

CENTERS FOR MEDICARE AND MEDICAID SERVICES

PRACTICING PHYSICIANS ADVISORY COUNCIL

Hubert H. Humphrey Building
Room 505A
Washington, DC

Monday, December 3, 2007
8:30 a.m.

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Open Meeting

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Dr. Simon: Good morning to the council members and the public. This is December 3, 2007. Our chairperson, Dr. Anthony Senagore, is out today, and in his absence Dr. Tye Ouzounian has graciously agreed to be the chairperson today, and so with that, I'll introduce Dr. Ouzounian.

5

Welcome

6

Dr. Ouzounian: Good morning. I'm Dr. Tye Ouzounian. Today I will be substituting as chairperson of the Practicing Physicians Advisory Council. It is my pleasure to welcome you to Washington, D.C. on this occasion of the 62nd meeting of the Council. I'd like to extend a cordial welcome to my colleagues and fellow council members. I appreciate your willingness to adjust your schedules to allow time to travel here today and participate in this important meeting. Your considered input and guidance on the various issues that CMS staff will present here today influence the outcome of regulations and instructions which directly affect the physician community. I encourage your thoughtful and practical input on the many healthcare issues before us. As you look at today's agenda, you can see many issues CMS will be presenting to us for our advice and feedback. Topics include: Physician Fee Schedule Final Rule, Outpatient Prospective Payment System, and Ambulatory Surgical Center Final Rule. Stark Update, Overview of Medicare Demonstration Projects, and the 9th Scope of Work/Quality Improvement Organization Program. Of course, we will also receive quarterly PRIT Update, as well as the latest report prepared in response to our recommendations made during the August 27, 2007 meeting. As always, I am confident you will give your presenters your attention and the full benefit of your practical knowledge and insight. I'm sure you will agree this is a challenging agenda that will fully engage the Council for the entire day, and I look forward to a very productive session with discussion of the issues relative to the various Medicare Program areas. We welcome the opportunity to participate in crafting one of the largest, if not the largest health insurance program in the world, by providing timely feedback and advice, based on our clinical practices in the program.

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1 think through 3 major rules this year; the Physician, the Outpatient, and the Ambulatory Surgical Rules
2 were all very helpful, and we're going to get final reports as you heard earlier on those, because know
3 there's still some lingering issues, where some of you have questions and want to continue to talk about
4 issues in those rules, so I think that's a real opportunity. So in this regard, we have a very full agenda, as
5 you heard and we once again appreciate all of you coming prepared to discuss and give us your insights in
6 terms of these issues that are out there.

7 One issue I know that's on your minds that's not on the agenda but it has to be said, because it is
8 kind of the elephant in the room is of course the Sustainable Growth Rate, and certainly the updates that
9 we're looking at on January 1 as we go forward. I think as everybody here in this room knows, this is an
10 issue before Congress, not before the agency at this time, but I know I and the rest of the staff would like to
11 hear your thoughts on this issue as we go forward and as we talk about the various issues. It's hard to not
12 connect this issue with other things that are going on, so again, while it's not something that's in the
13 regulatory framework, it's something that Congress will be dealing and Congress by the way comes back
14 this week after a 2-week break, and we are as interested as all of you are, in terms of the actions that'll be
15 taken over the next 3 weeks. Nevertheless, I think this is an opportunity for you all to share your thoughts
16 on that important issue as we go forward. So again, thank you all for being here, and appreciate the time
17 you're taking away from your practices to be with us and we look forward to a good and productive
18 meeting. Yes, Dr. Grimm?

19 Dr. Grimm: Would you mind commenting on is there any kind of formal effort to address this
20 issue in Congress over the next few weeks? Because this issue comes up, obviously January 1, we're not
21 December 5th by the time they get in Congress. Is this on the front burner? Or what is the process here that
22 we're looking at that we can take back to our constituents?

23 Mr. Kuhn: Yes, it's you know, again, I can't speak for the Congress specifically, but just some
24 observations that I've seen. When we talk to members of Congress or their staff up there, this is a very
25 important issue to them in terms of healthcare. I think if you look at healthcare issues, this and the

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1 Children's Health Insurance Program are the two top issues that they're grappling with in terms of
2 healthcare right now, and two issues they want to find resolutions for and move forward, so it is, again on
3 their top 2 agenda items. The House, as we all know, in terms of the Champ Bill that they passed earlier
4 this year, has addressed this issue and in a 2-year type form. The Senate has indicated that they'd like to
5 take up something as early as this week and try to move forward, so that they can begin a dialog between
6 the two bodies as we go forward, so I see positive movement up there right now. We'll know more I think
7 later this week, what the Senate has to say on this, but I think they all understand this issue. I think they
8 understand the 10% cut that's looming on January 1. I think they've heard from all of you and colleagues
9 from across the country of what that could potentially mean in terms of access to care and the quality of
10 care that's out there, so it's pretty serious issue with them as it is with us. So we'll know more I think as
11 they convene and hopefully by week's end or early next week, we'll all have a better picture. Yes, Dr.
12 Bufalino?

13 Dr. Bufalino: Mr. Kuhn, could you give us some insight as to what you think about the
14 modification that has been proposed to PPAC going forward, we've understood that that was in the initial
15 Champ legislation and that, wondered about your insight as to whether we're going to expect some
16 modifications of this group.

17 Mr. Kuhn: Yes, the issue that you're raising there is an interesting one in that Congress is, has
18 listened to a lot of folks who have made recommendations, whether it's MedPac and others about
19 opportunities to get a little bit more robust consideration of issues relating to how the 5-year review works
20 and the RUC process and would like to create a more robust oversight function within the Department of
21 Health and Human Services to look at that, and so they put a proposal in their legislation in order to kind of
22 create such an entity. But as they looked kind of where CMS was, they said well how would CMS go about
23 staffing this? And they know that we have this committee, and they said, can't CMS put forward with the
24 existing resources, another committee, or would it be better to kind of fold PPAC into this new entity as
25 they go forward, and so that's what they decided to do. Was to go ahead and say let's fold PPAC into this

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1 new particular committee. We have not as an agency opined on that yet. Whether we find that acceptable or
2 whether we think we can support two. It is kind of a resource issue and I think we and Congress are going
3 to have to have further discussions on that and we'll see what the Senate has on that. So we haven't taken a
4 formal position yet, but I know at our last PPAC meeting, I had conversations with several of you one on
5 one, who expressed concerns about this, and so I appreciate that. And I think during the day's discussion if
6 you all have additional thoughts on that, I think that would be good things, and to get us as formal
7 recommendations would be helpful. Thanks.

8 Dr. Ross: In that same vein, I mean I'm sure you'll poll the members of this Council, in order
9 "save dollars" if you feel that combining the two together, to make it more robust, as you say, I would think
10 that this able-bodied Council could probably serve that type of purpose for you. And I mean, we can roll up
11 our sleeves. We want to maintain this Council, obviously. We don't want to lose the voice of our
12 constituents. And if it means taking on a little more work in order to suffice, I'd be one to say that I think
13 many of my colleagues would be willing to do so.

14 Mr. Kuhn: That's good to hear, because there might be a duality role that we could look at that,
15 because still kind of opine on the major issues that are out there, but also get into the technical side in terms
16 of looking at the RVUs issue, etc., and I know on this committee, I think we currently have now and Ken
17 can correct me, but certainly have in the past, that members of the various specialty societies that actually
18 serve on the RUC for those societies, so I know within this committee, there's a lot of expertise in that area
19 and then of course, Ken himself is our, CMS's representative on that. So we have the nucleus of that kind
20 of expertise here already, so that's good to hear, thanks.

21 Dr. Bufalino: Thank you.

22 Dr. Ouzounian: Thank you, Mr. Kuhn. On behalf of the Council, I'd like to thank you for your
23 contribution to commitment to these quarterly meetings. At this time, I invite Dr. Kenneth Simon,
24 Executive Director Practicing Physicians Advisory Council and Medical Officer in the Center for Medicare

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1 Management to present his responses prepared by the Centers for Medicare and Medicaid Services, to our
2 August 27th PPAC recommendations. Dr. Simon?

3 PPAC Update

4 Dr. Simon: Good morning, the first recommendation, from Agenda Item E, Coverage with
5 Evidence Development. PPAC recommends that CMS increase awareness and education among medical
6 specialty communities regarding the availability of coverage with evidence development and funding of
7 clinical trials.

8 The response: Coverage with Evidence Development will only be used in the context of a national
9 coverage decision. CMS may require Coverage with Evidence Development as a condition of coverage,
10 when there is limited evidence of benefit of a particular service. In addition, every national coverage
11 determination final decision that is made is followed with the Center for Medicare Change Request
12 Package. That package includes the NCD Manual Instruction, detailed business requirements, targeted to
13 systems maintainers and contractors that must implement the NCD policy, and an updated claims
14 processing manual, if applicable, explaining the coding and payment scenario, specific to the NCD policy.
15 Further, every business requirement document, includes standard language directed at all CMS contractors
16 responsible for implementing the NCD. That language indicates that a related provider education article
17 referred to as “MLN Matters” article, will be available on the CMS website shortly after the change request
18 is released. The MLN Matters article is a detailed, plain text synopsis of the NCD policy and corresponding
19 implementing instructions. The MLN Matters list serve subsequently sends notification of the article to the
20 contractors, who in turn post it or post a direct link to it on their websites. All affected Medicare contractors
21 also include information about them in their own list serve messages within one week of the availability of
22 the MLN article, and include the article in their next regularly scheduled bulletin. Medicare contractors also
23 host regular provider supplier contractor advisory group meetings, comprised of members of their
24 respective provider supplier community. The MLN Matters website is comprised of quite an extensive
25 array of provider education tools in and of itself. It uses mechanisms such as the Internet, national

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1 educational articles, brochures, fact sheets, web-based training courses and videos to deliver a planned and
2 coordinated provider education program that's designed to accommodate busy healthcare professionals
3 with the least amount of disruption to their day to day business. National Coverage Determinations as well
4 as prospective NCDs under review, are communicated to the public and the healthcare industry at large
5 through other means as well, depending upon the complexity, interest and/or sensitivity of the issue, CMS
6 also utilizes guidance documents, question and answer documents, individualized list serves, open door
7 forums, town hall meetings, Medicare coverage development and coverage advisory committee meetings,
8 technology assessments, a quarterly provider update in the *Federal Register*, as well as informational
9 meetings upon request. The medical specialty community can track new National Coverage Determinations
10 issued by CMS on the coverage center website. And one can reach that by going to CMS.HHS.GOV and
11 look for the coverage center webpage.

12 Agenda Item G, Recovery Audit Contracts. 61-G-1: PPAC recommends that CMS continue to
13 work collaboratively with the American Medical Association to disconnect payment denials for anesthesia
14 when a RAC retroactively determines that surgery was unnecessary.

15 The response: CMS will continue to work collaboratively with the AMA and other appropriate
16 stakeholders on all RAC issues.

17 61-G-2: PPAC recommends that CMS direct the RAC program to create clear, uniform
18 notification and demand letters. The objective of the letters should be to decrease confusion and
19 inefficiency and increase clarity and compliance.

20 The response: CMS is moving towards standardized letters for use for each RAC. CMS anticipates
21 the standardized letters will be available by March 8th, in the Medicare Financial Management Manual,
22 Chapter 4, Section 100. Use of the standardized letter will be required. However, each RAC will have
23 additional information pertinent to each overpayment identification. We will seek input from the AMA and
24 the American Hospital Association as we develop these standardized letters.

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1 61-G-3: PPAC recommends that CMS and its contractors consider the medical necessity of each
2 service provided downstream of a denied service on the original merits based on the information that was
3 available to the downstream provider at the time the downstream service was provided.

4 The response: CMS appreciates PPAC’s concern on this issue. The RAC team will continue to
5 work collaboratively with provider associations such as the AMA and the AHA on these types of issues.

6 61-G-4: PPAC recommends that CMS direct the RACs to provide to PPAC data reflecting the
7 percentage of physician chart audits that result in payment modification.

8 The response: CMS does not have enough data yet to answer this question. We are currently
9 working with the RACs to gather this data, and will make it available in the future.

10 61-G-5: PPAC recommends that CMS provide PPAC with RAC audit data specific to physicians
11 only, not combined with any other provider.

12 There has been a pie chart that has been listed in each of the Councilmembers’ response report. In
13 addition, numbers associated with these percentages are not available for the FY 2006 data, however, CMS
14 releases the 2007 RAC findings, we will include both physician numbers and percentages. We anticipate
15 that the data for FY 2006 and 2007 will be available for the next meeting, and we will have representatives
16 who work on the RAC program to come to the Council to share that information and be able to engage in
17 dialog with you on that issue.

18 Agenda Item H: Medically Unlikely Edits. 61-H-1: PPAC recommends that CMS make the MUEs
19 available to the public.

20 The response: CMS is in the process of serving a national medical association, such as the AMA,
21 the American Hospital Association and others, specialty societies, contractor medical directors,
22 components within CMS, program safeguard contractors, and other stakeholders for their perspective
23 regarding the possible public release of MUEs. In particular, CMS is interested in the assessment of the
24 advantages and disadvantages of such release.

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1 61-H-2: PPAC recommends that CMS allow the use of modifiers—including modifiers 59, 76, 77,
2 and 91—when medically necessary and appropriate, that exceed MUE limits.

3 The response: The MUE project is currently allowing the use of modifiers 59, 76, 77, 91, and the
4 anatomical modifiers when medically necessary and appropriate.

5 Agenda Item I: Physician Proposed Rule. 61-I-1: PPAC recommends that CMS consider using
6 data from the Physician Insurers Association of America because it is more timely than data CMS currently
7 uses.

8 The response: CMS is engaged in conversations with the Physician Insurers Association of
9 America, to gain a better understanding of the data it collects, including the cost and limitations of the data
10 from the source.

11 61-I-2: PPAC recommends that CMS provide the geographic practice expense data that will be
12 used to calculate the proposed geographic adjustment factor changes so that PPAC can verify the agency's
13 calculations. PPAC recommends that CMS update the payment localities every 3 years using the 5-percent
14 threshold. PPAC recommends that CMS maintain reimbursement in counties remaining in the original
15 payment localities by establishing a geographic payment floor.

16 The response: CMS appreciates the comments from PPAC on updating the geographic localities.
17 We are studying this issue closely and will take these recommendations into consideration when making
18 changes to the locality structure. We do not have a legislative authority to establish a geographic payment
19 floor. The data used to collect the Geographic Practice Cost Index comes from publicly available sources,
20 such as the census bureau, and the Department of Housing and Urban Development.

21 Agenda Item L: Medicare Contractor Provider Satisfaction Survey. 61-L-1: PPAC recommends
22 that CMS incorporate into the MCPSS a measure to assess satisfaction of physicians, who have participated
23 in the RAC program.

24 The response: The Medicare Prescription Drug Improvement & Modernization Act of 2003,
25 specifically Subtitle B, contracting form, Subtitle B, § 911.b.3.b, calls for the agency to develop

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1 Dr. Ouzounian: Thank you.

2 Ms. May: Good morning. The Physician Fee Schedule Final Rule for 2008 was put on the display
3 at the *Federal Register* on November 1, 2007. And was published on November 27th of 2007. We received
4 approximately 20,000 comments. We've since posted to our website, on November 21st revised files for the
5 GPCIs, anesthesia, and practice expense RVUs and this was due to minor technical errors. Revised files
6 were sent to the Medicare contractors, and we are in the process of drafting a correction notice. The
7 correction notice will include changes to addenda A, B, C, D, E, and the preamble, and is expected to be
8 put on display toward the end of this month. Also, the American Society of Anesthesiologists brought to
9 our attention an error regarding the '08 Anesthesia Conversion Factor. The national conversion factor in
10 the November 27th rule for anesthesia, was \$16.33 and the recalculated anesthesia conversion factor is
11 \$17.82. The major issues in the final rule, not represented on this slide, but Herb did talk about the minus
12 10.1 percent update and while Congress has intervened previously, all that I can say at this point, is that
13 CMS is prepared to update our payment systems as necessary if legislation is passed. In regards to the
14 completion of the 5-year review of work. Last year at the conclusion of the 5-year review, we deferred
15 making decisions on anesthesia services, and 50 other codes. In the NPRM this year, we proposed to accept
16 the RUC's recommendation of a 32% increase in the work of anesthesia services, and this change was
17 finalized in the final rule. We also finalized the proposed RVUs for all the remaining 5-year review codes,
18 and are accepting the results of the refinement panel for 14 home and domiciliary codes. The two audiology
19 codes that went to the refinement panel will remain valued as proposed, and there will be no increase. The
20 work adjustor was also updated to reflect increases and this is about 12%. In last year's final rule, we
21 finalized a new practice expense methodology, which uses a bottom up methodology for direct cost and
22 supplementary survey data for indirect cost. This is the second year of a 4-year transition, and we will
23 continue to work with the medical community to ensure that the practice expense inputs are correct. We
24 continue to work with interested parties to obtain additional information regarding utilization rates. The
25 current practice expense methodology takes into consideration the cost of the equipment being used in the

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1 procedure or service, and assumes a 50% utilization rate for equipment, and some specialties, and MedPac
2 believed that this is too high, while we've heard from others that they believe it is too low. Finally, we will
3 continue to work with interested parties to secure the most reliable and accurate interest rate data available.
4 We will retain our current 11% interest rate associated with obtaining medical equipment being used in the
5 performance of a specific service. And this is based on the analysis of small business administration interest
6 rates.

7 Also, § 1848 of the Act, requires us to review and if necessary adjust the GPCIs at least every 3
8 years. It also requires us to phase in the adjustment over 2 years and to implement only one-half of any
9 adjustment if more than one year has elapsed since the last GPCI revision. We are scheduled to next update
10 the GPCIs effective January 1 of next year, and the final rule makes public the new budget neutralized
11 GPCIs. After evaluating comments, though, we did not finalize the California locality proposals. We
12 decided not to finalize any proposals at this time, but we do intend to conduct a thorough analysis of
13 approaches and to look at reconfiguring the localities, and we will address this again in future rulemaking.
14 For Telehealth, we received requests to add also in addition to the neurobehavioral status exam, which we
15 did add to Telehealth services, we were also requested to add subsequent hospital care and
16 neuropsychological testing. And we received comments in the final as to how we could determine when
17 subsequent hospital care is actually a follow-up inpatient consultation and specific information on neuro-
18 psychological testing. So we will continue to look at this.

