

CENTERS FOR MEDICARE AND MEDICAID SERVICES

PRACTICING PHYSICIANS ADVISORY COUNCIL

Hubert H. Humphrey Building
Room 505A
Washington, DC

Monday, December 5, 2005
8:30 a.m.

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1 Open Meeting

2 Dr. Castellanos: Good morning. I'd like to see if we could get started today on time. We're going
3 to try to keep the agenda on time. All of you recognize that there's a storm that may be coming in to the
4 area, and a lot of us have planes to catch, so let's try to be as prudent as we can. For the Council, we're
5 going to try to keep on schedule. Any recommendations that you have, I'd like to make them as we go
6 rather than at the end, and Dana, if you have any slowing or speeding up, let me know. And I certainly
7 recognize, I'm sorry to use the word "potty" breaks, we'll do them for sure. [laughter] Again, good
8 morning. I'm Dr. Ronald Castellanos. I'm Chairman of the Practicing Physicians Advisory Council. And
9 it's my pleasure to welcome you on the occasion of the 54th meeting of the Council. I'd like to extend a
10 cordial welcome to my colleagues and fellow council members. As always, I appreciate your willingness to
11 travel here to Washington, D.C. to participate in this very important meeting, especially during this very
12 busy holiday season. Your considered input and guidance on the various issues that will be presented here
13 today, significantly influences the outcome of regulations and instructions, which directly affect the
14 physician community. As you look at today's agenda, you'll see the issues that will be presented to us for
15 consideration. These topics include the Physician Voluntary Reporting Program, the Competitive
16 Acquisition Program, the Physician Fee Schedule and Outpatient Fee Schedule Final Rules, a follow-up
17 presentation on Recovery Audit, and of course, we'll receive our quarterly PRIT Update, as well as the
18 report of our recommendations from the August 22nd, 2005 PPAC Meeting. I'm confident you will give our
19 presenters the full benefit of your practical knowledge and insight. I'm anxious to get started with the
20 agenda we have before us today and look forward to a very productive session, and a discussion on the
21 issues relative to the various Medicare Program areas. These are really exciting and challenging times in
22 addressing issues in our health care delivery system. And we are privileged to have the opportunity to be
23 actively engaged in shaping this best system. At this time, it's my pleasure to ask Mr. Herb Kuhn, Director
24 of the Center for Medicare Management, Centers for Medicare and Medicaid Services, to welcome you and
25 to say a few words to kick off our session.

26 Welcome

27 Mr. Kuhn: Dr. Castellanos, thank you very much for those introductory remarks, and again I want
28 to welcome all of you and thank you all for your continued service to this committee and appreciate

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1 everyone being here. This is our last meeting of the year, and for some of you, it's the second to last
2 meeting. As many of you know, our meeting, first meeting of the spring will be the last meeting for several
3 of you. We'll have some new members for PPAC then into next year. So for all of you then, thank you for
4 your service. As always, we have a pretty full agenda today. I think it's loaded not only with current topics,
5 things that are happening now, but also, as always, looking at topics, things that will happen, play out over
6 the next several years, so you can give us the early guidance and early indications of things that we ought to
7 be looking at as agency. So thank you for looking at those agendas and helping us make those kind of
8 agendas that best serve us and best serve you as we go forward. Just to wrap things up, I'll also echo what
9 Dr. Castellanos said. We're very aware that there is potential storm. We know that many of you are
10 extremely busy in your schedule. You've already given up one day here. I would shudder to think that if
11 you would miss a flight, you would lose a full day of work tomorrow, knowing that it's the holiday season
12 and all that you've got going to lose 2 days in the month of December would not be good. So we'll do all
13 we can to stay on schedule, and as a matter of a fact, staff—we got together last night—and we made some
14 revisions in the schedule to even shorten the schedule today so we could try to get you out even earlier. I
15 think that's reflected. But if we can move as aggressively as possible, today, hopefully we can even shorten
16 that a little bit more for everybody's convenience. So we'll endeavor to do that. If we hear reports of things
17 changing weather wise, we'll let all of you know. Obviously, there's not a window to look out to see what's
18 happening outside, but as staff and others get reports, we'll share those with you and keep you updated
19 accordingly. So with that, I'll turn it back to Dr. Castellanos. And again thank you for being here.

20 Dr. Castellanos: Mr. Kuhn, thank you again for these welcoming remarks. And myself personally,
21 and the rest of the council members want to thank you and Dr. Tom Gustafson for your commitment to be
22 here at this meeting. We really appreciate the time and effort and the interest that you show. It's really
23 appreciated by the council members and I wanted to make sure you both appreciate that. PPAC Update, Dr.
24 Ken Simon, Executive Director, Practicing Physicians Advisory Council, Center for Medicare Management
25 will provide us with an update on the August 22, 2005 recommendations of the Council, and the responses
26 prepared by the Center for Medicare and Medicaid Services. Some of you know Dr. Simon, working here
27 at CMS, but he wears lots of different hats, and some of you may or may not know that he's very actively
28 involved in his state, in Mississippi, with the Katrina Recovery problem and programs based in Mississippi.

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1 And some of you also may know that he's a general and vascular surgeon, and he still puts time in at the
2 University of Mississippi in their vascular surgery department to continue his skills. He keeps being
3 connected with the practicing physician community. And I welcome Dr. Simon and will look forward to
4 your comments.

5 PPAC Update

6 Dr. Simon: Thank you. Good morning, Dr. Castellanos. To review the recommendations from the
7 August 22nd meeting, the Agenda Item C, relating to the update of PPAC recommendations, 53C.1, the
8 Council recommended that CMS again review the Council's recommendation that physicians be allowed
9 30 days to submit verification of drug administration. The response is that CMS appreciates the Council's
10 recommendation regarding the potential for increased administrative burden under CAP, which is the
11 Competitive Acquisition Program. As we explained in detail, in the Physician Fee Schedule Final Rule, we
12 do not believe that there is a danger of a significant increase in burden, but we will monitor and evaluate
13 the situation as we gain more experience with the operation of the CAP Program.

14 Agenda Item 53C.2. The Council recommends that CMS share with PPAC at its next meeting, an
15 update on the Recovery Audit Contractors and their efficacy. The Council will receive an update later today
16 on the Recovery Audit Contractors Program so that there will be an opportunity to get updated as well as to
17 exchange dialog.

18 Agenda Item D under the Prescription Drug Program. 53D.1. The Council applauds CMS's efforts
19 to disseminate information about the Part D Prescription Drug Program to the public. CMS acknowledges
20 the comments submitted by the Council and will continue to educate and update both beneficiaries and
21 providers on the Part D Prescription Drug Program.

22 53D.2 The Council recommends that CMS work with the Office of the Inspector General to
23 provide definitive guidance on whether manufacturers' Patient Assistance Programs contribute to patients'
24 true out-of-pocket costs. CMS agrees and is currently working with the Office of Inspector General on this
25 very complex issue concerning the Patient Assistance Program. CMS expects to have guidance and will
26 have Q&As regarding the same prior to January 1, 2006.

27 Agenda Item F, under the Surgical Care Improvement Partnership Program. The Council
28 recommends that CMS recognize that data collection is expensive. If it becomes part of the cost of doing

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1 business, the expense must be adequately compensated by CMS and other carriers. CMS believes that
2 while it is reasonable for Medicare to provide additional payments for improved outcomes, it should not
3 pay more simply for the use of information technology. Although improvements in data collection may
4 appear expensive, looked at in isolation, we need to consider how data can be gathered in a way that both
5 minimizes burden on providers and that helps to improve their productivity, while at the same time
6 improving the outcomes of the care they deliver. We will have to examine any possible payments tied to
7 data collection with these considerations in mind. In the future, electronic health records hold substantial
8 promise to minimize any data collection burdens through automatic reporting of data for performance
9 measurement. Note that under current law, except possibly in a demonstration project, no additional funds
10 are available to pay for data collection.

11 Under the Competitive Acquisition Program. 53.G-1. The Council recommends that CMS not
12 allow CAP vendors to discontinue provision of drug covered under the CAP to a patient regardless of a
13 patient's ability to meet co-pays. CMS does not require any provider to waive co-insurance on a routine
14 basis. CMS published in both the CAP July 6, 2005 Interim Final Rule with comment, and in the Final Rule
15 which was published on November 21, 2005, the timing and the detailed steps that an approved CAP
16 vendor must follow before discontinuing the shipment of drugs to a participating CAP physician for a
17 beneficiary who does not meet its cost sharing obligations.

18 53-G-2. The Council recommends that CMS revise the CAP requirements so that physicians may
19 choose to participate on an individual basis, and are not obligated to join as a group. CMS response: In
20 order for a physician who is in a group practice to choose to participate in the CAP on an individual basis,
21 that physician must not have reassigned his or her benefits to the group. We stated in the CAP Final Rule,
22 that when a physician reassigns his or her benefits to the group practice, that that physician will be billing
23 Medicare using the group's PIN. Thus, the group will make the choice about whether to participate in the
24 CAP. We also stated that if a group practice physician maintains a separate solo practice, he or she could
25 make a separate determination of whether to participate in the CAP for the solo practice if using his or her
26 individual PIN for the solo practice. CMS will closely monitor physician status at the time of election to
27 reconcile physician participation as a group practice, and/or individual provider and ensure adherence to the
28 CAP agreement.

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1 53.G-3. The Council recommends that CMS remove CAP vendor prices in calculating the average
2 sales price, commonly called the ASP, because such inclusion is duplicative and unfair to physicians who
3 do not participate in CAP. CMS agrees and has accepted the Council's recommendation. We announced
4 this change in the Physician Fee Schedule Final Rule, published November 21, 2005.

5 53.G-4. The Council recommends that CMS work with Chairman Bill Thomas of the House Ways
6 & Means Committee, to clarify how Congress intended the average sales price and the competitive
7 acquisition program to function independently of each other. CMS recognizes the leadership role taken by
8 the House Ways & Means Committee Chairman, Bill Thomas in suggesting several refinements to the
9 CAP. We have accepted his and the Council's recommendation that the CAP and ASP are to function
10 independently of each other. We discussed this analysis in the most recent CAP rules.

11 53.G-5. The Council recommends that CMS reevaluate its contention that working with CAP
12 vendors will not increase the administrative burden of physicians, and that physicians be given 30 days to
13 submit the bill for administration of drugs, instead of 14 days. CMS appreciates the Council's
14 recommendation regarding the potential for significant increase to administrative burden under CAP. As
15 we explained in detail in the Final Rule, we do not believe that this will occur, but we will monitor and
16 evaluate the amount of burden as we gain more experience with the operation of CAP.

17 53.G-6. Given that CMS has recognized the increase to pharmacists of dispensing drugs, and has
18 added 2% of ASP to cover pharmacy overhead costs to the ASP plus 6% formula, the Council recommends
19 that CMS treat physicians equitably, and add 2% of ASP for reimbursing physicians, using ASP plus 6%
20 formula, and add a dispensing fee for physicians using CAP. CMS would like to note to the Council that
21 CMS has chosen not to finalize the ASP plus 6 plus 2% provisions in the outpatient rule. Therefore, the
22 issue of inequitable treatment of physicians does not arise.

23 Agenda Item H. The Physicians Regulatory Issues Team, Commonly called the PRIT Update.
24 53H-1. The Council recommends that CMS allow electronic resubmission of denied electronic claims.
25 Medicare contractors have implemented the technical parts of this requirement (the computer code to do the
26 denials) at all MCS contractors, but to date, have not yet activated this edit at any contractor site. The
27 Program Integrity Group is currently working with the appeals division to pilot test the requirement that
28 contractors deny resubmitted medical review denials. As part of the test, CMS will assess how we can

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1 allow providers to resubmit denials electronically. Further, CMS will identify which educational efforts
2 contractors need to implement to have providers comply with the requirements of the CR. CMS will
3 publish a MedLearn Matters article which is currently under development on this subject.

4 Agenda Item K, related to the Physician Fee Schedule and Outpatient Fee Schedule proposed
5 rules. 53K-1. The Council requests that CMS present to PPAC the specific amounts of new money in the
6 sustainable growth rate, commonly called the SGR, that can be attributed to the new benefits resulting from
7 the Medicare Modernization Act, to assess the affect of the new money on reaching the SGR target. CMS
8 agrees. Information about the factors that are included in the SGR is included in the Physician Fee
9 Schedule Final Rule, which was published November 21, 2005. Section 6-11 through 6-13 of the Medicare
10 Modernization Act, provide Medicare coverage for an initial preventive physical examination,
11 cardiovascular, and diabetes screening test. We estimate that new Medicare coverage for these preventive
12 services will increase spending for a physician’s services under the SGR, by 0.34%. This approximates
13 \$230 million. Section 4-13 A of the Medicare Modernization Act establishes a 5% increase in the Physician
14 Fee Schedule payment for services established in physician scarcity areas. Section 4-13 B of the Medicare
15 Modernization Act improves the procedures for paying the 10% Physician Fee Schedule Bonus payment
16 for services provided in health professional shortage areas. We estimate that the provisions of Section 4-13
17 of the MMA will increase Medicare Physician Fee Schedule payments by 0.1% or approximately \$70
18 million. We estimate that all of the statutory provisions for 2005 will increase Medicare spending for
19 physician services by 1.2%.

20 53K-2. The Council recommends that CMS present to PPAC its plan to monitor critical subsets as
21 possible indicators of barriers to access to care, such as new versus established Medicare patients, patients
22 without Medigap coverage, and specialty versus primary care physicians, and that CMS develop a plan to
23 address possible declines in access before problems become widespread. Because it is very difficult to
24 accurately predict the likely impact of payment reductions on access to care, CMS recognizes the need to
25 conduct continued monitoring. To respond to anecdotal reports on beneficiary access problems, CMS
26 implemented a multi-faceted monitoring strategy that includes analyses of a number of physicians billing
27 Medicare in a year, and their corresponding average caseload. The proportion of physicians accepting
28 assignment, analyses of claims data focusing on the proportion of visits for new versus established patients,

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1 and most importantly, analyses of survey data on beneficiary access to both primary and specialty care.
2 We're not analyzing the results of our latest activity, and will be prepared to discuss this with the Council
3 at the next meeting.

4 53K-3. The Council recommends that CMS not institute the 4.3% decrease in the Physician Fee
5 Schedule conversion factor but instead use the MedPac recommendation of a 2.7% increase, while working
6 to fix the SGR. CMS does not have the authority not to implement the calculation of the update, as
7 specified in Section 1848, D-4 of the Social Security Act.

8 53K-4. The Council recommends that CMS provide PPAC with a response by December 5, 2005
9 as to whether incident to drugs can be removed from the SGR retrospectively using an administrative
10 approach. CMS provided information regarding this recommendation in the Physician Fee Schedule Final
11 Rule. CMS does not have the statutory authority to remove drugs retrospectively from the SGR.

12 53K-5. PPAC recommends that CMS delay implementation of changes in methodology in practice
13 expenses until the American Medical Association, and other specialty societies have an opportunity to
14 review the methodology in more detail and assess the impact. CMS agrees and CMS withdrew its proposal
15 to change the practice expense methodology for 2006.

16 53K-6. To facilitate the medical communities review of the new practice expense relative value
17 units, PPAC recommends that CMS provide the Council with (1) examples of how new values are
18 calculated, (2) actual new practice expense values for each code in addition to the values for the first year
19 of transition, (3) the source of the data for each specialty, (4) the budget neutrality adjustment applied, and
20 (5) the impact of the changes by specialty. This information should be provided before the changes are
21 implemented, and with sufficient time for CMS to consider alternative proposals. CMS plans to meet with
22 representatives of physicians groups to discuss the methodology prior to making a new proposal. We
23 expect the first meeting to be in January 2006. We expect to be able to report on these discussions at the
24 next PPAC meeting.

25 Agenda Item M. Alliance for Cardiac Care Excellence Program. The Council recommends that
26 CMS assume an active role to ensure that the ACE Program works to reduce cardiovascular health
27 disparities among minorities and increase minority's access to high quality cardiovascular care. CMS
28 agrees with the Council's recommendation and will encourage each of the ACE groups to incorporate a

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1 disparity focus into their goal statements. CMS will also suggest the active recruitment of organizations
2 with a predominantly minority-group constituency for future membership in ACE.

3 That, Mr. Chairman, concludes the comments to the responses from the last meeting.

4 Dr. Castellanos: Thank you, Ken. We certainly appreciate your efforts. Are there any questions or
5 comments or further questions from members of the Council?

6 Dr. McAneny: Yes, on 53F-1, where we talk about reasonable for Medicare to approve additional
7 payments for improved outcomes but not information technology. Data collection is not simply the use of
8 information technology. Part of data collection is anyone who is academic sending or does clinical trials in
9 a private practice setting recognizes, is a very meticulous process, if you're going to actually develop data
10 that has any meaningful value for which to make decisions. So data collection is not just information
11 technology and it's not just marking a box for G-Codes if it's done well. So I would like to recommend that
12 CMS work with the NIH and with other entities that do clinical trials to determine fair reimbursement for
13 the data collection, with or without the use of information technology.

14 Dr. Castellanos: Is there any further discussion on that motion?

15 Dr. Przybalski: I would echo that comment. I mean if you look at folks that have participated with
16 any of the outcomes research data, including the surgeons' data bases, they've had to hire a single FTE to
17 help collect that data that data even if it's done prospectively, they're doing that. So there is a cost
18 attributable to this. And if we are certainly going to be involved in voluntary reporting of data with the
19 eventual less voluntary reporting of data, there's a cost to it and there's got to be a way to account for it.

20 Dr. Castellanos: Are there any other comments? I think we're going to have some more discussion
21 on that with the Physician Voluntary Reporting Program, but we'll delay that discussion until we get to
22 that. Dana could you read back that motion, please?

23 Ms. Trevas: PPAC recommends that CMS work with the NIH and other entities that do clinical
24 trials to determine fair reimbursement for data collection with or without the use of information technology.

25 Dr. Castellanos: Is there a second to that motion?

26 [Seconds]

27 Dr. Castellanos: OK. All in favor?

28 [Ays]

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1 Dr. Castellanos: Opposed? Are there any other motions or discussion concerning—Dr. Przyblski?

2 Dr. Przyblski: Two things I wanted to thank CMS for responding to the Council's
3 recommendation about delaying the practice expense implementation until we have a better look at that, so
4 that's very much appreciated, and I have a question about 53K-4, the topic of the drugs and removal from
5 the SGR is a frequent topic of discussion that we hear over and over again. And my understanding is that
6 AMA has invested some time and legal counsel that disagrees with that opinion, and I think Congress has
7 made comments that disagrees with that opinion. Is there something written in detail as to why CMS
8 counsel feels that it does not have the authority to remove it retroactively, and the comment also doesn't
9 address it from today on, meaning pro-actively removing it. It simply addresses the fact that they do not
10 have the statutory authority to remove it retroactively. So I'd also like the answer to the question as to
11 whether from now going forward, it can be removed.

12 Mr. Kuhn: On the retroactive removal, well let me back up a minute. In this year's Physician Fee
13 Schedule regulation, we did ask for comments on this issue, and we received a lot of good thoughtful
14 comments and information, and I think we had a pretty good thoughtful discussion there in terms of our
15 response. On the retroactive nature, removing drugs from SGR, the dilemma that we have is that again,
16 legally, we don't think that the authority is there, and particularly the problematic issue is that the way the
17 current statutory authority reads is that after a 2-year period, those years are basically locked down in terms
18 of the auditing procedure. So even if the retroactive authority is there, in looking back, you couldn't go
19 back to 1997. You could really only probably go back 2 years at best, but even that, we think is a difficult
20 argument for going backwards. On a go forward basis, it looks a little bit easier, and those are policy
21 questions that we continue to have and we're looking at and discussing with Congress right now, but no
22 final determination has been made in terms of a go forward basis. But it does look a little bit more
23 promising on a go forward basis.

24 Dr. Castellanos: Dr. Sprang?

25 Dr. Sprang: On 53K-3, which is obviously again, a major issue, and I'm sure we'll have more
26 discussion on throughout the day, but just the way that recommendation was worded, I can see CMS's
27 response, it's going to have major, major impact on [inaudible] physician service, and on access to care in
28 '06, so I would just like to change the way, and make a recommendation, that the Council recommends that

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1 CMS and the Secretary of HHS actively support an increase in the Physician Fee Schedule conversion
2 factor for 2006. I'm sure there'll be a lot more discussion on that topic, as the day progresses, but I just
3 think for now, we've got this one in front of us, I just think that's something that CMS and Secretary of
4 HHS can do and would like to make that recommendation.

5 Dr. Castellanos: Is there a second to that?

6 [second]

7 Dr. Castellanos: Dana, could you read that back to us please?

8 Ms. Trevas: The Council recommends that CMS and the Secretary of Health and Human Services
9 actively support an increase in the Physician Fee Schedule conversion factor for 2006.

10 Dr. Castellanos: Any further discussion on that motion? Seeing none, all in favor?

11 [Ays]

12 Dr. Castellanos: Opposed? Are there any other questions. Dr. McAneny?

13 Dr. McAneny: On Item D-2, with the patient assistance programs, whether or not that contributes
14 to out of pocket expenses, I think we will be discussing Part D later in the Agenda—that didn't get
15 deleted—maybe it did get deleted? There's no Part D discussion. Then I would like to do several things.
16 One is to find out whether or not there is any update on what the OIG is thinking because as we look at
17 many of our patients who are needing of expensive medications, if free drug that's given by the drug
18 company or by a charitable institution or by anybody doesn't count towards the patient's true out-of-pocket
19 expense. They will never be able to meet their share of the Part D in order to get the benefit if they're in
20 that large group of people who fall above the dual eligibles and the income limits. There are a lot of our
21 patients who we see who without the free drug from drug companies would not be able to access most of
22 these medications. So I'm very concerned that that hasn't been forthcoming, and I'm also very concerned
23 because if those donations of medications by the pharmas do not count toward the true out-of-pocket
24 expenses, then they may discontinue their programs. I recognize that this group is only really concerned
25 about Medicare, but I treat 26% of uninsured patients too, and being able to have access to those
26 medications is crucial to being able to continue to take care of those patients. So I'm hoping that there is
27 some sort of an update that you could give us.

28 Dr. Castellanos: I don't hear a motion on that. Is there a motion that you would like to make?

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1 Dr. McAneny: First I'd like to hear whether the OIG has given any sort of indication of which way
2 it's going, and then if it hasn't yet, then I will make a motion.

3 Dr. Simon: The OIG is in the process of preparing a response to the agency, and we should have
4 that sometime this month. And we would envision that there would be Q&As that we would post on the
5 website to make the public aware of the information provided to us by the OIG by the first of the year.

6 Dr. Gustafson: In short, the information you have in front of you is the update. That's as much as
7 the Department is capable is saying at this point.

8 Dr. McAneny: Then I would like to make a motion, Mr. Chairman. I'd like to move that CMS
9 encourage the Office of the Inspector General to continue counting patient assistant programs as part of the
10 patients' true out-of-pocket expense.

11 Dr. Castellanos: Is there any further discussion on that? My understanding of this, this is not just
12 from the pharmaceutical industry, but also across the board assistance.

13 Dr. McAneny: Any way they can get it.

14 Dr. Castellanos: Is there any other further discussion? I didn't see a second. Was there a second to
15 that motion?

16 [Second]

17 Dr. Castellanos: All in favor?

18 [Ays]

19 Dr. Castellanos: Opposed? Are there any other discussions on the responses? Dr. Grimm?

20 Dr. Grimm: On 53G-6, I'm curious if you, the solution that CMS has given in recognizing
21 increased pharmacists in the ASP plus 6 plus 2 provision that instead of addressing the issue that dispensing
22 drugs costs more money, that their solution was to just eliminate any payment whatsoever, and there was
23 no explanation as to rationale for that. Why was that eliminated, and does that say that work does not exist
24 when you dispense drugs? Or you just decided that this was an easier way out of that problem.

25 Mr. Kuhn: We'll have a further discussion on this afternoon, when we talk about the outpatient
26 proposal, but basically, as we looked at the data that was there—well, first of all, backing up a moment,
27 Congress did unlike in the physician space, in the outpatient area they did recommend that there be an
28 additional fee for the dispensing side. So that's why CMS put forward to recognize that. But as we looked

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1 at the data that we received, we found that there was really no differential there, so it was truly a data
2 driven exercise, that got us the outcome that we did, to come up with the ASP plus 6 in the outpatient
3 setting and no additional fee for dispensing. But again, I think Jim Hart will be here this afternoon and will
4 give a further detailed discussion of that then.

5 Dr. McAneny: Back to the Part D, items D-1, and 2. As part of the information about the
6 prescription drug payment plan, as all of these vendors are now submitting their applications to become
7 vendors for Part D, it occurs to me that with every HMO patient I take care of or PPO or anybody with a
8 pharmacy benefit that part of the success of that program depends on the ability to get an occasional
9 exception. Yet with the programs I work with, currently, I've discovered that the application form to apply
10 on the patient's behalf, to appeal for a different drug tend to be quite lengthy and detailed, and the cynical
11 part of me suspects that that length and detail that they request on those applications might be set up as a
12 deterrent for physicians to assist patients in requiring an application. Now when Medicare did the HICVA
13 1500, that really simplified things in terms of making everybody start to minimize and make a uniform
14 application. And I would like to recommend that PPAC recommends to CMS that it require all of the Part
15 D carriers to have a simplified and uniform form for appeals for beneficiaries who need drugs that are not
16 on the approved formulary.

17 Dr. Castellanos: Is there any discussion on that motion? Dana could you read that back, please?

18 Ms. Trevas: The Council recommends that CMS require Part D carriers to have a simplified
19 uniform form for appeals on behalf of beneficiaries who needs drugs that are not on the approved
20 formulary.

21 Dr. Castellanos: Is there a second, I didn't—

22 [Second]

23 Dr. Castellanos: All in favor?

24 [Ays]

25 Dr. Castellanos: Opposed? Are there any other questions or comments concerning the replies?

26 Ken, again, we thank you very much. Appreciate it. The PRIT Update. It's now my pleasure to welcome
27 back Dr. William Rogers. As most of you know, Dr. Rogers is the medical officer to CMS administrator,
28 Dr. Mark McClellan. Dr. Rogers will provide us with an update on the Physician's Regulatory Issue Team,

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1 better known as PRIT. As all of you know, Dr. Rogers wears a lot of hats, but one of them is still a
2 practicing physician. In fact, he worked in the emergency room on Saturday night, and that's why he
3 wasn't able to recover enough to come out to dinner last night. We certainly appreciate your being here,
4 and we certainly appreciate your staying connected with the practicing physicians community.

5 PRIT Update

6 Dr. Rogers: Thanks, Ron. I actually got creamed Saturday night! But that's the way the business
7 goes in emergency medicine. Before I start, I should mention to Dr. McAneny's comment about the
8 standard form, we actually have a standing committee and we meet monthly. And there are representatives
9 from the pharmaceutical, drug stores, and AMA, and some patient advocacy groups, and we have discussed
10 this standard form issue, and I think the feeling is that we don't have the authority to mandate that the PDPs
11 use a standard form when they do the appeals, but the patient rights, I think, are pretty well protected in the
12 regulations, and I think the appeals process will work smoothly. But the program won't work to push costs
13 down unless there's, it's fairly effective at getting physicians to use the drugs that the PDPs can get at the
14 most reasonable price.

15 I came through the screening along with Ron and a bunch of other PPAC members, and so I
16 thought this cartoon was perfect for the timing there. It's a new service that we're providing now that
17 there's a Medicare payment. [laughter]

18 I'm going to go over a few of the issues that we've been working on here lately with the PRIT.
19 We've had an exciting quarter. There have been a lot of different things that have been going on and we've
20 developed dialog with some specialties that we didn't have dialogs with before and it's been a lot of fun.
21 And most of my meetings have been in California, recently, which has been the best part of it. I'm still
22 waiting for my first Hawaii meeting. Laboratory frequency edits. This was an issue that was brought up at
23 my last AAFP meeting, and this has to do with the problem if patients have to switch for instance, in
24 hypertensives to a new drug which requires say, a liver profile, and the patient's already run up against
25 their annual limit for the number of times that test can be repeated. And so what we're doing now is trying
26 to figure out whether that's going to be a problem. How frequently that might happen. And it may be
27 necessary to address the issue of the frequency edits. Also, at the House of Delegates meeting, at the
28 American Academy of Family Physicians, we had two rural health issues come up. The first one was a

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1 requirement that at least 50% of the staff of a rural health clinic be midlevel practitioners. It turned out that
2 that's in statute, and so we don't have the authority to change that. But it was a four-member family
3 practice group that was staffing a rural health clinic and they really didn't need to have a midlevel, and so
4 they felt that the requirement that 50% of their staff be midlevels was burdensome. But we can fix that;
5 Congress can.

6 The other issue that they brought up was the requirement that somebody with experience in
7 emergency medicine, a physician or midlevel, be available within 30 minutes to respond to calls from
8 critical access hospitals. And although the 30 minutes is probably reasonable for real emergency, it
9 certainly isn't reasonable if the issue is routine order for a laxative or something like that, so we're looking
10 at ways to clarify the standards and the Conditions of Participation, where they're outlined. An issue from
11 the anesthesiologists had to do with the way anesthesia bills crossover from Medicare to Medicaid in
12 Illinois. And it turns out that the Medicare Program always crosses those over in units and Medicaid
13 Program in Illinois pays in minutes, so that further compounds the underpayment that the anesthesiologists
14 are running into now. Illinois Medicaid suggestion was that we change the Medicare Program [laughter]
15 which would have thrown every other secondary payer into a tailspin. And we decided that probably wasn't
16 a good idea, so we're working with them to fix it on their end.

17 This is an exciting solution to a problem. Physician practice had to pay PSA bonus payments to
18 their members of their groups who practiced in multiple locations and it was very, very problematic to
19 figure out how many dollars to give each of the physicians. And we just released software called the
20 Medicare Remit Easy Print Software, which allows you to slice and dice your Medicare payments and
21 makes it very easy to calculate these sorts of things or other kinds of incentive payments or things that your
22 practice might do. So this was a great step forward, I think.

23 Use of macros. This is an issue that we've been working with AAMC and others on, and this has
24 to do with permitting teaching physicians in cases where the residents note is entirely and completely
25 satisfactory and requires no editing and requires no embellishments to use a macro, which would cause the
26 dictation system to print the standard teaching physician attestation I was present during the key
27 components of the procedure and agree. And what we, after a long discussion, has decided is that this is
28 sort of the way the world works now anyway, so we might as well accept it. Of course the teaching

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1 physician is responsible for the quality of the overall note. But if the teaching physician is entirely
2 comfortable with everything the resident's written, feels that there's not a thing to be added to, then it is
3 permissible to use a macro to do the teaching physician attestation. So we're going to actually manualize
4 that because it's such an important issue for teaching programs. But it's absolutely not permitted for the
5 resident and the teaching physician to use a macro—each of them. Almost all of the note, obviously, has to
6 be customized to the particular patient that it concerns.

