
22 electronic prescribing. So even if the DEA starts allowing electronic prescribing of narcotics, one doesn't  
23 have to worry about that for the purpose of this measure because many physicians feel that what has been  
24 proposed thus far is too complicated and wouldn't be practical, so we don't suggest in this measure that you  
25 have to electronically prescribe narcotics even it becomes legal, because the two factor authentication and  
26 those things cause some complexity.

27 Here is what a qualified system is. The four components of it, it really comes down to three,  
28 because three and four are basically the same thing, at least as it is now. Has to be able to generate an active

1 medication list incorporating electronic data received from applicable pharmacies and PVMs if available,  
2 has to allow eligible professionals to select medications, print prescriptions, electronically transmit  
3 prescription and conduct alerts, those are checks for safety. And third, has to give information as to lower  
4 cost therapeutically appropriate alternatives, but that is by way of a formulary which is the last item. So has  
5 to be able to generate the medication list, conduct alerts and deal with, get information from the formulary  
6 that the patient has through their benefit plan. How do you know if you have a qualified system? Well one  
7 talks to the vendor for one thing. There are two types of electronic prescribing systems. One is a stand  
8 alone system, and the other is part of an electronic health record, so for those of you who may be interested  
9 in this, who don't have such a system, you'll have to make that basic decision for the long run. Of course,  
10 electronic health record and have that a module of that would probably be optimal. And in this case, there is  
11 the certification process, call the CCHIT and if your electronic health record meets CCHIT certification  
12 standards for 2008, then all those functionalities are met by that system. The stand alone system is not  
13 subject to CCHIT certification, so you have to talk to the vendor about it, but get some kind of commitment  
14 or understanding that they do meet those functionalities. Do we certify systems? No, we don't. Do we have  
15 a list of those systems that meet those qualifications? No. It's not anything you have to get approved from  
16 CMS. It's basically just the same as PQRI. You are asserting you have a qualified system when you submit  
17 these G codes. It's not something that really, it's between, it's a statement by the physician and it's up to  
18 you and the vendor to deal with the vendor and make sure you have such a system.

19 The part D standards are part of the statute that we have, that the Secretary's required to utilize  
20 part D standards to the extend of feasible and practical, and what that means and how that relates to these  
21 functionalities, there are a variety of part D standards and some of them are not related to the  
22 functionalities that are required to report this measure. One of them, for example, is called RXFill, which  
23 would give physicians ability to determine when they are on the electronic prescribing system, if their  
24 patient picked up the prescription and had it filled. That's not something that's widely adopted yet, and so  
25 it's not required as a functionality. It is a part D standard but it's not a required functionality. So it doesn't  
26 mean that every part D standard you have to have as part of your functionality. It only means that those  
27 functionalities have to utilize a part D standard. It's sort of like if you have a computer with office  
28 programs, and you have a word processor, this is telling you when you have a word processor, you should

1 use WordPerfect for example. That's the way the part D standard, it's the standard, it's not the  
2 functionality. The system has to have the functionalities, and in this case it has to use the part D standard,  
3 and that's how those two relate. So it's basically the version of messaging, and again, how are you going to  
4 know that this is the case?

5 I'll get to that in a second, but it basically has to do with one can do to SureScripts RX Hub  
6 website and if the vendor uses that network, it's sort of like a train track and if they use that network, then  
7 they use part D standards. This is the reporting denominator. These are office visit codes. It means  
8 whenever you bill one of these codes, the measure becomes reportable. It doesn't deal with hospital care for  
9 example, and there's arguments I supposed that can be made about that both ways. How come it doesn't  
10 include hospital? Well, hospitals basically, as facilities will determine what kind of systems they have in  
11 place and we've had some engagement with professional association representatives that are, that the  
12 membership is primarily hospital-based types of physicians, and there's a concern that of course once  
13 you're in the denominator here for the incentive, you may potentially be in the denominator for the  
14 disincentive. And if you don't have any control over how the system, whether the system is going to be  
15 adopted—but in the office based setting, the physicians have the most control over the system, the ability to  
16 adopt it or not adopt it, so that's what these codes are limited to. And for the incentive and then assuming  
17 this was the method for the disincentive, then for that, too. There is a further limitation in terms of who can  
18 be eligible for the electronic prescriber incentive, and to be eligible, 10 percent of your part B allowed  
19 charges have to be made up of these codes, or represented by these codes. So it's only 10 percent, but it is  
20 10 percent. That's unlike PQRI, there's no such limitation, so for a physician that has never uses these  
21 codes or uses these codes for less than 10 percent of their part B charges, they're not eligible for the  
22 incentive program, and conversely assuming the same system when the disincentive comes into effect, they  
23 wouldn't be liable for the penalty as well. At any rate, that's how that works. Physicians don't have to be  
24 concerned about the 10 percent. The agency will apply that when it makes its determination. It may be  
25 something one wants to consider if they know they don't have any office visits, then they won't really, this  
26 is really not relevant to them. But if they're not sure if it's 9 percent or 11 percent, we'll determine that  
27 retrospectively and it doesn't stop one from reporting.



1           The numerator codes, as I mentioned, there's only three. All prescriptions were electronically  
2 prescribed, no prescriptions were generated, some or all were written or phoned in, and there's those  
3 specific exceptions, so what it means is for those office visit codes whenever you submit them on a claim,  
4 one also should put this G code along with it, and has to do it at least 50 percent of the time to qualify for  
5 the incentive payment. I talked about the selection of a system, functionalities compliant with part D  
6 standards. I mentioned ERH versus stand alone systems and those things to consider. I previously talked  
7 about the RX Hub which would give you indication of where the part D standards are being met, so if your  
8 vendor uses SureScripts RX Hub, then you know that they use part D standards. If they don't use that  
9 system, and we're not saying you should or have to use that, the vendor has to do that, there are  
10 competitors, one would need to deal with the vendor however.

11           We have lots of information about electronic prescribing and many other things having to do with  
12 the related PQRI. This is not technically part of PQRI. It's a separate incentive program. Now some of you  
13 may say to me, well this is great but it doesn't make much sense to talk about electronic prescribing and  
14 then tell us that we have to submit information on a code on a claim form. That doesn't sound very  
15 electronic to me. And you're right. But just like many of the PQRI related legislation that's taken place,  
16 Congress doesn't give us much time to implement. This we've got six months, just like we had six months  
17 for PQRI like we had about four months for the MCIA enhancements. So we're not given too much time to  
18 implement these things. The only way to implement the electronic prescriber incentive program right now  
19 is to have physicians report a measure a la PQRI. However, for the future, Congress have provided the  
20 Secretary the authority to make a change. And that change would be that we could make the determination  
21 of whether instead of that 10 percent of these particular office visit codes, it would be a certain number of  
22 times the physician prescribes under part D. So not electronically prescribes, but any prescribing. And then  
23 a certain number of a certain percentage they elect certain amount of electronic prescribing as well. Now  
24 we can't get that information right now. But we hope to be able to get that information through what they  
25 call PDE data or part D Event data. It means that when the pharmacy benefit plan sends in the claims, they  
26 send in information just like you do, when you submit claims for physicians, and if we, through that data,  
27 were able to determine who prescribed and did they electronically prescribe, then we could get that  
28 information electronically through that data. And at that point, all the physician would have to do is just

1 electronically prescribe, since that's what we're interested in anyway, not burdening you with additional  
2 reporting responsibilities. So we would get the information, you would electronically prescribe, and if you  
3 met the qualifications, the agency would send you payment, and that's how that would work. As far as  
4 what's the right number of prescribing events to have this apply, what's the right number of electronic  
5 prescribing? That would again be part of rulemaking. It would be something that based upon information  
6 that we analyze and come up with a proposal and then have it be subject to comment by the public and then  
7 make a final determination on that and finalize that. So we hope to have that perhaps implemented by as  
8 early as 2010. So possibly the reporting would only be through the claims-based system, electronic  
9 prescribing would only be a one-year thing, perhaps longer. But that will remain to be seen in the future. So  
10 that's where we are with this I think very exciting program. Tom mentioned how the way PQRI works,  
11 there's again been, it's been a learning curve I think for us all. And we've learned a lot but there's some  
12 real benefits from it. You talked about attributing, how you attribute resource use to physicians. When you  
13 use pure claims-based measures, you of course have to attribute it, because when a physician sends in a  
14 claim they're not also providing you with lots of inferences about quality. But when a physician reports on  
15 PQRI, they're telling you I'm responsible for this patient, and I have some quality data I want to tell you  
16 about the patient, so I think diabetes has something to do with the kind of care I'm providing because  
17 you're picking the measures. So there's a lot of real advantages to PQRI and how it works and the self-  
18 reporting and self-attribution by the physicians, and also we have a tremendous number of measures  
19 available for all types of practitioners across the board. Even in PQRI this year, we had a measure for  
20 chiropractic services, which we expanded in that way. So any rate, it's a very exciting program from that  
21 and certainly represents the broadest, most comprehensive quality reporting program that exists in this  
22 country and it's not just focused purely on primary care but certainly includes that. Any rate, that's where  
23 we are and I'll be happy to take any questions or comments.

24 Dr. Bufalino: Thank you.

25 Dr. Smith: The PQRI thing to me was enormously frustrating on many counts. One is that I was  
26 down in my office, which has 2.5 providers, functionally, who entered all these data because the other  
27 people didn't have time, and if I put one more thing on top of my nurse, she was going to quit and that was  
28 going to make a worse disaster and I'm not kidding about that. And I put in, I estimated about two hours a

1 week, for twenty-five, twenty-six week, 2007, didn't get anything, have absolutely no idea why, have  
2 attempted a number of times to find my way through the website reports and so on and try and figure out  
3 why I didn't qualify for a payment, and I can't find my way through. I have never been able to figure it out.  
4 I didn't both for 2008 because I finally woke up and did the arithmetic and said that if I spent  
5 approximately 50 hours of my time trying to report this and I was going to get a bonus that was worth  
6 \$1000 or \$600 it wasn't quite worth it. And I think from talking with people on some of the committees I'm  
7 on, from listening to conversations just in the hallways as colleagues are grumbling, if you want to put it  
8 that way, about things, I think a tremendous number of physicians feel this way. The time investment  
9 required is by no means repaid by the potential bonus, and then when one discovers that we're expected to  
10 put in an enormously greater amount of time trying to report these things, may or may not get the bonus,  
11 but if we're not successful, we're going to show up on a website as not producing quality, that's really a  
12 rather terrifying concept. So I think there are some major flaws with the program, that need to be addressed.  
13 There needs to be a simplified way of reporting very, very quickly. There ought to be a way to find out in  
14 February if the reporting period starts in January, find out in February whether or not you're on the right  
15 track, and make the website negotiable. I mean that would help a lot. But there are big problems with the  
16 system as it currently stands in terms of the time required versus the payment and the punitive approach to  
17 posting the names of people who don't make it.