19 We also add CORF policies to the regulations and this just includes finalizing a number of
20 changes to the CORF regulations to ensure that our regulations reflect the statutory requirements to the
21 Physician Fee Schedule payment methodology rather than the reasonable cost per BBA 1997. For therapy
22 caps, there were quite a few discussions or finalized policies. § 201 of [tricia] extended the exceptions
23 process until December 31st of 2007. In the final, we briefly discuss the expiration process for therapy caps
24 and we announced the dollar amount of the cap for 2008 and that is \$1810 per beneficiary for physical
25 therapy and speech language pathology, and \$1810 per beneficiary for occupational therapy. Cap supply to

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1 outpatient therapy services, except those provided in the outpatient hospital. In this rule we finalized our
2 proposals concerning the timing of recertification of plans of care. The application of consistent standards
3 across all settings and updating the personnel qualifications for therapists. We also expand the grandfather
4 clause, to include those practicing in the home health setting. We will delay implementation of the
5 consistent standards for 6 months, and the personnel qualifications for 2 years to allow for individuals and
6 facilities time to come into compliance.

7 In regards to the Physician Assistance and Quality Initiative Fund this has been updated and will
8 provide \$1.35 billion in 2008. CMS will use this fund to continue the PQRI bonus payments. We estimate
9 the bonus payments will be approximately 1.5% of allowed charges for participating professionals, but the
10 exact percentage payment will be determined after the 2008 claims are tallied. And also in the rule, we
11 continued to study the malpractice RVUs for the technical component of a service. For radiology, we
12 received requests to make changes to the RVUs of the technical component part of 600 codes, suggesting
13 that we either flip the RVUs with each of the component parts, so the technical component RVU becomes
14 the practice component RVU, or CMS makes the RVUs of the technical component equal to the RVUs of
15 the practice component. In the proposed, we asked for comments on how facilities purchase medical
16 malpractice insurance, and how the liability for their technicians is insured. And we did not receive a lot of
17 data, but we will continue to look at this issue.

18 And I believe as Ken mentioned, Amy had talked about at the last PPAC meeting, the use of PLI
19 premium data and as he indicated, we are continuing to work with the PIAA staff and look at this. We do
20 have some operational concerns about the confidentiality of data, since we do now obtain this information
21 from the Department of Insurance.

22 For IVIG, we have finalized our proposal to continue payment for G0332 in 2008, and assigned
23 the same level of practice expense RVUs as last year. We also created 2 parallel G codes to allow for
24 appropriate Medicare reporting and payment for alcohol and substance abuse assessment and intervention
25 services that are performed in the context of the diagnosis or treatment of illness or injury. And these as

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1 HCPCS codes G096 and G0397. There were CPT codes that were approved for these services, and they
2 will not be recognized because they incorporate screening and Medicare does not cover this, since we don't
3 have specific statutory authority.

4 Other Part B policy issues in the final rule include the Average Sales Price. In January of 2007,
5 MedPac recommended we clarify our policy, and although we did not establish a specific methodology,
6 manufacturers must use, for the treatment of bundled price concessions for the purpose of calculated ASP
7 at this time, we have restated our existing guidance, in the preamble of the final rule that in absence of
8 specific guidance, manufacturers may make reasonable assumptions in their calculation of ASP. And
9 manufacturers are to submit their reasonable assumptions, along with their ASP data. We will continue to
10 monitor this issue and consider comments. Also we did not , we were going to maintain the 5% wholesale
11 average manufacturers price and the average manufacturer price thresholds. The rule also incorporated the
12 CAP refinements, that is the Competitive Acquisition Program, and this includes the provisions for the
13 collection of beneficiary co-insurance, the approved CAP vendor appeals, for denied drug claims, the
14 definition of exigent circumstance or the description of process for requesting removal from the CAP
15 program. And we also, for labs, we discuss the reconsideration process, and this is outlined in the final rule,
16 and payments for new tests established through gap filling by contractors is described.

17 For ESRD facilities, in the final rule, we have two updates. We are updating the wage data and
18 implementing a third year of the transition using a 25-75 blend of the old MSA-based wage index, and the
19 new CBSA-based wage index. And we are reducing the wage index floor from 0.8 to 0.75 for 2008, but
20 MMA § 623 requires us to annually update the drug add-on adjustment to reflect the estimated growth in
21 ESRD expenditures, from the previous year. And the final update to the composite rate is 0.5% for a total
22 drug add-on adjustment for 2008 of 15.5%.

23 And that is all that I have. If you need the updated files or any additional information, this is our
24 website. Thank you.

25 Dr. Ouzounian: Council have any questions for Whitney? Dr. Bufalino.

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1 Dr. Bufalino: Yes, I was wondering if you could address the PQRI for 2008. How is it that you're
2 planning on handling that? Will it be a full year of data acquisition before the reimbursement is provided to
3 the practices? Will it be a 6-month cycle like this last month? I'm assuming that we're expecting a
4 reimbursement sometime in the next 3, or the first quarter of '08 for the 2007 data, but just curious to have
5 you outline that.

6 Ms. May: I would look to Tom Valuck, who is in charge of the PQRI Program. What I can say,
7 though, is that there are a total of 119 quality measures selected from the 148 we proposed across the
8 following 7 broad categories. So this is something I think for Tom Valuck and his staff.

9 Dr. Snow: Ms. May, can you tell me why CMS did not choose or chose to use no portion of the
10 Physician Assistance and Quality Initiative fund to partially offset the proposed the 10.1% decrease, when I
11 understand Congress specifically had talked about using part of that fund at least for that purpose.

12 Ms. May: Well that would have to come from Congress. The direction to do that would have to
13 come from Congress. We don't have discretion to do that.

14 Dr. Snow: It was my understanding that there was some discussion by Congress to do precisely
15 that. Am I incorrect?

16 Dr. Hambrick: I think there was discretion given to the Secretary and I think that those options
17 were discussed within CMS and I think that Tom Valuck, obviously, as Whitney has indicated, would be
18 the more appropriate person to ask that question. But it was decided to put it toward the bonus. But as far as
19 specifically the steps that led up to that, I think Dr. Valuck would be probably the appropriate person to
20 address those concerns.

21 Dr. Sprang: Just in follow-up to the Act, it does seem and now in the AMS testimony, they give a
22 lot of discussion on that issue, and actually raise the question, their interpretation anyways, that CMS could
23 have used it in any way they wanted, especially to help use it to decrease the decrease we're going to get in
24 physician payment. I think their position was that if you have just in quality assurance, then it affects the
25 percentage of the physicians, and they may get some increase in payment. If you actually used it to

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1 decrease the 10% decrease we're going to get, then you would actually have it affect all physicians. As far
2 as quality improvement, I think most of us know, an easier way to keep track of that data is with
3 information technology. If physicians are decreasing their revenue they're not going to have the money to
4 buy information technology systems, and thereby not be able to as well, follow some of the quality
5 initiatives. So I think several people, and apparently the comments were made, almost everybody who
6 made comments, suggested that it be use to decrease the 10% decrease we'll get. So it's kind of, when
7 almost everybody recommended that, when it affects all the physicians, instead of just a few, it just is hard
8 to understand why that money wasn't used—it would have decreased it 2%, so it would have gone from
9 10% to 8%, so it's, I think it's hard to kind of conclude that this was the best use of the money. And
10 Congress, at least from all the things that I've seen, did give CMS the ability to use it that way, they just
11 chose not to. And CMS even said almost all the comments were to use it for that. So based on that, I'm
12 going to make a recommendation. PPAC recommends that CMS use the Physician Assistance and Quality
13 Initiative fund to partially offset the negative update and allow all physicians to benefit equally from the
14 fund. You need that repeated, or you got it? Good.

15 Dr. Bufalino: Second.

16 Dr. Ouzounian: Discussion? Seeing no discussion, all in favor?

17 [Ays]

18 Dr. Ouzounian: All opposed? Motion carries.

19 Dr. Sprang: Motion carries.

20 Dr. Ouzounian: Further comments? Questions for Whitney? Thank you, Ms. May. Moving on to
21 Tab E, let's proceed with the agenda and focus our attention on the Outpatient ASC final rule. Stephanie
22 Kaminsky joins us today to address the Council on the fine points of the Outpatient final rule. Since
23 September of this year, Stephanie has served as Deputy Director of the Division of Outpatient Care in the
24 Hospital and Ambulatory Policy Group in the Center for Medicare Management. Immediately prior to this
25 position, she worked in the Office for Civil Rights at HHS in numerous capacities, including HIPAA

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1 Privacy Policy and Outreach. Prior to that, she worked as a private sector attorney as a healthcare associate
2 in a national law firm and as an in house counsel for managed care company. Stephanie would like the
3 Council to consider the following questions in providing feedback on this topic. Number one, suggestions
4 for disseminating information to physicians and ASCs regarding the revised ASC payment system,
5 particularly with respect to new ASC procedures. Number two, thoughts regarding efforts to incur quality
6 in ASCs, including suggestions for appropriate quality measures. Number three, recommendations for
7 disseminating information to physicians, regarding services that are not covered under the OPPI inpatient
8 only and surgical procedures that are excluded from the ASC payment. Please welcome Ms. Kaminsky.

9 Outpatient/ASC Final Rule

10 Ms. Kaminsky: Morning. It's a pleasure to come here this morning and brief you on the Outpatient
11 and ASC rules, and without further ado, I'll get going. As you can see, there are a number of topics that I
12 intend to cover this morning with respect to the Outpatient Prospective Payment System, we have new
13 quality measures that I'll be discussing, expanded packaging, for certain services, some new composite
14 APC groups, a new policy for devices, which are replaced with partial credit. Some new policies with
15 respect to drugs and biologicals, and radio pharmaceuticals, PET scans, and brachytherapy sources. And
16 then with respect to the ASC payment system, I would like to discuss a little bit about how we got to where
17 we are today. We have a revised payment methodology, which I'm sure many of you are aware of, that was
18 issued back in August, and with the updated November rule, we have updated our payment rates in
19 accordance with that revised payment policy. Part of that new payment policy is a very much expanded list
20 of ASC procedures. We have some policies I'd like to discuss with respect to device-intensive procedures
21 in this setting as well. I want to explain the way ASC covered ancillary services are handled, the transition
22 for implementation of these revised rates. There's a 4-year transition that we'll discuss and then how the
23 system will be updated after a certain number of years.

24 So we've already, you've already some of the questions that we would like some feedback on,
25 from the Council. A lot of it with respect to the ASC policies, since they are new and they have some

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1 important impacts in terms of decision-making by physicians, so it would be great to get the Council's
2 input on those questions.

3 And here are some websites with additional information if you would like to go further than this
4 discussion.

5 So just getting into the OPSS, as I'm sure you're aware, the OPSS rates are based on Relative
6 Payment Weights, calculated for groups of services, that we call APCs that are similar in terms of clinical
7 characteristics and resource costs. CMS annually updates the APC groups and weights, using the most
8 recent claims data, cost reports, and wage indices. For the current rule, like the physician rule, it went on
9 public display November 1st, and it was finally published in the *Federal Register*, last week, November
10 27th, whenever that was. Public comments for the new HCPCS, only for the new HCPCS codes will be
11 accepted through January 28th, 60 days. And then there are a number of policies, perhaps it will be a relief
12 to know, that have not changed. Clinic and emergency visits, drug administration services, and rate setting
13 methods for device-dependent APCs. At this point, we are not, this year, for CY08, that is, we will not be
14 making an adjustment for charge compression, although we did talk about that a little bit in our rule and our
15 intentions to be further exploring that topic for future years.

16 One of the big changes are the quality measures that are incorporated into the rule. For CY08,
17 OPSS payment is estimated to increase by approximately 10% from '07 to \$36 billion and we have
18 included 7 reporting standards for emergency department acute myocardial infarction transfers and
19 perioperative care. Those are the two areas that they come in—that's our first step toward value-based
20 purchasing. There were others that were proposed for diabetes, heart failure, and community acquired
21 pneumonia, but those were not adopted at this point. And then by law, from the Tax Relief Healthcare Act
22 of 2006, hospitals that fail to report will receive a 2-percentage point reduction to the payment update, and
23 that will begin obviously in CY09, because the reporting occurs in CY08.

24 In our rule this year, we changed some policies and we did some expanded packaging. Just to give
25 you a little bit of history, since 2000, over all packaging has decreased, and procedure groupings have

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1 grown smaller and it was our thinking that smaller payment bundles provide payment incentives to increase
2 service complexity. However, our intention is to have more efficiency, and larger payment bundles promote
3 efficiency and stability of payment over time, and also provide hospitals flexibility to manage their own
4 resources. So the current policy is that packaged services include low-cost drugs and supplies, anesthesia,
5 certain equipment, operating and recovery room costs, and those kinds of things. Moving forward, into
6 CY08, we extended our current packaging policy to a number of supportive and ancillary services, so that
7 payment for these services are wrapped into the primary diagnostic or therapeutic modality, which we think
8 these are typically provided with. We examined services looking for categories of ancillary items and
9 services, which we believe could be appropriately packaged into larger payment packages for the
10 encounter. And we looked at a large set of HCPCS codes to come up with this and I just wanted to mention
11 as you may already understand, although separately payment is no longer made when these HCPCS codes
12 are reported, the cost of these items and services are included in the costs of the claims on which they
13 appear and would thus contribute and therefore do contribute to the median cost for the primary service,
14 that are separately paid. So those costs are bundled then. And you can see the list of services that I'm
15 talking about right there.

16 We also have a new composite APC policy, we are again, encouraging efficiencies, by making one
17 comprehensive payment for several major services performed together. The composite payment is for
18 services which are usually part of the same encounter, although in that case, if either of those services, or
19 any of those services were provided separately, a separate payment would or could be made. In CY07,
20 when patients undergo multiple major procedures in a single episode of care, hospitals receive payment for
21 each component. But now, in '08, for these composite APCs, which include low-dose prostate
22 brachytherapy, cardiac electro physiological evaluation and ablation, and extended assessment and
23 management, there will be one comprehensive payment for these services when they're performed together.

24 With respect to devices, when manufacturers give some sort of a credit to hospitals for
25 replacement of implantable devices, in '07, for these types of expensive implantable devices, replaced

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1 without cost or with full credit we reduced the APC payment by the amount of the estimated device cost.
2 We're keeping that policy when there's a total credit given to the hospital, but in addition, when hospitals
3 receive partial credit, which means 50% or more, toward the replacement cost, we will be reducing the
4 APC payment by 50% of the estimated device cost. So in a sense, they will be certainly made whole, if not
5 maybe even more than whole with this policy.

6 With respect to drugs and biologicals, which have a very complicated statutory history, even in the
7 last several years, as you may recall the MMA mandates payment based on average acquisition cost,
8 including pharmacy overhead costs. In '07, average that we used for drugs that were not packaged, average
9 sales price plus 6%, again that's for drugs that were over \$55 a day. In '08, our policy is ASP plus 5% for
10 drugs over \$60 a day. We updated that threshold, the packaging threshold, from \$55 to \$60 using the
11 producer price index for prescription drugs. We used hospital claims data, the actual claims data, which
12 showed us that the mean drug cost would actually be ASP plus 3%, including the acquisition and pharmacy
13 handling costs, and so in order to make this a more palatable transition, we're doing a transition right now
14 toward complete use of that claims data, wherever it leads us. In this case the average between ASP plus 6
15 and the ASP plus 3 was ASP plus 4.5 and we rounded that to ASP plus 5. And that's our policy for this
16 coming year.

17 With respect to radio pharmaceuticals, again, under the MMA that also was to be paid by the
18 average acquisition cost, although we don't have ASP data for that, so we had to come up with a different
19 policy to get to our current payment. In '07, all radio pharmaceuticals meeting over that packaging
20 threshold were paid at cost, using the hospital overall cost-to-charge ratio. In '08, we've split radio
21 pharmaceuticals into 2 groups; there are the diagnostic pharmaceuticals, which will be packaged into the
22 associated imaging procedures, in accordance with our expanded packaging policies, and also the
23 perspective payment rates for separately payable therapeutic radio pharmaceuticals will be based on mean
24 costs from the claims data. This is including the handling costs and this is our effort to switch to a
25 prospective payment type data collection and system of payment for the radio pharmaceuticals because at

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1 this point, we believe we have enough data to come up with a mean cost, as opposed to the past, where we
2 were paying at cost, using the cost-to-charge ratio.

3 In terms of PET scans, in '07, PET CT scans relatively new technology were assigned to a new
4 technology APC. And diagnostic, and the FDG, which is the diagnostic radio pharmaceutical, that's used
5 with the PET CT was paid separately at charges reduced to cost. In '08, it's a different landscape. We are
6 reassigning the PET CT scan to a clinical APC for non myocardial PET scans, and then again, consistent
7 with our updated packaging policies, the FDG will now be packaged into the payment for the PET and PET
8 CT as part of the expanded packaging, as a diagnostic radio pharmaceuticals. Multiple myocardial PET
9 scan services continue to be paid through the same APC as single myocardial PET scan services. We didn't
10 see a big difference there.

11 With respect to brachytherapy sources, also have had a very interesting Congressional history. In
12 '07, they were paid at cost using hospital overall cost-to-charge ratio. But that Congressional mandate has
13 expired for '08, and going forward, we will be paying for the sources, the seeds etc., based on source-
14 specific median costs for brachytherapy sources are reflected in claims data. That, based on the Tax Relief
15 and Healthcare Act of '06, we created separate APCs with differential payment for stranded and
16 nonstranded sources. Again, that was directed by Congress. But now, with our new policy, basing the
17 payment on the median costs, instead of on direct costs, you know, based on the median cost, i.e., an APC
18 rate, etc., these sources will be eligible for an outlier payment, and the 7.1 rural adjustment, which is new
19 for '08.