7 Hospital provision of continued medical education has been a problem. Obviously there are
8 STARK problems with this if it represents a cost to the hospital and is provided free to the physicians. But
9 it's such a common occurrence, particularly in rural areas that we really need to provide clarifying language
10 on that. The AMA wrote a letter to Dr. McClellan. And I think that's going to be really the vehicle for
11 some clarification on this, but the final response to that letter's not completed yet. Electronic resubmission
12 of denied claims. Ken spoke to that. Obviously a big issue, and since we're trying to move everything in an
13 electronic direction, going back to paper claims seems like a step backwards.

14 Like it or not, the Medicare Program as the bull in the china shop is becoming sort of the de facto
15 policy maker for a lot of payers, Medicaid Programs and commercial payers. And this and another, one
16 would not think that we were doing many issues for pediatricians, since there aren't that many kids that get
17 Medicare, although there are some. But it's important to them what our policies are and what we publish
18 because often it affects the Medicaid Programs. And so what they have asked us to do is to publish RVUs
19 for noncovered codes in the physician rule and this apparently is very helpful to them if those are public
20 when they deal with the state Medicaid Programs. And so we have published a number of them. There are
21 two more, the one for vision screening, and the one for hearing screening, that we didn't manage to get into
22 the rule this year. I'm hoping that we'll get it into the rule next year. There's some very reasonable
23 arguments against us publishing information that doesn't really directly have anything to do with Medicare,
24 but the fact of the matter is, I think that physicians like to have one policy, even if it's a bad policy, rather
25 than 70 bad policies. And so I think that we really need to sort of shoulder the burden and step up to the
26 plate and realize that we are the bull in the china shop and we need to help physicians get paid properly by
27 other plans, too.

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1 ASP problems. Dr. McAneny's not going to let us forget that this is an issue. I think that the
2 market is responding to the forces and we're seeing far smaller differences than we were seeing certainly a
3 year ago, but we're still very interested n hearing from physicians about particular drugs that they're having
4 problems with.

5 Recover Audit Contracts. We're going to have an update on that toward the end of the day. The
6 demand letters I think are going out now to physicians. We haven't heard anything from any physicians
7 who have been directly impacted. I know Ron's in a RAC state, and I don't think that he's got any horror
8 stories so far.

9 Competitive Acquisition Program. Amy Bassano's going to give us an update on this at 3:00.
10 Obviously this is an issue of great interest, particularly to our oncologists.

11 Cardiac rehab. This is an issue that we talked about for a couple of meetings consecutively, but I
12 think we're reaching closure on this. The work completing coverage analysis and expect to have a proposed
13 decision memo released this month and the part of this issue that I'm interested in is the issue of whether
14 it's OK in a small hospital to have the emergency physician, as long as the emergency physician is very
15 close by and can respond to emergencies, be the supervising physician. I don't think the emergency
16 physician should get paid for doing it, since they're not doing any extra work, but it allows the programs in
17 the small rural hospitals to stay open. If we say that it's got to be a physician who's being paid to sit there
18 and supervise, then these small hospitals will have to close their programs.

19 My cartoon dropped off of the slide and it was the best one! This is the rules concerning DME.
20 Hospitals are being paid huge amounts of money by Medicare to educate residents and we require that they
21 pay all or substantially all of the costs involved with that resident education. So there really could be
22 problems if residents were spending a huge amount of time at other places getting their education and costs
23 were being assumed by those other places and not being reimbursed by the hospitals. So that's the reason
24 for CMS's interest in this. There's a lot of Congressional interest, because obviously we want to encourage
25 primary care experience in the community and there are a lot of physicians who happily get involved with
26 these programs, and maybe the standards that we have set are a little bit too involved and burdensome and
27 so we're actually having a meeting about this in the next week or so internally to discuss reasonable
28 approaches to this. But you know, one option would be to allow the physicians to attest that 90 or more

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1 percent of the time that they've spent with residents is spent in providing clinical care and allowing that to
2 satisfy our requirement that they not incur a cost.

3 So those are the big issues. I didn't put up our recent speeches and travel, but I thank the PPAC for
4 the opportunity to continue to provide this report, and I look forward to your issues and your concerns.

5 Dr. Castellanos: Thank you, Dr. Rogers. We appreciate your cartoons and your comments. Thank
6 you. [laughter] Are there any comments or questions to Dr. Rogers? Dr. Przyblski?

7 Dr. Przyblski: Similar to the RVUs for pediatric codes in neurosurgery, we noticed the series of 5
8 codes that were developed in '05 for the '06 fee schedule that were valued by the RUC, Medicare made a
9 noncoverage policy on them, but published none of those RVUs, and those are actually codes that would
10 apply very frequently to the Medicare population—

11 Dr. Rogers: Medicaid you mean.

12 Dr. Przyblski: No, Medicare population, because most of those codes are going to address patients
13 who have subarachnoid hemorrhage or some sort of a vascular disease, so in a similar way it will be helpful I
14 think for all physician groups not just neurosurgery, regardless of whether CMS makes a noncoverage
15 decision on a particular code to at least publish the values because as you correctly pointed out, third party
16 payers use that information and in the absence of any information, we're stuck.

17 Dr. Rogers: Well, if you send me the codes, it sounds like the same sort of issue.

18 Dr. Przyblski: I'd be happy to.

19 Dr. Castellanos: Are there any other questions. Dr. McAneny?

20 Dr. McAneny: Couple brief things. One is on the, your last slide about graduate medical
21 education. It would be wonderful to have that rearranged, because it's not just primary care where the
22 education occurs outside of a teaching hospital setting. We try to be good citizens and take residents and
23 fellows into our practice to show them outpatient oncology and we discovered that our local university not
24 only wanted to charge us for the resident or fellow's services, but to have us pay the salary they would have
25 been doing had they stayed at the university, as well as pay them that salary themselves, so they wanted to
26 double dip on that. And they told us that it was a CMS requirement that we could not accept this resident in
27 and have them just continue paying the salary. Which seemed to me to be a strange thing, since it slows me
28 down by about 20 to 30% if I'm trying to teach somebody while I'm talking. So I think if we're going to

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1 continue having good graduate medical education in the outpatient area, that that would be exceedingly
2 valuable.

3 I think I'll wait on the ASP till we get to CAP.

4 Dr. Castellanos: I had a couple of questions and comments, as far as RAC goes, I did get some
5 follow up information in Florida. We'll present that this afternoon. One of the things you presented last
6 time and I think it's really important that you continue to do that is that list of drugs that are just not
7 available at cost at ASP plus 6%, especially with respect to this CAP enrollment, which is going to be
8 sometime in April. I think it's prudent for the medical community to be kept apprised of that watershed
9 list as you did provide us last time. And I'd appreciate if you could continue to provide us with that list.

10 Dr. Rogers: Well, frankly, Ron, at the moment, I think all of the issues that we had on the list have
11 been resolved. The market in most cases has responded, and in a few cases, our price was wrong, and we
12 corrected the price.

13 Dr. Castellanos: I can tell you in the urology community, that's not the correct. And I can talk to
14 you about it. There's still a few drugs that we still cannot buy at ASP plus 6%.

15 Dr. Rogers: We only know what we hear.

16 Dr. Castellanos: Right.

17 Dr. Rogers: But we have followed up on each of the issues that we have been provided with, and
18 so we would like to hear if there are other drugs that there are problems with. And talking to Barb's issue,
19 here, that sounds like a completely confused situation there. The issue that we're doing with the graduate
20 education doesn't have anything to do with physicians paying hospitals for the pleasure of having a resident
21 in their practice. It has to do with our requirement that if a physician, for instance, was spending a lot of
22 time preparing lectures, or was spending time calculating or setting up schedules or things like that, that
23 those costs really should be borne by the hospitals, so the hospital should be paying the physician group for
24 those costs, because those costs aren't being paid through the E&M-Codes and the CPT-Codes by the
25 Medicare Program. So they are basically, we are paying the hospitals to arrange schedules, to do lectures,
26 and to do all those things, and the money's staying in the hospital, but the service is being provided by an
27 uncompensated physician. So it sounds like you're being asked to do far more than CMS is asking you to
28 do. [laughter]

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1 Dr. Castellanos: Are there any other, Dr. McAneny?

2 Dr. McAneny: I'll just add one to piggyback on your comments about the ASP is that we recently
3 ran in my practice, the protocol analyzer for the commonly used chemotherapy protocols for this year with
4 the ASP plus 6 the current demonstration project. And I think it doesn't, the red ink is red ink, and I think
5 that can be seen even though the numbers are obviously too small. This column is on the Medicare's
6 currently who have Medigap insurance. And this column is those people who do not have any co-pays
7 available. And then I ran this further to look at the ASP and looked at the G-Codes going away for the
8 chemotherapy infusions, the loss of the 3%, the fact that nurses continue to want raises for some reason and
9 that cost of living and power and everything else continues to go up and everything does and I think it
10 doesn't take much to see that the Medicare ASP plus 6 for people who have co-pays is now significantly in
11 the red, and almost all of the people, every regimen that I treat people with for folks who don't have co-
12 pays, and that by the CMS fee schedule, says that's 20% of Medicare beneficiaries. A fifth of the people we
13 take care of and I know that number is exceedingly accurate in my practice. That those people are all
14 significantly in the red. So for those of us who are trying hard to figure out how we're going to continue to
15 take care of 100% of Medicare patients, it's really got us under the gun. And I don't have—oh, I have lots
16 of recommendations...[laughter] but probably none of them will go very far. But I think that we're headed
17 for a significant crisis in that as this gets rearranged at least for oncology.

18 Dr. Castellanos: Are there any other comments? I just have one more comment and I'd like to
19 make a recommendation. I think the CME question needs to be solved, and we need an answer promptly on
20 that. That affects the whole medical community throughout the United States, so I'd like to make a
21 recommendation that Dr. Mark McClellan give us a prompt follow-up answer to the question of the CME
22 Programs, whether they can be funded by the local hospitals or local medical communities. Is there a
23 second to that?

24 [Seconds]

25 Dr. Castellanos: Dana can you read that back?

26 Ms. Trevas: The Council recommends that Dr. McClellan follow up promptly on the issue of
27 Continue Medical Education, and whether it may be funded by local hospitals and medical communities.

28 Dr. Castellanos: That's correct. Is there any discussion on that motion? All in favor?

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1 Dr. Gustafson: Dr. Castellanos, just a point of clarification, here. Are you referring to continuing
2 medical education of practitioners already in, out in the community practicing? Or are you referring to the
3 sort of thing Dr. McAneny was referring to?

4 Dr. Castellanos: The ones in the community practicing.

5 Dr. McAneny: Just providing CME.

6 Dr. Castellanos: Continuing Medical Education. It's the hospital paying for CME credits and
7 giving CME credits and giving it to us so it doesn't look like a kickback from the hospital.

8 Dr. Gustafson: I understand, thank you.

9 Dr. Przyblski: The motion as described uses the word "promptly" as opposed to time certain. I
10 don't know if you might want to alter it by next meeting, by—what does promptly mean?

11 Dr. Castellanos: I'd like to get it as soon as possible, not just for us, in this community, but for the
12 general medical community in its entirety.

13 Dr. McAneny: Another question on your resolution. All you're requesting is an answer? You
14 don't want to suggest that that answer be that yes they can?

15 Dr. Castellanos: I think we all want that. I think we need an answer to whether that is acceptable.
16 But I'll be glad to take an addition to that motion.

17 Dr. McAneny: And that's PPAC recommends that the answer to that question be "yes." [laughter]
18 A prompt positive answer to the question of whether or not hospitals can fund continuing medical
19 education. How about that for an editorial?

20 Dr. Castellanos: That's fine.

21 Dr. Senagore: Just a hypothetical on that—why would that not be construed as a benefit as part of
22 your staff dues, rather than something that would be considered compensation. That would seem to be an
23 administrative solution to the problem, and avoid any issues of STARK violation.

24 Dr. Castellanos: It's just that we need an answer.

25 Dr. Senagore: I'm leading the witness to maybe this can be part of your—

26 Dr. Castellanos: We just need an answer.

27 Dr. Urata: Another reason why it ought to be free is because doctors donate a lot of time on all
28 these committees that keeps the hospital running and maintains high qualities in hospitals. There's HIM

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1 committee, there's the CCU committee, there's the medical surgery committee, OB committee, M&M
2 committees, quality of care committees. And many of us donate our time to those committees at least once
3 a month or once every two months. We don't get paid for that. But in return we get some CME, which is
4 one of the purposes of the part of the CME for our hospitals makes sure we're practice up to date. And we
5 hear about new things going on and we invite a specialist to come up and give us a lecture on these new
6 things that happen every day in medical care. So I suppose if our hospital didn't do it, we wouldn't have as
7 much CME.

8 Dr. Castellanos: I think your points are well taken. Is there any other discussion?

9 Dr. Grimm: Could you repeat the proposal?

10 Dr. Castellanos: Dana, could you repeat...

11 Ms. Trevas: PPAC recommends that Dr. McClellan provide a prompt and positive answer as to
12 whether Continuing Medical Education can be funded by local hospitals and medical communities.

13 Dr. Castellanos: Is there a second to that motion?

14 [Seconds]

15 Dr. Grimm: The only change that may be changed, funded to provided—provide, I don't know if
16 you have objection to...

17 Dr. Castellanos: Fund or provide.

18 Dr. Grim: Change it to providing.

19 Dr. Castellanos: Any further discussion on that? Dana one more time, I apologize.

20 Ms. Trevas: The Council recommends that Dr. McClellan provide a prompt and positive answer as
21 to whether Continuing Medical Education can be funded or provided by local hospitals and medical
22 communities?

23 Dr. Castellanos: All in favor of that motion?

24 [Ays]

25 Dr. Castellanos: Opposed? Is there any further discussion? Dr. Rogers, thank you again. We
26 certainly appreciate your efforts. There's going to be a little change in our schedule—the time frame on the
27 schedule. We're going to take a break now and we're going to reconvene here at 9:40 for the Physician

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1 Voluntary Reporting Program, and we'll end that around 11:30. We'll go to lunch from 11:30 to 12:30 or
2 so, and then we convene back here for the afternoon session to start out with the Physician Fee Schedule.

3 Break

4 Physician Voluntary Reporting Program and Provider Education and Outreach

5 Dr. Castellanos: As we continue today's agenda, it's my privilege to introduce to you our
6 distinguished panel. Our next topic is going to be presented by Dr. Trent Haywood. Dr. Haywood is the
7 Acting Deputy Chief Medical Officer of Clinical Standards and Quality. As you may recall, this is Dr.
8 Haywood's third presentation to our Council. And he joined us on the May 23, 2005 PPAC Meeting. At
9 that time, he discussed quality measures as they relate to the Pay for Performance Initiative. And our other
10 guest speaker, Dr. Mike Rapp, actually needs no introduction at all. [laughter] He's well known to all of us.
11 He's a colleague and a former PPAC Chairman. Together they're going to provide detailed insight
12 regarding the development of designated codes, quality measures, how the measures will be used, the
13 implementation process, and ultimately, the transition to Pay for Performance arena. Further, they will
14 explain the Provider Outreach Plans and activity schedule to allow this initiative. As you know, both of
15 these are practicing physicians also. They both work in the Emergency Room. Dr. Haywood, in fact,
16 worked this past weekend, he told me, in Chicago in one of the emergency rooms. And Mike Rapp is still
17 working sometimes in the emergency room and thinking about doing free clinic work in the DC area. These
18 fellows are still connected to the medical community and we appreciate them being connected to the
19 Practicing Physician community. While you listen to their presentation, please consider the following
20 questions: What is your advice for using claims data for reporting quality data? What can we do to improve
21 the system to maximize physician participation? Do you envision other mechanisms to collect data to avoid
22 chart extraction? And to what extent do you believe that the hospital data collection alone can be used to
23 access physician services? Please welcome Dr. Haywood and Dr. Rapp.

24 Dr. Haywood: Thanks Dr. Castellanos, for that introduction, and I think we'll start off by walking
25 through some of the PowerPoint presentation to set the context for this morning's conversation. Are we
26 prepared? Thanks. As Dr. Castellanos had indicated, previously I've been here on several occasions,
27 talking to you overall about our quality agenda. If you recall, some of the key take homes from previous
28 conversations were one, that we were all in agreement that we need to make certain that quality remained at

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1 the focus and at the forefront of our activities. Second, that to the extent possible, we can really start to
2 address this issue of variations as some of the Wenberg information I presented earlier had talked about
3 some of the variations, and third, how we can start this process of aligning our financial system to actually
4 support those quality initiatives, those quality endeavors, so that we can align our goals with our actual
5 payment structure. So this Physician Voluntary Reporting Program is one of our first, from a nationwide
6 basis, as you know, overall, we've had some demonstration previously. We've had conversation around the
7 Physician Group Practice demonstration and some of the other activities that we've done. This is the first
8 step in which we are actually talking about the Voluntary Reporting Program, which is intended to be our
9 first pilot program at a nationwide level.

10 Again, program goals. There's 2 primary things as we indicated at the outset that we want you to
11 try to help us wall through on this pilot program. One is the infrastructure. We spent a lot of time in the past
12 with our doctor's office quality project, looking at performance and measuring activity and looking at ways
13 in which we can actually collect information as it relates to performance measures. One of the conclusions
14 that came pretty apparent from that process because it took the traditional chart-based approach, is that
15 traditional or paper-based approaches to quality measures on the national level is quite cumbersome at
16 minimum and more likely just not feasible. That to really start off with a program nationwide that is going
17 to require physicians and to hire data abstractions and the like to actually do this activity was pretty much a
18 nonstarter. So one of the things we started talking about was other approaches in which we could actually
19 be able to collect that data, and I'll talk a little bit more about that but one thing to keep in mind is the
20 reporting infrastructure for the collection of the data. The second thing that we want to talk specifically
21 about is the feedback mechanism that loop to the clinicians out there, so that it's not just a matter of
22 measurement activity, but it really still remains consistent with that goal of quality improvement and so we
23 believe important to that, and paramount to that activity is the provider feedback mechanism. And so to the
24 extent possible, how that process plays out as well as how we can improve any content that you think may
25 be missing from that activity, so those are the two prongs.

26 As we quickly indicate, while through some of the slides, honestly the goal is higher quality across
27 the board, not only for the benefit of patients, but also to the extent possible that we can redirect resources
28 to improve the overall efficiencies of the system. We want to accomplish that. So higher quality care costs

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1 more to provide, higher quality is worth more. Some of the current literature that you may have seen,
2 whether it be in Health Affairs or some other article, they're starting to actually suggest, and I previously
3 provided that to PPAC, that there's starting to be some information that says not only do we want higher
4 quality, but they start to show some evidence that it may actually be more efficient, meaning that areas in
5 which we're starting to see higher quality actually have lower costs in their system, compared to errors that
6 do not provide the same level of quality. And so to the extent that we can start to align those activities so
7 that we get higher quality and better use of our resources, then that's the win win that we're looking for.

8 So how do we get there? In the past we've talked about some of the metrics, and we'll talk a little
9 bit more specifically on that activity, but obviously one of the things that we want to make certain that we
10 do for any of this activity to be beneficial for all of us is to make certain that we have the appropriate
11 metrics. So we spent a lot of time in Dr. Rapp's office, and others, spent a lot of time on the metrics. Where
12 do we start? How do we actually start with that evidence-based approach to metrics, just sticking our toes
13 in the water? Obviously, they have to be valid, reliable and evidence-based. This also may concern that
14 once we have those type of measures that they're implemented in a way that's actually beneficial for our
15 quality improvement activity, and to the extent possible that we limit any unintended consequences, which
16 is a key factor for this activity. In addition to the measure, obviously we have the mechanism for how do
17 we actually report the information, so how do we actually get the information from that bedside, get it
18 actually out to external stakeholders. And then that 4th bullet, talking about providing that feedback
19 mechanism. And then finally, one of the things that is not specifically discussed today, although it may
20 come up in the questions is the financial incentives. Once you have that information, how do you actually
21 link it? There's a lot of different ways to do different designs and linking payment ultimately in some form
22 of Pay for Performance as it relates to the metrics is not central to today's conversation, but I'm sure it may
23 come up. In the past, we've talked about that specifically in the physician group practice demonstration, is
24 one example. And we've talked about it in other demonstrations where CMS is currently testing different
25 models in which you're linking payment to that actual performance metric.

26 So as it relates to that first prong, on measures and where we've been able to acquire the measures,
27 first we really tried to look for any way in which we can actually have some consensus around the measure
28 that there's been some external vetting. Again, keep it in mind this is not a process whereby the federal

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1 government is dictating to physicians the practice of medicine. Instead, we've actually worked with
2 clinicians going out and trying to do the evidence-based research, working with clinicians, such as the
3 AMA physician consortium, NCQA, through the HEDIS measures that you all are quite familiar with, and
4 those two organizations worked with us to actually get metrics into the national quality form for
5 endorsement. That was just completed early fall this year on having a set of measures that primarily focus
6 on primary care, but they were ambulatory based measures. In addition, we started reaching out broader,
7 saying that if we were going to really move in this direction, we wanted not only primary care measures,
8 but we really wanted to try to get a broader spectrum on the quality of the services provided. And start to
9 look at ways in which we could improve that. And so we've continued to reach out to physicians. And then
10 finally, through any of our contractors, whether it be our QIO organizations or other, to continue to make
11 certain that we're hearing from clinicians out there as to what the best metrics should be.

12 And as I mentioned, the National Quality Forum is that one vehicle out there where there's
13 consensus derived process across the board, so not only do you have clinicians at the table, and purchasers
14 at the table, but you also have academicians, researchers, and most importantly you have consumers at the
15 table as well to make certain that not only are we doing the right thing, from a standpoint of clinicians and
16 purchasers, but also from the standpoint of the consumers out there, the patients out there.

17 And then finally this highlights where we've been in the past, where some of the metrics come
18 forward and we'll talk more specifically, but ambulatory care measure, I briefly just mentioned. Diabetes
19 measures had previously gone through and National Quality Forum has gone back subsequently. And then
20 there's been some limited measures as it relates to beyond primary care on the specialty side, and one
21 example at the bottom, the 2 examples at the bottom where we've gotten more into that is with hospital
22 voluntary reporting and specifically working with the American College of Surgeons and many others on
23 the Surgical Care Improvement Project.

24 The reason I want to stop for a second and highlight the Voluntary Reporting Initiative on the
25 hospital side, even though this is, we're going to talk specifically about physicians today, is because it gives
26 you a sense of the model and the road map that we used previously on the hospital side. Similar to what
27 we're doing today as we start talking about the pilot project for physicians, we did this same activity on the
28 hospital side, where we started out sticking our toes in the water on a national level, saying let's come out

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1 with a pilot program, start with some small set of metrics, being able to build out that infrastructure, that
2 reporting capacity, also building out that feedback mechanism to those hospitals, and make certain that
3 we're doing this in the collective fashion moving forward. And so we did that approximately 18 months
4 before we ultimately launched the Hospital Compare website in April of this year. So this is the same
5 model and this gives an example of some of the support we had. Hospital leaderships start off with
6 American Hospital Association, Federation of American Hospitals, Association of American Medical
7 Colleges, supported along with joint commissions CMS, NQF, ARC, AMA, ANA, and others. They really
8 came together to make that pilot program to be as successful as possible before we actually finally were
9 live with the Hospital Compare website.

10 Again, as we started out on the process which this highlights, we started out with a small set,
11 initially ten measures, be able to build out that reporting capacity around that infrastructure, modifying that
12 reporting capacity to any extent possible as well as improving the process, the feedback mechanism, and
13 then ultimately in 2004, Congress acted in the Medicare Modernization Act in providing a financial
14 incentive for those hospitals. So initially we had about 10% of the hospitals, roughly around 492 hospitals,
15 and now we have approximately 4,000 hospitals. Keep in mind that not only do we have hospitals that are
16 part of the Medicare Modernization Act and financial incentives, but a lot of critical access hospitals have
17 stepped forward without even financial incentives to also provide their information to show the quality of
18 the services that they're providing as well.

19 Part of the process—this just highlights what we did as far as that feedback mechanism, submitted
20 that information through the QIO data warehouse and then ultimately what the hospitals did was registered
21 on the Quality Net Exchange. So this is a QIO-Quality Net Exchange. This allows for security information
22 to be provided to those hospitals with a designated administrator provided that information to that
23 individual and being able to have that feedback mechanism so that we can actually have dialog and
24 discussion about how they improve not only the process but the content that ultimately leads to quality
25 improvement.

26 So with that as backdrop, we're going to talk specifically now about the Physician Voluntary
27 Reporting Program. As I started at the outset, this is a pilot program similar to what we did in the hospital.
28 It is voluntary. There's nothing mandatory about this process. It is voluntary with the anticipation that what

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1 we will do is similar to the hospital, we will improve the reporting infrastructure, being able to find out
2 which ways work, which particular measures work best through our reporting process, and also improve the
3 feedback mechanism, both in terms of the process and in terms of the content. The way it's designed, it
4 says Petition cares by submitting G-Codes on claims forms. Let me pause here for a second. As I started
5 out at the outset, I said we had a pilot project called Doctors Office Quality Project, in 3 states, where we
6 looked at collecting measures. And one of the things that we did was actually have our data abstractors go
7 into those physician offices and work with the physician offices and to be able to collect that information.
8 Needless to say, even though we had experienced data abstractors submitting that information in through
9 from the chart-based approached, it still is labor-intensive for our own chart abstracting. So these are
10 people that already have experience, that are going into the physician office, and still find that it takes quite
11 an amount of time to actually be able to collect that information from a paper-based system. Where we
12 would ultimately like to go, and I think all of us collectively would like to do would be to go to EHR to be
13 able to actually have systems that will electronically be able to provide that information so that it's not only
14 less burdensome, but most importantly, that it's part of the Care and Management process. So not only are
15 you submitting information in the standpoint of being able to provide that information to external
16 stakeholders and that you have that information, but most importantly, at the time of taking care of that
17 patient, you have the care and management process there that cues you in. As Dr. Castellanos alluded to
18 earlier, I happen to work in the ER in the VA system, whereby we have EHRs and so when I see patients, it
19 allows me to know the benefit of before I actually provide a medication, what that patient's clearance is. It
20 automatically calculates it for me. It automatically lets me know if there's a potential drug interaction,
21 things of that nature. So that's ultimately where we would like to go, is to really move toward EHRs. In the
22 interim, the current recognition is that is just not where we currently are. We hope to move there,
23 depending upon which information source you look at—MGMA said that at best 15% of clinicians had
24 EHR capacities in their current settings. Even with that 15%, it doesn't really get it down to whether or not
25 you can actually export information as it relates to clinical information. If you looked at, I talked to Beth
26 McGlynn and some of her information, she'll tell you even physicians' offices that had EHR she still had to
27 actually go in there and collect that information. It wasn't able to be exported. And so that we all know
28 collectively, we need to work on EHR. So in the interim, what we've basically done is say hey, we've had a

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1 process before where we've been able to look at and try to get a little more clinical data by relying on the
2 system that most people have currently which is the administrative system whereby you're providing
3 information to CMS and so thus we created the G-Codes whereby physicians can actually provide
4 information to us, clinical data information to us, using the system that's currently available. So when they
5 see a particular patient and it's time to bill for that particular patient, they can put on that particular claim
6 information revolving to those services. And we'll give, we may, I think we'll talk specifically about that.

7 Let me talk a little bit about ultimately what it is designed to do. There are 2 things that will come
8 out of the process at the end of the day. One is that we'll be able to provide clinicians with a sense of what
9 the denominator catch was for those patients. And I'll give a quick example. If you're a primary care doctor
10 that's taking care of diabetic patients, then, through that system, we'll be able to tell you this is the number
11 of diabetic that our client systems say that you've actually cared for as it relates to the Medicare population,
12 and this is roughly where you've told us that clinical quality has been on those particular patients. In
13 addition to that, it also does is let's you know what you reporting, how accurate that reporting has been, and
14 is that consistent with what you've been thinking as far as the level of reporting? If not we need to have
15 dialog about whether or not the process of actually capturing the reporting that you provided, or whether or
16 not it is, but you need to actually improve your reporting. So at the end of this, we think there are going to
17 be 2 primary rates. There's going to be a reporting rate that says, OK, how well did I report as it relates to
18 the denominator we have, and then secondly, how well did I say we actually performed in our physician
19 office relevant to those particular patients?

20 Now the process by which this is current and the level at which it's current, I think we talked a
21 little before about this, but when we say at the physician level, what we mean is that it's going to vary
22 according to that tax ID, because the unit of analyses that we're going to use is at the tax ID number.
23 Because of UPIN right now, we're hoping at some point the National Provider Identifier will allow us to
24 get at a more granular level, but currently the most specific we can get is at that tax ID number. Others have
25 come up to me asking if there's ways to do this or get beneath that. What we've tried to do at this early
26 stage is not focus on redesigning the physician's office in the sense of having people concerned about their
27 business practice. For whatever reason you set up a particular association from a business standpoint. We
28 did necessarily want to spend our energies focused on whether or not that appropriate so the tax ID is

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1 designed to actually illustrate that physician office. And that's the unit of analysis. Individually, we
2 anticipate that physicians' offices will still be going back, looking at their particular services and seeing
3 how accurate it is, whether there be amongst their different colleagues as to how well they can actually
4 improve that activity. So keep in mind this physician office level is pretty much at the office level
5 according to that tax ID. As far as the other process, real quickly, as far as making sure that you're able to
6 actually have the feedback reporting. Because we're taking claims data up front, there's no true sign in on
7 the front end. In other words, we already have the information as it relates to the claims that you submit. If
8 you add the G-Codes, then we'll have the specific information related to the performance. But to actually
9 close the loop and be able to receive feedback reports, you must go through the Quality Net Exchange and
10 sign on because we want to make certain that we secure that process and that anyone that's getting the
11 information is actually the person that is actually notarized to receive that information; that the person
12 that's responsible at that individual physician's office has give us assurances that yes, they can receive that
13 information. So we're going to start that process. We're anticipating starting that process in February,
14 whereby on the Quality Net Exchange, we'll have opportunity for physician's office to go on and say, yes, I
15 intend to participate. And then, at some later point, in the, probably toward the summer, we'll actually walk
16 whoever you've assigned to be that actual administrator, walk them through the full registration process to
17 be prepared for the first report. And then the final first reports are anticipated to come out in mid to late
18 summer.

19 Dr. Urata: Can you sign up later in the year, or just one sign up?

20 Dr. Haywood: No, it's throughout. Thank you for asking the question. Let me just highlight that as
21 well because we want to make certain everyone's clear on that. This is a pilot in its phase-in approach, and
22 you can sign up at any time. So for those that are struggling currently for multiple reasons, people come up
23 to me for whatever, their business cycle, a lot of different reasons why they may not be ready to go in
24 January or February, but they may be ready later on in the year, that's appropriate. And one of the things
25 we've asked our contractors to make certain of on the intent page, where I said in February, there'd just be
26 on the website, that says you intend to participate. One of the things that we've asked them to do is to
27 highlight for us whether or not you intend to participate in the first 2 quarters or in subsequent quarters of
28 2006. So we know for a variety of reasons, people's business cycle may not allow them to participate in the

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1 first half of the year, but they may be able and ready to participate in the second half. And so that allows us
2 to have a sense of people that are going to be ready to participate, but they're going to need to wait until the
3 second half of the year to be able to participate.

