

CENTERS FOR MEDICARE AND MEDICAID SERVICES

PRACTICING PHYSICIANS ADVISORY COUNCIL

Hubert H. Humphrey Building
Room 505A
Washington, DC

Monday, March 6, 2006
8:30 a.m.

Council Members

DR. RONALD CASTELLANOS, *CHAIRMAN*
DR. JOSÉ AZOCAR
DR. CARLOS HAMILTON
DR. JOE W. JOHNSON
DR. BARBARA L. MCANENY
DR. GERALDINE O'SHEA
DR. LAURA POWERS
DR. GREGORY PRZYBLSKI
DR. M. LEROY SPRANG
DR. ROBERT URATA

Members-Elect

DR. VINCENT J. BUFALINO
DR. TYE J. OUZOUNIAN
DR. JEFFERY A. ROSS
DR. KAREN S. WILLIAMS

Staff Members

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

MS. MELANIE COMBS
Senior Technical Advisor
Division of Analysis and Evaluation
Center for Medicare Management

DR. THOMAS GUSTAFSON
Deputy Director
Center for Medicare Management

MR. JIM HART
Director, Outpatient Services
Center for Medicare Management

MS. BARBARA HOFFMAN
Director
Division of Chronic Care Improvement Program

PPAC Meeting Transcription – March 2006

DR. JEFFREY KELMAN
Medical Officer
Center for Beneficiary Choices

MR. HERB KUHN
Director
Office of Professional Relations
Center for Medicare Management

MS. VASUDHA NARAYANAN
MCPSS Project Director
Westat

DR. WILLIAM ROGERS
Director
Physicians Regulatory Issues Team
Medical Officer to the Administrator
Centers for Medicare and Medicaid Services

DR. KENNETH SIMON
Executive Director, PPAC
Center for Medicare Management

DR. TOM VALUCK
Medical Officer
Center for Medicare Management

Public Witnesses

DR. JOHN H. ARMSTRONG, American Medical Association

MS. DANA TREVAS, Rapporteur
Magnificent Publications, Inc.

PPAC Meeting Transcription – March 2006

A G E N D A

Morning

Page

Welcome	4
Dr. Ronald Castellanos	
Welcome	5
Mr. Herb Kuhn	
PPAC Update	7
Dr. Kenneth Simon	
PRIT Update	18
Dr. William Rogers	
Moving toward Pay for Performance	29
Dr. Tom Valuck	
Update on Implementation of the Part D Drug Program	54
Dr. Jeffrey Kelman	
Recognition of Dr. Bernice Harper	67
Dr. Castellanos & PPAC	

Afternoon

Medicare Contractor Reform	69
Dr. Tom Gustafson	
Physician Fee Schedule & Outpatient Fee Schedule Final Rules The 2006 Administration and its Application to Contractor Oversight and Performance Evaluation	74
Mr. David Clark	
Ms. Vasuda Narayanan	
OPPS Multiple Imaging Update	84
Ms. Jim Hart	
Recovery Audit Contract (RAC) Update.....	91
Ms. Melanie Combs	
Ms. Connie Leonard	
Public Testimony	94
American Medical Association	
Dr. John H. Armstrong	
Medicare Health Support.....	97
Ms. Barbara Hoffman	
Review of Recommendations/Wrap Up	111
Dr. Castellanos	

PPAC Meeting Transcription – March 2006

1 Open Meeting

2 Dr. Castellanos: Good morning. I'm Dr. Ronald Castellanos, Chairman of the Practicing
3 Physicians Advisory Council. It's my pleasure to welcome you on the occasion of the fifty-fifth meeting of
4 the Council. I have a few announcements that I'd like to make. First, as many of you know, along with Dr.
5 Barbara McAneny, Dr. Chris Leggett, who is not going to be here today—Chris had his leg operated on and can't
6 travel—and Dr. Rebecca Gaughan, this is my last meeting as a member and chairman of the PPAC Committee.
7 This is following a 4-year tenure. I also welcome the newly selected PPAC members, who've agreed to join
8 us today. Now, they will be sworn in next meeting, which is in May, so they're really here as participant,
9 and we kind of ask you not to make too many suggestions, [laughter] as you're not really sworn in as
10 members today. We'll hear more about this from our newest members in a bit when Mr. Herb Kuhn has his
11 remarks. In addition, I'd like to welcome my colleagues and fellow Council members. As always, I
12 appreciate your willingness to travel to Washington, D.C., to participate in this very important meeting.
13 Your considered input and guidance on the various issues that will be presented here today significantly
14 influences the outcome of regulations and instructions which directly affect the physician community. And
15 third, on behalf of the entire Council, I would like to publicly acknowledge and congratulate Dr. Bernice
16 Harper on her recent retirement. As you know, Dr. Harper paid a pivotal role in facilitating our quarterly
17 meetings and her presence and gracious manner will certainly be missed. We all wish Dr. Harper a very
18 healthy and happy retirement. [applause] As you look at today's agenda, you'll see the issues that will be
19 presented to us for consideration. The topics include Pay for Performance, and Update on the
20 Implementation of the Part D Program, Outpatient Multiple Imaging, the Medicare Contractor Provider
21 Satisfaction Survey, an Update on the Recovery Audit Contracts and the Medicare Health Support. Of
22 course, we're going to receive the Quarterly PRIT Update, as well as the latest response report to our
23 recommendations from the December 5, 2005 PPAC meeting. I am confident you'll give our presenters
24 your attention and the full benefit of your practical knowledge and insight. I'm anxious to get started with
25 the agenda we have before us today, and look forward to a very, very productive session with a discussion
26 of the issues relative to the various Medicare program areas. These are exciting and challenging times in
27 addressing the issues in our healthcare delivery system, and we are privileged to have the opportunity to
28 actively engage in shaping the best possible system. At this time, it's my pleasure to ask Mr. Herb Kuhn,

PPAC Meeting Transcription – March 2006

1 Director of the Center for Medicare Management, Centers Medicare and Medicaid Services to welcome
2 you and introduce the newly selected PPAC members.

Welcome

4 Mr. Kuhn: Thank you, Dr. Castellanos and thank you particularly for the very kind words about
5 Dr. Harper. We all know Bernice did a wonderful job for us here, supporting this organization as well as
6 just being a devoted and an outstanding public servant for many years. So she's going to be missed and
7 your words are very much appreciated for her, and I know we'll pass those along to her.

8 First of all I want to welcome our guests and our newest members. We've got four new members
9 that will be coming on the PPAC. And it looks like all 4 are here and as soon as I wrap up here, I'd rather
10 than just me doing an introduction for them, I think what we'll do is just go around the room and ask them
11 to introduce themselves and just tell a little bit about themselves, just so the group as a whole can know
12 who they are and hear from them directly. They won't be sworn in until the next meeting, but we're thrilled
13 that you all could take the time to participate in today's meeting and get a sense of flow and I think you'll
14 get a real good sense of the richness of the discussions that we have around this table, and the usefulness of
15 this group. In that regard, I want to welcome everybody to a new year, as Dr. Castellanos said, PPAC has
16 been meeting for a long time, and I think not only for the agency, but I think for the stakeholder community
17 as well have found this to be a very useful panel, and I think that's evidenced by the hard work that PPAC
18 did last year. I think they were enormously helpful to the agency, of helping us vet issues. I think under Dr.
19 Castellanos's leadership, we continue to evolve the organization to the point now where instead of just
20 looking at the here and now in terms of issues, we're trying to do a lot more long-range projection with
21 PPAC and I think that's been helpful to the agency to be able to understand the issues early, to have
22 comments from you all to help us think as we have future regulations. And that's been very helpful to all of
23 us. So again, thank you all very much for coming to this first meeting of the year. We're glad you're here.
24 And with that, let me just now kind of turn to our guests and ask to go around the room. And Dr. Williams,
25 let's start with you, and if you could just well where you're from, a little bit about yourself, and then we'll
26 just move around.

27 Dr. Williams: My name is Dr. Karen Williams. I'm a native of Washington, D.C. I'm a practicing
28 anesthesiologist at an academic institution here in Washington, George Washington University Hospital. I

PPAC Meeting Transcription – March 2006

1 have been a management person, a leader in my community, as well as politically active in my anesthesia
2 national society. I ran the operating room at the National Institutes of Health for many years. Also went
3 into private practice to learn about Medicare and various payment methodologies and now I'm back in my
4 academic institution at George Washington University. I'm very happy to be here.

5 Mr. Kuhn: Glad you're here. Thank you. Dr. Bufalino.

6 Dr. Bufalino: Thank you. My name is Vince Bufalino. I'm an interventional cardiologist in
7 Chicago. I run a 55-person cardiology group in suburban Chicago, where I direct a single specialty heart
8 hospital. There in the community, I've been very involved in the Heart Association for the last 20 years. I
9 sit on their national board and chair the advocacy committee for them nationwide at this time. Thank you
10 and it's a pleasure being here.

11 Mr. Kuhn: Glad you're here. Thank you. Dr. Ouzounian.

12 Dr. Ouzounian: My name is Tye Ouzounian and I'm an orthopedist. I control a private practice in
13 Los Angeles. I've been representative for the American Academy of Orthopedic Surgeons on the PEAC for
14 whatever, 6 or 7 years, whenever it was instituted, and I've been active on the RUC for about that same
15 length of time. So thank you for the invitation.

16 Mr. Kuhn: Glad you're here. And Dr. Ross.

17 Dr. Ross: Good morning. Jeffrey Ross, from Houston, Texas. Chief of our Diabetic Foot Program
18 at Baylor College of Medicine, and at Ben Tobb County Hospital. I'm a sports medicine and diabetic foot
19 specialist, podiatrist, representing the American Podiatric Medical Association. I've been in private practice
20 for over 25 years, but also do academic teaching at the Baylor College of Medicine. Native of Rhode
21 Island, but Houston, Texas has been my home. Glad to be here and a wonderful part of this organization.
22 Thank you.

23 Mr. Kuhn: Thank you all again, for taking the time to be here on a meeting before you're actually
24 sworn in again to get a sense of how we do business here. I'm grateful that you're all taking the time to
25 participate, and your willingness to serve on this panel, and we look forward to swearing you in next
26 meeting. In that regard, let me also make the offer of the offices here at CMS to support you in anything
27 that you need. Other members of PPAC, I think, will share with you as they need data, as they need
28 information, to better understand some of the issues that might be before them in discussions, or in between

PPAC Meeting Transcription – March 2006

1 meetings if there's information that you seek or you need, by all means, feel free to contact us to follow up
2 and we'll be there to help support you in any way that we can. So again, welcome. Glad you're hear. Dr.
3 Castellanos, I'll turn it back to you.

4 Dr. Castellanos: Thank you, Herb. I appreciate your welcoming remarks, and on behalf of the
5 Council, I appreciate the commitment both you and Dr. Tom Gustafson made to this committee. We really
6 appreciate both of your being here for this meeting. I want to personally thank you again and your staff for
7 the prompt action in the implementation of the Deficit Reduction Act provisions. It was done in a very
8 timely and efficient manner, and I appreciate your letter to Mr. Bill Thomas, the Chairman of the House
9 Ways and Means Committee. It was certainly appreciated. I know it's a little inappropriate, but I'd like to
10 make a motion at this time. PPAC recognizes and sincerely appreciates the effort Mr. Herb Kuhn and his
11 staff did in implementing the Deficit Reduction Act provisions in a time and efficient manner.

12 [Seconds]

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

14 [Ays]

15 Dr. Castellanos: Opposed?

16 Mr. Kuhn: Thank you very much. I appreciate that.

17 Dr. Castellanos: At this time, I invite Dr. Ken Simon, Executive Director Practicing Physicians
18 Advisory Council, Center for Medicare Management, to provide us with an update on the December 5th
19 recommendations of the Council and the responses prepared by the Centers for Medicare and Medicaid
20 Services.

21 PPAC Update

22 Dr. Simon: Good morning to the existing and new council members. Would you like a CMS
23 response to that recommendation that you just gave, Dr. Castellanos? [laughter] Looking at agenda item C,
24 54C-1, the Council recommended that CMS work with the National Institutes of Health and other entities
25 that do clinical trials, to determine fair reimbursement rates for data collection, whether or not information
26 technology is involved. The response: The administrative cost of a clinical trial includes the cost of data
27 collection, which is derived from the clinical trial's budget. The budget is determined by the NIH in the
28 clinical trial centers that are participating in the trial. CMS does not have the statutory authority to provide

PPAC Meeting Transcription – March 2006

1 separate reimbursement for the collection of data at this time, irrespective of whether information
2 technology is involved or not.

3 54C-2. The Council recommends that CMS and the Secretary of the Department of Health and
4 Human Services actively support an increase in the Physician Fee Schedule conversion factor for 2006.
5 CMS has worked with Congress to secure passage of the Deficit Reduction Act, which froze physician
6 payments at the 2005 rates. CMS has worked to implement a process that isn't burdensome for physicians.

7 54C-3. The Council recommends that CMS encourage the Office of the Inspector General to
8 continue counting patient assistance programs as it's part of the patient's true out-of-pocket expenses.
9 Pharmaceutical company patient assistance programs can provide coverage for particular drugs that are
10 included in the Medicare Drug Benefit. This assistance would remain independent of the Medicare drug
11 coverage as it was before 2006. Any assistance a pharmaceutical patient assistant program provides to a
12 Part D enrollee for prescription drugs that would have been covered under his or her Part D plan would not
13 count as an incurred cost that would be applied toward the enrollee's true out-of-pocket cost balance or
14 total drug expenditures.

15 54C-4. The Council recommends that CMS require Part D carriers to have a simplified, uniform
16 form for appeals on behalf of beneficiaries who need drugs that are not on the approved formulary. CMS is
17 working to minimize the impact of Part D on practices in 3 ways: First, we're developing a website which
18 will aggregate all of the forms in one place, simplifying the office staff task of finding and printing the
19 form. Two, we are working with the AMA workgroup on Part D to develop a standard form, which can be
20 used by plans in situations where they do not need detailed drug specific information to process the
21 exception request. And lastly, we are working to reduce the number of prior approvals required by the
22 PDPs to an absolute minimum. For instance, we're asking the PDPs to drop the prior approval requirement
23 for drugs that are also sometimes covered by Part B, as long as the practitioner writes a Part D diagnosis
24 and the words "Part D" on the prescription.

25 Agenda Item D under the PRIT Update. The Council recommends that the CMS administrator, Dr.
26 Mark McClellan, provide a prompt and positive answer as to whether continued medical education can be
27 funded or provided by local hospitals for the medical community. The agency is actively considering this
28 issue at this time, but has yet to reach a final determination.

PPAC Meeting Transcription – March 2006

1 54-L-2. The Council recommends that CMS allow electronic resubmission of claims denied as a
2 result of minor mistakes. The Council requests that representatives of PRIT evaluate the issue and present
3 their findings at the next PPAC meeting. Medicare contractors have implemented the technical parts of this
4 requirement. The computer code in essence to do the denials. At all MCS contractors but to date, none have
5 not activated these edits at any contractor site. The program integrity group is currently working with the
6 appeals division to pilot test the requirement that the contractors deny resubmitted medical review denials.
7 As part of the test, CMS will assess how we can allow providers to resubmit denials electronically. Please
8 note that all denials that result from this requirement are medical review denials. Few medical review
9 denials are the result of clerical errors. Further, CMS will identify which educational efforts contractors
10 need to implement to have providers comply with the requirements of the CR. CMS will publish a
11 Medlearn Matters article, which is currently under development. In order to carry out the testing of the
12 requirement, CMS has requested a new remark code that will inform the provider that the carrier has paid
13 for the service, but in the future will not. Use of this remark code will allow CMS to assess the impact of
14 the requirement and provide in context specific education. The approval of the code is imminent. And CMS
15 will use the new code at a contractor site until we have determined that the providers understand and are
16 able to comply with the requirements of the CR.

17 Agenda Item F. The physician Voluntary Reporting Program in standards. The Council recognizes
18 that the Physician Voluntary Reporting Program will require additional physician office staff, training on
19 the use of G-Codes, reconfiguration of computer programs and increased costs to physician practices.
20 Therefore, the Council recommends that any effort to recommend quality measures and reporting must
21 come after physician payment reform is enacted, and current regulatory and administrative demands are
22 reduced. Otherwise, efforts to improve care will be impeded. The Council recommends that instead of
23 implementing the current Physician Voluntary Reporting program demonstration project, CMS work with
24 each physician specialty group to determine appropriate scientifically valid quality measures, adjusting for
25 illness, severity of condition, socio-economic factors, patient compliance, and co-management of patients.
26 Further, as with the Hospital Voluntary Reporting initiative, PPAC recommends that CMS reimburse
27 physicians for data collection. The Physician Voluntary Reporting program is one that is entirely voluntary.
28 This program was designed to help us better understand how to develop a program that incorporates pay for

PPAC Meeting Transcription – March 2006

1 reporting. CMS has been working in a collaborative fashion with the AMA on the development of category
2 2 CPT-Codes as a vehicle for reporting clinical activities relating for PFR, Pay for Reporting. If Congress
3 moves to pay for reporting, or pay for performance, we will continue to work with each physician specialty
4 organization to help develop and determine the appropriate clinical outcome measures. We identified a core
5 starter set of 16 measures that has been released. The number of measures in the start set that apply to any
6 given physician is now smaller. While we have received recommendations for coding specifications, and
7 other measures, we have not received feedback that questions the underlined scientific basis for the
8 measures themselves.

9 Agenda Item 54F-2. The Council recommends that CMS request input from appropriate specialty
10 organizations with an interest in the issues already included in the proposed pilot program. In addition, as
11 with the Hospital Voluntary Reporting initiative, PPAC recommends that CMS reimburse physicians for
12 data collection. The CMS response for this agenda item is the same as I just previously state for 54F-1.

13 Agenda Item 54F-3. The Council recommends that CMS work in conjunction with developers and
14 certifiers of electronic medical records to develop software that facilitates the collection of data that CMS
15 would like to gather for quality assessment purposes. Our response, CMS supports the use of electronic
16 medical records including as a means to facilitate quality measurement. The adoption of electronic health
17 records is an administrative priority. Through the efforts led by the Office of the National Coordinator on
18 Health IT, it's anticipated that the certification of electronic medical records will be addressed. In addition,
19 CMS is specifically engaged with the physician community and software developers on designing a process
20 that will make this collection of data less burdensome. It is anticipated that later this summer, we should
21 have more specific information to report to the Council.

22 Agenda Item 54H-1. The Council recommends that CMS change the methodology for measuring
23 practice expenses to one based on measurable data, rather than assumptions. The response: CMS uses
24 measurable data to the maximum extent possible. Unfortunately, it's not feasible to assign practice expense
25 relative values to over 7,000 physician services without making reasonable assumptions. For example,
26 indirect expenses account for nearly 2/3s of the total practice expense payments. There is no one generally
27 accepted methodology to allocate indirect expenses. And to this end, I should add that CMS has just
28 recently had a town hall meeting related to the practice expense methodology that was open to the public in

PPAC Meeting Transcription – March 2006

1 an effort to gain additional input, ideas, from the community at large to help us determine what steps and
2 options we should give consideration to in revising the practice expense methodology.

3 54H-2. Given that the Physician Fee Schedule Final Rule indicates that the statute gives the
4 Secretary the authority to specify the services in the sustainable growth rate calculation, PPAC
5 recommends that the Secretary use all means available to avoid future decreases in the conversion factor,
6 including but not limited to, removing drugs from SGR calculation, adding new money to the system for
7 good measurements of practice expenses, identifying both the immediate and subsequent costs that result
8 from adding new screening benefits, and working with Congress to create a system in which money for
9 services provided under Part B be shifted from Part A to Part B when appropriate. CMS response: We
10 believe that fully addressing the situation will require legislative action by the Congress. We look forward
11 to working with Congress as it explores a legislative resolution to these challenges. As a growing number
12 of stakeholders now agree, we must increase our emphasis on payment based on improving quality and
13 avoiding unnecessary costs to solve the problems with the current physician payment system. The Centers
14 for Medicare and Medicaid Services has already taken a number of important first steps in developing the
15 standards, the information and systems needed to improve us toward a payment system that encourages
16 quality, supports physicians in their efforts to provide the most effective care, and avoids unnecessary cost.
17 These steps will prepare us quickly and efficiently and enable us to implement a fully modified payment
18 system, should Congress make that possible.

19 54H-3. The Council recommends that CMS actuaries explain to the Council their methodology for
20 evaluated costs of all new services resulting from the addition of new screening benefits, including
21 colonoscopy, the Welcome to Medicare physical, etc. Our response: We will invite OAC to discuss these
22 issues at an upcoming PPAC meeting.

23 54H-4. The Council recommends that CMS share with PPAC the methodology used to determine
24 the update given to Medicare Advantage Plans to account for new benefits. And as in the previous
25 response, we will invite OAC to discuss these issues at an upcoming PPAC meeting.

26 54H-5. Because the average sales price, ASP methodology was not intended to cover the handling
27 and storage of drugs, because a suggestion was made to add 2% to cover inventory costs to hospitals, and
28 because no codes exist for inventory pharmacy services for physician practices, PPAC recommends that

PPAC Meeting Transcription – March 2006

1 CMS reevaluate the adequacy of the ASP plus 6% methodology for reimbursement. CMS response: Section
2 1847 A of the Social Security Act requires use of the ASP plus 6% payment methodology for drugs and
3 biologics furnished infinite to a physician service, except in limited instances. The costs of handling drugs
4 are paid through the Physician Fee Schedule practice expense RVUs for the drug administration code.
5 Studies by the GAO, Office of Inspector General found that physicians generally can obtain oncology
6 drugs for prices below Medicare reimbursement. In addition, the OIG studies of widely available market
7 prices for Part B drugs will provide another opportunity to assess the adequacy of the ASP plus 6 payment
8 methodology. We will continue to monitor our claims data and other data on acquisition costs for hospitals
9 and evaluate the adequacy of the payment level established in fiscal year 2006 and publish it in the Final
10 Rule.

11 54H-6. The Council recommends that all physicians who have primary responsibility for treating a
12 particular type of cancer be included in the oncology demonstration project. CMS response: The oncology
13 demonstration for 2006 applies only to the specialties for hematology or oncology. The demonstration is
14 similar to last year's demonstration in terms of the specialists who were included. That is, oncologists and
15 hematologists providing office-based cancer care. Expansion of the demonstration will require additional
16 funding and approvals. CMS will consider the issue further if any future demonstrations are developed.

17 Under Agenda Item I, the Competitive Acquisition Program, the CAP Update, there were no
18 recommendations by the Council.

19 Agenda Item K, the Recovery Audit Contractors Update. 54K-1. The Council recommends that a
20 representative of CMS and the corresponding RAC meet with the care and medical director in each of the 3
21 states in the demonstration project. CMS response: We agree. CMS met with the contractor medical
22 directors in the states affected by the RAC demonstration project on January 30, 2006. The CMDs thanked
23 CMS for providing the briefing and indicated that they looked forward to future briefings on the RAC
24 findings. Representatives from the Program Integrity Group will make a presentation at today's meeting.

25 54K-2. The Council thanks CMS for having RACs recognize the issue of underpayment, and
26 recommends CMS find an incentive for RACs to identify underpayments. Further, CMS should reimburse
27 physicians when underpayment is identified. The response. We agree. CMS plans to publicly announce the
28 plan to financially compensate the RACs for identifying an underpayment in the near future. When a RAC

PPAC Meeting Transcription – March 2006

1 identifies an underpayment, the RAC must first notify the appropriate fiscal intermediary/carrier, who will
2 validate the underpayment and adjust the claim, making the appropriate payment to the provider.

3 And the last recommendation, 54L-1, the Council recommends that Dr. Barbara McAneny be
4 reinstated for a second term on PPAC. The response: After careful review of the information submitted on
5 behalf of all of the nominees, included current Council members under consideration for PPAC, the
6 Secretary of HHS has selected the following new members: Dr. Vincent Buffalino, Dr. Karen Williams, Dr.
7 Ty Ozunian, and Dr. Jeffrey Ross. That concludes the response report.

8 Dr. Castellanos: Thank you, Dr. Simon. Are there any comments or further questions from
9 members of the Council, to Dr. Ken Simon?

10 Dr. McAneny: I have a couple of questions. On 54C-1, the concern that the PPAC had last time
11 was more the coverage with evidence development, clinical trials, and not all clinical trials. It seemed to me
12 that your response looked at clinical trials in general, and our concern really was those trials that are set up
13 as part of coverage with evidence development and those clinical trials did not, these are set up in such a
14 way so that if for example with the colon cancer trials, they intend to determine coverage on that, yet there
15 is no decision on what happens if a patient refuses to go on trial. Are they still allowed the therapy? And
16 that's the instance where there was no money in those projects that I've seen at least for the physician data
17 collection. Yet, when we do a standard clinical trial for anyone else, the data collection is a very expensive
18 part of what we do, and in order to get any sort or reasonable, clean data, that is useful for decision making,
19 you need to have good data managers. You need to have it audited. You need to have a whole process
20 occur. And our concern was that that was not going to happen with these coverage with evidence
21 development trials.

22 Dr. Simon: With the existing statutory limitations, there is currently no vehicle for which CMS to
23 provide reimbursement for data collection. As an aside, there actually was a request submitted to the CPT
24 Editorial Panel at this last meeting in February to develop codes along those lines. So I would anticipate
25 that later in the year, we'll find out whether the CPT Editorial Panel actually approved codes designed for
26 the collection of data. But at this time, CMS does not have the statutory authority to provide separate
27 reimbursement for data collection.

28 Dr. Castellanos: Are there any other questions or comments for Dr. Simon? Dr. McAneny?

PPAC Meeting Transcription – March 2006

1 Dr. McAneny: On C-3, I just wondered if you knew whether or not any of the pharmaceutical
2 companies planned to continue their free drug programs. Our concern was that, and we can talk about this
3 more I guess during the Part D part, but one of the concerns was that as we develop Part D, many patients
4 who do not even have their \$250 deductible, much less their share of the co-pay in the first batch before the
5 doughnut hole will never be able to get to that place where they're receiving assistance, because they
6 simply don't have the money. And we were really hoping that the free drug that pharmaceutical companies
7 have been generous with and giving to patients with no other resources would be counted towards that. So
8 we're disappointed that it's not, but also concerned that some of the pharmaceutical companies, because
9 they can't count this toward the patient's true out-of-pocket expenses and kick them into getting assistance
10 with Part D, will stop doing their free drug program, which is going to hurt poor people that we take care of
11 a whole lot. And I'm wondering if CMS has any data on what the pharma response is going to be toward
12 this decision from CMS.

13 Dr. Simon: I don't have any information at this specific time. We may be enlightened by Dr.
14 Kelman's presentation. In the event that he isn't aware, we will look into it and then share that with the
15 Council at the next meeting.

16 Dr. Castellanos: Are there are any other questions? Dr. Przyblski?

17 Dr. Przyblski: I was a little bit confused about the response to 54H-2. My understanding, or
18 interpretation of the response was that some Congressional action would be required to deal with those
19 things. And we had a discussion about removal of drugs from the SGR at the last PPAC, and my
20 understanding from Mr. Kuhn was that that is in the authority going forward, but not retrospectively. So
21 has that changed or was this statement just overly broad?

22 Mr. Kuhn: No, I think what we had at the last meeting, the discussion, is that we were continuing
23 to review for our final regulation. And I think we were pretty clear in the final regulation, our authority's
24 pretty limited here in what we can do in taking those drugs out, both retroactively as well as prospectively.
25 So that as we looked at what our opportunities are, it's very limited.

26 Dr. Przyblski: Limited meaning that it can't be done?

27 Mr. Kuhn: I think that's what we're saying.

28 Dr. Przyblski: Thank you.

PPAC Meeting Transcription – March 2006

1 Mr. Kuhn: You bet. Thank you for asking.

2 Dr. Castellanos: Dr. McAneny?

3 Dr. McAneny: On H5, I just wanted to make the comment that having read the GAO report, etc.,
4 about the ASP, that some drugs are over and some drugs are under and the assumption seems to be made
5 there that because some are over and some are under, that it all comes out equal. The problem is that when
6 you're seeing patients, you don't order the whole list and get them in equal amounts. You order the drugs
7 that are needed for the patient who walks into your office that day. So what a lot of physicians are finding
8 is that if you happen to have patients who need a lot of those drugs where the amount you pay is greater
9 than the amount you are reimbursed, and you didn't get to order those drugs where the amount you pay is
10 less than what you're reimbursed, it does not even itself out. So a lot of practices are struggling to make
11 sure that we don't end up with more of the underpayments than necessary. So that methodology there they
12 might go back and look at perhaps a more weighted average of what people actually order in their practices,
13 rather than just summing up all of the drugs, and saying it comes out even in the wash.

14 Dr. Sprang: Back to C3, that Barb brought up as far as the assistance programs in drug
15 companies—I had a patient in the office last week who has severe Osteoporosis in on Forteo and it's about
16 \$600 a month for Forteo and she doesn't make that much money. And she was getting it through the drug
17 company through an assistance program. She was just informed because they would no longer do that
18 because the government is covering it with Part D programs. And so she will actually have to stop her
19 medication because she can't afford it.

20 Dr. McAneny: On L2, when you're talking about the Medicare contractors and you're talking
21 about having a new remark code that informs the provider that the carrier has paid for the service and in the
22 future will not, can you give us an example of what payment that might be referring to?

23 Dr. Simon: It would be referring to the service that was provided that prior to enactment of this
24 demonstration project would have been automatically denied. And through this pilot testing, they would, if
25 it was questioned that it was an unnecessary service, or it was deemed to be denied not for clerical errors,
26 then that would come under medical review, they would usually then send out information to the physician
27 to gain more insight as to whether the service was appropriate and therefore warranted for reimbursement
28 for the service provided. Under this program, it would automatically pay for that service and just indicate

PPAC Meeting Transcription – March 2006

1 that in the future, they would further review this claim, gather more information, and in the event that it
2 was either an error, intentional error, or if it were not a clerical mistake, if you will, then they would not
3 pay for the claim and have further dialog with the provider in question.