20 So let me switch gears and talk a little bit about our ASC payments. The ASC payment system—it
21 is exciting stuff, it is some real change and we're pretty excited about it. The current system provides
22 payment for more than 2500 surgical procedures across 9 payment groups. This is what's been in place for
23 a long time now, many years. And these payment groups, they were clinically disparate, they were last
24 rebased years ago, in March '90, using '86 data, very outdated and the payments were wide-ranging, from
25 \$333 to \$1339. The MMA came in and required CMS to revise the ASC payment system by January 1st,

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1 2008, next month. We issue our NPRM outlining this new payment system in August of 2006, actually, and
2 we put out a final rule explaining the payment system, which I'll explain, is tied to the OPSS APCs, or
3 relative weights, I'm sorry. We put out that final rule in August of this past year. But we didn't put out our
4 final payment rates at that time. However, we did put out those final rates in the November rule. In order to
5 get those rates, what we did, we tied the ASC rates to the OPP relative weights as I explained a moment
6 ago. That was based on a November '06 GAO report in part, that found that the relativity among the ASC
7 procedures was comparable to their relativity in the outpatient setting. So in order to get our final rates, we
8 multiply the ASC conversion factor by the OPSS relative payment weights for CY08. The CY08 OPSS
9 ASC final rule provides updated final '08 rates. The ranges, again, quite large. In terms of what the
10 payments are and the conversion factor, which is about 65% of the OPSS rates, is 41 for '01. So we used
11 the IPSS pre-classification wage indices, and the labor-related factor here is 50%, just slightly different
12 than the OPSS one, which is 60%. The payments here are capped, that are usually performed in the
13 physicians' office setting, at the physician's office rate, and this was to ensure that there was no incentive
14 to move from the physician's office to the more resource intensive ASC setting. Beneficiary copayment is
15 20% here except for screening, flexible sigmoidoscopies, and colonoscopies, where the law requires 25%.
16 Many of the policies, the final payment policies, do parallel the OPSS, consistent with PPAC's
17 recommendations that uniform payment policy should apply across settings.

18 Per the MMA, the revised payment system must be budget neutral. In CY08, the final rule
19 implements the budget neutrality adjustment of 65% of the OPSS conversion factor. That's what I was just
20 talking about a moment ago with that \$41 figure. This was derived from a complex set of assumptions. It
21 accounts for shifts in sight of service and lower cost in the ASC relative to hospital outpatient departments,
22 again, consistent with the GAO report recommendations. Going forward, CMS will scale the weight so that
23 changes to the OPSS weights do not increase or decrease the aggregate ASC payments. Because there are
24 different services that are performed in both settings, so we need to rescale them in the ASC setting.

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1 OK, so as I mentioned earlier, in the August 2nd, ASC final rule, we expanded access to
2 approximately 790 additional surgical procedures. We include all surgical procedures, except those that
3 pose a significant safety risk, or are expected to require an overnight stay. That was our criteria, it was as I
4 understand it, loosening of what was there before, and it allowed for much more expanded list. And then
5 even going forward to November, what we just published, we added more procedures to the list, bringing
6 the total to about 3400 covered surgical procedures. So a lot more opportunity to surgical procedures in the
7 ASC setting.

8 In terms of the device-intensive procedures, as under OPSS, ASC payment for high-cost devices,
9 are packaged into the associated procedure payments. The same payment for the device will be made under
10 the OPSS and ASC payment systems. Budget neutrality adjustments are applied only to the service
11 component of the ASC payment. Not to the device portion. The same ASC policies as the OPSS are going
12 to be applied related to the full credit, no cost, and partial device replacement policies that I mentioned
13 earlier. And devices with OPSS pass-through status are paid separately at a contractor-determined price.
14 The contractors are setting the rates there.

15 And then finally, there will be some ancillary services that are not packaged into the surgical
16 procedure that will be paid with a different methodology than the general procedure, than the general
17 surgical procedure. These are defined as services integral to and provided immediately before, during, or
18 after the covered surgical procedure. And those include radiology services, paid separately under OPSS,
19 and in that case the payment methodology will be the lesser of the ASC rate or the Physician Fee Schedule
20 non facility practice expense. Drugs and biologicals paid separately under OPSS, again, the non packaged
21 ones, and those will be the OPSS payment methodology of ASP plus 5%, and then the brachytherapy
22 sources will be separately paid, and again, just like in OPSS, that will be based on a prospective payment
23 rate.

24 As I mentioned, we have a transition of four years to bring this new payment into its full
25 implementation. For next year, it will be 25% of the new payment system, 75% of the old. It's a blended

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1 rate. And as you can see, that just ratchets up until 2011, when we will have 100% of the revised rates. The
2 ASC payment system will be updated annually, and the OPPTS rulemaking cycle allowing for changes in
3 medical practice and public comment each year, consistent with PPAC's recommendation regarding a
4 systematic and adaptable payment system for ASC services. And then, although it won't kick in for a few
5 years, ultimately the conversion factor update is going to be in CY2010, based on the CPI for all urban
6 consumers, the CPIU.

7 So that is the discussion, as you see, Carol Bazell is the director of the division. I'm the deputy
8 director and you're welcome to contact either one of us with follow up questions etc., going forward.
9 Thank you very much.

10 Dr. Ouzounian: Thank you, Ms. Kaminsky. Are there questions or comments from the Council?

11 Dr. Grimm.

12 Dr. Grimm: Yes, one thing was confusing to me, you mentioned that in subsequent years, CMS
13 would scale weight so the changes to the OPPTS weights do not increase or decrease aggregate ASC
14 payments. Does that make sense to you? That on one system which does exactly the same procedure would
15 not affect the same system in another building?

16 Ms. May: Well, as I understand that's based on the budget neutrality requirement, and in order to
17 keep the pot of money consistent, or at that fixed rate where it's starting, you need to, if there are
18 movements in the scaled weights on one side of the equation, you can't necessarily bring that over to the
19 other payment system, because it could throw the budget neutrality out of whack. And as I understand it,
20 that's based on the fact that there are different services provided in the hospital setting, as opposed to the
21 ASC setting, you know, find more obviously in the hospital setting, mostly surgical in the ASC setting.
22 And so the way that these services scale, or not scale, or their relative weights to each other are different.
23 So you need to do that for budget neutrality purposes.

24 Dr. Grimm: But it, the costs increase in the hospital. And they make a rationale for that. And you
25 pay a higher price for whatever that is—how does that budget neutralize out? Who is the other side of that?

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1 You say it has to stay budget neutral, but the ASC center doesn't pay, doesn't decrease. Subsequently, you
2 say budget neutral, but who's—if something's costs increase on one side, where is its budget neutrality
3 come from?

4 Ms. Richter: I think you need to think of this system as—

5 Dr. Grimm: I just don't understand how this works. It's confusing.

6 Ms. Richter: Really just the idea here is because the service mix is different in order to keep the
7 total payments constant. In both systems you may get to a point where if you just use the outpatient, which,
8 remember those weights are relative weights, so they're just looking at costs compared to the other services
9 in the system, that because the service mix is so different, you may come to a point where just using the
10 outpatient weights without rescaling them could lead to an increase or a decrease in total payments to ASC,
11 without looking separately to maintain the budget neutrality in that other system.

12 Dr. Grimm: That's exactly what my point was. Is you're just saying—maybe I'm
13 misunderstanding you. You're saying that if it increases on the one side, it's going to decrease on the ASC
14 side. But it says here it's not going to.

15 Ms. Richter: It's to make it budget neutral within each payment system.

16 Dr. Grimm: I understand that, budget neutrality, but somebody has to pay for this to make it
17 budget neutral. And you're saying that the ASC would have to if the, maybe I'm misunderstanding this, but
18 you're saying that if a hospital gets paid more, the ASC is going to get paid less to make it budget neutral.

19 Ms. Richter: No, this is just looking at the relative weights, and making sure that updating the
20 relative weights doesn't in and of itself increase or decrease the total payments to either ASCs or outpatient
21 hospitals. And so we want to make sure that the weights are appropriately relative so that the ASC
22 payments, the total payments don't change, when the rates are updated. The weights are updated, excuse
23 me. The same way that we currently make sure that the updates to the weights of the hospital outpatient
24 APC weights don't in and of themselves increase or decrease total payments to outpatient hospitals.

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1 Dr. Grimm: Do I understand correctly that if the outpatient, the hospitals get paid more, the ASC
2 is not going to get paid less. Is that correct?

3 Ms. Richter: Again, it's [laughter]

4 Dr. Grimm: I want a yes or no to this because that's exactly the question I'm going to—when I go
5 home tomorrow, that's exactly the question they're going to ask me. Say if they get paid more, are we
6 going to get paid less because of this budget neutrality issue. That is the question on the table, yes or no.
7 Not—

8 Ms. Richter: The budget neutrality is system specific. So the hospital system has to stay budget
9 neutral and the ASC system has to stay budget neutral. It's unclear, we don't, you don't know until you sort
10 of crunch the numbers as I understand it, whether a change over on one side of relativity will impact, or
11 how much it'll impact up or down, a change on the other side, when you have fewer services on one side.
12 But it ultimately has to get spread in relativity to keep it budget neutral to—

13 Dr. Grimm: Then the answer is yes.

14 Ms. Richter: Unclear

15 Dr. Grimm: The answer is yes, the answer is yes. Because what you just described is yes. If the
16 hospitals get paid more, the ASCs get less because of budget neutrality.

17 Ms. Richter: But each budget neutrality calculation is separate. So in other words, what we're
18 trying to do is make sure that the ASC—

19 Dr. Grimm: But you said the total has to be the same.

20 Ms. Richter: What we're trying to make sure is total ASC payments do not change because of the
21 weights, just as we make sure that total outpatient payments don't change because of the weights. So it
22 doesn't, there's no cross-system subsidization here. It's not if outpatient payments go up, ASC go down.
23 It's that we need to rescale—

24 Dr. Grimm: Then the answer is no. [laughter]

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1 Ms. Richter: Yes. Yes, the answer is no. Total ASC payments—we did this to make sure that total
2 ASC payments would not change in the aggregate because of the relative weights in the outpatient hospital
3 setting.

4 Dr. Grimm: Thank you, I just, I just wasn't clear on that thing.

5 Dr. Ross: Yes, I have a question regarding one of the lines that you had on payment cap for new
6 ASC procedures that are usually performed in the physician's office setting at the physician's office rate.
7 My question is how do we determine what procedures that have been performed in the past in an office
8 setting that now may need to be performed in either the ASC or hospital setting. Let me give an examples.
9 This may be due to facilities that used to be in the doctor's office, that are no longer available. In other
10 words, you had a little small surgery center or you had a small little operatory that no longer is available, or
11 if malpractice carriers now tell the practitioner, You can't perform that in the office setting. Or specialty
12 societies say that that's not safe to perform that procedure in the office setting. You need to take it to either
13 the hospital or the ASC. So the question is, is the ASC going to be paid at that rate now and being
14 penalized because the procedures used to be performed in the office setting?

15 Ms. Kaminsky: As I understand it, there's an office setting list of services. I'm not sure if it's tied
16 to the physician fee or just separate and so it would really be based on whether or not this service actually is
17 on that office-based list or not. I suppose to the extent that that gets updated and changed if something
18 ultimately, if the practice changes—

19 Dr. Ross: Well, the question is who recommends these changes and how are these changes
20 implemented?

21 Dr. Hambrick: Well, certainly as we set the system up for this year, we looked at the percentage of
22 procedures on the office, that were done in the system in the office. We also looked at other data like, from
23 the RUC that would say that it was performed in the office, primarily those types of things and for which
24 there were inputs. Obviously, if there were office-based inputs, we could not use that system. So as we go

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1 forward, because I think your question is about how you effect a change as you go forward. We certainly
2 be, you could right into us to let us know those kinds of things, however just be mindful—

3 Dr. Ross: Would the RUC make those recommendations, in other words? Or who would be
4 making those recommendations for change?

5 Dr. Hambrick: I would say, I mean just this is, we haven't discussed it internally. I would say that
6 if you are aware of something where that has happened, but be mindful that what happens in one
7 jurisdiction may not be in another jurisdiction. So you may have one carrier, or I'm sorry, insurance carrier
8 saying no you can't do it here, or one state that says no you can't do it here, but in the other 49, that's not a
9 restriction. So we will look at the data as it comes in and if there were a procedure that you felt should be
10 changed, or that type of thing, certainly you could write in to us, and then if it conforms with all of our
11 other requirements for ASCs versus office-based, we would take a look at it. Can't promise that we'll
12 change it from an office-based procedure, but we certainly would look at that.

13 Dr. Ross: So the specialty societies or the individual groups would probably make the
14 recommendations to CMS saying that these procedures now no longer are applicable toward the office
15 setting and should be performed in either the ASC or hospital setting.

16 Dr. Simon: I think to go back and answer that question historically, the RUC has not been
17 involved in the selection of procedures that are added or not added to the ASC list. Typically the specialty
18 societies and/or specific physicians would write the agency, or call the agency, requesting that services be
19 considered by the agency to be added to the ASC list. Under the old criteria, procedures had to be not
20 longer than 90 minutes in duration, not have general anesthesia, not longer than 90 minutes duration, not
21 involve major body cavities, not be life threatening or involve major blood vessels and could not have a
22 recovery time of greater than 4 hours. With the advent of this new prospective payment system, the
23 recovery time has been increased up until 12 midnight, so that in and of itself, would allow more
24 procedures, which traditionally have been prohibited from being performed in an ASC setting to now be
25 considered for addition to the ASC list which many were for this upcoming calendar year. There, many of

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1 the office-based services, which were provided 80% of the time or greater in the office setting were not
2 added to the ASC list under the existing system because then it created the potential for people to look at
3 financial incentives to make determinations in terms of where patients would receive the site of care.

4 Dr. Ross: Right.

5 Dr. Simon: Consistent with the recommendations that the Council had provided during the course
6 this past year, this new system provides an opportunity for financial incentives to not be a variable in the
7 equation to determine whether patients receive the care, because the payments will be more consistent
8 across the settings. Having said that, there were a number of services that at the time that the last final rule
9 was for ASCs was published, we had received a number of requests from various specialty societies,
10 recommending that services be considered for addition to the ASC list, that were not eligible under the
11 existing system. We took those requests from the prior final rule, as well as looking at the clinical
12 landscape of other office-based services that had not been requested by specialty societies, to consider
13 whether they should be added to the list. As a result, there were a total of about 790 or 800 new office-
14 based services added to the ASC list. So there's roughly about 3400 services now that are eligible to be
15 covered under the Medicare approved ASC prospective payment system.

16 Dr. Ross: OK. So it's an ongoing process.

17 Dr. Simon: Yes. So it will be updated annually as specialty societies, individual physician groups,
18 and others submit requests to the agency, seeking to have services added to the ASC list.

19 Dr. Ross: OK, thank you.

20 Dr. Hambrick: If I could just add, once those types of requests or information provided to the
21 agency, it would be helpful if we had some sort of hard, objective data about what's going on in those
22 areas, not my carrier won't let me do it, so forth and so on. Because obviously if you're going to make a
23 national decision, we would need as much objective data as we could.

24 Dr. Simon: And patient safety is an issue. Under the old system, there were a number of services
25 that specialty societies had requested, or some individual physicians had requested to be added to the ASC

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1 list, and recognizing that ASC provides services for patients of all age groups, our particular focus is
2 focused on patients in the Medicare-age population. And so we do look at a variety of data resources to
3 help us determine whether it is medically reasonable, safe, and necessary for those services in the Medicare
4 population to be performed in the ASCs in a safe competent fashion. So there are a variety of different
5 variables and information sources that we use to help determine when and if those services should be
6 available in ASCs.

7 Dr. Bufalino: I had a question for Ms. Kaminsky. Looking at the composite APCs and this
8 bundling of services, could you comment on do you see the reimbursement now going down for the
9 multiple procedures done in the same setting, whether it's brachytherapy, electrophysiology, I mean
10 cardiology's my world. If we're going to do an electrophysiology study and an ablation in the same setting,
11 I mean the work is still being done, I mean whether you're bundling them or billing them separately, will
12 the reimbursement change?

13 Dr. Hambrick: I think we gave a number of examples in the rule and you can obviously, you don't
14 usually go to our website, but if you did, you would find in the text there are a number of examples. Some
15 of them in the composite APC world, some of them went up, some of them went down, so it depends on the
16 mix of services that you would do on that particular day, which would determine whether, with our new,
17 2008 composite, whether the hospital would see an increase or a decrease. But it was variable. The example
18 I thought that was in there for the electrophysiology went up, but don't hold me to that because I didn't
19 look at it before I came down.

20 Dr. Bufalino: So that's a facility payment as opposed to the physician reimbursement?

21 Dr. Hambrick: Oh yes, this is all facility. We're talking about all facility payment. We're not
22 talking about physician payment. So physicians will continue to bill as they have billed in the past.

23 Dr. Bufalino: I understand. Thank you.

24 Dr. Grimm: One concern we have in brachytherapy world is we have patients, Medicare patients
25 scheduled to be treated in January. In the final rule, as you're probably aware, that Ken and maybe some of

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1 the others indicated to you, is it's a real serious problem there, in that the final rule doesn't allow for
2 payment for the brachytherapy sources at an ASC center. And this needs to be resolved immediately.

3 Ms. Kaminsky: Well I think it allows for brachytherapy sources, but this is a problem I think
4 under Stark, so it's a self-referral problem. It's not a generalized problem as I understand it.

5 Dr. Grimm: I don't know what you mean by generalized problem. It's a generalized problem for
6 everybody because they can't order the seeds legally, because it's a DHS designated service. That was
7 supposed to addressed in the final rule, was not addressed in the final rule, was an oversight I believe. Now
8 [if?] it] was an intent of Medicare to not provide for brachytherapy services in outpatient surgery centers. It
9 needs to be corrected immediately. And I don't know what the solution'll be to that, but I do want this
10 committee and CMS to be aware that this is a serious problem that affects patients that are already being
11 scheduled for procedures in January.