18 Dr. Rapp: Okay, well those are all good points. Many of, I think we've heard all of those points.  
19 We sought to address a number of them as we've gone on. You're talking of course about 2007. And 2007  
20 was our first foray into it based upon existing measures, existing systems, and so forth. First of all, with  
21 regard to the time involved, I think one frustration that you mentioned I think is a definite valid frustration  
22 and that is the part that you have a hard time figuring out from the reports that were provided why you  
23 didn't satisfactorily—

24 Dr. Smith: You can't get at the report. It's not a question of—

25 Dr. Rapp: Step one is getting to the report. You suggested that you had surmounted that hurdle, so  
26 I didn't address that.

27 Dr. Smith: [no]

1 Dr. Rapp: But there are many, that is a frustration. I can give all the rhyme and reason about why  
2 that is, but I won't spend time doing that. But I will say that for 2008, we're looking first of all to make it a  
3 lot easier to get the report and secondly, to make the report a lot more meaningful to people. I think for the  
4 claims-based in particular, it does not provide you with well, why is it that when I reported the quality data  
5 code, it wasn't considered valid. I think when you have a chance to look at this report, we tried to provide  
6 that information at the aggregate level here, so by measure, we've listed in here what percentage of the  
7 quality data codes were accepted and what were the various reasons why they weren't. It may be surprising  
8 to you for example, that in the diabetes measures, there is an upper age limit, that I think many people  
9 missed, of 75 years of age. So the measure doesn't apply for patients over 75. Yet in 30 percent of the case  
10 of the quality data code being reported, it was reported for people over 75. That's just how the measure was  
11 specified by the measure developer and owner, which is not CMS and went through the consensus process  
12 with that upper age limit. But that's an example of it's important to pay attention to the specifications.  
13 Secondly, and I think although this was not provided at the individual level, next year we do intend to  
14 provide that at the individual level, but for now, those measures that you reported, I think that's will give  
15 you certain information. Secondly, for those that didn't qualify for the bonus, we're going to, as I  
16 mentioned earlier, based upon some technical issues, rerun the 2007 and it's very likely that those, some  
17 individuals that didn't qualify will have qualified and we will send them a more detailed report and a check.  
18 Secondly, 2007 was 2007, and for 2008, there were more simplified approached for reporting that could be  
19 used. In particular, for the second half of 2008, 15 consecutive patients for the measures groups, such as  
20 diabetes was all that required, and third, as I mentioned for 2008, registries. The one, even if they chose not  
21 to participate so far, could still participate in by using a registry and reporting that way. So I think you have  
22 many valid points that you've made. I can only say that both Congress in expanding reporting options  
23 authority that we had and internally were working to try to address all those and will continue to do that,  
24 but the way it was for 2007 doesn't mean it's the way it's going to be for 2008 and the success I think will  
25 be a substantially higher, especially when we apply these additional analytics, and we're going to do our  
26 best to provide information. With regard to the final point that you, the one point that you made, well it's  
27 just not worth it. We don't have authority to do it a different way. There could be different ways. For  
28 example, in this case, it's 2 percent of your total allowed part B charges. That means physicians who have a

1 lot more part B charges of course will benefit from the incentive program. That probably does disadvantage  
2 certain fields, perhaps primary care would be one of them. But that would be something that Congress  
3 would have to address. They could conceivably give us authority to deal with that. That hasn't happened so  
4 far, but we don't have any ability to modify that basic thing. We have one decision to make, which is did  
5 they qualify or not qualify and if they did, pay them the 2 percent of total allowed charges.

6 Dr. Snow: I'd like to expand a little bit—you mentioned the technical problems with calculating  
7 who was eligible. Does that involve this claims splitting problem?

8 Dr. Rapp: Yes. To briefly address some of the technical—there are three major problems. One was  
9 an NPI issues. To both have your quality data codes considered, and to have your part B charges  
10 considered, you had to have an NPI with it. Now that was a basic requirement that was set up at the  
11 beginning of the program and widely announced. But it turned out that 12 percent of the quality data codes  
12 didn't have NPIs that came through the claims process. In some instances, the physicians thought they were  
13 submitting an NPI. In come cases, their electronic data interface software took it off. So I'm showing the  
14 detail with which we've analyzed this. In some cases, clearing houses took them off. We didn't find any  
15 instances where if the NPI for the rendering NPI came into the carrier that it was taken away by the carrier.  
16 It was pre-carrier. But it affected 12 percent of the quality data codes. So that's one issue. I'm pleased to  
17 say that for 2008, that problem has gone away. The reason it's gone away is physicians, there's an edit at  
18 the claims-based, for the claim. If you don't have an NPI, the claims get sent back and our management  
19 reports indicate that issue is gone. All of the claims now coming in have NPI, so that 12 percent of invalid  
20 quality data codes are now valid. The split claim, which you mentioned, that some clearing houses take the  
21 claim and separate the quality data code for the whole rest of the claim. There was a basic business  
22 requirement. You had to put the quality data code on the claim. If the carrier did, the way the analytic  
23 worked this year, that quality data code wasn't considered. That affected about 6 percent of the quality data  
24 codes. And we have found that in about one-third of those cases, by going back and getting the claim,  
25 looking for the same date of service for a claim and a quality data code, we can bring them back together.  
26 And that's what we're going to do for 2007 and 2008. So one of the concerns doctors have, well, I'm only  
27 learning about this split claims now. That's going to affect me for 2008. No, it won't. Because to the extent  
28 we can bring them back—now if all you did was submit a quality data code separately and it's not really a

1 split claim, it's just how you submitted, that won't be taken care of. But if it got split through this technical  
2 issue, we're going to bring them back together for 2008 and we're going to bring them back together for  
3 2007 and that will mean that some of the doctors that didn't qualify would have qualified. The other issue,  
4 and this is a fairly substantial issue, diagnosis, affected 13 percent of the quality data codes. Not all of the  
5 measures have diagnoses, but for those of you that are familiar with how the claims system works, there's  
6 what they call a base diagnosis, which is all of the diagnoses that you've put on. You've mentioned, I think  
7 four diagnoses and then there's what they call a line item diagnosis. So for your procedure, like if you see  
8 an office visit, you're supposed to indicate, through what they call a diagnosis pointer, which diagnosis. If  
9 you have diabetes and coronary artery disease, you indicated this is diabetes. Well, you were required under  
10 the program to do that same thing for a PQRI quality data code, since it's treated like any other procedure  
11 code. Well, it turns out that in many instances, in some instances we have multiple diagnoses, so this idea  
12 of having to point to a diagnosis was a problem. So now we're going to change that technical issue by  
13 going for 2008, although that same basic business requirement of pointing the diagnosis is there, we'll look  
14 at any of the diagnoses on the claim. So we'll consider that. We'll do that for 2008, we'll do that for 2007,  
15 rerun that for the doctors that didn't get an incentive, and hopefully, there'll be a number that qualify.  
16 Estimates of how that will work out. There are about 13 percent of the quality data codes that were invalid  
17 because of diagnosis and about a third of those, we believe, that appropriate diagnosis will be there, so  
18 that'll affect a number of cases.

19 Dr. Snow: What about the fifty diagnosis, such as diabetes, that you can't put on a paper claim, for  
20 instance, if that's what you happen to be coding for because your other four diagnoses have to be taken for  
21 the particular episode of care?

22 Dr. Rapp: Well, I mean, that is a basic, the diagnosis has to be there. Otherwise it's not, the quality  
23 data code doesn't pertain to measure. So it's got to be somewhere on the claim. We can't infer the  
24 diagnosis because otherwise, we'd be inferring it for when doctors don't report and then they would be  
25 considered invalid so the diagnosis does have to be on the claim. It's just that we're not going to say, oh it  
26 only counts if it's here on the claim. It's going to count if it's anyplace on the claim. So I think those are  
27 big important issues. It took us a lot of time to figure these out because like was mentioned, the doctors  
28 really can't figure it out from the feedback report and we had to do a lot of inquiry investigation to do this.

1 Dr. Bufalino: But do you see, Mike, that expanding beyond four? I mean a lot of us have a  
2 difficulty, our group didn't qualify, because it fell to five or six or seven on that particular visit and it got  
3 thrown out.

4 Dr. Rapp: Well, I don't want to say that's not my job, but how the claim processing system  
5 works—this is an example of we had to take the claims system, the way we found it. If it allows 20  
6 diagnoses, that's fine with us. It's just that we can't, in the PQRI world, don't have the ability, tell Jeff—in  
7 fact that would be Jeff's job really, to change how the claims work, so [laughter] he's the right man to talk  
8 to. So we kind of have to take the system the way we have it. It just turns out that the business requirements  
9 are a little too refined. It was really designed when you have multiple NPIs on the same claim, but it turns  
10 out that's really not very common. It's very uncommon, for multiple NPIs to be on the same claim, so it's  
11 not necessary. So any rate, that's how we're going to make that change. So the other things would be good,  
12 but beyond my pay grade or outside it or something.

13 Dr. Bufalino: Could we get those other folks in? Go ahead, Karen.

14 Dr. Williams: For the ePrescribing for hospital-based physicians, there's two different types of  
15 physicians; some that are definitely working the hospitals, others that have their own group but are based in  
16 the hospital. Can you talk about the distinction between those two groups as far as qualifying for  
17 ePrescribing?

18 Dr. Rapp: Well, the denominator, the codes in the denominator are listed there. So if they're in the  
19 denominator, then they apply regardless of the place, the site of service doesn't matter, it's just that some  
20 types of services are quite, some services are specific, like emergency department, for example. They're an  
21 E&M service, but it's specific for the emergency department. They're not in the denominator. In your case,  
22 you're an anesthesiologist, right? So possibly you would have some office type, some occasion to bill  
23 office visit codes. If that's the case, and they accounted for 10 percent of the part B allowed charges, you  
24 would be eligible for the incentive, even though there's no codes for anesthesia for example. But you may  
25 have office visit codes that you could readily qualify. But there's no limitation by site of service.