4 Dr. McAneny: So there would be a service that you submitted that you would get paid for and then
5 that would have a code on it that said next time you submit this code, we're not paying for it.

6 Dr. Simon: Correct.

7 Dr. McAneny: Can you give an example of what codes that might be, or what services that might
8 be done on?

9 Dr. Simon: No.

10 Dr. McAneny: OK.

11 Dr. O'Shea: I had a question on F-1, specifically if Dr. Rapp was able to respond to this. I saw him
12 earlier and if he can—I'd like some feedback as to the results of the initiation and the initial responses of
13 what groups and what physicians, whether it's numbers or programs, that did respond and join the
14 physician voluntary reporting program. We had an introduction at our last meeting and I'd like to know
15 what kind of reporting has been done so far.

16 Dr. Simon: I know that Dr. Trent Haywood, who is the project person for the Voluntary Reporting
17 Program, has been in constant communication with all of the medical specialties and has worked closely
18 with all the little specialties in the development of the performance indicators that are currently under use.
19 Dr. Rapp may be able to enlighten us in terms of the current activity of those codes. But the G-Codes that
20 have been created to use for the Physicians Voluntary Reporting have been in place and operational since
21 January 1. The agency has been working with the CPT Editorial Panel in an effort to transition from
22 creating and using G-Codes to using some of the category 2 preventive medicine codes. So at least at the
23 last CPT meeting, about 3 weeks ago, there were several new codes that are under development and review
24 by CPT and it's anticipated that those codes will probably be released 3 times a year. With the intent that
25 by the end of the year, we should probably have a host of new category 2 codes that clinicians will be able
26 to use to identify the type of care that they're providing to their patients in the office setting. So I think that
27 the Council should stay tuned; that at each meeting, there will be an opportunity for us to update you in
28 terms of where we are in terms of the Physician Voluntary Reporting Program.

PPAC Meeting Transcription – March 2006

1 Dr. O'Shea: Dr. [Zahns?] I just asked and I don't know the gentleman yet, but Dr. Valuck will be
2 reporting and I would just ask if Dr. Rapp could also have a follow up during that same time.

3 Dr. Simon: I don't know if he's here.

4 [off mike—I think he stepped out]

5 Dr. O'Shea: If he could be part of it then?

6 Dr. Simon: Sure.

7 Dr. Powers: Does that mean that you will be accepting the use of those CPT-Codes when they
8 come out?

9 Dr. Simon: That is the current plan, that the category 2 CPT-Codes would be used to identify the
10 performance indicators and that there still possibly could be a role for G-Codes in the event that
11 recognizing that CPT-Codes generally are more specific than meaning for G-Codes, that in the event that
12 we are not able to either create a CPT-Code that would capture the type of service that the agency is
13 interested or it's not able to be done in a timely fashion, then we still would reserve the right to be able to
14 create G-Codes to be used.

15 Mr. Kuhn: And I might add, as I think this was one of the good takeaways from the program was
16 when we announced the program, late October of last year, the medical community came forward and said,
17 we understand what you're trying to do in terms of pilot test this, so you can see if you can capture this data
18 in the claims based system if the Congress ultimately goes to a pay for reporting program, so we can pilot
19 test it, perhaps this year or next year, and be ready to go whenever Congress acts. And they made 2
20 recommendations. One was go to the category 2 codes, which we heartily embraced and said yes that
21 sounds like a great idea. And as Ken said, I think the CPT Panel is working overtime to make sure that they
22 can issue sets of codes 3 times a year, which I think is just terrific. And the second part is they said, you've
23 got 36 codes out there, but let's see if we can prioritize. Are there a subset of those codes that you really
24 want to try to focus on to try again test the system. And so we agreed. And so we reduced the set from 36 to
25 16. In late December, announced that these are the 16 we really want to focus on. So I think there were 2
26 innovations on this that the medical community came forward on. And as there's others, we hope to work
27 together on that because we do want to make this work for everybody.

PPAC Meeting Transcription – March 2006

1 Dr. Castellanos: Are there any other questions? Well, thank you very much for your report. It's my
2 pleasure now to welcome back Dr. William Rogers. As most of you know, Dr. Rogers is the medical office
3 to the CMS administrator, Dr. Mark McClellan. Dr. Rogers will provide us with an update on the
4 Physicians Regulatory Issues Team, better known as PRIT.

5 PRIT Update

6 Dr. Rogers: Thanks, Ron. Pleased to be here and welcome to the four new members. I'm going to
7 go through the PRIT Report in a little more detail, because I don't think the new members probably know
8 as well as the old members exactly what we do at the PRIT. We've been very busy the last few months,
9 helping make sure that physician issues are dealt with in Part D. There have been plenty of them. And I
10 think Ken's report particularly, on the issue of the excess of number of prior authorizations pointed out
11 some of the steps that we've taken to try and reduce the burden on physician practices. So I'm going to go
12 through some of the issues in detail that we work on everyday to try and fix problems that providers are
13 having with the Medicare Program. And Ken already mentioned the one issue that we were asked to look
14 into at the last meeting. For instance, one of the issues that was brought to us by an internist was that the
15 ASP payment for tetanus vaccine was inadequate. Because he was being told by his provider that the only
16 kind of tetanus vaccine left available was the preservative free, so-called Dekavac. And we did some
17 research and we found out actually that there's plenty of the old tetanus vaccine. I say the old, the original
18 tetanus vaccine available. And it's available at, don't tell anybody outside this room, but it's available
19 below ASP, and so we've communicated that and made sure that that problem is actually not a problem.
20 Diabetes self-management training. When we decided which ICD9s, which diagnoses would allow
21 coverage of diabetes self-management training, a couple of relatively rare causes of diabetes, like having
22 your pancreas removed, were left off the list of diagnoses, and so we're working to add those back on there
23 so that patients will have access to this important benefit. Public availability of NPI numbers. Practices
24 were concerned that when they get a referral from another office and they need to report the NPI, it would
25 be really helpful if their offices could access a directory of NPIs so they could fully fill out their claim form
26 without making a lot of phone calls and there are some privacy issues here, but I think that the outcome
27 here is going to be adequate to provide that kind of access to information for the offices.

PPAC Meeting Transcription – March 2006

1 Provider response time. This was one of 2 issues that we picked up at the last AFP National
2 Meeting, and this had to do with our requirement that practitioners at critical access hospitals respond to
3 emergency department patients within 30 minutes. And this was all patients, regardless of the severity of
4 their symptoms or need, and it's actually a more stringent requirement than we apply to other hospitals, and
5 it seemed to us that there might be a fair way to bring some balance to this. And so we're looking at
6 perhaps embracing the EMTALA definition of an emergency as a way of refining this requirement with a
7 half-hour response time.

8 Cross-over anesthesia bills. This is one of the in the weeds type issues that we help physicians
9 with. Physicians in Illinois had a problem that the Medicaid Program in Illinois was taking the crossover
10 claims from Medicare and those crossover claims were coming in units, which are 15-minute periods, and
11 they were paying them at the Medicaid minute-rate. So the payment was going from almost nothing to a
12 little bit less than nothing and we've been working with the company that actually processes those claims to
13 get it fixed. And I think we'll probably have it fixed next week.

14 The form out of the remittance notices. Practices, particularly practices that were trying to allocate
15 special payments, wanted the ability to take the information Medicare about payments and convert them to
16 Excel spreadsheets, or whatever format they found most useful for allocating the payments to the members
17 of the group. And this is a wonderful thing that our staff did, developed with a contractor, this Medicare
18 Remit Easy Print software, which allows office staff to easily slice and dice the payment information in any
19 way that's helpful for them.

20 Use of macros. AAMC brought this issue to us. We had sort of not addressed the new challenges
21 of electronic health records, one of which is the macro, which are ubiquitous, and so we brought some
22 clarity to what our policies are concerning the use of macros for the teaching physician attestation, and
23 because it's so important to compliance officers, it's actually be placed in the manual.

24 Electronic resubmission of denied claims is the issue that Ken talked about. Clarifying the rules
25 concerning voluntary GME. This is a very difficult issue, and we've met with AFP, with AOA, AAMC on
26 this issue. Herb is very involved with getting a resolution. We had a conversation with Dr. McClellan about
27 it last week, and what we'd really like to see happen is for physicians who like have residents in their
28 offices be able to continue to provide that critically important service with a minimum of burdens from

PPAC Meeting Transcription – March 2006

1 CMS. At the same time, we have a responsibility to make sure that Congress's intent, which was that the
2 hospitals, which are getting these I would say fairly generous IME and DME payments, that those hospitals
3 are paying all, or substantially all of the costs involved with training these residents. And so that's the fine
4 line that we're walking and I guess I'm on the side of minimal documentation, and we're going to hash this
5 out and I think we're going to come up with a good resolution. But those of you who are members of the
6 AAFP and AOA should be very proud of your organizations, because they've done a great job of
7 representing your interests.

8 ASP. I just want to say that we're still very engaged, making sure that physicians feel that they
9 have access to a sympathetic ear here at CMS. There have been challenges, particularly with things like
10 gamma globulin, and the staff in Baltimore have been very, very aggressive about trying to resolve what we
11 can resolve and I think things are a lot better than they were when the new system was imposed by
12 Congress and we're trying to make sure that problems that still are out there get addressed quickly because
13 it sure has an impact on the offices of physicians that administer a lot of medications.

14 Recovery Audit Contracts. Dr. Castellanos is in Florida, maybe he can give us an update. We have
15 not actually heard much in the way of complaints and we've done everything we can to make sure that
16 physicians know that we're interested in hearing but I'm open to any stories that anybody has about bad
17 experiences.

18 Cardiac Rehab. Competitive Acquisition Programs. I'm not going to say anything about this. This
19 is been a challenge as everybody knows, and if there are any questions about this, we're going to have to
20 bring in somebody who's involved with the details of getting this Congressionally mandated program
21 deployed.

22 Cardiac Rehab Supervision. This is at least from my perspective, a real great story. Rural hospitals
23 mentioned to me a couple of years ago when we were visiting rural hospitals and critical access hospitals
24 and in rural Washington state and Oregon that they were having problems keeping their cardiac rehab
25 programs open because they were using their emergency physician, who was in the next room, as the
26 supervising physician to meet the requirement for supervising physician. They weren't charging for that
27 physician's services, but that physician was playing that role that's required in regulation. And that seemed
28 OK to me, since as an ER doc, who happened to work last night, I know that it's going to be the ER doc

PPAC Meeting Transcription – March 2006

1 that's going to be resuscitating the unfortunate patient who collapses during cardiac rehab, something that
2 happens very, very infrequently. So it seemed to make sense that that should be the supervising physician,
3 but we had not made it clear whether or not that was permissible. And so on January 4, a new national
4 coverage decision was released, which addressed a lot of issues in cardiac rehab. Amongst them, this one.
5 And I think the outcome was very good, and there's a link there on our website for those that want to read
6 the full Cardiac Rehab National Coverage Decision.

7 So that's my report. And that's my phone number, that's the cell phone that's on my left hip, and
8 the email address for the blackberry that's on my right hip, and we look forward to staying in touch.

9 Dr. Castellanos: Thank you, Dr. Rogers. Are there any comments or questions for Dr. Rogers?

10 Dr. O'Shea: Though I have questions about the Recovery Audit Contracts. I'm from California,
11 and I want some more clarity, or really transparency. The forms that I've heard about are like demand
12 letters, and yet I haven't seen any of them, and I just think that maybe in these states where it would be nice
13 to have a doctors have an [cough] and I don't know if this is MedLearn or where we can do it, but what's
14 the difference between somebody just saying, "It's being reviewed," and having a denial letter come?
15 Versus this one? So I just think there should be more information that's gone out. Because I never got any
16 except for being at this forum, from CMS or stating that you as a provider you're part of this recovery
17 audit. I'd like to know what the letter looks like?

18 Dr. Rogers: OK, you mean the letter that's sent out by the Recovery Audit Contractor?

19 Dr. O'Shea: Yes. Do you have a copy is what Barbara said, but I said I would like to recognize the
20 form.

21 Dr. Rogers: OK. I'm sure that we can get that for you.

22 Dr. O'Shea: Can we get it today? Do you think?

23 Dr. Rogers: We'll give it a try.

24 Dr. McAneny: I'd like to make a recommendation that CMS provide an on-line directory of the
25 NPI numbers for use by physicians. I know you're working toward that, but right now, to try to get through
26 to another office and make sure that we've got all of their proper numbers, and if you enter the digits
27 wrong, etc., or if the staff doesn't recognize that they're supposed to enter the digits of the individual

PPAC Meeting Transcription – March 2006

1 physicians, that's different than if you're getting the referral from a group, or you need the group's NPI
2 number. It gets very confusing, and so it would be very useful to have that.

3 Dr. Castellanos: And your recommendation is?

4 Dr. McAneny: That CMS provide an on-line directory of NPI numbers for use by physicians.

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

6 Dr. Rogers: I guess I would just say those kinds of recommendations from the PPAC are very
7 helpful. To the extent that you can help make sure that organizations don't allow privacy concerns to trump
8 the concerns of the efficient operation of the office, that also helps us. Because sometimes we find
9 ourselves caught between the two competing demands.

10 Dr. Castellanos: Any other discussion on this? Is there a second?

11 Dr. Urata: Second.

12 Dr. Castellanos: All in favor?

13 [Ays]

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

15 Dr. Przyblski: Dr. Rogers, thanks for your email and response to my previous question about some
16 codes that were not published and in your summary, although you didn't talk about it, were the RVUs for
17 pediatric codes, and the same issues still exist for several of the 5 neurosurgery codes that I had mentioned
18 before; some were published, some were not. And the issue for physicians is that obviously a lot of payers
19 use RV, RVS in some format to make determination for fee schedules and when CMS does not publish
20 those even though the RUC has forwarded those to CMS, then oftentimes third party payers simply have no
21 information to base a fee schedule on. So I'd like to make a recommendation that PPAC requests that CMS
22 publishes in the proposed and Final Rules the relative value units that have been forwarded by the RUC for
23 new physician services for which CMS has made a non-coverage decision. This way, even though there's a
24 non-convergence decision, the information is publicly available to the third party payers to make their own
25 decisions about it.

26 Dr. Hamilton: Second.

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

28 [Ays]

PPAC Meeting Transcription – March 2006

1 Dr. Castellanos: Opposed?

2 [off mike discussion]

3 Ms. Trevas: PPAC recommends that CMS publish in its proposed and Final Rules the RVU
4 forwarded by the RUC for new physician services for which CMS has made a non-coverage decision?

5 Dr. Przyblski: Correct.

6 Ms. Trevas: Thank you.

7 Dr. Castellanos: Dr. Rogers, I have a comment. Because in our community, we're seeing a lot of
8 problems with this medically unbelievable edits. I was wondering if you've had much conversation in the
9 medical community concerning that.

10 Dr. Rogers: Yes, we have. The issue was brought to us by the College of American Pathologists,
11 primarily. Although urology and dermatology have also been vocal about this. The issue is because we
12 process a billion claims a year, figuring out who—in a sort of automated way—who is trying to defraud the
13 program. And one valuable way to do that is to look for people who are submitting medically unbelievable
14 numbers of claims for something. And I would prefer to call it “Medically unlikely,” rather than medically
15 unbelievable. And since we would have to change the acronym, it's appealing. But if somebody submits a
16 20 biopsy specimens for 20 consecutive patients, that's medically unlikely, and then those claims should
17 pop up for manual review to see if this someone who's billing fraudulently. So a list was generated by a
18 contractor of what were called medically unbelievably edits, and some of those are more in the medically
19 unlikely category than medically unbelievable. So I think after discussing the problems that this would
20 present for particularly pathologists, the approach to this is being looked at a little harder, and probably the
21 resolution will be to develop a category of truly medically unbelievably edits—hysterectomy on a male
22 patient, and then medically unlikely edits—20 consecutive patients with 20 biopsy specimens apiece—and
23 automatically denying the medically unbelievable ones, and impossible ones, and then maybe coming up
24 for a threshold for auditing the unlikely ones. So there is definitely, the people in Baltimore who are
25 involved with this are very aware of how the system works and the challenges and were very easy to talk to
26 about this.

27 Mr. Kuhn: And I might just add that right now, that the current list of the MUEs that are out there
28 are not scheduled to go into effect. They're going to go through another round of public comment on this.

PPAC Meeting Transcription – March 2006

1 So I think we want to make the process as transparent, as helpful as possible, and I think as Dr. Rogers said,
2 get at the issues that are really out there—gender specific codes, multiple codes, for a particular procedure,
3 amputation of an arm the third time, things that are truly unbelievable. And that's what they're trying to get
4 to.

5 Dr. Castellanos: I guess my major concern is that this was instituted by CMS under the National
6 Correct Coding Initiative, and it's really able to capture typographical errors, and ensure program integrity,
7 but you've expanded this to reasonableness. My concern here is that some of these edits, especially in
8 urology, is going to significantly negatively impact patient care. And I can give you a code that
9 substantiates that. And I guess my real question is why hasn't this gone through a formal rulemaking
10 process, rather than hiding in or sliding it in the NCCI?

11 Mr. Kuhn: Again, I think the point is that they are not scheduled to go into effect now. There is
12 going to be a public comment. The document was released so people could see it. We're going to go
13 through a formal comment process on it. So it is going to be processed through the system, so people have
14 a chance to react, to comment, and in order that we can get a good and appropriate list that people
15 understand and has some real merit and real basis behind it.

16 Dr. Castellanos: Well, I'd like to make a recommendation that CMS withdraw the Medical
17 Unbelievable edit proposal, and resubmit that through the normal formal rulemaking process, working in
18 close association with the medical community. Is there a second?

19 Dr. McAneny: Second.

20 Dr. Castellanos: Is there any further discussion? Does everybody understand what we're talking
21 about?

22 Dr. Przyblski: I guess I'd like some clarification. Already on a quarterly basis, edits are submitted
23 for physician specialty societies to review, so that process already exists and it seems that this is following
24 that similar process.

25 Dr. Castellanos: Well, it isn't. Because it was initially a 45-day question period, now it's been
26 extended to 60 days, and you're talking about a lot of CPT-Codes, and it really affects patient care. I can
27 give you an example. In urology, it's standard to take 12 biopsies on the prostate. And we do standard 12
28 biopsies. But when we send that to the pathologist, under the medical unbelievable edits, he's only going to

1 be able to get paid for 2 of them, and it's really important for me and my care of my patients, and in the
2 urology community. But this can be extended not just to urology, but to general surgery, I'm sure, and
3 neurosurgery, dermatology, OB/GYN, so I think it's really something that we're talking about more the
4 care of the patient than, we're talking about payment changes. We're talking about creating new coverage
5 instead of doing it separately, it's being done under Correct Coding Initiative. And I really think it's
6 important that we, the medical community, have an ability to be able to comment on this in a constructive
7 way and working with CMS in a constructive way, rather than as I perceive it's being done at this time. Dr.
8 Urata?

9 Dr. Urata: What kind of work will it take to change it over to Dr. Castellanos would like to have it
10 done? I mean does this mean you have to start all over? In view of the fact that you've already done some
11 work on this.

12 Mr. Kuhn: I think what he's recommending is kind of the procedure that we've got going forward
13 already right now, so I think we're very synched up in terms of what he's recommending and what our
14 plans on a go-forward basis are already.

15 Dr. Castellanos: I'm not aware of your plans, and that's why I'm bringing up this motion. Dr.
16 Sprang?

17 Dr. Sprang: I was just going to say, just being consistent with that, too, sometimes when we're
18 doing colposcopies of the cervix, vagina, vulva, we could take 5, 6, 10 different biopsies if there are that
19 many different sites that look suspicious. And so the number itself, could be rather large depending on what
20 you're actually seeing when you're doing it. And the number shouldn't generate an unbelievable
21 conclusion.

22 Dr. Rogers: I don't think that anybody was suspicious that 99% of physicians were doing more
23 biopsies than was appropriately and clinically indicated. I think the desire was to develop an automated
24 system to catch the fraudulent billers; you know, the office in Florida, well, it could be any place I
25 suppose...

26 Dr. Castellanos: Thank you, Bill! [laughter] I really needed that.

27 Dr. Rogers: The urologists office in Florida, where the urologist is always attending meetings and
28 is never there...[laughter] And these people do this. It's remarkable. I mean we catch offices that are

PPAC Meeting Transcription – March 2006

1 supposedly infusing IVIG and you got to the office and it's closed and it's shuttered on the day that 500
2 bills for IVIG were submitted, so this technology makes it possible to catch some of these people. So it's an
3 important initiative, but on the other hand, we don't want to get in the way of clinical practice of medicine.

4 Dr. Simon: And I would just add one point of clarification. This is not part of the Correct Coding
5 Initiative. This is a separate process entirely from the Correct Coding Initiative. So I don't want anyone to
6 leave here thinking this is part of the correct coding initiative. Its mission and its purpose is 180 degrees
7 opposite from what CCI's designed to do.

8 Dr. Castellanos: Well, there is a motion on the floor. Dana, can you read that back?

9 Ms. Trevas: PPAC recommends that CMS withdraw the proposal to create a list of medically
10 unbelievable edits and resubmit the proposal through the normal formal rulemaking process, working
11 closely with the medical community throughout.

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

13 [Ays]

14 Dr. Castellanos: Opposed? Thank you. Are there any other questions for Dr. Rogers?

15 Dr. Przyblski: I'm not sure that Dr. Rogers, you're the appropriate person to address this, but I'll
16 ask and you can help me. We've recently been faced with a new CPT-Code that was brought forth for
17 which an individual physician requests that CMS evaluate for coverage or non-coverage decision, and I
18 was curious as to what that process is. Because it seems like an individual has been able to muster up the
19 full force of CMS to evaluate and I'm not sure that that's within the rules, or what the rules are, how do I
20 find out those rules?

21 Dr. Rogers: No, it's absolutely within the rules. Anybody can request a national coverage decision
22 on any service and we have a division which does primarily just those national coverage decisions. It's a
23 very scientific process. It's very apolitical, and I remember a Congressman, who's actually, well anyways,
24 a Congressman who's no longer in Congress, who tried to get involved in that process, and it's very, very
25 scientifically based and so if this physician's made a request, that's perfectly appropriate and I'm sure it'll
26 get the same kind of unbiased review that all the other proposals get.

27 Dr. Przyblski: Is this true for new services as well as services currently covered?

28 Dr. Rogers: Well, if it's currently covered, you wouldn't be asking for coverage, right?

PPAC Meeting Transcription – March 2006

1 Dr. Przyblski: No, for evaluation whether it should not be covered.

2 Dr. Rogers: No.

3 Dr. Przyblski: I can understand if it's a new service, the issue coming up, what if it's a service
4 that's currently coming up?

5 Dr. Rogers: Then you'd also ask for a national coverage decision. If it's currently covered and the
6 national coverage decision decided that it wasn't reasonable and necessary, then the national coverage
7 decision, a negative national coverage decision would be released, and it would no longer be paid for.

8 Dr. Przyblski: Thank you.

9 Dr. Simon: To add to that, keep in mind that the agency underwent a paradigm shift where it was
10 published for your information, Greg, in April '99 in the *Federal Register*, making the process very
11 transparent, where there is an outline of the elements that will be required for anyone to submit a request
12 for an NCD, which can include either national coverage determination unlimited, national coverage
13 determination with limitations, or a national non-coverage determination as well. And that can be an
14 individual, it can be a specialty society, it can be manufactures, it can be anyone from the community at
15 large if they meet all of the elements of requirement for the application, it will go before the coverage and
16 analysis group within OCSQ and then they have within 90 days to react to the application and the
17 requestor, to indicate what the next steps will be as it relates to submission of their application.

18 Dr. Powers: Would it be possible for us to get a copy of that just emailed to us later on?

19 Dr. Simon: It should be on the website, actually under the OCSQ cap website.

20 Dr. Castellanos: Are there any other questions or comments? I can't believe there's no other
21 questions! [laughter] Dr. McAneny.

22 Dr. McAneny: Actually, with the discussion on the medically unbelievable edits, you said that that
23 was published someplace. Was it in the *Federal Register*? Where is that? It would be nice to have that
24 reference. Would have been nice to have that reference before the meeting actually so that that could have
25 been discussed. But I would love to have also emailed the reference to read that and then I wasn't fast
26 enough Mr. Chairman, to get in a recommendation I wanted to make in during Dr. Simon's part. Can I do
27 that now?

28 Dr. Castellanos: Yes.

PPAC Meeting Transcription – March 2006

1 Dr. McAneny: PPAC recommends that CMS measure the cost of data collection incurred by
2 physicians in the planned coverage with evidence development program and recommends that as these
3 programs are developed, those costs be conveyed to Congress for inclusion in the Physician Fee Schedule
4 and furthermore, that these trials be conducted with the same regulatory requirements as any other trial
5 such as participation in an IRB or not penalizing patients who decline to participate.

6 Dr. Castellanos: Is there any discussion on that motion. Dana—you have a puzzled look on your
7 face.

8 Dr. McAneny: If I had WyFi I'd email it to you. [laughter]

9 Ms. Trevas: We'll work that out one of these days. PPAC recommends that CMS measures the
10 costs of data collection incurred by physicians in planning the coverage with evidence development
11 program

12 Dr. McAneny: In the planned.

13 Ms. Trevas. In the planned—

14 Dr. McAneny: Coverage with evidence development is the name of the program.

15 Ms. Trevas: Coverage with evidence development program, OK. Once the data collection is
16 developed that the costs be conveyed to Congress for inclusion in the Physician Fee Schedule and also, that
17 trials be conducted with the same regulatory requirements as other clinical trial such as IRB participation
18 and not penalizing patients who decline to participate.

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

20 Dr. Urata: Second.

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

22 [Ays]

23 Dr. Castellanos: Opposed? Are there any other comments or questions for Dr. Rogers? Seeing
24 none, and being from Florida [laughter] and being a urologist, I need a break for 2 purposes. We'll meet
25 back here at 10:00.

26 Break

27 Dr. Castellanos: Thank you all. The next topic is Moving Toward Pay for Performance. As we
28 continue today's agenda, it is my pleasure to introduce you to Dr. Thomas Valuck. Dr. Valuck is the

PPAC Meeting Transcription – March 2006

1 medical officer in the Center for Medicare Management where he advises the Center Director, Herb Kuhn,
2 and the Deputy Director, Tom Gustafson on clinical issues related to payment policy, including Pay for
3 Performance. Prior to joining CMS, Tom is a physician. He was trained as a pediatrician. During his stay at
4 the University of Kansas, he got his masters degree in Hospital Administration and actually worked as a
5 hospital executive at the University of Kansas Medical Center. He then had a fellowship at the Robert
6 Wood Johnson Scholar, he's worked in the Senate and he's got his law degree at Georgetown. He worked
7 for the law firm Latham and Watkins. Tom as you will find, has a broad overview of CMS Pay for
8 Performance activities and presents an opportunity for physician involvement in CMS implementation of
9 Pay for Performance. During his presentation, Tom would like us to consider the following question. CMS
10 is interested in practicing physicians' experience with private sector pay for performance initiatives. And if
11 you've been involved in a private sector pay for performance program, please comment on the benefits, the
12 cost to your patients, your practice in both the clinical and administrative business perspectives. Please
13 welcome Dr. Tom Valuck.

Moving Toward Pay for Performance

14
15 Dr. Valuck: Thank you, Dr. Castellanos. As you mentioned, I have been invited here today to give
16 an agency wide overview of our Pay for Performance initiatives. On slide 2, you see how the overview will
17 be structured. First, I'll be using the quality improvement roadmap to give contacts to where Pay for
18 Performance fits into the rest of our quality initiatives. Second, to talk about the demonstrations and pilots
19 that we have ongoing. Third, move to the actual programs, voluntary, pay for reporting and pay for
20 performance. And then, I'll finish with a look to the future and also discuss opportunities for practicing
21 physicians to participate in CMS's implementation of Pay for Performance.

22 On the third slide you see an introduction to the quality improvement roadmap. The roadmap was
23 released in this past summer with the theme of improving quality while avoiding unnecessary costs. You
24 see the vision and aims there that are the same as the vision and the aims of the IOM for quality
25 improvement in our healthcare system. On the 4th slide, the need of the quality improvement roadmap is the
26 5 strategies. And I'm going to address each of the five strategies in turn, because I think this really does
27 give a good overview, a good context for where Pay for Performance fits in with the rest of the quality
28 initiatives at CMS. The first strategy on slide 5 is working through partnerships. You see many of the usual

PPAC Meeting Transcription – March 2006

1 suspects there, the various CMS components working within the agency, but also working externally with
2 Congress, MedPAC, other federal and state agencies, but as a focal point, I want to specifically mention the
3 quality alliances. This is the place where CMS is working very closely with health professionals and
4 providers, payers, purchasers and others in the development of our Pay for Performance initiatives. At this
5 point, of course the work is heavily focused on measures, which are the foundation for Pay for
6 Performance. But the idea is that Pay for Performance is not merely a regulatory fiat, but that we're
7 collaborating with the industry and working toward consensus on things like the measures.

8 Second strategy on slide 6 is that CMS will measure quality and report comparative results.
9 Obviously this has a direct tie to Pay for Performance. The measures that I mentioned are the foundation
10 for our Pay for Performance programs, in that you cannot manage what you don't measure, I learned as a
11 hospital executive. And then also the reporting aspect is essential. The administration is pushing, as you've,
12 I'm sure been following, consumer directed health care and CMS is doing its part in getting to the reporting
13 through measures and contributing to transparency in our healthcare system.