4 The benefits we've talked about a little bit. I'm not going to highlight on all of this except the
5 second bullet. One of the things that we do think as far as that feedback mechanism is to try to feedback not
6 only your information, but to the extent possible, to devise some type of benchmark whereby you can see
7 how some of your peers have been doing it. Probably at a minimal, at a national level, if not at more local
8 level.

9 I'm going to talk about that a little bit more specifically so let me slip to the next slide. This slide
10 if you can you may want to file that in your handout. This is currently [off mike discussion]. This is the
11 template that we currently have in mind, OK. And this is why I say at some point, as we provide, have
12 dialog and discussion, we definitely want feedback from clinicians as to how beneficial it is as the current
13 template and at some point whether or not we need to add additional information or modify it. What you'll
14 see in this template at top, you see the traditional information, what the date was, so that you know how old
15 the data is, and then the next you see the tax ID, which I'd indicated is the billing number that we will
16 currently be utilizing. Then underneath it you start the actual report. Now the three boxes that are in the
17 center that says "current reporting," what that allows you to see, so if you look in the middle of those
18 columns, what you see is one that says "current reporting" and then you see the 3 columns to the right, it
19 says "current performance." So let's focus for now on the current reporting. What that allows you to do as I
20 indicated, is if we were going to be able to get a sense of what the reporting rate is, and there's been a lot of
21 conversation as you probably well know that, as people talk about Pay for Performance, they normally talk
22 about starting out, you're really talking about reporting, and to the extent possible, can you start out just
23 looking at how well people are reporting it at some point down the road being able to get at actual
24 performance. So this allows 1, to be able to get a sense of how well their reporting. So let's just take that
25 first example at the top. So it's acute myocardial infarction. Estimate arrive for AMI. So if you look at our
26 reports, what our system would be able to tell is OK, you submitted Part B claims that had patient with this
27 condition, you had 60 in that reporting period. Of those, you provide some information on those patients,
28 for 30 of 60. So that gives you a reporting rate of 50%, so you would have a sense of how well your

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1 reporting is in comparison to what we're receiving. Now move over to the other 3 columns on the
2 performance rate, just to be clear. Now what we ended up doing is if you notice that even though we said
3 that we had 60 patients as far as with that condition, if you look at the denominator there, you see that the
4 denominator is 40. So there's 20 different. Well, the reason is, because we made certain that as part of the
5 activity when it comes time for your performance measures, that there's medical exclusions, there's other
6 reasons why even though our conditions say yes, that patient may have AMI, there's a reason why they
7 may not have been a candidate for aspirin. They may have allergies, or some other reasons why they
8 weren't a candidate. And so because of that, your denominator would be different as it relates to
9 performance, so you have a 40 there. And then you see for those 40, what did you report? It's the same 30.
10 So, you really, when it came time for actual performance, you saw that your performance was 75%. So you
11 made certain that of those that were actually, that would be eligible for that particular measure, you
12 performed at a 75%. And then all the conditions on down the line, and so these are just some of the
13 examples, the AMI, pneumonia, diabetes, heart failure, that follow that same pattern that with the notion of
14 being able to start to provide some feedback to clinicians out there on this type of reporting mechanism,
15 and have physicians tell us how successful, how accurate it is as it relates to their current understanding of
16 their clinical practice. And really start to have that type of dialog. And so with that, I want to turn it over to
17 Dr. Rapp to talk a little bit more about the specifics and the mechanics of the process.

18 Dr. Rapp: Thank you, Trent, and thank you, Ron. One of the questions that Dr. Castellanos did not
19 bring up was the issue of the reporting piece itself, so I think that we'd be interested in having some
20 feedback on that, because that's one of the significant benefits that we see to the physicians. As you know,
21 there's no money attached to this, which is a bone of contention, but we look for a way to make it
22 beneficial to physicians nevertheless, and we look at this feedback that you can get as a significant potential
23 benefit. So any way that we can make that better, and you can give us some information on that, that would
24 be helpful.

25 Trent went over this to a certain degree, but let's just start again with a measurement of quality.
26 The first thing that you have to have is some clinical data necessary to measure that quality. Usually, claims
27 data is not sufficient to do that and so you have to come up with some other source for that clinical data and
28 the options would be chart abstraction, the electronic medical record, or in this case, what we're doing of

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1 course is to enhance the current claims data. And the way we're doing that is with order term G-Codes,
2 which are HCPCS temporary codes, and the way that we've developed these into the Physician Voluntary
3 Reporting Program is to have 4 possible G-Codes as a set, related to each quality measure. So the first of
4 any of the G-Codes that you have would be that the desired process or outcome was achieved. The second
5 G-Code for each set would be that the desired process or outcome was not achieved, and the third or fourth
6 G-Code—some have only 2, some have 3 or 4, if there's a 3rd or 4th G-Code, then that would be an
7 exclusion.

8 Dr. Urata: Is this in addition to the E&M-Code?

9 Dr. Rapp: Yes.

10 Dr. Urata: So you would be doing E&M-Codes, then your G-Codes.

11 Dr. Rapp: Right, so your normal claims process, you put down a diagnosis code, your ICB9-Code.
12 In addition, you put down a CPT-Code of some sort, which could be an E&M-Code. It could be something
13 else in the case of procedure for example. So once you've put those—I'm going to go through in more
14 detail, but once you've put those 2 down, those identify the type of patients that we're talking about. And
15 you find that from the specifics, or the specifications that I think you got a copy of. But after that, then what
16 the G-Codes are, is means for you to add some additional data that you would not normally submit as part
17 of the claim, which is clinical data, which as I say, I'll go over in more detail. And then those G-Codes
18 would indicate that, will relate to a desired process or outcome at that forum of quality measure, and then
19 this is the data that you would put in there. And 1, would be as I say, that it was achieved, 2, not achieved,
20 or 3 or 4, that there was some exclusion criteria. Now quality measures typically have rather specified
21 exclusions and in this case, to make it not as complicated as we might make it, in other words for
22 physicians to have to review each and every exclusion criteria in a quality metric, we'd leave it up to the
23 physicians to decide whether they don't feel, that even though the particular diagnosis, like diabetes,
24 applies, that they don't think that this particular quality metric is appropriate. In which case, it's basically
25 taken out and not considered. But we leave that up to the physicians.

26 As I was just sort of discussing, a quality measure basically is a percentage measure composed of
27 a numerator and denominator. It's got exclusion criteria specified in it results in a percentage calculation.

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1 For example, the percentage of patients with diabetes for whom the most recent Hemoglobin A1c test was
2 less than 9 would be an example of a quality measure.

3 And as I mentioned, the way we have it worked out here, the first G-Code would indicate that it
4 was achieved. That patient would be counted in the numerator. The second G-Code, not achieved, the
5 patient would not be included in the numerator. And the third or fourth G-Code exclusion the patient would
6 not be counted in either the numerator or the denominator. So you get in the denominator by being a patient
7 that fits in the population of the quality measure. You're a diabetic, and you had an office visit. That would
8 get you in the denominator.

9 Dr. Urata: That would be from your diagnostic code, ICD-9 Code?

10 Dr. Rapp: Yes, that comes basically from the claim, so once we get the claim, and it says diabetic,
11 a particular E&M service that's specified in the metrics itself, then that patient would be in the
12 denominator. And then the report that Trent went over, if you didn't report any G-Codes you would have
13 basically 0% although you might have 100 patients, for example. So you'd have a 0% reporting rate. If you
14 reported on 50 of those, then you would have a denominator still of 100. 50 you would have reported on, so
15 you'd have a 50% reporting rate. And then with regard to that 50 that you reported on, then they go over to
16 that second set, and then we decide OK, did you report a number the first of the G-Codes, in which case, it
17 would result, if all 50 that you reported on had Hemoglobin A1c less than 9, then you would have 100%
18 rate in terms of that performance on the metric. If it was less than that, then you would have a lower
19 reporting rate. And some of those 50 would fall out if you decided that the metric wouldn't be appropriate
20 at all. So that's basically how it works.

21 So as I mentioned, it takes going through it a couple of times. As they say, repetition is the key to
22 learning, so I repeat myself. The denominator code defines the population for whom the G-Code numerator
23 applies, ICD-9 Code, the CPT-Code and in some cases other criteria, such as age, some of our screening
24 criteria are just based upon age.

25 The denominator code. It's relationship to the quality measure. If the patient claim form includes
26 any of the identified denominator, then it's included in the denominator, unless it's excluded by the 3rd or
27 4th G-Code, that's what I just went over with you.

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1 And the exclusionary criteria as I mentioned are decided by the physician, based upon the G-Code
2 and are not specified in the measures. So, in terms of how it will work in practice in your office, the
3 physician or the coder will determine whether the denominator specified in the ICD-9 or CPT-Codes are
4 applicable, so for example, in the diabetes, is this an ICD-9 Code for diabetes? If the denominator specified
5 code is applicable, then you report one of the, then we ask you to report of the list of G-Codes in addition to
6 doing the normal things that you do with the claim form.

7 So here's an example. The measure is Hemoglobin A1c control in patients with Type I or Type II
8 diabetes. In that case, the denominator specifications that we have are ICD-9 Codes for diabetes, for
9 polyneuropathy and diabetes, for diabetic retinopathy, for diabetic cataract and diabetes in pregnancy,
10 that's not gestation. So any of those, so to get into the denominator, they have to be one of those, we'll be
11 looking for those in the reporting, one of those ICD-9 Codes, and one of the next particular codes. So as
12 you see, it wouldn't be for example, surgical procedure to debrided something for a diabetic foot infection.
13 That wouldn't apply because this particular measure is intended for primary management of diabetes, so it
14 only relates to E&M-Codes that you see identified there. But they include home visits and domiciliary
15 visits and nursing facility visits. The G-0344 is the Welcome to Medicare code.

16 So that gets you in the denominator. Once the physician identifies that that particular patient that
17 he or she saw was in the denominator, or the coder does, then they look to the G-Codes and we ask that
18 they put one of the four G-Codes in the, on the claim form, which is just reported like any other CPT type
19 code. So if the first G-Code, the diabetic had the most recent hemoglobin A1c within the last 6 months
20 documented as less than equal to 9, and so the intermediate outcome is achieved. The second one it is
21 greater than 9. Intermediate outcome is not achieved. The third the diabetic patient wasn't eligible
22 candidate. For some reason, the physician didn't feel it was an appropriate measure for that particular
23 patient, or that 4th, the G-Code, another exclusion, that the clinician had not provided care for the diabetic
24 patient for the required time, that is 6 months.

25 Dr. Senagore: So if I'm a surgeon and I see someone for colon cancer. And I put colon cancer,
26 diabetes, mallatis and HI fibrillation so that my preoperative studies can be reimbursed, so they have a code
27 to tie to those diagnostic tests, am I then on the hook to comment with a G-Code for HI fibrillation diabetes
28 mallatis or—

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1 Dr. Rapp: Are you putting an E&M-Code down?

2 Dr. Senagore: Yes, 99204.

3 Dr. Rapp: OK. If you put an E&M-Code down, then technically you're not really on the hook for
4 anything, because as I say it's a voluntary process. But in general, we have some additional instructions,
5 and in this case, the instructions indicate that it's intended for the primary management of diabetes, so in
6 this case, you wouldn't be viewed normally as the primary person providing the primary management of
7 that particular patient's diabetes. Attribution obviously is a complex issue when you get into trying to do
8 quality measurement through the claims process. And I think there's nobody that's going to say that this
9 isn't a work in progress to a certain extent, so one of the benefits of it, starting off as a voluntary, and sort
10 of pilot type process, is we're going to learn from it. You'll learn from it, and one of the benefits I think of
11 participating in it is you help design the system; you help us find where the bugs are and improve. So I
12 don't think anybody's going to sit up here and claim, we've got all this figure out. But on that particular
13 point, we've got it figure out, it's just out how are we going to make it so that it doesn't look like you're not
14 reporting on things that you need to be reporting on, but we'll try to deal with that. Yes, sir?

15 Dr. Grimm: Just to follow up on Dr. Senagore's question, does that imply that if the diabetes is not
16 the first diagnosis that it falls out?

17 Dr. Rapp: No, I don't think we have specified it necessarily to have to be the first diagnosis.

18 Dr. Grimm: OK, and then a follow up question, I noticed in a lot of these, if you look at one of
19 your G-Codes, I haven't provided that care for the past 6 months, yet your E&M-Code is often a new
20 patient or consultation, which by definition means you haven't seen that patient for that period of time. So I
21 was wondering what the rationale was for choosing those codes because I would think by default, that G-
22 Code would automatically come up because they haven't taken care of that patient in that time period.

23 Dr. Rapp: It's an effort to try to align the measures with other specifications. The Hemoglobin
24 A1c level is something that is one of the ambulatory care measures, that's been endorsed by the NQF, and
25 so they have certain specifications. And they talk about a time period like that. So the reason for it is an
26 effort to align it with other measures, which is something that one wants to try to do. One of the things that
27 we don't want to do is have something for the Medicare Program and have something that you have to deal

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1 with with private payers, and have something totally different. So to the extent that we can align the
2 measures—that’s the reason for that.

3 Dr. Senagore: That measure though it tied to existing patient codes, so if you excluded the 9920
4 codes from that series, you would avoid the first time visit to a doctor and then you would know for sure
5 that you’re having an existing relationship between that patient and that physician.

6 Dr. Rapp: OK.

7 Dr. Grimm: And that would be the consultation code as well, because if I am the primary care
8 doctor, seeing the patient for the first time, and I don’t have that lab value, I’m going to report the 4th G-
9 Code automatically, so it doesn’t make sense to collect that data because you know that’s what’s going to
10 happen.

11 Dr. Rapp: Although we kept out the consultation codes because again that was felt not to be
12 indicative of being the primary manager of—

13 Dr. Grimm: ...happen though.

14 Dr. McAneny: I worked through these codes for a fictitious patient who had lung cancer, diabetes,
15 heart failure, and Osteoporosis, which is not an uncommon combination in my life. And that would tell me
16 that that I had to then report on 19 codes. So if I have to report on that many codes, that’s about 10
17 additional minutes of work that I’m going to have to do. If 40% of my practice is Medicare, and there’s
18 going to be that many codes on every one I see, then that’s going to add, if you say 5 minutes for patient,
19 12 to 15 Medicare patients a day, that’s an extra hour, hour and a quarter at the end of the day that I’m
20 going to have to add in to do this. Plus, if I’m seeing this lung cancer patient and I’m listing their diabetes
21 and their heart failure, and I stop their aspirin because I’m going to give them chemotherapy and make all
22 their platelets go away, and then they go see Laura, and they’re diagnosed with brain metastasis, and then
23 they go see Peter who starts decadron and radiation therapy and the patient’s blood sugars go nuts, then
24 they go back to Gerry to manage the sugar 2 months later, and the Hemoglobin A1c is off the map because
25 we messed it all up. Does she then get dinged for being a bad doctor because the Hemoglobin A1c is
26 messed up?

27 Dr. Rapp: Well, number one, nobody’s going to get dinged for anything. It’s a voluntary program.
28 It’s designed to give feedback to the physicians, which is going to be confidential. Nobody’s going to be

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1 publicizing this in the newspaper or website or anything. It's going to go only back to the doctor that
2 submits it. With regard to the burden that you mentioned, I would suggest that one of the probably most
3 important aspects of this is that in so far as a physician decides to report on a given quality metric, that they
4 report on all the patients that they see with that quality metric because only by having a high reporting rate,
5 will a performance metric itself be of benefit. If you only reported on 10% of the patients, that are
6 potentially in that denominator, and you got a performance rate of 100% on that 10, it's not too meaningful.
7 So in so far as a physician says, you know what, I could potentially report on 19 measures, one thing that
8 you might consider is just identifying 3 or something, 4 whatever, that you personally are going to report
9 on. There's no necessity to report on more, but if you select out a small amount, that would at least give
10 us—then when you got the feedback on them, it would be meaningful to you and I think most helpful. So
11 that's an option that you may want to consider.

12 Dr. Castellanos: Why don't you let him finish the presentation and then ask questions.

13 Dr. Haywood: Yes, let me just add on that particular example real quick, though. One of the
14 reasons, as Mike had indicated, that we really want to do the pilot is to actually work through some of these
15 technical issues. I mean that's the benefit of having a pilot versus going live without having a pilot process.
16 As we've been having conversation with clinicians, and particularly as we've been having conversation
17 with primary care physicians, the question's been whether or not in order to testify, whether or not we need
18 to have a smaller set of measures just to test that so that more than necessarily individually picking as
19 whether or not, we collect, say, from the primary care standpoint, let's get some agreement about a smaller
20 set, a subset if you will of those measures that we can all kind of collectively focus on with more than
21 likely is going to be your traditional players; diabetes, coronary artery disease, heart failure, let's just start
22 at some level on that line. We may be a few exclusions being counted on vulnerable elderly where we still
23 have some concerns about our vulnerable elderly population. So I think you're going to hear more about
24 ways in which we can actually streamline our process. The short of it as Mike had indicated though, is the
25 benefit of this is to do exactly that walk through some of the technical issues. Without a doubt, just to be
26 clear on the burden, if you're not collecting and reporting information, and suddenly you have been asked
27 to collect information, there is a burden. OK, there's no way around the fact that there's going to be a new
28 burden and so what we're trying to say is that given the reality that where we're all headed, how do we

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1 kind of make this burden less cumbersome as possible. And so that's why we're coming to PPAC and
2 continue to reach out to physicians so you guys can help us figure out ways in which we can reduce that
3 burden and that actually leads to that quality improvement that we want.

4 Dr. Rapp: So I'll continue on. So as I mentioned, the specifications related to the measures in the
5 instructions, provide a little bit more detail. And on this particular one, you see the instructions indicate that
6 it's not anticipated that clinicians would use this indicator if the clinician is not providing services for the
7 primary management of diabetes.

8 So I'll give you next another example, which is probably harder in so far as this presents a
9 difficulty of attribution that I would say we haven't totally worked out. But this is for Osteoporosis
10 screening in elderly female patients. The denominator here is female patients 75 years of age or older, and
11 an E&M visit. In this case, the attribution issue derives from once you have a patient 75, the E&M visit is
12 not too specific and theoretically you could report this at every visit for virtually every doctor. So that does
13 create a problem.

14 The numerator though we have is that the patient be documented to have been assessed for
15 Osteoporosis, not documented, or that not an eligible candidate, similar to the other. And we try to deal
16 with the issue of attribution by these instructions that this would be reported by the appropriate G-Code, but it
17 should be provided only on an annual basis. It's estimated that the clinic will assess will include counseling
18 about the risk of Osteoporosis. So the annual basis is designed to try to deal with the attribution issue. In
19 Medicare of course, there is no designated primary care physician. So that unless Medicare were to adopt
20 such a practice, one can't really specifically say well, only a particular doctor could report this. There are
21 possible ways that one can deal with that, such as identifying the frequency of visits and so forth that some
22 private plan have used, but at any rate, I'm sure you'll identify a potential attribution problem here and
23 readily recognize it. [laughter]

24 So in conclusion, the G-Codes, we feel do offer an efficient means to report clinical data. It uses
25 the claims submission process, rather than separate data submission. The clinical data can be identified at
26 the time of the visit, rather than going through the more complicated chart abstraction. It does serve an
27 important purpose, which is to help assess health care quality. It provides important aggregated information
28 to which physicians generally may not have access, and finally, I believe it is compatible with the

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1 traditional approach of physicians to quality assessment, which requires one to have some method of
2 basically bringing together the data with regard to a group of patients, rather than considering each one
3 separately as they see them.

4 I'll spend a couple minutes going through the Outreach Program. This is not my program, but the
5 person who was on the schedule to present this, Robin Fritter, wasn't available to do it. So she asked me
6 just to present this briefly. This voluntary initiative first of all is sort of a combined effort. It involves the
7 Center for Medicare Management that Herb is in charge of. But it also involves the Office of Clinical
8 Standards and Quality, which is where Trent and I work, so it's sort of a combination. Robin is discussing
9 more from the CMM side of the voluntary outreach program, but in addition, on the website on the quality
10 page, we have some information about the voluntary reporting program, which includes the specifications
11 which were handed out to you which basically came from where we have them posted.

12 But in any event as far as the Outreach, the audience would be physicians, health care
13 professionals and professional associations. We've had contact with all of these in trying to help
14 individuals and groups learn about the program and give us feedback and provide a vehicle to answer their
15 questions. In terms of the Outreach strategy, it includes the various products, dissemination methods,
16 central office contacting national associations, regional offices involved in Medicare contractors. Next.
17 There's a website that has pertinent information that you can get in addition, as I mentioned, there's a link
18 off the Quality Initiatives site that you see on CMS.gov, where you can get more information. And also
19 we've set up, it's not on this slide, but as I mentioned on the Quality Initiatives, we have an email address.
20 So if you go home and you say oh darn, I wish I had mentioned this little aspect of the program, you can
21 just email it to that particular email address. It'll come to one of the staff that works for me and we're
22 collecting that information and trying to deal with it.

23 We have as you know on Medicare site, MedLearn articles that describe this and there's one on
24 this program. We have list serves that you use, and highlights on related CMS websites. So for
25 dissemination we're posting information on the website, sending information by the list serves, we're
26 working with professional associations, CMS frequently exhibits at Continuing Medical Education
27 programs. We have open door forums that you're no doubt familiar with, Medicare contractors and CMS

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1 regional officers, in as much as the Medicare contractors, are involved directly with the claims process
2 itself, and this is a claims-based reporting system, and they'll be involved in giving information.

3 And there's a key website that you see. The question that Robin asked to be presented; are there
4 any other effective ways to directly reach physicians with our PVRP, our messages?

5 Dr. McAneny: What was that email again?

6 Dr. Rapp: The email for...

7 Dr. McAneny: Where do you want comments going?

8 Dr. Rapp: [laughter] I knew you'd get me on that. The email address is—I'd have to get it for you.
9 But I can get it for you after the—I'll get it for you.

10 Dr. McAneny: Is it MikeRapp@CMS.HHS.Gov? [laughter]

11 Dr. Rapp: Well if you want to you can send it to me at Michael.Rapp—use that, and I'll forward it.
12 But I'll get you the actual address so maybe my email box won't get even more full. [laughter] And this is
13 Robin's email address, in case you decide you decide you want to contact her. OK, that's it for the
14 presentation.

15 Dr. Castellanos: Mike and Trent, thank you very much. As you can tell already, there's a lot of
16 interest in this program. A lot of questions and a lot of concerns. I think we all have to recognize that Pay
17 for Performance is here. It's not going to go away. And we're very unique in the position where we are
18 today that we can input, maybe have some direction, and help CMS formulate this ambitious program. Are
19 there any questions? Dr. Urata?

20 Dr. Urata: Are you going to be able to look at individual patients, like for example, Hemoglobin
21 A1c and chart out over a year or 10 years how their Hemoglobin A1c has done under a person's care?
22 Because that seems to me to be an important aspect of quality care. It's have you improved the patient's
23 Hemoglobin A1c, and if not, why not, and that kind of stuff.

24 Dr. Haywood: I mean the short is definitely in terms of this pilot, I don't know about long-term,
25 individualized care. We are trying to move toward a more patient-centered approach. As far as the pilot, I
26 can tell you for the pilot, we will not be following the individual patient level longitudinally. Because a lot
27 of conversation about such an approach, long-term as far as Medicare, really starts to manage our patient
28 population and moving towards their goal.

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1 Mr. Kuhn: That's a good point. And one of the things that Congress is asking, and certainly we're
2 asking, if you moved away from not only reporting, but ultimately into payment issues, how do you reward
3 and active and successful management of chronically ill patients? And I think those are some of the
4 questions we're to continue to ask ourselves and certainly the thing that we're all going to have to address
5 as we go forward.

6 Dr. Castellanos: Dr. Hamilton?

7 Dr. Hamilton: Thank you very much for that discussion. It was extremely helpful. I learned more
8 about in the last few minutes than I've learned in a long time. But on this related to the Hemoglobin A1c, I
9 have questions. To what group or what individual would one address some suggestions about the way to
10 word this and make it really reflect quality of care rather—would you guys be the right people? Let me
11 suggest that Hemoglobin A1c at 9 is so high that it wouldn't even come close to being anything related to
12 the word "quality." [laughter] And this is not funny, this is really serious. That is too high to be quality
13 meaningful. But on the other hand, if that person's Hemoglobin A1c has been 12 and you've reduced it to 9
14 and a half, that represents heroic efforts, which should be rewarded. So the way that ought to be phrased, is
15 that the Hemoglobin is documented as less than or equal to and you could debate what, whether it's 7 or 7.5
16 but one of those would probably be right, or has been reduced by 1.5% over the last 6 months or the last 12
17 months. That kind of answer would really give you some information about the quality of care for your
18 diabetic patients. But it's the decrease. If you reduced it from 12 to 9.5 that should be a plus. If the
19 Hemoglobin A1c is down in a range where there really is quality benefit, say in the 7, perhaps 7.5%, that
20 should also be credited. So I would rephrase this so that it really reflects quality of care for diabetes.

21 Dr. Haywood: Let me just answer on that one, and I'd be the candidate why that one can be
22 rephrased, which is, believe it or not, if you looked at where we currently are with the measurement and
23 and the life and national quality forum, and Mike alluded to this earlier, about consensus, there's been a lot
24 of consensus in particular on measure as to what is poor control. So that measure if you even looked at the
25 way Mike put the descriptor up there, it talks about poor control. There's a lot of debate currently about
26 what is good control. Is it 7, is it 6? Where do you push the limits? And so there has not been any
27 consensus yet. And so what we did was to say OK, given where the current measurement consensus is,
28 which in on poor control, we'll look at poor control as the starting place, and to the extent that the

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1 community at large moves toward an actual final determination as to good control, then we'll visit that
2 particular metric. The final thing I will comment on that is if you actually believe it or not, if you look at
3 some of the HEDIS data on this particular, even poor control, I believe the numbers are 29 or 35% still
4 have poor control. So even though we all know collectively as clinicians that is not something we consider
5 quality, we still have a long ways to go even on that poor control measure, so that's the backdrop behind
6 that measure; that we took a measure that obviously from a clinician standpoint you wouldn't say indicates
7 good control, and so this is one of those inverse measures, really looking at poor control and how many of
8 our beneficiaries fall into the category of poor control and how many of those we can move into better
9 control.

10 Dr. Hamilton: Well, I understand that. And I understand where you're coming from. But in the
11 first place, there has been a consensus. There have been several consensus conferences over the last 2 years
12 [coughing] in January of this year, which was a diabetes care implementation conference of what the
13 previous consensus was of what we ought to be doing, so there are consensus publications, and I'll be glad
14 to send those to you. But the other thing is that if you really want to measure quality, you need to measure
15 quality. I mean you can't measure quality by counting junkyard cars.

16 Dr. Haywood: But let's be clear, I'm going to push back only because I want to be really clear on
17 this. You can measure quality in terms of what's being provided on the good side, or you can measure
18 what's not being provided. I mean there's 2 different ways—at least 2 different ways of looking at quality.
19 Whether or not you're receiving it, or whether you're not receiving. So what I'm going to say is there's
20 been consensus stating that's the good quality from various groups, so ADA may come out with something,
21 the endocrinologists may come out with something. Different organizations may come out as to their
22 independent consistent statement about what is good quality, but as it relates to ultimately getting into a
23 consensus process like the national qualify forum and the diabetes alliance to come through and come to a
24 conclusion, say yes, this is a standard that we're going to go on for good quality, that's the lynchpin that
25 we're waiting on and—

26 Dr. Hamilton: Well, I will send you that information, because these organizations were
27 represented at these consensus conferences that were held within the last year.

28 Dr. Rapp: The only thing that I would add is that Carlos is, Dr. Hamilton is an endocrinologist.

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1 Dr. Haywood: Yes, that's clear. [laughter]

2 Dr. Rapp: So we're not going to argue with him about what's good and bad, I don't think.

3 Dr. Haywood: I just want to be clear on the process though.

4 Dr. Rapp: Just to amplify what Trent has said, there's an aspect of what physicians can be held
5 responsible for, so I believe that the reason for the actual HEDIS measure is that what is, if the person
6 doesn't have bad control. People will agree that if it's over 9, it's bad.

7 Dr. Hamilton: Well, I think you get lots of different opinions about that. Because certainly 9 is
8 bad, nobody would argue with that.

9 Dr. Rapp: That's what I mean.

10 Dr. Hamilton: But you could be a lot lower than 9 and still be bad. But the point is, is that the
11 change, that's why I phrased my suggestion, that you ought to have either a quality number in there and/or
12 a reduction of whatever, 1.5% over the previous 6 to 12 months, so that if you reduce from 12 to 9.5, you
13 get credit for providing good care to that patient, even though you haven't gotten to a level that you would
14 like to have, you've really done some good things.

15 Dr. Rapp: But just to add to what Trent was mentioning as well, and I think this is important for
16 physicians to understand, CMS is not seeking to set itself up as the arbitrar of measurement. We utilize and
17 derive our measures from other consensus processes.

18 Dr. Hamilton: Well, that's why I'll send this you because that has already been determined.
19 There's no question.

20 Dr. Rapp: And the consensus process that has been basically, the only organization that identifies
21 itself, although there's lots of methods of consensus that identify themselves as the consensus body for
22 quality measurement is the National Quality Forum. So the other consensus bodies that you're talking
23 about are looked at more as developers of measures, and after they're developed, they go through a broader
24 consensus process, which is the NQF. So the measure that you're talking about, it sounds perfect good, but
25 it hasn't gone through that process, so if we were to adopt it, it would be somebody might say well this is
26 CMS selecting from a number competing measures.

27 Mr. Kuhn: And I think you've raised 2 important points. One I'll just follow up with what Mike
28 says is that CMS is trying to do here is erect a platform from which we can gather the data. We'll leave it to

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1 the community at large to develop the measures and develop the consensus process. I think you make a
2 good observation. It's one that we heard earlier through our process that 9% maybe is not the best
3 threshold, but at least the current publicly consensus processes of what they've brought forward, I don't
4 think anybody in this room wants CMS to also be the one in charge of saying this quality and this isn't in
5 terms of the development of the measures. And so we're trying to step back from that and let a consensus
6 process drive that. And I think that's the right way to go and I think people will probably agree.

7 Dr. Hamilton: I will send you this information because there is a better way.

8 Mr. Kuhn: But the other point you make is a good point. Also a good point is also kind of driving
9 a little bit in terms of the payment and do you reward absolute level of performance, or do you reward
10 relative improvement. And I think those are also, as I mention those other questions, those are also
11 questions we're asking ourselves. I know Capitol Hill's asking themselves, as we move from the reporting
12 to the payment, those are absolutely fundamental questions that have to be answered as we go forward here
13 of what are you trying to reward in the process.