26 Dr. Williams: You said before that the hospitals weren't included in this ePrescribing.

27 Dr. Rapp: Well, it's a physician, I meant that, for some codes, there are some E&M codes and  
28 particularly emergency visit E&M codes that are site specific, and E&M service for emergency physician is

1 billed with a code that's not up there. But insofar as you bill with those codes, the site of service is  
2 irrelevant. So perhaps I was confusing there.

3 Dr. Standaert: Quick question. Why doesn't CMS offer a voluntary certification program for  
4 vendors who are providing ePrescribing software, so the physician who's going to buy the software solely  
5 to meet this program knows what they're buying is actually going to meet your requirements so they don't  
6 get dinged later for not having done so?

7 Dr. Rapp: Well, again—

8 Dr. Standaert: Just as a voluntary thing. Can't vendors come and say will you approve our  
9 software so the people who then go buy it know that it meets your certifications.

10 Dr. Rapp: Yes.

11 Dr. Standaert: And then they're done.

12 Dr. Rapp: I did mention the CCHIT certification process. So that is an existing certification  
13 process and it does pertain to EHR vendors. So if you have a system, an electronic prescribing system  
14 that's part of a module of an EHR system, there is that certification. It's the 2008 CCHIT certification. For  
15 a stand alone system in 2009, CCHIT is planning to have certification for those stand alone systems. They  
16 just don't have it now.

17 Dr. Standaert: So they go to them to get certified.

18 Dr. Rapp: Exactly.

19 Dr. Standaert: And then you accept their certification?

20 Dr. Rapp: Well, we accept the statement of the doctor. We're not certifying vendors, CCHIT does,  
21 but the way this measure works is the physician is indicating that they have a qualified system, and so it's  
22 really up to the doctor to do it, and we're just alerting you to the things that one needs to ask the vendor.  
23 But we're not going to come and say oh, that system really isn't.

24 Dr. Giaimo: In a practice where you have a physician and a nurse practitioner both seeing patients,  
25 who do you break that down as far as how you can't get 2 percent plus 2 percent again or how do you break  
26 that down. You have 100 patients, they each see patients intermingled. How would you break down their  
27 bonuses.



**PPAC Meeting Transcription – December 2008**

1 Dr. Rapp: Okay, so the way the PQRI and Electronic Prescribing Incentive program works  
2 currently, and this will be an additional option in 2010, but it's at the individual level. So it depends under  
3 who's NPI it's billed. The nurse practitioner sometimes bill what they call incident to services. Again,  
4 claims is not my area, but I've heard enough about it on these calls where I get asked these kind of  
5 questions. But when it's incident to, the nurse is actually billing under the NPI of the physician. So in that  
6 case, it'll count toward part B services for the physician. It'll count for reporting for that physician. If the  
7 nurse has a different NPI and under that, there'll be a separate determination for the nurse or the physician  
8 assistant, and the incentive there, and qualification would first of all be determined whether the 50 percent  
9 or 80 percent reporting took place, and then the 2 percent of that NPI's allowed charges, all of it paid at the  
10 tax ID number level.

11 Dr. Giaimo: Tax ID number for the practice, and that's how you get your denomination.

12 Dr. Rapp: Right.

13 Dr. Giaimo: Thank you.

14 Dr. Rapp: You're welcome.

15 Dr. Bufalino: Thank you Mike, thank you for joining us.

16 Dr. Rapp: Thank you.

17 Dr. Bufalino: We'll have some recommendations to follow. We'll actually sneak the RAC in now  
18 before the break. Before you run out, I'm sorry to bother you. Two seconds while you're here, we just take  
19 advantage of you being here this morning. Wanted to make sure this afternoon if there was anything that  
20 you wanted to express to the Council at all, particularly the interest was around the new transition in terms  
21 of how we're ending and how we're starting a new administration, take a moment to hear your thoughts.

22 Mr. Kuhn: I appreciate that very much and one, thank you all for one, your service, as always.  
23 This will be my last meeting [chat off mike]. Let me try this a little easier. One, thank you, Dr. Bufalino, I  
24 really appreciate this. And what I think just the thing I would just say is once again thank you all for your  
25 service, as we say time and time again, this is the Practicing Physicians Advisory Committee. You all are  
26 extraordinarily busy. I know the trips that you make here to Washington takes a lot of time out of your  
27 individual practices and so we appreciate that very much. We have begun in earnest on the transition efforts  
28 so far. We have been meeting regularly with the transition team, some really terrific folks for the new

## PPAC Meeting Transcription – December 2008

1 administration are helping make the process hopefully as seamless as possible. They're getting our full and  
2 complete cooperation for data and information needs that they need to make their plans. I think they  
3 understand fully many of the things that we have in the cue right now, many of the things that you're  
4 discussing at this very meeting, and I think will be fully prepared to hit the ground running when things  
5 begin on the 20<sup>th</sup> of next month. So I think the transition continues to go well. But I think as what you're  
6 hearing here, as part of this meeting, particularly with the last two presentations, is that the continued effort  
7 to move forward to drive to value in our healthcare system, to try to drive greater measurement, to try to  
8 push in different areas where we haven't been before continues at a pretty good pace now, and I think we'll  
9 only accelerate as we go forward. And as a result of that, that's one of the reasons I wanted to come and  
10 listen to this particular discussion. Because I think this issue of the resource use reports and these issues are  
11 extraordinarily important as we go forward. And thinking those through, helping us get those as correct as  
12 we possibly can, because I will tell that the new administration has a great interest in those. The Congress  
13 has a great interest in those, and CMS has a real interest in those as do many others. So I think to have your  
14 practical thoughts on these and how they might play out for us as we go forward, a lot of work to do but I  
15 think we're going to continue to make good progress in this area. So again, thank you all, as I was starting  
16 to say earlier, this will be my last meeting with you all in my current role. So I've enjoyed getting to meet  
17 some of you over the last several years, and again thank you all for your participation.

18 Dr. Bufalino: A round of applause. [applause]

19 Mr. Kuhn: Thank you all.

20 Dr. Bufalino: Thank you. Shifting gears back, and we'll try to get our last presentation in before  
21 we take a break. So Melanie Combs-Dyer's joining us again, here to talk about the RAC. She's joined by  
22 Lt. Terrence Lew, who are here to kind of go through the basics of this program. We've had a number of  
23 iterations and we're anxious to hear your update in terms of what's going to happen in 2009.

### 24 RAC Update

25 Ms. Combs-Dyer: Thank you so much for inviting us here today. Just to put into context a little  
26 bit, you guys have seen this before, but the background about the Recovery Audit Contractor program starts  
27 with the Improper Payment Information Act. That's the Act that requires all federal agencies to measure  
28 their improper payment rates, and take actions to lower those rates, and just a refresher, improper payments

1 means both overpayments and underpayments. Section 306 of the Medicare Modernization Act required us  
2 to do a demonstration program that ran from March of '05 to March of '08. The demonstration is now  
3 done. Section 302 of the Tax Relief & Healthcare Act of 2006 requires CMS to take the RAC program  
4 permanent and nationwide and do it by no later than January 1, 2010. And so we're here today to tell you  
5 about where our plans are in making that happen. And again, both statutes give the Recovery Audit  
6 Contractors the ability to be paid differently from our regular contractors. They do much of the same kind  
7 of work, requesting medical records, receiving medical records, reviewing claims, looking for improper  
8 payments, but they're paid differently. They're paid on a contingency fee basis, and that's what makes  
9 them different from our regular carriers and FIs. Just a quick refresher again, demonstration RAC program  
10 that demonstration RACs were given about \$317 billion worth of claims. This is on the next slide, and the  
11 demonstration RACs found about a billion dollars in improper payments. The demonstration RACs repaid  
12 about \$37 million back to providers. So again, one billion in over payments, 37 million in underpayments.  
13 And everybody always asks about the appeals. In our three-year report, that we put up on our website back  
14 in June the appeals at that point were around 4.6 percent of all the determinations that the RACs had made  
15 were overturned on appeal. We've updated that number. That's now 6.8 percent of all determinations made  
16 by the RACs were overturned on appeal. And we will continue to update that number, again, the appeals  
17 continue to work their way through the system, and we will continue to update that number.

18 At this point, I'm going to turn it over to Terry and he will update you on where we are with  
19 bringing up the new permanent program and some of the changes that we have in place for the future.

20 Lt. Lew: Good afternoon. Thank you again for inviting us today. My name is Terry Lew. I'm a Lt.  
21 in the Commission Corps of the US Public Health Service. To back up, the Tax Relief and Healthcare Act  
22 authorized a permanent RAC program. We issued a request for proposals, and on October 3, we signed  
23 contracts with four permanent RACs. One for each quadrant in the country. Unfortunately, on November 3,  
24 we had to issue a stop work order to each of the four RACs. There was a protest filed, with the Government  
25 Accountability Office, by two of the unsuccessful bidders, and as a result, the RAC work is on hold for  
26 approximately 100 days while the GAO makes their decision on the merits of that protest. So we anticipate  
27 that the permanent RACs will not be up and running any sooner than mid-February 2009. We go to the next  
28 slide, please. This is a slightly revised version of the chart you may have seen earlier. It has the four

1 geographic regions and the taupe states, those were the first round. They were initially supposed to be  
2 going now. That's not going to happen due to the protest. We may be able to roll those into the green states,  
3 which are going to be starting provider outreach no early than February 2009, and the earliest that any  
4 provider correspondence would be March 2009. Again, that depends to some degree on what the GAO does  
5 with the protest. They may well come out with a Decision sooner. They may take the full hundred days so  
6 these dates are subject to change. The blue states then would be the third round of the national expansion.  
7 Claims would be available to the RACs in mid-June 2009, provider outreach would begin in July 2009, and  
8 again, the earliest any letters would go out to providers would be in August 2009, subject to change,  
9 depending on the outcome of the protest.