14 The third strategy is actually Pay for Performance, and since I'm going to be addressing that in
15 more detail, I'm not going to spend more time on this slide. But I'll move to slide 8, which is strategy
16 number 4, encouraging the adoption of electronic health records. In some respects, the department has a
17 couple of parallel initiatives going on here that really are very closely integrated and strongly supportive of
18 one another. One is the implementation of Pay for Performance. The other is encouraging the adoption of
19 electronic health records. Like the consumer directed health care that I mentioned, the adoption of
20 electronic health records is a primary initiative for the administration, and we want to implement Pay for
21 Performance that is supportive of the adoption of beneficial electronic technology. Obviously with the huge
22 amount of data that's going to be required for a Pay for Performance Program, ultimately, electronic
23 systems are going to be the way to go.

24 The fifth strategy is to promote innovation and also to build the evidence base for the effective use
25 of technology. As we implement Pay for Performance, we want to be mindful that we not undermine what
26 some might say is the best part of the American health system, which is our innovation, and we want to be
27 able to contribute through the measurement of quality and what works in our system to understanding how
28 to more effectively use technology. The next slide shows then, what in my thinking in how I do my work

PPAC Meeting Transcription – March 2006

1 on a daily basis since my focus is Pay for Performance, another way to look at the quality improvement
2 roadmap is to make strategy number 3 kind of the lead strategy and look at how the other 4 strategies
3 contribute to how we're going to implement pay for performance. So in other words, we're going to be
4 working for example through the quality alliances, through partnerships, obviously measuring quality and
5 reporting comparative results is going to be central to Pay for Performance and we're going to do it in a
6 way that encourages the adoption of EHRs and also promotes innovation and builds the evidence base.

7 So what does Pay for Performance mean for CMS? Well, like the them of the quality improvement
8 roadmap, Pay for Performance parallels that as a mechanism for promoting better quality while avoiding
9 unnecessary costs. Another way to state that is the use of explicit payment incentives to achieve identified
10 quality and efficiency goals. Why Pay for Performance? I don't need to spend a lot of time here. You all
11 are on this Council because you're well aware of the problems that we have with our system in quality and
12 you're well aware of the need to avoid unnecessary costs. I would like to point out though—sometimes
13 when I'm addressing audiences, when I say, remember that our current system encourages resource
14 consumption and quantity, as incentive, and not the improvement of quality or avoiding unnecessary costs,
15 people get puzzled looks. And I often get questions so, I know that you all know what that means, but it's
16 just something that we need to constantly remind people that the current fee schedules and even the
17 prospective payment systems do not yet incentivize quality and the avoidance of unnecessary costs to the
18 extent that's going to be necessary for the future. The next slide is one that often seen in various forms. Just
19 points out the unsustainable trend in costs, in spending that we have in the Medicare Program.

20 The next slide is the support that we have for Pay for Performance. Starting with the President's
21 budget, there is strong support in the 2006 budget, and that continues in the 2007 budget that was proposed
22 in February. Congress has obviously been interested in Pay for Performance and other value-based
23 purchasing tools. In the MMA, a number of demonstrations have been set up through MMA mandates, and
24 then in the recent Deficit Reduction Act, we saw Pay for Performance provisions for hospitals and home
25 health agencies. MedPAC continues to be a strong proponent of Pay for Performance. In their 2005 Report
26 to Congress, we saw several recommendations, and then in the 2006 Report that just was released last
27 week, a lot of not so much new for Pay for Performance but a lot of referring back to the recommendations
28 that were made in 2005 regarding Pay for Performance. The IOM, not only their previous reports that have

1 contained Pay for Performance as a recommendation, but also they have a new 3-part series. The first part
2 was released in December on measures, the second part released last week on the role of the quality
3 improvement organizations, and then the third part will be on payment incentives. In the private sector,
4 we've seen movement toward pay for performance and also for private plans. So clearly, a lot of activity
5 and a lot of support for Pay for Performance. Some would say the train has left the station.

6 So in terms of the elements that are required in implementing a Pay for Performance initiative, this
7 slide summarizes what I spend almost everyday thinking about and acting on. The measures as I said are
8 the foundation of Pay for Performance. I'm not going to talk about everything on this slide because I'm
9 supposed to be giving an overview here and not a detail about the implementation, but I did want to
10 mention patient experience. I've talked about quality and I've talked about cost, but patient experience is
11 also a part of this equation. And the CAC surveys that are being developed are going to ultimately be a part
12 of Pay for Performance. In terms of the data infrastructure, the idea is to keep the burden for both the
13 providers and for CMS as low as possible, figuring out ways to collect, analyze, validate data and allow for
14 an appeals process, without making this overly burdensome on everyone involved. In terms of the payment
15 methodology, here's where many of the policy questions are presented. Do you reward simply attainment
16 of a threshold, or do you reward improvement, or both? Is the payment made in terms of a bonus or in
17 differential and how does that affect the incentives? Those are all policy questions that we're currently
18 considering along with our stakeholder partners. And in terms of the public reporting. Different audiences
19 obviously we've got to reach out and connect with each of them, and then also the importance of public
20 reporting for transparency and consumer-directed healthcare.

21 The next slide is a single slide to capture all of the Pay for Performance demonstrations and pilots
22 that we have going on at CMS. In my full hour presentation, I usually have a couple slides for each of
23 these, but I'll just run through them quickly with high level overview. For the premier hospital quality
24 incentive demonstration, 270 hospitals are reporting quality measures for 5 clinical conditions. Top decile
25 performers can earn a 2% bonus. Second decile performers for each of those 5 clinical conditions can earn
26 a 1% bonus. And on the other end, low performers, who don't exceed their baseline after a three-year
27 period can be penalized. CMS paid out, based on the first year of performance, paid out almost \$9 million
28 in bonuses to the high level performers, and we also saw aggregate improvement for each of those 5

1 conditions. And so this is evidence of early success with a Pay for Performance demonstration. The second
2 demonstration mentioned there is the Physician Group Practice Demo, this is large group practices, given
3 not only quality incentives, but also cost avoidance incentives. The third is geared the MMA §649 demo is
4 geared toward small and medium-sized group practices, using information technology to coordinate care.
5 Section 646 demo, this is the 5-year looking for transformational improvement; integrated systems
6 suggesting and acting on ways to make transformational improvements in the healthcare system in their
7 communities. The Medicare Health Support Pilots and other disease management demonstrations, I noticed
8 on your agenda, you're going to be hearing more about that, so I'm not going to talk about that at this time.
9 The oncology demonstration is in its second year. More substantial program, this is part of a staged
10 approach. You'll hear me say that as I talk about the ongoing programs for Pay for Performance. But
11 moving from a relatively simple reporting on symptoms last year to a more sophisticated G-Code reporting
12 on actual compliance with evidence-based standards in the second year of that program. We are currently
13 also developing nursing home and end-stage renal disease demonstrations that have Pay for Performance
14 elements to them. And then gain sharing is another perspective on Pay for Performance. In the mandated
15 gain sharing demo in the Deficit Reduction Act, there are both quality as well as cost measures, and we've
16 been considering how we're going to measure quality and cost both before and after a patient is treated in
17 order to get a longitudinal perspective in how gain sharing can work in the hospital environment.

18 So how is CMS structured to implement Pay for Performance? We have a quality council, that
19 meets regularly, this is chaired by the Administrator. And one of the recurring agenda items is Pay for
20 Performance. We have another group that meets regularly, the Pay for Performance Forum, which is
21 chaired by the agency wide lead at CMS, at this initiative, is Terrace King the Deputy Director of the
22 Office of Clinical Standards and Quality. We also have work groups for each of the 5 primary settings
23 where we're implementing Pay for Performance. And some of them had subgroups like the physician work
24 group has subgroups that are looking at the quality measures, and a subgroup that's looking at the cost
25 measures, and then ultimately will want to link those for comprehensive view of performance. And then
26 also considering measures and other ways to align the Pay for Performance initiatives across those 5
27 settings.

PPAC Meeting Transcription – March 2006

1 So what are the ongoing programs that are implemented, moving again from the demos and pilots
2 to the actual implementation of ongoing programs? I'll talk about the hospital quality initiative, the
3 physician voluntary reporting which I know you're familiar with so I won't spend a lot of time there. I want
4 to bring you up to date on what we're doing with physician resource use, and then also mention home
5 health agency Pay for Reporting. The hospital quality initiative was mandated by MMA §501B provided
6 for a 0.4% differential for reporting on the starter set of 10 measures and gained a very high participation
7 rate early on for relatively small incentive. And then we have public reporting as an element of the 501B
8 program through the hospital compare website. The DRA, §501A extended Pay for Reporting through 2007
9 and 8 and actually the law says subsequent years, with the 2% payment differential on an expanded set of
10 measures. The law instructs the Secretary to look at the IOM's report that I mentioned previously from
11 December on performance measures and move toward the implementation of those measures as an
12 expanded set for hospital Pay for Reporting. Now, we also had a provision in 5001B to develop a plan for
13 the implementation of Hospital Pay for Performance beginning in fiscal year 2009. So you can very clearly
14 see the staged approach here, moving from Pay for Reporting to an expanded measure set, an extension of
15 Pay for Reporting, to Pay for Performance, if Congress were to follow on the plan that CMS submits for
16 implementation of Pay for Performance by 2009 with an actual statutory program that would allow us or
17 instruct us to do that. So that's hospitals. The second setting, physicians. As you know, we had voluntary
18 reporting program, which began in January, with the 16 G-Codes and physicians ultimately receiving
19 feedback on their reporting accuracy and quality of care. I just wanted to throw in a slide that might or
20 might not be new to you. I don't know whether Trent mentioned this. I was at the presentation at your last
21 meeting, but I don't recall whether that this draft report was done at this time. Notice it is marked "draft,"
22 in all caps and bold, so this is nothing that the agency can be held to. But I just wanted to put this up here,
23 because I think it helps to explain what we're trying to accomplish with the voluntary reporting program.
24 It's a little hard to read. Hopefully it's easier to read in your notebooks. But apparently, it's not. [laughter]
25 So I'll read it for you. Under the diabetes row, if you can make that out, you'll see we always use
26 Hemoglobin A1C as our example, so I'll go back to that one. There will be G-Code measures related to
27 that, as I'm sure you know. In the first 3 columns, give the physician an idea of their reporting rate, just
28 based on the claims-based information. If you had a patient with diabetes, did you report the measure as

1 was expected. So that's what the first 3 columns are. Just about reporting, getting practice with reporting,
2 CMS being able to get data in, physicians being able to get familiar with the use of the G-Codes. The
3 second three columns are related to the specific numerator and denominators of the G-Codes. In other
4 words, for that set of diabetic patients, how many of them met the measures which indicate that the
5 Hemoglobin A1C should be—I believe it was less than 9. This may have been revised, and in fact this is
6 not the best example to use because this G-Code measure has changed. But anyway, being in the area of
7 quality versus non-quality would be indicated by the results of those second 3 columns there. So it's
8 basically a two-part report. Now again, this is a draft. I don't want to focus overly on this, but the idea is to
9 be able to give physicians feedback both on their reporting rates and on quality of care to the extent that G-
10 Codes, which we all recognize are not particularly sophisticated, can actually give an indication of quality
11 of care. So on the next slide, to go along with our efforts on development of quality measures, the overall
12 goal is to ultimately link quality and cost for a comprehensive assessment of performance. I will say we're
13 further along in quality than we are in cost, but I do want to make you all aware of our early steps toward
14 being able to measure physician resource use. We have a 3-part project going. It looks like 2 parts here, but
15 a last bullet under Episode Group Evaluation is really a very intensive third part that we've undertaken,
16 which is our work with the quality alliances and with others who are also looking at physician resource use.
17 So next time I do this presentation, I'm going to make that a separate bullet. In terms of physician profiling,
18 in their 2005 report to Congress, MedPAC recommended that CMS confidentially share with physicians
19 claims-based information about their relative resource use. The idea being the agency has a huge amount of
20 information. Why aren't we putting that into a report and giving that back to physicians? Well as it turns
21 out there are actually some pretty good reasons why we haven't done that before. But we wanted to see if
22 we could take a shot at getting something out to physicians that would be meaningful and actionable. So we
23 chose to look at utilization of echocardiograms and MRIs and CTs in 2 states. And we developed a resource
24 use report and then took that back to physicians in those states in small focus groups and said is this
25 something that would be useful to you? And what we found was, even though we had some very good
26 minds working on how to glean the very best information out of the claims data that the claims data just
27 doesn't provide enough context to make these resource use reports meaningful and actionable for
28 physicians. What we're looking at is potentially making the report narrow enough to adjust for some of the

PPAC Meeting Transcription – March 2006

1 problems that we saw in those initial reports. For example, there was a lack of standard by which to
2 compare the number of echoes that CHF patients should have. So where to start. And then there were
3 problems with the risk adjustment and problems with finding the right peer group, problems with practice
4 differences, those kinds of things that claims-based data just can't help us adjust for. So we're trying to see
5 if taking that to a very narrow condition with a relatively homogeneous set of clinicians and patients would
6 be one way to use this kind of feedback report. And we'll have further information for you as we progress
7 on that project.

8 In terms of the episode group reevaluation, you may be familiar with this sort of software that
9 takes more of a longitudinal look at the services provided to a specific patient by specific provider or set of
10 providers to capture the total costs over a period of time for chronic disease or over a time limited acute
11 illness. The idea is to look at these software programs and determine whether they can help CMS provide
12 meaningful comparisons of actual to expected costs at the physician level. And as I pointed out, we are
13 working very closely with a number of entities that are looking at using this technology to better understand
14 costs at the physician level. And our work, for example, with the AQA is to develop a standardized
15 reporting format so that physicians don't get 6 different reports from 6 different payers all structured in a
16 different way so that and potentially even in conflict with one another. So again, we're working
17 collaboratively on our physician resource use initiative.

18 I just want to mention quickly that home health agencies were also a part of DRA §5201. They
19 will be receiving a 2% payment differential if they report on a standardized set of measures and then
20 MedPAC is going to do an evaluation of home health Pay for Performance and report to Congress in June
21 of 2007.

22 So in terms of a look to the future, CMS has been working on a white paper that captures actually
23 a lot of what I've just said in a lot more detail and the idea is to give the public some insight into where
24 we're headed, but even more importantly to seek public comment on where we're headed on that
25 framework that we set forward. And this is a very important I think step in where we're headed for Pay for
26 Performance, and I think we would assume that all interested parties would be commenting on that white
27 paper. In terms of the second bullet there, IOM Payment Incentives Report. I already mentioned that 3-part
28 series, the last part is on payment incentives and we're looking forward to that. I also mentioned that

PPAC Meeting Transcription – March 2006

1 MedPAC is staying after us on implementation of Pay for Performance and how to do it correctly and
2 we're working collaboratively with them. Congress obviously been interested in PforP and we expect
3 legislation in—I shouldn't say we expect—there's the possibility of legislation in 2006 particularly with the
4 need for the Physician Fee Schedule to be addressed again in 2006. As I discussed, we have a lot of
5 demonstration and pilot activity going on, getting periodic reports, beginning from of the MMA mandated
6 demonstrations, like the Premier Hospital Demo, and then we have other opportunities to participate
7 coming up. We just had the one on the 5-year demo for transformational quality improvement. So be on the
8 look out for those opportunities. Implementation of DRA provisions, which will be happening this year in
9 the hospital, and home health settings, which I already discussed, and then also just a reminder that 2006 is
10 the year of measure development, as a priority, to lay the foundation for Pay for Performance, and of course
11 all of you will have opportunities to participate in that through your medical societies. So thank you. And I
12 look forward to your questions.

13 Dr. Castellanos: Thank you very much, Dr. Valuck. Before we go into questions, he did ask us if
14 any of us had any personal experience with Pay for Performance in the private sector. Does anybody have
15 any?

16 Dr. Powers: I wouldn't say experience, but we have been getting the quotes from some of the
17 private sector companies that are working with us, and actually, they're not really, some of the companies
18 are working with us for us to work directly with them in getting evidence-based guidelines into the system.
19 So we're having good relationships with that, just like we are with CMS. But there are some other
20 companies out there that have chosen their own indicators and who are judging physicians based on
21 indicators that they haven't previously published, and are reporting that already to the community. They're
22 grading doctors, and a lot of that is based on economical issues rather than evidence-based issues. So we
23 appreciate the opportunity to be a part of this.

24 Dr. Castellanos: I'd like to comment on an experience I had peripherally. As a urologist, we do
25 male infertility, and we work very closely with the reproductive endocrinology physicians in our
26 community. In the 1992, Senator Rob Wyden enacted legislation where each of the in vitro fertilization
27 clinics were to support their statistical data. The initial endpoints were delivery rates. A number of
28 problems quickly arose. One was it was an unfunded mandate. And the large clinics, as opposed to the

1 small clinics each paid the same, and this cost several thousands of dollars. A second problem was there
2 was a real delay between the lag between providing the data and having it published. And especially in this
3 field, the cutting edge is great demands and changes. One of the surprising problems were that as a result
4 practices, because the data was published, were competing against each other. And one way to increase the
5 delivery rate, which was the endpoint, was to implant more embryos. And by implanting more embryos, we
6 had multiple births. And this was an expected result, because each group was trying to get the best
7 statistics, because the statistics were published and people were judging each facility based on the studies.
8 What happened is some practices would accept easier patients and had better success rates. And the
9 practices, especially if you had a number in the community, would compete against each other. And as you
10 would expect, some of the patients that had poor prognoses were indirectly penalized, because they were
11 not being cared for by these clinics. They were comparing each other. I think the real problem here is that
12 the government forced these mandates on us without funding. And made the physicians compete against
13 each other, and one of the side effects were the multiple embryos. To its credit though, it did make the
14 poorly performing facilities improve their statistics. So that's the bottom line improvement. That's the
15 experience we had because we work directly with them. Does anybody else have any comments? Dr.
16 Sprang?

17 Dr. Sprang: Just kind of consistent with what you just said. Again, obviously, being an OB/GYN,
18 we work with a lot of reproductive endocrinologists. In some of the clinics, we're obviously putting 5, 6, 7
19 embryos back in to get better success rates of pregnancy, but then also multiple, multiple gestations.
20 They're also if the patient was 40 or above, they were just not taking those patients into the clinic because
21 their success rate is lower. So it's actually excluding some patients who may have had a chance, but not as
22 much of a chance, so a lot of times, I would say, the unintended consequences, and you've got to just take
23 all of those into account.

24 Dr. Valuck: Yes, definitely, and I think this is why it's so important to have the physicians who
25 are going to be participating in these programs be a part of developing those measures. For example, as a
26 physician, you would probably want to counter balance that measure on the success rate with the multiple
27 gestation rate, so that you could reward the counter balancing quality measure as well.

28 Dr. Sprang: And even age of patients.

PPAC Meeting Transcription – March 2006

1 Dr. Valuck: And other risk type adjustments so that you don't get the cherry picking type
2 situation. And this is why we have the staged approach toward the implementation of Pay for Performance
3 because we don't have all of the answers. We can't anticipate all of those unintended consequences. This is
4 a very serious business and we want to do it right, one step at a time.

5 Dr. Castellanos: Are there any other examples? Dr. McAneny?

6 Dr. McAneny: I'm an oncologist. In my practice, 3 of the 9 medical oncologists received multiple
7 page forms by a specific commercial health plan who has responded to pressures in shall we say the St.
8 Louis area, to respond to certain payers, certain corporations' push to make things cheaper. What we found
9 was that this form that was created to look at "quality," really had very little to do with that. It was not how
10 do you take care of a given patient, would you do with a certain situation—it was comparing these 3 out of
11 the 9 of us, I don't know why—with some group, where they said you are an over-utilizer in X, Y, and Z.
12 You do this that and the other. We were never given any data as to who this comparison group was, but
13 clearly they were all a lot cheaper than we were, and the implication was very clear that their plan was to
14 try to figure out which of the physicians in the group were cheaper, or intimidate people into doing less
15 than they currently were, in order to be on their preferred physician panels. And we've gotten several that.
16 The other thing that we've gotten from some of these groups is once you are notified that you are an
17 expensive physician—they never say it that way, they say you're not performing to the same level as your
18 peer group. But when you look at it, what it really means is you're more expensive. In their yes. That what
19 they want to do is to do disease management and what they consider as disease management is what's
20 going to "save them money," is that they will send letters to our patients instructing them to call some
21 disease management nurse somewhere across the country who doesn't have any knowledge of what this
22 patient has and go through. Now interestingly, I purchase my health care for my office from this same
23 organization, who then called up my office manager after a complicated cardiac pace-maker thing and
24 suggested that what she really needed to do was to fire her current physician and go to one of their centers
25 of excellence, elsewhere, where they I assume have a contract. So what's happening is, under the name of
26 providing quality, it is really trying very hard to focus on economic credentialing, selecting physicians
27 compared to groups we have no control over on criteria that have not been well-validated and I think
28 anybody who works in the quality field is going to recognize very soon that to really do better outpatient

PPAC Meeting Transcription – March 2006

1 care, you need to spend more time with patients, follow them up more closely, do all of those volume and
2 intensity creating activities that are going to then turn around and penalize us in the end.

3 Dr. Valuck: That's helpful. Thank you.

4 Dr. Castellanos: Are there any other examples? Dr. Sprang.

5 Dr. Sprang: Just another example. Obviously the lowest cost, what I've seen some of them do is
6 actually no one group or other physician group is doing what they're saying is lowest cost. What they'll do
7 is look at a number of groups, take the lowest cost per segment of the care, and take the lowest one from 5
8 different groups, add those together, and say that that then is your goal. And nobody's accomplishing that
9 goal, but it's just if you take the best part or the best section of half a dozen groups and bring all those
10 together into one example, it's just totally unrealistic, because nobody's accomplishing it. But they have
11 broken it up to come up with that number.

12 Dr. Valuck: Has anyone experienced anything that was meaningful at all to you through some of
13 the private sector initiatives. You mentioned that there was some improvement seen.

14 Dr. Castellanos: There was some improvement in the lower numbers. It really was. And that's
15 very positive. And hopefully that's one of the things that we're going to see with Pay for Performance. Are
16 there any other questions that you want to bring? Dr. Hamilton?

17 Dr. Hamilton: I just wanted to ask you a question about the diabetic questions that were on your
18 Pay for Performance list. At the last PPAC meeting, we read what those questions were and we had
19 reviewed that information and I know that the endocrinology community had responded to you about some
20 improvements that they thought might make those questions more meaningful. Have any of those been
21 incorporated, or do you still have issues or need documentation as to the nature of the hemoglobin A1C
22 levels and so forth?

23 Dr. Valuck: Dr. Trent Haywood, who is our Deputy Chief Medical Officer for the agency, who did
24 present on the details of the physician piece—he is actually the agency lead for implementing the physician
25 voluntary reporting program. He would have been the one who would have received the letter and he would
26 be the one who would have acted on it. Sometimes, I become aware of those issues at that level of detail
27 just because of my close working relationship with Trent. I was not aware of that letter or the response. If

PPAC Meeting Transcription – March 2006

1 you can catch Mike Rapp—I don't know—he was here earlier, he is actually the Director of our Quality
2 Measurement Group at CMS and I can assure you that he would know the answer to that.

3 Dr. O'Shea: Dr. Valuck, I have 2 questions for you please. And if you can, the voluntary reporting
4 program began in January 1 of 2006, so you've had just a little over 2 months. I'd like to know how many
5 physician or physician groups have joined the voluntary program as of this date.

6 Dr. Valuck: We don't actually query the system on a weekly or a daily basis to know how many
7 physicians are participating. Our expectation is that the number would be small. With the physician
8 voluntary reporting, we're even a step back before where we started with the hospitals with the pay for
9 reporting. So where we say we walk before we run with hospitals, we're actually crawling before we walk
10 with the physician voluntary reporting program because as I said, the issues are so complex and we want to
11 do it right and we want to do it with input from the endocrinologists on the diabetes measures, etc. So that's
12 going to take time to work all that out. We are planning toward pay for reporting and we would expect then
13 of course with a more substantial incentive that there would be more physicians participating. Our initial
14 projection of what we were hoping to see in terms of involvement and I hesitate to throw percentages out
15 there because you're going to say did you meet the 5% next time. When we came back. But it's in a very
16 low range. And that will give us enough information to see whether CMS can efficiently and effectively
17 collect that information and whether we can give those reports back to physicians that will be meaningful
18 so that when we actually do come up with something a little higher stakes, on voluntary, like the pay for
19 reporting, that we can do it right.

20 Dr. O'Shea: Hopefully, you'll get some more participants.

21 Dr. Valuck: I agree.

22 Dr. O'Shea: And have a number for us.

23 Dr. Valuck: Yes, the more the better. Because it is an opportunity for physicians also to get
24 experience with that kind of reporting and though we're ultimately moving to an electronic based reporting,
25 there will be a period of time where we're still looking at manual reporting of G-Codes primarily, or
26 category 2 codes.

27 Dr. O'Shea: This actually is why I'm asking. It was large groups that did join on that already had
28 electronics and those are the things that I wanted to see, if there was some self-selection going on. And I

PPAC Meeting Transcription – March 2006

1 understand that it's hard to get people to volunteer when it's so very new and not really sure of what their
2 outcomes or what they're going to get for participating. My other question is in your report on CMS's
3 PforP demonstration pilots, the physician group practice demonstration, there was a portion there where
4 you said they were given cost avoidance incentives? Can you elaborate on that, what kind of cost avoidance
5 you incentivized?

6 Dr. Valuck: Again, when I talk about costs, I'm talking about avoiding unnecessary costs. We all
7 know that there are unnecessary costs in the system. The problem is just getting to those and rooting them
8 out. The physicians in the PGP demo have the opportunity to save costs relative to a standard for that
9 patient population. That goes into a pool and then, and this is where the linking with quality comes up. If
10 they can save costs and at the same time, meet stringent quality measures, and I can't tell you exactly
11 what's being measured in that demo, because I don't know it to that level of detail, but if they can meet
12 those quality measures, then they get paid out as an incentive a portion of that savings. So again, it's this
13 comprehensive view of performance, where cost and quality are linked.

14 Dr. Castellanos: Are there any other questions?

15 Dr. McAneny: Yes, there always seems to be the assumption that IT equals quality. And I think it
16 is necessary but not sufficient for that. I think in this day and age where we have declining reimbursements
17 and David Braylor has said that he thinks the average cost per physician is \$42,000 I believe, if I'm
18 remembering the number correctly, to install and then \$16,000 a year for updating it, I find that a little low
19 in my own practice. It's costing me a lot more than that, every time you turn around they have new
20 computers and things you need. So I think that right now, if we try to focus on outcome measures, which I
21 recognize is the ultimate goal, then a couple of unintended consequences will occur. For one, no matter
22 how good, for example, a surgeon is, a certain percentage of people are going to have post-op infections.
23 Nobody's infection program can get that rate down below about 3%. Yet if you're the unlucky surgeon
24 who has that infection, are you then going to work for free to take care of that patient? That seems to be the
25 implication as people talk about how we pay more for complications and less for care done right. It seems
26 that if you're going to assume a 3% infection rate, then the costs of care for all surgeries ought to be
27 elevated to spread that 3% across all the surgeries because there's nothing the surgeon can do to get it lower
28 than that given rate. So I think things like that need to be taken into account.

PPAC Meeting Transcription – March 2006

1 I think that in areas where, particularly if you do something where you're penalizing people rather
2 than bonusing that what will happen in areas that have social economic disadvantages, the Navajo Nation
3 comes to mind to me. That no matter how good an endocrinologist is at talking to patients about getting it
4 down, if all they have to eat is mutton stew and fry bread, their control is not going to be great. And if you
5 penalize a person who's working on the Navajo Nation for not having the same hemoglobin A1Cs that
6 someone has in Marin County, then I think that you will discover that very soon, people who are practicing
7 in that area can't make it and they leave, because if you cut another 1 or 2% off that, those people are out of
8 luck. They're eeking out an existence as it is, and they will lose it from that, or they will very quickly figure
9 out how to dodge those patients who are going to make their system look bad. So I would say that the
10 penalty, and I understand that there's always the urge to penalize people for "doing a bad job," but I think
11 that those practices where doctors have gotten together and figured out good pay for performance ones are
12 the ones that focus on improving the processes and recognizing that a lot of the times, at least part of the
13 outcome is not entirely within the physician's control.

14 So I would like to make some recommendations. One is that PPAC recommends that the payment
15 methodology be a bonus rather than a differential, in order to avoid damaging practices serving patients
16 who are social economically disadvantaged or noncompliant.

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

18 [Second]

19 Dr. Castellanos: Is there any discussion on that? I'm going to ask Dr. Azocar to comment on your
20 personal experience. The Council members know, and CMS knows what's happening in your practice in
21 your community.

22 Dr. Azocar: In my practice, is primary care in Springfield, Massachusetts and happen to be inner
23 city. We are facing a situation that is shared by most of the primary care practice where we have a
24 population which is very complex from a medical point of view, from the socio-economic view also. The
25 compliance rate is very high. The number of complications and the outcomes obviously are very poor. And
26 most of these practices are from a financial point of view are just surviving. And very fragile to any
27 decrease in any reduction in the income. We have some extra expenses. For example, when you live with
28 minorities, or you need translation languages, for example, you need to increase the cost, it's very difficult

PPAC Meeting Transcription – March 2006

1 to attract physicians and retain physicians in those areas. It's difficult to survive doing primary care, and
2 where I am, quite a few primary care offices are closing. The outcome from this one is that most of that
3 population, very complex population, will end up having no providers or end up in the ERs where the cost
4 is going to be tremendous, or in any case, the outcomes is going to be so much more complex. For
5 example, in diabetes, we're going to have a lot of complications. Renal failure, need for transplant, hemo-
6 dialysis and everything else. I think that this is a problem that requires a careful look and I'll be happy to
7 collaborate in doing something to avoid something that we anticipate is going to come out. A large
8 population in Medicare that will have no providers, an increased number in the financial costs to take care
9 of these patients, and I think in that population, education is a real cost-effective and will improve the
10 outcome. Unfortunately, this kind of activity, such as preventive medicine, they are most of the time, or in
11 fact, not covered. There is no reimbursement for that. I think that this is a particular situation. This may be
12 a good time to reconsider the approach of those particular populations—usually inner city, under served
13 areas.