12 Ms. Kaminsky: And I think the problem is limited to a self-referral problem, but it is a problem,
13 we're aware of it, and I know that there's going to be a Stark presentation later this afternoon with—

14 Dr. Grimm: Think we might bring it up with Romano, then?

15 Dr. Simon: Yes.

16 Ms. Kaminsky: That would be a good idea.

17 Dr. Grimm: OK. Thank you. Appreciate it.

18 Dr. Bufalino: I'm sorry, one last question. On the quality measures, can you speak to the quality
19 measures that you're going to be looking at on the emergency room, department transfers for acute MIs?
20 You talked about that, and I guess who we're evaluating—you evaluating the hospital who sees the patient?
21 The hospital who receives the patient in transfer? Is it both hospitals and what are you measuring? Because
22 there's a fair amount of controversy around managing acute heart attack care and whether or not the
23 patients, will the referring hospital be allowed to be compensated for the work they did before they
24 transferred, or is all the care going to be in the receiving hospital that received the patient in transfer?

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1 Ms. Kaminsky: You know that's a really good question, and I don't know the answer to that one. I
2 had assumed it was the receiving hospital that was doing the reporting. I can tell you the measures, I
3 thought they were on the slide, but I'll just read them out loud to you. I'm not sure it will get the heart of
4 your question, but in the ED arena, it's emergency department transfer for acute myocardial infarction,
5 aspirin at the time of arrival, emergency department transferred for AMI, median time to fibrinolysis,
6 emergency department transfer, fibrinolytic therapy received within 30 minutes of arrival. So that's the
7 receiving side. Again, I don't know the question about that transferring hospital, how that works.
8 Emergency department transfer median time to electrocardiogram, emergency department transfer median
9 time to transfer for primary PCI. So those all seem to be occurring in the reporting I assume would be going
10 on solely on the reporting, on the receiving side.

11 Dr. Bufalino: Actually a lot of those are in the first patient, those are things that happen when they
12 arrive at the first hospital, so it's time to treatment, time to aspirin, to EKG, so I guess because they're, I
13 just understand that there's a fair amount of controversy as to who's getting the balance of payments, and
14 that the initial hospital's hesitant to transfer that patient because they're receiving no reimbursement for
15 whatever work they're doing, and all the reimbursement's going to the ultimate receiving hospital.

16 Dr. Hambrick: Well, first I wanted just to address the quality issue. Even though it is in our rule
17 and it's going to be our payment, the quality arena of CMS actually addresses this, so we can pass those
18 concerns along to them and ask them to clarify it so the hospitals will know who and how it's going to be
19 divvied up and that sort of thing. Secondly, as far as actual treatment for the patient, before transfer,
20 whatever arrangements are in place now for payment, like if you gave an aspirin, and you put the AKG and
21 you did the monitoring and you had you know critical care for an hour and blah blah blah blah, those same
22 arrangements whatever they are, are in place now. So as far as the quality piece of it though, we'll have to
23 find out whether you're going to split it, whether there's going to be some other way to look at that. But as
24 you mentioned some of those things are at the originating hospital, let's call that the first hospital, and some
25 of those things are at the other hospital.

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1 Dr. Bufalino: Would you mind asking them to get back to me?

2 Dr. Hambrick: Sure, sure.

3 Dr. Bufalino: Thank you.

4 Dr. Simon: We will address those issues and bring clarity to it at the next meeting, for your
5 concerns.

6 Dr. Bufalino: Great, thank you.

7 Dr. Sprang: [inaudible] commend CMS for recognizing that where would the services provided,
8 you want it to be the most efficient, less costly, and clearly I think, outpatient or offices less costly, even
9 less anxiety for the patient, and more convenient for sure. But as was pointed out several times, the process
10 that you're using this to kind of do this seems exceedingly complex. They're capping the ambulatory care
11 centers at what happens in the office is going to make it impossible for some of the procedures to be done
12 in the ambulatory care center because we'll actually be less reimbursement than costs for them doing it. By
13 having ambulatory care centers' rates being adjusted more based on the CPI, and hospitals being based on
14 the hospital market rates, you're going to get more divergence again, between the ambulatory and the
15 hospital settings. The more divergence, the more likely you're going to actually shift patients who could
16 have been done in the ambulatory center, to be done in the hospital, which is not the desirable goal. The
17 more simple we can make the process, the more open, so that we have some of the other goals in CMS as
18 far as consumer directed healthcare if they understand the differences, and understand what the costs are,
19 what it costs to go to the hospital, what it costs to go to the ambulatory care, you may actually have more
20 positive effects in accomplishing your goals. So everybody admits how complex this is, looking at all the
21 different steps it's taking, I'm going to make a recommendation to kind of really try to come up with a
22 much simpler, much better system, so, PPAC recommends that CMS develop a simpler, better, alternative
23 approach such as paying the ASC defined flat percentage of what's paid to the hospitals per procedure, per
24 year. So everybody would know up front, if the hospital gets this much, the ambulatory care gets this much,

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1 because it's the same percentage every year, much simpler to do and much easier to go forward, letting
2 everybody know what they're getting paid and know whether they can do it.

3 [multiple seconds]

4 Dr. Sprang: CMS develop a better, simpler alternative, such as paying ASCs, and this is just an
5 example, a defined flat percentage of what is paid to the hospital, for each procedure and that would not
6 vary from year to year. So it would not vary every year.

7 Dr. Ouzounian: Dana do you have that in form? OK. There's a motion that's been seconded. Is
8 there discussion?

9 Dr. Ross: Just a friendly comment on this—that's where I was coming from with my questioning.
10 Basically I was looking at if you're capping the surgery centers you're taking the incentive away from
11 doing it, in that setting and you're then, as you heard just a moment ago, you're throwing it back to the
12 hospital setting, which probably will cost everybody more in the final analysis. And that's basically what
13 my line of questioning was about. When we take these procedures from the office setting and bringing
14 them to the surgery center, it's going to be much safer, particularly for the beneficiaries and you heard Dr.
15 Simon talking about immuno suppression, high risk of infection, less circulation, high risk. And then in the
16 hospital setting, where you have a greater chance of MSRA or other infections or other complications.
17 You're much safer and you have lower costs in the ambulatory surgery center setting. And I think that's
18 where we're coming from with this resolution.

19 Dr. Sprang: Just adding. And cost is obviously extremely important. But from the patient's point
20 of view, there's much less anxiety and things for the patient to have something done in the office or in
21 ambulatory setting. Many patients are afraid to even go to the hospital. Less expense, less anxiety, and
22 more convenience all make it a very desirable place to provide care and I think we all want to provide care
23 in a setting that is the most appropriate for that procedure.

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1 Dr. Simon: But I think under the new system, the payment for the office-based procedures will be
2 the lesser of either the APC, 65% of the APC rate, or the non facility practice expense payment for that
3 service. For the physician.

4 Ms. Kaminsky: So it's the same. It should be the same. I was trying to double-check about what
5 happens to the physician payment if you were to move it to the outpatient and how that compares to either
6 the office-based or ASC setting, but in terms of incentives and whatnot, the whole idea was that it should
7 be pretty much equivalent to office-based versus ASC. It's the same payment to the physician.

8 Dr. Sprang: But if the cost is so low, then it can't do it in the ASC, and somebody that needs a
9 little more anesthesia, a little more something they're going to end up in the hospital, not in the ambulatory
10 care center, and the hospital is not where you want to be. The hospital is the last place you want to be.

11 Dr. Ouzounian: So further discussion? OK, all in favor?

12 [ays]

13 Dr. Ouzounian: All opposed? The motion carries. Further comments, discussion, or questions
14 from the Council? OK, thank you, Ms. Kaminsky. I think we're right, actually, on schedule, 3 minutes
15 ahead. We'll take an 18-minute break. [laughter] We'll resume promptly at 10:30.

16 Break

17 Overview of Medicare Demonstration Projects

18 Dr. Ouzounian: Welcome back from the break everybody. Tab G, our next speaker, we'd like to
19 recognize Ms. Linda Magno, Director of Medicare Demonstrations Program Group in CMS's office of
20 Research, Development, and Information. Linda and her staff are responsible for developing,
21 implementing, and managing, Medicare demonstrations of new models of healthcare delivery for the
22 nation's 40 million elderly and disabled beneficiaries. Linda will provide an overview of the goals and
23 current status of 5 demonstrations and asks that we consider the following questions in providing helpful
24 feedback to her group. For the medical home—can small practices meet the medical home requirements?
25 Should CMS recognize different tiers of medical homes, based on the extent to which they can deliver

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1 medical home services? Will physician practices restructure the organization and delivery of care for only
2 part of their patient population, or should CMS attempt to conduct a demonstration in the areas where the
3 private sector is also paying for the medical home model? How should the performance of a medical home
4 be measured? In regards to electronic health records, what are the core functions of an EHR ought to be
5 required to ensure that Medicare does not pay incentives for the use of an EHR merely as an electronic file
6 cabinet. If a patient does not have an EHR at the onset of the demonstration, it must have one and be able to
7 report quality measures by the end of the second year. Is that sufficient time for practices that have not yet
8 adopted an EHR? What are likely to be the effective ways of recruiting physician practices into this
9 demonstration? Ms. Magno.

10 Ms. Magno: Thank you very much. Can everybody hear me without my using the mike? OK.
11 Good. As Dr. Ouzounian indicated, I'm going to be giving an overview of 5 Medicare demonstrations that
12 I've been asked to speak about. These include the Premiere Hospital Quality Incentive Demonstration,
13 which was CMS's first Pay for Performance Demonstration, in Medicare Fee for Service. Our Physician
14 Group Practice Demonstration, the Medicare Care Management Performance Demonstration, and all three
15 of those are already underway, and then I'll be talking about 2 additional demonstrations that are on the
16 drawing boards; the Medical Home Demonstration, and the Electronic Health Records Demonstration.

17 The Premiere Hospital Quality Incentive Demonstration, as I indicated, was CMS's first Fee for
18 Service, Pay for Performance demonstration and it began in 2003. We worked in partnership with
19 Premiere, Inc. which is a volume purchasing organization, and also a quality improvement organization.
20 Some of their members, some of their owners actually, operate Premiere Perspectives, which is a quality
21 improvement organization and which collects a great deal of quality data. The demonstration was designed
22 to use financial incentives to encourage hospitals to provide high quality inpatient care and to test the
23 impacts of those quality incentives on hospital performance over time, and compared to other hospitals, not
24 in the demonstration. The demonstration currently is operating with about 250 hospitals in 36 states. It
25 operated for 3 years in its first phase. Its second phase, which I'll describe a little bit, started 2006. The

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1 demonstration was designed to test the hypothesis that quality-based incentives would raise the entire
2 distribution of hospitals' performance on selected quality metrics, and to evaluate the impact of incentives
3 on quality and on cost. Hospitals have been scored over the course of the demonstration, hospitals have
4 been scored on quality measures related to five conditions; we're using, I think it was a total of about 30
5 measures in phase one, and now in year 4, the beginning of phase 2, we've increased that to 36 measures
6 and 21 test measures, so we've significantly expanded the number of measures for which we're collecting
7 data. The 36 are for actual performance, and the 21 are to test the viability of those measures on a broad
8 scale basis. We roll up the individual measures into an overall score for each condition, and we then array
9 the hospitals into deciles for each condition to determine the top performers, and we pay the incentives
10 separately for each condition. The five conditions that we're addressing are heart failure, community
11 acquired pneumonia, AMI, heart bypass, and hip and knee replacement. We have the results from years one
12 and two and we're currently working through the results on year 3 and doing our evaluation of the first
13 phase of the demonstration. But during years 1 and 2, the average quality score improved 15.7% over a 3-
14 year period, from the base year through year 2. And the first year, we awarded \$8.9 million in incentive
15 payments to 123 top performers out of the, at the time it was close to 260 or so hospitals. A few hospitals
16 have dropped out and some others have consolidated. In the second year, we awarded \$8.7 million to 115
17 top performers. And when I say top performers, for the first phase of the demonstration, we were basically
18 awarding incentive payments of 2% for hospitals in the top decile, and 1% for hospitals in the second
19 decile, for each of the two years, and for each of the five conditions, and then in the third year, there is a
20 penalty for hospitals that are in the bottom two deciles, a penalty of 1% or 2% if they don't exceed
21 benchmarks that were established by kind of the bottom of the distribution in the first years. In the first year
22 of the demo. So if they don't get at least above the bottom, then they face a penalty of 1% in the second
23 from the bottom decile and 2% in the bottom decile. I'm happy to report that virtually all hospitals
24 outperformed at least that level. I think there might be a handful, as in fewer than a dozen that may face any

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1 penalty in that third year. But as I say, we're still calculating those results, but just based on preliminary
2 information, it's pretty small number.

3 In phase 2 of the demonstration, we've modified the incentive structure somewhat, and rather than
4 paying only for the highest 2 deciles, and no one else, in the interest of encouraging and continuing to
5 encourage efforts to improve, throughout the distribution, what we've done is we've provided, we're
6 planning to provide incentive payments for all hospitals that exceed a mean from the baseline period for the
7 second phase of the demo, and that baseline is 2 years prior, and we'll reserve 40% of the funds that we're
8 using in this demonstration to pay those incentive payments, but then the remainder is divided between
9 additional payments for the highest attainers those in the top 2 deciles, and that will be another 30% of the
10 funds available for the demonstration, and then finally for those who make the highest improvement, as
11 long as they've exceeded that mean baseline, we're interested in rewarding those hospitals that have
12 increased their performance the greatest, or had the highest degree of improvement in their quality scores.
13 And as I say, the goal there is, the goal overall is to spread the incentive payments more widely and to
14 promote efforts in improvement throughout the distribution and not have it just be those hospitals in the top
15 2 deciles and to reward the highest levels of improvement for any organization that does exceed the
16 baseline performance.

17 Some of the lessons learned to date, as we see them are that value-based purchasing can work.
18 What we have seen and what the hospitals participating in this demonstration have told us, is that it
19 provides focus for the hospitals on quality improvement efforts and that the incentives make a difference.
20 We're also finding that modest dollars can have big impacts. I think that the largest incentive payment to
21 one of the larger hospital, and one that had highest performance in the first 2 years in all 5 conditions, was
22 on the order of half a million dollars. It may be a bit more than that. But in the scope of its overall
23 payments, it's a fairly modest amount, but we believe these modest amounts are having big impacts. We're
24 seeing continued improvement year over year, and what we're also seeing and again, more anecdotally
25 what the hospitals are telling us is there's a very important spillover to overall quality and not just teaching

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1 to the task if you will that hospitals making improvements in one area that some of the kinds of changes
2 that they're making in order to improve performance in a specific condition is, there is spillover to other
3 conditions. That's been particularly true in the surgical area, where certain of the measures around pre- and
4 post-surgical antibiotics and so on, are spilling over not just, spilling over beyond the conditions that we're
5 measuring for to other conditions throughout surgery. And I think there's some areas along those lines that
6 have been described.

7 Some of the value added is we believe this demo's allowed us to do a proof of concept that's been
8 useful in the development of the agency's proposal for national value based purchasing program and our
9 report to Congress on a hospital value based purchasing program, was I believe, released in the last 2 weeks
10 and is available on our website, and I'm sure lots of other places. And then we also have learned that the
11 demonstration hospital's improved care and reduced morbidity and mortality for thousands of patients. As I
12 say, our formal evaluation is still underway, and we're hoping to have it out later this year.

13 The second two demonstrations that I'm going to talk to you about, I think I mentioned that last
14 time, I was here, and I'm not even sure when that was, about, that was half a year ago or a year and a half
15 ago. But in any case, both of these are now up. They weren't both at the time. The physician group practice
16 demonstration and the Medicare care management performance demonstration. And there are certain
17 similarities between these 2 demonstrations in terms of what we're measuring, but in terms of payment
18 models and the types of physician practices that they're aimed that's very different. On the physician group
19 practice demonstration, which started in April of 2005, is focused on large physician group practices. This
20 was mandated by the Benefits Improvement and Protection Act of 2000. As I say, it's focused on large
21 group practices; 200 or more physicians are what we were aiming for when we were soliciting participation
22 in this. The goal was to encourage coordination of Medicare Parts A and B services, to reward physicians
23 for improving quality and outcomes, to promote overall efficiency and delivery of care, and to identify
24 interventions and care management practices, that yielded improved outcomes and savings. The design is
25 such that we pay these practices on an ongoing basis under the regular Fee for Service system. We did not

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1 specific particular models we wanted the practices to test or use, we really gave the physician practices as
2 much flexibility as they wanted in terms of redesigning care processes, delivery design, organization and so
3 on to be able to achieve outcomes but our focus has been on performance on 32 quality measures and on
4 growth rates, comparing the growth rates of patients in these practices to the growth rates of other patients
5 in the local markets served by these practices. And to the extent that growth rates for the physician group
6 practices are more than 2 percentage points less than the growth rates for the comparison group population,
7 then the performance, the savings derived from that difference are shared with the group practices, partly
8 on the basis of the efficiency on just having achieved the savings, and then partly on the basis of their
9 performance score with respect to the quality measures. And the quality measures, there are lot of them, 32,
10 as I mentioned, are being phased in over the 3 years of the demo. So the first year, we were focusing on 10
11 measures around diabetes care, the second performance year, we added a number of measures, I think 7 to
12 12, maybe 12 measures for heart failure and for coronary artery disease, and then in the third year, we've
13 added measures for hypertension and some prevention measures, part of the overall population.