10       There are three basic ways that the RAC identify the claims they're going to review; data analysis,  
11 any interesting or aberrant patterns they may detect with that analysis, published reports, OIG, GAO, CERT  
12 reports, and then in-house knowledge and expertise. Once they have identified the claims they're going to  
13 review, there are two types of review; automated review, where there can be a certainty that an improper  
14 payment did indeed occur, or complex review. And that's where there's some doubt as to whether an  
15 improper payment may or may not have occurred. Those complex reviews are the ones where they'll be  
16 requesting medical records from providers. The RACs will be required to secure approval from CMS  
17 before they begin doing any reviews, however. New issues they will have to propose to us. We have a  
18 process for reviewing them. New issues are things that they would like to look at. They've reviewed the  
19 reports, they've done their analysis and they think that there's a high likelihood that there're improper  
20 payments in X, and so they'll come to CMS and they'll say we'd like to look at X. We have a board that  
21 will review those proposals, and if justified, will allow them to move forward. Those issues will be posted  
22 on each RAC's website. So the four RACs across the country, each one will be required to have a website  
23 where they will post those new issues, those things that they're going to be looking at. The RACs will be  
24 able to look back three years from the claim paid date. So this is a change that we've put in for the  
25 permanent program. Also, the RACs will not be able to review any claims paid prior to October 1, 2007.  
26 We heard loud and clear during the demonstration, we are trying to minimize the burden on providers. We  
27 are trying to be as reasonable as we can and create a program that will work both for the RACs. We are  
28 attempting to identify and correct as many overpayments, improper payments as we possibly can, but at the

1 same time, we do want to be fair to the provider community. And we'll touch a little more later on some of  
2 the lessons learned through the demonstration. One important point, medical review policies are the same  
3 for the RACs as they are for FIs, carriers, and MACs. There's nothing different about the medical review  
4 process. They'll use the same NCDs, LCDs, guidelines that other Medicare review organizations are using.  
5 Also, we've required that the RACs have qualified staff to conduct the reviews; nurses, therapists, certified  
6 coders, as well as a physician medical director.

7 So the process of requesting medical records. The RACs will send out letter to providers  
8 requesting medical records, just as in the current medical review processes through the FIs, carriers, MACs,  
9 as well as the CERT program, the Comprehensive Error Rate Testing program. RACs will pay for inpatient  
10 hospital records, however, they will not pay for outpatient records. Providers are required to respond to the  
11 RAC letters. We certainly would not want them to ignore them and hope that the request will go away. If  
12 the providers do not reply within 45 days with the requested records, that is going to be an automatic  
13 denial. So again, we would encourage providers to respond in a timely manner, supply whatever  
14 information the RAC has requested. CMS has established medical record limits and I'll touch more on  
15 those in a moment. Providers are encouraged to identify point of contact. One person on their staff that all  
16 RAC correspondence will be funneled through. And then once the providers have collated the records to be  
17 submitted, those can be submitted via postal mail, fax, mailed on CD or DVD. At this point, the RACs are  
18 not going to be set up for full electronic, that interchange, there's not going to be a way to submit EHRs  
19 directly to the RACs. However, we are exploring the possibility of electronic submission of imaged  
20 medical records. More information to come on that shortly.

21 This is a summary of the medical record limits for FY 2009. CMS may change them from year to  
22 year once the RACs are operational. We'll see how things go and we may change them for the next year,  
23 however, again, we believe that the limits as currently established are the best balances we can develop  
24 between protecting providers from undue burden of responding to 100s and 1000s of medical record  
25 requests, while still giving the RACs an adequate universe of claims from which to do the reviews. Briefly,  
26 inpatient facilities 10 percent of average monthly Medicare claims, per 45 days, per NPI, with a maximum  
27 of 200 medical record requests. We are still investigating how exactly this is going to work for facilities  
28 with multiple NPIs, multiple campuses, the objective is not to overwhelm a hospital with five, six, seven,

1 eight, nine, ten NPIs, but at the same time, our goal is not to give a pass to a large organization. We want to  
2 be fair to everyone and that is one of our goals as we move forward with the permanent RAC program.  
3 Other part A billers, 1 percent of average monthly Medicare services, again with the 200 record cap per 45  
4 days, per NPI. For physician practices, solo practitioners, ten records, small partnerships, two to five  
5 individuals, 20 records, small groups, six to 15 individuals, 30 records, and large groups of 16 or more  
6 providers, 50 records per 45 days per NPI. Now this is not per individual physician NPI. A large medical  
7 group is not going to have, a large medical group with 50 providers is not going to receive 500 medical  
8 record requests per 45 days. The idea is to look at the group size. Also for practices that have part time  
9 providers, practices that have significant turnover throughout the year, the idea is to look at FTEs. To look  
10 at positions. So if you have a practice with 10 providers working part time, the limit would be, 10 providers  
11 working part time, but one FTE, the limit would be 10 records per 45 days. And then the last point on there,  
12 other part B billers, DME, lab, 1 percent of average monthly services, maximum of 200 again, per 45 days  
13 per NPI.

14         These are lessons learned throughout the demonstration. Again, we are trying to minimize  
15 provider burden. We want to make this as providers as possible. To that end, we've imposed a limit on the  
16 number of medical record requests per 45 days and we've limited the RAC look back period. In no  
17 circumstances are they allowed to look beyond 1 October 2007 and they are not allowed to look more than  
18 three years in the past going forward. So if the RACs were in operation today, they would have about a 14-  
19 month window that will gradually expand until we get to three years and then it will be rolling forward  
20 from there. Second key to success, we are attempting to ensure RAC accuracy. Each RAC is required to  
21 have a physician medical director, certified coding staff, nurses, therapists, we also have the New Issue  
22 Review Board at CMS. And that's the process by which we're going to review RAC proposals for things  
23 they'd like to look at, determine the merits of those proposals, and allow them to move forward, or say  
24 perhaps you'd like to work that up a little more and come back to us. We also have a RAC validation  
25 contractor. That's something new. They'll be looking at RAC findings and validating them, insuring that  
26 the RACs came to the right decision. We'll be publishing annual accuracy rates as well. Maximized  
27 transparency. We are trying to be as transparent as possible. The RACs, before they proceed with any  
28 reviews are going to be required to post those issues to their websites. The RACs are required to have

1 websites, and those will need to be up and running before any reviews can begin. Vulnerabilities are going  
2 to be posted to the web, so the RACs will have on there: These are the things that we're looking at, and  
3 these are the things that we've found. Again, we're trying to get the word out to the provider community,  
4 maximize transparency, be above board as possible. Also, the RACs are required to have a claims status  
5 website by 2010, and that's to prevent that feeling that you've sent your medical records off, it's been a  
6 month, it's been five weeks, it's been six weeks. What's going on? The RACs will be required to allow you  
7 to query the status of records you submitted and find out where they are in the review process.

8         So as providers, what can you do to get prepared for RAC audits? Do your research, know where  
9 previous improper payments have been found, because that is where the RACs will be looking. Explore  
10 OIG reports, CERT reports, the demonstration RAC report also lists some things that the demonstration  
11 RACs found. Know if you are submitting claims with improper payments. The goal of all this is to pay the  
12 claims correctly the first time, not pay them improperly, then go back and have to fiddle with them to get  
13 them right. We want you to be prepared to respond to RAC requests as quickly as possible, as completely  
14 as possible. The RACs will send out those request letters and you will have 45 days to respond. Again,  
15 ideally you'll be able to identify a point of contact for the RACs, your office manager or someone who's  
16 designated as the person for RAC correspondence. And finally, appeal when necessary. We would certainly  
17 hope that the RACs make the decisions in all cases, we realize that there can be disagreements. You have  
18 all the same appeal rights as you would under any other medical review scenario, while we certainly would  
19 not encourage to appeal everything the RAC does, if you feel strongly, if you disagree strongly with the  
20 RAC, certainly avail yourself of the appeal process. That's why it's there.

21         The RAC website. This is the best place to go for any updates. We do post information there  
22 periodically. I don't know the exact process, but I believe there is a way by which you can request email  
23 updates any time new information is posted. That information should be on that site. We post information  
24 all the time, and we encourage you to visit the site and check it out.

25         Melanie, myself, and the RAC email address. If you have any questions, we'd love to hear from  
26 you. It's [RAC@cms.hhs.gov](mailto:RAC@cms.hhs.gov). And at this point, we'd be happy to take any questions.

27         Dr. Bufalino: Conversation? Joe?

1 Dr. Giaimo: What is the reason why physicians won't be compensated for copying records and  
2 hospitals will? What was the decision process with that?

3 Lt. Lew: There is a practice expense component of the RVU system and the theory is that you are  
4 compensated for any of your medical record requests that the RACs produce via that element of your  
5 current reimbursement. Now with that said, that may not highly be accurate or appropriate for [inaudible]  
6 organizations that are hit with the maximum number of requests per period. We can certainly take that back  
7 to the provider payment group, but that's not something that's in our domain.

8 Dr. Ouzounian: When you request a recovery, an overpayment from a provider, is it based solely  
9 on the claim that's reviewed, or is there going to be an extrapolation process?

10 Ms. Combs-Dyer: The Recovery Audit Contractor is in the demonstration program as well as the  
11 new permanent Recovery Audit Contractors are allowed to use extrapolation. The demonstration RACs  
12 even though they had the authority to do extrapolation, they did not choose to avail themselves of that  
13 process. We don't know whether the permanent Recovery Audit Contractors will choose to use  
14 extrapolation or not, but they do have it at their disposal. It's one of the tools that they have, they will have  
15 to follow all the same rules and regulations that the regular carriers have to follow that are spelled out in the  
16 Program Integrity manual about using the right statistician and choosing the correct sample size and all  
17 those rules, but yes, they will have the ability to extrapolate.

18 Dr. Bufalino: Just one comment as we go to the other side, I guess some of us are concerned about  
19 the fact that since now RAC contractors are commonly known as the bounty hunters in this community, the  
20 fact that they earned \$200 million in the first round, you would have thought that there would be an  
21 opportunity to compensate physicians for the record review in their offices. No different than in the hospital  
22 where they have to get someone to find the record, copy the record, and mail the record to you, the same  
23 process is in place for most of the doctors and for larger groups where there's 50 physicians or 20  
24 physicians, that you're going to get 50 records every 45 days sounds like a significant job for a member of  
25 the staff. So you know we'd ask you to really take a serious look at that again.