14 Dr. Castellanos: Jose, would it be fair to ask you to tell them why, what are you doing with your
15 practice, and what you intend to do?

16 Dr. Azocar: My practice is one of the 4 practices in that city that in the year, this year, are trying to
17 close the doors, because it is not cost-effective financially. We cannot keep it open as a business. And being
18 a private business, not being a health center or hospital, I mean, you don't get any kind of funds for
19 translation, for education program, for this kinds of things, and it's a very complex situation. Tremendous
20 amount of problems. I think that the amount of people that we see with four complex problems is the
21 majority of the patients. High insulin, mental issues, substance abuse with all the complications of HIV,
22 Hepatitis C, this is a particular situation that you wouldn't see if you practiced in Beverly Hills or Rodeo
23 Drive or someplace else. And I think that this population is very needed and deserves some particular
24 approach, and this is a good time maybe to look into that.

25 Dr. Valuck: Yes, I'm hearing loud and clear that we want to make sure that however we
26 implement pay for performance, we don't do it in a way that causes an access issue or cherry picking, but
27 another way to look at that is if a practice can figure out ways to improve quality while avoiding
28 unnecessary costs, there's also going to be an extra reward there. So maybe it's building in some of these

PPAC Meeting Transcription – March 2006

1 preventive measures and other things into the incentives so that we can address some of the things that are
2 going to be most important to the populations that we've been talking about in the last couple of comments.
3 But there ought to be a way to get more money to providers who are providing high quality of care in those
4 areas and not just in Beverly Hills.

5 Dr. Castellanos: I hope you hear the message what he said. He is a physician who is ultimately
6 qualified, is closing his practice because he can't financially make it. And that's an example, and that's
7 happening all over the United States today. Now there's a motion on the floor. Dana would you mind
8 repeating that please?

9 Ms. Trevas: PPAC recommends that CMS use a payment methodology that uses bonuses rather
10 than differentials to avoid damaging practices that serve patients who are socio-economically
11 disadvantaged or noncompliant.

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

13 [Ays]

14 Dr. Castellanos: Opposed? Are there any other motions? Dr. McAneny?

15 Dr. McAneny: I think Jose's example is very good about the fact that if for example, if he's going
16 to keep his diabetic population out of the hospital, out of Part A services, and he's going to use outpatient
17 procedures to prevent the complications of diabetes that are the ultimate outcome, that more Part B services
18 are going to be needed in order to avoid the more expensive Part A hospital part. Yet, what I would like to
19 say is that given that many Pay for Performance measures will require more Part B services, which will
20 increase future volume and intensity of physician service, and therefore lower future conversion factors as
21 calculated through the SGR formula, and therefore penalizing physicians for doing the quality measures
22 that CMS has requested, that therefore, PPAC recommends that CMS delay the implementation of Pay for
23 Performance measures until the SGR is replaced with an equitable system.

24 Dr. Powers: Second.

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

26 Ms. Trevas: I only have the recommendation.

27 Dr. McAneny: You don't want my whereases? [laughter] Can I read it again? Yeah, I want the
28 entire thing, because before when we did the coverage of evidence development it was just clinical trials

PPAC Meeting Transcription – March 2006

1 should play for data. Given that many Pay for Performance measures will require more part B services
2 which will increase future volume and intensity of physician services, and lower future conversion factors
3 as calculated through the SGR formula, if we had I-chat, I could just ship it over to you.

4 [off mike discussion]

5 Dr. McAneny: and penalize physicians for doing the quality measures CMS has requested, PPAC
6 recommends that CMS delay the implementation of Pay for Performance measures until the SGR is
7 replaced with an equitable system.

8 Dr. Castellanos: Dana, I hate to ask you to go back, but I think it's important.

9 Ms. Trevas: Given that many Pay for Performance measures will require more part B services
10 which will increase future volume and intensity of physician services, and lower future conversion factors
11 as calculated under the SGA formula—

12 Dr Castellanos: SGR.

13 Ms. Trevas: SGR, sorry. and penalize MDs for doing the quality measures CMS has requested,
14 PPAC recommends that CMS delay the implementation of Pay for Performance measures until the SGR is
15 replaced with a more equitable system.

16 Dr. Castellanos: Is there any comment on that? Dr.

17 Dr. Urata: Isn't that something that Congress has to do? Not CMS?

18 Mr. Kuhn: This is clearly something in the purview of Congress but I just make one observation
19 about this. One of the things is Dr. Valuck is going through the various demonstrations, obviously there's a
20 proof of concept in each of those demonstrations that we're trying to get. For many of them, looking at how
21 we can improve and get highly reliable care, more consistently. All of the things that we hope to all achieve
22 in terms of our payment systems and what we're trying to do, but in particularly in the Physician Group
23 Practice demo, the PGP demo, I think it's very appropriate in terms of thinking through this resolution
24 that's before you, is that I think one of the things that most frustrating to the physician community, and us
25 at CMS is these silos of care we have out there between Part A and Part B. Physicians can do everything
26 possible and everything that's appropriate to deal with the patient. They may say the overall program
27 savings because they presented a hospitalization, but what they see is there's more spending on the Part B
28 side, but on the Part A side, there's all these savings, but again there's all these silos of care. What the PGP

PPAC Meeting Transcription – March 2006

1 does, that demo, it begins breaking down those silos. And it's looking at the savings in the totality of the
2 care that's out there. That's directionally where we would want to go, and I would hate to see that we
3 would derail something like that, with kind of holding back, and so just something to think about as you go
4 forward. Because the proof of concept here is how do we begin, if a physician is performing at a high level,
5 if new technology is there that's saving on the Part A side, but transferring those services to the physician
6 side in their office, we need to reward that kind of stuff. We don't need to penalize it. And that's what
7 we're trying to do with the proof of concept on the PGP and some of the other things we're looking at.

8 Dr. Castellanos: Are there any other comments? Dr. Sprang?

9 Dr. Sprang: The same consistent with that. Obviously, I think where Barbara's trying to go is just
10 we need the SGR formula addressed for us to kind of go forward on any of the other things. Again, I'm an
11 OB/GYN from Illinois. Our liability premiums for a normal OB/GYN are \$150,000 a year. For me to try to
12 be more involved in P for P, I would probably need to go to an electronic health care record, which I intend
13 to do, but you need to have the resources to be able to do that. And it's just going to be difficult to meet the
14 information, providing the information without electronic healthcare records, it will be difficult to buy
15 them. If you don't have the resources to buy them. So they do go hand in hand, and unless the SGR formula
16 is readdressed, and we get 5% decreases for the next 8 years, the 2 can't work—they won't work together
17 unless one's resolved. You can't really expect the other one to go forward. I think that's what Barbara's
18 saying, too. And just, the reality of it is if you don't have the resources, you just not going to be able to do
19 it.

20 Dr. Castellanos: Are there any other comments? I'm going to call the question, then. All in favor?

21 [Ays]

22 Dr. Castellanos: Opposed?

23 Ms. Trevas: Dr. Castellanos? There was a question about whether that should refer to the volume
24 intensity to physicians or rather can it also refer to all providers?

25 Dr. McAneny: Volume and intensity of physician services.

26 [off mike]

27 Dr. McAneny: Oh providers, versus physicians?

28 Ms. Trevas: Yes, that was the question.

PPAC Meeting Transcription – March 2006

1 Dr. McAneny: As long as it implies the outpatient Part B part.

2 Dr. Castellanos: Are there any other motions?

3 Dr. McAneny: This actually refers to those demonstration projects that you were talking about,
4 and I agree that that's definitely a step in the right direction. And I think that the idea of doing the, and I
5 forget what the term is at the moment—the gain sharing, of the physicians for decreasing costs is a definite
6 step in the right direction. One of my concerns however with the group demonstration projects is that they
7 are all aimed at large, vertically integrated systems, and that there are no pilot projects that I'm aware of
8 that CMS has put forward to look at the site where most of the practice of medicine occurs in our country,
9 which is in little bitty, one- and two-doctor practices, who still are going to find themselves at more of a
10 disadvantage with these big systems because they are living a lot more on the fringe. So I would like to
11 make the motion that PPAC recommends that some pay for performance pilot projects be directed toward
12 small practices, rather than all being directed toward the large, vertically integrated systems. In other
13 words, I don't know how you guys are going to do it, but I really would like to see, figure out a way that
14 you can do a pay for performance in a small area in a small practice and give them the same opportunity to
15 earn that bonus that you're giving the large vertically integrated systems.

16 Dr. Castellanos: There's a motion on the floor. Is there a second?

17 [seconds]

18 Dr. Castellanos: Any discussion on that motion?

19 Dr. Azocar: Yes. If it could be added that example for small practices can cover diverse socio-
20 economical areas. As a friendly...

21 Dr. McAneny: OK. Small practices, especially

22 Dr. Hamilton: Diverse, geographic and socio-economic demographics.

23 Dr. McAneny: Works for me.

24 Dr. Castellanos: Can we repeat that recommendation?

25 Ms. Trevas: PPAC recommends that some of the pay for performance pilots be directed towards
26 small practices and those that cover socio-economically and geographically diverse populations, and not
27 just large vertically integrated practices.

28 Dr. Castellanos: I think it should be to include.

PPAC Meeting Transcription – March 2006

1 Dr. McAneny: Yes, toward small practices, especially those with diverse geographic and socio-
2 economic.

3 Dr. Castellanos: There's a motion on the floor. It's been seconded. Any further discussion? All in
4 favor?

5 [Ays]

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

7 Dr. McAneny: One more quick one. It's my last meeting, you know? [laughter] PPAC
8 recommends that CMS initially focus on process measures rather than outcome measurements. This is
9 because we all would love to have better outcomes, but in order to get there we're going to have to look
10 first at our processes and that's a more fair measurement right now than it is to say we want all the diabetics
11 to have a hemoglobin A1C of 6.

12 Dr. Castellanos: Is there any discussion on that? Dr. Urata?

13 Dr. Urata: One of the things that we're dealing at now at JCAHO, where they look at process in
14 our hospital, and they have this issue with abbreviations. And I think hospitals are going to have a hard
15 time complying with that. Abbreviation issues. If my records come from my clinic to the hospital, those
16 count as, they look at those records. And if I have a bunch of abbreviations, which I have, that means our
17 hospital flunks that part of the process measure. Yet, the outcome of my patients might still be excellent. So
18 there are some areas in process it doesn't make sense to measure, and I think the final outcome is what,
19 how the patients are doing. So I kind of think that outcome is more important than process. But on the other
20 hand, I suppose you could measure both. So that's why I don't think you should just concentrate on
21 process. Because process does not necessarily mean that your outcome's going to be good.

22 Dr. Powers: Yes, there are a lot of areas where process, you have to accept process as the measure.
23 And I think the measures that we put forth for neurology are all process measures. I think we've been able
24 to demonstrate through just looking at the JCAHO Stroke Centers, there are a lot of process measures with
25 that, and they've been able to demonstrate improved outcome by complying with process measures. So one
26 doesn't negate the other. I mean you can have improved outcome by complying with process measures.

27 Dr. Urata: You're requesting process only, isn't that correct? In your motion?

1 Dr. McAneny: My recommendation was that CMS initially focus on process measures rather than
2 outcome measures because I don't think we're ready yet for that. I think for example to use yours about the
3 abbreviations. If use or non-use of abbreviation has no bearing on the final outcomes, then that's just the
4 wrong measure and we ought to throw that one out and focus on something that does eventually have a
5 bearing. But you might be able to say my outcomes are all absolutely wonderful and I might be able to say
6 well, gee, mine aren't nearly as good as yours, but if we're starting at disparate places, at least if we put
7 reasonable processes in to place and are graded on how well we do that, then the expectation is that
8 eventually we would have better quality of care and better outcomes but I don't think that the healthcare
9 system is in the situation where we can right now focus on outcomes. Because if you have a great outcome
10 for somebody who comes in with complicated pneumococcal pneumonia, ventilator and need dialysis and
11 is in shock, is it because you did a good job, or the nephrologists, or the pulmonologist, or the ICU doctor,
12 or whom? We're not ready to grade all of you on that outcome yet. But we might be on the process by
13 which you got that patient going through the system so that they could achieve that outcome. So that's
14 really just my goal is to start with processes before going to outcomes.

15 Dr. Urata: Does this mean then that hemoglobin A1Cs are not good outcome measures? Because
16 in fact that seems to me that would be a good—

17 Dr. Powers: They're not.

18 Dr. Castellanos: They're not outcomes.

19 Dr. Hamilton: It's their definition of outcome. The hemoglobin A1C is a process. I mean you can
20 talk about the outcome of your process, but it's still a process. The outcome is whether or not 20 years from
21 now the patient winds up on dialysis or has an amputation. And that may have nothing to do with the
22 hemoglobin A1C. It may have much more to do with whether they smoke or not and there are lots of
23 factors involved, so that we are talking about processes to some extent, at least for the diabetic parameters.

24 Dr. Castellanos: There's a motion on the floor. Is there any further discussion? Dr. Sprang?

25 Dr. Sprang: Where is [inaudible] actually outcomes versus process? What's in the system right
26 now?

27 Dr. Valuck: Our approach has been a mixed structure process and outcome measures depending
28 on what's appropriate for the condition, and where we are in terms of level of sophistication. In measuring

PPAC Meeting Transcription – March 2006

1 whatever we're looking at, that probably a mix is ultimately where you want to be, but definitely to start,
2 you would focus on process over structure, because those are the usually the easiest measures to put in
3 place. That's not to say we don't have some outcomes measures now, and it's not to say we won't be
4 moving toward more, but we'll always want a mix, and I think it's a little hard to talk in the hypothetical
5 about we should be here, not there, and Dr. Haywood, who was here at your last meeting, would be a better
6 person to address specific examples. But we can do that at a future meeting if that's desired. But our
7 perspective is a mix.

8 Dr. Castellanos: There's a motion on the floor—

9 Dr. Sprang: What I'm hearing I guess, I'm almost like amended or add to it—and outcomes where
10 they can be appropriately documented related to the patient care or something. I just don't think we should
11 totally eliminate outcomes.

12 [We're not]

13 Dr. Sprang: Read your motion once more then. Because it seems like—I just think we should get
14 outcomes in there somehow when they are appropriately documented related to the patient care.

15 Dr. Castellanos: Let's read the motion once again so we all understand it.

16 Ms. Trevas: PPAC recommends that CMS initially focus on process measures rather than outcome
17 measures.

18 Dr. McAneny: The reason I put "initially" on there is I really do recognize the goal is better
19 outcomes. We all know that. But I don't think that very often we have a good way to determine to use the
20 amputation example. At this point in time, if you took everybody who takes care of diabetics and just said
21 you've got this many people who've had amputations, and you've had less, and therefore you are a better
22 doctor and deserve a better payscale than this other guy with more amputations. We don't know how to
23 measure that well enough to be fair yet. We don't know how to measure how many noncompliant diabetics
24 were in your population. How many were also smokers? How many also weighed 350 pounds? How many
25 were also had no ability to take care of their lipids or had various other things going on? I don't think that
26 for the majority of true outcomes that we are at the point as a science that we can ascribe that on a single
27 physician level to say that is your bad outcome, but it's his good outcome. So I think that if we start

PPAC Meeting Transcription – March 2006

1 working through processes initially, then I think working toward eventual outcomes is the right answer. But
2 I think we need to again walk before we run.

3 Dr. Ross: If I may indulge, I know we're not official members yet. But I would like to comment
4 just on some of the things that have been said and go along with Dr. McAneny. Particularly on outcomes
5 when it comes to diabetics. If for instance an amputation takes place, it doesn't necessarily mean that the
6 patient's under poor control. They could have a mishap. They could have a skeletal deformity, Charcot
7 Arthropathy, any particular incident that caused stepping on a nail or shoe irritation which leads to an
8 amputation. It's got nothing to do with the A1C. I also wanted to talk about just for a quick second about
9 prevention. In the areas that the primary cares or the internists deal with diabetic education, with obesity
10 and talking about obesity, how many co-morbidities of obesity lead to these other diseases that when you
11 look at outcomes, it's how you treated the obesity or how you educated those individuals and how you
12 prevented obesity, particularly in children, which lead to co-morbidities later on in life. And then, in
13 addition to the skeletal deformities, some of these children then lead on to depression, or lead on to
14 substance abuse, so how we deal with mental health as well as physical health. So those are other areas that
15 you need to take into consideration.

16 Dr. Castellanos: I think we could discuss this a long, long, long time, but we're not going to solve
17 the society problems at this time. I think there is a motion on the floor and I would like to deal with that at
18 this time. Dana, I hate to ask you...

19 Ms. Trevas: PPAC recommends that CMS initially focus on process measures rather than outcome
20 measures.

21 Dr. Castellanos: Is there a second to that motion? All in favor?

22 [Ays]

23 Dr. Castellanos: Opposed?

24 [Nay]

25 Dr. Castellanos: Can we raise our hands all in favor? Six. All opposed? The motion passes. Are
26 there any other motions today? We're a little behind and I'd like to push a little bit.

27 Dr. Powers: I have a question. Maybe this could be answered at a different time, but we always
28 avoid the question, and maybe it's because the answer is possibly obvious, but I wondered if some creative

PPAC Meeting Transcription – March 2006

1 person within CMS has been looking at, or maybe for legal reasons it cannot be done, incentivizing the
2 beneficiary to be compliant. You know, they are some programs in other insurance companies, where
3 you're incentivized by a lower premium if you quit smoking. I understand there may be, for instance, if the
4 beneficiary was able to make some improvements based on recommendations from physician in
5 compliance with some of these measures that we're doing, some simple things.

6 Dr. Gustafson: I'll take a stab. This is actually something we've been discussing internally with
7 both recognizing it may have some appeal if appropriately targeted, also recognizing that it's going to be a
8 little difficult to figure out just how to do that, how to target it. We're dealing with a population in our
9 program that has multiple chronic conditions and so forth, and who gets the bonus if they do the right thing
10 and who doesn't? So it's an idea worth of some further attention. I would say we're in the sort of analytic
11 and research end of that at the moment and in a walk before you run kind of notion, I don't think that's one
12 we would necessary be advancing in the next couple of years. But we do want to find out some more about
13 that, look at what private sector organizations may have been doing there, what their success or experience
14 or lack thereof may have been.

15 Dr. Powers: Then I have a brief supportive recommendation, that PPAC supports the efforts of
16 CMS to explore the possibility of incentivizing beneficiaries to be compliant with processes that are being
17 measured.

18 [second]

19 Dr. Castellanos: Is there any more discussion on that motion? All in favor?

20 [Ays]

21 Dr. Castellanos: Opposed? Are there any other motions or discussions? Dr. Valuck, I guess you
22 can understand there's a lot of interest on Pay for Performance. [laughter] And we certainly appreciate your
23 being here and thank you, and we'll look forward to seeing you at other meetings.

24 [chat]

25 Dr. Castellanos: Our next is Update on Implemenation of the Part D Drug Program. Our next
26 speaker is very well known to us, please welcome back Dr. Jeffrey Kelman, Medical Officer in the Center
27 for Beneficiary Choices, in CMS. Dr. Kelman joins us today to provide an update on the Implementation of
28 Part D Drug Program. You may recall that Dr. Kelman briefed this Council at our May 2005 and August

1 2005 meetings, keeping us apprised of the progress of that multi-faceted initiative. Today, he'll bring us
2 an up-to-date implementation phase of the Part D Program.

3 Update on Implementation of the Part D Drug Program

4 Dr. Kelman: Thank you. Thank you for having me back. The last few times I was here, it was
5 before benefit implementation. Now it's post-launch, and as you know, there have been issues, so I should
6 be able to take care of this in the 2 minutes left to me. [laughter] What I'd like to do since I've kept
7 everybody up to date on what the benefit is, I'm going to avoid repeating myself at all. And I'd like to, if
8 we have time, discuss the issues since January 1 and then the solutions we've been going towards, and then
9 ask for certain very specific advice on one area and then open the questions, assuming we have time. The
10 issues have generally been different ones than we predicted going in, and I suppose it's always the issues
11 that you don't actually foresee that are more complicated. A lot has to do with enrollment and
12 disenrollment. Part of it is that there are 2 ways of enrolling in the Part D Program. One is autoassignment
13 for all of the full benefit dual eligibles on Medicaid, who are automatically autoassigned, starting
14 November 15th, and auto enrolled January 1. There's also direct enrollment for people who are either in a
15 retiree plan, or people who just voluntarily enroll in either an MA plan with a PD or a freestanding PDP,
16 and each is complicated and different in a different way. Bear in mind that under the Part D benefit, CMS,
17 all the free standing PDPs and the MAPDs and every network pharmacy in the country has to be linked
18 electronically through the so-called troop facilitator, which is a variation of the existing pharmacy switch.
19 This is not a trivial effort. We're expecting, remember to make it in numbers, there are 35 data elements
20 that are reported here and of course to the plans, every time a drug changes hands at the pharmacy counter,
21 and clearly billions and billons of data elements in a year, all of which have to be stored, shared, parsed,
22 protected via encrypted. And it's clearly not trivial. To give you some idea, for a dual eligible, there's a
23 connection between state files, which determine by the way, not only dual eligibility, we defined Medicaid
24 from the state files, but also location, because as you know, for residents in long-term care, who are dual
25 eligibles, there are zero co-pays. For dual eligibles for the community, it's one dollar, three dollar. These
26 files have to connect to CMS files, which then have to connect to the plan files, which then have to connect
27 to the true facilitator files, which then go back and make a circle. In non-dual eligibles, you have the plans,
28 CMS, whatever 3rd party, if there is any 3rd party, and then the true facilitator, because this is an ongoing

1 real time benefit. When somebody ends up at the pharmacy counter, presents a prescription, the pharmacist
2 has to know exactly what the co-pay is for that individual, and that determination is based not only on the
3 plan and the drug, but on where that person is in the benefit. Are they in the deductible phase, are they in
4 the coverage phase, are they in the so-called doughnut hole, or are they in catastrophic? And so this, as they
5 say, is not uninvolved. [laughter] We also have problems with late enrollment. Going into the program,
6 following the Part C rules, effective enrollment is the first of the month, whether or not that change is made
7 at any point in the previous month. Somebody can enroll electronically on March 31st and the enrollment is
8 effective April 1. Considering that that enrollment involves files from the plan, states, 3rd party and CMS,
9 which have to ready at point of sale the next morning, again, this is as they say, mathematically, is a non-
10 trivial solution. Getting the correct co-pays is an issue. By the way, we would rather, to protect the
11 beneficiary, delay disenrollment, have them on 2 plans, which is better than no plans, because at least if
12 there are 2 plans, there may be confusion at the counter but you can do that reconciliation later. The
13 beneficiary gets his drugs. You need to link to state files to get the exact correct co-pay. State files come in
14 on a monthly basis, they have to made interoperable, sent out to the plans. So identifying a beneficiary isn't
15 enough. They have to be identified with the correct cost-share. If they have a wrong locator code, then in
16 long time care, they won't get zero co-pays, they'll get one dollar, three dollar co-pays, and again, the
17 identification of somebody in long-term care comes from the state files. For Part C, of course, this may
18 have been less critical, because it's not a point of sale use. For Part D, it's critical, I would make every
19 effort to make it usable the next day.

20 There are formulary issues. As you know, each plan can have a different formulary after approval
21 by CMS to meet our guidelines. They allow different drug lists, different tiering, different drug utilization
22 management. Each one has to fit into a practicing physician's ability to access. There are B versus D issues.
23 I could spend the rest of the day talking about Part B versus D issues, which would really bore you, but
24 basically some drugs paid for Part B previously will still be paid for by Part B, but are also paid by Part D
25 in certain circumstances. To give you the example, which is in certain ways the most extreme,
26 methotrexate. Methotrexate, bought as an oral drug, at point of sale, as a substitute for chemotherapy, has
27 been and will be Part B. On the other hand, methotrexate for arthritis is Part D. And methotrexate for
28 transplants is part B if the transplant was paid for by Medicare. If it was not, it's Part D. So you can have

PPAC Meeting Transcription – March 2006

1 somebody with a transplant not paid by Medicare, who then ages in and gets methotrexate as Part D. They
2 then get cancer, and it changes to Part B. Unfortunately at that point, they get arthritis, and it changes back
3 to Part D. Now it's very hard to set up a computer system to deal with this because we're talking about
4 intent of physicians. There are transition issues, making sure everybody gets a transition part of their drugs
5 and how that interacts with drug utilization management. There are exception and appeals issues. We have
6 a regimented exceptions and appeals timeline. There's an expedited time line and a non-expedited. We
7 talked about it last time. However, the actual access and the form may be different plant to plan. There are
8 long-term care issues and this by the way, I did know was going to be a big problem. There are 15,800
9 nursing homes in the country. They have a million full benefit dual eligibles, 1.6 million total, we expect
10 penetration for Part D in this group to highest. It's 70% already because of the full benefit dual eligibles. I
11 expect by the end of the year to be 85 or 90% because of their very high drug use. Access means something
12 completely different. Even if we had a pharmacy outside every nursing home in the country, it would be
13 irrelevant. Because nobody expects people to leave their bed, get their drug and come back. We had to
14 create different access standards. Tri-care. 90% within 2 miles of the city, 90% within 5 miles of the
15 suburbs, 70% within 15 miles in the country. And the rural areas is irrelevant here. What we did, we have
16 to create a system of complete access that doesn't have patient mobility as an issue. There's also the
17 question of pharmacy providers. Nursing homes typically, but not always have one pharmacy per nursing
18 home. Part D involves networks of many pharmacies per beneficiary. Lastly, and I bring it up—it's not
19 really a Part D issue, but I heard it was discussed earlier. The manufacturer pharmacy assistance program.
20 As you know, there have been changes of that and we can talk about them, although technically speaking,
21 the changes aren't directly related to Part D. Let's see if I have time for any of the solutions, or I could just
22 leave you with that.

23 The solutions. What our approach has been and continues to be, and this by the way, I was
24 changing my notes here about an hour before we came in because this is real time issues and everybody's
25 been working 7 days a week on this is first of all constant file update. We are basically sending files
26 between the states, the plan, CMS, and pharmacies on a 24-hour basis, 7 days a week. They're being
27 refined, they're going back to Medicare beneficiary data base and the plan database. Remember the biggest
28 strain on data bases in the history of the program was January 1st, where you suddenly have the potential for

PPAC Meeting Transcription – March 2006

1 40 million new people coming in. I mean even traditional Medicare in '65 was basically a paper claim. And
2 if any of you were around at SSI when that was put in, you remember what happened. This was an
3 incredible stress and it's refining much better. We're getting more accuracy. In fact, we're getting close to
4 complete accuracy. We're using case work for individual problems. We've basically converted many of our
5 customer service representatives in the regional office to specific case workers. Problems referred in, called
6 into 1800 are distributed in the regional office and in the central office. The individual issues are dealt with
7 in the regional office, and then the planned contract officers try to put systemic reaction, systemic response
8 with the plans. That seems to be working. I mean most of the people from CMS in this room have been
9 involved in casework more than they imagined they ever would be. We have a point of sale WellPoint so-
10 called solution, so called WellPoint, it's actually Well Care, but this gets at the fact that a full benefit dual,
11 who enters a pharmacy without a plan for various reasons, either that a state file missed them, a CMS file
12 missed them, a plan file missed, can be enrolled at that point of sale, and get their drugs and the correct
13 assignment and back end reconciliation will take place later. This has been widely used and quite
14 successfully. We extended it into the long term care as well. Because people in long-term care are even
15 more vulnerable and need their drugs on a higher basis. We're doing plan to plan reconciliation and some
16 front end to the beneficiary for excess co-pays. The beneficiary other than getting money back, if he has
17 been charged an excess co-pay, is not going to be involved with the reconciliation.

18 In terms of long-term care, we spent a lot of December, trying to make sure that the institutional
19 patients, enrollees, were identified. And we ended up using a lot of different methods. We used the trade
20 associations. We used 1800Medicare, we used the web tool for plan identifier, and then we also initiated a
21 fax system unique to this population where we let the homes fax in their list of patients, we identified them
22 using the customer service reps working at night, and faxed back the plan identification in the BIN PCN
23 numbers when necessary. And I'll tell you, we finally, at least as of 2 weeks ago, we had answered 500,000
24 fax requests, and if that's not a record, I don't know what is. But it made it much easier going into January
25 1st.

26 One of the nice things was that even in the states, during the transition period, allowed pharmacies
27 to access Medicaid for dual eligibles. Almost none of this went on in long-term care. They stuck with the
28 system, and so that process seems to have worked.