14 Dr. Hamilton: One of the big arguments against this whole process that you will hear from time to
15 time is that it will cause physicians to select only the so-called good patients. Those patients that really do
16 what you tell them to do; take your medicine, follow your diets and all that stuff. The ones that don't, we'll
17 send them to somebody else because I don't want that black mark on my card.

18 Mr. Kuhn: The issue of noncompliant patients is certainly one we're dealing with, too.

19 Dr. Hamilton: This particular way of changing the phrasing of this would help address that issue.
20 If you have gotten a bad patient into being a better patient, then you ought to get some credit for it. And this
21 would be a way to do that.

22 Dr. Castellanos: Dr. Azocar?

23 Dr. Azocar: Yes, actually, arises the point that one of my concerns, there are some practices, some
24 physicians, which happen to be many in the taking care of certain minority groups where the risk factors
25 and the compliance and other issues affect the outcome and are significantly higher, so different. So that
26 may be a bias when you try to compare physician groups that practice, that cover different populations. It
27 may be convenient, now that you are at this stage of the pilot to kind of consider the possibility of that
28 viability on the patient population.

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1 Dr. Haywood: Yes, this is one of those areas in which we've talked internally and starting to talk
2 externally with some of the lead physician organizations that serve the under-served populations. Because
3 this is one of those scenarios where we don't want to risk adjust away the problem. In other words, if the
4 under-served community is having higher impact from diabetes and things of that nature, we want to make
5 sure that they have quality of service really to the extent possible that can actually improve their overall
6 health outcomes. At the same time, we don't want to disincentivize clinicians taking care of those patients
7 for concern that somehow their performance measure is going to be negatively impacted. And so through
8 this pilot program, and through vehicles, we're really trying to work on this particular issue. How do we
9 make certain that we minimize our unintended consequences, and actually provide if nothing else, provide
10 incentives. And people have talked about different ways of approaching that particular scenario. And part
11 of it is going to play into ultimately, once you start talking about linking it to payment, things of that nature,
12 whether or not you end up providing incentives for people to take care of those patients or disincentivize
13 those. And there's ways to incentivize people to actually do the right thing for those particular patients. So
14 part of that is in the ultimately how you actually use the [coughing]. But I agree, that's one of the specific
15 areas that we have highlighted as a key concern about unintended consequences, if the desire, if the
16 ultimate desire once you start linking it to payment does not appropriately account for that.

17 Dr. Hamilton: Well, we will get you some information on this related to the Hemoglobin A1c
18 because it really would be helpful to get this right the first time.

19 Dr. Haywood: Yes, and I think that's pretty—we will welcome that information and to the extent
20 that National Quality Forum has come to an agreement that we're unaware of now—I'd be surprised—but
21 if we're unaware of that, let us know.

22 Dr. Castellanos: Dr. Senagore?

23 Dr. Senagore: I just wanted to believe that the [off mike] performances here be ultimately driving
24 the reimbursement, but I have a question about methodology. And this is very distinct from what industry
25 does in terms of quality improvement. And I would suggest an alternative for you to consider, that rather
26 than micromanaging care, you're moving to a process that you will be able to better tie physicians to
27 patients in terms of identifying data. Why not go for the \$40,000 foot view—why not, who cares with the
28 Hemoglobin A1c is? But what is Dr. Hamilton's amputation rate? What is Dr. Hamilton's renal failure

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1 rate? What is the dialysis rate? What is the blindness rate from retinopathy? Those are true outcome
2 measures and whether the Hemoglobin measure is 8.9 or 9.1 or whatever doesn't matter in that schema.
3 And then what you'll be able to do is have a dataset of better outcomes and worse outcomes and pick better
4 providers. If his amputation rate is zero, whatever he does, who cares what the Hemoglobin A1c rate is?
5 He's a superior provider. And if you could come at it from that way, it would avoid all of this interim step
6 of minimal data inputs really to try to drive a process. And I'll give you one example that's clear. 20 years
7 ago, hormone replacement therapy was standard of care, a good thing. All the data now suggests it doesn't
8 derive any of the benefits we thought that it did, yet had you chosen that as one of these G-Codes, everyone
9 would have been dinged on it, and we would not have moved care.

10 Dr. Haywood: Yes, let me address 2 things that your anecdote gave, and the second thing address.
11 On the first issue, no matter where you go, if you sit around the table, or even if you're by yourself, and
12 look in the mirror you're probably going to have this argument, which is process versus outcome or all of
13 the above. And we've continued to say is that to the extent possible, we don't think it's a one way or the
14 other way. We really want to be able to as we indicate get at outcomes, which is what you're talking about,
15 getting at true outcomes, but in the interim, also looking at the processes that we believe lead to those better
16 outcomes. And there's also some systems and structural things that we haven't talked about today. Just to
17 be clear on the outcomes when you really start talking about outcomes, more or less, what you really end
18 up starting to get into quickly, you start getting into conversation about what the appropriate risk
19 adjustment is, the issue that Dr. Azocar just raised about who you keep in that denominator, who you keep
20 out of that denominator? You quickly have to get into those type of debates about whether or not we have
21 the appropriate risk adjustment methodology or not to be able to get out and then you also just to be clear,
22 on the outcomes, you also normally start getting, quickly start getting into debates about whether or not the
23 sample size is large enough to be able to discern outcomes in comparison to process. So it's not that we're
24 not trying to get there. We are trying to get there, collectively, again, keeping in mind that CMS is not
25 trying to do this alone. Collectively. That's where we want to be able to go towards outcome. Hemoglobin
26 A1c is just the intermediary outcome. It's not a process. It's an example of an intermediary outcome, but
27 that is exactly where we want to go, ultimately, is to be able to—

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1 Dr. Senagore: I respectfully disagree, and I'll take an example from my specialty for rectal cancer.
2 There was a Swedish trial that said that if you gave preop radiotherapy the results were better. It dropped
3 the recurrence rate of 25% to 15%. Sounds pretty good. The problem is 15% is a recurrence rate was far
4 higher than any good surgical groups were getting. The reality was you had bad surgeons trying to be made
5 a little bit better by radiation, which was very expensive and toxic and it took 2 more trials, to show what it
6 really did. You needed better surgeons doing a good operation and then appropriate use of an adjuvant
7 modality. So had you just chosen doing radiotherapy and you're good to go, would not have driven the
8 outcome measure.

9 Dr. Hamilton: Just in defense of what CMS is doing though, the Hemoglobin A1c is a very
10 effective way to predict these outcomes that you mentioned. Certainly there would be advantages to using
11 the outcomes as the absolute measure—

12 Dr. Senagore: But even your comment about trends is an issue, right?

13 Dr. Hamilton: But on the other hand, well what you're talking about those outcomes are also very
14 closely related to the years that that person's had diabetes. And you will before you start getting meaningful
15 data, you will have to follow those patients over a much longer period of time. The Hemoglobin A1c has
16 the advantage of showing effective treatment trends over a shorter, 3-6-12-month period. And I think that I
17 would keep the Hemoglobin A1c as your endpoint for these studies with the realization that that's just a
18 reflection of the ultimate outcomes that Dr. Senagore mentioned.

19 Dr. Senagore: With all the year's that Medicare's been in place, there is no data set to say that the
20 amputation rate in Medicare beneficiaries from the time they start to the time they succumb is 12%. That
21 the renal failure rate is 18%. We have no data to go back and build. I mean if you look at like the UK, that's
22 much further along in this sort of process. That's how their strategy goes. They start with outcomes, look
23 back at data, now their NHS has been in place since what, '46, '47? So they have a longer data set. But they
24 said here's the outcomes that we considered undesirable, and these are rates that we considered too high.
25 Now let's go back and look at who were better practitioners who weren't, what evidence-based data applies
26 to that, rather than just arbitrarily picking something like this that it may be the best thing since sliced bread
27 to do it, but maybe there's a test that's going to come up 5 years from now that even better predicts that.

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1 Dr. Hamilton: Well, there are a lot more people with diabetes that die that don't have amputations
2 or have go on dialysis. So if you really want to use an endpoint you ought to use survival.

3 Dr. Haywood: Just to jump in, which is risky, given that any time I can have two PPAC members
4 argue versus me, [laughter] the only thing real quick before we move on real quick to other questions, the
5 other reason we keep talking about process as well as outcomes, because we do want both, is that to the
6 extent that we're talking about quality improvement which I said is one of our goals, that evidence base to
7 be able to show clinicians based upon in comparison to peers, not only if you just had your outcomes, but if
8 you're able to be able to show them this is what your peers are doing on process that are evidence-based
9 that are related to those outcomes, then that allows for those clinicians to be able to target some of those
10 acts—so not disagreeing with anything that you said, but that's the other benefit of actually looking at
11 process measures, is being able to hopefully provide that feedback mechanism to those clinicians so they
12 can improve their overall quality.

13 Dr. Simon: I think also continued as well, because I think that if you look at outcomes, there's no
14 Medicare data, but if you look at outcomes for example for diabetics that undergo amputations, we know
15 that for those individuals once they sustain an amputation, whether it's a digit or at the TMA level, 50% of
16 those diabetic patients will be bilateral amputees within 5 years. So then it relates back to the quality of
17 care. If they are in fact actually being followed, their diabetes is being managed appropriately, whatever
18 that number is for that Hemoglobin A1c, if they're getting the appropriate treatment and getting appropriate
19 preventive care, meaning that they're shoes and socks are taken off at each visit, and they're getting
20 evaluated to be assessed for pulses and tissue loss, then you will in fact not only save money, but improve
21 the quality of life for that diabetic patient. So I think it's a continuum where you have to look at both the
22 intermediate outcomes as well as the long-term outcomes that you're referring to that ultimately will
23 achieve success, both in terms of cost savings for in this case for the agency, but more importantly improve
24 the quality of care for the patients so that they don't get on that road where they're then faced with losing
25 their independence being placed in assisted living homes, or in nursing homes, etc. So it's not a perfect
26 system at this point, but I think that depending upon the road and we've chosen the road that we're
27 embarking on, that ultimately gets us to that desired endpoint where we can achieve savings and improve
28 the quality of care for patients.

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1 Dr. Castellanos: Dr. Powers, Dr. Grimm, and then Dr. O'Shea.

2 Dr. Rapp: I might just mention something about what Dr. Senagore brought up and I think he's
3 talking about clinical data registries or something similar to that that they use in the UK. Next week, on the
4 8th of December, actually, CMS is hosting in collaboration with the ambulatory care quality alliance a
5 meeting where we're going to actually explore the issue of clinical data registries, and the possibility that
6 those might be a vehicle to assess physician performance, but something like that, much more than a
7 claims-based system like this would potentially do exactly what you're talking about if one set up the
8 diabetes registry, or just or other registries, so we're going to have an all-day conference on that. I can send
9 invitation to the members of the PPAC if any of you happen to be in Baltimore on the 8th of December, you
10 can come to it and I'd be interested in having you.

11 Dr. Powers: I had a problem with using—I think you have to use process measures because I sit in
12 a different situation that Dr. Senagore does. I take care of patients who are going to die no matter what you
13 do. My ALS patient is going to die and my job is to make the rest of their life better, and so that they don't
14 die in pain. And I take care of [inaudible] patients and those patients are going to die. But I have to make
15 sure that their quality of life is better; they don't have seizures, whatever. And that's why we need to have
16 process measures. You're sort of in a way looking at outcomes as good, for certain diseases, but you have
17 to look at the Hemoglobin A1c, because if you're not taking care of the patient ahead of time, if you're
18 looking, if you start looking at managing the patient, then they're not going to need those amputations. I
19 mean you're starting backwards by looking at the outcomes first.

20 Dr. Grimm: First of all, I've been in the Quality Assurance business for about 5 years, so I'm very
21 familiar with this process of how to establish quality assurance right from the beginning, and process is the
22 first thing you have to establish in terms of can you get this in place, so that people—and then you have to
23 establish a cut point. And a cut point is a consensus of experts and Medicare then is using the experts that
24 are available. They're not going to work separate from you, Tony, or anybody else, and say we're just,
25 that's just going to be an arbitrary sort of cut point. They're going to have to find one. And I tell you when
26 you get a group of people into it the cut point gets pretty low, so that everybody accepts it to begin with at
27 least, and then you can move it up. And as Carlos was saying, there's a spectrum here, which you're trying
28 to move up what is quality. Because what quality is for me and what's quality for somebody else is much

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1 different because my experience and everything else. So there is a spectrum here. So what you try to do is
2 you try to move everybody up the scale. But you can't do that initially. Initially, you have to start at a very,
3 very basic point. But more importantly to all of this is one thing I know, having a business, is this takes
4 time. And it takes money to be able to do this stuff. And you've addressed that. And I was interested in the
5 fact that the hospitals get some incentives to do this, yet there's nothing here for the physicians to do this,
6 and I want to know why? What is the rationale for that? Is that, doctors don't need it? Or the hospitals
7 deserve it more? Tell me why? Why do they get a 4% incentive and we're not getting that?

8 Dr. Haywood: I'm hearing my first argument for the Hill to go ahead and quickly implement Pay
9 for Performance today [laughter]. No the reality is as I started out, I tried to highlight, and this is going to
10 continue, I think to be an issue of conversation, even throughout the pilot programs, so let's be clear on that
11 particularly as it relates to different physician offices, or totally different things as to how much of an
12 impact as far as their cost is going to have. On the hospital side, though, to be clear on that model, what we
13 started out with, it didn't get paid up front. They only got paid later on in 2004 when the Hill actually
14 moved. But we already had the infrastructure in place. We already had tested report mechanisms. We
15 already had tested the feedback mechanism as well so there wasn't dollars. No, we don't like hospitals
16 more than physicians or anything of that nature, but it is really the same model whereby starting out we did
17 work with clinicians. Again, on a voluntary basis, just like hospitals, everyone didn't step up, they had their
18 own reasons for stepping up or being able to step up at that time, where others cannot. And then, once the
19 financial incentive kicked in then more of the hospitals are able to step up. And we think similar, to be
20 honest, that's going to happen on the physicians' side as well, that there are going to be some physicians
21 that are ready and available and able to actually participate and help us, whether it be in conversation like
22 this, or whether it be actually submitting the data to us up front, and then improving that reporting
23 mechanism and improving that feedback mechanism. And then we'll see down the road whether or not the
24 Congress acts on that and actually links some financial incentives for this as well.

25 Dr. O'Shea: I can see from the testimony that's been given, that hopefully the audience and the
26 [inaudible] do recognize that clinicians are actually about all we get. That's truly what we do everyday. But
27 one thing I wanted to readdress, is that we hope that CMS recognizes the administrative burden that this is
28 going to place on most physicians. And that when you look at that, the smaller practices make a less than 3,

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1 2, or 1 practitioner practices are 50% of the practices in the United States, and that all of the costs that it is
2 going to have to come along with going on to this voluntary program is not really being addressed. So what
3 I think that you have to recognize is that you're selecting out larger practices, or practices that already have
4 EMRs and so you're skewing the data even to begin with that you're collecting. And I know again, it's just
5 a pilot; you're just trying to test the waters to see but you're testing it in a way that doesn't address the way
6 that specialty physicians and organizations work, nor are you really looking at, I'd say, the majority of
7 practices within the United States. And I'd like to make recommendations.

8 Dr. Castellanos: Please.

9 Dr. O'Shea: PPAC recognizes that the Physician Voluntary Reporting Program will require
10 additional staff, training on the use of G-Codes, reconfiguration of computer software programs, all of
11 which means increased cost to physician practices. PPAC advises that any effort to implement quality
12 measures and reporting must come after physician payment reform and a reduction in current regulatory
13 and administrative demands. Otherwise, efforts to improve care will be impeded. PPAC recommends that
14 CMS—

15 Dr. Castellanos: One at a time.

16 Ms. Trevas: One at a time then I need to repeat that.

17 Dr. O'Shea: OK. I'll go slow. May I please start at PPAC advises that any effort to implement
18 quality measures and reporting must come after physician payment reform, and a reduction in current
19 regulatory—

20 Ms. Trevas: [off mike]

21 Dr. O'Shea: PPAC advises any effort to implement quality measures and reporting must come
22 after physician payment reform and a reduction in current regulatory and administrative demands.
23 Otherwise, efforts to improve care will be impeded.

24 Dr. Castellanos: Is there a second to that?

25 [Second]

26 Dr. Castellanos: Any further discussion on that motion as it's presented?

27 Dr. McAneny: I think that regulatory administrative demands is key here because even though you
28 do not what this to be a chart review, even if I'm looking to see whether or not an Osteoporosis patient has

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1 been given that G-Code that year, there will be, I have to do a chart review to figure out whether I did it,
2 you know. I see hundreds of patients. I can't remember which one I coded a G-Code for Osteoporosis this
3 month, much less this year. And then for most, even with electronic health records, the way old records are
4 put in is that they have to be scanned in, because you can't just get rid of them. If you scan them in, they
5 are by definition not searchable. So if I'm to go back and find out all of the details of whether somebody's
6 internal carotid or internal mammary was used, or whether or not they have had their Hemoglobin A1c
7 taken this year, then I still have to go back and do that chart review. And my third concern is that even if
8 for example, Carlos takes these patients and spends huge quantities of effort on them, and they still eat pie
9 and ice cream all day long and they still have terrible Hemoglobin A1c's and they still get their
10 amputations, weren't his efforts worth anything? Shouldn't he be still paid for making the effort to deal
11 with the noncompliant, socio-economically disadvantaged whatever, whatever, whatever patient that is
12 going to have a bad outcome? This will really make it difficult for physicians to do that, and so I would
13 strongly echo what Laura said earlier about making sure you have significant process measures in there. If
14 he documents that, he really tried, sent them to the dietician for the 17th time, etc., and they still eat pie for
15 breakfast, there's not much he can do about it. But his efforts are still worth paying for.

16 Dr. Castellanos: Any further discussion?

17 Dr. Leggett: I think Dr. O'Shea's comments are well advised frankly, because as this entire project
18 moves from voluntary to mandatory which clearly is going to happen, the burden that's going to be placed
19 on the physician offices is going to be tremendous. No one can sit here and convince me that the voluntary
20 participation after this is going to be reviewed in retrospect is not going to evolve into something that says,
21 if it in fact works, that now we just want everybody doing it. Because if we are truly about quality, and you
22 find in this pilot that it somehow gets us closer to that point, I can't imagine that it's not going to be some
23 sort of mandatory movement across the United States to have more physicians doing it. And then as that
24 evolves, you're going to have a disaster on your hands. Because now you've got to choose a variety of
25 areas of medicine in which you have to define not you, being CMS, because we know you're not doing it,
26 but from your, the people that you bring to it, you're going to have to define kind of what areas in all of the
27 diseases that are out there, that you want to start evaluating this quality issue, and frankly, I find that that's
28 going to be momentous at best. And I guess the only last comment I'd like to make is that I just want to be

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1 on record of having said that physicians care about quality, and the idea that we have to be paid in order to
2 upgrade quality is disturbing, and it borderline insulting. I know that there are doctors out there who are not
3 following guidelines and who are not practicing good medicine, but this notion that money will make us do
4 it is a bit distressing.

5 Dr. Castellanos: Just to add a comment about cost because I looked into it in my office. I'm going
6 to have to redesign my work flow between the clinical and office buildings and office staff. I'm going to
7 have to change the internal billing software. I'm going to have claim the clearing house software, the
8 scrubber's software, the software center healthcare providers and CMS. I don't have internal people on
9 that. I've had an estimate and it's about \$15,000. That's a lot of money to do a voluntary project. And I do
10 want you to understand that that's money that today, with potential decreases is going to be difficult. We
11 have a motion on the floor. Could we read that again please?

12 Ms. Trevas: The Council recognizes that the physicians Voluntary Reporting Program will require
13 additional staff, training on the use of G-Codes, reconfiguration of computer programs, and increased cost
14 to physician practices. Therefore, PPAC advises that any effort to implement quality measures and
15 reporting must come after physician payment reform is enacted and current regulatory and administrative
16 demands are reduced, otherwise, efforts to improve care will be impeded.

17 Dr. Castellanos: Is there any further discussion? All in favor?

18 [Ays]

19 Dr. Castellanos: Opposed? Thank you. Dr. Sprang? Dr. Przyblski?

20 Dr. Przyblski: A couple of things. You had asked some questions for us to sort of ponder. One of
21 those was sort of using a hospital data collection information and at least in my experience, a lot of times
22 the ICD-9 Codes that the hospital's chosen are not the same ones that the physicians would have chosen, so
23 I would urge some caution there as to the consistency between hospital and physicians in ICD-9 choices.
24 One is in the reporting. The report looks nice. It shows you how often you reported and how often you are
25 successful. I presume that and maybe I'm falsely presuming, that you would give comparisons either
26 nationally or regionally, because I think the only way that you're going to affect behavior is that people
27 know where they stand relative to their peers. So that I think would be important in any reporting. As a
28 surgeon, I sort of looked at all of this, and thought well this is going to be very easy. There are only 2

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1 things that apply to me; preoperative antibiotics and thromboembolic prophylaxis and when I read through
2 the details of this, I found exactly the opposite, at least for neurosurgery. As Dr. McAneny had already
3 pointed out, many of the measures that you're looking at are age-only driven with E&M services, so that's
4 Osteoporosis in the woman over the age of 75, falls in men and women over 75, hearing and urinary
5 incontinence in men and women, mammography in women over the age of 40, pneumococcal vaccine in
6 people over the age of 65. So any E&M service provided, if I wanted to volunteer to participate, that is as
7 you've already mentioned, already half a dozen things that I in a sense ought to be reporting on for every
8 patient that I see in the office. I know that's not your intent, and may the instructions be altered to say if
9 you are the primary care physician of this patient, or if you are the geriatrician of this patient because I
10 suspect you're expecting a subspecialist that's related to that particular problem is taking care of it as
11 opposed to any physician that's taking care of it. On the flip side, antibiotic prophylaxis seems to be a
12 rational thing, yet there are no neurosurgery CPT-Codes in that list, and there may have been a reason to
13 have it or not have it, and you may be able to enlighten me on that, but for thromboembolic prophylaxis
14 what I looked at in multiple different surgical disciplines, it was not all of the codes, it was some of the
15 codes. And there may be rationales again for that, but now if you're trying to reduce the burden on the
16 physician to voluntarily report, I now have to actually pay attention in neurosurgery to a very long list of
17 CPT-Codes which is not all inclusive, to see if it fit, or didn't fit, and when I went through the neurosurgery
18 codes, there were things that made sense, and there were a lot of things that didn't make sense. So that
19 obviously adds to the burden, and makes it less likely that I would voluntarily report.

20 Dr. Haywood: Thanks for those comments. We'll definitely to the extent possible, clarify
21 instructions. Because we don't want to confuse anyone out there as to what we're requesting and you're
22 correct, our intent is for those type of metrics that are dependent upon a primary care of management, that
23 we don't want the surgeon reporting those particular services. Kind of reminds me of one time I was
24 visiting a hospital, and the surgeon was joking, saying that our activity at the time which was not related to
25 voluntary reporting was making him feel like a charlatan, because he's walking around with the
26 stethoscope, and his colleagues was asking him why? [laughter] But the reality is we definitely don't want
27 that, so yes, you're correct for a surgeon, primarily it would be antibiotic and thromboembolism, just so
28 you know and we're going to revisit this issue, so I'm glad you raised it. We had a lot of debate about the

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1 specification on those particular metrics. And this is kind of that push and pull between what's already in
2 the NQF process and what had already been spec'ed out and versus many other surgeon specialties coming
3 to us saying—the reality is neurosurgeons and other specialties came to us saying the reality is that beyond
4 what's in the surgical care improvement project is where a lot of that specification came from for those
5 surgeries, is that they were doing the same thing and it was definitely appropriate and it was evidence-
6 based for their services as well, and so Ken Simon and some of us internally, we're still debating as to
7 whether or not she would go ahead and expand it or not, and we were actually waiting for some of this type
8 of dialog and discussion to hear it from the clinicians out there whether it would be appropriate to go ahead
9 and expand that to include other surgical services. So to the extent that we're hearing more and more of
10 that, then I think we will be revisiting that and going ahead and expanding that, and then the issue that you
11 raised that we didn't necessarily speak specifically about, but that's a good point, that by not expanding it's
12 forcing you to have to take another additional step, and so instead of reducing burden, which is what we
13 want, we may be actually increasing a barrier that we shouldn't. So we'll definitely take that under
14 advisement.

15 Dr. Simon: And that was part of the real discussion in that the standard of care for a number of
16 procedures is to give antibiotics preoperatively and looking at the NQF data, that existed, they had a finite
17 group of procedures and so we were struggling with whether to expand that list though it hadn't been vetted
18 through the NQF process or to just use the NQF process. So we do appreciate the comments that the
19 Council is providing in this regard.

20 Dr. McAneny: I agree that physicians shouldn't have to be paid extra to provide quality care, but I
21 don't think that what we're trying to do here really with the whole Pay for Performance thing is to pay for
22 extra quality care. It's documenting for dollars. And in this case, it's documenting for no dollars. So I think
23 that we need to recognize that documentation is an expensive process, like Dr. Castellanos mentioned, but I
24 think that what you're hearing around the table is that we all would like to be able to prove that in some
25 manner that we are providing good quality care and I think that all physicians would like to be able to
26 prove that and to figure out if they're not, how to get there. But I don't think this is it. So I'd like to make a
27 recommendation if I might.

28 Dr. Castellanos: Please.

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1 Dr. McAneny: PPAC recommends that instead of implementing the current PVRP demonstration
2 project, that CMS goes to each specialty and determines appropriate scientifically valid measurements,
3 adjusted for illness severity, socio-economic factors, patient compliance, and co-management of patients
4 and like the hospital program, pays for data collection.

5 Dr. Castellanos: Is there any discussion on that? Dr. Grimm?

6 Dr. Grimm: Yes, I'd like to just poll the PPAC members here. How many of their specialty groups
7 are already doing that very same thing? How many are already in the process of providing quality measures
8 to Medicare already? Almost all the specialties are already doing that, Barbara, so I don't think that's a
9 pertinent issue in this discussion, because that's exactly what they're doing. I don't see the point of, I mean
10 why ask them to do that if it's something they're already doing?

11 Dr. McAneny: Well, I think that this particular program is not using those particular, for example,
12 the quality oncology practice initiative is not these measurement and it's not the ones that are being used.
13 And I think that as you've heard around the table, that the measurements—

14 Dr. Grimm: This is not a quality measured process. This is a process, maybe I'm
15 misunderstanding, but he's emphasized several times, this is not a quality program that they are
16 implementing. They're just looking at the process of this and they're using some very simple quality
17 measures. But to suggest that this is going to end up as the quality, correct me if I'm wrong Trent, but that's
18 not what the point of this is. Right?

19 Dr. McAneny: It's listed under P for P on the website.

20 Dr. Haywood: Let me just—I know you guys have a motion on the floor, so I don't know if it's
21 appropriate for me or not to—

22 Dr. Urata: It hasn't been seconded, though.

23 Dr. Haywood: So,

24 Dr. Castellanos: It's appropriate to have discussion.

25 Dr. Haywood: OK, so I'm part of that. The clarification I think is required I guess a little bit. As it
26 relates to the measures, we definitely are receiving input and continue to receive input from all the specialty
27 organizations on pretty much across the board. And we've done that not only independently, meaning
28 working with them one on one, but also collectively, whether it be through the Ambulatory Care Quality

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1 Alliance, or others working with the AMA Physician Consortium, so to the extent possible, we're definitely
2 reaching out and getting that type of feedback. As it relates to the measures that you currently see, right
3 now, I'd last look at this, I think is appropriate for roughly 23 specialties at best. These kind of 36
4 measures. It doesn't encompass all services at all by any stretch of the imagination, nor does it encompass
5 all specialties. What we definitely want to be able to do as part of that process is broaden that activity to
6 actually encompass more service and more specialties to the extent possible. Again, keep in mind, with our
7 process, it has been that the clinicians actually come to us and tell us where they currently are on the
8 particular metrics and how it makes sense for us to move forward on certain particular metrics and not, so I
9 don't think the characterization that we've chosen measures that other specialties have not necessarily
10 supported is not quite accurate. They've been through some type of consensus process or are going through
11 that currently consensus process. The final thing is I think in the next few months, you will actually see as
12 part of what CMS and AMA Physician Consortium and others are doing is to actually broaden that to
13 where those are specialties that don't currently have measures, will also have metrics. I did want to
14 highlight segue for a second, and then I'll turn it back to the motion at hand. I did just want to highlight
15 because I've heard this conversation and as a physician, I guess I would be offended, too, if somebody
16 walked in while I was taking care of a patient and said that I'll give you just a few more dollars if you take
17 care of him correctly. [laughter] That's not the CMS approach on all this, in fact, one of the reasons why
18 we're so eager to move forward on the pilot is because we're concerned that our financial system currently
19 as constructed does not actually support that activity. In other words, at minimum, we're neutral and at
20 worse, we may be negative toward physicians that are actually taking those steps. And so to the extent that
21 we can actually start supporting those individual clinicians and moving our financial system in a way that
22 actually supports quality and is not adverse to quality, that's what we're trying to do here, so it's not
23 anything and any disrespect to clinicians out there. Instead it's saying, listen, we have a problem, and we
24 think it's not the clinician, we think the system is the problem, and we need to actually redesign our system
25 to support the activity that we think clinicians are actually out there trying to achieve but for some system
26 concerns. And so to the extent that we can align our financial system to support that, that's what we're
27 trying to do. This pilot just to conclude on what you started, Peter, this pilot is designed to start that process
28 by allowing us to see, can we collect information and to the extent possible, in the least burdensome

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1 manner available and then can we actually improve that feedback mechanism to clinicians, so that they can
2 actually have the information and improve their quality. So we welcome any comments or suggestions on
3 how we can actually achieve that so we can make it as least burdensome as possible, and provide that
4 information back to clinicians so we can improve the quality.

5 Dr. Castellanos: There's a motion on the floor. Is there any more discussion on that motion?

6 Ms. Trevas: Could you read that back, please?

7 Dr. Urata: Was there a second to that motion?

8 Dr. McAneny: PPAC recommends that instead of implementing the current PVRP demonstration
9 project, that CMS goes to each specialty and determines appropriate, scientifically valid measurements
10 adjusted for illness, severity, socio-economic factors, patient compliance, and co-management of patients,
11 and like the hospital program, pays for data collection.

12 Dr. Castellanos: Does everybody understand the motion? Is there a second to that motion?

13 [Seconds]

14 Dr. Castellanos: Any further discussion?

15 Dr. Przyblski: I would support the idea, I think that the concept that was being discussed that
16 specialties are already necessarily getting that information to CMS is not accurate. I mean NQF is
17 providing some information. Clearly you've heard from the neurosurgery standpoint, when I look at even
18 the two surgical measures, the one that we have reporting measures on is probably the least agreed upon in
19 our specialty, meaning there's not a lot of even good class III evidence for thromboembolic stuff. Whereas
20 we actually have some Class I evidence on the antibiotic stuff and there's no reporting required for CPT-
21 Codes in the neurosurgery section. So I would say that the specialties aren't necessarily getting that
22 information out to CMS so I think that the motion is very appropriate.