26 Ms. Combs-Dyer: We will certainly go back and look at that. We just would like to remind you  
27 though, under the demonstration program, we suggested to the demonstration RACs that they put in place  
28 medical record limits. Two of them decided that they would, and one of them decided that they didn't want



1 to. The two that did, did not have a sliding scale of any sort. They chose numbers like 100 medical records  
2 per 45 days, no matter whether you were a 700-bed facility, or a solo practice physician. So we feel like  
3 we've at least, we're heading in the correct direction, by establishing the medical record limits that Terry  
4 just went through a minute ago. We think it's fairer to have a smaller number of medical records be  
5 requested from a smaller practitioner than from a large facility. But I do hear your point, that it's still is  
6 something that PPAC would like to see us change and we will certainly go back and ask if there's any kind  
7 of adjustment that can be made to the physician payment system, so that medical records can be paid for  
8 separately.

9 Dr. Bufalino: Thank you.

10 Dr. Smith: I'm following up on this medical records thing. You're discriminating enormously  
11 against the small practice. I mean it's really heavily weighted. You're saying the solo practitioner has to  
12 submit 10 records every 45 days, which could be a huge number per year, but the large group of 16 people  
13 can't have to do more than 200 in a year even if they had a 150 physicians in the group. So it at least needs  
14 to be linear. If you're going to limit it to 50 records for a group of 16 plus, it ought to be one record for a  
15 solo practitioner.

16 Ms. Combs-Dyer: Thank you for the suggestion. We'll take it back.

17 Dr. Smith: It's really heavily weighted against the small practices.

18 Dr. Standaert: One, I'm glad to see you're [inaudible] that this is going nationwide. We're  
19 concerned about you. [laughter] Second, last time you were here, a number of us has expressed concern  
20 about this review process, and the cost of review, and all these sorts of issues. And I thought last time you  
21 were here, we had asked for data on the claims amounts that were actually reviewed, that were actually  
22 appealed, and how much those claims were and was there a threshold that which people just weren't  
23 appealing because the appeals process was too expensive. And frankly, as I'm thinking about it, I've never  
24 seen data and I don't think anybody's ever shown us data on how much these claims for improper  
25 payments, how much they were; what's the size of the judgments against the providers were? What kind of  
26 dollars are we talking about? And again, is there a threshold at which people just aren't appealing because  
27 of the cost of the appeals process and do you know anything about the cost of the appeals process? Does  
28 that makes sense?

1 Ms. Combs-Dyer: I think so but I think what you're asking for is not aggregate appeals data, but  
2 appeals data down to the provider level. Is that you're asking for?

3 Dr. Standaert: No, more of a cost data. My issue is this. If you have, say a RAC comes through  
4 and tries to collect \$10 million from a hospital. The hospital may well appeal that because that's a large  
5 sum of money and they'll spend thousands and hundreds of thousands of dollars on lawyers to get \$10  
6 million back. But say you come to a provider, and you ask for \$5,000, but it's going to cost the provider at  
7 least \$1,000 to get a letter from a lawyer, much less to look at anything. They're not going to appeal and  
8 they're just going to lose. And then in your data, well only 4 percent get turned over on appeal. It's because  
9 people aren't appealing because it's too expensive. And that whole subset of data of what are the values of  
10 these judgments, what are the values that are being appealed, what is the cost of the appeals process and is  
11 there a threshold at which, a dollar threshold, not an individual provider level, but a dollar threshold at  
12 which providers have really made the judgment that it's not worth appealing, and those are essentially, they  
13 just won't appeal because it's too expensive. That's what we've sort of been after the last couple times you  
14 were here.

15 Ms. Combs-Dyer: I may have to take your number and give you a call afterwards to make sure  
16 that I'm understanding exactly how you want the data arrayed. I don't believe that we included that data in  
17 our three-year evaluation report from the demonstration program. But we may have enough data that we  
18 could go back and do that. And I'd certainly be happy to take that back to the office and see if that's  
19 something that we could do. Were you also asking about the cost to the provider of filing an appeal? That's  
20 information that we don't have. We didn't gather any information from providers about that, so that piece  
21 of it I couldn't—

22 Dr. Standaert: Wouldn't that be useful data to have?

23 Ms. Combs-Dyer: We can certainly ask if that's something that could be included on our provider  
24 survey. We will be doing a provider survey asking about how fair they felt like they were treated during the  
25 Recovery Audit Contractor process and that perhaps is something that we could gather in that way.

26 Dr. Standaert: Okay, thank you.

27 Dr. Bufalino: Could I follow up on Chris's question? One of the things we were talking about, we  
28 weren't sure of how it's treated. So if we're reviewing medical record X and we find a problem, and that

1 that problem is audited and found to be improperly paid, will the RAC auditor go back and say now,  
2 Bufalino you've had 100 of those in the last year, so we'll take this problem, multiply it times 100 and say  
3 that's your claim. Is that—

4 Ms. Combs-Dyer: Yes. That is the extrapolation process, and yes they are allowed to do that, but  
5 they have to make sure that they are working with a statistically valid random sample that's required by all  
6 of our manuals. And so in order to be able to look back a year for all of your E&M services, if that's what it  
7 is, they would have to figure out what that number is that statistically valid random sample and in staying  
8 within the limits of 10 records per 45 days or 50 records per 45 days, review enough claims until they had  
9 reviewed a statistically valid random sample and then do their extrapolation.

10 Dr. Standaert: So even if they find a problem, they can't just say we need enough records to  
11 actually hit our statistical target. They can only do this sort of 10 for every 45 days. So if you have 1000 of  
12 these procedures, they're going to need 150 or 200 records, which is going to take them three years to get  
13 to hit a statistical sample of that 1000 procedures.

14 Ms. Combs-Dyer: That is correct.

15 Dr. Standaert: Okay.

16 Dr. Giaimo: Are there different levels of review process? Will there be one for a smaller claim,  
17 versus a hospital? Because as individual practitioners, your resources are much less than a large hospital  
18 facility. Is there just one review process, or are there a number of different types of review processes?

19 Ms. Combs-Dyer: The review—

20 Dr. Giaimo: For claims, for claims to go and have that I guess, contest the review.

21 Ms. Combs-Dyer: Are you talking about the appeal process?

22 Dr. Giaimo: The appeal process, yes.

23 Ms. Combs-Dyer: The appeal process under the Recovery Audit Contractor program is identical to  
24 the appeal process in the regular Medicare world, so the same process that you use to appeal carrier denials,  
25 that would be the same process that would be in place to appeal a RAC denial.

26 Dr. Giaimo: Is that process readily available to us? That process, as far as, how difficult is that, to  
27 go through the appeal process?

**PPAC Meeting Transcription – December 2008**

1 Ms. Combs-Dyer: It's my understanding that it's a relatively simple process. But you could  
2 certainly invite someone to come and give you a presentation on the Medicare appeals process.

3 Dr. Arradondo: Would you refer to your slide number five, top of page 3, to follow up with Dr.  
4 Standaert's question.

5 Ms. Combs-Dyer: This is the background demonstration findings?

6 Dr. Arradondo: Yes. You said that as of June 30, the 6.8 were overturned, and you referenced that  
7 the previous data you gave to us actually you gave it to us on two different meetings, was 4. something.  
8 The previous two times you gave us the total data, as well as the 4. percent. This time you just gave us the  
9 6.8 percent. So the relevant question is what percent of the total determinations were appealed? That's the  
10 missing data that you had given before.

11 Ms. Combs-Dyer: I did not bring that information with me today because I had previously shared  
12 that with you. I was not focusing my presentation today on appeals. But the next time you guys have a  
13 meeting, I believe we will actually have a new updated numbers. And I would be happy to bring back all  
14 the appeals data at that time and give you a full rundown on the appeals statistics.

15 Dr. Arradondo: The only reason I asked is because the previous one, a third of the appeals were  
16 overturned, and it worked out to be 12, 14, 13 percent were appealed and 4 percent were overturned. Your  
17 headline was the 4 percent. We had the headline discussion. And we won't go through that today, but this  
18 time, the question then is, if it's still just 14 percent appealed, 6.8 percent is darn near 50 percent of 14  
19 percent, so that's an important piece of information. On the other hand, if it's still just a third, a shouldn't  
20 say just, but to take your side of the headline, making it less or more, if it's just a third of the appeals are  
21 being overturned, then the data that's missing here would be say 21 percent, 20, 21 percent of the total  
22 determinations were appealed of which 6.8 is still about a third. That's the missing piece that Dr. Standaert  
23 was raising among his other questions. And it would be interesting to know whether that changed. In other  
24 words, we need both the numerator and the denominator information.

25 Ms. Combs-Dyer: And I'd be happy to bring all that with me the next time I come.

26 Dr. Snow: And to follow up on that, I think it was important. I think it was asked last time. The  
27 data we're interested in is the physician data. How many physician appeals are there and what's the  
28 percentage of overturned there.

**PPAC Meeting Transcription – December 2008**

1 Ms. Combs-Dyer: I'm certain that we don't have our numbers broken out that way today. We may  
2 be able to get a break out of part A and part B, but I don't think we have a break out of physician only. I  
3 will see if we can come up with that statistic.

4 Lt. Lew: Going forward, we have revised the RAC data warehouse, which is our central  
5 clearinghouse for RAC related information and we will hopefully be able to break out in the future in great  
6 detail the percentages of claims from X type provider versus Y type provider and Z type provider. So we  
7 should be able to have greater appeals detail, and greater detail in general in the future.

8 Dr. Bufalino: Why don't we wrap things up. Thank you for being here. And we'll take a 10 minute  
9 break and come back. [chat]

10 Break

11 Dr. Bufalino: Ms. Thew would you mind indulging us for a moment and just we just cover a  
12 number of the members are going to get on airplanes and so before we lose everybody, we'd like to just get  
13 an opportunity to hear some recommendations put on the table from the last two sessions. So would you  
14 like to jump in Greg? You want to do yours before you leave?

15 Dr. Przyblski: These aren't exactly related to the last two sessions, but are leftovers from our  
16 introductory conversation. One was one that Pamela asked me to give regard HACS and then another one.  
17 Ready? PPAC recommends that no further HACS be added until evaluation of current HACS shows that  
18 the program is achieving the goals that CMS has outlined and PPAC requests that this analysis be presented  
19 to PPAC in the June meeting.