PPAC Meeting Transcription – March 2006

1 The transition policy. We've extended the transition policy to March 31st. We've also asked the
2 plans and they've responded appropriately to suppress step edits for these beneficiaries, or formulary drugs,
3 prior authorization, quantity limits, step therapy. There are a couple of exceptions, and this comes up all the
4 time, at least it comes up to me all the time. One are excluded drugs. As you know, benzodiazepine can
5 never be paid under Part D. Nor can barbiturates, nor can prescription vitamins, certain other drugs in the
6 1927 list. We allow B versus D prior authorization. And the reason is that the Part D plans again can't by
7 law pay for drugs that would have been and should be paid for under Part B and that's an issue. And the
8 last is we allow safety step edits and safety checks. I get calls about this almost on an hourly basis. And I
9 have 2 examples. Both of which have come up in the last 3 weeks. One was a prior auth that actually
10 stopped dispensing a Dijoxin pill, which makes no sense by the way, because Dijoxin is generic. There's no
11 reason in the world for a plan to put a prior authorization for economic reasons on Dijoxin. After a number
12 of calls, it turns out that the reason they did it was that it was a relatively high dose, outside of usual
13 indications. It was 0.75mg. When I was a resident, there was a very well known cardiologist who used
14 doses much higher than that all the time. But in this case, when we found the provider, he had actually
15 written 0.25mg, his handwriting was like mine, and it came up as 0.75mg and the pharmacist couldn't
16 dispense it. In this case, considering it was an elderly person, this prior auth probably saved his life. We're
17 also getting a lot of prior auth issues with the mental health drugs. And there are a lot of mental health
18 drugs that are being used outside standard doses by psychiatrists perfectly appropriately. The mental health
19 center, community centers, we have a regular standing mental health pharmacy call and I talked to the
20 mental health community AIPA[?] all the time and it's hard to argue the fact that some psychiatrists, used
21 to using drugs, will appropriately use higher than indicated doses. Unfortunately, not everybody's a
22 psychiatrist and we've been seeing, and the first time that I've been seeing it because of these issues, the
23 fact that a lot of atypical anti-psychotics particularly are being used in very high doses. The last example
24 was somebody, and this was actually nobody's ill practice, who had step edits, in fact he had quantity
25 limits, step edits for mental health drugs, she was on Seroquel, Billphy[?], and Zyprexa at the same time.
26 Now it turned out in this case, and they're all high doses, that they're written by three different doctors.
27 And the patient was unable, the problem, when you actually got down to the beneficiary level, was no
28 longer actively able to engage in activities in their adult day center. Of course they were not actively

1 engaged in their adult day care center—they were sleeping all the time! [laughter] In this case, it was
2 actually appropriate, and again, one of the interesting side effects that we didn't expect entirely of the Part
3 D benefit is you are going to get finally unified drug lists for all Medicare beneficiaries in the program, and
4 you have a chance of actually looking for drug interactions, drug overdoses, drug repeats, that we actually
5 never had before. And I mean in the institutional setting, we as a provider community were also accused in
6 the past of using physical restraints excessively. I think that has mostly passed, and I think in most places,
7 the use of physical restraints has diminished if not disappeared, Unfortunately, we're getting a lot of issues
8 with chemical restraints. And it may be that one of the values of Part D is making us re-look at that.

9 Exceptions and appeals. We have a time line. We've all talked about that. The expedited timeline
10 takes it to an independent review entity in 4 days, who was a CMS contractor, not a plan contractor. It's
11 important to remind people that prior authorization is not an exception. It's just a fulfillment. If it's turned
12 down, it becomes a re-determination then it fits immediately into the exceptions process, and it can be
13 overturned in 4 days. We're making efforts to simplify and standardize the process, linking the process to
14 forms from a central location, and trying to put in all the contact numbers to make it easier for physicians.
15 The formularies themselves are available on our website and on various private vendors, including
16 Hippocrates, and that we're trying to find ways of linking directly to the exceptions, appeals, and drug
17 utilization management technique pages of the plan.

18 In one minutes, I'd like to talk about manufacture pharmacy assistance programs. It's true that on
19 the one had, a lot of manufacturers have now withdrawn from the field. It has nothing to do with Part D.
20 Part D is completely compatible with manufacture pharmacy assistance programs. They're free to wrap
21 around Part D, provide drugs to people who are deserving if they wish. Many have decided they no longer
22 wish to do so and unfortunately we can't mandate that they do so. But it was never part of the plan, it was
23 never part of the regulations, it was never part of our guidance. If they were dual eligibles, or people on
24 low-income subsidy who need these plans, the manufacturers can provide them as they did in 2005. Which
25 gets me to my last point, which is the low-income subsidy. These are people who aren't Medicaid. They
26 aren't full benefit duals. They're between 100 and 150% of the Federal poverty limits and have certain
27 asset requirements. If they fill out the application, they can get low income subsidy help, which is a
28 complete benefit. There are minimal premiums—2-dollar, 5-dollar and general co-pays, minimal

PPAC Meeting Transcription – March 2006

1 deductible, no gap, minimal cost share, and basically minimal payments in the catastrophic. It's a complete
2 benefit. There are 8 million people we'd like to reach at least in this group, and it has to be done
3 voluntarily by an affirmative action. If they don't fill in the application, they never actually get the benefit,
4 and they won't get enrolled in a plan. And I'd like health trying to figure out how the physician community
5 can help in the patients whom they have—it usually obvious. Patients who don't comply for medication
6 because they don't have the money, should be the ones who are directed to this resource, because we'll get
7 much better compliance. I mean the stories you hear about people splitting pills, taking their animals' pills,
8 deciding to take pills instead of food, should be gone next year if we get the right response on low-income
9 subsidy, certainly, at least in low income seniors. Because that group of people, what my economist friends
10 tell me, are sensitive to drug costs. Should be in the group we're giving extra help. Thank you.

11 Dr. Castellanos: Thank you, Dr. Kelman. I now hope the floor to the Council for its discussion and
12 any recommendations. Dr. Powers?

13 Dr. Powers: I just have a comment on the issue of benzodiazepines and barbiturates. There are
14 legitimate uses for benzos and barbiturates in the field of neurology, particularly Clonazapen, which is an
15 anti-epileptic medication, and then also it's used for anti-spasticity, and we have patients who are very well
16 controlled on Phenobarbital as a legitimate, anti-epileptic medication for years and years and years and all
17 of the sudden, it's not paid for. Now I don't care to ask someone to pay for medication that doesn't cost
18 more than a pack of cigarettes, if they have money. But some of my patients don't smoke and they don't
19 have money and they have been effectively cut off from a medication, suddenly cut off from a medication
20 that they have been on for sometimes 25, 30 years.

21 Dr. Kelman: This is actually statutory, it wasn't policy. These drugs are in the 1927 D2 list for
22 historic reasons. It turns out that for the dual eligibles, 49 states, Medicaid will continue to pay these drugs.
23 I think Tennessee is the one upset and it's not for lack of our effort. And I don't disagree with the fact that
24 they have very good clinical uses. But I'm sorry to say it would take statutory change to get the barbiturates
25 and the benzodiazepines out of the 1927 list.

26 [chat]

27 Dr. Powers: The other problem that we've experienced from some of the plans is that when they
28 tier the drugs, they're tiering them economically. I meant to send this to you, but I don't have the actual

1 paper in hand, where a patient received recommendations from their pharmacy program that a list of anti-
2 epileptic medications that they're recommending be tried, instead of the medications they were being given
3 and number one on the list was a medication called Philbanmate[?], which we have for the most part quit
4 using, except in exceptional circumstances because it has a lot of risks. It's not that it's not useful and it's
5 not a good drug, but it's very high risk. Requires intensive monitoring. And requires even having the
6 patient signing forms and things in order to use it, that they'll agree to get testing. But that was the number
7 one drug on their list. Is there any chance of ever going to a single formulary?

8 Dr. Kelman: Well, not under the Act. But the tiering is interesting, because whatever the
9 recommendations are, the provider can still write for a third tier drug. It just costs more, and even saying
10 that, that in Part D is unique I think in allowing the tiering price to be appealed. If somebody needs the
11 drug, they can appeal from a non-preferred tier to a preferred tier.

12 Dr. Powers: But what it's doing is it's putting that onus on us with these pharmacies acting
13 irresponsibly by recommending these—

14 Dr. Kelman: Well, the pharmacies aren't supposed to recommend anything, obviously. They're
15 supposed to dispense drugs. I mean they never were, even commercial formularies.

16 Dr. Powers: This isn't the pharma, this is the Program.

17 Dr. Kelman: Oh, the plans.

18 Dr. Powers: Yes.

19 Dr. Kelman: But the plans can tell the beneficiary, I suppose, that there's a cheaper version or a
20 cheaper drug that they might use, but they can't recommend clinical course. And they're not supposed to.

21 Dr. Powers: We also found that at least initially, and I'm not sure if this has changed yet, but none
22 of the plans are available to the patients in our area contain the medication gabapantene, which is widely
23 used for pain in epilepsy.

24 Dr. Kelman: I think it's one of the anti-convulsives, and I'm fairly certain that all the formularies
25 have to have—this is neurology, right? Have to have it on it. If they don't have it on there, it's not there at
26 all, in a generic form, or a brand form, let us know.

27 Dr. Powers: OK.

28 Dr. Castellanos: Are there any other questions or comments? Dr. McAneny?

1 Dr. McAneny: I don't know why you think we couldn't listen all day to Part B and Part D, it
2 would work for me, but I do have a couple of questions on that. One is that currently in the Part B setting,
3 we spend a lot of time working with our carrier medical directors about drugs that are not in the compendia,
4 and using off-label indications for drugs that appear in peer reviewed literature. So one of my concerns is
5 that as more and more chemotherapy becomes oral, and will therefore be in the Part D part, one of my
6 concerns is will I still be able to get off-label indicated drugs through Part D for patients, and the second
7 question on the Part B, D is there any intent on CMS's part to move any of the injectable drugs from Part B
8 into Part D?

9 Dr. Kelman: Going backwards, we are looking internally on that second question without any
10 conclusion yet. It would take statutory change. Going to the first question, which is a very good question,
11 as you know, we've required as one of the six classes that all chemotherapy be available on the Part D
12 formularies. So all drugs that are licenses chemotherapy. Now technically speaking, and it goes back to
13 §1927 again, that medically accepted use is use that's either FDA on-label indication, or found in one of the
14 compendia, AHFS drug decks USDI, but even beyond that, a formulary drug that in theory could be prior-
15 authed, for an off-label and an off-compendia use, could be brought on with an exceptions and an appeals.
16 To be honest, I haven't seen, and anything's possible. We don't really see Part D plans using prior auth to
17 prevent chemotherapy or that kind of drug for cancer. I mean if you see that happening, let me know. But
18 that's not a major enough issue that I don't believe the battle will be fought out there.

19 Dr. McAneny: OK. We do have a lot of difficulty now with getting things on the compendia.
20 They're purchasing one another and rearranging how they do things and it's terribly slow to get the
21 injectables on the compendia for given indications and so now that there is an explosion of new
22 medications, which are oral, I think it's going to overwhelm the compendia folks to be able to keep up with
23 all this and I'm worried that it will lag behind. I was also wondering if you're monitoring the amount of
24 time that physicians are spending appealing this, the Part D coverage decisions, because even though we
25 applaud you for streamlining it and putting it on the website and having one form and all those things that
26 you're doing, everything you can do to help with that, I still have 2 pharmacy techs in my office who are
27 busy full time all day long helping people figure out which drug is on their particular Part D plan and which
28 is not and how do we get it appealed and it's already starting to be a major time consumption.

PPAC Meeting Transcription – March 2006

1 Dr. Kelman: I don't disagree. We're trying to give every effort to try to reduce the appeals and
2 exceptions times. I'm hoping by the way that the worst, clearly the worst had to be in the beginning of the
3 program, because you have the entire population changing from a formulary to a new formulary or from no
4 formulary to a new formulary. In theory, once the program is running and you have people either changing
5 plans or aging into Medicare, and getting new formularies, you should have a small number and if you have
6 a smaller number, the whole access problem will be easier. But I understand the stresses on physicians who
7 take Medicare patients in the first few months, because everybody is switching formularies at the same
8 time. And again, it's never been done in this country.

9 Dr. Castellanos: Are there any other questions or recommendations?

10 Dr. McAneny: I have some recommendations.

11 Dr. Castellanos: Please.

12 Dr. McAneny: The first one is that PPAC recommends that CMS monitor the amount of time
13 physicians spend appealing Part D pharmacy coverage decisions, and the costs of care related to the
14 substitutions of medications.

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

16 Dr. O'Shea: Second.

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

18 [Ays]

19 Dr. Castellanos: Opposed?

20 Ms. Trevas: I'm sorry, can I have a second—

21 Dr. Kelman: What was that second issue? I didn't understand it either.

22 Dr. McAneny: When, for example, Nurontin's not on the formulary, and you end up having to
23 substitute Neurontin for someone with a chronic pain situation, as Dr. Powers was referring to, what that
24 means when those substitutions are going to occur is they're going to be back in our offices. They're going
25 to be saying I've had 3 more seizures this week. What's going on here? It's going to take more physician
26 time to sort out the changes that have occurred and once again, as soon as we do that, the volume of
27 intensity goes up, the conversion factor goes down, and we get nailed again.

PPAC Meeting Transcription – March 2006

1 Dr. Kelman: That issue does come up, by the way, and we are already looking at that. To balance
2 that off, the general projections are because of the low-income subsidy beneficiaries, who are actually able
3 to take medications for the first time, if you believe medications work at all, and not everybody may, in
4 theory, it should reduce secondary cost from hospitalization and increasing morbidity. In other words, the
5 group can get medications because they get coverage for the first time, and this group by the way, almost
6 never has drug coverage. In theory compliance should—I mean we're expecting a reduction in Medicare
7 overall costs for them. I mean it's the famous story of using the Emergency Ward to treat asthma because
8 you couldn't afford an inhaler. If you can afford inhalers, you don't go in the Emergency Ward. It should
9 reduce the cost of the Emergency Ward and introduce the costs in Part A, B, and that we are looking at.

10 Dr. McAneny: This would be a great place for a G-Code demonstration project of how much time
11 did you spend monitoring changes, etc. for that. Just a hint.

12 Dr. Castellanos: Do you have any other recommendations.

13 Dr. McAneny: Yes, but we haven't voted on that one yet.

14 Dr. Castellanos: Yes, we have.

15 Dr. McAneny: Oh did we? OK. I would like to have PPAC recommend that CMS use evidence-
16 based medicine and peer review journals to allow off-label uses of medication covered under Part D, just to
17 get it in there.

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

19 [Seconds]

20 Dr. Castellanos: All in favor?

21 [Ays]

22 Dr. Castellanos: Opposed? Dana, you have that? Dr. McAneny?

23 Dr. McAneny: Would you humor me for one more? I would like to have PPAC recommend that
24 the injectable drugs currently available in Part B be left in Part B and not transferred to Part D. And the
25 reason for that is—

26 Dr. Kelman: No drug in Part B is under Part D, at least in the foreseeable future. That's not the
27 moment on the cards.

PPAC Meeting Transcription – March 2006

1 Dr. McAneny: I misunderstood you then. I thought you said that this was something that CMS is
2 looking at whether or not they were going to move the Part B drugs into Part D.

3 Dr. Kelman: No, there's a question of moving the Part D drugs into Part B. But your point is not
4 unreasonable to make, but under current law, there's no change in Part B or Part D under the present
5 system. It would take a statutory change to make any movement in either way.

6 Dr. McAneny: So your comment earlier that you were saying that—

7 Dr. Kelman: I thought you meant it the other way. I thought you were worried about—

8 Dr. McAneny: So there is no CMS is not looking in any way at taking the injectable Part Bs and
9 moving them into a Part D benefit.

10 Dr. Kelman: No.

11 Dr. McAneny: That's just not on the table.

12 Dr. Kelman: No.

13 Dr. McAneny: OK, I withdraw that motion. Thank you. I misunderstood.

14 Dr. Castellanos: Dr. Johnson?

15 Dr. Johnson: Question. Some of the local pharmacists in the area who fill in the prescriptions
16 wanted me to ask a couple of questions. You have addressed them in your solutions in identifying much the
17 issues they were concerned about, but they were talking about the length of time in dealing with the
18 telephones on the wait, sometimes up to 45 minutes to be answered, and also, by about 11:00, they had an
19 hour backlog, and by about 1:00, 2 hours backlog on filling the prescriptions, having problems with I guess
20 the coordination with the files that you were talking about going with the deductibles and getting all the
21 information. But the question on a national, now these are Rite Aid, CVS, Walmart and local pharmacists
22 etc, pretty much across the board in my area. Is that backlog on filling the prescription pretty much across
23 the nation?

24 Dr. Kelman: It's actually reduced. We're doing monitoring on a regular basis, looking at that. Part
25 of it was just shake out in the beginning. Pharmacists didn't know to call, the plants couldn't quite know
26 what to deal with this. They've never dealt with as many Medicare beneficiaries. There's a whole
27 pharmacist group and pharmacy open door forums, which we have to address all the local pharmacy
28 questions. And I think there's a pharmacy open door forum coming up. Because those are real issues.

PPAC Meeting Transcription – March 2006

1 Pharmacy access to drugs. But they might better be addressed—and we could talk hours about the
2 pharmacy networks, but they may be better addressed in the pharmacy open door forum, or the pharmacy
3 provider calls.

4 Dr. Johnson: No it was just a curiosity on the filling of the script. Was that pretty much standard
5 across the nation on the waiting time?

6 Dr. Kelman: No, now they're further down. We do, what do they call them, secret shopper type
7 calls, where we're monitoring the actual waiting time at pharmacies.

8 Dr. O'Shea: Does there exist a difference in benefit for a person, a senior living in a supervisory
9 setting versus a nursing home?

10 Dr. Kelman: The only institutionalization is defined by the Act, as a licensed nursing facility, an
11 IMD statement, the hospital, a state mental health hospital, and ICFMRDD, care facility for mental
12 retardation developmental disability. Those are the only ones who get the zero co-pays if they're full
13 benefit dual eligibles. The other full benefit dual eligibles have \$1, \$3 co-pays until they reach catastrophic,
14 then they have no co-pays.

15 Dr. O'Shea: OK, so if I'm taking care of my mom at home, or if they're in a group home, they
16 don't get the same, unless they're in again—

17 Dr. Kelman: And the reason is that the only ones who have a person needs account spend down to
18 \$30 and in some states \$60 a month are the ones in those three defined settings. In theory, your mother
19 could have more assets, up to the Medicaid 100% FPL or whatever the state Medicaid is, so presumably
20 might be able to afford \$1, \$3. Basically, people with long-term care, with \$30 a month maximum in the
21 states to follow it up, to \$60 a month, really can't afford to pay co-pays. That was their rationale behind it.
22 I'm sorry to say that because we delayed, I have another call, believe it or not at noon.

23 Dr. Castellanos: Well, we certainly appreciate your being here—

24 Dr. Kelman: We have one other thing, we have some handouts, if you're interested, on tip sheets
25 on Part D that we'd like you to look at and see how they fit in. And I appreciate the opportunity to give you
26 an update.

27 Dr. Castellanos: Dr. Kelman thank you very much. [applause] We're going to take a little change
28 in the program. Dr. Tom Gustafson will give his report at 1:00.

PPAC Meeting Transcription – March 2006

Recognition of Dr. Bernice Harper

Dr. Castellanos: Now I have the distinct pleasure and honor in recognizing Dr. Bernice Harper. Dr. Harper could you stand up so we can—we all know you. Let me give you a little background on Dr. Harper. She's been a very quiet, nonassuming individual. But this woman in her life, has done more for the chronically ill patient than we will ever, ever know. She's a pioneer in the care of the sick and chronically ill and terminally ill patient. She's a legend in the field of long term care. Dr. Harper began her career at the Children's Hospital Society in California as a medical social worker. She then joined the staff at the City of Hope National Medical Center in California. She later accepted a position at the United States Public Health Service. She's authored many articles and many books and one of her books that's best known is *Death, the Coping Mechanism of the Health Care Professional*. Before her retirement, Dr. Harper was the Medical Care Advisor for the Centers for Medicare and Medicaid Services. She's been a driving force in working with the provider organizations, addressing significant health care issues, affecting millions of Medicare and Medicaid beneficiaries. Dr. Harper's career has been filled with many, many accomplishments. She's been on the President's Initiative for Historical Black Colleges and Universities. She's an international speaker and advisor. She's attended conferences all over the world, to include Israel, Sweden, she's traveled to South Africa and Zimbabwe and resulted in assisting hospices in America, to establish the foundation for hospices in the Sub-Sahara Africa. And she serves now as president of that organization. Dr. Harper has received many, many awards and recognitions. She got a Bachelor's of Science Degree in education, her Masters in Social Work, a Masters in Science and Public Health, and a Doctor of Law Degree. But more important, and I think it's important to everybody in CMS and the PPAC Committee, it's been a privilege and an honor to work with you, and to be associated with a person of your caliber. To be able to call you a friend and a colleague. And we sincerely appreciate you. And every time I see the color purple, I will always, always smile. Thank you very much. [applause]

Dr. Harper: Thank you, Dr. Castellanos. [off mike]

Dr. Castellanos: She's a very woman of extreme modesty.

Dr. Harper: Thank you, Dr. Castellanos, Dr. Simon, Dr. Gustafson, Mr. Clark, and members of the PPAC advisory council. You never know what a difference a day will make, and so when Mr. Clark called this morning and said that you were demanding that I come in [laughter], I got up and got here. My

PPAC Meeting Transcription – March 2006

1 husband wanted to know why Mr. Clark didn't send the car for me. [laughter] and I told him that he should
2 remember that I work for the federal government. And we have our limitations, we have our strengths. So I
3 am here. It has been a pleasure for me to be associated with the Practicing Physicians Advisory Council all
4 these years, and with the staff members. I could not have accomplished any of this without the help of
5 everyone. All of the staff members from the people who led us in at the door, the guards, the housekeepers,
6 the facilities and of course the policy people, we couldn't have accomplished this. And it's been my
7 pleasure And someone had said to me that I had spoiled the members of this committee?

8 [We love it!]

9 Dr. Harper: And someone said to me, Bernice, you are internationally known, and why are you
10 doing these luncheons and things for the doctors? I didn't have to answer. Dr. Carbo, one of your former
11 physicians answered. She said we get nurturing when we see Dr. Harper. So if I've nurtured you, it's been
12 my pleasure. And I think the highest honor you can pay to someone is to nurture them and to love them and
13 to care about them and to be compassionate. I know you're going to continue to grow and develop and that
14 you're going to help to solve the problems in health care for the American people. And thank you very
15 much. [applause].

16 Dr. Castellanos: As a token, and in remembrance. We're going to miss you. We love you and
17 you're always going to be a part of this committee.

18 Dr. Harper: Thank you very much.

19 Dr. Castellanos: We're going to break for lunch now, and we'll be back at 1:00.

20 Afternoon

21 Dr. Castellanos: I know a lot of us have planes to catch this afternoon, so we're going to really try to start
22 right on time. I wonder if all of us could take a seat at this time. I believe most of us, or all of us will
23 recognize our next speaker as a regular participant in the PPAC meetings. Dr. Tom Gustafson is the Deputy
24 Director of the Center for Medicare Management in CMS. In addition to his input to our discussion on
25 various topics today, he's also prepared to provide the Council with an update on the Medicare Contractor
26 Reform. Dr. Gustafson has his Ph.D. from Yale in economics, but like all of us, he has some very unique
27 talents and interests and hobbies. And one of the hobbies that I found out about him is he likes to build and
28 make kayaks. And he's been doing that—he's got a place up in New England where he's been doing it, and

PPAC Meeting Transcription – March 2006

1 if any of you have any interest in building and making a kayak, I found an excellent resource for you. Dr.
2 Gustafson, please.

3 Dr. McAneny: What's the CPT-Code for that? [laughter]

4 Medicare Contractor Reform

5 Dr. Gustafson: You mean the doing it, or the consultation? [laughter] OK thanks very much. I'm
6 going to go through this pretty quickly. The basic outlines of this are familiar to the members who have
7 been on the committee. I'll try to give enough background for those of you who are just arriving so you
8 have a sense of what we're up to. And this is mostly just a status update. Where are we on what is in fact
9 one of our major administrative and operational projects that we're undertaking over the next 5 years? The
10 first slide shows just to give you an overview. Recent legislation required us to replace all of the existing
11 fiscal intermediary and carrier contracts and that will be the first time this has ever been done. Most of the
12 existing contractors have been with the program since its inception and there has not been a regular process
13 for recompeting that workload. So we will now be in a mode where we are doing that, we're operating
14 under something call the Federal Acquisition Regulations, as you can see in the third bullet. An implication
15 of that is that on approximately a five-year cycle, we're supposed to recompet these contracts.
16 Competition has a telling affect on people's behavior. And if someone is threatened with a loss of
17 workload, this tends, we believe to cause them to pay more attention to it and so forth. We will be putting
18 together at an organizational level, the Part A and Part B administration of the program. So there will no
19 longer be a distinction between fiscal intermediaries and carriers, but there will be a single organization that
20 we will contract with in each jurisdiction, which will accomplish both of those functions. Now that's not
21 the same thing as saying the claims payment system will be the same or that there won't be distinctions
22 between the various work components that may be part of those contractors and in fact that's certainly to be
23 expected. But we will have a single home, a single organization, in each of these areas. The statute
24 provided a 6-year period for us to complete this transition. We have a plan that proceeds somewhat more
25 quickly than that, or at least that's the plan. And we are going to be operating three cycles of procurements
26 around the country to do this, as I'll explain in just a moment. The next slide is a map. This is the new
27 pretty version of the map. This is actually the simpler of the two that I will show you. This relates to the
28 durable medical equipment contractors, which we're attempting to award, or have awarded right at the

1 moment, are attempting to implement. The same layout will apply for the home health and hospice
2 specialized carriers, specialized MACs when they come up toward the end of the 5-year period. So this is
3 kind of an overlay and each of the jurisdictions that I'll show you in a moment fits within the boundaries
4 that are shown here. We have 4 what are now called Durable Medical Equipment Regional Carriers at the
5 moment, and they have approximately these boundaries. We will be moving 3 or 4 states around to make
6 them correspond to the new picture. The next slide shows you the new A and B jurisdictions. Now if I
7 showed you the existing map, it would be very complicated. This is a whole lot simpler. We have
8 contractors who are operating in both California and Maine, I believe and it's sort of a crazy quilt of stuff
9 that has resulted from historical accident as much as anything else. This consolidates the map of the US
10 into 15 areas. And the 15 fit within the 4 that I showed you so the boundaries are contiguous, and each of
11 these is give or take about the same size in terms of number of beneficiaries, number of providers, so they
12 are all at roughly the same scale and they are at a scale which corresponds to our largest FIs and carriers at
13 the moment. So we think we're in a world where we have proof of concept. Somebody can run something
14 this size and make sense out of it. So we will be putting these 15 contracts up for bid in the next few years.
15 The organizations may win more than one of them. That obviously remains to be seen. And these are
16 proving to be fiercely competitive. We have a large number of folks who are currently with the program,
17 who want to stay with the program. They're making that very clear. They're clearing their decks and
18 getting ready for action in terms of the competition, and we have new entities, who are interested in coming
19 in and getting a share of this business. The overall business is in the vicinity of \$2 billion a year. So it's not
20 at all trivial, and we think that again the benefits of competition will shine through here.

21 The next slide shows you the transition schedule. This is the highly simplified version. I can
22 assure you there are hideously complex versions back at the office that we could trot out if we really
23 wanted to scare you. But this shows you the three cycles that we are and will be engaged in. Each one of
24 these bars represents the period that it takes us to go through one of these things. It takes about a year in
25 each case to go from sending an RFP, Request for Proposal, out on the streets, seeing who wants to come
26 play. Talking to them all about it. They respond. We go through an elaborate internal process to review
27 them, we go to an award, once you have the award, you know who's going to get the work, and the
28 outgoing and incoming people start working together, form working teams of one sort or another, and then

PPAC Meeting Transcription – March 2006

1 you come to the point then that's identified there as cutover. So that means were we adhering to the
2 schedule shown on the first bar, we would be expecting to cut over the DME work in July of this year. As it
3 is, we have a protest on that award. The award did go out on schedule. We have a protest on the award,
4 which is threatening the timing on that. We haven't yet resolved exactly how that will be proceeding. We
5 expect to probably proceed with 2 of them where the protest does not affect them. That's in the northeast,
6 right away. And the other 2 we'll need to straighten out, as there are some legal proceedings going on there.
7 The start-up cycle is kind of the training wheels. We're going to do it with the DME medical carrier guys
8 and change them over into what will be the DME MACs and then we will have one jurisdiction, which I'll
9 show you in a minute, that's of the AB variety. That's identified as J3. This is our new internal language.
10 Jurisdiction 3 is going to be up first. I'll show you J3 in a minute. Then the 2 big cycles where you can see
11 that 3rd bar down there has J4, J5 and J12. That's a good chunk of the West between those 2 cycles there,
12 will come sort of on each other's heels. We staggered them slightly to give ourselves a little bit of an
13 administrative break on this and then on cycle 2, we'll come up with the rest of them.