14 On the 10 practices participating in this demonstration, represent 5,000 physicians and about
15 almost 225,000 assigned Medicare Fee for Service patients, and when I say assigned, we attribute patients
16 to practices based on where they receive the bulk of their ambulatory E&M visits, in this case dollars,
17 actually. So these are the practices, wide range of locations from across the country, some significant
18 presence in rural areas, which I think is interesting and also valuable experience. And then a number of
19 different models, including a faculty physician group, but also an IPA, that has been used where the IPA is
20 really working with, I think, it's about 70 small practices, and the IPA basically serves as the organizational
21 entity that we interface with so it eases the, it's been easier to manage this demonstration and have an entity
22 that's doing a lot of, it's already doing contracting work, but it's also doing a lot of the educational work
23 around the data collection, the use of the measures, and so on. And then data are aggregated across those
24 practices. And that's Middlesex Health System is the IPA model.

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1 As I mentioned, we assigned patients to the practices based on where they received the bulk of
2 their care and then we compare those patients year over year growth rates, to the year over year growth
3 rates of other patients, not seen by those practices, but in the same market that the practices are drawing
4 their patients from, and we share up to 80% of the savings. The savings are divided between, as I
5 mentioned, the 80% that's under the white space in each of those bars, is divided between quality
6 performance and the mere existence of savings, and the quality component is rising over time from 20% of
7 the 80% to 40% in the third year. And the savings are capped at 5% of total Medicare A and B expenditures
8 for this population.

9 The 32 measures that we're looking at are shown here under each of the conditions where we're
10 measuring; diabetes, heart failure, coronary artery disease, and then hypertension and cancer screening.
11 We're currently in the third performance here, and we are in the process, in the actual operation of the third
12 performance year. We're in the process of calculating savings and performance payments for the second
13 performance year, and the first performance year, we reported on results last summer. All 10 groups
14 improved quality relative to their base year on all 10 diabetes measures. Two of the groups saved more than
15 2% and therefore shared in savings. Six of the 10 groups' expenditures grew between 0 and 2% lower than
16 the comparison group, and so we hope that we'll see continued, a continued gap between their growth rate
17 and a comparison group such that we'll be able to share savings in a subsequent year. That 2%, by the way,
18 is a cumulative 2% over the 3 years of the demonstration. It's not 2% on an annual basis that they have to
19 be, so as I say, that's the reason that we're hopeful that the ones who grew between 0 and 2% will get cross
20 that 2% threshold this coming year.

21 And just in terms of some, just one quick summary of the results. On the left side of this slide, we
22 have the number of diabetes measures that had increased scores, and then for each of the practices, how
23 many of the measures they increased their scores relative to the baseline. And you can see that all of the
24 practices increased their scores on at least 4 of the measures, most of them on 7 or more measures. And
25 then on right side of the slide, the ten measures that we were collecting for diabetes, the number of

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1 practices that had increased scores during the first year. So you can see that for something like lipid tests,
2 all 10 PGPs, all 10 of the practices had increased scores for lipid testing. It's hard for me to read that
3 because of the slide ending, but 9 of them increased performance there we go, on pneumococcal vaccine,
4 and 9 of them on urine protein tests and so on. So we saw wide improvement across the PGPs and also
5 across each of the measures that we were collecting.

6 And one of the things that we're currently evaluating in addition to the overall performance, is to
7 really, is to look at this issue of identifying the interventions within the practices that yielded. The
8 improved outcomes and savings, because the PGPs had a great deal of flexibility in how they reorganized
9 care and other steps that they took. The analysis and the evaluation is a much more comprehensive type of
10 evaluation in trying to drill down and see what the relationships were between what the practices actually
11 did and what they delivered. And we think that that will be particularly valuable. A number of the practices
12 engaged in very formalized care management or disease management types of approaches internally, to
13 focus on diabetes care and also on heart failure care. We'll be looking at the relationship between patients
14 who were in there and growth rates of those patients over time, in those programs, within the practices and
15 other patients either within the practices with the same conditions, or patients outside of the practices to see
16 to what extent those were the types of intervention that yielded savings, or whether it was other things. And
17 some of the other things that the practices did were focused on care transitions and a lot of focus on patients
18 who were discharged from the hospital on doing follow up with patients who again hospitalized to ensure
19 that they were brought back into the practices shortly after being discharged from the hospital in an effort
20 to prevent readmissions. Some practices focused on end of life care and on working on referral
21 arrangements with [inaudible coughing] care programs in their local communities with hospices where
22 appropriate. Some of the other value added, as we see it, from this demonstration is that it has been helpful
23 in informing agency policy on a number of key issues related to development, related to measurement of
24 cost and quality for physician practices. It's helped us to develop operational models for collecting

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1 physician practice data on quality and efficiency that can be applied to program wide initiatives such as the
2 physician quality reporting initiative.

3 The Medicare Care Management Performance demonstration is at the other end of the spectrum
4 and is focused not on large practices, but on small practices, and this was mandated by § 649 of the
5 Medicare Modernization Act. It provides for paying for performance for MDs and ODs, who achieve
6 quality benchmarks for chronically ill Medicare beneficiaries and who adopt and implement CCHP
7 certified EHRs and report quality measures electronically. The demonstration is designed to be budget
8 neutral, is required to be budget neutral, so we will be monitoring it over the course of demonstration, in
9 order to determine whether or not adjustments in incentive payments have to be made to meet that budget
10 neutrality requirement. The goals of the demonstration are to improve quality. We're using the same
11 measures as in the physician group practice demonstration and to improve the coordination of care for
12 chronically ill Medicare beneficiaries, and it's also to promote adoption and use of health information
13 technology by small and medium-sized physician practices. So in addition to whatever incentive payments
14 we'll be making for quality performance, there's also an enhanced incentive for practices that report quality
15 data electronically to us over the course of the demonstration.

16 The demonstration is being conducted at about 700 primary care practices. About 2300 physicians
17 were initially enrolled. We've had a little bit of attrition. The practices are in 4 states; Utah, Massachusetts,
18 California, and Arkansas. And when I say a little bit of attrition I think we're down to about 680 practices.
19 Some signed up and when they realized they actually had to do something like report data to us, they
20 decided they weren't so interested. But the others are and I'm actually happy to report that we've been
21 collecting baseline data for the practices. I mean we have baseline data from more than 90% of the
22 practices in at this point, and most of the slowdowns in collecting that data, which still has to be in a couple
23 weeks ago, were actually in our systems rather than on the part of the practices. You can see the breakdown
24 the practices here in terms of size, so again, the bulk of the practices were as intended under 10 physicians.
25 For the first year, the data that we're collecting now, there's an initial pay for reporting incentive for

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1 reporting baseline data and those incentive payments max out at either \$1000 per physician, or \$5000 per
2 practice. After the baseline period, for each of the 3 years of the demonstration will be Pay for Performance
3 incentives, which can go from, they can rise up to \$10,000 per physician or they cap out at \$50,000 per
4 practice. And an annual bonus for electronic reporting, which I mentioned previously, this added incentive
5 is basically upping the Pay for Performance payment by 25% for those practices that report measures
6 electronically. It can be up to 25%, it's basically tied to the number of measures that they actually report
7 electronically. The practices have to eligible for quality bonus in order to get the electronic reporting bonus
8 so that electronic reporting bonus can be up to \$2500 per physician per year up to \$12,500 per practice per
9 year so as you can see, over the 3 years, on the maximum total payments, counting the first year, the initial
10 pay for reporting or baseline Pay for Performance, in the 3 years of performance, is up to \$38,500 per
11 physician, or \$192,500 per practice. As I say, the demonstration started—I guess I didn't say it, but it has
12 started. It started July 1st of '07 and we've collected data from 90% of the practices. What we've learned
13 about this demonstration that I think has been particularly valuable as we think forward to other
14 demonstrations including the 2 that I'll be talking about next, are that with respect to smaller practices, I
15 mean they truly do have very limited resources in the way of staff and time. When somebody's out, they
16 miss, when somebody's out sick, the practice may not be able to participate in web access or other training
17 sessions that we've scheduled for how to use the quality tools or for other aspects of the demonstration.
18 And that makes it particularly challenging to deal with these small practices, either on our part in terms of
19 having to schedule multiple opportunities and hope that the same folks don't miss multiple times, or
20 practices dropping out, and that may for all I know, and I don't know that we've determined this, may be
21 some of the reason for some of the attrition with the few practices that have dropped out. Smaller practices,
22 as we know already, have limited IT experience, and need much more assistance, much more hand holding,
23 just walking through some of the steps. Registering for the data system that we use, the secured data
24 transmission system has taken a lot more effort on their part than they anticipated, I think, or than we
25 anticipated, and so we've worked through a lot of those steps. We'll be in better shape the next time we do

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1 something with small practices, but until you actually do it you don't know how well things could work.
2 Our secure transmissions with QIOs and hospitals and other entities how all those work when moved down
3 to the level of a small practice.

4 And again some of what we see is the added value here in this demonstration is that it has
5 established foundation and platforms for implementing some of our other physician demonstrations, which
6 I'll be talking about and then again, using the lessons from this as well as the physician group practice
7 demonstration to shape some of the value-based initiatives for physician services under Medicare.

8 The Tax Relief and Healthcare Act of 2006 mandated the development of a Medical Home
9 Demonstration § 204 of the Act, a medical home demonstration designed to redesign the healthcare
10 delivery system to provide targeted, accessible continuous and coordinated family centered care to high-
11 need populations. And that's language directly from the statute. The demonstration is again, these are some
12 of the key parameters from the statute: is expected to last for 3 years, to be conducted in 8 sites, urban, rural
13 particularly underserved areas, it's centered around the concept of a personal physician. I'll talk a little bit
14 more about that in a moment, with monthly care management fees paid to the practice, plus shared savings,
15 above and beyond to the extent that there are savings above and beyond those fees that are paid in advance,
16 then those savings would be shared, similarly to the Physician Group Practice demonstration, it's focused
17 on high-need patients, especially those with multiple chronic conditions. In the Medical Home definition, in
18 the statute is a physician practice responsible for targeting beneficiaries for participation, for providing safe
19 secure technology to promote patient access to personal health information, for developing a health
20 assessment tool, and for providing training programs for personnel involved in care coordination. The
21 personal physician, in the context of the statute, must be board certified, must provide first contact, and
22 continuous care for individuals under his or her care, must have the staff and resources to manage
23 comprehensive and coordinated health care for each individual, must perform medical home services, and
24 may be a specialist if that specialist is really serving in this context. Medical home services and there's
25 quite of bit of detail in the statute, include ongoing support oversight guidance to integrated cost discipline

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1 plan of care, developed in partnership with patients and all other physicians furnishing care to them, and
2 other appropriate medical personnel or agencies. Evidence-based medicine and clinical decisions support
3 tools to guide decision making at point of care, based on patient specific factors, health information
4 technology to monitor and track health status of patients, and to provide patients with enhanced and
5 convenient access to services and encouragement of patient engagement in the management of their own
6 health, education and support systems. And I think that's quite a menu. We'll come back to that when we
7 discuss the questions.

8 The electronic health records demonstration is the last demonstration I wanted to touch on. Some
9 of you may have heard about this. There's been a fair amount of press since the Secretary announced this
10 on a recent trip to Cincinnati, Ohio. It's the Secretary's initiative. The goal is to support the President's
11 Executive Order and encourage adoption of electronic health records by small physician practices. This is
12 the President's Executive Order to promote across all federal agencies and programs, the adoption and use
13 of electronic health records that are CCHT certified. CCHT is the Certification Commission for Health
14 Information Technology. And will provide for standards for interoperability of such health technology. The
15 demonstration is also intended to be an opportunity for private payers to align with the Medicare model,
16 including chart or value exchange or better quality initiative locations, but other avenues as well for private
17 payers to align their incentives with ours and be able to ideally kind of tilt the scale, or reach a tipping point
18 toward adoption of electronic health records by small physician practices. The demonstration is expected to
19 last for 5 years. And we'll be recruiting up to 2400 practices in up to 12 sites, randomized into intervention
20 and control group practices, for purposes of demonstration design and being able to evaluate the results. It's
21 modeled in many ways after the Medicare Care Management Performance demonstration and platforms.
22 We'll be using the same quality measures. There will be a bonus for use of CCHT certified EHRs, but
23 rather than just for using those EHRs for reporting quality and getting a bonus, the bonuses here will be tied
24 to greater functionality, and will be assessing the degree to which practices are using what functions in an
25 EHR and the more sophisticated or more aggressive use they make of EHRs then the greater the bonus on

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1 top of the quality payment, but again, the quality payment will be the most significant component of
2 incentive payments in this demonstration. But the quality-based, the actual performance-based payments
3 don't actually start until the 3rd year. Our plan right now is that in the first year, the practices can be in the
4 demonstration and if by the end of the first year, they're using the EHR for certain core functions, as yet to
5 be determined, then they would get a modest incentive payment for that. If they don't have things in place
6 by the end of the first year, they can stay in the demo through the end of the second year, but by the end of
7 the second year, they both have to be using those minimum core functions and reporting quality metrics to
8 us. If they can't do those, then they won't continue on into the third and subsequent years of the demo,
9 starting as I say, in the 3rd and subsequent years of the demo, will be a performance-based payment and an
10 added bonus, based on EHR functionality.

11 And I think that covers it. We don't know the sites of the demonstration yet. We're not quite sure
12 how we're going to go about identifying and selecting those sites, but I spend a lot of every week having
13 conversations about just those issues, among several others. So this is kind of what we know about the
14 electronic health records demonstration to date. And everything I've told you is subject to change.

15 [laughter] The Medical Home Demonstration is subject to change, too, because in the legislation that was
16 passed by the House and I guess the Senate is doing a mark up this week, there is an improved expanded
17 Medical Home demonstration which would supersede the one that we're working on, but delay it all by a
18 year. And would add some bells, whistles, and so on. So I know we'll be implementing, or designing and
19 implementing some sort of medical home demonstration, but as I say, that's subject to change depending
20 on what Congress decides to do. And with that I think we can turn to the discussion questions.

21 Dr. Ouzounian: Thank you, Ms. Magno. Questions or discussion from the Council.

22 Dr. O'Shea: Ms. Magno, thank you very much for your presentation. I had asked at our last
23 meeting to actually have a little bit more feedback to the Council on demonstration projects, and I
24 appreciate your presentation very much. If I could, I had a specific question on slide 17, and this concerns
25 the Physician Group Practice results, the first year result. I see from a prior slide that your processes and

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1 outcome measures showed improvement in care, but I have some questions on what the feedback from the
2 groups themselves were as far as expenses that it took for these practices to achieve the 2% increases. All
3 10 groups improved quality as far as what was related, it says. Two of the 10 groups saved greater than 2%
4 and shared these savings. So we get a 20% improvement as far as the reimbursement for these groups. It's
5 the next line I really questions on. Six of 10 groups' expenditures grew between 0 and 2% lower than
6 comparison groups. So I got, 60% grew between 0, which is nothing, and 2% lower. Can you just interpret
7 that for me?

8 Ms. Magno: Sure. It's shorthand. The savings model that we're using the Physician Group
9 Practice demonstration is that we're comparing the Medicare per capita expenditures, risk adjusted, on a
10 per beneficiary basis, for patients assigned to a physician group practice, a particular one, to the year over
11 year growth of a comparison group of patients, those not seen by the group practice, but from the same
12 market area.

13 Dr. O'Shea: OK, so that was outside of these ten groups?

14 Ms. Magno: Right. So we take an area like Geisinger service area, and we've got everybody who's
15 seen by Geisinger and is assigned to Geisinger because they received the prevalence of their ambulatory
16 E&M care at Geisinger, and then we look at everybody else in the same counties that Geisinger draws its
17 patients from. So central Pennsylvania, who's not seen by Geisinger, not even a little bit. We drop anyone
18 who's touched by Geisinger at all, in order to have two distinct groups, and we compare their growth rates,
19 year over year. To the extent that the Geisinger patients' growth rates are more than 2% less than the non
20 Geisinger group's growth rates, then Geisinger shares in the savings. And the 2% so that the 2% is really
21 designed, given the way, given, I mean they're kind of the statistical, there could be that much variance
22 statistically in year over year costs, given the variability of Medicare expenditures and in order to not be
23 paying bonuses or incentive payments on what can be some random variation in year over year growth, we
24 wanted to make sure that the growth was at least 2%, and then beyond the 2%, we share in the savings with
25 the sites. So two sites beat the 2% target in terms of keeping their growth lower than their comparison

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1 groups, by more than 2 percentage points; the gap was more than 2 percentage points. The other 6 groups, 6
2 of the other 8 groups, the gap is between 0 and 2 percent.

3 Dr. O’Shea: And again, statistics can be definitely a conundrum that between 0 is what I was kind
4 of benched at. But apart from just statistics, can you tell me that these 10 groups gave you feedback that
5 said that this not only, and this is really what I would want to know, that it improved their patient outcomes,
6 but that the expense that was carried by the physician groups was reaped back from doing this. So only 2
7 out of the 10 got the increase—

8 Ms. Magno: And began to reap anything back.

9 Dr. O’Shea: ...but the other 80% actually it cost them more to do these outcome data for you. And
10 do you have any other feedback for us from what the other groups said it cost them to do this? And was it
11 for them, good business practice?

12 Ms. Magno: At this point, but none of them have dropped out of the demo.

13 Dr. O’Shea: They haven’t dropped out.

14 Ms. Magno: No. They’re still in it and we’ve actually decided to go ahead and extend it for a year.
15 They would like us to share in the first dollar, if they need that 2% target, they would like to share
16 everything. That’s a position we’re not comfortable with and it was a condition of the, in the approval of
17 the demonstration that we not share that first 2%. I mean the groups feel, and I understand their position
18 that they’ve made an investment in redesigning care and in changing the way in which they practice, and in
19 focusing on quality improvement and so on, but they believe that that investment will eventually pay off.
20 And we hope that it will, for all of them, and as I say, I mean they have up to 3 years to beat that 2% and
21 then the amount at which they can share is quite significant, because they can share up to 80% of that
22 difference once they hit that 2% and that’s, I think a very important aspect of this. And we hear a lot from
23 the groups, asking them to consider eliminating the 5% cap and since nobody’s reached it yet we don’t,
24 we’re not too worried about it. We’re more concerned about seeing hopefully all the groups beat that 2%
25 threshold to begin with and be able to share in some savings. Our goal also is to really get a sense from the

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1 groups and from our evaluation of what particular aspects of what they did led to savings, because as I'm
2 sure all of you are aware, we have lots of people in CMS who can figure out—if we know what that what is
3 that we want to pay for, we can figure out a price to pay for it. I mean the shared savings model is not
4 necessarily a model we would carry forward programmatically. It's very complex, it's very resource
5 intensive. It's retrospective—you got to wait for a long time to get all the data in to be able to then turn
6 around and figure out who gets paid what. It's not the way one ideally designs incentive structures or
7 anything else, but it was a way in this case to find some groups that were willing to make investments that
8 they thought were worth making, basically to put their money where their mouths sometimes are. And see
9 what happened, without it costing the program, and putting the program in a position where it's paid on a
10 prospective basis for services that wouldn't necessarily have paid off, and so we think from that standpoint,
11 we'd like eventually to be able to figure out what it is—what are the things that may be worth paying
12 additional for, differently for, in the program to yield these same kinds of results on a broader basis, and
13 where you don't have to rely just on very large groups and so on.