20 [Second]

21 Dr. Bufalino: Do you have that Dana? Second, thank you. Any discussion? All in favor?

22 [Ayes]

23 Dr. Bufalino: Thank you.

24 Dr. Przyblski: The second, for myself, PPAC recommends that CMS revises the policy of  
25 nonpayment of HAC conditions to allow payment when the condition occurs despite the fact that providers  
26 for that particular condition followed the pertinent evidence-based medicine guidelines.

27 Dr. Bufalino: You have that Dana? Thank you. Second?

28 [Second]

**PPAC Meeting Transcription – December 2008**

1 Dr. Bufalino: Any discussion? All in favor?

2 [Ayes]

3 Dr. Bufalino: Thank you. Okay, anyone else? Janice? No. This side? Frederica, why don't you  
4 start?

5 Dr. Smith: I've got two. One short one and one longer one. One relating to PQRI. PPAC  
6 recommends that physicians should have real time access to whether they're reporting data correctly. In  
7 other words, can access the data during the calendar year during which the reporting is supposed to occur,  
8 thereby giving them the opportunity to adjust their reporting to meet the requirements.

9 Dr. Bufalino: Second?

10 [Seconds]

11 Dr. Bufalino: Discussion? All in favor?

12 [Ayes]

13 Dr. Bufalino: Thank you.

14 Dr. Smith: And the second one is concerning unfunded mandates and expanding on the  
15 discussions we've had about the ePrescribing a couple of times today. Let me just give a little background,  
16 because I'd like to have it in the minutes, and that is that there's been a lot of discussion about health  
17 information technology, having the potential to improve quality of care. I think most of accept that general  
18 concept, but its implementation is extremely expensive. The one thing we didn't mention today is the  
19 ICD10 issue, which is according to the Nachimson Advisors' report, that was released recently is estimated  
20 to cost \$83,290 for a three-man practice to convert to ICD10 up to \$2.7 million for a 100-man practice. I  
21 should probably say person, and not man. Electronic prescribing is estimating to cost \$8,000 per provider  
22 for the first year, and \$3 to \$4,000 per year there after to maintain it. EMR installation costs are in the \$30  
23 to \$50,000 per provider for the first year and \$4 to \$5,000 per provider year thereafter to maintain it. The  
24 Physicians Foundation Study, this summer, found that 49 percent of primary care physicians expect to limit  
25 or close their practices by 2011, and only 17 percent said their practices were financially healthy or  
26 profitable, which is a scary figure. So the recommendation is PPAC recommends that CMS delay  
27 implementation of any new IT requirements until an independent study can assess whether such  
28 requirements would have a catastrophic effect of putting physicians out of business and thereby

**PPAC Meeting Transcription – December 2008**

1     accentuating the already severe problem of patient access to care. And a second recommendation would be  
2     that—

3             Dr. Bufalino: Let her get just the—could you go back to just the end of the recommendation.

4             Dr. Smith: Okay. Recommendation: PPAC recommends that CMS delay implementation of any  
5     new IT requirements until an independent study can assess whether such requirements would have a  
6     catastrophic effect of putting physicians out of business and thereby accentuating the already severe  
7     problems of patient access to care.

8             Dr. Bufalino: Could I have a second for that?

9             [Second]

10            Dr. Bufalino: Discussion?

11            Dr. Przyblski: Just quick comment, new implies what? Meaning is ICD10 new or old?

12            Dr. Smith: ICD10 is new. That's not yet, they haven't promulgated regulations on it.

13            Dr. Przyblski: I just wanted to make sure that that was not something that someone could construe  
14     as well, we've talked about it, therefore that's old and doesn't count.

15            Dr. Smith: No, ICD10 is very much new and mandatory EMR IC is new. The concept of EMR is  
16     out there, but mandatory is another issue.

17            Dr. Bufalino: Okay. All in favor?

18            [Ayes]

19            Dr. Bufalino: Thank you. Part two?

20            Dr. Smith: Part two, I suppose could be substituted for part one, depending on people. But PPAC  
21     recommends that any IT changes required by CMS should be funded fully by CMS. The cost of  
22     implementing such changes should be fully funded. Not \$2,000 on \$8,000 for the whatever.

23            Dr. Bufalino: Second?

24            [Second]

25            Dr. Bufalino: Thank you. Any discussion? All in favor?

26            [Ayes]

27            Dr. Bufalino: Thank you. Moving along, I think Joe has one.

**PPAC Meeting Transcription – December 2008**

1 Dr. Giaimo: PPAC asks CMS to provide clarification of the appeals process for RAC reviews at  
2 our next meeting.

3 [Second]

4 Dr. Bufalino: Any discussion? All in favor?

5 [Ayes]

6 Dr. Bufalino: Thank you. Art?

7 Dr. Snow: PPAC commends CMS and strongly recommends they proceed expeditiously to  
8 develop the medically reasonable approach of valuing a decrease in the incidence of hospital-acquired  
9 conditions instead of the medically unreasonable approach of absolute elimination of hospital-acquired  
10 conditions.

11 [Seconds]

12 Dr. Bufalino: You have that, Dana? You think? [laughter] Any discussion? All in favor?

13 [Ayes]

14 Dr. Bufalino: Thank you. Leroy second one, I'm sorry, Art.

15 Dr. Snow: PPAC recommends that CMS require the RACs to reimburse all providers for the costs  
16 of filling the medical record requests.

17 [Seconds]

18 Dr. Bufalino: Any discussion? All in favor?

19 [Ayes]

20 Dr. Bufalino: Thank you.

21 Dr. Smith: Can I raise another one related to that?

22 Dr. Bufalino: Okay, go ahead.

23 Dr. Smith: PPAC recommends that the number of records requests be linear relative to the number  
24 of physicians in a practice, and not skewed toward small groups and solo practitioners bearing a heavier  
25 burden.

26 [Second]

27 Dr. Bufalino: Any discussion?



**PPAC Meeting Transcription – December 2008**

1 Dr. Snow: I would suggest that we try to specify that a little more. That was the third one I was  
2 going to make. Let me just throw this out there and we'll see which one of these two we want to go with.  
3 PPAC recommends that CMS limit the RAC record request for solo practitioners to three records each 45  
4 days per NPI, because that's the way they listed it in the slide, in order to be equivalent to the number  
5 requested for larger groups.

6 Dr. Smith: I'll accept that as an alternate.

7 [Second]

8 Dr. Bufalino: Okay. Any other discussion? All in favor?

9 [Ayes]

10 Dr. Bufalino: Thank you. Leroy?

11 Dr. Sprang: Related to PQRI. PPAC commends CMS for the progress they're making with PQRI  
12 and recommends that CMS continue to work towards greater transparency in all aspects of developing the  
13 PQRI Program, especially data used for the measure selection and the implementation processes.

14 Dr. Bufalino: Okay Dana? Second?

15 [Second]

16 Dr. Bufalino: Any discussion? All in favor?

17 [Ayes]

18 Dr. Bufalino: Thank you. Chris.

19 Dr. Standaert: I have a few. One of this, I'll try to clarify this, I brought up before. We're going to  
20 RURs. PPAC recommends that CMS strongly consider the ultimate use of RURs in the medical  
21 marketplace when designing provider measures and reports and report their plans to PPAC.

22 [Seconds]

23 Dr. Bufalino: Thank you.

24 Ms. Trevas: Could you repeat that?

25 Dr. Standaert: PPAC recommends that CMS strongly consider the ultimate use of RURs in the  
26 medical marketplace when designing provider measures and reports and that they report their plans to  
27 PPAC.

28 Dr. Bufalino: Any discussion? All in favor.

**PPAC Meeting Transcription – December 2008**

1 [Ayes]

2 Dr. Bufalino: Thank you.

3 Dr. Standaert: Two others on the things we were just talking about, the RACs. PPAC  
4 recommends that CMS make efforts to obtain data on the cost of the RAC appeals process for providers  
5 and institutions.

6 [Second]

7 [off-mike discussion]

8 Dr. Giaimo: Mind was just about reviewing the appeals process, but not specifically related—

9 Dr. Standaert: Mine was find out how much it costs to appeal.

10 Dr. Bufalino: Second?

11 [Seconds]

12 Dr. Bufalino: Discussion? All in favor?

13 [Ayes]

14 Dr. Bufalino: Thank you.

15 Dr. Standaert: I have one more.

16 Ms. Trevas: Can I get clarification?

17 Dr. Standaert: Sure.

18 Ms. Trevas: I'm sorry, was that for individual providers, or for all providers?

19 Dr. Standaert: The process to providers and institutions.

20 Ms. Trevas: Okay.

21 Dr. Standaert: And then last one, where do I start here? PPAC recommends that CMS provide data  
22 on the amounts of decisions appealed in the RAC demonstration process, particularly as related to the  
23 amounts of decisions on improper payments in general.

24 Dr. Bufalino: Second?

25 [Second]

26 Dr. Bufalino: Any discussion? All in favor?

27 [Ayes]

1 Dr. Bufalino: Thank you. Anyone else? Good. Thank you for your patients Ms. Thew. We  
2 welcome you to PPAC. Ms. Thew is the Director of the Division of Benefit Integrity. She's been with CMS  
3 since 1996. In her previous life was a lawyer and focused on state regulatory complaints, particularly in  
4 skilled nursing facilities. Glad to have you. Please.

5 Medically Unlikely Edits Update

6 Ms. Thew: Thank you. It's been several months since I've talked to you about MUEs. And I think  
7 I'm going to give you some basics and then give you some new information, things we're doing right now.  
8 As you know, Medically Unlikely Edits is a national CMS program, and it is designed to reduce the paid  
9 claims error rate. It's been in place since January 1, 2007. MUEs are applied at the list of contractors you  
10 see on this slide. MUEs adjudicate on the single claim line and we have quarterly updates to the files that  
11 we have. MUEs are based on single units, well, an MUE is based on a unit of service. And I like to read the  
12 definition because it has many parts. An MUE for a HCPCS CPT code is the maximum units of service that  
13 a provider would report under most circumstances for a single beneficiary on a single date of service. So  
14 the MUE checks for the same patient, same date of service, same provider and same HCPCS CPT code.  
15 You've seen the criteria before that we use to develop MUEs. They start out, the easy criteria of an  
16 anatomic consideration, a cataract surgery could only be two for two eyes, but we also look at code  
17 descriptors, manual instruction, CMS policies, and then nature of equipment and procedure service. Things  
18 like a power wheelchair. You're probably only going to need one power wheelchair. Let's hope that's true.  
19 A 24-hour urinalysis would be an MUE of one because it could only be billed once in a 24-hour period.  
20 And then we use clinical judgment where that's important when there isn't something more definitive to  
21 guide us and the clinical judgment that we rely on comes from CMS physicians and coding specialists.