14 If you see the next slide, it shows you where we are on the DME MAC procurement. We
15 announced these awards in January. ABCD are the four regions of the country. And those are the folks who
16 won those awards. We have 2 protests, one in C and in D, which are affecting the progress there. So I can't
17 give you really a whole lot more detail on that. We're back and forth with the General Accounting Office—
18 what used to be the General Accounting Office, now the Government Accountability Office—is the party
19 that entertains the protests, and sort of serves as an appeal function, and they are working that through, and
20 we expect an answer from them early in May about exactly what we need to do about. The next slide shows
21 you that's J3, it's the intermountain West, and we have the Request for Proposal already issued on this. The
22 Request for Proposal is gigantic because this is one of these circumstances when you try to figure it out
23 mostly in advance, as opposed to just kind of saying, you all come and we'll pay you later. It has to be done
24 in a very precise kind of way. And we're looking to award that contract in June. The next slide shows you
25 what's up with the Cycle 1, as opposed to the training wheel cycle and I won't read this all to you but you
26 can see that it's another calendar of gala events to be expected. The next slide is attempting to capture why
27 this should matter to you guys. We kind of hope that the whole transition process, the competition process,
28 will be largely transparent to physicians and to other providers, that it will not affect you in your day to day

PPAC Meeting Transcription – March 2006

1 business in any immediate sense. We do hope that once we get there, we actually plan that once we get
2 there, the MACs will serve a very useful function in terms of improving coordination of administration,
3 both the standpoint of beneficiaries and of providers. Because by and large, you'll have a single
4 organization, single point of contact. The role of competition is noted there in the 3rd bullet. Speaking about
5 competition among physician practices today, I'm pretty sure you understand some of the points of this. It
6 does cause you to pay close attention, and providers will have input on how these guys are doing in
7 surveys, that Dave Clark will be along to explain to you in a minute. The next slide makes note of some
8 issues that the committee was concerned about at one recent briefing. What's up relative to carrier medical
9 directors? This is obviously a key point of impact, and key point of interaction with the practicing
10 physicians. My recollection is, I'm sure this is in our records and minutes someplace or other that you
11 passed a recommendation that we ensure continue access and the agency has taken that very seriously. And
12 that is basically the standard we're adhering to. So that access is intended to remain the same. Now in J3,
13 we did not require ACMD in each state. Some people had suggested that although that was not the
14 recommendation of your committee, if I recall correctly. We're required the offerers to have at least one
15 and to explain to us how they will maintain a decent standard, an appropriate standard of access to the
16 carrier medical director function. So that you can get on the phone and get somebody to talk to without
17 unreasonable delay or hassle. They're also supposed to be working with the specialties in their area, so
18 we're expecting them to form relationships, if they don't already have them, we may very well have
19 successor organizations here that are the same as the existing organizations, but to have relationships with
20 the specialties in their areas so that as medical issues arise, that are outside of their immediate kin, there's
21 somebody they can get a hold of, there's a committee they can look to, and that sort of thing. The bottom
22 bullet means no change, so that these guys will be required to adhere to the program integrity manual, just
23 as the existing carriers are. So that's intended to reassuring, I guess, because at least we put it all out there
24 in a manual where people can see it. The next slide makes note of local medical review policies. We
25 changed the nature of what we were doing on this sometime recently. We now talk about LCDs as opposed
26 to LMRPs and the basic picture here is that the consolidation of jurisdictions will result in some greater
27 standardization of these policies. The process by which that is supposed to happen is supposed to be an
28 interactive one. It's not just take the least common denominator, or the one-size-fits-all approach, but for

PPAC Meeting Transcription – March 2006

1 those areas where there are divergences in the existing LCDs in the various areas that a contractor succeeds
2 to, they're supposed to try to work through those in consultation with the medical community to see why
3 they are different, do they need to continue to be different, what needs to happen that would make sense out
4 of all of that.

5 Next slide notes that there will be a cluster of contractors behind the MACs from the standpoint of
6 the providers. We refer to these as functional contractors. We have a language which refers to specialty
7 contractors. Those would be the DME MACs, or the home health MACS. These functional contractors
8 would be where we have peeled off particular functions. Some of that exists already today. The QICs, the
9 qualified independent contractors, the programs safeguard contractors, and the beneficiary contact centers,
10 otherwise known as 1800 Medicare, all of those things will need to be integrated with and work together
11 with the MACs. The MAC again becomes the sort of central node, the face of Medicare in the local
12 community and some of these other functions get spun off to specialized contractors behind the scenes.

13 Last slide just reminds you of who I am, and gives you a website where there is yet further
14 information about all of this should you have questions. I'd be happy to entertain any you have at the
15 moment.

16 Dr. Castellanos: Dr. Gustafson, thank you very much. Are there any questions, comments from the
17 Council to Dr. Gustafson? Are there any recommendations that any of you would like to make at this time?
18 Seeing none, I want to thank you very, very much and we appreciate the brevity of your report. [laughter]
19 We're almost catching up. The Medicare Contractor Provider Satisfaction Survey, the 2006 Administration,
20 its application to contractor oversight and performance evaluation. As we continue our presentation, let me
21 introduce Mr. David Clark, and Ms. Vasuda Narayanan. Mr. Clark really needs no introduction. I think all
22 of us have seen him at a number of our meetings. He's the Director of Provider Relations and Evaluations
23 in the provider communication group. He's been with CMS for over 15 years, starting in Chicago where he
24 was born, moving to the Philadelphia region, as an associate regional manager, and now in Baltimore
25 Washington. He's been a part of the CMS staff. If any of you ever try to get him on the phone, and you
26 hear classical music in the background, just kind of turn it down a little bit because he's a real fan of
27 classical music I understand. But more important he has a really unique hobby and interest. He's a student

1 of Chinese art and he takes private lessons on a weekly basis in Chinese art. I just think these are very
2 interesting things about some of the people we deal with.

3 [??] Trying to give a human face to the bureaucrats? [laughter]

4 Dr. Castellanos: Absolutely. Be it kayak making or Chinese art. Ms. Narayanan is the Project
5 Director at Wetstat, the contractor administering the survey. As a team our speakers will give us the status
6 of the project implementation, the results of the pilot survey, and how the data will be collected and will be
7 used. Our speakers would like us to consider the following questions during their presentation. They would
8 like some idea of how they could get the physician to respond to the survey, whether they should contact
9 the physician, the office manager, the staff, and what should be done to increase the saliency of this survey
10 among the physician community and what methods work best to obtain a response from physicians? And I
11 would like an answer to that also. [laughter] I'll turn the meeting over to Mr. Clark and Ms. Narayanan.

12 Physician Fee Schedule & Outpatient Fee Schedule Final Rules

13 Mr. Clark: Dr. Castellanos, thank you very much. Vasuda and I are delighted to be here to share
14 with you information about this very exciting project that we're working on. It sort of segues from what
15 Tom was just talking about with the MACs, that within the MMA legislation is a requirement for the
16 agency to conduct a provider and beneficiary satisfaction survey, and to the end for the provider side,
17 we've been working on this for about 2 and a half years now and we're into the national implementation of
18 this survey, which is a first for the agency, a first time on a coordinated, national basis that we have gotten
19 or will be getting information from providers that will allow us to get some understanding of how our
20 contractors are performing and particularly as we move in this MAC environment, which, as Tom said, will
21 fundamentally change the way in which we do business in terms of our Medicare contractors. Just like to
22 highlight a little bit of what Dr. Castellanos was saying in terms of the input that we're looking for from
23 you this afternoon. We have piloted the survey. We are now into the data collection phase for the national
24 implementation and as was indicated, our interest really fixes on this middle bullet here—how do we
25 increase the saliency of the survey among the physician community? We're going to show you data as we
26 get into the presentation about our numbers and where we are right now in terms of physicians and
27 providers responding to the survey. But and we'll also talk about the work that we've been doing in terms
28 of just educating the provider community and informing them of MCPSS. When you look at, I guess the

PPAC Meeting Transcription – March 2006

1 challenge for us in getting this started, is that there are some 1.2 million physicians and providers that
2 participate in the Medicare program. And the challenge for us is how do we keep this in front and get the
3 information to a small subset of providers? The 25, actually 28,000 providers that are a part of our sample
4 frame, so that they're aware of it, they understand the importance of it, and then, actually respond to the
5 survey. When you look at our numbers and where we are with the responses so far, you'll see that there's
6 some work that we still have to do with respect to the physician and other billers under Part B. That's what
7 we're looking for from you; to help us with is there language that we need to use? In terms of how we write
8 and talk about the survey? Are there particular individuals in the practice that we need to send the
9 information to or make sure it gets directed to them? So that it gets to the attention of the physicians in
10 those practices, and then hopefully respond to the survey by sending the information in or going on line as
11 its available.

12 As is indicated, Vasuda and I will give you an overview of MCPSS, share with you where we are
13 with the national implementation, with the lessons learned with the pilot—as I said, we did conduct a pilot
14 and we will talk a very little about that—and then the importance of MCPSS and how we'll be using the
15 results. On the last 2 items, Alan Constantian was not available to join us this afternoon for the presentation
16 and how the data will be used. And I'll talk about that and cover the points that he has to share.

17 First of all, MMA, as I said, it's an MMA requirement to do the provider satisfaction survey. It's
18 rooted in the law, very clearly stated, and that's our first objective, is satisfying that requirement. Also, as
19 we go into a MAC environment and looking at performance, and paying for performance, there's a need for
20 an objective measure, provider, for evaluating contractor performance and provider satisfaction fills that
21 need. And we're trying to do that and meet that requirement through the provider satisfaction survey, or
22 MCPSS as use the name and coined it in our communications. And also, it's our joint commitment to
23 providers in terms of getting their input and participation in making the best program available for our
24 Medicare beneficiaries.

25 We have developed and identified a sample of 25,000 providers. It includes all of the Medicare
26 Fee-for-Service contractors. We have a representative sample for each of the contractors, the Part A, Part
27 B, the RHHIs as well as the 4th provider type. The data collection for the survey started January 3, 2006. At
28 this point, we're now following up with non responders by post card and through telephone contact to try

PPAC Meeting Transcription – March 2006

1 and get a direct response in terms of completing the survey. As I say, we recognize up front, it's a very
2 huge challenge in terms of trying to get that small sample frame within the providers that participate in the
3 Medicare Program. And to accomplish that, we went through an extensive effort. We developed not only
4 on the CMS website, on the Westat's website, all of the contractors have links to and information about
5 MCPSS. We tried to use the listserves through our contractors as well as the listserves available internally
6 in CMS. We had a press release. We tried to use the trade press in encouraging it to include articles about
7 MCPSS and putting information into various newsletters as well. A fairly aggressive effort. I think
8 probably one of the larger ones that we've had to date, certainly within the providers. We've developed a
9 media kit and we've also worked with our contractors at their various local meetings that they participate at
10 a local level, to share information with providers again encouraging them if they are selected for the survey
11 to be sure to turn that information in and make it available. Our media kit and information that we have
12 about this survey is available at the website, listed here, www.mcpsstudy.org. Now I'd just like to walk
13 through the time lines in terms of the survey and where we are and what's coming up next. We started out
14 with our roll-out activities, sort of culminating around December 15th, but we really started a lot earlier than
15 that in terms of getting teed up, getting the language ready, getting press releases cleared and getting
16 information out to different providers types, but roughly the middle of December. As I said, data collection
17 started on January 3. We expect that the data collection reports and study updates have been coming into
18 CMS so we have been monitoring the response rates for all of the provider types, the contractors, also
19 monitoring it geographically to see if there are particular regions or areas where we need to do additional
20 work. The messages on the IVR systems with our contractors encouraging participation on the survey,
21 those were updated in the middle of February, and will continue to run through the end of the data
22 collection period, which ends April 28th. We expect the results will be available on a web-based system by
23 early July in terms of the responses for the survey and making that available for really all 3 levels. One, a
24 public area on the website, where individuals can go and get basic information about the survey. There will
25 be another level of access for our contractors whereby they'll be able to actually get to data and manipulate
26 data for their particular contracting service area. And then finally, CMS and Westat will be able to take a
27 look at the survey results as well, and try to understand and utilize those results.

PPAC Meeting Transcription – March 2006

1 I'll turn this over to Vasuda, who will share with you information about the national
2 implementation.

3 Ms. Narayanan: Thanks David. As David mentioned, the national implementation started on
4 January 3. And it started with a survey notification package being mailed out to all the sampled providers,
5 and this survey package included a letter on CMS letterhead signed by the administrator, a letter on
6 contractor letterhead, the respective contractor letterhead, with a note from the contractors to the providers
7 urging them to complete the survey, and instructions for how they could go about completing the survey.
8 The instructions included the methods by which physicians and all the other providers could complete the
9 survey and we gave them a couple of options right up front. One option that was highlighted is that they
10 could go to the website to complete the survey on a web application, or else they could call in for a paper
11 copy of the same survey. And the reason for giving everyone the paper option is we recognize not everyone
12 may have ready access to a web application in their own offices, and hence a paper option for all the
13 providers. David also mentioned we are now in a non-response follow up stage. So around the first week of
14 February, we started contacting those who hadn't yet responded by the website and yes, the data collection
15 period is about 16 weeks. But the reason for starting the follow up early is to use the follow up as a gentle
16 nudge to get them to complete it on their own over the web survey, or else give them the option of
17 completing it over the telephone with an interviewer. But before these packages went out, in December we
18 called all the sampled providers and the physicians to find out who would be the relevant contact person for
19 this survey. We wanted to make sure that the packages were being mailed out to the appropriate person,
20 and it was a short screener call to determine the contact, and as well as the contact information, as the
21 address, telephone number for the contact person. And this is where we're going to need your input. Based
22 on those calls, it seemed like either the office manager or the billing manager was the most appropriate
23 person for this particular survey because we are talking about the facility's interaction with the contractor
24 for claims processing and all the claims processing related tasks. But this is something we wanted to ask,
25 again the end, to get your input on was that the right way to go about it. The sample as David mentioned,
26 includes 28,000 providers and they are spread across approximately 53 contractors, 26 fiscal
27 intermediaries, 19 carriers, 4 RHHIs, and 4 DMERCs.

PPAC Meeting Transcription – March 2006

1 These numbers that you see on the slide there were the numbers as of last week, and of course as
2 of Sunday last evening, the numbers have climbed up and the overall response rate is now at 28%, which
3 FIs at 32, the carriers at 21%, RHHIs at 31%, and DMERCs at 43%. This distribution kind of mirrors what
4 we had during the pilot as well. DMERCs and RHHIs we got high response rates from them, and the
5 carriers were where we fell behind in the response rates, and kind of give you an indication of the relative
6 importance of these samples: The carriers, as you see there, constitute about 40% of the overall sample and
7 of the carrier sample, the physicians constitute 63% of the carrier sample, or 25% of the overall sample. So
8 the physician group is a pretty sizeable group in the overall sample and in the carrier sample. So kind of
9 very critical to ensure that we maximize the response rates, not only for all the provider types, but also for
10 the physician group. And the reason why we want to maximize response rates is to reduce the non-response
11 bias. With high response rate, we ensure that the quality of the data is better. That's what we're trying to
12 ensure by trying to maximize the response rates. And this is a cart looking at it a little differently, looking
13 at it by Part B and again, in the Part B group, the numbers as of last evening, the overall was 24%, with
14 physicians at 20, licensed practitioners at 22%, the DME suppliers at 43 and the others at 14%. Again,
15 emphasizing the need for us to really place emphasis on the physician group.

16 As David mentioned earlier, we've been employing a number of strategies to maximize the
17 response rates. A very aggressive campaign with the trade press to get the first story about the survey itself
18 and the next part would be to follow up with the trade press once the results are available in July. That's
19 going to be another, because the story in July will provide impetus to next year's implementation of the
20 survey as well, and we have been aggressively using all the CMS provider channels to get the information
21 out to physician groups and all provider groups. The last piece is the criticality of the telephone follow up.
22 That's where we are putting a lot of emphasis now in those non-response follow up interviews to make sure
23 we again get to the right person, and if the person has time, to get them to complete the interview over the
24 time. But of course, they do have the option of at that time saying, if they would rather complete it over the
25 website, or a request for a paper survey. Either of those are an option. But our first option would be to try
26 and complete the interview over the phone. With that, I turn it back to David to talk about how we are
27 going to use these results.

PPAC Meeting Transcription – March 2006

1 Mr. Clark: The Medicare Contractor Management Group where Alan is the deputy, that's the unit
2 that is really the principle customer on the survey results. That unit has responsibility for contractor
3 oversight. They are largely responsible for moving the agency into this MAC environment, setting up those
4 complex requests for proposals as Tom mentioned, doing the evaluation and making those contracts and
5 overseeing those contracts once they're set up in place.

6 In order for them to use the results of the survey, these are some of the things that are pretty
7 important to them. First of all that it's quantitative and methodologically sound in terms of the survey and
8 the science that goes into the survey so that our samples are representative of the providers across the
9 various contracts, the provider types that they serve. And most important, that the results actually do
10 measure differences in satisfaction that then can be used administratively by this unit. We're looking for a
11 uniform measure of performance and to that end we're looking at developing a composite score if you will
12 for each of the contractors that would be a rate in figuring out how to look at those results to assess
13 performance. The sample had to be national in scope and in conducting the survey annually, probably with
14 the same timeline and schedule that we're on right now, whereby we're drawing the sample toward the end
15 of the summer, scrubbing the data, validating the address information and contact information that we have,
16 getting the survey out in the field in early January, finishing up with the data collection period, and then
17 getting results and reports out by the summer, starting that all over again, going through the OMB
18 clearance. And that's pretty much the cycle that we hope to continue. If it's well with the MAC contracting
19 processes that we discussed earlier. And then also to focus on key stakeholders, which of course would be
20 the providers in terms of getting provider and physician input into contractor performance.

21 In the short term, we hope to establish a baseline of performance for key contractor performance
22 elements that are included in the survey. That's very important for us particularly as we go forward with
23 moving toward a MAC environment, that we sort of borrow from the Hippocratic Oath that as we go
24 forward with contract reform, that we do no harm. That we at least try and evaluate and have some baseline
25 understanding of what separate satisfaction is in any of those given areas where we're converting from the
26 current contracting process to a MAC environment; that we're identifying or have the ability to identify,
27 based on those results and particularly this whole cycle, national areas, where their strengths and
28 weaknesses are opportunities for improvements. And that sort of triggers the other thought in terms of how

PPAC Meeting Transcription – March 2006

1 the contractors will be using this information for process improvement as well. So that we can assist
2 contractors in localized process improvement efforts with the results of the survey. Now, that's not to say
3 that the survey will override other efforts for monitoring our progress and monitoring how we're
4 implementing the contract reform activities. But it will be in conjunction with those local efforts that will
5 be driven largely by our regional offices. In the long term, we look to include the MCPSS as a dashboard
6 item that the Medicare Management group will be using in its oversight of contract activities, and also as an
7 element that will be used as part of the award fee or paying for performance within the contractors as well.
8 Very early in that process right now, having some discussions with MCMG in trying to figure out how best
9 to make that actually work.

10 Contact information. Those are the key numbers for individuals that are working on the Provider
11 Satisfaction Survey. We also included website information where you can download the actual survey,
12 information from the pilot, some of the results, there's also the media kits that we talked about and we're
13 hoping that the trade press that's present today would also be able to use some of that information as
14 they're developing articles and information in various newsletters and trade press encouraging physicians
15 to participate in the survey.

16 That concludes the materials that we have to formally present. I think, just in closing, that the
17 survey is a real opportunity for providers to give some feedback into a much more formal process as how
18 contractors are serving and meeting their needs as they participate in the Medicare Program. Thank you
19 very much for your attention and thank you for allowing us to participate in today's meeting and share this
20 with you.

21 Dr. Castellanos: Thank you, Mr. Clark and Ms. Narayanan. I appreciate your being here. Perhaps
22 before we go into questions, we could try to answer some of these questions that they asked. Does anybody
23 from the Council have any idea who would be best to respond, the physician, the office manager, or staff
24 member?

25 Dr. McAneny: The way it works in my office, and I think in many offices, is that the lower level
26 questions or concerns or I don't understand why this claim got bounced type questions are handled by the
27 billing staff, and a lot of offices, I think, of any size, have one or two people who are Medicare only, so that
28 person handles most of the stuff and would be able to get you more specific information than was in your

PPAC Meeting Transcription – March 2006

1 survey, rather than just satisfaction, but how many calls? Not just are you satisfied with the number of
2 questions you can do in one phone call and how often do you receive the correct information? They would
3 really have an idea of that because they're the ones who, if it's not correct information, know that it gets
4 bounced again. The office manager is sort of the next step, or the billing manager, depending on the size of
5 the office, in terms of where the questions go if that isn't resolved. The ones that come up to me to handle
6 in our office are the ones that are going through reviews and have gone through this entire process and then
7 the other place that's really important to perhaps survey are the CAC members, because if you, for
8 example, if I have a problem and it becomes a recurring issue, and I'm sure my Care & Medical director
9 would tell you that I'm a frequent pen pal of his through email and he's wonderful. I hope you don't fire
10 him because I said that. He's wonderful. And is really willing to pass on a lot of information, but then if I
11 hear this over and over again, the next place we take this is to the CAC for discussions and then, at that
12 point, I'll find out that yes, a lot of other practices and other specialties have had the same kind of issue, so
13 I think that there is, you need to tailor make the question that you're asking to the various level in the
14 practices.

15 Dr. Castellanos: Any other comments? Dr. Urata?

16 Dr. Urata: Yes, for my practices, I'd say the manager is the best person and he can consult with
17 billing. He's pretty much how things go between Medicare and the billing person.

18 Dr. Powers: I think there are a lot of solo neurologists out there; a large number of private practice
19 neurologists are solo, and in that case, I imagine that a lot of them are their own practice managers and in
20 that case, I'm not sure that they would have difficulty answering the question so much as they're more
21 likely to answer the survey as long as it's reasonably short.

22 Dr. Castellanos: My experience is it would go to the billing personnel, the billing supervisor. Stay
23 away from the physician, because he's not going to really know the answers. Next question is what should
24 you do to increase the saliency of the survey among the physician community? Any questions there?

25 Dr. McAneny: To the office manager?

26 Dr. Castellanos: I just think you really need to let them know that this is a tremendous missed
27 opportunity. It's their chance to get in a reply. It's their chance to be heard. It's their chance to have that

PPAC Meeting Transcription – March 2006

1 voted counted, and you really need to express that to, in my opinion, to the billing supervisor, or the office
2 manager. Any other comments?

3 Dr. Urata: You can always attach a penalty if they don't fill it out. [laughter]

4 Dr. McAneny: You're not making that as a motion, I hope.

5 Dr. Urata: No, I don't make motions. You do. [laughter]

6 Dr. Powers: Or how about guaranteeing the response—if you answer the survey you will get the
7 results of the survey sent to you instead of having to go after it on the website, something on that order?

8 Dr. Castellanos: And the last question, and I'm anxious to hear everybody's response is what
9 methods work best to obtain a response from physicians? David, we're going to ask you that question.
10 What has been your experience?

11 Mr. Clark: The telephone has helped us quite a bit in terms of contacting the billing staff and
12 phrasing it with them, but it's still something of a challenge.

13 Ms. Narayanan: I would second what David said. Expecting them to respond based on the letter
14 that went to them is being very optimistic. It's the non-response follow up by telephone that seems to help.
15 And also allowing them some time to response, not expecting a response overnight, being patient,
16 consistent and patient seems to be working.

17 Mr. Clark: Is there a better time to make that call? At the beginning of the day, end of the day?

18 Dr. Urata: I'd say beginning. For me it would be the beginning, because toward the end of the day
19 I don't have time, nor patience.

20 Dr. McAneny: I would say that the best time would be shortly after there's been some sort of a
21 contact with Medicare with needing information or needing a review, because I think frankly if you called
22 up most physicians in the middle of a busy practice day, they'd go let's see, I'm half an hour behind—
23 everything's fine! [laughter] But I think that you get better information if you contact—you know, you
24 know who has made contact. You can get that kind of information. And you kind of know when they've
25 made it and if you've called them within say, a week, of getting that contact, then they would have it
26 fresher in their memory and be able to say yes, it took me oh, 10 minutes on the phone to get what I
27 wanted, I thought that was great. Thank you. Or gee I sat on hold for an hour and they'll remember that it
28 was in the beginning of a clinic.

PPAC Meeting Transcription – March 2006

1 Dr. Castellanos: And I know I spoke to the AMA today. I know you've have a lot of support from
2 the American Hospital Association, the Osteopathic Association, and I think the AMA is going to try to
3 give you some support on this, too. And as you mentioned, there's some people from the trade press. And
4 believe it or not, people do read what you write, and if you could let them know the importance of this,
5 from our viewpoint and from the Medicare beneficiary viewpoint, I think that would be helpful.

6 Dr. Sprang: Just a couple thing that you said, giving the physicians the opportunity to make a
7 difference, say that you could make the system better and maybe improve the ease of use, in
8 reimbursement. But then sending out the information with phone calls, as you said, but I think even when
9 you talk to them, giving them the opportunity is there a better time that we can call you later during the day
10 because you catch them in the middle of office hours and they're late, they're just not going to be able to do
11 that. They may say my office is done at 3 or 3:30, if you call me back then, I can talk to you. And there's
12 some that obviously are very much into electronic media and may much prefer to see it electronically and
13 on email and be happy to respond that way. Giving them the opportunity to do it the way it's easiest for
14 them.

15 Dr. Azocar: I would say if you combined the survey with any activity response by CMS or if you
16 can associate to any other institution, like AMA, and there is some kind of educational activity, one hour,
17 one day, whatever, and you introduce that survey there, I think you may get maybe a good time.

18 Dr. Powers: Have you contacted MGMA?

19 Mr. Clark: Yes.

20 Dr. Powers: Because they're, I mean you're going to go to the office managers, and that's the
21 largest organization. If you had problems with neurologists responding, we have an organization, too, of
22 practice managers.

23 Dr. Castellanos: Are there any other questions?

24 Dr. O'Shea: Mr. Clark, I reiterate the same. Sometimes it's hard to reach those people that don't
25 want to be reached, so actually talk to the people that are already the engaged, and that might be the state
26 associations. Those are the kinds of things that state associations would put down on their websites. So
27 sometimes don't go to the large organizations, but to smaller organizations, regional ones. They're always
28 looking for something interesting to put on their websites.

PPAC Meeting Transcription – March 2006

1 Dr. McAneny: When we do have the MACs, which we neglected to ask Dr. Gustafson questions
2 about, but when we do have the MACs, are there going to be surveys like this as well for that? Will we be
3 able to evaluate ease of contact, etc.?

4 Mr. Clark: That's what this survey—

5 Dr. McAneny: Well, when it goes on and we actually have the new contractors out there.

6 Mr. Clark: This will be repeated on an annual basis. Yes.

7 Dr. McAneny: Is there any reason why, you just said are you satisfied or not satisfied instead of
8 asking more data driven questions, like how many minutes did it take you to get to such and such a person?
9 Or previously there had been a survey that looked at the accuracy and completeness of information
10 received that I think was the OIG, I'm not sure. And I assume that you're doing those kind of sort of
11 biopsies of the processes as well?

12 Mr. Clark: That's generally through the normal monitoring and oversight activities of the
13 contractor performance. For the satisfaction survey, we have the need for the uniformity in terms of
14 responses so that we can compare results across contractor types. There is an opportunity for providers to
15 include in, to write in additional information outside of the questions, that is pooled, it's rolled up, it's kept
16 confidential in terms of more identifiers on that information, and it's part of our analysis as well.

17 Dr Castellanos: Are there any more comments or questions? Well, we certainly appreciate your
18 being here, Ms. Narayanan and David Clark. Thank you again for your presentation. Our next presentation
19 is on OPPS Multiple Imaging. Our next speaker has joined us on numerous occasions. Mr. Hart has briefed
20 us in the past on various aspects of the outpatient services. Today, he will address the Multiple Imaging in
21 the Outpatient Setting, as a follow up to a discussion which surfaced during the December 2005 PPAC
22 meeting. Mr. Jim Hart is the Director of Outpatient Services in CMS with the primary responsibility of
23 overseeing Medicare Fee-for-Services Hospital Outpatient services, and preparing the outpatient fee
24 schedule. Mr. Clark, would you like to begin?

25 OPPS Multiple Imaging Update

26 Mr. Hart: Thank you again for having me here today. I understand you're running a little bit late
27 today, and perhaps I could help by getting right to the point. There's something very restricted—a very
28 narrow question you asked me to get back with a response to today, so I included in my slide a good deal of

PPAC Meeting Transcription – March 2006

1 background that we don't need to repeat in any detail, so if you go to maybe the 7th slide, briefly, as Dr.
2 Castellanos said, the last time I was here, we discussed a number of issues that came up at our last
3 rulemaking cycle, and one of them was the issue of whether to apply a multiple service reduction to
4 imaging procedures. And I discussed various reasons why we had decided to defer that, not to finalize the
5 proposal last year, but to continue studying it. And in the course of discussing it, I made the observation
6 that we had noticed in many instances, not all, not most, but in many instances, the Physician Fee Schedule
7 rate for imaging services was actually higher than the rate on the outpatient side. And a number of the
8 members of the Council expressed a little surprise at that, asked for some more information, and that's why
9 I'm back here today. If you look at that slide, there are several examples of the phenomenon I was
10 describing earlier and first an apology. There's a type on the page. It says the FY2007, that should read
11 2006. I wasn't trying to practice my clairvoyant powers and predict next year's rates, I just made a type,
12 sorry. So these are this year's rates on the Medicare Physician Fee Schedule side and the OPPS side. And
13 let me describe to you exactly what we're looking at, because that may answer some of the questions and
14 some of the things you've observed yourself. First of all, these are both national rates on each side, the
15 Physician Fee Schedule and the outpatient rate. They do not, for example, reflect the application of
16 geographic adjustment factors, either the GPCI on the physician side or the wage index on the outpatient
17 side. On the Physician Fee Schedule side, what you're seeing represents the RVU for the technical
18 component of the imaging service, times the conversion factor. And it's important to emphasize if folks
19 have been trying to look these things up, that exact number is actually printed in no table that the Physician
20 Fee Schedule publishes. There is a lookup table on the Internet that I could leave the URL for, which you
21 can get that rate, by telling it not to apply the geographic adjustment factor but it's not actually printed
22 anywhere. So again, that's the RVU for the technical component times the conversion factor. On the
23 outpatient side, similarly as I said, it's a national rate. It does not reflect the application of the wage index,
24 which we apply to about 60% of our outpatient rate. It is instead the APC rate, which is the weight times
25 conversion factor, the APC rate for the APC to which the code is applied, and this number is printed in our
26 Addenda Tables, Addendum A and Addendum B. I gave you 3 examples there, and you can see one CT
27 and two MRIs where the physician fee technical amount is considerably higher—in one case almost \$400
28 higher, another case, about 57, and the top case about \$139 higher than the corresponding outpatient rate.

PPAC Meeting Transcription – March 2006

1 There are about 600 codes for imaging services and in about 150 of the cases, we see this phenomenon, so
2 it's about 25% and about 3/4s it's the other way around. Some are pretty small differences. I think the \$400
3 one I show up there is about the largest difference that there is.