23 Dr. Castellanos: Is there any other further discussion?

24 Dr. Urata: I could support the second part of the motion which is pay for data collection, although
25 I don't think that'll ever happen because it's not legislated.

26 Dr. Castellanos: Dana, could you read that once more and then we'll take a vote?

27 Ms. Trevas: Instead of implementing the current Physicians Voluntary Reporting Program
28 demonstration project, PPAC recommends that CMS go to each physician specialty group to determine

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1 appropriate, scientifically valid measures adjusted for illness, severity of condition, socio-economic factors,
2 patient compliance and co-management of patients and like the hospital program, pay for data collection.

3 Dr. Castellanos: Thank you. All in favor of that motion?

4 [Ays]

5 Dr. Castellanos: Opposed.

6 [Nay]

7 Dr. Castellanos: Is there any other discussion? I think we have some questions they asked, and I
8 think it would be appropriate that we try to respond to their questions. One is: What is your advice for using
9 claims data for reporting of quality data? Anybody want to comment on that?

10 Dr. Przyblski: The easiest time to be able to send you any information is when I'm sending a CPT-
11 Code about that information. The patient information is fresh in my mind. This would seem to be least
12 burdensome way to get the data to you.

13 Dr. Hamilton: Yes, I agree. I think it's logical.

14 Dr. McAneny: Yes.

15 Dr. Castellanos: It's logical.

16 Dr. Hamilton: The place to have that diagnosis. That ought to be your...

17 Dr. Urata: I would see that I would have to produce, unless you produce for us, a new claims form
18 with all those G-Codes with instructions on it. I mean that's how we do it now. Is we develop our own
19 ICD-9 Codes and E&M-Codes on one billing slip. So I would have to do a second page of a billing slip
20 with all this information on it, or at least the G-Codes with some indicator of what it stood for. And maybe
21 you could produce that for us, or suggest it for us, so that we could just download it and put it with all our
22 Medicare patients.

23 Dr. Senagore: You mentioned earlier do we know that these G-Codes will make it through current
24 scrubbers without kicking claims out and will that impede your ability to get a bill out the door depending
25 on your individual billing program?

26 Dr. Grimm: Does checking off a G-Code affect payment for the other codes.

27 Dr. Rapp: No.

28 Dr. Grimm: OK, that's critical.

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1 Dr. Rapp: There's a zero amount of money as far as the billing and it will not impact it one way or
2 another. If the claim is billed without a G-Code it goes through, if it's billed with a G-Code, it goes
3 through. Although I'm not in charge of that part, but I'm sure that that's the case.

4 Dr. Hamilton: It disturbs me a little bit about that last motion made—you would have to concede
5 that CMS has the option to do a pilot, then they could choose what they want to put in the pilot. If you
6 really followed the admissions of that motion, it's going to be to put the pilot totally on hold and ask
7 every specialty organization what parameters of quality they would think ought to be assessed. That's not a
8 pilot. You're likely to get hundreds and hundreds of issues that would be appropriate measures of quality.
9 But that's not really a pilot program, and CMS should be able to choose what issues they want included in
10 the pilot. Perhaps it would be better to suggest that appropriate specialty organizations related to the issues
11 in the pilot are asked to comment directly to CMS about the use of those criteria.

12 Dr. Castellanos: Do you want to make that as a motion?

13 Dr. Hamilton: Well—

14 Dr. McAneny: Friendly amendment.

15 Dr. Hamilton: Well, since we've already approved the previous one, I think it would have to be a
16 new motion. But yes, I would suggest that CMS, that PPAC ask CMS to request comments from
17 appropriate specialty organizations that have an interest related to the issues that are already included in the
18 proposed pilot program for their assessment.

19 Dr. Castellanos: Is there any discussion on that motion? Seeing none, is there a second to that
20 motion? Do I hear a second?

21 [Second]

22 Dr. Castellanos: Dana could you read that back to us please?

23 Ms. Trevas: PPAC recommends that CMS request input from appropriate specialty organizations
24 with an interest in the issues already included in the proposed pilot program.

25 Dr. Castellanos: Does everybody understand that motion. All in favor? You've got to raise your
26 hands.

27 Dr. Grimm: I have a question, is that in addition to the last motion that was passed or it is—

28 Dr. Castellanos: It's a separate and distinct motion.

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1 Dr. Grimm: And then are they consistent?

2 Dr. McAneny: Well, they're not. One says have it go away and put it back to the drawing board,
3 particularly because measuring quality is so very, very complicated and has so many convoluting factors.
4 But I guess this one I would take as if they elect to reject that one and not take this back to the drawing
5 board, then they at least ought to go to the specialty societies for the one that they're doing and get more
6 data and suggestions.

7 Dr. Castellanos: I think it's possible to have 2 separate motions.

8 Dr. Hamilton: Yes, I think so.

9 Dr. Castellanos: I think it's possible to have 2 separate motions. Is there any further discussion?

10 Dr. Urata?

11 Dr. Urata: I think they're going to deny the first one.

12 Dr. McAneny: I do, too.

13 Dr. Urata: The first one is inappropriate, that's why I voted against it, and this one might be more
14 palatable.

15 Dr. Castellanos: So you're speaking for the motion?

16 Dr. Urata: I'm speaking for the motion.

17 Dr. Castellanos: Is there any further discussion on the motion?

18 Dr. Sprang: Just to if you want to add to it, the payment portion for doing the work, the second
19 part of her motion.

20 Dr. Hamilton: We can certainly add that to the second motion if the first motion is kicked out.

21 Dr. Sprang: As well, correct.

22 [chat]

23 Dr. Castellanos: So you're asking for a friendly amendment to what's on the table. May I ask what
24 that is?

25 Dr. Sprang: That we add the second part of Barbara's as far as payment for—

26 Dr. Castellanos: Why don't you just tell us—

27 Dr. Sprang: Her wording, rather than try to create it—

28 Dr. McAneny: And like the hospital program, pay for data collection?

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1 Dr. Sprang: Yes.

2 Dr. Urata: Why don't we make that a third separate motion?

3 Dr. Castellanos: No I think that needs to be included in this.

4 Dr. Sprang: Yes, it can be added to this.

5 Dr. Castellanos: Dana can you read that back to us please?

6 Ms. Trevas: PPAC recommends that CMS request input from the appropriate specialty
7 organizations with an interest in the issues already included in the proposed pilot program. In addition,
8 PPAC recommends that like the hospital Voluntary Reporting Initiative, CMS should pay for data
9 collection.

10 Dr. Castellanos: Is there any further discussion on that motion? Since there's been an addition, I'll
11 ask for a second for that again.

12 [Seconds]

13 [discussion off mike]

14 Dr. Castellanos: Reimburse physicians. Thank you, doctor. I'll call the question. All in favor?

15 [Ays]

16 Dr. Castellanos: Opposed? I guess we still have a couple of more questions that they really asked
17 us to go through, and the easiest one is what can we do to improve the system to maximize physician
18 participation? Anybody want to comment to Dr. Haywood.

19 Dr. Hamilton: I think the last 2 votes would suffice for that—

20 [chat]

21 Dr. Castellanos: Another one is do you envision other mechanisms to collect data to avoid chart
22 abstraction? Any other besides EMR, I think we've talked about that. Dr. McAneny?

23 Dr. McAneny: I think that another reasonable way to pursue this goal of collecting data—I think
24 it's premature to try to do it now with this program, however, we all know that like Pay for Performance,
25 that information technology services are coming and I think that these 2 things need to be along parallel
26 tracks so that as HER programs are developed, and get sort of the CMS stamp of approval somehow, which
27 would be very helpful to people who are going to make these large and expensive and recurrent purchases,
28 that if you knew which pieces, which fields of data collection you were going to have, that you say, here's

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1 the checklist of things that we want included on an electronic health record, so that then when we go out
2 and purchase one, it's there. We slam it out drop it down, send it off to you and you have data that's easy
3 to collect. I think right now, we'll be abstracting charts and flipping through pages to figure out which G-
4 Code applies to which patient we're seeing. So I think those 2 tracks in parallel would be ideal and would
5 really help you get good data.

6 Dr. Castellanos: Would you like to make a motion?

7 Dr. McAneny: OK. I think I would, PPAC recommends that CMS work in conjunction with the
8 developers and certifiers of electronic health records to develop programs, software that includes those
9 quality measures that you wish to have measured. Is that on the fly, but OK?

10 Dr. Castellanos: Could we say electronic medical records rather than health records?

11 Dr. McAneny: Yes. EHRs are the coming thing.

12 Dr. Castellanos: It's EMR right now. Dana could you read that back, please?

13 Dr. McAneny: Without the ums and uhs?

14 Ms. Trevas: PPAC recommends that CMS work in conjunction with developers and certifiers of
15 electronic medical records to develop software that includes quality measures that CMS would like to
16 have.

17 Dr. Castellanos: Is there a second to that?

18 [Seconds]

19 Dr. Castellanos: Any further discussion? All in favor?

20 [Ays]

21 Dr. Castellanos: Opposed? And the last question is to what extent do you believe hospital data
22 collection alone can be used to assess physician services?

23 Dr. Sprang: I think many of us do much more in the office than in the hospital setting for many
24 physicians, it would be a very, very small part of their what their activities, so I don't think it's a good
25 representation for physicians.

26 Dr. Castellanos: More specifically, in urology 65% of our practice is office-based, so you would
27 lose a tremendous amount of data and access to quality of care just using hospital data.

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1 Dr. Urata: My way of thinking is that if you do great care in the office, your patient won't have to
2 go to the hospital. [laughter]

3 Dr. Haywood: I like your thinking.

4 Dr. Urata: So if you focus on the outpatient services, then hopefully your inpatient will diminish.

5 Dr. Grimm: Just one other comment about this second question what can you do to improve the
6 system to maximize physician participation. I think one of the issues that will come up is that physicians
7 fear that this information is going to be misused. I think that will be a very, very important issue in terms of
8 how to address it when you present it to the larger physician population, how that's going to be handled.

9 Dr. Castellanos: Do you want to make a motion on that, or just a friendly comment.

10 Dr. Grimm: Friendly comment. I think it's pretty intuitive, but just so it's on the record.

11 Dr. McAneny: Just a quick comment on that. The other thing that's going to make hospital data
12 really hard to use to interpret what goes on in physicians' offices, the increasing use of hospitalists, where
13 there are seem to be developing 2 separate systems, so what goes on in the hospital will tell you about the
14 quality of the hospitalists more than it will the guy in the office.

15 Dr. Castellanos: Well, Trent and Mike, we certainly appreciate your being here. You were actually
16 a good eye opener for all of us. And please understand that our comments are constructive and not
17 destructive and we all recognize that this system is going to go forward. We're going to break now and
18 we'll try to meet back here at 12:30.

19 Dr. McAneny: And they're both wearing great ties. [laughter]

20 Break for Lunch

21 Afternoon

22 Physician Fee Schedule

23 Dr. Castellanos: As we said, we have a very, very busy schedule this afternoon. Again, good
24 afternoon everyone. Our next 2 topics will be combined and presented by Mr. Terry Kay, and Mr. Jim Hart.
25 Mr. Kay serves as Deputy Director of the Hospital and Ambulatory Policy Group. In his position, he is part
26 of a management team responsible for payment policy for Medicare services provided both by the hospital,
27 physicians, nonphysician practitioners, clinical labs, ambulances, ambulatory surgical centers, and others.
28 In addition, he has just recently served as the Acting Director of the Division of Practitioner Services for

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1 the Centers for Medicare Management, until a replacement is named for Steve Philips. And Steve left CMS
2 in October. Jim Hart is the Director of Outpatient Services in CMS with the primary responsibility of
3 overseeing Medicare Fee for Service Hospital Outpatient Services, and preparing the Outpatient Fee
4 Schedule. Dr. Peter Bach is also going to be here. Dr. Peter Bach is a Senior Policy Advisor to CMS
5 administrator, Dr. Mark McClellan. Dr. Peter Bach is a pulmonologist. He worked in Sloane Kettering
6 Hospital, and is very, very, very informed about the cancer groups that he's going to be talking about. Mr.
7 Kay, would you like to begin?

8 Mr. Kay: OK, thank you. Very nice to be here again. I've had the opportunity to do this a few
9 times and it's always been interesting each time. Today we're going to make our comments reasonably
10 brief so that we can save time for question answers, as part of our session. I'm going to talk about the major
11 highlights of the Final Rule for the Physician Fee Schedule for 2006. The issues that I'd like to talk about
12 and again, I'm just going to sort of highlight these, are summarized on this side and then the next slide, the
13 issues here, the negative update for 2006, what we're doing on practice expenses, our new policy on
14 multiple procedure payment reductions, and some technical changes we made for the professional liability
15 RVUs. Some of the other issues that are in the Final Rule this year we expanded the telehealth benefits
16 somewhat. And for 2006, the therapy caps for outpatient therapy will be back, and we expanded glaucoma
17 screening a little bit, and as indicated, Dr. Bach will speak about the oncology demonstration.

18 I understand you've already talked about the negative update this morning, so again, I've just sort
19 of again summarizing that. The update is a minus 4.4%, so that translates into these new conversion factors
20 for 2006 for the Physician Fee Schedule and there's a separate fee conversion factor for anesthesia, since
21 the anesthesia services are paid on a somewhat different methodology. Practice expenses, the relative
22 values for practice expense represent a little over 40% of the total payment and again I think most of you
23 know this, but just to summarize it, the practice expense portion of the fee schedule covers the direct
24 expenses for running a practice, so the clinical staff, medical equipment and supplies, and then there's an
25 indirect portion of the payment and that covers billing, heat, light, phones and so forth. One thing to point
26 out is that whenever we make any changes to practice expenses, to the practice expense relative values, the
27 changes are made in a budget neutral way so that inevitably if there's a change in the payments, then
28 there's sort of so-called winners and losers because of that budget neutrality provision. Earlier this year, we

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1 had made a proposal to revise our methodology, but for the Final Rule, we indicated that we're not, we're
2 going to basically leave the practice expense relative values where they are. Same as for 2005 except for a
3 couple exceptions. We have new codes in CPT that we had to establish values for and also the Medicare
4 Modernization Act required that we make some changes for drug administration for urology services, so we
5 have done that. But otherwise, we deferring on our proposal for practice expense and what we're planning
6 on doing as next steps, we still like our original proposal. We still like the basic idea for direct expenses
7 from converting from the current top down methodology to sort of a bottom up methodology, but we
8 definitely want to make sure that our proposals and our values are correct, and we want to make sure that
9 our methodology is understandable. And we also believe that the proposal will benefit from input from
10 physician groups. And so what we're planning on doing before we make any more proposals on practice
11 expense, we're planning early next year, January or maybe early February, that we would announce a
12 public meeting, again, to go over what we have in mind for a proposal, provide any information that
13 physician groups are interested in that would help make sure that our proposal is understandable. After we
14 do all that and we have a series of discussions, we'll provide information at the meeting in January or
15 February, and we'll put information on our web page and we'll do all that before we make another proposal
16 next year.

17 One new policy that we have in the Final Rule this year is multiple imaging procedure discount.
18 The concept is similar to what we've already been doing for surgery, where we reduce payment by 50% for
19 the second procedure when it's done on the same day as another procedure. In this case, the policy refers to
20 multiple imaging. There's 11 selected families of procedures that this applies to, so this policy's not for all
21 imaging, it's 11 specific families. Within those families, we have 2 exceptions where deferring applying the
22 policy to transvaginal ultrasound, and ultrasound of the breast. We want more time to consider the
23 comments we received regarding those 2 procedures. And the basic idea here is that as with surgery, we
24 think that there are some efficiencies when more than one procedure is done on the same day, so if 2 of
25 these procedures are done in the same day, then we'll reduce the lower paying of the 2 procedures. It's
26 going to be a 2-year phase in. So the first year, 2006, the payment reduction for the second procedure will
27 be 25%. And then we'll move to 50% the following year in 2007.

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1 As I said, I'd like to just note a couple of technical changes we made to the professional liability
2 indexes. They're fairly technical. They don't have much of an impact. The professional liability RVUs only
3 represent maybe 3.2% of the total payment, but we received comments from some specialties and from the
4 RUC to make these technical changes, and we thought they made sense, so we went ahead and proposed
5 and finalized them. We're excluding from our data any specialty that performs the service less than 5% of
6 time, we've excluded their data and we do not have professional liability information for clinical psych,
7 social work, occupational therapy, and the others on the chart. And we crosswalked those for 2006, we're
8 crosswalking these specialties to the lowest risk factor.

9 There are a specific list of services that can be done as a telehealth service, for Medicare Part B.
10 For 2006, we're adding one additional service. For 2006, Medical nutritional therapy can be done as a
11 telehealth service.

12 The therapy cap issue, we discussed that in the regulation and I wanted to mention it today in this
13 presentation. Basically as a reminder that the therapy caps for outpatient therapy will be back for 2006. The
14 Medicare Modernization Act had placed a 2-year moratorium on the caps, but that moratorium expires, so
15 January 1st, 2006, there will be 2 caps for therapy. There's one cap that's combined for physical therapy
16 and speech. And then there's a second cap that's for occupational therapy. Both caps are set the same
17 amount, \$1740 each.

18 One additional expansion of benefits is for screening for glaucoma. Starting in 2006, we've
19 included Hispanic Americans age 65 and older to the glaucoma screening benefit. This was based on a
20 review of the medical literature suggesting that the Hispanic Americans now qualified as being in the high
21 risk group.

22 And that is a summary of the major highlights of the Rule this year. I guess what I'd like to ask is
23 whether you would like to discuss the oncology demo now, or save that for after Jim Hart?

24 Dr. Castellanos: Why don't we discuss what you presented, and then when Dr. Bach presents the
25 oncology demonstration project, we can discuss that if that would be OK, then we're not confusing issues. I
26 guess I have a couple of questions. One is under the multiple imaging procedures. In urology and oncology,
27 it's not uncommon to do chest, abdomen, and pelvis. All three at one time. Especially in testicular tumors.

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1 Now you mentioned that first one is 100% then the second one is 25% discount the first year, and then 50%
2 the second year. What happens if we have a 3rd one on top of that, what happens to that?

3 Mr. Kay: Well, again, it's only the 11 families, but if it's more than 2, they would get the
4 reduction also.

5 Dr. Castellanos: They would get the same as the second.

6 Mr. Kay: Yes.

7 Dr. Castellanos: So if it's contiguous as in these families, for 3, which is not uncommon in
8 oncology or urology, that would be a 25% reduction on the second, and a 25% reduction on the third, is that
9 how I understand it?

10 Mr. Kay: Right, and that's identical to the general concept that we do for multiple surgery. But
11 again, I'd also note that they all have to be done on the same day for this policy to apply.

12 Dr. Castellanos: I guess I'll just finish. I had one other issue about the practice expense RVUs for
13 the urology drug administration codes. We certainly appreciate CMS doing that. The only question I have
14 in discussion of the Rule, you made this update, but if you look at the RVU addendum, this does not reflect
15 any update and we've written a letter to you about that. I think that must be an oversight, but I wanted to
16 make sure you were aware of that.

17 Mr. Kay: That's correct, and we appreciated your letter, and we do have a correction notice being
18 drafted now and we expect that would be part of it.

19 Dr. Castellanos: Dr. Grimm?

20 Dr. Grimm: Getting back to this multiple imaging procedure discount. It would appear to me that
21 if I was looking at this from a physician or a diagnostic imaging center, if somebody was going to cut down
22 my payment based on a daily rate, or a daily number of cases that were done, that I'd simply break these
23 things out and do them every single day over a 3-day period to get a full reimbursement. That doesn't,
24 that's obviously not the goal here, and my question is, is how do you prevent that gaming of the system.

25 Mr. Kay: Well, that is an excellent point and it's something that we are concerned about. Our plan
26 is that we would, as this is implemented, we'd monitor the claims that we receive and see if we notice any
27 dramatic change in billing patterns for these services. At this point, we don't have any specific proposal,

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1 but if there was a dramatic change in practice, it's something we would probably look at in the future. We
2 don't have anything, no specific proposal right now.

3 Dr. Castellanos: Let me just speak to that. I don't think any physician is going to subject a patient
4 to two days of contrast, 2 days of being NPO, inconvenience. I would think and hope that no physician
5 would do that except under very dry circumstances.

6 Dr. O'Shea: I have a question for you. I might be under felonious supposition, but I have some
7 information that says that there is also a provision in the new fee schedule that modifies Medicare payment
8 for dispensing fee, for inhalation therapy drugs? Didn't see that in your presentation, so I have a question
9 about it's a dispensing fee of \$57 for a 30-day's prescription for the first time beneficiary uses it, then after
10 that a 90-day dispensing fee. Who is this paid to? Whom is going to receive this dispensing fee?

11 Mr. Kay: This payment would basically be for the supplier of Buterol and those drugs. I didn't
12 discuss it, but Amy Bassano is the lead for that particular portion of the Rule and she will be on the agenda
13 a little later in the afternoon. If you would like I will make sure she's aware of your interest, and you could
14 either bring it up during her session or talk to her afterwards.

15 Dr. Simon: I was going to say it is \$57 for the first month. To the supply fee, and then for each
16 subsequent month, it's \$30—

17 Ms. Bassano: Just to clarify, it's \$57 for the first month in a patient's lifetime that they receive it,
18 and it's \$33 all subsequent months.

19 Dr. O'Shea: And Amy this was actually directed at, we have inhalation and a thing like oxygen
20 suppliers. These are medical providers that way. We're not talking about a drug company.

21 Ms. Bassano: Right, the people who supply—

22 Dr. O'Shea: The supplier.

23 Ms. Bassano: Correct.

24 Dr. O'Shea: OK, thank you.

25 Dr. Powers: First a question about the therapy caps because I take care of people who need a lot
26 more therapy. Where did that number come from, the 1740?

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1 Mr. Kay: 1740? It's basically required by law. This therapy cap provision goes back to the
2 Balanced Budget Act of 1997. It started out as a \$1500-cap, and then it has gotten updated for inflation
3 over the years.

4 Dr. Powers: Was that based on a study that patients needed that much...

5 Mr. Kay: No, I'm trying to remember. Basically it was hard-coded right into law, and I don't
6 know basically what—

7 Dr. Powers: Is there a potential opportunity, even though it may go into effect by law or whatever,
8 is there potential opportunity to eventually get a carve-out for stroke, traumatic brain injury, and spinal
9 chord injury? Because those clearly need more therapy than that. Those patients clearly need more therapy
10 than that to become functional. Otherwise they're going to be in a nursing home.

11 Mr. Kay: At this point, I mean over the years, frankly, we've looked at the therapy caps, and
12 we've looked at alternatives, and we're very interested in any ideas. But at this point, a change, it would
13 require a change in law for us to have an exception process, or to change the dollar amount. But again, if
14 you have particular ideas about that, I would very much welcome your thoughts about that. When we've
15 talked to some others in the past about stroke patients for example, that they say it was hard to sort of
16 narrow that down, and it seemed like there was so much variation in the need for therapy in different
17 clinical groups like that. But anyway, like I said, we would welcome any thoughts you have about
18 developing future alternatives to the cap.

19 Dr. McAneny: Along those lines, I think that might be something that we should discuss in a
20 future meeting as well as which providers can apply for those codes, etc., because that's sort of a gray issue
21 as well as there's lots of other qualified providers other than the ones on your list. But my major question is
22 on the SGR, which you know, you're well aware that we feel that that's a fairly flawed schedule. But in
23 reading this Physician Fee Schedule, and recognizing that one of the 4 factors in the SGR is the estimated
24 change due to change in statute, I really had some questions about how you came up with the 1.2% increase
25 that were related just to the statutory change, given all the changes that they were. Also, on page 747, of the
26 fee schedule, it states that the statute provides the Secretary with the clear authority to specify the services
27 which are included in the SGR. So the election there was to include power wheelchairs, which we learned
28 at a previous PPAC was \$1.2 billion in Harris County, Texas, alone, and I can't imagine that with power

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1 wheelchairs being included in the SGR that that's something that we are really responsible for, given that
2 there were some fraud inquiries there. But also, my major concern is how the new codes that were added
3 come up to that small a number, when there was a significant increase given to the Medicare Advantage
4 Plans because of these new codes. So one of my concerns is whether or not the downstream effect of doing
5 these new services ever gets considered. For example, in your list of new services, you talked pretty much
6 about just giving glaucoma screening to Hispanics over 65, and giving the diabetes and the cardiovascular
7 screening, but are there any considerations of how much downstream services were developed because they
8 discovered that somebody had cardiovascular disease and then went on and did lipid testing and then put
9 them on various anti-lipid agents, and then did the liver testing necessary, or when they did the
10 colonoscopies, which I didn't even see mentioned as a new service, to account for a change in the SGR,
11 and those are not terribly cheap, when you do that you're going to find a certain amount of polyps and a
12 certain amount of colon cancers which will then go on and get therapy and each of these screenings that we
13 do, the welcome to Medicare physicals. We do this physical. We discover, oh my gosh, you're a diabetic,
14 you didn't know it. That means you need X, Y, and Z services. We'll set you up for the ophthalmologist,
15 we'll do all of the things we need to do, yet my fear is as you look at the implications for this in the SGR,
16 that you're just looking just at that screening service, and not at all of the downstream care that gets
17 delivered because that screening services documented certain things. So I'd love to hear a discussion about
18 how you calculated and how you decided what should be included in that coverage for changes in statute
19 part of the SGR.

20 Mr. Kay: OK, first, just a clarification. The power wheelchairs that you mentioned—power
21 wheelchairs are not in the SGR. There is a new service that was created this year, which we have a G-Code
22 for for physician involvement with ordering power wheelchairs. That's what's in the SGR. That's a very
23 small item of probably \$4 to \$5 million range, not the \$1 billion for the whole power wheelchair benefit. So
24 just to correct that point. And the other discussion as far as how the actuaries compute the SGR and take
25 into account sort of for a new benefit, like the welcome to Medicare visit and any sort of direct and indirect
26 increases in expenditures that result from that, I guess all I can say is we talk with the actuaries and Rick
27 Foster, the Chief Actuary for the Agency, who has indicated that they do in fact compute no only the direct
28 expenses, but the indirect additional expenditures that result from additional benefits. I would just say, I

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1 mean I've heard Rick Foster indicate that it is obviously a challenge when you look at patterns of billing,
2 it's a challenge to look at and identify the indirect expenditures, because there's nothing about the claims
3 themselves that will indicate that it was attached to some other benefit. But they do do their best to do that
4 and they make an initial estimate, and then they revise their estimates for 2 subsequent years. So they feel
5 pretty confident of their estimates and we believe we do what you're suggesting.

6 Dr. McAneny: How then do they do it for determining the increase that was going to be given to
7 the Medicare Advantage Plans, which my understanding of this was it was in part due to these new services
8 that we're going to be providing?

9 Mr. Kay: I guess I'd have to follow up on that one. I'm not as familiar with the Medicare
10 Advantage Program, but that's something that we'd be happy to research for you.

11 Dr. Castellanos: Are there any other questions for Mr. Kay? Dr. Przyblski?

12 Dr. Przyblski: First on the diagnostic imaging procedure discount. You made an allusion to it's
13 similar to what's done in surgery, but surgery is really done to professional component, where this
14 specifically is addressing the technical component. And is there a rationale that you're focusing on that part
15 of it as opposed to the professional component? When we look at surgery services, one of the reasons that
16 there's a reduction is that there is obviously overlap that's going on. You know the patient already; you're
17 not seeing him twice as often pre- and post-op and the same is really happening with the imaging when
18 done at the same setting. The patient's not being reintroduced twice and all of those expenses are not being
19 incurred twice. Why did we focus on the technical component?

20 Mr. Kay: First of all thank you for that question because that provides clarification. I don't think I
21 noted that in my presentation. The multiple imaging reduction applies to the technical portion of the
22 payment only. That the physician interpretation of the image is still paid at 100% regardless of how many
23 are done on any given day. And basically, our rationale was that we looked at the individual services, and
24 we looked at sort of the details of what's involved in doing them and at least at this point, we felt that for
25 the technical component, that we could identify where we thought there was overlap. You only have to
26 greet the patient once. There's some efficiencies in some of the positioning and so forth, whereas for the
27 physician portion of the interpretation, that we basically saw it as the physician needed to do the
28 interpretation and the fact that there was more than one done on the same day, at least at this point, we

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1 didn't identify significant amounts of efficiencies in doing more than one, but who's to say what the future
2 might bring? Right? But at this point, I'm just saying that in case there's some proposal somewhere down
3 the line, I don't want anybody to point to today's comments that we never said we were going to exclude
4 looking at efficiencies in other services. But at this point, we felt we could identify the major efficiencies
5 for the technical component, and we were leaving the professional service as 100% payment.

6 Dr. Powers: Is it time to make recommendations based on Mr. Kay's—OK. PPAC recommends
7 that CMS change the methodology for measuring practice expense to one that is based on measurable data,
8 rather than assumptions.

9 Dr. Castellanos: Is there a second?

10 [Seconds]

11 Dr. Castellanos: Is there any discussion on that motion? Dana could you read that back, please?

12 Ms. Trevas: PPAC recommends that CMS change the methodology for measuring practice
13 expenses to one based on measurable data rather than assumptions.

14 Dr. Castellanos: I'll call the question, all in favor?

15 [Ays]

16 Dr. Castellanos: Opposed? Thank you. Are there any other comments or questions. Dr. Sprang?

17 Dr. Sprang: For the last question there, we would appreciate obviously the Council's views on any
18 operational impacts of the proposals, the most obvious being the negative 4.4% decrease in the sustainable
19 growth rate calculation. Obviously numerous people can make comments, but I'll just say [inaudible] has a
20 very high overhead. I'm an obstetrician gynecologist, our liability insurance is \$160,000. Numerous
21 physicians in my state are literally leaving the state, are closing their offices because they can't afford to
22 keep their offices open. As much as we, and I take care of a fair amount of Medicare patients. As much as
23 we want to do that, if you're having trouble keeping your office open now, you're going to be forced to
24 keep as many slots open for patients that can at least cover the cost of keeping the office open. No matter
25 how noble the mission, no resources, no mission. So with this cut, I do think there's going to be significant
26 problems with access to care for Medicare patients. I'll certainly continue to see the patients I have, but to
27 see new Medicare patients, I may need to keep those slots open for patients that can cover my costs, or I
28 may not be able to keep my office open as much as I want to do that, and obviously provide the best care. It

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1 may just be not doable. Physicians' offices are small businesses, and like any other small business, if your
2 costs are greater than your reimbursement, your business closes. And I think this is going to have a real
3 negative impact for physicians across the country and become most of the other payers also based what
4 they reimburse on Medicare some fraction or percentage of it, it's going to be a decrease across the board.
5 And I just think the ripples across the United States for 2006 are going to be extremely dramatic in a
6 negative impact on Medicare patients.