22 I want to talk to you about the players in the development process for MUEs. We start with our  
23 contractor, Correct Coding Solutions, CCS, and CCS is charged with reviewing all the HCPCS CPT codes,  
24 assigning provisional MUEs, interacting with other players in this process, the national health  
25 organizations, reviewing their comments, analyzing data, responding to comments, and most importantly,  
26 working with CMS to come up with our final MUE value. The next slide, you see that we also include  
27 workgroups comprised of contractor medical directors from FIs, carriers, DME MACs, and we have a  
28 special group of contractor medical directors who are pathologists who help us with pathology MUEs.

## PPAC Meeting Transcription – December 2008

1 CMS physicians and coding specialists, however, have the final decision on MUE values and they are  
2 involved in reviewing comments that we get and requests for reconsideration for the MUE values that we  
3 set. And as you know, our process also involves national healthcare organizations who have been gracious  
4 enough to lend their support and expertise to this process. We work with the AMA, which helps us work  
5 with national, medical, and surgical societies, national professional societies, we work with the American  
6 Hospital Association and the Federation of American Hospitals. We also work with laboratory and DME  
7 organizations. We send out proposed MUEs and we allow a 60-day period to give us feedback on the  
8 proposed MUE. We closely consider the comments we receive and take them into account when the final  
9 MUE is set.

10 I want to be clear that we don't set an MUE and just walk away. We have a refinement process  
11 that I think we had just started when I last spoke with you. We look at 100 percent of the submitted claims  
12 in a 6-month period, to see how our MUE stacks up against the level of units of service that have been  
13 submitted on claims. As a result of the review, we might increase an MUE. We might decrease, for largely  
14 it's going to remain the same. We have looked at data from 2006, 2007 and we're almost finished  
15 reviewing 2008 data. At a carrier or DME MAC, if a claim [line?] exceeds the MUE, the claim line is  
16 denied and the provider can appeal. At an FI, the claim is returned to the provider. Appeals and claim  
17 adjudication issues are addressed by our local Medicare claims processing contractors.

18 On the next slide, this is elementary, things to consider when a claim is submitted and it certainly  
19 works to help be sure the claims fit in with our MUEs is the CPT code being used correctly, the units of  
20 service counted correctly, are the services all medically reasonable and necessary, and then if guidance, we  
21 suggest that providers work with the national healthcare organization that focuses on the type of service, or  
22 procedure, or specialty that's at issue. We do reconsider MUE values that we've set. If there is an  
23 alternative recommendation, if it's submitted with rationale and supporting documentation to our  
24 contractor, who's address is shown here, we will consider it. The request is reviewed by our CMS work  
25 group. We encourage providers of course, to first discuss their issue with the appropriate national  
26 healthcare organization, and I also want to be clear that reconsideration is different from an appeal.  
27 Reconsideration would be asking us to change an MUE value that's already been set.

1           Modifiers may be applied and will affect the way an MUE operates. I want to be clear, though that  
2 modifiers do not bypass MUEs. Modifiers allow a provider to report medically reasonable and necessary  
3 units of service in excess of an MUE value, and you see here a list of modifiers that could apply. We  
4 always remind providers to make certain that services are medically reasonable and necessary and that  
5 when reporting the same code on separate claim lines to select the appropriate modifier to append to the  
6 additional claim line. I could give you an example, but that gets dangerous because I'm not the clinician  
7 here in the room. But the example I understand would make sense to you is that if there's a skin biopsy  
8 done on two sites on one arm, you would report the procedure on two lines of the claim, using a modifier  
9 on the second line, to show that it's a distinct procedure.

10           The news that I hope I'm bringing to you today, but I hope you're already aware of is that we have  
11 published the majority of MUEs effective October 1 of this year. The slide gives the website, where you  
12 can access the MUE tables. And as you can see, we've published over 8100 codes that are relevant to  
13 practitioners and DME suppliers and over 5800 codes related to hospital outpatient services.

14           You can also learn more about MUEs and how everything works at the CMS website. It has a nice  
15 list of frequently asked questions. Or through Medlearn. [discussion of slide order] We will be publishing  
16 additional MUEs in subsequent versions. We have not published all of them now because of concerns of  
17 fraud and abuse. We have not published any MUE values of 4 or higher. We've held back some MUEs of  
18 values between one and three. Those MUE values that we keep confidential are not going to be released by  
19 national healthcare organizations or CMS contractors, but this is simply a handful of the lower level one to  
20 three MUEs that we're holding back at this point. When you do the math, we have developed over 17,000  
21 MUEs and the last bullet on this slide, I'm told is not really relevant to physicians, but in case any of you  
22 wondered about a delay in implementation similar to the Correct Coding Initiative, there is no delay.

23           We do expect the MUE program as I said, to reduce the paid claims error rate through correct  
24 coding, and result in the payment of medically reasonable and necessary services. If providers are billing  
25 correctly and are using modifiers appropriately, in the majority of cases, their services should not be  
26 exceeding the MUE and should be processed appropriately through the claims processing system. Slide 18  
27 gives you the information that I talked about earlier and then slide 19 gives you a real person who you can  
28 contact if you have any concerns.

1 Dr. Bufalino: Thank you. Questions?

2 Dr. Standaert: What is an MUE of one to three versus a four? What does that mean? I have no  
3 idea.

4 Ms. Thew: Oh, if the MUE is set at, well, two because you might do cataract surgery on two eyes,  
5 that would be one that's released because it's a value between one and three. So we released most of the—

6 Dr. Standaert: Two, meaning it can be done twice? I guess I'm trying to figure out where the  
7 number comes from.

8 Ms. Thew: On one day, one provider one patient, you couldn't, I assume you couldn't take  
9 cataracts out of more than two eyes.

10 Dr. Standaert: Out of three eyes, yes that would be sort of hard, yes. [laughter] Okay, I got that  
11 part. So the number of how many of these procedures can be done in that, this says values of one to three  
12 are not published. Some aren't and things above four. So things you can't do more than four more time are  
13 not published?

14 Ms. Thew: Where we have a set an MUE of four or higher—we have not released those MUEs.

15 Dr. Standaert: So you can do it up to three times, but once you hit four, then it's an MUE,  
16 essentially? That's what you're saying?

17 Ms. Thew: No. The MUE could be one, the MUE could be two, it could be three, it could four, it  
18 could be on up--

19 Dr. Sprang: The severity of how bad...

20 Ms. Thew: But the only ones we've published are the ones an MUE value of, codes that have an  
21 MUE value of one, two, or three.

22 Dr. Standaert: So it's a degree of severity? It's not how many times you do it. I'm trying to  
23 understand what the numbers relate to.

24 Ms. Thew: The number is the MUE value, it's the edit. It would be one for a power wheelchair.  
25 Because on one day, you should not get more than one. Exactly.

26 Dr. Standaert: And two for cataracts, and three for something you can something three times  
27 maximum, and four is something you can do logically four times, maximum in one day. Is that what I'm—

28 Ms. Thew: Yes, yes.

**PPAC Meeting Transcription – December 2008**

1 Dr. Standaert: Okay, gotcha.

2 Dr. Bufalino: Other questions. Hearing none, thank you for joining us. Moving right along, we  
3 will bring us to our last presentation, which is Dr. William Dolan has joined us from the AMA and is here  
4 to present the AMA testimony. Welcome, Dr. Dolan.

5 Public Testimony: American Medical Association

6 Dr. Dolan: Thank you, Mr. Chairman. I also want to say for the rest of the Council, I am a  
7 practicing orthopedic surgeon from Rochester, New York. Thank you for having us. And I'm sorry I don't  
8 have a PowerPoint to show you, so you'll have to listen to me. [laughter] As you know, significant changes  
9 are happening in Medicare on several fronts. These changes raise critical issues for physicians, especially in  
10 the current economically stressed environment. We urge CMS to aggressively work with us, the physician  
11 community to resolve these issues that I will address today. Resolve these issues before moving on to many  
12 other issues as suggested by Mr. Kuhn today.

13 Physicians face a whole new landscape on quality reporting, such as the PQRI that you have been  
14 talking about. Physicians want to provide, as you know, quality care the highest quality care to their  
15 patients and the AMA wants to help the physicians advance that goal. The CMS is about to launch the third  
16 year of PQRI and in the near future, CMS will make public whether physicians successfully participating in  
17 PQRI. The book you received today does not have the names as we suspect will be made public. Yet, there  
18 are significant problems still with 2007 PQRI that have yet to be resolved and these problems are  
19 preventing successful participation in the program. We would be anxious to review the report that Dr. Rapp  
20 did give us. The AMA's worked steadfastly with the CMS to identify these problems, and we are extremely  
21 disappointed that the CMS failed to address these concerns in the Physician Fee Schedule Final Rule. Now  
22 as you know, approximately 16 percent of physicians attempted to report on measures in 2007 PQRI, but  
23 only half, only half of them received bonus payments. There is still widespread confusion and no clear  
24 direction from CMS why so many physicians were unsuccessful in reporting. Without a clear  
25 understanding, it is nearly impossible to improve the success rates. Dr. Smith's comments could be  
26 multiplied by thousands. In our comments on the proposed Fee Schedule Rule, we requested CMS  
27 implement additional educational and outreach on PQRI to help increase successful participation. Yet,  
28 CMS did not seriously consider this request in the Final Rule. We feel CMS must make changes now to

1 assist physicians in successful PQRI participation. The AMA sent a letter to CMS just recently and you  
2 have that in your written statement, with urgent PQRI recommendations. We urge PPAC to recommend  
3 that CMS immediately act on these recommendations. PQRI problems aside, physicians also face dramatic  
4 changes in Medicare's physician enrollment arena. CMS announced sweeping changes to the already  
5 backlogged enrollment system in the Medicare Physician Fee Schedule Final Rule. These changes that are  
6 scheduled to go into effect in 2009. While CMS has assured the AMA that they will phase these in slowly,  
7 we are deeply concerned, given the current problems that the system can handle further changes at this  
8 time. One of the most troubling changes is the CMS's plan to repeal the ability of physicians to  
9 retroactively bill. Instead, physicians essentially will be able to bill only from the date they filed an  
10 enrollment application that is subsequently approved by the contractor. CMS in effect has materially gutted  
11 an ability by the physicians to retroactively bill. This will cause extreme financial pressure for physicians  
12 who are treating patients while contractors unnecessarily require the physician to refile and refile new  
13 enrollment applications, thereby establishing a delayed application filing date. Medicare enrollment  
14 changes are not ready for prime time. The process is already strained beyond capacity and processing  
15 delays are contributing to serious physician cash flow problems. Thus, we urge PPAC to recommend that  
16 CMS do three things: Withdraw the Medicare enrollment changes in the Physician Fee Schedule Final  
17 Rule; relax criteria for advance payments to physicians nationwide and ensure that all physicians and  
18 especially all contractors are aware of this option; finally, monitor physician satisfaction with the  
19 enrollment process and take appropriate actions to resolve them. If you talk to my business manager, help  
20 her with her gray hair.