4 Dr. O'Shea: I'm trying not to be obtuse, but the outpatient truly is outpatient if that's done by a
5 clinician that has the services in an outpatient setting and that MPFS is in hospital. Am I right or wrong?

6 Mr. Hart: The outpatient rate there is the facility fee for the hospital doing the imaging services.
7 The technical component is the Physician Fee Schedule equivalent to that, and I'm not a fee schedule
8 expert but it's—

9 Dr. O'Shea: Maybe I'm making the wrong delineation. I'm trying to delineate between an
10 inpatient—I've got a hospitalized patient, I ordered MRI of the brain, versus other. Am I totally off?

11 Dr. McAneny: That's Part A.

12 Dr. O'Shea: Oh, see?

13 Mr. Hart: If it's in the inpatient hospital stay, it would be wrapped into the inpatient. This is the
14 outpatient—Ken?

15 Dr. Simon: The technical component for the Medicare Physician Fee Schedule refers to the
16 payment that you would receive if you performed that study in your office. The outpatient payment right
17 there refers to the facility payment that the facility, the hospital will receive if that procedure is performed
18 in the outpatient setting.

19 Dr. McAneny: And that's their total reimbursement for what I would consider the tech fee.

20 Dr. Simon: For the technical component of that test, correct.

21 Mr. Hart: As distinct from the professional fee, going in either circumstance, which is the same.

22 Dr. Simon: And recognizing that that's just one component. The physician reimbursement consists
23 of 3 components; the physician work, the practice expense, and the professional liability component. Those
24 3 components collectively equal 100% of the payment, which when multiplied by the conversion factor
25 renders the final reimbursement for the service that's been provided.

26 Mr. Hart: So again, I believe that was the information in which you were interested in my
27 following up with and I don't know if there are any other questions.

PPAC Meeting Transcription – March 2006

1 Dr. Ouzounian: I'm sorry to come into this a little bit late, but if I understand part of the
2 discussion, it's that you're not going to pay more than the OPPTS on the in-office site, is that correct?

3 Mr. Hart: There is a DRE provision that goes into effect next year, that provides that you make
4 this comparison that I just showed between the technical component on the physician side, and the
5 outpatient rate, national rates prior to the application of the geographic adjustments, and that you pay the
6 outpatient rate if lower. Now, I emphasize again, and apologize for my type, those were 2006 rates. New
7 rates go into effect for next year. You know where both sides are gearing up to go through their regulation
8 cycles to recalculate the rates, and—

9 Dr. Ouzounian: I'm not sure when the correct time to bring it up is, but some of us have spent
10 about 4 years trying to develop the right expenditure for the in-office cost, which is the—

11 Mr. Hart: On the physician side.

12 Dr. Ouzounian: On the physician side. And what you're really saying is that's going to be
13 disregarded and you're going to use the OPPTS rate in '06, and the question is how do we get that—

14 Mr. Hart: That's what the legislation provides for.

15 Dr. Ouzounian: So there's really no way of readdressing that? For us as physicians to readdress
16 that?

17 Mr. Hart: It's a statutory provision so and you know, I'm not the Physician Fee Schedule, but it's a
18 statutory provision, so we don't have any discretion about it and—

19 Mr. Kuhn: But you're correct in your assumption that Congress made a determination to synch all
20 the payment rates up based on the outpatient, so that's what we'll be doing.

21 Dr. Castellanos: I think you said this was a mixed bag, and I know I talked to Dr. Rogers, and I
22 can show you national statistics where some of them are cheaper are some are out, and as you said, I think
23 it was like 25% and that's a fair assumption. Now I understand what you're saying is we're going to match
24 the OPPTS record. How about when the OPPTS is higher? Are you going to increase the physician?

25 Mr. Hart: That is not what the statutory provision provides for. And beyond that I can't address it.

26 Dr. Castellanos: Can you give us any rationale beside that? I mean it just...

27 [off mike—Thank Congress passed it. Laughter.]

28 Dr. Castellanos: That's the best answer I could have asked for, thank you.

PPAC Meeting Transcription – March 2006

1 Mr. Hart: That's what Congress told us to do.

2 Mr. Kuhn: And also Jimmy, there's also some changes in ASC versus OPPTS as well. You might
3 want to just mention that as well.

4 Mr. Hart: Well, we have provision for—you're talking about the new ASC?

5 Mr. Kuhn: In the DRA, in terms of...

6 Mr. Hart: Oh, yes, there's a cap in ASC facilities to the outpatient rate, as well that is in effect in
7 2007, until we implement the new system which is called for by the beginning of 2008.

8 Dr. Castellanos: That's very interesting if you look at those statistics, because the freestanding
9 outpatient has about 2,200 charges which are lower than the hospital based study, and they have about 10%
10 of that or about 226 that are higher, yet you're moving the higher ones down, but not the lower ones up. I
11 mean this is the same, I understand that [it's a Congressional provision], but it does concern some of the
12 practicing physicians.

13 Dr. Azocar: In your presentation in relation to the payment for multiple imaging procedures, I
14 understand there is going to be a 50% discount when there are 2—

15 Mr. Hart: Not on the outpatient side, at least not yet. We proposed that last year, but we deferred
16 adopting the proposal while we study the structure of the imaging rates on the outpatient side more. So not
17 yet on the, physician side, I'll let Dr. Simon address that.

18 Dr. Simon: The Physician Fee Schedule side, as was published in the Final Rule, there are 11
19 families of services which pertain to both MRIs, CAT scans, and ultrasound, looking at contiguous body
20 areas. Abdomen, pelvis, the lower extremity, the upper extremity, head and on the professional side, for
21 those studies, those multiple diagnostic radiologic studies that are performed in the same session on the
22 same patient, the technical component, the higher of the technical component of the two studies will be
23 paid at 100%. The small of the second study will be paid at 50% of its usual cost. And that is to take effect
24 in 2007, where there will be a 25% reduction in the technical component on the physician side in 2007,
25 which will then be increased to 50% of the technical component for the second study when done, again, on
26 the same patient multiple studies in the same session in 2008. But it will not impact the outpatient side.

27 Dr. Sprang: Yes, just trying to understand. Did you actually say that in 25% of the physicians' fees
28 were higher?

PPAC Meeting Transcription – March 2006

1 Mr. Hart: If you make this comparison I described, in 25% about 150 out of 600 codes, the
2 physician technical component is higher than the outpatient—

3 Dr. Sprang: So 75% of the time, the physician is less which is what we were saying up front. So it
4 sounds like, the data you gave is consistent with what we said last time, and certainly consistent with my
5 experience. But 75%--25%? Not so mixed. But in my area, since your last meeting, I did go—

6 Mr. Hart: In your practice, there may be very few.

7 Dr. Sprang: Yes, and I did go and actually look at the data from our hospital and from one of the
8 offices, and it was consistently half as much as the hospital, and so then the hospital said well maybe our
9 quality is better. The problem with that answer is that we have the same radiologist read them, so the
10 quality is identical, and it was literally half. So it is just concerning. So be it.

11 Dr. Simon: I think to respond to your comment, there was a review of both ultrasound studies
12 pertaining to both the breast as well as the vaginal region. And it was decided in the Final Rule in the
13 physician side not to include those two organ systems in the multiple procedure discount.

14 Dr. Sprang: [off mike] across the board, like pelvic ultrasounds, dexascans, and what does it cover,
15 what doesn't it cover?

16 Dr. Simon: You mean how [inaudible] the 25%?

17 Dr. Sprang: No, no, now exactly the changes that are going to be made?

18 Mr. Hart: The changes on the physician side or the outpatient?

19 Dr. Sprang: Physician side.

20 Mr. Hart: I'd have to ask Dr. Simon to...

21 Dr. Simon: For those contiguous areas, they're listed by CPT-Code, and I can get you a copy of
22 those eleven families that are listed by CPT-Code, where the multiple procedure reduction would be in
23 effect.

24 Mr. Hart: For example, if I remember correctly, Ken, X-Rays are not in those families.

25 Dr. Simon: It was principally CT scans of abdomen, pelvis, ultrasound on the abdomen and pelvis,
26 MRI. But there are specific codes that were listed in each of those families.

27 Dr. Sprang: As far as any other procedures like that, like say dexascans for bone densities. Does
28 that come under this at all?

PPAC Meeting Transcription – March 2006

1 Mr. Hart: No.

2 Dr. Castellanos: No.

3 Dr. Simon: No, it did not.

4 Dr. McAneny: I'm a little dense here, but I don't quite understand where the hospital's cost-to-
5 charge ratio multiplies into this. Is it already figured into what we're seeing?

6 Mr. Hart: Yes. It's already figured into the figures that you see there. The cost-to-charge ratios are
7 something that we use in the process of setting our rates on the outpatient side.

8 Dr. McAneny: So is that one rate that you sort of take all of the hospitals' cost-to-charge ratios set
9 them up so that you get an average one and then use it for fees, or—

10 Mr. Hart: Not exactly.

11 Dr. McAneny: Or it's very different from hospital to hospital?

12 Mr. Hart: We get charges on claims and we have to convert those to costs. And the charges on the
13 claims usually point toward revenue centers in the hospital. We can get those cost-to-charge ratios from the
14 hospital cost report from the revenue center. So we take the charges, use those cost-to-charge ratios,
15 convert them to cost, and that's how we begin to develop the median cost on which we base our APC rates.
16 We develop median costs for each code, so we can, it's call the 2x rule to make sure there's not too much
17 variation, and then of course we weigh all of the services to find the median for each APC. But the cost-to-
18 charge ratio is like step from getting to the charges on the bill to cost.

19 Dr. McAneny: So when they get this number here, this is the median APC number.

20 Mr. Hart: This is the median. This is the rate—the median is used to set the weight for each APC.
21 The medians are related to the mid-level clinic visit median, and using that as one, the others are arrayed
22 above and below and then that gives the weight—1.5, 0.5, whatever it might be. This number here is that
23 weight for the APC, times our conversion factor, which is about \$60.

24 Dr. McAneny: OK, then if you're the provider, critical access hospital, or you get the rural up[?]
25 for hospitals, is that figured into that weight as well?

26 Mr. Hart: No, that's in addition, adjustment.

27 Dr. McAneny: So if their a critical access hospital, then they would take this—

28 Mr. Hart: Well, it's not critical access hospital, it's sole community hospital.

PPAC Meeting Transcription – March 2006

1 Dr. McAneny: Sole community. So if they're a sole community hospital, they take this OPPS
2 number multiply it times that? That may also be where some of the discrepancy comes in, for those of us
3 who are living in rural areas.

4 Mr. Hart: Although that just went into effect, of course in January.

5 Dr. Castellanos: Are there any other questions for Mr. Hart. Well, we certainly appreciate
6 answering our questions. I think it kind of clarified where we stand, and I'm glad to hear that it is a
7 statutory...[laughter] Very happy to hear that. Again, thank you very, very much for being here. We do
8 have a few minutes. There is a schedule break from 2:15 to 2:30, why don't we meet back here in about 10
9 minutes so we can maybe stay ahead of schedule, if that's OK.

10 Break

11 Dr. Castellanos: Recovery Audit Contracts. Many of you remember our next presenter, Melanie
12 Combs. Melanie's joined us many a time in May in December of 2005, she addressed the PPAC meeting.
13 In May, Melanie was joined by Dr. Jesse Polansky, to introduce us to the Recovery Audit Contract. At the
14 December meeting, she was joined by Jerold Walters in providing the latest information concerning this
15 initiative. By way of background, Melanie has her Masters Degree in nursing, prior to joining CMS, she
16 worked for the Maryland PRO, and the Maryland Department of Health. Today, Melanie helps CMS
17 remain compliant with the Improper Payment Information Act, and is involved in the Recovery Audit
18 Contractor demonstration. She was going to be joined by Connie Leonard, but Connie's kind of tied up in
19 traffic. And Melanie feels that we should get going. So Melanie, please.

20 Recovery Audit Contractors Update

21 Ms. Combs: Thank you very much. There's 3 things that I'm going to be talking about today in
22 this brief update on the Recovery Audit Contractors. The first is underpayments, the second is a contractor
23 medical director briefing, and the third are the recovery audit contractor letters. At the December PPAC
24 meeting, Gerry and I gave you an update on the RAC demonstration as it was unfolding at the time. And
25 we raised for you an underpayment issue; whether CMS should incentivize the RACs to find
26 underpayments, and if so, how should we do it? And we actually asked you guys for some advice and
27 suggestions on how we could do it. And at the time, one of the suggestions that you made was that the
28 contingency fee, the incentive payment to the RAC could be taken out of the physician underpayment, the

PPAC Meeting Transcription – March 2006

1 amount that was owed back to the physician. The RAC could take their piece of it and give the rest of it to
2 the physician, because that was still more money to the physician. Gerry made the comment at the time
3 that that would work until the point that one physician didn't want to do that. And that would cause pain
4 and agony for CMS. And so we really wanted to find some other way of solving this problem of providing
5 an incentive to the recovery audit contractor, when they find an underpayment situation, and where
6 Medicare owes money to the provider, without taking the recovery audit contractors' contingency fee out
7 of the providers' share. You also suggested that CMS brief the Contractor Medical Directors—the carrier
8 and the FIs and the QIO medical directors, about the RAC demonstration. Let me first talk about what has
9 happened on underpayments. CMS has modified the Recovery Audit Contractor contracts to pay the RACs
10 the same contingency fee for finding underpayments that they get for paying overpayments. And the way
11 that we decided to do that was to take the contingency fee that we're going to pay them out of the CMS part
12 of the pie, and if you look down at the little chart, you can see it, and please note, the pie pieces are not
13 drawn to scale. That just happened to be the only graphic that I could find. All of the money that is
14 recovered by the Recovery Audit Contractors, is divided into three parts. One part is the Recovery Audit
15 Contractor piece, that's their contingency fee. One piece is to cover the CMS administrative fees, for
16 example, there are more appeals because of the Recovery Audit Contractors, and so we have to have money
17 to pay the appeals contractors for these appeals of RAC overpayments, and then, of course, a portion goes
18 back to the trust fund. So what we decided to do was pay the underpayment contingency fee out of the
19 CMS administrative piece of the pie. The next slide talks about an update that we gave to the contractor
20 medical director in the states of California, Florida, and New York. We invited the CMDs from the carriers,
21 the DMERCs, the FIs, and the QIOs, in these states, and of course, it would be the DMERCs that have
22 beneficiaries that reside in these three states, even though the DMERCs aren't, they don't have a physical
23 location in each one of these states. The CMDs were happy to hear the presentation. And we had a nice
24 dialog with them. So far, none of them are hearing very much from the provider community about the RAC
25 demonstration, but they feel like now they are clear on what's happening, and they certainly know who to
26 go to if any questions arise.

27 The next slide talks about the contact information if you want to get a hold of me, or Connie. You
28 can write to this email address, but we did hear on our way down this morning about one concern that the

PPAC Meeting Transcription – March 2006

1 Council had about the RAC demonstration, and that had to do with the letters that the Recovery Audit
2 Contractors send out. There are two types of letters that are sent out by the RACs. One is a request for
3 medical records and one is a request for the overpayment. Give me back the money. We sometimes call
4 that a demand letter. I'm not sure which letter is of concern, but I'm guess it's the demand letter and not the
5 medical record request letter. I can tell you that CMS plans this summer to have up a website that will have
6 copies of sample letters from all 3 states of all varieties. For example, it might have a letter from California
7 requesting medical records. It might have a record from California, demanding money back from a Part B
8 provider, demanding money back from a Part A provider, demanding money back from a Part D provider,
9 just whatever the different flavors and varieties of the letters would be. Will all be on a website, hopefully
10 this summer, if we can get everything technically to line up. But in the meantime, I have with me today, a
11 copy for the PPAC members of the letter from California, a sample letter from California, this is what I
12 would call the Demand Letter, and this is using the same language that is used by the carriers, the FIs and
13 the DMERCs. We can send out through Kelly Buchanan a copy of the actual language from the manuals
14 that we tell all of our contractors; carriers, FIs, DMERCs and RACs to put in their letters, and I would ask
15 that if anyone has any concerns about language in this letter, that they also consider whether this is RAC-
16 specific language, or this is demand letter language in general that's giving you heartburn. In other words,
17 we need to know whether we need to go back and tell one or more of the Recovery Audit Contractors to
18 change their specific language or do we CMS need to change the language that we require of all of our
19 contractors?

20 I was hoping that Connie would make it here on time today because she had the hard copies of the
21 CMS required language and you could actually hold them up side by side and know if there was a
22 particular word or a particular sentence that was of concern, you'd be able to tell whether that was specific
23 to the RAC letter, or if it was a sentence that was required by CMS. Unfortunately, we're not going to be
24 able to get that to you here today. But again, Kelly can email it out to folks afterwards. I think the next slide
25 is, actually that's it. I'll open it up to questions.

26 Dr. Castellanos: Thank you Melanie. Does anybody have any questions for Melanie? I do,
27 Melanie. Being in Florida, I've had some colleagues that have asked me that have received letters to
28 request records, and that's been a good time ago. And they wonder what's going on? How can I find out?

PPAC Meeting Transcription – March 2006

1 Do I call? When will I be notified? Will I be notified either way? And right now they're kind of hanging in
2 the breeze, wondering what's going on. What should I tell them?

3 Ms. Combs: I believe that there is a requirement that the RAC get back to the provider either way.

4 Dr. Castellanos: Is there a time limit on that?

5 Ms. Combs: I don't know whether or not there is. I can certainly check on that and get word back
6 to you.

7 Dr. Castellanos: If there isn't a time limit, I would suggest something reasonable and I would
8 certainly suggest that you need to let these physicians know either way; that a review was done and we
9 found there was no cause to be alarmed, or the review was done, etc.

10 Ms. Combs: That sounds reasonable. Or the review is still underway and we don't know but we'll
11 get back to you.

12 Dr. Castellanos: Should we as a PPAC make that recommendation? Or is it good enough what—

13 Ms. Combs: It's good enough what you suggested, thank you. Any other questions?

14 Dr. Castellanos: Melanie, as usual, thank you very much we certainly appreciate seeing you.

15 Thank you again. Our next presenter just stepped out just for a few seconds, so we do have a few minutes,
16 so I apologize for the delay. At this time, I am pleased to welcome Dr. John Armstrong, who will be
17 addressing the Council with statements prepared by the AMA on Physician Quality Initiatives, and
18 Implementation of the Part D Drug Program and the RAC Audits. Dr. Armstrong is a member of the Board
19 of Trustees of the AMA. He's a general surgeon and a trauma surgeon. He's working Gainesville, Florida
20 at a level one hospital, and he's becoming a Gator fan. [laughter]. Dr. Armstrong.

21 American Medical Association – Public Testimony

22 Dr. Armstrong: Thank you, Mr. Chair for that kind introduction. Mr. Chair and members of the
23 Council, good afternoon. At the outset, I'd like to update the Council concerning an urgent issue—
24 Medicare physician pay cuts. In early February, Congress enacted a physician payment freeze for 2006,
25 reversing a scheduled 4.4% pay cut that began January 1st. We are grateful for this intervention by
26 Congress and the Administration, and also appreciate that CMS has automatically adjusting physician
27 claims submitted between January 1st and February 8th, when the freeze was enacted. However, the crisis
28 continues. By not keeping up with practice inflation, a freeze is a de facto cut. Further, a 5% physician pay

PPAC Meeting Transcription – March 2006

1 cut is projected for January 1st, 2007, and projected cuts totaling 34% are expected, through 2015. A
2 stabilized Medicare pay structure that provides positive payment updates to physicians is critical for
3 enabling physicians to make the significant investments needed to purchase health information technology
4 and participate in quality care initiatives. These investments are necessary to achieve policymakers' vision
5 of a transformed Medicare payment system that provides access to the highest quality of care for our
6 patients. The American Medical Association shares in this vision. And to assist in achieving it, we have
7 long been committed to quality. The AMA convened physician consortium for performance improvement
8 has developed physician level performance measures that are the foundation of emerging physician quality
9 reporting activities in both the public and private sectors. The consortium brings together physician and
10 quality experts from more than 70 national medical specialty societies, as well as representatives from
11 CMS and other federal agencies. It is essential that physician measures used by CMS be developed in a
12 collaborative process by physician specialties as exemplified by the consortium, and then vetted through
13 multi-stakeholder groups, such as the National Quality Forum, and the Ambulatory Care Quality Alliance.
14 In addition, the measures used by CMS physician voluntary programs, the PVRP, must reflect the
15 collaborative work already undertaken by the AMA, CMS, and the rest of the physician community. To
16 further address the PVRP, the AMA has made numerous commitments, as listed in our written statement.
17 Some highlights. By the end of 2006, with allocation of additional AMA resources, the consortium plans to
18 have approximately 140 physician measures covering 34 clinical areas. The consortium is reviewing PVRP
19 hospital facility measures for conversion to physician level measures where appropriate. If a facility
20 measure does not translate to a physician level measure, the consortium will propose appropriate
21 alternatives. The AMA is also fast-tracking approval of CPT-2-Codes for reporting approved physician
22 level performance measures. As we continue developing quality initiatives, it is also important to eliminate
23 major barriers to optimizing quality. The SGR is one such barrier. Let me re-emphasize an earlier point;
24 positive physician payments, not the steep pay cuts that occur under the SGR, are vital for supporting the
25 HIT investments and quality innovations necessary to benefit patient care and generate system-wide
26 savings. Thus we urge that Pay for Performance initiatives be premised on elimination of the SGR in favor
27 of a physician payment system that meets practice costs.

PPAC Meeting Transcription – March 2006

1 Next, I'd like to address the Medicare Part D drug program, which began January 1st. We
2 understand most of the early system's failures in rolling out the new benefit have been corrected and we
3 appreciate CMS's efforts in this vein. Yet, problems remain. The AMA is committed to addressing these
4 problems with CMS. Last June, we launched a working group comprised of physician, pharmacist and
5 patient organizations. With CMS help, the working group developed a standardized voluntary form to
6 streamline communication between physicians and pharmacists, concerning drug plan coverage policies.
7 This form is posted on the CMS and AMA websites. We also thank CMS for approving our request that
8 Medicare plans provide patients with 3 months of drug refills under the coverage and payment policies of
9 their old drug plan. This will allow patients time to consult with their physicians to determine whether a
10 change to a similar but different brand of drug would be medically advisable. The working group is now
11 creating with CMS a model standardized voluntary form for physicians to use when supplying plans with
12 information regarding formulary exception requests. This form will assist physicians in helping patients
13 quickly get prescriptions filled that the plan does not normally cover. We look forward to continuing our
14 work with CMS, to help Medicare patients and physicians better utilize the drug benefit.

15 Before closing, I'd like to comment on the RAC audits. There has been wide spread confusion and
16 anxiety among physicians, as the audit process has progressed. We met with CMS last week and as a result
17 late last Friday, we were provided with copies of demand letters mailed by the RACs to physicians in
18 Florida. We look forward to reviewing these letters. We also discussed with CMS its new policy to provide
19 incentives for the RACs to identify underpayments, and we will continue to provide feedback on that
20 policy. We look forward to meeting with CMS on a monthly basis to discuss outreach, and concerns about
21 the RAC audit process. We appreciate CMS's response to our concerns and we look forward to an ongoing
22 open dialog to resolve RAC issues as they arise, including a clarification of the key deadlines that apply to
23 the recoupment and appeals processes. Well, in sum, the American Medical Association reiterates a strong
24 commitment to working with CMS in transforming the Medicare Program into one that supports physician
25 investment and the tools and initiatives needed to deliver the highest quality of care to our patients. Finally,
26 I'd like to give a special note of thanks and gratitude to 4 members of this Council. Drs. Castellanos,
27 Gaughan, Leggett, and McAneny. This is your last PPAC meeting, and the American Medical Association
28 appreciates your service and important contributions to our patients and the physician community. We also

PPAC Meeting Transcription – March 2006

1 welcome the new members who are being sworn in today; Drs. Bufalino, Ouzounian, Ross, and Williams,
2 we appreciate your commitment to our patients and the physician community, and we look forward to
3 working with you. Thank you for the opportunity to be here today, and I look forward to your questions.

4 Dr. Castellanos: Thank you, Dr. Armstrong. Are there any questions that the Council may have for
5 Dr. Armstrong.

6 Dr. O'Shea: We appreciate your input. I'll just have to say that the AMA has always been a
7 resource, for we on the Council, we do a lot of our own work, we have other organizations that also give us
8 some information, but we look forward to hearing more from you over the next few years in the capacities
9 that you have, and we look forward to working with Maureen also. Thank you very much.

10 Dr. Armstrong: Well, it's our pleasure, as I shared with you earlier, the American Medical
11 Association is about helping doctors help patients, and we look for organizations that view work the same
12 way and clearly we are aligned when it comes to work with the PPAC.

13 Dr. Castellanos: Dr. Armstrong, thank you again. We appreciate your being here.

14 Dr. Armstrong: Thank you.

15 Ms. Combs: Dr. Castellanos, I have the letters that have the CMS required language in them.
16 Connie has just arrived, and if I could just pass them out, so that you guys could have them so you can
17 compare them to the language from the Recovery Audit Contractors. That way if you have any suggestions
18 or comments about changes, you'll know whether to direct it to the RAC project, or the general
19 overpayment demand letters.

20 Dr. Castellanos: Can Connie stand up just a second? Connie, we just introduced you. Connie
21 Leonard is a project officer for the Recovery Audit Contractor demonstration. She's been with CMS for 6
22 years in the Division of Medicare Overpayments, and I'm sorry about the traffic.

23 Ms. Leonard: Oh, it's my fault! I'm terrible with directions and ... [laughter]

24 Dr. Castellanos: Well, thank you for being here.

25 Medicare Health Support

26 Dr. Castellanos: Our next topic is a Medicare Health Support. As a way of prefacing this
27 interesting topic, please consider that chronic conditions are a leading cause of illness, disability and death
28 among the Medicare beneficiaries and account for a disproportionate share of the healthcare expenditures.

PPAC Meeting Transcription – March 2006

1 Section 721 of the Medicare Prescription Drug Improvement and Modernization Act of 2003 authorized the
2 development and testing of voluntary chronic care improvement programs, now referred to as Medicare
3 Health Support Programs. These programs are designed to improve the quality of care and life for people
4 living with multiple chronic illnesses. Barbara Hoffman is the Director of the Division of Chronic Care
5 Improvement Programs. She's responsible for the Medicare Health Support Program. She also serves as
6 practitioner faculty in the Johns Hopkins University School of Medicine, Business, and Professional
7 Development Program, and maintains a national certification as a physician assistant. Ms. Hoffman would
8 like the Council to consider the following questions during her presentation. Does the Council have any
9 suggestions for other national or local opportunities to engage physicians? Do you foresee any future issues
10 or concerns as the programs proceed? And last, do you have any suggests to mitigate and respond to these
11 issues and concerns. Please welcome Ms. Barbara Hoffman.

12 Ms. Hoffman: Thank you, Dr. Castellanos, and thank you to the Council for the opportunity to talk
13 with you about a very exciting program, Medicare Health Support. The program is intended to improve
14 self-care of Medicare beneficiaries with chronic conditions and to result in decreases in Medicare costs and
15 improvement in quality and satisfaction. The program incorporates a number of approaches that have been
16 used in other venues. But combines these approaches, and offers them for the very first time to Medicare
17 Fee-for-Service beneficiaries. Approaches such as disease management, new communications technologies,
18 and enhanced support for evidence-based medicine. As you all know, much of chronic care management
19 involves self-care when the beneficiary is away from the physician's office. Medicare health support is
20 testing ways to provide that support to our beneficiaries in ways that are effective and satisfying to our
21 beneficiaries, and to the physicians who care for them. I will go through quickly. I know it's been a long
22 day. But history and context of this program, the program design, and the current status, and then looking
23 forward as this program evolves. Dr. Castellanos has already shared the questions that I appreciate your
24 feedback on. Certainly your feedback need not be limited just to these questions.

25 In 2003, the MMA was passed, demonstrating the Secretary's commitment to early prevention and
26 quality improvement, and in transforming Medicare from simply paying bills to improving quality and
27 containing costs. One of the ways that this transformation was realized was the creation of chronic care
28 improvement programs under Fee-for-Service Medicare. Those programs are now referred to as Medicare

PPAC Meeting Transcription – March 2006

1 Health Support. This legislation also directs the Secretary to expand successful programs or program
2 components. I won't belabor the fact in terms of the impetus for change, as you all know, Medicare
3 beneficiaries—our numbers are increasing as we baby boomers age in. Chronic disease prevalence is
4 increasing, health care costs are increasing, and reports of quality failings, due to factors, such as
5 fragmentation of care are widespread. Clearly chronic conditions drive disproportionate Medicare costs,
6 and in fact, many of our beneficiaries have more than a single chronic condition. In fact, nearly 2/3 have 2
7 or more, and almost a quarter of them have 5 or more chronic conditions. These beneficiaries are seeing
8 multiple physicians and filling multiple medications. The 23% of beneficiaries accounting with 5 or more
9 chronic conditions, account for more than 2/3 of Medicare spending. And they are challenged to coordinate
10 their care between multiple physicians and multiple medications. Beyond cost, we know that multiple co-
11 morbidities carry significant risks, and in the JAMA article last summer, Dr. Cynthia Boyd encouraged us
12 to look carefully at this population. We are currently in phase 1 of Medicare Health Support. This is the
13 pilot stage and the developmental phase. CMS has identified approximately 20,000 beneficiaries in each of
14 8 regions to participate. These individuals are invited to participate. We'll talk about that a bit more in just
15 a moment, and are matched with 10,000 beneficiaries in the same region, who are serving as a control or a
16 comparison group. Those 10,000 are not invited to participate. Implementation of our programs began in
17 August of 2005 and our last program launched in January of 2006. By overlaying the program on Fee-for-
18 Service Medicare, participation in Medicare Health Support does not require beneficiaries to choose
19 different providers, to change plans, or to give up any benefits. The program is entirely voluntary. The
20 20,000 beneficiaries in each group have been invited to participate, and may choose to accept the invitation
21 or decline at any time during the three-year pilot phase 1. The invitation goes to beneficiaries who qualify.
22 We'll talk a little bit in a moment about eligibility criteria. The selected beneficiaries must have at least one
23 threshold condition of heart failure or diabetes, but these beneficiaries have many more co-morbidities.
24 Medicare Health Support is not a new benefit. It is not frozen in shape. As we are in this phase 1 pilot
25 program, we are looking to learn and adjust the program as we proceed. The programs take a holistic
26 approach, and so although these beneficiaries do have heart failure or diabetes among their conditions, the
27 programs are providing supports to beneficiaries that are consistent with that beneficiary's unique situation.
28 The programs provide support in self-care, in understanding and adhering to their physicians' plans of care,

1 but it is not a substitute for care. We believe that this approach will help to gain the trust of beneficiaries
2 and of their providers and caregivers. The program is not exclusively disease focused. The programs
3 include social, financial and other issues that affect beneficiaries' ability to provide their own self-care.