7 Dr. O'Shea: I would have to restate and also support what Dr. Sprang just said as an internist in
8 primary care, you will find more especially small practices not being able to tolerate the decreases in
9 reimbursement because we actually are small businesses, and so I have families that also rely on me for
10 their support. So what he's saying is very true. What my comment would be, and I think you understand
11 this already, Mr. Kay, but to watch in other ways than just the larger portion. What we've heard again and
12 again and so far CMS doesn't see any scale, doesn't see any indication that there is a decreasing access to
13 care. Well, you will over this year. And you will see physicians not being able to accept new Medicare
14 patients and if there's any way that you can monitor that more closely, it won't be in the larger practices, it
15 won't be in the larger maybe specialty and subspecialty groups, but it will be in primary care and we'd like
16 you to watch for that because we are again the largest group and we're going to be taking the largest hit, I
17 think.

18 Dr. Azocar: Some practices, particularly in my practice, and many other, which I knew in the inner
19 city has Medicare and Medicaid population over 80%. And when you talk about this percentage of
20 reduction, close to 5%, we're talking about significant decrease in the resources and that requires an
21 adjustment. One of these adjustments may be to refuse the number of patients with Medicare. Now for
22 some clinics, that might be an option. But for others, mainly those in the inner city, which take care of a
23 large population with high morbidity, that would mean just close the business. And from the financial point
24 of view, these patients will eventually end up going to the ER with severe complications that you could
25 have treated earlier in a clinic. So I anticipate that this is going to affect significantly the clinical outcome
26 in some communities, particularly those clinics which have a large population, large percentage of patients
27 with Medicare and Medicaid.

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1 Dr. McAneny: In the fee schedule, you also commented that the proposed decrease between 2006
2 and 2012 is a minus 27%, while your estimate of MEI is going to increase 19%. After the last PPAC and
3 the Interim Final Rule, I put out a query on a thing we have called Docnet, which is an email discussion
4 group that goes across New Mexico, and I'm going to read you a brief email that I received from one of the
5 4 internists in a small town in Northern New Mexico in Raton. It says: There are 2 young internal medicine
6 docs here who are looking at alternatives for employment that are not medical. No one has made a move
7 yet, but they are getting ready financially so that they can bail out soon when the time to do so arrives. At
8 least one of these docs is already screening out Medicare, and other patients with reimbursement problems.
9 He is reducing Medicare patients because of declining reimbursement combined with complex health
10 problems and excessive time demands and has tried to shift to younger patients with better insurance and
11 less time consuming health problems. Preventative health visits, colds etc. He makes a lot more money,
12 50% more than I do as a result. For the moment, I am trying to maintain the Medicare population I have,
13 and add a few each week, but I am not sure how long I can continue to do that. Here in Raton, if you are an
14 older, sick Medicare patient, there is a good chance that I am your doctor. I am one of 4 internists here.
15 There are 2 family practitioners and 2 nurse practitioners as well. If there's a \$5 fee to resubmit a corrected
16 claim, then a \$500 surgical bill will be minimally impacted, but a \$30 to \$40 office visit at a PCP will be
17 hit hard, especially when it comes on top of projected cuts already planned in the program. I really do think
18 that that will kill a lot of small rural practices like mine with more than 50% Medicare. It certainly requires
19 me to actively reduce my Medicare patient population.

20 This is a primary care internist who has been in Raton, New Mexico, and he did give me
21 permission to use his email. But it was echoed all through this email discussion group by multiple small,
22 rural practices. In New Mexico, we're not big enough to have inner cities, so we don't have that many
23 problems there. But I truly am afraid for the access to care, as is he, and he points out that once physicians
24 depart from the actual practice of medicine, I doubt that very many will ever come back. So my concern is
25 still as we've addressed in previous PPAC that Medicare just looks at the big picture, the number of people
26 participating in Medicare, and not looks at the access of seniors or look for canaries in the mine, the people
27 who can be the early, maybe the inner city, maybe the rural docs, somebody before the whole system
28 crashes down. These patients that we take care of, you know, this best generation of patients is incredibly

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1 rewarding to take care of. But as the number of patients in Medicare increases, and the number of available
2 physicians decreases, there simply are going to be choices that are going to be made because there are not
3 enough hours in the day to take care of everybody. So my fear is that the access of seniors will be severely
4 impacted by the fact that if you only have so many slots in the day, you'll fill them with people who keep
5 your practice afloat so you're also there for the patients of tomorrow. So again, we've sent this
6 recommendation several times requesting that Medicare really look at what this Physician Fee Schedule is
7 going to do to access and find some way to get an early warning system, before the whole system crashes
8 about our ears.

9 Dr. Senagore: Just a portion about the practice expense methodology. There was a significant
10 amount of energy that was used in the original transition, and early on we actually tried to introduce real
11 economic data for inputs and were forced down a path of not being able to do that. It's a little frustrating
12 after all that effort now to hear that there will be another process that will be time-consuming again. Will
13 medicine get an opportunity to truly discuss what that methodology will look like, particularly in the face
14 of a negative SGR this year?

15 Mr. Kay: I indicated earlier, we're planning a public meeting. I think it will probably be early
16 February. And we'll go through what our proposal was, what our intent was, we'll provide update
17 information on what the values would be under our proposal, so everyone is aware of what it is and
18 understands how the values are computed. And as far as additional work, I would just note that under our
19 original proposal, where we were talking about using the so-called bottom up methodology, that basically
20 what we were saying is we wanted to base the direct expenses off of the inputs that we had already been
21 given by the specialties and the AMA through the relative value update committee process, so we already
22 have a data base for all the direct expenses for virtually all 7,000 physician services.

23 Dr. Senagore: Are you talking about CPEP data?

24 Mr. Kay: Yes.

25 Dr. Senagore: I would submit that a far more rigorous look was done by the practice expense
26 committee at those inputs. And some of the original inputs were exorbitant for a number of codes and under
27 a peer review, really never stood the test of time. So to go backwards from there, I guess I'm concerned that
28 that really means for codes.

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1 Mr. Kay: But just to clarify that and then again like I say, I would encourage you to come to our
2 meeting if you could. Over the last 6 or 7 years since the original CPEP data was provided, the relative
3 value update committee has looked service by service, at what the inputs are, the staff time, equipment,
4 supplies, and have made in many cases, many revisions, so we've gotten to the point where we're more
5 comfortable with the inputs that we got through the RUC process than what we had originally back in 1997.

6 Dr. Senagore: That's what I'm saying. So it'll be the PEAK revised data that you'll use as inputs.

7 Mr. Kay: Right.

8 Dr. Castellanos: Are there any other questions? Dr. Przyblski?

9 Dr. Przyblski: Sort of a three-parter and I know you probably hate those. One is on back on the
10 SGR, and I think we all understand that that's not exactly in your control and requires some Congressional
11 action, but we heard earlier today from Mr. Kuhn about the drugs used in the SGR and that there may be
12 some remedy at least going 2 years back and going forward, and rather than this topic coming up every
13 year for as many years as I can remember, it would be nice to finally put that to rest and say, yes, we'll take
14 it out, at least now going forward and perhaps back 2 years. So that the impact is not as great. On the
15 practice expense side, I'm thankful that CMS at least allowed another year for some comment and thought
16 about the change so that we can offer additional advise about it's reasonability if you will. Last year we had
17 heard from CMS representatives at the RUC that CMS had set aside money for potential data gathering,
18 such as the SMS survey that the AMA put out, and the AMA chose not to do that. Is that a dollar dedication
19 that would be considered again for 2006 or not? So that's a specific question, and then with respect to PLI,
20 you know that the surgeons in general as well as others have had concern about not using the dominant
21 specialty approach. I'm appreciative as I think all of us are that at least the 5% threshold has been accepted
22 as a recommendation, and perhaps you may consider for at least low volume services to use a dominant
23 specialty approach. Again, because it is always underestimating the cost of the dominant service provider
24 by weight averaging it with lower PLI cost specialties. So that is a request. And last of all, there have been
25 discussions at the PLI work group at the RUC about using alternative sources of data, such as PIAA and
26 there was some effort as to, at least on a pilot project look at a couple of different states to see if that data
27 could be used or not. One of the RUC's criticisms is that the data that's been used has always been fairly

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1 old and sometimes more than several years old, whereas our premiums are going up on an annual or a
2 semi-annual basis and I was hoping for an update as to the status of that alternative data source.

3 Mr. Kay: OK, I guess just very quickly, I would just say about the SGR that frankly there's
4 nothing new I can add to the conversation. That we certainly considered the comments we received over
5 the years on the SGR, and the biggest impact on the SGR for the taking the drugs out back to 1997,
6 basically we don't think we have statutory authority for that. Prospectively, it's something that the agency
7 could continue to look at but we didn't do anything on that issue this year. The practice expense, we are
8 interested in, we've been relying on the AMA's SMS survey, and sooner or later it seems we're going to
9 need some kind of a way to update that, and I expect that will be one of issues of discussion in the February
10 meeting on practice expense. For PLI, again, we could continue to look at refinements to PLI. We've been
11 reluctant to move off of the current methodology, and to the extent that we do make any changes, we want
12 to make sure that we don't have inadvertent consequences for other portions of our fee schedule and the
13 methodology that we use because we base it on our typical inputs. But there is a lot of averaging that goes
14 on in the fee schedule. And the PLI data, we're continuing to look at that issue. We're definitely looking
15 for ways to make our current data collection process more efficient. Frankly right now, we make phone
16 calls to state insurance agencies and surely there's a better way to do it and so we're very much interested
17 in refining and so that's sort of an open issue. We're aggressively looking at that.

18 Dr. Castellanos: Are there any further comments or recommendations? Dr. McAneny?

19 Dr. McAneny: I have a couple of recommendations that I'd like to make. One is that given that the
20 Physician Fee Schedule did say that the statute provides the Secretary with the clear authority to specify the
21 services included in the SGR, I would like to recommend once again, that the Secretary use all the means
22 available to avoid the future decreases in the conversion factor, including but not limited to, removing
23 drugs from the SGR, adding new money to the system for good measurements of practice expense, and for
24 all the costs from the new screening benefits and to work with Congress to create a system where the
25 money for services provided under Part B can be shifted from Part A where appropriate.

26 Dr. Castellanos: Is there any discussion on that motion?

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1 Dr. Leggett: Yes, I have a question, maybe Ken can answer it. You've made that recommendation
2 maybe 3 or 4 times without hearing any response to it, and I was just curious what has been the response to
3 this point?

4 Dr. Simon: Are you responding to the question relating to the SGR?

5 Dr. Leggett: Right, specifically this recommendation, which we've made at least twice before I
6 think.

7 Dr. Simon: I think we've—

8 Dr. Leggett: And as it relates to getting the drugs out of the SGR.

9 Dr. Simon: We have discussed this internally with the leadership as well as with our general
10 counsel, and as they continue to query folks on the Hill we have still yet to get clarity that we do in fact
11 have the authority to be able to remove drugs from the SGR.

12 Dr. Castellanos: I think there's a difference this time. We're not asking you retrospectively, I think
13 your question was from now on, I didn't hear the retrospective approach.

14 Dr. McAneny: I didn't put retrospective in there because I based this one on the statement in the
15 fee schedule that says the Secretary has clear authority, etc., etc., page 747.

16 Dr. Simon: But that's not new authority.

17 Dr. Castellanos: Is there any further discussion on that motion? Is there a second?

18 [Seconds]

19 Dr. Castellanos: Dana could you read it back, please?

20 Dr. McAneny: If not, I can.

21 Ms. Trevas: One part I didn't get. Given that the 2005 Physician Fee Schedule Final Rule
22 indicates that the statute gives the Secretary the authority to specify the services in the sustainable growth
23 rate calculation, PPAC recommends that the Secretary use all means available to avoid future decreases in
24 the conversion factor, including but not limited to, removing drugs from the sustainable growth rate
25 calculation, adding new money to the systems for –

26 Dr. McAneny: Good measurements of practice expense.

27 Ms. Trevas: OK, good measurements of practice expense, better calculating the costs of new
28 screening benefits—

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1 Dr. McAneny: I was talking about those downstreaming costs—maybe I should put the word
2 “downstreaming.”

3 Ms. Trevas: Are those indirect? Subsequent? OK. And work with Congress to create a system in
4 which money from services for Part B are shifted to Part A when appropriate.

5 Dr. McAneny: No, wrong way.

6 [chat]

7 Dr. McAneny: For services provided under Part B can be shifted from Part A, where applicable.

8 Ms. Trevas: OK, where money for services provided under—

9 Dr. McAneny: Where money for services provided under Part B can be shifted from Part A, where
10 appropriate.

11 Ms. Trevas: OK.

12 Dr. McAneny: Can I speak to that for a moment? Part of that is that we watch the pay for
13 performance data. We know that what happens when we do a good job is that the savings are on the
14 hospital side, and yet the more good job we do, the more times we see people to keep them out of the
15 hospital, the more we increase the volume and intensity of our services, and the more the SGR bites us and
16 says now we get to decrease everybody’s conversion factor because your volume of intensity went up,
17 whereas the majority of the savings were on the hospital side. I’m hoping that as they do the MACs, the
18 Medicare contractors, and the same person is starting to do Part A and Part B that maybe we’ll break down
19 those silos and be able to see Medicare as a whole for services, and not just Part A and Part B but be able to
20 put the money where the services are. And the rest of it is just that we are in a crisis. We have a major
21 program that provides huge quantities in this country, and we’re at risk or this. And so I wanted to convey a
22 sense of that urgency to the Secretary that we need to work on this now before this thing falls apart, and we
23 need to find any way we can, under the authority he has, to put the money in the system to make sure that
24 we can still take care of seniors in the next few years.

25 Dr. Castellanos: Dana could you read that back before we vote on it please?

26 [chat]

27 Ms. Trevas: Given that the Physician Fee Schedule Final Rule indicates that the statute gives the
28 Secretary authority to specify the services in the sustainable growth rate calculation, PPAC recommends

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1 that the Secretary use all means available to avoid future decreases in the conversion factor, including but
2 not limited to removing drugs from the sustainable growth rate calculation, adding new money to the
3 system for good measurements of practice expenses, identifying all the costs of adding new screening
4 benefits, and working with Congress to create a system in which money for services provided under Part B
5 be shifted from Part A to Part B when appropriate.

6 Dr. Castellanos: Thank you. Is there any further discussion.

7 Dr. Senagore: One only needs to look at the continued reductions and length of stay for
8 hospitalized patients and realize that all of that burden for care has been shifted now to the office practice to
9 the benefit of the hospital because the DRG rates have not changed all that much, they realize most of the
10 savings from those reductions and don't provide the resources or the personnel that are now delivering that
11 care.

12 Dr. Castellanos: Any further discussion? Dr. Przyblski?

13 Dr. Przyblski: In what was read out, I didn't hear the downstream word in there, as far as
14 downstream expenses, so.

15 Dr. Castellanos: We took that out.

16 Dr. McAneny: Should be put it in?

17 Dr. Senagore: I think a point is well made that you can look at the expenses from the perspective
18 of yes, there's these additional tests that have to be paid for and completely ignore the fact that those test
19 results in procedures or other services beyond that. So I do think that that's an important part of that. And I
20 agree with the motion, but I don't want the motion to simply imply that the Medicare Part B increases just
21 related to this. Realize that there are a lot of services now being performed in the outpatient setting, that are
22 not done in the inpatient setting, irrespective of these new regulations, and there is no way to account for
23 those now new Medicare Part B dollars being spent that the hospital is no longer spending.

24 Dr. Castellanos: Would you like to make a friendly...

25 Dr. Senagore: Yes, please.

26 Dr. McAneny: I'd accept that as a friendly amendment, so we can just put downstream in there.

27 Dr. Castellanos: We're going to add the downstream.

28 Ms. Trevas: Downstream costs—

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1 Dr. McAneny: Downstream worked for me. Let's see, the immediate and the subsequent costs, the
2 costs of all the treatments of conditions discovered through the screening programs, but that's a wordy way
3 to say that.

4 Ms. Trevas: Immediate and subsequent?

5 Dr. Simon: ...it's trying to estimate the cost of care, the cost of subsequent care that will occur as
6 a result of obtaining and performing the screening test and that's what's done to provide the estimate. It's
7 trying to determine if the screening tests are done, what percentage of patients will require the subsequent
8 care, be they E&M visits, surgical care, therapy care, etc.

9 Dr. McAneny: And actually I have a subsequent motion I'd like to make that addresses that.

10 Dr. Castellanos: We have a motion on the floor. Does everybody understand that? We know what
11 we're voting on? I'll call the question. All in favor?

12 [Ays]

13 Dr. Castellanos: Opposed? Is there any other motions?

14 Dr. McAneny: Yes.

15 Dr. Castellanos: Dr. McAneny?

16 Dr. McAneny: The one that explains this is—

17 Ms. Trevas: Hold on one second please. Thank you.

18 Dr. McAneny: PPAC recommends that the CMS actuaries explain to PPAC their methodology for
19 the evaluation of the costs of all of the new services downstream from the new screening services,
20 including colonoscopies, welcome to Medicare physicals, etc.

21 Dr. Castellanos: Is there any discussion on that motion? I'll ask for a second.

22 [Second]

23 Dr. Castellanos: Dana could you repeat that for us or read it back?

24 Ms. Trevas: PPAC recommends that CMS actuaries explain to PPAC their methodology for
25 evaluating costs of all new services downstream from new screening services, including colonoscopy, the
26 welcome to Medicare physical, etc.

27 Dr. Castellanos: All in favor?

28 [Ays]

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1 Dr. Castellanos: Opposed? Are there any other—

2 Dr. McAneny: One more.

3 Dr. Castellanos: One more motion.

4 Dr. McAneny: One more and then I'll shut up at least for a while. PPAC recommends that CMS
5 share the methodology of determination of the updates given to the Medicare Advantage Plans to account
6 for the new benefits.

7 [Second]

8 Dr. Castellanos: Is there any discussion on that motion? Is there a second? Let's read it back, first,
9 I'm sorry.

10 Ms. Trevas: PPAC recommends that CMS share with PPAC the methodology used to determine
11 the update given to the Medicare Advantage Plans to account for new benefits.

12 Dr. Castellanos: I'll call the question. All in favor?

13 [Ays]

14 Dr. Castellanos: Opposed? Are there any other motions? Well, we still have a lot of presenting on
15 this. Jim Hart is here as Director of Outpatient Services and his responsibility is overseeing the Medicare
16 Fee for Service Hospital Outpatient Service, and he has a presentation for us.

17 Outpatient Fee Schedule Final Rule

18 Mr. Hart: Thank you very much, and as Terry said, it's a pleasure to be here. We published our
19 Final Rule on November 10th of this year and as in the case of Terry, I am going to concentrate only on a
20 few of the highlights of the rule. Specifically I want to talk about the payments for Medicare Part B drugs,
21 both the acquisition costs and the pharmacy overhead cost, and payments to rural hospitals, and finally, our
22 proposal which we did not finalize, to discount in the outpatient setting, the multiple imaging procedures.
23 We pay for Medicare Part B drugs in the outpatient setting about \$2 billion, this year. Prices under an
24 MMA provision are currently for this year, based on average wholesale price, about 83% of average
25 wholesale price. Of course the issues with that, as a base of payment are very well known to everyone and I
26 won't belabor that. The Medicare Modernization Act told us that this coming year in 2006, we should set
27 payment for acquisition cost on the basis of average acquisition cost, and in doing so take into account a
28 GAO survey on hospital drug acquisition costs. The MMA also said that the Secretary may determine an

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1 additional payment amount for drug overhead, and in doing so, take into account MedPac study on drug
2 overhead. In the proposed rule, we propose to pay a total of ASP plus 8% for drug costs, to distinguish in
3 that overall payment of ASP plus 8% between an ASP plus 6 payment level for acquisition costs, and an
4 additional 2% for drug overhead. The ASP plus 8 figure was based on our analysis of our claims data from
5 which we can derive an estimate of median hospital cost for drugs and that suggested ASP plus 8 is the
6 overall level for acquisition and overhead cost, and out of the ASP plus 8, for various reasons we
7 determined that ASP plus 6 was about the right level for acquisition, and the additional 2% for overhead. In
8 the Final Rule, we changed that in 2 ways. One, we went to an overall level of payment of ASP plus 6 for
9 acquisition and overhead. This was merely based on following the same data, our claims data, and due to
10 updates in the data more recent claims, changes in cost-to-charge ratios and so forth, the overall level came
11 out at ASP plus 6, rather than the ASP plus 8 that we were using in the proposed rule. So that was our first
12 decision. Just to pay for ASP plus 6 for overhead and acquisition.

13 And our second decision unlike the proposed rule, is just that we were no longer going to make a
14 distinction in that overall payment level, how much was for overall, and how much for acquisition. They're
15 both in there, based on our analysis of the data, but we didn't feel in the Final Rule, like we had to make a
16 distinction. But it's important to emphasize that ASP plus 6 represents a payment both for acquisition and
17 for overhead costs of drugs.

18 Radio pharmaceutical drugs, of course, were a special case, because radio pharmaceuticals are not
19 required currently to submit ASP data, and we have proposed in the proposed rule to require the radio
20 pharmaceutical manufacturers to begin submitting data in 2006, so that we could set payment rates in 2007
21 on it, and in the meantime we would pay for each claim based on the hospital's cost-to-charge ratio applied
22 to the hospital charge. So payments reduced to cost on the claim. In the Final Rule, we did adopt the
23 proposal to pay, at least in the interim, charges reduced to cost for the acquisition and overhead costs of
24 pharmaceuticals, but we did not finalize the ASP reporting proposal on the basis of pretty consistent
25 comments that we would not be able, there was no viable way to get from ASP reporting by manufacturers
26 to a per-dose price that we would really need to set a payment level. And we're going to continue to study
27 that charges reduced to cost methodology in the future, and may propose something else ultimately.

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1 For rural hospitals. Currently, rural sole communities in small rural hospitals are held harmless to
2 the payments that they received prior to OPSS in 2000, but that provision expires at the end of this year.
3 And the MMA required the Secretary to conduct a study of rural hospital costs, compared to urban hospital
4 costs, and it proposed an adjustment if the study indicated that was appropriate. We did conduct a study for
5 both the proposed and the Final Rule and in the proposed rule, the study indicated a 6.4% increase was
6 appropriate for rural sole community hospitals alone, and that other rural hospitals did not show cost
7 differences, so shouldn't get an adjustment. In the Final Rule, the finding was the same with regard to who
8 should get the adjustment, but the final data in the rule indicated that an adjustment of 7.1% would be more
9 appropriate and so we went with that in the Final Rule.

10 Finally, we had proposed in the summer that we would discount payments, following a MedPac
11 recommendation. We would discount payments for multiple diagnostic imaging procedures when they are
12 performed in the same session with a patient, and we identified as the Physician Fee Schedule did, 11
13 families based on imaging modality and contiguous body parts, and we proposed a 50% reduction when
14 those procedures were performed within a family. We received however in response to our proposal, a
15 rather challenging comment that pointed out a feature of our rate setting methodology in the outpatient
16 setting, it only applies in the outpatient setting, that may render that adjustment kind of unfair or
17 inequitable. And essentially, what they said was that it seems that our rates, our initial rates for imaging
18 procedures may already be capturing the efficiencies of the second and subsequent imaging procedures,
19 because of our use of the cost-to-charge ratios; that hospitals when they report their costs on the cost report,
20 the efficiencies of the second and subsequent images are already in there, and therefore if we were to take a
21 50% or any reduction on top of that, we would essentially be giving them a double hit. We looked into that
22 data as much as we could, and we could find, we found a lot of information that either is consistent with or
23 at least tends to some degree support that argument, and we found nothing to refute that argument with, so
24 in the Final Rule, we did not adopt the proposal. However, we are going to continue studying this, and
25 continue studying our overall rate structure for imaging and we may well be coming back to this subject in
26 the future. But for now, we decided not to go ahead with our proposal for the imaging reduction. That's
27 about it.

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1 Dr. Castellanos: Thank you, Mr. Hart. We appreciate your patience. Are there any questions for
2 Mr. Hart? Dr. Hamilton.

3 Dr. Hamilton: I wanted to ask you a question about the radio pharmaceuticals. In our specialty,
4 radioactive iodine is used in the outpatient environment for the treatment of patients. I know that's not part
5 of Part B, but is the payment for the radioactive iodine that is used in the outpatient, how is that determined
6 and is it, will it be a part of the Competitive Acquisition Program or is it paid for separately, and how is that
7 determined?

8 Mr. Hart: I can't address whether it's going to be a part of the Competitive Acquisition Program
9 again Amy who's here maybe will address that, I don't know. And off the top of my head, I assume that
10 we're paying for that substance with the methodology I described before, which is that we take the charges
11 on the hospital's bill, use the cost-to-charge ratio for the relevant department and convert that to cost and
12 pay that.

13 Dr. Hamilton: When it is used in a physician's office, that is not a part of a hospital department,
14 how is that paid for under those circumstances?

15 Mr. Hart: I think for radio pharmaceuticals in physician office, that it's kind of carrier-based
16 pricing now, I believe.

17 Dr. Hamilton: Well, it's very erratic, apparently around the country, there are—

18 Mr. Hart: Yes, I believe it is.

19 Dr. Hamilton: There are a number of locations around the country where they have a great deal of
20 difficulty getting this paid for in any reasonable way. And I was just curious as to what could be done to
21 establish some sort of a more uniform policy about that that would make this something that physicians can
22 in fact continue to do in their offices.

23 Mr. Hart: A uniform policy in the physician office side is sort of beyond my bailey wick, and I'm
24 not sure under the current law. Those may be able to say what the flexibility if any under the current law.
25 But again in the hospital outpatient setting, it's the methodology of charges.

26 Dr. Hamilton: Well, I guess the real question will come when Ms. Bassano talks about whether or
27 not this could be included in the Competitive Acquisition Program. We had suggested that it be included
28 and I hope that it will be.

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1 Dr. Castellanos: I have a question about the imaging. Again, I know we heard Mr. Kay give us a
2 presentation for the physician services on a free standing X-ray. Is there going to be a difference between
3 that and the hospital? And if there is, how do you justify that?

4 Mr. Hart: A difference in the rates?

5 Dr. Castellanos: Well, one is being discounted as I understand, and one is not being discounted.

6 Mr. Hart: One of the things I think this may address your question. One of the things that we
7 discovered when we were looking into this criticism that was made to us is that when we compared the
8 physician office rates, and the hospital outpatient rates, we found that in about half the cases, the physician
9 rates were higher than the hospital outpatient rates. And in some cases, significantly higher. And that was
10 one of the things that suggested to us that it may well be the case that on the hospital outpatient side, we're
11 capturing these efficiencies already, and that therefore, a further reduction on top of that would be, as I said
12 before a double whammy, and that suggest that it's probably, at least plausibly true on the physician side,
13 that those efficacies aren't being captured and the reduction is more justifiable. So there already are
14 differences. And the question is to try to come up with an equitable—given the differences in the
15 methodology, to come up with an equitable rate structure on both sides. We have a different sort of
16 situation because of our use of the cost-to-charge ratios and that's what we're going to try to come to grips
17 with this year and subsequently.

18 Dr. Castellanos: I just find that very hard to believe and accept, based on the experience in my
19 community. It's much more expensive getting a CAT scan at the hospital than it is at the physician's office.
20 And I can get you that data. I mean, it's not even close.

21 Mr. Hart: Well, again, we found that in over half the cases, the reverse was true. And I don't
22 remember—

23 Dr. Castellanos: Is it possible, and we could ask PRIT perhaps, in their report, Dr. Rogers, to
24 provide that data for us at the next meeting? Because I find it, personally, I'm not sure if the rest of the
25 members do, I find it just impossible to understand. Because I know that's not the way it's in our
26 community. I order a lot of X-rays and I send them to an outpatient facility because it's, excuse my
27 language, a heck of a lot cheaper than in the hospital. But I'd like other comments from the Council
28 members, what their experience is. Dr. Sprang?

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1 Dr. Sprang: Clearly in our office, we do ultrasounds, we do bone densities. I specifically send my
2 patients not to the hospital, but to outpatient facilities to get CTs, it's always half to 2/3s the cost.

3 Mr. Hart: The outpatient?

4 Dr. Sprang: The outpatient, compared to the hospital. And if we do a CT in the hospital, for an
5 abdomen and pelvis, it's \$4,000. I can get it down as an outpatient for \$2,000. Everything that we order, I
6 specifically try to not use the hospital because it's significantly more money. I mean we do coposcopies in
7 our office. I do it in my office, I charge \$150 to do the procedure. There's no office fee. I do that same
8 procedure in the hospital. The hospital charges \$700 for using their room, and then the pathologist charges
9 2 or 3 times more than what the outpatient pathologist charges. So it's dramatically higher.

10 Dr. Castellanos: Dr. Urata?

11 Dr. Urata: The expenses of a hospital are a lot higher than expenses of an ambulatory imaging
12 center or an ambulatory surgical center. For one thing, the private ambulatory centers are going to get paid
13 what they charge for the most part. The hospitals have to eat a lot of nonpayments, including what
14 Medicare doesn't pay by the way. And in addition, the hospital imaging center has to be manned and
15 operable 24-hours a day in case there's an emergency. At least that's the way it is in my community. So the
16 expenses of a hospital and the charges of a hospital will probably be much higher. That's the advantage of
17 an ambulatory imaging center or surgical center. They can be so much cheaper but they take the cream
18 away from the hospitals.

19 Mr. Hart: This is why we were surprised that in half and more of the cases, the hospital outpatient
20 rates, the national rates, were lower.

21 Dr. Urata: There's got to be a mistake somewhere.

22 Dr. Sprang: It's not consistent with the [inaudible].

23 Dr. McAneny: I can't resist. [laughter] And you knew that. I actually showed this a little earlier
24 because I wanted to make sure that Bill Rogers saw it, but I also wanted to make you see it on the Average
25 Sales Price plus 6%. I've been in practice for 25 years, doing oncology. We take all comers; uninsured,
26 Medicare, no Medigap, and so we ran our numbers and I'm going to hold it up again. In terms of how
27 we're doing under ASP plus 6 with the G-Codes, the current demonstration project, with the 3% transition
28 fee, with the new infusion codes, and estimating a chair time of \$150 an hour for the cost of simply having

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1 a chemotherapy chair in a facility with lights on and heat and all that, and what I discover is that I am
2 mostly, if people have no co-pays, I am in the red. If they have, if I can collect 100% of Medicare co-pays,
3 which happens about 95% of the time, about half of my codes are in the black, but half are in the red. But
4 when you average out the fact that this one-fifth here and four-fifths there, it puts me pretty close to
5 breaking even on Medicare and does not give me any excess dollars in the practice of Medicare patients to
6 do all of the pay for performance upgrades, capital, all the stuff that I would need to do that. When I
7 calculate the lack of the G-Codes, and the fact that my nurses continue to want raises and that prices
8 continue to go up and I look at what I'm faced at in the future, when I estimate 3 years from now what my
9 costs will be, this is Medicare with 100% recovery, which means they have a Medigap, under ASP plus 6,
10 and this is 20% of my practice that does not have a co-pay and they are in the red. And that is
11 unsustainable. I can't control the costs of the drugs, I can't work any harder and faster, I can't make up on
12 an E&M-Code when I lose \$3,000 every time I give somebody Herceptin. So I would like to make a
13 recommendation.