14 Dr. O'Shea: I look forward to hearing more from you when you get more data on that.

15 Ms. Magno: We're looking forward to getting more data, too. So.

16 Dr. Grimm: On the Medicare Care and Management Performance payments. There is a curious
17 way of pay per physician, but then also there seemed to be a cap that you placed on the practice, which
18 would seem to be a disincentive for a larger practice to participate. Can you explain why you would make
19 a—like a 10-group practice would be paid less in this scenario, than a 5-group practice per physician.

20 Ms. Magno: That is true and part of the reason for that is to the extent that, I mean this
21 demonstration evolved over a long period of time, but to the extent that some of the payments were really
22 intended to provide some return on investment for practices that were adopting health information
23 technology, that's really a process wide expense, and doesn't necessarily grow continuously with the
24 number of physicians. So based on some work that the Bridges to Excellence program had done, and we
25 had done some work with Bridges at the point, at the early point at which we were developing this

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1 demonstration. I believe that they were capping things at a practice level. We found it practical to do so just
2 in terms of the incentive structure, and in terms of the dollars we had to work with and our expectation of
3 what we might see returned in savings from practices of this size and with the numbers of patients
4 involved. That's something that can certainly be looked at again more broadly, programmatically. I think
5 some of it depends on what we think we're paying for, but because some of this was focused on systems
6 costs that occur at a practice level, and are not continuously increasing with the number of physicians, we
7 simply decided—

8 Dr. Grimm: But isn't there time and expense for each individual patient, each one of these things
9 get reported and isn't that how some of these payments get determined?

10 Ms. Magno: Well, it's not the time and expense of reporting the quality data. I mean the practices
11 are still getting paid Fee for Service for whatever they're doing to patients, and so and we've come up with
12 a reporting tool that has been a fairly well accepted and easily used tool. As I say, we've collected baseline
13 data from 90% of the practices, with very little concern, or confusion, or questions expressed about them.
14 So it's really more a matter of as I say, the fact that some of the demonstration has some of its roots in the
15 notion of helping to incentivized the adoption and use of health IT and giving practices something of a
16 return on their investment for health IT.

17 Dr. Bufalino: Ms. Magno, one other question. A lot of these are obviously disease management
18 oriented programs that are physician-based. The one demonstration you didn't cover today was the
19 industry-based demonstration program, they used to call it chronic care improvement. I know there's some
20 new set of initials for it now. Do you have any comments on that or is that something that someone will
21 bring back to us in the future? It's that eight-site—

22 Ms. Magno: Right, it's a Medicare Health Support program, is the way CMS branded it. And it's
23 being operated out of another component rather than the demonstrations group.

24 Dr. Bufalino: Oh, OK.

25 Ms. Magno: So I'm sure that...

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1 Dr. Bufalino: Thank you.

2 Dr. Ross: As Dr. Grimm mentioned, in the future for Fee for Performance, if a larger group is
3 looking at their reimbursement, or they're looking at their incentive conditions, then it would seem again,
4 I'm going back to his point, that the smaller groups are probably going to be incentivized a lot better than
5 the larger groups. So in terms of Fee for Performance, the question is going to be what kind of formula will
6 you derive, or if this is going to evolve after the demonstrations take place.

7 Ms. Magno: I'm going to turn it all over to Liz and her folks, because if something goes beyond a
8 demonstration then a lot more people that I weigh in and there's a lot more that has to be considered doing
9 something at a program level. But you know we're testing a variety of things. They're not, we don't
10 pretend that any of them is the be all or end all, is really necessarily perfect, is really for us an opportunity
11 for us to test a variety of mechanisms and to see what happens with those, and again, this demonstration
12 was really designed to deal with small groups so that the average size of the groups in this demonstration is
13 3.3 physicians. So a handful, so a relatively small proportion of the groups will even be affected by that
14 5%, by the 5-physician cap and that was the goal in terms of the target audience—

15 Dr. Ross: You try to keep the groups small, and then obviously—

16 Ms. Magno: Well, it's the area where there's the most concern, because other groups, you know,
17 the large physician groups, for example, in our physician group practice, some of those sites already had
18 electronic health records, or they were well on their way to getting them. But the lowest rate of adoption is
19 in the area of the solo practitioners, the small, the under five, the under ten groups, and yet a great deal of
20 care is provided by those practices, so the real goal is to get those practices to move, and if we're not going
21 to get them to move to be big practices and therefore all the advantages or infrastructure or whatever, not
22 that anyone's pushing them, not that I'm saying that, but if they're not going in that direction, for whatever
23 reasons, their own market structure and so on, if they're going to be small practices, then what does it take
24 to move small practices, and so the demonstration's really designed to focus on what it takes to move small
25 practices.

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1 Dr. Ross: But I think if you looked on your tables and you looked at how time intensive all these
2 stipulations with these conditions are, the question is how much more time does it take for that individual
3 practitioner to mete out those standards for that kind of care. And is that creating an additional burden in
4 terms of time intensiveness per patient, per 15 minutes, per 30 minutes slot in that practice, and for the
5 small practitioner, maybe so. But again, for the multi-specialized group, or for those groups that have
6 greater numbers, how much more time is it going to take and will it cost them more in terms of giving that
7 care versus reimbursement in the final analysis?

8 Ms. Magno: Well, and that's something that we'll have to look at. I mean we don't pay physicians
9 on the basis of their costs per say, and we're not necessarily looking exhaustively at their costs, but we are
10 finding that we've got lots of interest in participating in these and very little push back on either the number
11 of measures that we're looking at, or on the appropriateness of the measures or on whether or not by
12 delivering care that meets these standards, we can achieve the improved outcomes, and hopefully improved
13 outcomes in terms of utilization of resources, hospitaliza—you know, unnecessary hospitalizations, or
14 avoidable hospitalizations, avoidable ER visits and so on, that can allow us to reap some real benefits. And
15 if we begin to see those kinds of things, then we can potentially revisit the incentive structure, or other
16 aspects of the payment system, but I think at this point, the real reluctance on the program's part is to pay
17 more for something that's not necessarily a value, and to figure out what it is that generates the kind of
18 value that's worth paying more for. I keep saying part of what we're interested in with the large physician
19 group practices is kind of what's the what? What's the what that they're doing that allows them to achieve
20 these efficiencies, and that's part of what our evaluators are focused on as they look at the first and second
21 year results.

22 Dr. Arradondo: Thank you, Mr. Chair. I realize that we're over time, but I do have a series of
23 related questions to your series of related demos. I'm hearing that you want the practices to have EHRs,
24 you want them to in one, to have a plan for the patient. You want them to have a certified EHR and you
25 have some bonus payments and some other fees kind of built in. I'm curious in your Medicare Care

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1 Management Performance demo, the second one that you referenced, one of the criteria was to adopt a
2 CCHT certified EHR?

3 Ms. Magno: No, it was not a requirement. All that we're asking there is in order to get an
4 additional bonus on top of the performance payments, the practices have to report data to us electronically.
5 It does not have to be through a CCHT certified EHR.

6 Dr. Arradondo: But to be eligible for the bonus, in fact, they would have to use that. How many of
7 these practices had EHRs before they joined the demo?

8 Ms. Magno: I can't tell you the answer to that right now.

9 Dr. Arradondo: What proportion really?

10 Ms. Magno: I actually don't know. We are conducting a survey. We have something called an
11 Office Systems Survey that's been used as part of the doctors' office quality information technology
12 program that we'll be conducting for the demonstration practices.

13 Dr. Arradondo: So are you saying that some of them may not have had an EHR at all?

14 Ms. Magno: And they may not have one still, and they don't have to have one in the Medicare
15 Care Management Performance demonstration, they don't have to have one. By the end of the second year,
16 in the new EHR demonstration that we're still working on developing, they will have to have one by the
17 end of the second year to continue on into the 3rd year and beyond.

18 Dr. Arradondo: Have you determined what the cost might be to install an EHR, one that would
19 have the basic capability to win some of the bonus, or perhaps have the capability to do the additional
20 functionality that you want? Had you determined the cost of installing that, in say, the average practice?

21 Ms. Magno: I have not. There've been discussions about that and I just don't know the details
22 there. I mean there's a whole team of people in both the office of the National Coordinator for Health
23 Information Technology. Elsewhere in the office of the Secretary and in CMS, who are talking about these
24 kinds of issues in terms of what the potential for adoption is and what some of the costs associated with
25 adoption are. But I'm not familiar with the costs of those products, and the products themselves are

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1 changing, what's out there is changing even in response to the existing Medicare Care Management
2 Performance demonstration, some of the vendors that are out there marketing EHRs are trying to make sure
3 that they are developing tools that can easily produce the measures that we are collecting, even though, the
4 CCHT standards for reporting quality metrics have not yet been developed and so on. And we're very
5 sensitive to these issues; one of the points that we've tried to make in fact is if at a certain point, within the
6 framework of the demonstration, someone has a CCHT certified EHRs just because a new version, an
7 upgrade with additional functionality or additional standards for interoperability or reporting or what have
8 you comes out the next year doesn't mean we expect every practice to upgrade within that time frame,
9 because we all know how disruptive upgrading software can be. As somebody who refuses change
10 computers because she doesn't want to deal with whatever the new windows thing is [laughter]. We're
11 sensitive to these issues and the disruptions they can cause.

12 Dr. Arradondo: In a sense you raise one of the issues that someone willing to provide a Medical
13 Home has to consider; do they keep up with the latest iteration of computer technology, Q18 months,
14 maybe it's down to 12 or 10 by now, don't know, but the turnover for computer technology, just use
15 computer as a word for a lot of other things, that they would spend a lot of time doing that, as opposed to
16 say making comprehensive plans for the Medical Home healthcare provision of a particular family or a
17 particular individual.

18 Ms. Magno: We understand. I mean I will point out that the Medical Home, the requirements that
19 I laid out here for Medical Home are statutory requirements. The new legislation that the House passed that
20 the Senate may or may not, I don't know what will happen with it, but the expanded enhanced Medical
21 Home has 2 different, recognizes 2 different types of Medical Homes. One would be health IT enhanced
22 and one would not and it separates the requirements so there isn't a presumption that there would be health
23 IT in all practices serving as a Medical Home. We haven't yet determined with respect to the existing
24 legislation whether there's a way to interpret that such that all practices don't have to have CCHT certified

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1 EHRs. And we're at, we're still in the early design phase for that demonstration. But as I say, some of those
2 requirements are Congressional and we have limited flexibility in terms of what we can do with them.

3 Dr. Arradondo: But as I understood, and I'm not an expert on that particular one, but I remember
4 being briefed on it a couple of times and asking the same question. I thought they were saying that you
5 should move toward a Medical Home using some criteria, of the kind of beneficiary, for instance as well as
6 the kind of site of service, so that you had options for small sites as well as for large sites and not limited to
7 one kind of technique to achieve a competent Medical Home. I thought they just gave you a few things to
8 do, not all the things that you should or shouldn't do. So I thought you had more leeway than I'm hearing
9 you say you do.

10 Ms. Magno: I'm not sure. We have not sorted out yet with as part of our design process and as part
11 of sitting down with the attorneys how much flexibility we have within that language, to say that a Medical
12 Home doesn't have to meet all of the requirements laid out in the statute. One of the problems when
13 Congress decides to design demonstrations is that sometimes it makes them more complicated than we
14 might be inclined to do, recognizing that everything they put in with an "and" gives us much less flexibility
15 than things they put in with a lot of "or"s.

16 Dr. Arradondo: Sure, sure. Well, but Medical Home is not a new concept, so—

17 Ms. Magno: No, it's not but Congress is busy doing a lot of things to it.

18 Dr. Arradondo: Well the reason I raise the question is because all of these are related, and if
19 Medical Home, I realize that the one maybe most confounding variable in the Medical Home is to put it in
20 family-centered care to high need populations. I mean who is concerned about high need populations?
21 Much less, family care? Family-centered care in our system? So that, it seems to me your most formidable
22 requirement that Congress has put in. But there are some people who are in fact focused on family-centered
23 care in high need populations, so even that most formidable obstacle is not entirely without experience and
24 knowledge and data bases. So I'm just wondering how much of the other demos would inform the Medical
25 Home demo because it potentially is your most difficult one—

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1 Dr. Simon: I'd like to interject here—at this time I think we certainly, the Medical Home demo is
2 one that certainly is of concern not only to the medical community, but to CMS as well, and I would
3 envision that in 2008, and either the first or second meeting of the year, we will be able to have an
4 expansive discussion on the Medical Home. CMS has been working with both ACP and AAFP and other
5 stakeholders in creating the framework for the medical home, and as Ms. Magno has articulated during her
6 discussion, it is a work under that's in progress, and we do want to engage the Council for its input because
7 this demo will come before both the CPT and RUC editorial panels so that we would want to get the input
8 of the Council as well. So I would envision that either at the March or May meeting, we will want to have
9 an expansive discussion on the Medical Home so we'd be able to gather all the points that the Council
10 would want to raise to provide the agency input as well as with the input that it would receive from all the
11 other specialty societies to create this framework that would be implemented in October of '09, as I
12 understand it's currently, or January 1 of '09.

13 Ms. Magno: It's January or later.

14 Dr. Arradondo: It could be very useful, too, I think to bring it here, prior to publishing in *Federal*
15 *Register*.

16 Dr. Ouzounian: They can bring it back to the agenda and we need to move on, Dr. Jordan. I think
17 we can address comments to Ms. Magno by email, I believe. Is your email in your presentation?

18 Ms. Magno: Yes.

19 Dr. Ouzounian: OK, so we can address comments to her there or if appropriate, it will be put back
20 on the agenda—

21 Dr. Simon: Well, it was always planned to be on an agenda for '08, but in discussing in my
22 conversations with Ms. Magno, I wanted her to provide a brief overview of the Medical Home so that it
23 would serve, give you food for thought, so that when we come back in the next meeting or two, everyone
24 will have had an opportunity to think about it, talk with their respective specialty societies and then when
25 we discuss it, be able to share some meaningful information with us.

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1 Dr. Ouzounian: We need to move on Dr. Sprang.

2 Dr. Sprang: OK. Go ahead.

3 Dr. Ouzounian: OK, thank you. Thank you, Ms. Magno. Moving on to agenda item H, Dr. Rogers.

4 At this time we would like to direct our attention to the Physicians Regulatory Issues Team, the PRIT
5 Update. Dr. Rogers is Director of the PRIT in the Office of External Affairs. He is kind enough to address
6 the Council each quarter with the most up to date information, and as always we look forward to hearing
7 his latest report. Dr. Rogers.

8 PRIT Update

9 Dr. Rogers: Thanks Dr. Ouzounian. I want to reassure you you will be at lunch on time. [laughter]
10 You've seen the slides that for one reason or another we had a very limited number of issues this time, but
11 we do have some new cartoons and that's what you really are here for anyways. Unfortunately, the
12 projector's in the wrong place, but you've got your handout so you know what the...ACEP was very happy
13 that we put this cartoon on the slide.

14 We removed a bunch of issues just in the past month from our list of active issues. We normally
15 leave them up only for about 2 months, unless it's an issue that has real broad interest and so these are
16 really the sort of hot issues for us. We most recently got a report that Utah Medicaid, and we normally try
17 to avoid Medicaid issues, because they're much more difficult because of the shared responsibility between
18 the state and the federal government, but this really seemed to be a very legitimate concern. Utah Medicaid
19 decided that they were only going to use the '97 E&M documentation standards when they did audits, and
20 so if a practice was using the '95 guidelines, which is permitted by Medicare Regulations, then when they
21 were audited, they might very well find themselves in a difficult position and so we have had discussion
22 with Utah Medicaid, and actually Dennis Smith is engaged with State Medicaid Director to talk about
23 whether this is really fair to physicians who are trying to take care of Medicaid patients in Utah.

24 Simplifying the work of enrollment. Really has to do with the immense challenges that physicians
25 and other practitioners have had, particularly, I think in the last 6 months, with enrolling in Medicare or

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1 with changing their address or doing other things which require filing an 855. And we've gotten calls from
2 all over the United States, particularly, it seems lately, in California from groups that have had challenges
3 here and long delays in getting a functional provider number so they could begin to get paid for the care
4 that they are providing. And we're very enthusiastic and excited about the fact that the PECOS on line
5 version of PECOS is going to be live soon. It's in the final testing now, and I think once this is available
6 and physicians then can enroll, real time on line, with the system that will not allow for submission of the
7 application until all the fields have been filled in and the information at least seems to be consistent, will
8 reduce the amount of rework that has to be done by the carriers and by the physicians. There have been a
9 couple of other recent changes, one requiring that the carriers inform physicians within 14 days if there's
10 something that is required to process the application. And I think that was a very good requirement.
11 Unfortunately, we're seeing many times the address that the carrier has somehow doesn't end up delivering
12 that notification of deficiency to the physician who could address it and so it's a complicated sort of
13 moving target, and I think the online version of PECOS is going to solve a lot of these problems.