4 Beneficiaries who are eligible and who are invited are beneficiaries in Fee-for-Service who were
5 identified through claims review. These beneficiaries have at least one of the threshold conditions—heart
6 failure or diabetes—they meet minimum HCC risk scores of 1.3 or higher. They must be participating in
7 both Medicare Part A and Part B, and not be in a Medicare Advantage Program, ESRD or Hospice.
8 Throughout the program, beneficiaries may move in and out of eligibility and they can choose to participate
9 or not throughout the program. This program is unique in that it is a population-based model. CMS has
10 identified the population prospectively and set measurable goals for improving the population outcomes,
11 not just the outcomes of those beneficiaries who choose to participate. We have tied Pay for Performance in
12 terms of the monthly fees paid to these Medicare Health Support organizations. Their fees are at risk for
13 Medicare savings of the entire intervention group, as compared to the control group, for clinical quality
14 measures and for satisfaction measures. I will not speak to this slide, because I know that this group knows
15 more than any other the importance of beneficiary self-support. The common factors that contribute to a
16 crisis or a hospital visit include situations that are amenable to education and self-support, such as
17 forgetting to take medication, or not following a healthy diet.

18 We are up and running in 8 locations. Several of you come from these states; Florida, Illinois,
19 Georgia and Tennessee. We're also operating programs in Oklahoma, in western Pennsylvania, in
20 Maryland, and the District of Columbia, and in Mississippi. These organizations were chosen through a
21 competitive selection process, to find partners that we thought had models of interest and strong
22 capabilities. The geographies are different from one another. The populations are different, the health care
23 milieu is different. Each program is unique and trying some very interesting models. The populations that
24 are being served include urban, rural, and suburban settings. These serve diverse populations, including
25 beneficiaries who are poor, non-English speaking, and ethnically diverse. What you are seeing on this slide
26 is the range of age distribution between the programs, with the oldest beneficiaries in Florida and
27 Pennsylvania, and the percent of dual eligibles from a low of 14% in Florida, to a high of 42% in
28 Mississippi.

1 There is also a range of racial and ethnic diversity that is demonstrated in this slide. The programs
2 take various approaches to physician engagement. But all of them have strong national and local alliances.
3 Physician advisory boards are in place in these regions. Some advisory boards are providing guidance on
4 clinical guidelines to the programs, others are providing guidance on the program design itself. Information
5 exchange between the programs and the beneficiaries providers is ongoing and unique in each program.
6 There is exchange via fax, via phone, via web. Some of these programs are incorporating P for P models
7 with the physicians in the programs, compensating physicians for the time that it takes to respond to
8 inquiries from the programs or to develop care plans with which the programs can then guide beneficiary
9 behavior. CMS provides data and fees to the Medicare Health Support organizations who then manage the
10 relationships between their targeted beneficiaries and the physicians who are caring for those beneficiaries.
11 As I mentioned earlier, those fees are at risk for quality improvement, for cost savings, and for satisfaction.
12 Each of the programs is intentionally designed to offer flexibility and interventions. And each Medicare
13 Health Support organization is approaching the challenge a bit differently. The flexibility is intended to
14 allow the Medicare Health Support organizations to create programs that respond to the unique needs of
15 their diverse populations and the medical communities that serve them. Many of these programs share
16 common elements, such as 24-hour 7-day-a-week call center nurses, who help to guide the beneficiary in
17 understanding their condition, understanding their physician's plan of care, their medication, their chronic
18 condition. And in helping them to navigate what is a very complex health care system, even more complex
19 for these beneficiaries. Other features are unique to each program. Remote monitoring of blood pressure, of
20 weight, of glucose levels. Individual pharmacy interventions looking for drug interactions, drug disease
21 interactions, or duplicate medications. We already have a number of examples and anecdotal stories about
22 how these programs are working and I'd like to share just a couple of them with you.

23 One of our Medicare Health Support organizations reached out to a beneficiary to invite her
24 participation and learned that she spoke only Russian. The Medicare Health Support organization used a
25 translator on the phone to talk with the beneficiary and learned that she had just been discharged a week
26 earlier with a heart failure diagnosis. The beneficiary had misunderstood her discharge instructions and
27 thought that the hospital would be sending her her outpatient medication. Of course that did not happen,
28 and a week post-discharge, she was without medication and exhibiting signs and symptoms of worsening

PPAC Meeting Transcription – March 2006

1 heart failure. The Medicare Health Support organization helped to coordinate the communication between
2 this beneficiary and her physician, to get her back on medication. And potentially avoid an emergency
3 room or hospital admission. Similarly, one of Medicare Health Support organizations in reviewing the
4 medications with the beneficiary learned that this beneficiary was taking 2 different beta blockers; one
5 prescribed by an internists, one by a cardiologist. The Medicare Health Support organization helped to
6 coordinate communication with those providers and the internist suggested he discontinue his medication
7 and have the beneficiary continue with the beta blocker from the cardiologist. Many of our health support
8 organizations are finding that the social needs of these beneficiaries are far different than the commercial
9 populations that they've served in the past. One of our sites made a phone call in early November to talk
10 with a beneficiary who had diabetes among her conditions. It became very clear to the nurse speaking to
11 this beneficiary that she was not focusing much on her diabetes, and really not ready to focus much on her
12 diabetes. Her concerns were the grandchildren that she was the primary caregiver for. Her concern was
13 getting healthy food into the house and a Thanksgiving meal on the table. The Medicare Health Support
14 organization realized that trying to push through the medical issues was not going to help this beneficiary
15 gain control of her conditions and so working with social service agencies in the area, the social services
16 agencies were able to provide not only a Thanksgiving meal, but Christmas presents for the children and
17 stocking the kitchen with healthy food. The beneficiaries' anxieties were lowered, she formed a trusting
18 relationship with the Medicare Health Support nurse, and is now focusing on her diabetes and other
19 conditions.

20 So where are we now? Our infrastructure is assembled. Our programs are underway. Physician
21 engagement is strong and regional alliances are developing locally in these 8 programs. There appears to be
22 good support for Medicare Health Support and our response from beneficiaries is very encouraging. CMS
23 is very appreciative of our pioneering Medicare Health Support organizations and the physicians who are
24 working with them. We also have more than 35 organizations that are working with us to help raise
25 awareness about the program including AARP, the American Diabetes Association, the American Heart
26 Association among others. Support from these programs has been very important and invaluable in
27 launching Medicare Health Support, in raising awareness among beneficiaries and their caregivers and their
28 physicians and in giving a level of trust in the programs that this is truly a Medicare program. Additionally,

PPAC Meeting Transcription – March 2006

1 CMS is maintaining collaborate relationships with professional associations, including ACP, AAFP and
2 American College of Cardiology. Beneficiaries are eager to participate in this program. Before this call, I
3 checked on our latest numbers and we are over 110,000 beneficiaries participating nationwide. We are very
4 encouraged as are our Medicare Health Support organizations.

5 Clearly we are looking to improve health and quality life among our beneficiaries, and to lower
6 average Medicare Fee-for-Service costs. We're looking to reduce complications, emergency room visits,
7 and hospital admissions and to improve beneficiaries' adherence to evidence-based guidelines. We're
8 looking to improve the coordination of care through use of new information technology. We are able to
9 synthesize person level information from multiple sources into a single electronic records; information
10 from our participants, from CMS claims, from multiple physicians, from beneficiaries' caregivers. For
11 160,000 beneficiaries this year. These programs use sophisticated clinical decision support tools to help the
12 organizations identify modifiable health risks with the beneficiary, to help to track changes in the
13 participants health status, to generate preventive care reminders, and alerts for the nurses working with
14 these beneficiaries, and for the beneficiaries themselves, and in many cases, to generate these reminders
15 and alerts for the beneficiaries' physicians. We're looking to design programs that are acceptable to
16 physicians that are focused on the beneficiaries' total health, and importantly, that are adaptable, scalable,
17 and replicable nationally. We want to make sure that these work for all of our Medicare beneficiaries,
18 including dual eligibles. We want programs that can sustain the quality and cost outcomes that we are
19 optimistic about achieving, and to establish successful administrative and business models. In phase 1, we
20 are continuing to ask questions, to listen and learn, and welcome today as an opportunity to do that.

21 As we celebrate Medicare's 40th anniversary, Medicare Health Support is looking to focus on
22 prevention, on new public and private partnerships, on adherence to evidence-based medicine, and on
23 transforming and modernizing Medicare. We think Medicare Health Support has the potential of being a
24 win-win for CMS for our beneficiaries and for you. And welcome your feedback and your support.

25 Dr. Castellanos: Thank you, Barbara. We appreciate that presentation. Does, first of all, Barbara
26 had some questions, and maybe we should just open it up—does anybody have some questions to Barbara?

27 Dr. McAneny: I appreciated on the last slide that you were going to develop a business plan to
28 look at this, but it seems to me that rather than hiring one of those companies that were on the slides and

PPAC Meeting Transcription – March 2006

1 just saying we'll give you money but you'll lose a little bit if we don't meet these measures, it seems to me
2 that the proper comparison might be if you paid for translators in the hospital, you would not have needed
3 to pay for a nurse and a translator later on to explain to your Russian speaking patient that she needed to not
4 wait for her medicines to show up in the mail. If you paid for the dietician in my office, or the social
5 worker visit, it seems like we could overcome a lot of the barriers that we've placed in there and do it in a
6 less expensive program than what you're outlining. It seems to me that for a lot of these disease
7 management type models, that what we have done is erected barriers to care, because we don't pay for
8 social services. We don't pay for nutritionists, we don't pay for various things, and that creates difficulties
9 in getting patients the social support that they need to be able to comply with a regimen. And then we
10 create another layer of bureaucracy and another industry whose job is to overcome the barriers that we have
11 just set up. Seems to me that one of the cost-analyses that I would like to see occur as we're spending my
12 tax payer dollars on this, is would it be more cost effective to pay social workers, to keep nurses at the
13 bedside rather than having them on the telephone, and to pay translators, rather than having the physicians
14 have to pay the translator, and to make sure that all of these services are available to the physicians who
15 have primary responsibility for the care, rather than instituting a whole new nother layer of institutions in
16 that situation. To say one more thing, when I get a letter from a patient saying that they have received the
17 name of their contact nurse they're to call to ask questions about what their treatment regimen is, what
18 they're supposed to do if they have a problem, I have 2 hats on here. One is my hat as an oncologist, I tell
19 them do not call some nurse who lives a thousand miles away, call us. We have access to your medical
20 record 24-7, we know who you are, we know what you have, we understand what we can do in the in and
21 out patient service, and I don't want you calling somebody else who will confuse things. And the second
22 hat that I wear when I make this comment is I chair our local emergency medical services authority—don't
23 ask why an oncologist does that—it's a long story. But I do that and I know our emergency rooms are way
24 behind. I also know they use a system of cards and questions to answer those questions and when they get
25 to a certain point where it sounds like things are out of their control, or there's a certain liability risk
26 involved, the final common pathway is go to the emergency room. I don't want my patients to go to the
27 emergency room where they wait 8 hours and sit next to some guy with pneumonia til they have it also. I
28 want my patients to call me or the partner who's on call. So I think that really the proper way to look at a

PPAC Meeting Transcription – March 2006

1 “disease management” is to look at the physicians who are trained to manage those diseases and give them
2 the resources that you’re giving these programs to manage those very diseases. And I suspect we would do
3 a better job and it would be far more cost-effect. [applause]

4 Ms. Hoffman: Let me make just a couple of points. This is one model that we are testing. There
5 are also demonstrations that are focused on provider groups providing chronic care, so CMS is testing a
6 number of models, but I will take your questions, your concerns, and your perspective back to look at how
7 we analyze this program and what we learned from it. In terms of Medicare Health Support, these are not
8 advice nurses per se, who are working off standard protocols and directing people to go to emergency
9 rooms. The emphasis is to connect beneficiaries back to their provider.

10 Dr. Castellanos: I live in South Florida, and I happen to be a urologist, but I did listen to Green
11 Ribbon Health Presentation because it’s right in my backyard. In fact I went to that presentation. And I can
12 tell you that the physicians that were there, their concerns were the exact same ones that Dr. McAneny has
13 just said. Florida is a very litigious state, extremely litigious. And their concern is that you’re hiring a
14 medical health care support organization, or RN whose being paid by this to go out and interface with that
15 patient and then supposedly report back to the physician. Now the physicians felt there would be some
16 liability there on their part. The message didn’t get back to them or if the patient got sick, and there was
17 lack of communications, and their feeling was almost unanimous that it would be nice if Medicare could
18 pay these nurse and hire these nurses to work for the physician who has direct contact with the patient and
19 direct contact with the nurses, and don’t put this layer between the physician and the patient. Almost
20 unanimously at that meeting, the primary care physicians said we would love to be able to hire somebody
21 like that in our offices to go out, and to do the work that you’re doing. And they said we don’t know these
22 nurses. We don’t know if they’re qualified. They don’t know us. I get 20 letters a day from home health
23 care agencies to fill out and this is just another form letter that I’m going to get stuck with and there was
24 really a lack of understanding of the layer between the physician and the patient. That was the feedback.
25 Now, obviously I’m a urologist, and none of these chronic diseases affect me, but I’m not a primary care
26 provider for diabetes or congestive heart failure.

27 Dr. Przyblski: Given that this is a pilot project, and if I heard you correctly, it is a volunteer
28 program for those that are invited and they can drop out at any time, what happens to how your analyzing

1 the data at the end of this few years to the dropouts, because the conclusions that you might reach may be
2 influenced by who drops out and how you consider them in your comparison to the control group?

3 Ms. Hoffman: We will be analyzing on 2 levels. One is looking at participants. Although many of
4 these programs, many of these activities have been shown to be effective for those who participate. So
5 much of what we are looking to test is is this a program that has relevance in a larger Medicare—so that
6 looking at the entire population of the intervention group, participants and non-participants, compared to
7 the control group. Is this a program that is acceptable to physicians, as we've already talked about a bit, and
8 acceptable and effective for beneficiaries, so we'll be looking both at the participants, but separate from the
9 non-participants. But also looking at the entire intervention group because we're looking at whether this is
10 a model of care that makes sense, recognizing that a percentage of folks will not participate in it.

11 Dr. Castellanos: Are there any other questions or comments? Dr. Urata? I heard you clapping. I
12 just kind of would appreciate any comments you have as a primary care physician.

13 Dr. Urata: Well, in our community we have small practices, so the hospital hires a diabetic nurse
14 specialist and we send newly diagnosed diabetics, or we supposed to send them to this person at the
15 hospital. But the hospital has a hard time collecting fees to pay, so it's one of those things that the hospital
16 ends up covering at its own expense for the benefit of the community. And we have other areas there where
17 you cannot collect for patient education, because nobody pays for it but the hospitals. So what the doctors
18 do, we get together and ask the hospital to do it and the hospital says OK we'll do it, but they pay for it.
19 And I think if, I can't imagine what happens in bigger cities. How do these people get educated? And the
20 physicians can educate to a certain degree, and the nurse can educate to a certain degree, but there's
21 nothing that is really well organized. I know in some of the bigger hospitals they actually have diabetes
22 schools and things of that sort which sound really good, they last for a week, and the patient pays for it. But
23 I think that's an area that you're looking at through this program, and hopefully you'll find some good
24 things out of it.

25 Ms. Hoffman: Certainly the focus is to be looking at beneficiaries across the various places of care
26 and the multiple physicians and trying to coordinate that in a way that can't easily be done practice by
27 practice, but I appreciate the challenges.

PPAC Meeting Transcription – March 2006

1 Dr. Castellanos: Are there any other questions? Dr. Hamilton, as an endocrinologist and a
2 specialist in diabetes, how do you look at this program?

3 Dr. Hamilton: Well, I'm sorry, you called on me. [laughter] I was going to try to be nice and stay
4 out of it. I just think it's really nice that your agent was able to prepare Thanksgiving dinner and get
5 Christmas presents for your client's family. I would wonder where her family was when it came time for
6 the diabetes education and the supervision of her diet and so forth, but I guess that doesn't count. I can't tell
7 you how many patients I have had that I had sent, and advised, and urged, and cajoled and every other way,
8 tried to get them to avail themselves of diabetes education. And how many of them have told me that they
9 simply couldn't do it because it wasn't covered. Now whether it's covered in some places or not, I don't
10 know, but I cannot tell you how many times I've heard that story. Hundreds, maybe thousands. And for all
11 the stuff you do for people with diabetes, education is the one thing that really makes a difference. And to
12 be able to convince payers of that is something that we have not been able to succeed in doing. So you
13 know, you can fix them all the Thanksgiving dinners you want to, but unless you teach them how to check
14 their blood sugar, and how to adjust their medication, you know it's just not going to last more than one
15 day. And I just don't know how you convince the payers of the healthcare expenses in this country of that
16 simple fact. I mean, you talk about evidence-based, there is more evidence that would document the benefit
17 of a diabetes education than almost anything I can think of. And yet, over and over and over again, well it
18 wasn't covered by my insurance, or wasn't covered by something. And you know the question in my mind
19 is well, it's your body, and your health and your life, why didn't you just go pay for it? Oh my god! We
20 don't do that. We can't do that! It wasn't covered. I'm helpless. I can't do it. And yet I've got a nice car
21 sitting out in the parking lot and I've got nice looking clothes on and I plan to go out to dinner tonight, but
22 no way. I don't know what the solution to this is, but if you all want to come by and fix my Thanksgiving
23 dinner, I'll be glad to let you do it.

24 Dr. Castellanos: Are there any other questions or comments?

25 Dr. McAneny: There was an interesting article last October that did a summary of a lot of the data
26 that had been published both by the Congressional Budget Office and by some of the managed care
27 publications that did one of these mega reviews of about 44 different studies on disease management to see
28 whether or not it saved money, and basically to summarize those conclusions very briefly, was they found

PPAC Meeting Transcription – March 2006

1 that in fairly well educated, motivated patients, Yuppies mostly, that doing disease management worked. I
2 can get my Sandia National Labs engineers to measure their glucoses or to measure their, for me it's their
3 white counts, etc., and they'll calculate me the standard deviation of the mean. These folks will be
4 compulsive and they will do the whole works and for them, having someone else call them up and say did
5 you take your pills today etc., is very useful. When we get out on the Res, it's a different sort of a situation.
6 When I talk to my folks and we've got a lot of folks who aren't driving up in nice cars or wearing nice
7 clothes, they simply do not have the ability—some of them don't have a phone—to be able to try to do
8 something in that population. So I think the bottom line is where disease management works the best is in
9 motivated, educated people who understand their disease. So my question would be before we spent huge
10 amounts of Medicare resources on what I look at as unproven technology, this whole disease management
11 process, I think we need to do some very small focused pilot studies to see whether or not it works and
12 whether or not you can extrapolate from a small population into the generalized population. My greatest
13 fear is that this whole very fashionable disease management process will turn out to be the utilization and
14 review of the 1990s where we did all of this utilization review, hired all of the nurses away from the
15 bedside to sit on the phone and tell us whether we were doing what we should or what we shouldn't, and
16 then discovered that the amount of money we saved was almost enough to pay the salaries of the utilization
17 review nurses. So I would just want to put a note of caution and then I do have a recommendation.
18 [laughter] PPAC recommends that CMS run a pilot program giving the resources for disease management,
19 such as paying for translators, paying for social services workers, and management fees, to primary care
20 physicians and compare the costs of providing the same services through this other layer of industry, called
21 disease management.

22 Dr. O'Shea: Second.

23 Dr. Castellanos: Is there any discussion that motion? Dana, do you have it? You have that scorn on
24 your face again. [laughter]

25 Dana: I'm just trying to reword that last phrase. To make it a little clearer.

26 Dr. McAneny: Through the disease management industry, change it to that.

27 Dana: I already did that. OK, PPAC recommends that CMS run a pilot program in which it gives
28 the same amount resources currently spent on a disease management pilot, such as paying for translations,

PPAC Meeting Transcription – March 2006

1 social services, and management fees, to primary care physicians, and compare the costs of providing those
2 same services with those of the disease management industry.

3 Dr. Castellanos: I'm going to call the question now. All in favor? Is there any other discussion?

4 Dr. Urata: May I ask Ms. Hoffman's reaction to that motion?

5 Ms. Hoffman: Welcome my first time to PPAC.

6 Dr. Urata: You can say no reaction.

7 Ms. Hoffman: I think that—

8 Dr. Urata: Is this a possibility, a reality, or something that—

9 Ms. Hoffman: I guess my reaction is that we have some demos that are looking at this through
10 providers and that we need to look at what the costs are and what the cost savings are, and so I think it's
11 something reasonable for us to take back and look at.

12 Dr. Urata: Great.

13 Dr. Castellanos: Again, there's a motion on the floor, is there any further discussion? Let me call
14 the question, all in favor?

15 [Ays]

16 Dr. Castellanos: Opposed? Is there any other questions or discussion? Please, Dr. Ross.

17 Dr. Ross: Yes, just to offer just a little testimony to what we're doing, again back in my home
18 state with our board of health. I served on the Texas Diabetes Council for 3 years and I'm sure most of your
19 states do have, under the auspices of your state boards of health, a diabetes council, a smoke cessation,
20 heart disease council, what I've learned is that from a federal tier to a state level, to a local level, that's how
21 the impact is made. That's how the differences in behavior modification and compliance and outcomes are
22 achieved. What we've done on the local level is go from our state level to our communities with education
23 products, whether it's videos in English, Spanish, whether we've gone into the communities with programs,
24 with educators, going to the hospitals and setting up programs, but that's how you make the difference.
25 You make it on the local level with those types of interventions. And the outcomes are tremendous. We can
26 show such an example in San Antonio with obesity change, with diabetic numbers, because we have high
27 incidence along the Valley, and along the El Paso Rim that you just have to do something to get to these
28 people. And I think Dr. Hamilton was right. You've got to really get somebody or some people to work

PPAC Meeting Transcription – March 2006

1 with these people on a local level and individually. You just can't expect somebody to make a difference
2 because they've made a phone call. It starts from the very beginning. Once a diagnosis is made, how that
3 intervention is going to be carried out, and how that behavior is going to change as well.

4 Dr. Castellanos: Is there any other questions or comments?

5 Ms. Hoffman: I hope that I have not misrepresented these programs. They are not entirely
6 telephonic programs, and they do have components and interventions that are on the ground and much
7 more up close and personal to beneficiaries unique to the various programs.

8 Dr. Castellanos: Barbara Hoffman, we certainly appreciate your presentation. It's exciting to see
9 what CMS is doing and we wish you the very best of luck. Thank you. I'd like to take this opportunity to
10 allow the Council time to review the recommendations of today's presentations. Once the Council is ready,
11 Mr. Herb Kuhn, Director and Dr. Thomas Gustafson, Deputy Director, Center for Medicare and Medicaid
12 Management will assist with this portion of our meeting. Dana has that been circulated yet?

13 Ms. Trevas: No, you just made a recommendation.

14 Mr. Kuhn: While we're waiting for those recommendations and review all those again, Gus and I
15 have to run off to another meeting that they just called that we're going to have to go to. So Ken, Dr. Simon
16 will wrap things up for us when you've finished reviewing all the proposals that are out there. And before
17 we did leave, I just wanted to once again thank you all for the work today. And thank you to our new
18 members for being here and taking the time to spend the time here to be with us today and participate in
19 this meeting and understand the processes that we go through here and next meeting at least have a sense of
20 maybe some of the prestudy to do, and again, anything that we can do as staff here at CMS to help you and
21 prep you for meetings, we stand ready to do that and we're ready to go. The second thing I want to do is
22 just say to Dr. Castellanos and Dr. McAneny, thank you very much for your service to PPAC. It's been
23 great to have you all here, to participate in these meetings on a variety of different levels. I know when
24 folks become active in groups like this, they're active in other groups, and there's no question I've
25 encountered these 2 in other kinds of forums, and it's been terrific to know and make your acquaintance,
26 and your friendship, both professionally and personally. And particularly Dr. Castellanos I want to thank
27 you for your leadership and for chairing PPAC for about the last year and a half and I think some of the
28 innovations he brought forward and I will tell you as staff and Dr. Simon can echo this as well, he's been a

PPAC Meeting Transcription – March 2006

1 tireless advocate on your behalf, many phone calls and meetings between the sessions that we have here, in
2 order to help us be prepped, to help us make sure that we're staying focused on the appropriate issues, and
3 to make sure that we have the information available for all of you. So again, thank you very much. And
4 good luck to the both of you, and we hope to see you again on some other kind of forums, and I know we
5 will. I know we will. So with that, thank you all very much, and I'll turn it back to you, Dr. [applause]

6 Dr. McAneny: As one of the departing members, I would also like to say thank you to CMS and to
7 the CMS staff for giving me the opportunity to do this. It has been an incredible learning experience. I have
8 the utmost respect for CMS and for what you all do, and even though a lot of my comments are sort of
9 tough love, this is indeed a program that affects what I truly believe is the greatest generation, and I think
10 it's great work and we have got to keep doing it. Thanks.

11 Dr. Castellanos: I'll make some closing comments when the time comes, too. I think we'll just
12 take a few minute break until we have that.

13 Ms. Combs: Dr. Castellanos, this is Melanie Combs again. I have answers to your previous
14 questions, would you like me to send them out by email or go over them now?

15 Dr. Castellanos: This is better than email!

16 Ms. Combs: Your question earlier was when a provider receives a request for medical records
17 from a recovery audit contractor, will they be notified either way if the RAC found something or if the
18 RAC didn't find anything and the answer to that question is definitely yes, they will be notified either way.
19 And your follow up question was how much time will elapse from the time that they get the letter until the
20 time that they hear what happened, and the answer to that question is 60 days. By 60 days, the recovery
21 audit contractor should be communicating with the provider to say either here's what we found, we
22 reviewed, we've completed our review and we didn't find anything, or the review is ongoing and we expect
23 it to take so much more time. So 60 days.

24 Dr. Castellanos: Fine, thank you, Melanie, appreciate that. We'll take about a 5 minute break and
25 then we'll go ahead with our final closing comments.

26 Review of Recommendations/Wrap Up

PPAC Meeting Transcription – March 2006

1 Dr. Castellanos: I want to ask each of the members of the Council to please review the
2 recommendations, the draft of this meeting. And if there are any questions or corrections, or additions,
3 please raise your hand so we can recognize you. Does anybody have any corrections or additions to this?

4 Dr. McAneny: On Item G, the Update on Implementation of Part D drug program one, it was just
5 the amount of time involved with the cost-of-care related to substituting medications. The “to ensure
6 pharmacy coverage” doesn’t belong on there. It’s just that when a substitute a medication, there’s going to
7 be more care that gets delivered, so just deleting those last 4 words.

8 Dr. Castellanos: Deleting “to ensure pharmacy coverage.”

9 Dr. McAneny: Right because that’s not the cost of care, it’s to deal with the change that people are
10 going to go through because the medicine got changed.

11 [off mike discussion]

12 Dr. Castellanos: Are there any other corrections or additions? Well thank you. In closing, I’d like
13 to extend my appreciation to CMS for the opportunity and the privilege to serve 4 consecutive years as a
14 member and for the past year as chairperson of the Practicing Physicians Advisory Council. It was a
15 rewarding term and I am proud to acknowledge the Council’s accomplishments as well as the influence I
16 and other physicians have had in shaping the Medicare regulation and instructions from a practical
17 perspective. It is my hope that the Council’s achievements will continue as my distinguished colleagues in
18 both current and newly selected members continue in their advisory capacity of addressing the pressing
19 issues in our health care delivery system. I wish to thank you for your participation here, today, and I
20 believe again we had a very productive meeting. The CMS staff has worked hard in preparing such a
21 distinctive presentation and sharing with us their concerns and their specific requests for Council
22 assistance. Our hope is that our recommendations will enhance the regulatory process, and enable CMS to
23 move forward with its mission and goals to provide quality care and services to its beneficiaries and wide
24 variety of customers and providers. We also extend our appreciation to the CMS Staff, and the contractors,
25 who use their many skills, talents, and professionalism to make these Council meetings successful. These
26 meetings really require a lot of work and coordination and we certainly appreciate your efforts. The next
27 Council meeting is May 22nd and with that, yes?

PPAC Meeting Transcription – March 2006

1 Dr. Simon: I would just like to lead the Council in thanking you and Dr. McAneny in all your
2 work and efforts and I'd like to, I feel strongly that we will continue on with your legend
3 [laughter][applause]

4 Dr. Castellanos: Bob, if you can do that and follow in Dr. McAneny's shoes here.

5 Dr. Urata: I'd have to get computer literate real fast.

6 Dr. Castellanos: Again, I'd like to call the meeting adjourned. I'm going to miss you guys, and just
7 please keep up the good work.

8