14 Dr. Castellanos: Please.

15 Dr. McAneny: I'm making this in part because in the Physician Fee Schedule, it said that ASP was
16 not intended cover the handling and storage of drugs, and because ASP was not intended to cover the
17 handling and storage of drugs, and because a suggestion was made to add 2% to cover these inventory costs
18 for hospitals, and because there are no codes for inventory pharmacy services for physician practices, that
19 CMS reevaluate ASP plus 6 as an adequate reimbursement.

20 [Seconds]

21 Dr. Castellanos: Is there any further discussion on that motion? Could you read it back please?

22 [off mike discussion]

23 Dr. McAneny: OK, because ASP system was not intended to cover the handling and storage of
24 drugs and because a suggestion was made to add 2% to cover these inventory costs for hospitals and
25 because there are no codes for inventory pharmacy services for physician practices, that PPAC
26 recommends CMS reevaluate ASP plus 6 as an adequate reimbursement.

27 Ms. Trevas: Because the ASP methodology was not intended to cover handling and storage of
28 drugs, because the suggestion was made to add 2% to cover inventory costs to hospitals and because there

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1 are no codes for inventory pharmacy services for physician practices, PPAC recommends that CMS
2 reevaluate ASP plus 6% as an adequate reimbursement rate.

3 Dr. Castellanos: I did hear a second to that motion. Is there any more discussion? All in favor?

4 [Ays]

5 Dr. Castellanos: Opposed? I would like to make a recommendation that Mr. Hart at the next PPAC
6 meeting come back and present the data based on CMS's collection, comparing the costs of outpatient X-
7 rays versus the free standing. That would be considering the discussion we just had previously. I don't even
8 think we need a motion for that. We can just ask you to come back.

9 Mr. Hart: We'll make sure that's part of the agenda.

10 Dr. Castellanos: Just have you on the agenda, because that's for most of us, something that we're
11 not aware of. Is there any other discussion? I think we have one more presentation before we close for the
12 morning, or—do you have another?

13 Dr. McAneny: We have the oncology demonstration project. No we have a couple of things. We
14 have CAP and RAC. Dr. Peter Bach is going to be presenting the oncology demonstration project.

15 Oncology Demonstration Project

16 Dr. Bach: Good afternoon. I'll try and keep my comments fairly brief so we have some time for
17 discussion. I'm going to describe next year's oncology demonstration project, and its focus on quality and
18 how it's going to lead us to Pay for Performance. The basic idea of the demonstration is that office space,
19 for hemotologists, oncologists are going to be allowed to or asked to submit 3 codes just as they were last
20 year and those codes they're submitting will cover 3 inter-related items. First, for each patient that they are
21 treating, the patient's disease status, something I'll walk you through and as clinicians you'll see why we're
22 doing this, but I would say disease status as shorthand is just sort of a version of cancer stage, with the
23 important exception that disease status can change while stage is something that is attached to you from the
24 time of diagnosis and does not. Also, there will be a code submitted for the primary focus of each
25 evaluation and management visit, which is by the way, when they are allowed to submit the codes, in
26 contrast to the '05 demo where they submitted codes in conjunction with infusion chemotherapy. And the
27 third code, which simply captures whether or not the doctor reports that the management they're providing

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1 the patient and the context of that visit is adherent to practice guidelines and it says there, there's a bullet
2 that this is linked to the primary focus of the visit code, just above. I'll explain how that works in a second.

3 Question is how do docs participate? Well this pertains to patients with one of 13 cancer types
4 based on the ICD-9 codes, those of you who can count quickly will see that there are only 11 listed there. I
5 apologize for not including CML. The other distinction is colo-rectal, is actually 2 cancers, and those many
6 of you also appreciate, the head and neck is actually multiple cancers. But anyway just a typographical
7 error. I apologize. The patients have to be have an evaluation and management visit in the doctor's office
8 and on that date, the doctor can submit the codes in conjunction with the demo. We did this because this
9 emphasizes the doctor-patient relationship. It de-emphasizes, it continues to move us away from an
10 emphasis on compensation to the doctors through chemotherapy administration. A long standing problem
11 in the way we paid oncologists, so we got away in a major way by switching from AWP to ASP, but this
12 moves us even further way. And it covers the spectrum of what oncologists do, which is more than give
13 chemo. They counsel about chemo, they evaluate and restage, the reevaluate for recurrence, they survey
14 patients, and they orchestrate palliative care. And this code, and the ability to participate is independent of
15 the location where the patient gets treatment. So the oncologist can be treating the patient, they can be
16 getting XRT or radiotherapy, they can be taking oral chemotherapy, they can be receiving their
17 chemotherapy in a hospital outpatient department visit. If that doc is in a physician office, the doc can
18 participate in conjunction with the patient's visit.

19 The goals here first of all is to capture sufficient information to identify the scope of what is done
20 for our cancer patients, our beneficiaries, in oncologists' offices in particular visits. To better understand
21 the disease patterns in our beneficiaries, as you all know, things like the ICD-9 codes capture only at the
22 crudest level what diseases we are even seeing in our beneficiaries. They certainly don't capture any of the
23 nuances of those diseases, or at any particular point in time, whether or not the disease is metastatic or
24 recurrent or progressive. And also to assess the standards of current care amongst our beneficiaries, as
25 provided by hematologists oncologists. We are doing this through the physician self-reported comparison
26 of what they are doing to the practice guidelines. And I would emphasize that embedded in these guidelines
27 are quality measures, something I'm going to come back to in a second.

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1 So the disease, just to walk through these 3 fields, the disease status codes are 4 to 7 codes
2 available for each of the 13 cancer types. And so those of you again who are familiar with cancer will
3 appreciate that such a classification reducing all disease status within a particular cancer to 4 to 7 codes is
4 quite crude, but it's also pretty straightforward. The oncologist submits the code that best characterizes the
5 current disease status, because of course it changes. And here's just an example of 2 codes that are again
6 shorthanded. An oncologist might be seeing a colon cancer patient. They might select this first code, the
7 extent of disease is T1 to 4, and 1 to 2 M0. Those of you who are oncologists, recognize that as state 3
8 colo-rectal cancer, obviously surgically staged patient, with no evidence of disease progression, recurrence
9 and metastases, and those of you again, who are clinicians will appreciate that this is a patient who has an
10 indication to get [adjuvin] chemotherapy. An alternative code would be something like metastatic
11 progressive or recurrent. Three different disease status really, but we've lumped them together into a single
12 code, so this gives you a sense of both the detail, and the lumping that's gone on.

13 The primary focus of the visit is separated into 6 choices, really five and an other category, to
14 capture the range of what oncologists do with cancer patients. Work up evaluation, and staging, or decision
15 making, supervising therapy, or managing toxicity, or disease surveillance. Oncologists consider
16 surveillance something you do when there's no evidence of disease, either biochemical or radiologic,
17 versus expected management, where the disease or some sort of marker is obviously present, but stable, and
18 you're sort of watching for it to do something. And the last choice being palliative therapy or end of life
19 care, where it isn't expected that therapy, whether given or not would lead to life prolongation on the
20 average, and then other.

21 Then lastly, they're asked to reflect whether or not what they're doing within the context of that
22 visit in terms of evaluation or treatment or expected management for example, whether or not the treatment
23 adheres to guidelines. And they can say yes, treatment adheres to guidelines or they can say no for any of
24 the following reasons. No the patient's on an IRB-approved clinical trial, no, the treating physician,
25 probably the person coding this, disagrees with guideline recommendations, or no the patient prefers
26 alternative or no treatment, or no the patient has sufficient co-morbidity or performance status limitations
27 which preclude guideline recommended treatment, or no, there are guidelines lacking for this patient's
28 specific condition, and then there's an other category. This is for a particular focus of the visit code, as I've

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1 suggested, so if they say the focus of the visit is staging, then the guidelines that you look at are for staging,
2 and if the focus of the visit is treatment, the guidelines they should look at are treatment. The guidelines
3 that we have designated for this demonstration are those coming from the National Comprehensive Cancer
4 Network, or NCCN, which covers every single disease listed on the prior slides, or the ASCO guidelines,
5 which cover a subset.

6 Now why are we doing this and how does this all fit together? First of all, you can extract some
7 quality measures from the oncologist self-reported responses, if you will, about whether or not they're
8 following guidelines. We can also characterize the spectrum of care and variation. For example, right now
9 we don't know anything about how much of care is directed for our cancer beneficiaries at treatment
10 surveillance or palliation. We don't know much about resources. We know that they're being consumed
11 more and more each year, and growing very rapidly, but we don't know how much in terms of imaging and
12 blood tests are performed on cancer patients in a period of expected management surveillance, or how
13 much that varies, either regionally or between doctors' practices, and we hope that we can learn from these
14 patterns, and hope to get cancer care more efficient, and to get in more patient-focused. And we can also
15 learn in which diseases there are variations from guidelines and for what reason. For example, we would
16 expect that in some cases, we're going to see a high proportion of oncologists saying they're not following
17 guidelines because frankly they disagree with the recommendations. And other places, we'll see that the
18 recommendations do not sufficiently incorporate patient preferences or co-morbidities. These are 2
19 significant issues for a hematologist oncologist treating Medicare beneficiaries who are more elderly and
20 more frail than the patients who have been included in most clinical trials. Getting a handle on this and
21 figuring out what direction we need to go and to improve the care of our beneficiaries will require a better
22 understanding of these specific issues.

23 Here's an example of an extractable measure for those of you who are really inside the Beltway on
24 this whole quality thing. Let's take a widely accepted quality measure—a patient with node positive or
25 stage 3 colon cancer, that should read, is counseled about chemotherapy. That is in the case I just gave a
26 couple slides ago, the [inaudible] or the newer regimens for stage 3 colon cancer. The quality measure is
27 the patient is offered it, and in this demo, we can ascertain whether or not that occurs by combing the ICD-
28 9 codes for the cancer, the disease status code, that's stage 3, that the focus of the visit is supervising

1 treatment, and the guideline measure is yes, I'm following guidelines. And remember we can audit or
2 otherwise evaluate, using our claims. The J-Codes that are submitted in conjunction with treating that
3 patient, in determining if the chemotherapy is better recommended by the guidelines are actually being
4 given.

5 So what does this all mean? What does guideline adherence mean? Well, I'd emphasize that first
6 of all guidelines capture the current standard in practice and in cancer there is agreement between
7 guidelines. There's 3 or 4 sets of guidelines out there. There's really quite broad agreement between the
8 guidelines in the vast majority of cases and certainly in the diseases we're looking at. And in cancer, and
9 this is essentially unique to cancer, I believe, in clinical medicine, really the guidelines really do cover the
10 majority of what is done. Across the spectrum of illness. I think this is and I think probably cardiology is
11 the closest next specialty to have both the breadth and depth that we see in the cancer community in terms
12 of guidelines.

13 There are some other strengths and weaknesses. Guidelines have flexibility. Many different
14 regimens are included in many scenarios. If you look at the chemotherapies suggested for metastatic lung
15 cancer for example on the NCCN guidelines, I believe there are 7 different regimens proposed. Any of
16 those 7 would be appropriate and the docs could say yes, I'm following guidelines. They also can be
17 changed when needed, they're not hard coded, if you will, a term Terry used a few minutes ago. After the
18 ASCO meeting, often people start to wonder if we should change some of the practice standards for some
19 of the cancers, because guidelines are developed by external organizations like NCCN and ASCO, they can
20 be flexible and they can be updated. But of course, we have to concede that sometimes, recommendations
21 are based on consensus more than evidence.

22 So I want to emphasize this issue also of how guidelines could work to improve quality because I
23 promised that on the first slide. I want to back up to this quality measurement issue. And I think this is
24 going to come up at other points today as well, there really are 2 alternatives to measuring quality in sort of
25 broadly. One is to code specific quality measures, which we are doing in the Physician Voluntary
26 Reporting Program. That works extremely well in some cases. The alternative is to refer to, if you'll pardon
27 the colloquialism, deemed measures from the outside, such as the NCCN practice guidelines. As I said, the
28 guidelines do this latter thing; they refer to these externalized measures produced by these guideline

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1 entities. CMS has no say in what the content is, we have simply built in, if you will, the infrastructure for
2 collecting data capture, but the scientific and clinical community controls the guideline content and the
3 process for elaborating those guidelines. It's an important distinction. I believe we're working on both of
4 those currently at CMS as ways of measuring quality reporting quality and moving towards Pay for
5 Performance.

6 Anyway, last point, I believe, what deviations from guidelines could teach us. First of all, where is
7 the evidence weak or unconvincing? Where are docs telling us a lot of the times I don't believe this, I'm
8 not following it, I disagree with it? Where's physician education needed? If we have doctors telling us they
9 don't agree a lot of the time but the randomized control trial data are overwhelmingly positive, then there
10 might be an alternative response to it, like we need more CME. What practical questions need to be
11 studied? Where's there deviation from the guidelines that suggests that there's alternative approaches
12 which are equally efficacious? And a very basic question: Is greater resource utilization, because I
13 previously referred to the rapid growths in utilization we see in hematology oncology, is that greater
14 resource utilization associated with deviation or adherence to practice guidelines? It probably varies by
15 different side—I think that's my last slide. So thank you very much for your attention.

16 Dr. Castellanos: Dr. Bach, thank you. Are there any questions? Dr. Urata?

17 Dr. Urata: Are non-oncologists supposed to participate in this?

18 Dr. Bach: This a demonstration for hematologist oncologists practicing in the physician office.
19 We're taking several steps in different areas. I [inaudible] the Physician Voluntary Reporting Program. Is
20 that coming up, or has that already been discussed today?

21 Dr. Urata: Already discussed.

22 Dr. Bach: OK, so there are a number of different strategies being taken. That initiative as well
23 covers although it covers several specialties, not just one, it certainly doesn't have the breadth that we'd
24 eventually like to achieve. And here, too, this is a focused pilot project in a certain specialty in a certain
25 setting.

26 Dr. Senagore: Yes, just to follow up on that, I guess it's somewhat disconcerting that most
27 surgeons will follow up a T-3 unzero unzero and use similar resources and what not and we don't get to be
28 studied, nor reimbursed for doing what's really standard of care.

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1 Dr. Bach: The reimbursement here flows, the payment flows with the data submission, not with
2 the standards being adhered to or not. And so the oncologist—this is not Pay for Performance. They're not
3 being paid based on whether or not they're following guidelines or not, we're providing them payment for
4 submitting the data linked to whether or not their following the guidelines, and they get the same payment
5 either way.

6 Dr. Grimm: I'd like to report that as well that I'm sure you've recognized this already that
7 particularly, like prostate cancer, which is one of your primary, the number one cancer in men, is that
8 you're having oncologist, hematologists evaluating this. They're not appropriate physician to evaluate that
9 cancer because they manage in their practices, probably, I don't know Barbara, you can give an estimation,
10 but Ron and I, radiation oncologists and urologists manage prostate cancer almost exclusively. It's a very,
11 very small percentage of actual prostate patients that get treated by hematologist. So the point being—

12 Dr. McAneny: Yes, I would agree with that because generally we only see prostate patients, if we
13 are the person who finds them when we're looking for other stuff, or if they become hormone refractory
14 and are sent on. Plus on these guidelines, there are a lot of confusing ones, like G-9113 to me looks almost
15 identical to G-9126 and a lot of the lymphoma ones, there's G-9118 that says stage 1 follicular lymphoma,
16 etc., etc. stage 1, 2 not relapse, not refractory and then 3 the guidelines down, it says not relapsed and not
17 refractory, which is otherwise, it's the exact same verbiage

18 Dr. Bach: There is a CR going in with correct—G-91—I don't have them all memorized, but G-
19 926 was an error and there was a typo on one other set of codes as well. It was all being, in fact I think the
20 5 that you just pointed to are the ones that are getting some sort of modification.

21 Dr. McAneny: Right and one of the myeloma ones refers to CML.

22 Dr. Bach: Right, this is all part of the same coding correction that's going in.

23 Dr. McAneny: So all those kind of things will be clarified.

24 Dr. Bach: Yes.

25 Dr. McAneny: But I agree, we don't see the early prostates.

26 Dr. Castellanos: Is there any other discussion? I'd like to make a discussion. Peter, Dr. Bach, I
27 appreciate your being here, and I know you and I have had a personal discussion on this ahead of time. I
28 happen to be a urologist, and as Dr. Grimm said, the most common cancer in the male Medicare age group

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1 is prostate cancer, overwhelmingly and yet you're dealing with just a subset of oncologists. Now we went
2 through this demonstration project last year with oncology, and there was a lot of discussion about opening
3 that up to other specialties, and as I remember, the discussion at that time was that this was a program for
4 next year, but next year we'll consider it. Now here, you asked why you're doing the study, and you said
5 you want to spectrum of care. And I think that's excellent. You should get a spectrum of care of each of
6 these disease processes. You're not going to get that by just talking to the oncologists or the hematologists.
7 Again, you're, as you stated, this is no longer specific to chemotherapy. It's E&M management and
8 spectrum of care. Is there, Dr. Grimm, do you have a motion?

9 Dr. Grimm: Yes, I do a motion. PPAC recommends that all physicians involved in the care of a
10 particular cancer, oh, I'm sorry, I'll slow down. PPAC recommends that all physicians involved in the care
11 of a particular cancer be included in the oncology demonstration project.

12 [Second]

13 Dr. Castellanos: Is there any discussion on that motion? Dana could you read that back to us
14 please?

15 Dr. Urata: Can I just make a comment? I don't know if I want to be part of this, but I do take care
16 of with the help of oncologists, some cancer patients, because people otherwise would have to move to
17 Seattle or Anchorage. And I think I'm going to be part of one demonstration project, and I don't think I
18 want to be on this one. [laughter] So can you keep the primary care docs out of this? [laughter]

19 Dr. Castellanos: Can we say "primary responsibility?" A friendly amendment?

20 Dr. Grimm: Yes.

21 Dr. Castellanos: All physicians who have the primary responsibility.

22 Dr. Grimm: Involved in the primary care of a particular cancer.

23 Dr. Castellanos: Responsibility of treating the cancer involved to participate in this demonstration
24 project for office-based oncology services. Do you accept that as a friendly amendment, Peter?

25 Dr. Grimm: Yes.

26 Dr. Castellanos: Dana could you read?

27 Ms. Trevas: PPAC recommends that all physicians who have primary responsibility for treating a
28 particular type of cancer be included in the oncology demonstration project.

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1 Dr. Castellanos: Is there any further discussion? Call the question, all in favor?

2 [Ays]

3 Dr. Castellanos: Opposed? We're running a little late, but I think we're still going to be able to get
4 out of here by 4:00. I'd like to take a—I think we can still get out before 4:00.

5 Dr. Grimm: Ron before we break, because some people have to leave a little bit early here, this is
6 a nonsequitur, not related to this issue, but a proposal I'd like to present to CMS that PPAC recommends
7 that Barbara McAneny be reinstated for a second term in participation in PPAC.

8 Dr. Castellanos: Well, I certainly second that motion. [laughter] Is there any discussion on that
9 motion? You're not allowed to vote.

10 [chat]

11 Dr. Castellanos: All in favor?

12 [Ays]

13 Dr. Castellanos: I'd like to take a 5-minute break and then we'll come back with the next part of
14 the program.

15 Break

16 Competitive Acquisition Program

17 Dr. Castellanos: We'll now continue with our presentation with the most up-to-date information
18 regarding the Competitive Acquisition for Drugs Final Rule. It is my pleasure again to introduce Ms. Amy
19 Bassano. She's the Director, Division of Ambulatory Services, Centers for Medicare and Medicaid
20 Services. Prior to joining CMS, Amy worked for four and a half years in the Office of Management and
21 Budget as the lead analyst for both Medicare Part B and Part D drugs, and prior to 2000, she was a Part B
22 issue analyst in the CMS Office of Legislation. Please welcome Ms. Amy Bassano.

23 Ms. Bassano: Thank you very much. I'm happy to be here. Talk briefly about the most recent
24 changes to the Competitive Acquisition Program, most notably, we published as part of the Physician Fee
25 Schedule rule that was published last month, we included a number of changes to the CAP. As we said we
26 were going to when we suspended bidding earlier in the year, there are a couple of main changes that we
27 included in this rule, but want to point out that we did not respond to all of the comments we got as part of
28 the IFC, because we intend to publish an additional Final Rule once the program is up and running, and

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1 we have more operational experience, so the changes we made were the ones that we saw that would make
2 the most, increase the best for the bidding process, but we do plan on going back and publishing another
3 Final Rule later on in the future, once we have some experience with the program. The changes in this rule,
4 included establishing a process for vendors to furnish additional drugs in CAP. Right now or prior to this
5 where there was the list of drugs that we had established, but no real procedures for the adding additional
6 drugs at the NDC level. Also we updated the list of drugs to incorporate the most recent changes in the drug
7 marketplace and to address the changes in coding that would be happening as of January 1, and also to
8 allow vendors to offer new drugs that are new to the market during the course of the 3-year contract period.
9 Couple other changes were to improve the consistency between CAP and Medicare ASP payments, or
10 policies regard to waste of drugs, in particular for single use files we want to try and make that those
11 policies as seamless between the two as possible, and also establish a framework for vendors if they want to
12 enter into agreements with physicians to do things like collect the co-insurance. We could allow these
13 arrangements to take place as long as they're consistent with the appropriate regulations in law, such as
14 Anti-Kickback statutes and IG recommendations. On the same day we published this rule, we also
15 published a separate interim Final Rule that would exclude the units of drugs supplied under CAP to be
16 from the average sales price calculation. This is something that we received a number of comments on and
17 including I believe from the Council I believe that these system should be separate from each other and so
18 we are saying that at least for the first 3 years, of the first three-year contract that the manufacturers will not
19 have to submit as part of their average sales price, the sales that went under, that happened under CAP and
20 we are going to require the vendors to assist the manufacturers with this data so that they have good
21 information about what the sales and we can help to ensure the accuracy of the average sales price. That is
22 an IFC. We are taking comments on it, but since it does have the full force of a Final Regulation, and
23 vendors can be using this when they prepare their bids. Which leads me to the timeline of where we are to
24 implementing CAP. When the Final Rule was published on November 21st, that opened the bidding period
25 for vendors to submit their applications and bids. The bids are due to CMS at 5:00 pm December 22nd. We
26 had a vendor conference call last week for opportunities for vendors to ask us questions, which we
27 responded to questions on that, and also taking comments through our email box, so we can respond to
28 those questions that in the next several days because when the bidding process goes on, we can only

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1 communicate to the vendors through the website, so we will be posting additional information on our
2 website to help vendors along; any questions they have about their process, sorry, their bid, we would hope
3 to be announcing the winning vendors later on, early next year, in time to have a physician election period
4 in the spring of 2006. We'd have more information about that once we received the bids and further on the
5 process, but looking sort of an April-May time frame for that, and then with the ultimate goal of
6 implementing CAP on July 1, 2006. And the physician elections that do occur in the spring timeframe will
7 be for the remainder of 2006 calendar year, and there will be another election in the fall of 2006 for the full
8 calendar year of 2007. So and you can always look at our website for on CAP we have a lot of information
9 there for vendors, physicians, and other interested parties and like I said, we'll be posting additional
10 information there, as we get closer to the implementation date. That was a quick update, I'm happy to take
11 any questions you may have.

12 Dr. Castellanos: Thank you Amy. Are there any questions? Dr. Hamilton?

13 Dr. Hamilton: Amy, just in follow up to my previous question, does this website location list the
14 drugs that are a part of the program.

15 Ms. Bassano: There is a link to the drugs that are in there and in terms of the radio
16 pharmaceuticals, we did not include them in this round of CAP for a couple of different reasons. One,
17 trying to be as simple, as expansive, but as simple as possible, and because there are more complicated
18 payment issues with radio pharmaceuticals, we decided not to include them at this particular time. And in
19 terms of your question earlier about how they're paid, the MMA is actually has a sort of interesting
20 provision in it that says that radio pharmaceuticals are to continue to be paid the way they were before the
21 passage of the implementation of this act, so prior to December 7, 8th, 2003. And what that is is that it is as
22 Jim mentioned, it is at carrier discretion, so they could go a couple different ways on how they want to pay
23 for them, and that's why you've probably seen some differences of payment methodology across the
24 country. And the MMA reiterated that that's how they should continue to be being paid.

25 Dr. Hamilton: That really is a big problem. What would be the process of trying to get radio
26 pharmaceuticals included in this process?

27 Ms. Bassano: In CAP?

28 Dr. Hamilton: Yes.

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1 Ms. Bassano: I think it would be something of, as we gain more experience with it and where we,
2 since we don't have the payment information, right now, they have to bid off of the ASP, and if we don't
3 have the ASP for the radio pharmaceuticals and I think the manufacturers have concerns about submitting
4 ASP for these products, then it's harder for us to judge a standard of how vendors could bid for them. And
5 how could they be provided to given the CAP model of a vendor has to send them to the physician. The
6 vendor maintains title of the product until it's administered to the patient. So I think that it's one of the
7 more complicated products, something that we're going to be looking at going forward. We also excluded
8 controlled substances for many of the same reasons, that it was just a little bit more complicated and
9 wanted to think about how does this work with the most straightforward of drugs, and then in future rounds
10 of bidding, in future categories, can we expand it to include those.

11 Dr. Hamilton: Well, perhaps our organization could work with you to try to collect the data that
12 you need to make some kind of rational decision.

13 Ms. Bassano: Sure.

14 Dr. McAneny: First, thank you very much for having the CAP not contribute to ASP and therefore
15 price it way below any of us who elect not to participate in CAP could possibly get the drug, and for
16 clarifying that the vendor is responsible for shipping back drugs and taking care of that. And that's very
17 much appreciated. I still have a couple of things that I wanted to ask. In the process of a CAP vendor
18 deciding that the beneficiary doesn't meet their co-pays and is not participating their 20% of the costs of
19 the drugs, and then turning that supply line off of that patient, the Final Rule states that all we have to do as
20 the oncologist sitting face to face with that patient is to say, well, here is the grievance process from your
21 vendor, and we're out of it. But I'm not out of it. What happens in that situation is if I have a patient who is
22 undergoing chemotherapy and I cut off their supply of drugs, I think that constitutes abandonment, so that
23 if somebody's halfway through their treatment for Hodgkin's Disease, to take the worst case scenario, a
24 potentially curable cancer, and I'm saying, well, sorry, the drugs are gone. Here's where you call and good
25 luck to you. How do I do that? I can't do that to a patient and turn that off and just say good luck and go sit
26 with a cup by the road, and say will give chemo for food or something. I don't know what to do. So I would
27 like to hear how we can really get around that and in a timely manner with the appeals process, because if
28 there's an appeal process in the middle of a course of chemotherapy, and that appeals process goes all the

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1 way up to the ALJ, or whomever it goes to, that takes time. If you're treating Hodgkin's Disease or acute
2 leukemia, or any of a number of cancers, while I'm sitting around waiting for an ALJ hearing, the cancer is
3 not sort of sitting there waiting for the ALJ hearing. It's growing. So I don't know were I to participate in
4 CAP, what I would do in that situation. The only recourse that I'm given, were I to participate in this would
5 be to say forget it, I won't do CAP for anything. I'm signing out of CAP for everything. That puts—how do
6 you recommend that we deal with that?

7 Ms. Bassano: Well, I think we're sensitive to that and will be hoping that at least from the initial
8 levels, we would be working in the appeals process to get that done as expedited as possible in their special
9 dispute resolution issues available or processes available through CAP with or designated carrier who is
10 processing these claims and so we'll be paying great attention to that and trying to get them done as fast as
11 possible. I think though that, we would hope that the vendors would not be stopping the supply of the
12 particular products, but we have to recognize that they have the—

13 Dr. McAneny: They probably will.

14 Ms. Bassano: Well, but they have the right to stop doing that. And but from comments we
15 received is that a lot of these vendors are already providing or administering physician assistance programs
16 and they are very adept at working with them and we would hope that they would be able to then get the
17 beneficiaries enrolled in them and that this is the worst case scenario that we won't be encountering, but we
18 do as you mentioned give the physician the opportunity to opt out of CAP entirely in that situation.

19 Dr. McAneny: Again, and my comments that I made earlier this morning about Part D would
20 apply here, too. I would hope that Medicare would use it's authority to have one grievance form that has a
21 limited amount of data, is less than a zillion pages long, which most of them are, so that that itself does not
22 become a barrier to physicians' helping patients get through it. Because all of the processes say the patient
23 files the grievance. But in the real world, the patient comes to their doctor and says help me with this. What
24 do I do? And then they dump the paperwork on your desk. They go home and you do the paperwork. So we
25 need that. The other thing is I was sort of surprised to hear the process by which I can, if I wish, turn into a
26 collection agent for the vendor and try to collect their 20% and therefore expose myself to Kick-back
27 liability. I wondered are we giving psych consults for physicians who are willing to do this? It just seems so
28 amazing to me that unless they are offering some large quantity of money for my acting as a collection

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1 agent, this isn't what I wanted to do with my life, and I can't imagine that very many oncologists will. I
2 understand you're just leaving that up to the vendor, but I would like to hear a comment on whether or not
3 you're proposing any uniform grievance form, so that we can expedite and not create other barriers to
4 helping patients get their drugs.

5 Ms. Bassano: At this point, we don't have anything that's specific to CAP, but we can look into it
6 and see the forms Medicare-wide and how they'd be appropriate. There are some things that we've tailored
7 to CAP specific, but at this point, there's nothing on the grievance for the beneficiary level.

8 Dr. McAneny: I think you've done a remarkable job of trying to make regulations out of what I
9 view as a very bizarre law. [laughter]

10 Dr. Castellanos: Are there any other questions for Amy? Well, Amy again, we want to thank you
11 very, very much for being here again, and clarifying this program. Thank you. The Recovery Audit
12 Contract. This is an update, as you remember, as part of our recommendations at our August meeting, we
13 asked to have the Recovery Audit and update. Melanie Combs has been here a number of times. She was
14 first here concerning this issue in May 23rd, 2005 PPAC meeting. At that time, Melanie joined Dr. Jesse
15 Polanski in introducing us to the Recovery Audit Initiative. Today she is joined by Gerald Walters, who,
16 and we'll hear the latest information concerning this initiative and then we'll take any questions you may
17 have regarding this. By way of background, Melanie has a Bachelor's in Nursing. She has her Masters in
18 Health Care Administration, and prior to joining CMS she worked for the Maryland Peer Review
19 Organization in the Maryland Department of Health. She currently measures error rates in CMS various
20 programs. She helps CMS remain compliant with the Improper Payment Information Act, and she is
21 involved in the Recovery Audit Demonstration Project. Mr. Walters is Director of the Financial Service
22 Group in the Office of Financial Management. Please welcome both Melanie and Gerry.