14 The third issue I am sorry to report, this has been over a year that we've been working on this
15 issue. We've got DOD involved, Health and Human Services, of course, Public Health Service, and it
16 seems that we've almost reached a critical mass of lawyers involved with dealing with us, and that has
17 made it extremely laborious to come to a conclusion. I am told that in the very near future, within weeks,
18 we should have an official statement and hopefully that will address this issue, because there are a lot of
19 active duty military physicians who rely on moonlighting, both to maintain their skills and also to
20 supplement their income and I think that that's a very valuable role that active duty military physicians
21 sometimes perform in the civilian healthcare facilities.

22 CME provided free by hospitals. Anything that has Stark in it sort of frightens me, since I'm not a
23 lawyer, but the actual description of the statute and the references are on the PRIT website and the guidance
24 is pretty clear about what it is that hospitals are permitted to provide to members of their medical staff in

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1 the way of CME and so it's probably best if you just look at the website to get the exact wording and I
2 know Dr. Williams, I handed Dr. Williams a copy of that citation if you're interested in looking at it.

3 Finally Provider Enrollment and NPI. This was a question really that had to do with how small
4 sole proprietorships or LLCs dealt with issue of type I and type II NPIs and we were able to get appropriate
5 CMS staff to respond very quickly to this because obviously it was really important for these small groups
6 to know whether they needed a type II and so we were able to get an answer to that very quickly and post it
7 on line.

8 For some reason I thought this was just particularly funny. [laughter] I guess I don't have to read
9 the caption. So anyways, I look forward to your questions. We've got 5 minutes 'til lunch and that is still
10 my contact information, my email address, and my phone number.

11 Dr. Ouzounian: Thank you Dr. Rogers. Questions or comments for Dr. Rogers? Dr. Grimm?

12 Dr. Grimm: We talked about the brachytherapy sources being a PRIT issue. Is that not a PRIT
13 issue or will it be or how are we going to address that?

14 Dr. Rogers: I mean we're very interested in helping to explain the challenges that that presents to
15 physicians, particularly in your specialty. It's a very valid concern and so we'd like to be part of finding a
16 resolution to that if we can.

17 Dr. Grimm: Thank you.

18 Dr. Ouzounian: Thank you, Dr. Rogers.

19 Dr. Rogers: Thanks.

20 Dr. Ouzounian: Let's see, that will conclude the morning. We'll adjourn for lunch, and we'll meet
21 back promptly and start at 1:00.

22 Break for Lunch

23 Afternoon Session

24 Dr. Ouzounian: There's going to be a slight change in the format compared to what we've done
25 before. We will hear 2 presentations. We will then make our recommendations to CMS. We will then take a

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1 break. During the break, the recommendations will be printed and we will get them back at about the time
2 of the AMA presentation. And we will then finalize our recommendations after the AMA presentation. So
3 you need to be prepared to make your recommendations after the next 2 talks. And there will be the
4 opportunity to add something in if necessary after the AMA recommendations. But CMS would like us to
5 finalize the written recommendations before we leave here today.

6 OK, Item number J. Let's begin the afternoon portion of our meeting with our next guest, Mr. Don
7 Romano. Don is the Director of the Division of Technical Payment Policy in the Center for Medicare
8 Management. He joins us today to provide the Stark update and more specifically to outline the provisions
9 as they directly relate to physician practices and requirements under the Stark statute. I know we are eager
10 to hear the information Don has [to hear?] with us today. So with that, Don, would you please begin.

11 Stark Update

12 Mr. Romano: Thank you. I want to talk about 3 topics today and I'll try and move fairly quickly so
13 to leave time for questions. I want to talk about the phase 3 rulemaking initiative, the proposed physician
14 fee provisions that dealt with physician self-referral, and the DFR or the Disclosure of Financial
15 Relationships report on financial relationships between hospitals and physicians. The first topic, the phase 3
16 was the final rule that we published on September 5 is generally effective tomorrow. There are 2 exceptions
17 to that both related to the same topic; the so-called stand in the shoes provision, which converts what
18 formerly would have been treated as indirect compensation arrangements over into direct compensation
19 arrangements. That provision is generally not effective for arrangements that previously complied with the
20 indirect compensation arrangement exception, until the expiration of those arrangements. And that doesn't
21 matter whether it was an initial term of an arrangement or a renewal term. Those arrangements will not
22 have to comply until they expire. In addition to that, we recently published a very short final rule that
23 extends the period for one year for the Stand in the Shoes provision for compensation arrangements
24 between academic medical centers and physician organizations and between physician organizations and
25 section 501C3 Integrated Health [unintelligible] systems. Phase 3 rulemaking was a culmination of a

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1 rulemaking that began with a proposed rule in 1998. We had Phase 1 rule in 2001, and Phase 2 was issued
2 2004. Phase 3 is a comprehensive rulemaking. It did not add any new exceptions. It provided additional
3 clarity to existing exceptions and relaxed some restrictions in existing exceptions. Just briefly and notably,
4 I'll note that physician recruitment, rural health centers are now able to recruit physicians. We liberalized
5 somewhat the definition of hospital service area within that exception. Physician retention, another area
6 that we got an awful lot of comments on. There is now no need to have a written retention agreement, a
7 bona fide offer for the physician. What we heard was that a lot of physicians and the hospitals that they
8 plan on going to don't enter into such an agreement until it's too late for the existing hospital to try and
9 retain the physician. Nonmonetary compensation. We have not provided in response to comments that there
10 are potentially disastrous effects on not keeping really careful watch over the accounting. We've provided
11 for a, there's a provision where you can go up to 150% over the limits and as long as that is paid back
12 within the earlier of 6 months or the end of the calendar year, you will remain in compliance with the
13 exception. It's also possible to have one annual staff accretion event and that will not count towards the
14 limit.

15 Inter-family referrals, there's an additional means to calculate the test to see if there's nobody else
16 that's unrelated within 25 miles to treat the patient and that is we now provide for a 45-minute test. If it
17 takes greater than 45 minutes, you can refer without violating the provisions. Fair market value. This now
18 covers payments both to a physician and from a physician. Compliance training. You can now include
19 CME in the compliance training as long as the primary purpose of the training is for compliance.

20 Now under the Stand in the Shoes Doctrine that I spoke of earlier. The physician stands in the
21 shoes of a physician organization. Physician organization is defined as a physician, including a physician's
22 PC and that's something that we did in the phase 1 rulemaking is that we said that the physician and his or
23 her own solely owned PC are one in the same. A physician practice and group practice that meets the
24 requirements of 411.352. We have certain requirements for something to meet the definition of a group
25 practice, so we include not only those, but we also include other physician practices that don't meet that

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1 definition. As I said earlier, the effect of the Stand in Shoes provision is that physicians in a physician
2 organization will be deemed to have the same compensation relationship that the physician organization
3 has with the DHS entity. That basically means that the physician will have to meet a direct exception with
4 the DHS entity.

5 Already talked about the special effective dates and the final rule for AMC, so we can skip over to
6 the next topic.

7 Moving on quickly to the Physician Fee Proposals, we proposed changes on the following issues;
8 an anti markup provision for the technical and professional component of diagnostic tests, which we did
9 finalize. On burden of proof, an exception for obstetrical malpractice insurance subsidies. We already have
10 such an exception, but it's simply mirrors the requirements of the Anti-Kickback Safe Harbor that OIG has.
11 Restrictions on per Quick Lease Payments, period of disallowance, ownership or investment and retirement
12 plans. Provisions on set in advance, and percentage based compensation arrangements. Another variation
13 on the Stand in the Shoes and this one would mean that a hospital or other DHS entity would stand in the
14 shoes of a wholly owned subsidiary and have the same effect but from the top down instead of the bottom
15 up with respect to physicians. An alternative route for compliance, we hear all the time that Stark has
16 potentially disastrous consequences because it is a strict liability statute, there is no intent needed to violate
17 the provisions unlike the Anti-Kickback statute and that potentially innocent and inadvertent violations can
18 have huge effects when it comes to the number of claims that might be involved by the time that the
19 noncompliant arrangement is discovered. What we proposed is that if the parties to an arrangement are not
20 in compliance with a form or procedural requirement in that the noncompliance inadvertent and they meet
21 other types of conditions that we set forth, then that arrangement, nonetheless would be deemed to be in
22 compliance with that exception. What we also had a proposal on under arrangement, our practice thus far
23 has been to consider only the entity that is billing Medicare to be the DHS entity for purposes of the Stark
24 statute. The proposal would, if finalized, as proposed, would mean that both an entity that is performing the
25 DHS as well as the entity that bills for the DHS would be considered to be an entity for purposes of Stark.

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1 So for instance if a hospital and a group practice had a joint venture in which they owned an imaging
2 facility, the imaging facility would be a DHS entity as well as the hospital, in situation where the imaging
3 facility is doing the work and then the hospital's billing for it under arrangements.

4 Now the next topic, in office ancillary service exception, we did not make a proposal per se on
5 this. We sought comments as to whether we should make changes and if we decide that we think we would
6 want to then we would have to go out with the proposed rule on that. We got a lot of comments on this,
7 both for and against doing something to make changes to an office ancillary service.

8 I mentioned briefly before that we did finalize the proposal on the Anti-Markup provisions. That
9 all applied to the technical component and the professional component of diagnostic tests, if the billing
10 supplier ordered the tests, and if the TC or the PC were either purchased, or performed outside of the billing
11 supplier's office. So if it's performed outside of the billing supplier's office on a nonpurchase test, the Anti-
12 Markup provisions will apply, even if it's done in the office of the billing supplier, if it's a purchased test,
13 an outright purchase, the Anti-Markup will also apply. As I mentioned, we did not finalize the other
14 physician self-referral proposals, but we are actively working on them.

15 I'll move on to the 3rd topic now, which is the DFRR, the Disclosure Financial Relationships
16 Report. This grew out of something that we did last year with respect to the report to Congress and the
17 strategic and implementing plan, the DRA required us to study certain issues relating to physician and
18 specialty hospitals. And among the issues that we were required to study were whether the physician
19 owners had either disproportionate returns on their investment, such that for instance, they had a 2%
20 ownership in a specialty hospital, but received 3% or 4% of the distributions, and whether the investments
21 to the physician owners were truly bona fide. In order to get information for this study, which included a lot
22 of other issues as well, we sent a survey to 130 physician-owned specialty hospitals, and 320 competitor
23 hospitals. The survey was voluntary, notwithstanding that we have authority under regulations to compel
24 information concerning Stark relationships, because it asks questions that were outside the scope of Stark.
25 For instance, we had to ask questions concerning Medicaid treatment and different issues relating to

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1 uncompensated cares. There were 290 hospitals that did not respond to the survey. In the enforcement
2 section of the final report to Congress, we said that we would explore an annual disclosure process, to get
3 information related to financial relationships between hospitals and physicians. We indicated that we were
4 not going to limit our inquiry just to ownership or investment interest, but that we were also going to look
5 at compensation interest as well. So earlier this year, in May, we published a notice seeking comment on
6 the information collection requirement as required by the PRA, and we received comments from the AHA,
7 the Federation and a few other hospital associations. And in September of this year, we published a second
8 notice, which we revised the information collection, and the public had 30 days to comment to OMB.
9 OMB still has the package under review and will be discussing at some point the PRA aspects of this with
10 OMB. The comments to the OMB challenged our authority to collect the information as we proposed. They
11 are that we haven't complied with the PRA. And they also believe that the DRA directs CMS to capture
12 information only related to physician and specialty hospitals. Naturally, we have quite a different
13 perspective on those comments. Just dealing briefly with the mechanics of the DFRR, there are 8
14 worksheets altogether. The first one deals with hospital characteristics. On that first worksheet, it asks
15 questions related to ownership or investment information, and if there is not, are no physician owners or
16 investors, then much of the rest of the package can be skipped. In response to comments that we got on the
17 first iteration of the DFRR, we revised the information collection to capture both indirect ownership
18 relationships as well as direct ownership relationships. But we also did the same thing with respect to
19 compensation as well and 5 and 6 deal with payments to hospitals by indirect owners, and then investment
20 reconciliation. Then the last 2 worksheets deal with compensation. And again, we're interested in both
21 direct and indirect. Worksheet 7 deals with some of the more utilized exceptions, such as rental agreements,
22 personal service arrangements and recruitment, and then worksheet 8 deals with the other types of
23 arrangements. We have a cover note that we addressed to the CEOs and CFOs and we want to make sure
24 that this gets to the hospitals. There are significant penalties, as I'll mention in a minute, for not complying.
25 So we want to make sure that everybody does get the information collection and response to it. We have a

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1 confidentiality statement. We try to assure as best we can, that we do not intend to release this information
2 to the public, but rather we would release it only to the extent that we're required to do so by the Freedom
3 of Information Act, or by another law and the FOIA does have an exemption for confidential business
4 information. There is also a criminal statute the Trade Secrets Act that forbids us from releasing
5 confidential business information, except under some narrowly prescribed circumstances. So I just want to
6 assure people that this is not something that we plan on just handing out to the public. We think that most
7 of the information in fact that we get on this will be confidential business information. There is a process
8 for responding to the DFR. We'll post a list of the hospitals on our website, and contrary to what some may
9 have heard, we do not have such a list at this point in time. We intend to send the DFRR to 500 hospitals.
10 We'll email the DFR to the hospitals, except the small number which I believe is less than 10, for which we
11 don't have an email address, in which case we'll mail a hard copy. And then the hospital has 60 days from
12 that time to get it back to us.

13 As I said, there are potential penalties for not complying. It's up to \$10,000 a day. It's in the
14 statute in our regulations for not responding to a request for information. And we will review the DRFF,
15 but we will review it through a contractor that we have hired. The contractor will analyze it and if
16 necessary, the contractor will contact the hospital, request additional information. Where the contractor
17 believes there may be a problem, they'll send the information to us for review. Likewise if we believe it's
18 appropriate, we'll direct the contractor to forward the information to the appropriate program safeguard
19 contractor.

20 As far as the future goes, as we indicated in the report to Congress, we may engage in a annual
21 collection of information requirement, but we would like to get through the DFRR first. We would like to
22 evaluate that and see whether, depending on the results that we get, whether it makes sense to have an
23 annual collection and also we hope to be educated through the DFRR as to what that collection would look
24 like. And if we decide to do that, we would do that through a Notice of Proposed Rulemaking. And with
25 that I'm going to leave it now for questions.

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1 Dr. Ouzounian: Thank you, Don. Questions or comments from the Council members? Dr.
2 Bufalino?

3 Dr. Bufalino: Mr. Romano, I guess for many of us our first read of the Stark regulations back 8 or
4 9 years ago, were an attempt to balance fraud and abuse related issues, which I think it did a good job with.
5 The opportunity for patients to continue to have access and in environments where we could provide
6 efficient care, and as we've fast forward, it seems like the regulatory environment has gotten to the point
7 where it's now so onerous that most of us are spending multiples of 10s of thousands of dollars, on legal
8 fees, to have interpretation of this regulatory environment to a point that there basically are no
9 arrangements that hospitals can have with physicians any longer that seem to be within the guise of CMS,
10 and I guess we continue to be troubled by that and troubled by the increasing environment, where we know,
11 example is just in Chicago where you know you can't have it across the hall and you can't have it
12 downstairs, so these folks busted a whole through the ceiling so they put a stairwell between their upstairs
13 and their downstairs so they could be in compliance. And again, we're creating work arounds in different
14 environments because of this regulatory environment. I guess my long winded dissertation is about, you
15 know, do you see an end to this? We remain very concerned that this has gotten to a point that basically
16 physicians and hospitals sure can't be in relationships with each other any longer. We thought that we were
17 trying to instead of compete with our hospitals, work together with our hospitals in an environment where
18 we're trying to do cooperative things that are better for patient care and patient access.

19 Mr. Romano: Well, I believe that in the current regulatory environment, as well as the previous
20 one, and I really regard the current one as sort of a progression of what went before it and not necessarily a
21 sharp break in most instances, that there's still plenty of room for physicians and hospitals to have
22 relationships. I think to a large degree, the complexity of the rules is explained by the fact that there is a flat
23 prohibition in the statute, and then there are few statutory exceptions. Most of the exceptions have been
24 created by regulation. And so to the extent that we create additional exceptions to make more arrangements
25 possible, that adds a degree of complexity to the regulatory environment, as well as the fact that there are

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1 parties out there with their lawyers who look at things and say, well, we can't do this, but if we structure it
2 a certain way, there's no prohibition on us doing that, so that's what we'll do. And then 3 years, 4 years
3 after the fact, we'll look at that and we say, you know, that's really not what we think Congress intended
4 and so we need to address that, and a couple of the provisions in the Physician Fee Schedule are just that
5 type of reaction to what's going on in the marketplace.

6 Dr. Bufalino: The problem is that there aren't anymore this's. If at least, in the environment that
7 we've been in, basically almost every arrangement's been unraveled or in the process of being unraveled
8 and frankly our folks have not been able to come up with a single idea that fits within the regulatory
9 environment. And if that's the intent, I guess that's the intent. But you know from our perspective, at least
10 we can't see any clear avenue where you can have above board, clear clean relationships with your hospital
11 provider.

12 Dr. Romano: I guess we'll have to agree to disagree on that. I am in contact daily with a lot of the
13 practitioners, some of whom do have trouble structuring arrangements in terms of meeting the current rules,
14 or say, if you do finalize this proposal a certain way, we will have problems with that, but you know there
15 are plenty of other comments on the other side of that as well. You mention the fraud and abuse laws. And I
16 think when we regulate we do try and keep an eye on whether certain arrangements are abusive or
17 potentially abusive. At the same time, I think we also have to look at what Congress was doing when it
18 enacted the statute and say, is this type of arrangement really what Congress intended? And for example,
19 that was the genesis of our proposal under arrangements. Congress has a generally a prohibition on the
20 physician having an ownership interest, subject to some very few exceptions in the statute, and yet, if you
21 have a situation where the physician would not be able to let's say purchase an MRI facility and refer a
22 patient to that MRI facility, but now the arrangement is structured so that the hospital and the group
23 practice purchase the MRI facility or other, cardiac cath lab, or whatever, and then those services are billed
24 by the hospital, instead of the intervening entity, you've essentially gotten around the ownership
25 prohibition by doing that. Similarly there is a prohibition on ownership in part of a hospital, so if a

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1 physician can't have an ownership interest in part of a hospital that has a separate revenue stream, let's say
2 the radiology department, but yet the hospital could outsource that radiology department into an entity and
3 own it with the physician and the whole hospital exception is not going to apply to that. So some of our
4 proposals and we have gotten a lot of comments on that particular proposal, were aimed at trying to maybe
5 restore some of the arrangements to what we think Congress had originally intended. And I grant you there
6 is a lot of room for disagreement on that. We got plenty of comments that both supported that particular
7 proposal, as well as those that criticized it.