21 Finally, let me turn to another critical issue that was brought up a little earlier. Medicare  
22 nonpayment for certain healthcare associated conditions, or HACs, as designated by CMS. As you heard  
23 earlier, Medicare already bars payment for HACs not present on admission in the hospital inpatient setting.  
24 CMS may extend this policy to other settings, including physicians' offices. Now the AMA has major  
25 problems with this policy, as well as extending it to physicians' offices. For example, CMS does not have  
26 the statutory authority to extend the HAC policy to physicians' offices. In addition, the medical conditions  
27 covered by the HAC policy should be reasonably preventable through the application of evidence-based  
28 guidelines, yet many, many of us disagree with CMS that the conditions covered under the inpatient HAC



**PPAC Meeting Transcription – December 2008**

1 nonpayment policy are reasonably preventable. In other words, we don't think that some of these things  
2 that they have on their schedule are preventable. Also, expanding the HAC policy to physicians' offices  
3 should be extremely problematic, because the payment approach is much different from physicians' offices  
4 to the inpatient hospital setting. CMS should, instead, encourage compliance with evidence-based  
5 guidelines, rather than to extend the HAC policy. Therefore I would recommend that PPAC urge CMS to  
6 act on these and other concerns with the HAC policy that we have enumerated in our written statement. I  
7 thank you for the opportunity to address you here today. And if you have any questions, I'd be happy to  
8 answer them.

9 Dr. Bufalino: Thank you, Dr. Dolan. Questions for Dr. Dolan. Thank you for being here. Thank  
10 you for your recommendations. Any other recommendations after the testimony?

11 Dr. Ross: With the testimony that Dr. Dolan gave, I'd like to just reiterate that while waiting for  
12 the NPI enrollment process to be completed, physicians in the past have been able to retroactively bill  
13 Medicare. But with the new changes to Medicare enrollment, retroactive billing will be removed. This has  
14 created as you heard earlier, a great financial hardship to those Medicare providers. Therefore, PPAC will  
15 recommend that CMS withdraw those changes to the Medicare enrollment process as proposed by CMS in  
16 the Physician Fee Schedule Final Rule, until related physician payment and persistent delays are resolved  
17 nationwide.

18 [Second]

19 Dr. Bufalino: Second, so what would you like him to reread, Dana? The end?

20 Ms. Trevas: I'm assuming only the end is going to be—

21 Dr. Bufalino: The end is the recommendation?

22 Dr. Ross: Right, the preface was the background. The PPAC recommendation was the last part.

23 Dr. Bufalino: Motioned and seconded. Any discussion? All in favor?

24 [Ayes]

25 Dr. Bufalino: Thank you. Others? None. Thank you. So we have a couple three tasks left here.  
26 One is, I think it'll be important for us to be able to review the list of recommendations to date for the day  
27 and so we have a choice of 15 minutes, good. 15 minutes. Thank you. Two we have a survey here that is in  
28 your packets. If you haven't seen it take a look at it, fill it out. It's a PPAC feedback loop. Then, as we're

**PPAC Meeting Transcription – December 2008**

1 wrapping things up, I just ask Dr. Rich if he had another other closing comments for the afternoon or any  
2 message for the Council as they leave?

3 Dr. Rich: I think it was a good meeting. There a lot of very high policy level discussions going on  
4 here. It wasn't too granular and that's good, because I think there's a lot of big policy that's going to be  
5 carried on into the next administration, as Herb was saying, and I just echo his comments that there seems,  
6 the transition team's great, the people are great, and they are carrying the same message forward that we've  
7 been carrying, for the last year at least or more.

8 Dr. Bufalino: Any other comments from the Council?

9 Dr. Sprang: So what are you off to next?

10 [Dr. Rich?]: I'm going back to your world. Back to private practice.

11 Dr. Ross: I want to thank you publicly for being a part of us. I wish you luck in your continuing  
12 endeavors. [applause]

13 Dr. Rich: A straight up learning curve, so, I finally leveled off a little.

14 Dr. Bufalino: I guess Dana the question I have for you is are you planning on printing them or  
15 reading them?

16 Ms. Trevas: I think I [inaudible] if you prefer that.

17 Dr. Bufalino: Yes, why don't you just read them. I think that's going to be good enough. Unless  
18 the Council wants to see them in writing.

19 Dr. Snow: Well, and then we could have them emailed to us in the next couple days.

20 Ms. Trevas: Oh yes absolutely. That remains the same.

21 Dr. Bufalino: But I mean this is our best chance to kind of modify what's here because I think—

22 Dr. Simon: The revisions have to be made now, in the public meeting.

23 Dr. Bufalino: ... what the lawyers think on each of the levels—

24 Ms. Trevas: Given that they will be in the order in which they were received, not necessarily  
25 grouped.

26 Dr. Bufalino: Any order you got will be fine for us.

## PPAC Meeting Transcription – December 2008

### Wrap up and Recommendations

Ms. Trevas: Ready? Okay. PPAC recommends that CMS provide PPAC with regular updates on planning for the Physician Resource Use Measurement and Reporting Program; wait, that is the not the first one, I'm sorry. [off mike discussion] PPAC recommends that CMS expand its review of the Practice Expense GPCIs beyond taking testimony on geographic localities.

Dr. Bufalino: I think you could keep going and we'll stop you if—

Ms. Trevas: Okay. PPAC recommends that CMS reevaluate its formula for Practice Expense GPCIs to use actual practice expense data to make determinations, reporting back to the Council on its findings at the Council's second meeting in 2009; going back to the one I just read, PPAC recommends that CMS provide PPAC with regular updates on planning for the Physician resource use measurement and reporting program; PPAC recommends that CMS report on its use of downstream diagnoses that are not captured among the first four diagnoses in the claims data base; PPAC recommends that no further HACs be added until evaluation of current HACs shows that the program is achieving the goals outlined by CMS, and PPAC's request that that analysis be presented to the Council at the June '09 meeting; PPAC recommends that CMS revise its policy of nonpayment for HACs to allow payment when the condition occurs despite the fact that the provider responsible for that condition followed pertinent, evidence-based guidelines; PPAC recommends that physicians should have real time access to the data reported through PQRI, specifically whether the data has been reported correctly, so that they have the opportunity to adjust their reporting to meet the requirements; this is where it's kind of harder—okay. PPAC recommends that CMS delay implementation of any new IT requirements until an independent study can assess whether doing so would have a catastrophic effect of putting physicians out of business and accentuate an already severe problem of patient access to care; PPAC recommends that the cost of implementing any IT changes required by CMS be funded fully by CMS; PPAC recommends that CMS provide clarification of the appeals process for RAC reviews; PPAC commends CMS and strongly recommends that CMS proceed expeditiously to develop medically reasonable approaches of valuing decreases in HACs instead of the unreasonable approach of eliminating HACs. Is that right? Okay, is that correct? Okay. PPAC recommends that CMS require RACs to reimburse all providers for the costs of fulfilling medical records requirements;

**PPAC Meeting Transcription – December 2008**

1 [off-mike comment] Requests, excuse me. PPAC recommends that CMS limit RACs records requests for  
2 solo practices to three records per 45 days per NPI;

3 Dr. Snow: For solo practitioners.

4 Ms. Trevas: Okay. PPAC commends CMS for its progress on PQRI and recommends that CMS  
5 continue to work toward greater transparency in all aspects of developing the PQRI program, especially  
6 data used for measure selection and the implementation process. PPAC recommends that CMS strongly  
7 consider the ultimate use of RUR in the medical marketplace when designing provider measures and  
8 reports, and that they report their plans to PPAC. PPAC recommends that CMS make an effort to obtain  
9 data on the cost of the RAC appeals process to providers and institutions. PPAC recommends that CMS  
10 provide data on the amount of decisions appealed—do you mean determinations? Because that’s what they  
11 call them. Determinations is the amount—okay, okay. PPAC recommends that CMS provide data on the  
12 amount of determinations appealed in the RAC demonstration process, particularly as related to the amount  
13 of determinations of improper payments in general.

14 Dr. Standaert: That’s the word I was looking for. Thank you.

15 Ms. Trevas: Okay, thank you.

16 Dr. Simon: One questions—what is an RUR, spell it out.

17 Dr. Standaert: RUR?

18 Ms. Trevas: Resource Use Report?

19 [chat/laughter]

20 Dr. Standaert: Resource Utilization Report—is that what? You can use the acronym, or spell it  
21 out?

22 [chat over acronym off mike]

23 Ms. Trevas: And this is the final one, PPAC recommends that CMS withdraw changes to the  
24 Medicare enrollment process as proposed by CMS in the Physician Fee Schedule Final Rule until related  
25 physician payment delays are resolved nationwide. And that’s the end.

26 Dr. Bufalino: Thank you. Any comments? Additions, subtractions?

27 Dr. Sprang: Good meeting.

## PPAC Meeting Transcription – December 2008

1 Dr. Bufalino: Thank you. Dana and John, thank you for your help. We appreciate having you.  
2 Thank you to Ken Simon and the entire staff for organizing, structuring, and getting us in and out of town,  
3 so thank you for all that. Thank the guests for being here and Merry Christmas, Happy New Year. Have a  
4 good holidays. [chat]

5 Meeting Adjourned.