23 Recovery Audit Contract (RAC) Update

24 Mr. Walters: Thank you Dr. Castellanos. As you'll notice the bio for Melanie is the important one,
25 having that clinician background the QIO experience. And speaking of collection agents, [laughter] we're
26 going to talk about the Recovery Audit Demonstration. As Dr. Castellanos mentioned, Melanie was here
27 with Jesse Polanski last quarterly meeting, I believe, and I appreciate that. I managed to not be here that
28 day. We'll try to go through this. I know everyone wants to get out of here and generally there's a lot of

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1 questions related to this, so we'll be happy to answer as many as you like. What we're going to try to do
2 today is just sort of refresh your memories about what this demonstration is, and give you a little update
3 about the progress that we have, we want to discuss just a little bit some of our efforts in Provider
4 Outreach, where we've been trying to talk with people, and there's one new issue that we hear often, which
5 is what about my underpayments? What are you doing? So we'll touch a little bit on that, and I'll be
6 looking for some recommendations from the PPAC related to that.

7 And that's what I'm really trying to say here. And you'll have these in your package so I won't go
8 through some of these website addresses, but there's plenty of information out there. MedLearn articles,
9 you can see the statement of work, which is essentially our contract with these companies, our press
10 release. Let's talk a little bit about Congress. Mel and I were talking a little and when we first saw this
11 legislation in the statute, which is Section 306 of the Medicare Modernization Act, we sort of looked at one
12 another and said uh oh, simply because the way the legislation is written, this is going to be difficult to do.
13 And there are a lot of other pieces in the Medicare Modernization Act that in fact make this even more
14 complicated but we won't go into those. Essentially, Congress, having looked at our need for Medicare
15 integrity spending, had originally given us a graduated amount of dollars, going all the way to \$720 dollars,
16 from 1996 to 2003. Now in 2004, and 5 and 6 and beyond, it's capped at \$720 million. Well as we try to do
17 more and more integrity activities, we're jamming more and more into that fixed amount of dollars. With
18 Part D coming along, with the prescription drug program and other things, we'll need to get efficiencies, so
19 I think what Congress started looking at was what are there some ways that CMS can employ that are least
20 costly, let's put it that way. CMS had never had the ability to do certain kinds of contracting and the
21 legislation gave us that, so we believe that that is in fact what Congress wanted.

22 So what this was was Section 306 of the MMA, it's a 3-year demonstration. Looking to see if we
23 can find efficiencies and recover some overpayments and identify some underpayments and then we need
24 to recover, obviously, those overpayments. I think Congress looked at this; they found that there are
25 companies in the private industry that do this today. It's very common business practice. Some of you may
26 have had some experience with these from other private payers, as opposed to public payers. They are the
27 recovery auditors are paid on a contingency fee basis. The legislation required that we have it in the 2, at
28 least 2 states of the largest Medicare utilization. Since the legislation required at least 3 contractors, we

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1 chose to do 3 states, the 3 states being New York, California, Florida, that's obviously where the majority
2 of them.

3 So looking at this for informational purposes, in California, the recovery audit company is PRG
4 Schultz International. In Florida, it's Health Data Insights, and in New York, it's Connelly Consulting. I'm
5 not talking about any of the secondary payer stuff because there is a part of that to the demonstration, but
6 that's not important for this discussion.

7 Ms. Combs: Continuing discussion of background, I'm going to go through very quickly the RAC
8 review process. In May, 2005, we gave each of the RACs the claims data that had been processed for the
9 prior 3 years and every 3 months, we give the recovery audit contractors, another quarter's worth of claims,
10 so as they get new data, data falls off at the backend. It's no longer available to them, because it's passed
11 the reopening rules time frame. All of the recovery audit contracts are doing post-payment medical review.
12 None of them are doing pre-payment medical review. They're not looking at claims as they come in the
13 door before you get paid. They're looking at things that the carrier has already finished reviewing and
14 they're doing the two types of medical review that our regular carriers are doing. They're doing automated
15 review, looking for duplicates, looking for places where payment rules were not applied properly, where no
16 medical record is needed, and they're also doing our buzz word complex medical review, which is where
17 you actually do have to order up a medical record from the provider and review it to see if in fact the claim
18 was correctly coded, medically necessary, etc. Initially, the recovery audit contractors are not going to be
19 doing anything with the E&M levels of codes. They can still look for duplicates in E&M-codes, and they
20 can still look for global surgical violations, or things like that, but they will not be doing anything with
21 levels of codes; you billed at a level 3 and you should have billed at a level 4, or a level 2, and the reason
22 for that is that CMS is currently reviewing AMA's resolution 819 that talks about deferring to the billing
23 physician's judgement in one-level differences. And until CMS is done reviewing that resolution, we felt
24 like it was important to just leave off the table for the recovery audit contractors all of the E&M level
25 reviews. Once CMS is done analyzing AMA Resolution 819, we'll reconsider whether or not the recovery
26 audit contractors should be able to go after the E&M-codes, but at this point, they're off the table. The last
27 bullet point here is an important one and that is that we felt like it was very important to prevent
28 duplication. We didn't want the same claim that's already been reviewed by the carrier, they've already

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1 requested a medical record, to now get picked up by the recovery audit contractor and you to get another
2 request for a medical record on the same claim. So we built a data base that all of the carriers and the
3 program safeguard contractors, and the cert program and the QIOs all dump their information into, and the
4 recovery audit contractor, if they want to request a medical record, or they want to demand an
5 overpayment, they first have to check that database and make sure that nobody else has touched you for
6 that claim, before they're allowed to send out their request for medical records or their demand letter. And
7 we hope that that will prevent duplication on our part, and minimize the burden to providers. Let me add
8 one more bullet that you won't see on this slide, but I think it's an important one to add and that is that the
9 normal appeals process applies. That the recovery audit contractor identifies an overpayment, and sends a
10 demand letter, the normal appeals process applies, and the provider can go through that process to get that
11 heard. Perhaps it will be overturned, perhaps it won't but whatever that normal process is, they can use.

12 The next slide talks about the progress that our recovery audit contractors are making. All 3 of our
13 recovery audit contractors have issued requests for medical records and all of them have issued
14 overpayment demand letters. And I would say at this point, things are moving relatively slowly, perhaps
15 because it's a lot of data that we dumped on them, also it's a very complex program for them to understand
16 all of the Medicare rules and make sure that all of their algorithms fit our Medicare rules, and because
17 we've added a CMS QA process before they were allowed to go out and request medical records, or
18 demand overpayments, they had to run it by either Dr. Polanski or by me. We would pull a sample of
19 claims and review them and make sure that they really understood the rules and that they weren't
20 requesting medical records when they shouldn't, or they weren't demanding overpayments when they
21 shouldn't. And that's actually been a very valuable process. We've been able to learn through that process
22 that for example, we had not been giving them all the right data at the very beginning. And so now we've
23 fixed that problem, they're getting all the data they need, and things are running very smoothly. We expect
24 that probably the volume will pick up at all 3 of our recovery audit contractors after the holidays. We're no
25 longer feeling the need to review every batch of data that they come out with. It looks to us like they really
26 understand the rules, and are really able to stand on their own, and so we would anticipate that starting with
27 the New Year, the volume will pick up.

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1 We are gathering results from all of our recovery audit contractors in terms of what they're
2 finding, how many dollars they're collecting in overpayments and such, and probably with the next time
3 that you all have a quarterly meeting, we'll be ready to share some of that data, so you may want to invite
4 Gerry and me to come back and share that information with you. The next slide talks about our Provider
5 Outreach. This has been something that you told us was very important and we've been trying to follow
6 and I think it's been very beneficial. We've met with hospital and physician groups in all 3 states; we've
7 issue 2 MedLearn articles, held 2 open door forums, and we've participated in numerous conference calls
8 with national, state, and local provider organizations, particularly with the AMA and the AHA. We just
9 seems to be on the phone with them every month, trying to make sure that we're listening to them and
10 they're understanding from us and we're able to communicate well with the provider community. As a
11 segue to the next slide, one other thing that you recommended to us the last time that we were here, had to
12 do with underpayments. You told us that we really needed to think long and hard about how we were going
13 to handle underpayments. You told us that the provider community might raise some issues, and in fact,
14 they did. And so Gerry's going to take this slide and let you know what we heard.

15 Mr. Walters: Well as you might imagine, as the statute requires, these recovery auditors are to
16 look for underpayments. One would think that their business practices are geared toward finding
17 overpayments. It became complicated for us in looking at how do you financially incentivize someone to
18 find an underpayment, and if one thinks about this for one minute, if there's a 10% and I'm not saying that
19 that's what their contingency fees are, but a 10% contingency, why would Medicare pay \$110 for a \$10
20 claim? That's money coming out of the trust fund, not money going back in, so there's not been a recovery
21 to offset. So it's very complicated I think to look at that. We've been exploring some ideas. And we are still
22 open to other ideas, but I believe that we found a way to financially incentivize the recovery auditors to
23 target underpayments, rather than what many people think is just tripping over them. However, I would
24 point out that the recovery auditors' contracts do require them under contract to identify underpayments. So
25 there have really been 2 concerns; one is why aren't you financially incentivizing them? 2, are we going to
26 be paid for those underpayments? How am I going to be paid? And there's really kind of one more which is
27 sort of I would like to change all of the Medicare claims processing rules, and I would like to change all of
28 the payment policies, because I want to play in a bigger sandbox, and I'll try to talk about for a minute. But

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1 the answer to the question of will I be paid, the answer is yes, you will be paid. We have directed the
2 recovery auditors to notify the Medicare contractor when they find an underpayment, and then the
3 Medicare contractor will adjust the claim, CMS will tell them to do that, they will adjust the claim, and
4 they will pay the underpayment amounts. So we do want to incentivize the recovery auditors to actually do
5 some underpayment review. And again, like I said, their algorithms, their proprietary methods at looking at
6 health care claims really are focused, especially in the private business at finding where the business paid a
7 little bit too much and they'd like to get it back. As one might imagine, it's just like any sort of collection
8 agent type of business, these are very principled companies. CMS took great care in choosing the right
9 companies who had plenty of experience in both the provider communities and the hospitals, and with
10 physicians, so that they had a track record, where we felt that the relationship between them, CMS, and the
11 medical community would be one of some professionalism and maybe just a little bit of hand-holding. So
12 it's been quite an interesting thing. So we're exploring some ideas, we welcome anything from the PPAC,
13 if anybody has even thought perhaps how to do that, and lastly, let me just say, before we can do some
14 Q&A here is add a CMS to the beginning of this. We changed email systems, and they changed it on us, so
15 it is CMS[space]recoveryauditdemo@CMS.HHS.GOV. That was done after we prepared this slide and it
16 caught us off guard. So that is the new email address: CMS space recovery audit demo. And you can
17 certainly send us an email with any questions, or your colleagues and we will answer those. We do get
18 some in. We do try to answer them directly. There are certain things that obviously we can't disclose, if
19 people are asking well how much is the contingency fee and those kinds of things, so it's kind of
20 proprietary. So I think we're finished, unless Melanie has anything to add.

21 Ms. Combs: No.

22 Mr. Walters: Great! Thank you, Dr. Castellanos.

23 Dr. Castellanos: Thank you Melanie, thank you Gerry. Are there any questions? Dr. Grimm?

24 Dr. Grimm: Well, I have a solution to that. I think if you find an underpayment, you've actually
25 done a service for whomever you're doing that for free. And if you found \$100 of mine, I'd give you \$5.
26 I'll tell you that much. Maybe ten.

27 Dr. Urata: Don't tell him how much you'll get. [laughter]

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1 Dr. Grimm: If you found money that I didn't have before, I think that the physicians would not be
2 opposed to paying that.

3 Ms. Combs: That's a good idea, thank you.

4 Dr. Urata: I agree.

5 Mr. Walters: If I could address that. We have heard this kind of solution, actually I asked if you'd
6 be willing to pay, sort of let this contractor work both sides, for both the government and the physician and
7 hospital communities; however, if one person says I'm not going to pay, give me my money, I can't do it.
8 Under the demonstration, that would, I would have to have a buy-in from the entire physician and hospital
9 communities, [laughter] and that's not going to happen, we all know that. Because as soon as one person
10 says no.

11 Dr. Castellanos: Are there any other suggestions or comments? Dr. McAneny?

12 Dr. McAneny: Actually a comment on that. Currently there is a little cottage industry that will go
13 around and audit your practice and tell you where you're undercoating and they sell this based on a
14 percentage of what they find that you have truly undercoated, document it and help you resubmit it. So I
15 think that if you sell this as a service, that it would be reasonable. It's a reasonable business thing to do.
16 Trying to get all physicians to agree that the sun comes up in the east might be difficult, but I think that
17 that's worth a try. What did you mean by your last comment, of all the rules changeable in the bigger
18 sandbox? What did you mean by that?

19 Mr. Walters: Well, let me be more clear. What we find is you can go back and you look for
20 example at 3 years of claims. And you can go collect your money. What people are concerned about is well
21 what if my claim's 3 years old, can I look, like you said maybe hire a cottage industry company to sort of
22 come in and take a look, and send you all of mine. Well, normal claims processing rules apply. The
23 demonstration is not meant to throw out the claims processing and payment policies. It's really meant as
24 Congress intended to see if these companies could provide value to the Medicare Program, and at the end
25 will be required to do a report to Congress that will talk about the efficacy of the program in Medicare. So
26 that's what I mean. People seem to want, I want everything. I can't give them everything in this
27 demonstration.

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1 Dr. Castellanos: I did talk to the FMA, Fred Witson and [inaudible] Henderson. [inaudible] have
2 been send out to demand letters, however they have not identified any underpayments to date, interestingly.
3 The only surprise was they went back to 2001. Now, that was the only thing that Florida physicians were—
4 I knew they could go back 3 years. Now the question was, can they go back 3 years for underpayment also?
5 And I don't know if there's an answer to that. Well, once again, I think that gets into the issue, Dr.
6 Castellanos. I think that what we're saying is if it's an underpayment, and it's still within the claims
7 processing rules, like for inpatient hospital, I think it's 15 to 27 months, you can resubmit that claim and
8 then it can be adjusted and you'll be paid appropriately. I think what you're talking about going back to
9 2001 are claim dates that are processed, so it's quite possible that you had a service in calendar year 2001,
10 because we gave them fiscal year data, so it could possibly be that there is in some instances cases where
11 it's 2001.

12 Ms. Combs: The data we gave them was based on claims processing dates, and so the date could
13 be for a date of service a year earlier.

14 Dr. Castellanos: Now the other comment was and I did mention this last time, you said you
15 mentioned you had met with hospitals and physician organizations. I can only tell you that you have not
16 met with the Care & Medical director in our state. And I mentioned that to you last time. I spoke to Jim
17 Cochran myself, so I'd like to make a recommendation that a representative from CMS, the RAC
18 contractor meet with each of the Care & Medical Directors of each of the 3 states.

19 Mr. Walters: Thank you for the recommendation.

20 Dr. Castellanos: I'd like to make a recommendation and a motion on that.

21 [Second]

22 Dr. Castellanos: Is there any further discussion? Dana could you read that back to us?

23 Ms. Trevas: PPAC recommends that a representative of CMS and the appropriate RAC meet with
24 the Care & Medical Director in each of the 3 states in the demonstration projects.

25 Dr. Castellanos: OK, I'll call the question—all in favor?

26 [Ays]

27 Dr. Castellanos: Jim is very interested in meeting with you guys. The RAC contractors have been
28 in his office, using his computers, and he would just like kind of to find out what's going on. I mean it's not

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1 a big secret or anything. Are there any other questions? OK, we thank you Melanie and we thank you Gerry
2 for the big help you've given us at this time. We have one public testimony today. I'm pleased to welcome
3 Dr. Kim Hetsko. He is an internist from Milwaukee, Wisconsin. He's an associate clinical professor at the
4 University of Wisconsin. He's still actively practicing medicine and he's here today to represent the
5 American Medical Association. He'd like to address the Council with statements related to the Physician
6 Fee Schedule Final Rule, and Pay for Performance and Quality Measures. For you that are interested, the
7 AMA written testimony in its entirety will be found under tab M in the briefing book.

8 Public Testimony – American Medical Association

9 Dr. Hetske: Thank you very kindly. It's indeed an honor to be here, and especially with a number
10 of good friends from over the years, and I appreciate and am glad and happy to see you all again. Mr.
11 Chair, members of the Council, my name is Syrilamma Kim Hetsko. I'm an internist from Madison,
12 Wisconsin, with subspecialty interests in infectious diseases and laboratory medicine. I'm also a member of
13 the Board of Trustees of the American Medical Association and I'm Chair of the AMA's Board Task Force
14 on Quality, Safety, and the Electronic Health Record. And I've also been the board liaison to our
15 Physicians Consortium for Performance Measures. The AMA certainly appreciates the opportunity to be
16 here, today. First, I'd like to address an issue of great urgency, that you've already touched on a bit today,
17 and that is the flawed Medicare physician payment formula, or the SGR. The AMA has often discussed
18 with the PPAC the fundamental problems with this fatally flawed SGR formula and the serious threat it
19 presents to patient access. Today, that rings more true than ever. Unfortunately, only 26 days are left until
20 January 1st. At that point, a 4.4% Medicare physician pay cut will kick in. This will be the first in a series of
21 steep cuts over the next 6 years that will total an astounding 26%. These cuts are produced by this flawed
22 SGR formula. Clearly it is broken. And a very serious patient access crisis is looming. Physicians will not
23 be able to absorb these cuts and will be forced to limit services to Medicare patients. We need action now.
24 This year before the month of December is out. We urge PPAC to recommend that CMS give its full
25 support to Congress to enact positive physician payment updates immediately, beginning in 2006 that really
26 reflect the increases in medical practice costs.

27 Administrator McClellan has voiced CMS's positive support for updates for physicians. We urge
28 that steps be taken now to transform the support into the enactment of legislation this year. This will

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1 prevent Congress and the administration from having to struggle with this problem again early next year. In
2 other words, bottom line, we won't need to be back in their offices again in 3 weeks starting after January
3 1st and start the whole process all over again. A recent AMA survey shows that the pending draconian cuts
4 will impair access. They will also have a ripple affect across other payers, including tri-care which pays for
5 the medical care for military families and retirees. Intervention by the administration and Congress has
6 averted steep cuts for 2003 through 2005. We certainly are grateful for these good faith efforts.
7 Nevertheless, over the last 3 years, physicians have received less than half of CMS's own conservative
8 estimates of increases in medical practice costs. If the 2006 cut is imposed, average physician payments
9 will be less in 2006 than they were in 2001, and those are in real terms, real dollars, not adjusted for
10 inflation. Inflation is another good term too, that we're all familiar with. A look to the future under the
11 SGR is even more grim. Physician practice costs are expected to rise by an additional 15% from 2006
12 through 2011, yet during that time, Medicare physician payments will decrease by 26%. This is intolerable.
13 Businesses cannot survive these unsustainable cuts, especially physician practices, which typically operate
14 as small business. 50% of the docs in the United States are practicing in small physician practice settings.
15 Only physicians face updates of 7% below the annual increase in their practice costs. Updates for hospitals
16 and long-term providers will keep pace with their inflation index. Medicare Advantage plans will see
17 average updates of a positive 4.8% in 2006. It is time that parity for physicians be reestablished to preserve
18 Medicare patient access.

19 Next, I'd like to address a closely related topic of concern, providing the highest quality of care to
20 the patients we serve. And this has been discussed earlier today. The AMA appreciates Administrator
21 McClellan's commitment to continuing an ongoing dialog with physicians concerning various Pay for
22 Performance options. We wish to continue working with CMS and Congress to provide the highest quality
23 of care for the patients that we serve. In fact, the AMA and the leadership of national medical specialty
24 societies have invested extensive resources in quality improvement initiatives over the course of many
25 years including a deep AMA commitment to the physician consortium for practice improvement. The
26 AMA has committed millions of dollars and also a dozen staff, which are increasing greatly, to assist the 70
27 different physician groups to compile a list of scientifically based, evidence-based outcomes measures. Not
28 guidelines, not best practices, not efficiency measures, but really scientifically evidence-based measures.

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1 We have developed over 26 sets of data to this point in time in measures in the physician consortium for
2 performance improvement. And these range from things like diabetes treatment on the outpatient basis, to
3 depression. Many more of these measures and performance measures are in process. The consortium
4 developed measures are the majority of those that have been endorsed by the NQF and also AQCA, NQF—
5 National Quality Forum and AQCA, the Ambulatory Quality Care Alliance.

6 Over the last decade, the AMA has worked diligently, along with others to develop quality
7 measures that currently are the basis for various Pay for Performance initiatives. As we continue in these
8 efforts, we must act to eliminate barriers to maximizing quality care. Most importantly, if linked to Pay for
9 Performance, the SGR must be eliminated. It will prevent opportunities for investment and innovation that
10 will benefit patient care and will generate system-wide savings. Pay for Performance, and as discussed
11 earlier, Pay for Performance and the SGR are not compatible. Pay for Performance may save dollars for the
12 program as a whole, especially under Part A, but many performance measures ask physicians to deliver
13 more care under Part B, especially where the long term savings will really come under Part A. Even
14 recently, the Leapfrog Group has recently announced the results of a long term national study. It showed
15 that while Pay for Performance Programs can raise the quality of patient care, physician visits significantly
16 increased. And that's not AMA data, that Leapfrog data. The SGR results in payment cuts if utilization of
17 physician services exceeds the target. Thus, if the SGR is linked to Pay for Performance, more physician
18 services will be generated by the Pay for Performance Program, and then they will just turn around and
19 result in more cuts under the fatally flawed SGR program. Pay for Performance depend upon greater
20 physician adoption of the information technology is also highlighted by the Leapfrog study. Without
21 positive updates, health information technology by the practicing physician will not be possible. A recent
22 AMA survey indicates that steep pay cuts would cause more than half of the physicians to defer HIT
23 purchases. Thus implementation of Pay for Performance proposal should be deferred until the SGR is
24 repealed and a stable Medicare payment system is in place that actually reflects increases in physicians'
25 practice costs. We urge PPAC to make recommendations of this type to CMS. This does not mean we
26 cannot continue a meaningful dialog about quality initiatives that may ultimately be linked to a stabilized
27 Medicare physician payment system. Pay for Performance Programs must be done right to achieve their
28 intended goals. The AMA looks forward to this continued dialog between Dr. McClellan and leaders of the

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1 physician community. Working together, the administration, Congress and physicians can strengthen the
2 Medicare Program and correct problems that undermine the Medicare patient access to patients to the
3 physician of their choice, along with assuring high quality medical services.

4 Before closing, I'd like to also comment on the discussion we just heard. The AMA remains very
5 concerned about Recovery Audits. We recently learned that there is no process in place for refunding to
6 physicians any underpayments that are recovered during a RAC audit. We urge PPAC to request that CMS
7 correct this situation immediately. The AMA will continue to aggressively pursue changes with CMS on
8 this and other aspects of the RAC audits. We thank you very much for the opportunity to be here and join
9 you today and participate in this discussion. Thank you very kindly.

10 Dr. Castellanos: Thank you, Dr. Hetsko. We really appreciate your taking your time out of your
11 practice to be here. Are there any questions that you have for Dr. Hetsko? Again, thank you, we certainly
12 appreciate it. At this time I'd like to take the opportunity to allow the Council time to review the
13 recommendations made from today's presentation. Once Council's ready, Mr. Herb Kuhn, and Dr. Tom
14 Gustafson, Deputy Director, will assist with this portion of the meeting. So we're going to take about a 5
15 minute break. Thank you.

16 Review of Recommendations and Wrap Up

17 Dr. Castellanos: I don't think we can take any more recommendations, but is there an issue that
18 you would like to bring up?

19 [off mike discussion]

20 Dr. Castellanos: OK, fine. You have to excuse me, I'm usually dealing with my wife. Excuse me.
21 [laughter]

22 Dr. Urata: I'm sure your wife would say the same thing.

23 Dr. Castellanos: She'd tell me where the chair was.

24 Dr. Urata: It was brought to my attention that we might have had a little oversight, that is, and so
25 I'd like to make this recommendation to correct that and make sure we follow up on this issue of electronic
26 resubmission of bills that have minor errors on them. I guess currently there's an issue where we have to
27 resubmit with a paper bill rather than with another electronic bill, and it would be better to do it
28 electronically, not only if more efficient, but it's easier to do, and it should speed the process along. So I'd

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1 like to make a recommendation that PRIT (I need my notes here). I recommend PRIT follow up on our
2 desire to have electronic resubmission of claims denied for minor mistakes.

3 Dr. Castellanos: If I'm not mistaken, we made that similar recommendation last meeting.

4 Dr. Urata: Yes, it wasn't followed up on in the PRIT report today, according to Dr. Rogers, so to
5 make sure that he places a fair amount of emphasis when he works with the people involved, he'd like to
6 have our support of that, which I told him we would do. Can you read it back?

7 Ms. Trevas: PPAC recommends that PRIT evaluate whether claims denied for minor mistakes can
8 be resubmitted electronically.

9 Dr. Castellanos: Do you want to say PRIT, or do you, maybe it's better to say that the Council
10 recommends that CMS allow electronic resubmission of denied electronic data and ask PRIT to present to
11 us at next meeting?

12 Dr. Urata: That would be fine. Can you make that correction?

13 Ms. Trevas: PPAC recommends that CMS allow electronic resubmission of claims denied for
14 minor mistakes.

15 Dr. Castellanos: And the caveat having PRIT present that and follow up at the next meeting. We
16 don't have to, but if we do, he'll do it.

17 Ms. Trevas: The Council recommends that CMS allow electronic resubmission of claims denied
18 for minor mistakes. The Council requests that representatives of PRIT evaluate the issue and present their
19 findings to PPAC at the next meeting.

20 Dr. Castellanos: Is there any further discussion? All in favor?

21 [Ays]

22 Dr. Castellanos: Opposed? Is there any other discussion? Dr. McAneny?

23 Dr. McAneny: PPAC thanks CMS for having the Recovery Audit Contractors work towards a
24 mechanism to find and reimburse physicians for underpayment of claims and hopes to have follow up on
25 this, which they said they would.

26 Ms. Trevas: Could you repeat that?

27 Dr. McAneny: Thank CMS for having the Recovery Audit Contractors recognize underpayment
28 and encourages them to find an incentive to allow physicians to be reimbursed for underpayments

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1 [chat]

2 Dr. McAneny: The incentive to the RACs. Let me work on that for a minute.

3 [chat]

4 Dr. McAneny: Do you want me to read it? PPAC thanks CMS for having the Recovery Audit
5 Contractors recognize underpayment and recommends that CMS find an incentive for the RACs to identify
6 underpayment and CMS to reimburse physicians.

7 Dr. Castellanos: Dana, could you read that back to us please?

8 Ms. Trevas: PPAC thanks CMS for having the Recovery Audit Contractors recognize
9 underpayment and recommends that CMS find an incentive for the RACs to identify underpayments,
10 further CMS should reimburse physicians when underpayment is identified.

11 Dr. Castellanos: Is there any further discussion? Is there a second?

12 [Second]

13 Dr. Castellanos: All in favor?

14 [Ays]

15 Dr. Castellanos: Opposed? Are there any other motions or recommendations?

16 Dr. Hamilton: There are a few little adjustments on this...In the recommendation under Agenda
17 Item B, PRIT update, on the third line, where it says “continuing medical education can be funded or
18 provided by local hospitals,” instead of “and medical communities” that should be “for the medical
19 communities.” For their medical community, or for the medical communities. Then, under Agenda Item F,
20 on line 3, it says “therefore PPAC advises that any effort to implement quality measures,” I think that ought
21 to be “PPAC recommends to CMS.” OK. And then I think the next paragraph that begins “Now instead of
22 implementing the current physician voluntary reporting,” it should read “PPAC recommends that instead of
23 implementing,” so those would be identified as specific recommendations.

24 Ms. Trevas: OK.

25 Dr. Hamilton: Then on the last page I have, I think I have a duplicate page in my packet here, but
26 that’s not important. The last page that I have, on the top of the page, there are 3 lines just above Agenda
27 Item H. That last sentence that says “PPAC recommends that CMS work in conjunction with developers
28 and certifiers of electronic medical records to develop software that includes the quality measure,” I think

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1 that would be better said, if it says, “Develop software that facilitates the collection of data that CMS would
2 like to collect for the assessment of quality evaluation.”

3 Dr. McAneny: Yes, that’s true. That’s clearer.

4 Dr. Hamilton: I mean the software wouldn’t include quality measures, but it would include the, it
5 would facilitate the collection of data. And those are all that immediately came to my attention.

6 Dr. Castellanos: I guess we do need a motion for these corrections.

7 Dr. McAneny: So moved.

8 ??: Second.

9 Dr. Castellanos: Any further discussion on either one? I think we can put them all together. All in
10 favor?

11 [Ays]

12 Dr. Castellanos: Opposed? Is there any other business to come before the Council today? I’d like
13 to turn the meeting over to Mr. Herb Kuhn.

14 Mr. Kuhn: Thank you again for another very good meeting. I thought the richness of the
15 discussion was outstanding, particularly the session this morning on the Voluntary Reporting Program. I
16 think you gave us an awful lot of good information and we appreciate that very much. Dr. Castellanos,
17 thank you again for chairing the meeting and keeping us on schedule, moving forward. And in terms of the
18 recommendations and follow up with the 2 additional ones that we just had, we’re up to 19
19 recommendations from this meeting. We also have 2 additional follow ups, one is with the Recovery Audit
20 Contractors, and we hope by then as you heard from Melanie and from Gerry, we should have the initial
21 data in terms of the demand letters and things that have gone out, so we’ll have that information for you
22 and share it. Likewise, there was a request that Jim Hart return with data on imaging in physician office,
23 versus outpatient settings and the variation of the rates there, and we’ll have that data for you as well, in
24 addition to the 19 recommendations that you’ve put forward. So again, thank you all for making the trip,
25 happy holidays to all.

26 Dr. Castellanos: And I also want to thank all of you for your participation again. I believe again,
27 once we had a very, very productive meeting. The CMS staff members are worked really hard to get and
28 prepare this distinctive presentation and share with us their concerns and specific requests for Council

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1 assistance. Our hope is that our recommendations will enhance the regulatory process to enable CMS to
2 move forward with its mission to provide goals to provide the quality care and services to its beneficiaries
3 and wide variety of customers and providers. We also extend and appreciate all the CMS staff and
4 contractors, who use their skills, talents, and professionalism to make these Council meetings so successful.
5 These meetings really require a lot of work and coordination and communication. The next meetings, and I
6 have a schedule of those and I'd like to read that. The meeting is March 6, the following meeting is May
7 22, the following meeting out of that August 28, and the last meeting of next year is December 4. I want to
8 each of you and your families a very happy, safe, and healthy holiday season. With that the meeting is
9 adjourned.

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