8 Dr. Bufalino: So what would the agency be comfortable providing advice to people who are trying
9 to structure relationships, take a look at them before they implement an opportunity that has to be
10 [inaudible]?

11 Mr. Romano: Well, we have a formal advisory opinion process, but beyond that, we talk to
12 attorneys all the time. It's a remarkably small world I guess out there in terms of the number of attorneys
13 that regularly work on physician self-referral issues. And you know, within the confines of what we can do,
14 we try and provide clear guidance on that. But sometimes the only we can do that is through something
15 that's more formal.

16 Dr. Bufalino: Thank you.

17 Dr. Snow: Yes, it's my understanding that this Anti-Markup Rule then will apply to group
18 practices at this time, or as of January first?

19 Mr. Romano: That is the effective date, correct.

20 Dr. Snow: No exceptions, but you are working on that?

21 Mr. Romano: We are, the effective data is January 1st. We've gotten a lot of questions concerning
22 what does it mean to be in the office. A common question is well what is we have an office on the third
23 floor, but the imaging part of the business is in the basement? Or what if we owned the entire medical
24 office building, or we leased the entire medical office building and we have offices spread throughout
25 there, which is the offices—is it this one? Is it some of them? Or is it all of them for purposes of this? So all

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1 I can say at this point is that we are aware of those questions. We've gotten a lot of those from various
2 practitioners across the country, and we may be issuing some guidance on that.

3 Dr. Snow: Prior to January 1st?

4 Mr. Romano: I think if we decide to issue guidance on that, we'll do our best to get it out before
5 January 1st.

6 Dr. Sprang: Just continuing on the Anti-Markup, in provision where it says TCMPC, if the billings
7 player order the tests, exactly what are you including in diagnostic tests? Is that just MRIs and ultrasounds,
8 and stuff, is that blood work? What is diagnostic tests mean?

9 Mr. Romano: It's basically everything that's paid under the Physician Fee Schedule, not under the
10 CLEA schedule.

11 Dr. Sprang: So it does include blood tests.

12 Mr. Romano: [unintelligible]

13 Dr. Sprang: I think our attorneys interpreted it to mean that an ultrasounds, MRIs and other
14 diagnostic tests.

15 Mr. Romano: If it's paid under the Physician Fee Schedule, then it would be part of this.

16 Dr. Grimm: We brought this issue up earlier today, and I'll mention it briefly to you just to bring it
17 up officially, is the issue of brachytherapy sources and the ASC center. The final rule as it is interpreted, as
18 I understand it, mandates that ASC centers bill for seeds and sources, but it does not allow them—that's
19 illegal to do so, and so consequently it is as of January 1, would prohibit us from taking care of Medicare
20 patients in ambulatory surgery centers that are owned by urologists and almost are owned by urologists, by
21 the way. And so this was something that we were not made aware that this would happen. And I don't think
22 it was the intent of Medicare to deny coverage or care for prostate cancer patients in a timely fashion. And
23 this is being threatened right now, for our patients who are being treated in January and beyond that are
24 already scheduled. And so my question is, what mechanism or means do we have to correct this problem,

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1 and at least put it on a temporary basis until we can resolve the—there's no definition issues and [inaudible
2 noise].

3 Mr. Romano: Right. We proposed an exception to our definition of radiology to exclude radiology
4 procedures that were ancillary to the covered surgical procedure that were performed immediately prior or
5 during or after, and currently the rule was, until we made this change, if it was done prior or after, but not
6 the immediately before. Excuse me, it covered it if it was done during the procedure or immediately after,
7 but not immediately prior to the procedure. In the course of proposing that, we have comments about
8 brachytherapy. We did not propose that. It's not something that we felt we could finalize when we finalize
9 the OPPS rule, but however since being made aware of the issue, we are looking at it. We are looking at it
10 to see whether our current rules will accommodate that in terms of interpretation, and I really can't address
11 it more than that. Just that we are acute aware of the situation and are working at looking at it.

12 Dr. Grimm: Thank you. Appreciate it.

13 Dr. Ouzounian: If there's no further questions, we appreciate your willingness to come today.

14 Mr. Romano: OK. Thank you.

15 Dr. Ouzounian: To go over the, I think let's wait for the proposals. We're going to have one more
16 talk after the next talk, we'll do our proposals and then break so Dana can get them printed for us. Tab 9,
17 let's turn our attention now to Quality of Care issues and for that we are being joined by Dr. Paul McGann.
18 Dr. McGann is a board certified internist and geriatrician. In 2002, Dr. McGann joined the fulltime staff of
19 CMS initially in the Quality Improvement Group in OCSQ. He led the execution of Task 1A, nursing home
20 and Task 1B, home health, in both the 7th and 8th QIO contract cycles. The results of this work were
21 published in the *Annals of Internal Medicine* in September of 2006. In July of 2007, he was promoted to
22 Deputy Chief Medical Officer, CMS. Dr. McGann will discuss the major theme of the 9th scope of work,
23 and the role of QIOs in achieving the goals set forth in that proposal. Dr. McGann.

24 Ninth Scope of Work/Quality Improvement Organization

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1 Dr. McGann: Thank you very much. Thank you for inviting me here today. Dr. Stroud sends his
2 regrets. He was triple booked in this slot, so he sent me. The QIO Program is something, though, that I
3 know quite well. I've been working at CMS for about 5 or 6 years on the program. And before that I was a
4 practicing geriatrician. I was the founding clinical director at the J. Paulstick Center on Aging at Wake
5 Forest University with Bill Hazard for about 10 years. So the focus of what we're going to talk about in the
6 next half hour or so is quality. I know you spend a lot of time at PPAC talking about reimbursement issues,
7 and really I think we can say, if you've been watching the progression of the IOM's interest and Congress's
8 interest in quality issues in medicine in the United States, that in contrast to when I first got involved in
9 quality issues in about 2000, as we go into 2008 and 2009 in the next 3-year QIO contract cycle, we're
10 going to see some major changes in the next 3 to 4 years, as the quality measurement system that's evolved
11 over the last 6 years or so gets closer and closer and does touch the payment system. Today, I'm going to
12 address primarily the work that the Quality Improvement Organizations around the United States will be
13 doing over the next 3 years. As you know, QIOs began life as physician review organizations and 25 years
14 ago, initially focused on case review and hospitalization and evidence for hospitalization, and we're really
15 largely a regulatory body. Under Dr. Jenks's leadership was the last Quality Improvement Group Director,
16 that focus, although maintaining the focus on case review also evolved to look more and more at quality
17 issues, and in fact, the QIO program has provided a lot of the funding that's resulted in hospital compare,
18 nursing home compare and home health compare, all of which have been put up on the Medicare.gov
19 website, just in the last 5 years. So the QIOs changed their name in the year 2000 and they operate by
20 statute under 3-year contract cycles and it takes between 12 and 18 months to prepare one of these
21 contracts, and that's what our group has been involved with in NCSQ for the last 12 months. So we call
22 these contract cycles "Scopes of Work." We're currently finishing the 8th Scope of Work. The paper that
23 was mentioned in my introduction was an evaluation that I was involved in of the 7th Scope of Work, and
24 what I'm going to address today is what we are planning for the QIO 9th Scope of Work, which begins on
25 August 1st, 2008. So to put it simply, the aim of the QIO program now is dual. It's to help providers

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1 improve the quality of care they provide to Medicare beneficiaries. And also to provide protection for
2 Medicare beneficiaries and I'll explain that more in a minute. The major themes for the draft 9th Scope of
3 Work which is currently in OMB under a funding review are the four topics listed on the first slide there.
4 So they're called Patient Pathways, or care coordination, Patient Safety, Prevention, and Beneficiary
5 Protection. I'm just going to spend a few minutes going through each theme one by one. But before I do
6 that, I want you to know that in consultation with our stakeholders and with the Department of Health and
7 Human Services, there's really been a tremendous effort in response to the IOM review of our program that
8 was published in 2006 to redesign the QIOs and how they perform their work. And one of those redesign
9 elements is to try to better align the QIO work with the rest of what's happening in CMS and the
10 Department of Health. One example of that are the 3 focus areas that we've incorporated into all 4 content
11 themes that are on the board. The QIOs, more than ever before, are going to be connected to the Secretary's
12 concept of value-driven healthcare. More than ever before, they're going to continue their docket work in
13 physician offices for the adoption and use of health information technology, electronic health records, and
14 eprescribing. And there's a renewed focus now on the reduction of measured healthcare disparities across
15 the country as well. These 3 overarching or what we call cross-cutting themes are present in each of the 4
16 content themes in the contract.

17 So the first theme then to go over is probably the hardest to understand from the title and that is
18 Patient Pathways, or Care Coordination. And a lot of the concepts for work in this theme came from
19 published work from other geriatricians that you may be familiar with. In particular, Eric Coleman, at the
20 University of Colorado, who's done a lot of work in the last 5 years over the transitions of care that
21 Medicare beneficiaries experience as they're discharged from the hospital, and even in the nursing field,
22 Mary Naylor, at the University of Pennsylvania, has done some groundbreaking work on simple
23 interventions that can make the transition from hospital to home or nursing home or home health more
24 smooth. So that's the purpose of the care coordination theme, is to based on the evidence that's been
25 created to date, in terms of how to help Medicare beneficiaries better experience the transition from

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1 hospital to the community, a few areas in the United States, somewhere between 10 and 12 will be able to
2 get community leaders together in their areas and cross provider settings. It's the first time in the QIO
3 program that this has happened, where hospitals, physicians, nursing homes, home health agencies, and
4 even the emergency transport system can come together and make a proposal with funding under the QIO
5 program to better attain high quality care transitions for Medicare beneficiaries. Those of you who are
6 familiar with the Institute for Healthcare Improvement will know the collaborative method of
7 improvement, we have several collaborative experts now on staff that we didn't have before, among them
8 Joanne Lin, who's well known for her work in palliative care and the QIOs provide of course their usual
9 access to data analysis that can be shared with the providers that enter into these collaboratives and we're
10 hoping to affect the, to decrease the rate of unnecessary rehospitalizations in this theme.

11 The next theme is patient safety. This one's much more straight forward and greatly resembles the
12 patient safety work that the QIOs have already done under the 7th and 8th scopes of work. In this case,
13 following suggestions from the Institute of Medicine, we decided to greatly focus our efforts on some of
14 the activities that we've conducted in the past that have been most successful, based on the data that we've
15 collected. I've been involved in the first 2 bullets, which are reducing avoidable pressure ulcers in nursing
16 homes. We're extending that work now, to hospitals, since our preliminary data, we just published some of
17 this in the *Journal of American Geriatrics Society* in October shows that quite a number of pressure ulcers
18 that nursing homes are wrestling with are actually arriving from the acute care hospital. And so we're
19 hoping in the patient safety theme in the 9th scope of work, to get hospitals and nursing homes to work
20 together on this problem. We're also going to continue our work to reduce the use of physical restraints in
21 nursing homes, for those of you who are familiar with those numbers, know that that's been quite
22 successful over the last 5 years. In the hospital environment, there's a well described program now called
23 the Surgical Care Improvement program that's a suite of about 10 or 12 measures that have to do with
24 interventions within the hospital, and particularly post-operative arenas, to effect the reduction in the rate of
25 post-operative infections, and we're going to continue funding in that way.

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1 A new area that wasn't present in the 8th scope of work and which is turning out to be very timely,
2 even though we came up with it more than a year ago, is to organize technical assistance for hospitals that
3 are interested in both measuring and coming to grips with the escalating rate of methasone resistance
4 [unintelligible = aporase??] infections in their hospitals. This part of the 9th scope of work is now a
5 collaborative effort where we've partnered with both AHRQ and CDC to produce some very high quality
6 evidence-based interventions that have been already shown to reduce mercer rates in the hospitals that
7 abuse them.

8 And finally, a new area which reflects the changes with Part D focuses on improving drug safety
9 for Medicare beneficiaries.

10 Moving on to the Prevention Theme. How many, I'm just curious, how many physicians around
11 the table are familiar with the 8th scope of work DOQIT program? Not a single one—one of you, that's
12 good. Many physicians have given us positive feedback in the 8th scope of work on that and we intend to
13 build on those practices, depending on how you count them. It varies from 2500 to 3500 practices
14 nationwide that the QIOs in their state have assisted in adopting electronic health records. In the 9th scope
15 of work, again following Institute of Medicine recommendations, we've decided to focus the activity in 3
16 main areas, and in the core prevention activity on just 4 measures that have been shown already to be better
17 delivered on electronic health record. So on the core prevention activity, the four preventive measures that
18 we're going to track through the scope of work and help attain benchmark performance levels by the end of
19 the scope of work are the rates for influenza vaccination, pneumococcal pneumonia vaccination, according
20 to guidelines in the Medicare population, and then the rates of mammography for breast cancer screening,
21 and colorectal cancer screening. So it's a highly focused core prevention activity. The other 2 components
22 of this theme are shown on the slide for the first time ever. We're going to try to increase the identification
23 of Medicare beneficiaries with stage one or two chronic kidney disease, and as you know, according to
24 guidelines with intervention with ace inhibitors or angio tensor receptor blockers, it's possible to slow or
25 even prevent the progression of chronic kidney disease in older patients with diabetes, or hypertension to

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1 end stage renal disease. And of course that has obvious financial benefits over the long term for the
2 Medicare population, not to mention the beneficiary. And the final component of the prevention theme is
3 going to focus on the diabetic population in underserved areas of the country, and again build on the work
4 that we've already done along this line in the Doctors Office Quality Information Technology project of the
5 8th Scope of Work.

6 So moving on to the next theme, the Beneficiary Protection Theme is different than clinical
7 quality. It's really, if you read the statute, is the origin in the statutory authority of the QIO formally pro
8 gram. This part of the program is sometimes known as the case review part of the program. And there's
9 multiple dimensions to case review that the QIOs are charged by statute with doing in every state and
10 territory. One of the drawbacks the Institute of Medicine identified within the Beneficiary Protection
11 Theme or case review in the past, is that it tended to be a bureaucratic review with bureaucratic results that
12 didn't really materially affect the outcome or the quality of beneficiaries in the areas in which it was done.
13 So in the 9th Scope of Work, we've attempted to redesign the way case review is performed and the focus is
14 going to be on having the quality improvement part of the QIO more closely linked with the case review
15 part of the QIO so that the two endeavors can be linked and that there can be a demonstration that by
16 fielding beneficiary complaints, and performing case review, that a measurable improvement in the quality
17 performance data can be seen in that area. The slides that are coming next—so that's a high level overview
18 of what the 9th Scope of Work looks like. The slides that come next will sort of route what we're doing in
19 the 9th Scope of Work to the changes that were recommended by the Institute of Medicine in its review of
20 our program, which started about 3 or 4 years ago now and was published in book form, it's about 500
21 pages long, in 2006. So the IOM pathways to quality healthcare series—I highly recommend to those of
22 you who haven't been keeping up with the quality improvement literature, because there have been a lot of
23 advances just in the last 5 years, including these 3 books, published by the Institute of Medicine.
24 Performance Measure in Accelerating Improvement, the entire book focused on the Medicare Quality
25 Improvement program. And then the last one, which was published within the last year, Rewarding

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1 Provider Performance, Aligning and Symptoms of Medicare. And that has obvious relationships to the new
2 Hospital Value-based Purchasing Initiative and the PQRI program. So that's kind of the conceptual
3 framework on which this evolution of the QIO program is based.

4 Just to review the IOM report itself, there's 4 main bullet point that summarize this. I'm just going
5 to hit the highlights here and answer any questions you have in the question period. Basically, this 500-
6 page report that the IOM Institute on our program made these statements. The IOM did note that based on
7 the quality measures that have been developed and published to date, that the quality of healthcare that
8 Medicare beneficiaries experience is in fact improving over time, albeit slowly. The second bullet that's of
9 relevance to the redesigning of our program is that although the quality measures show that quality of care
10 is improving over time, it's much more difficult to attribute any of that quality improvement to the actions
11 of the QIO program, and the IOM made several specific recommendations to try to correct that.
12 Nevertheless, in the Institute of Medicine's point of view, it was important to continue the Medicare QIO
13 program and they recommended some elements of redesign in order to make it more effective.

14 They made many recommendations, which I'm going to enumerate in a minute. But I tried to do a
15 high level overview of what the IOM was saying. And the IOM went back to this notion—remember I
16 presented the three main domains of quality improvement in the clinical quality improvement side, and
17 then the final theme was this beneficiary protection or case review theme. In the IOM's opinion, it was very
18 important that CMS focus QIOs attention on technical assistance to providers for quality improvement.
19 And this has obvious relations to the various value-driven healthcare initiatives that we've already
20 mentioned. They also said in the second bullet there, that it was important to change the governance base
21 and the structure. Many of those recommendations could only be accomplished through legislation, and
22 although we're doing the best we can, before there's a legislative change, to improve governance and
23 reduce conflict of interest. And then they did criticize CMS itself for its management of data systems and
24 program evaluation, and that system has been redesigned, and there's intense work going on now before the
25 beginning of the 9th Scope of Work for us at CMS to do a better job with our data calculation and getting

1 relevant and accurate data to providers in a timely fashion. So that's a very high overview of what the IOM
2 was saying.

3 The IOM made 8 specific recommendations, which are summarized on the next 3 slides. The first
4 one is really what I already said, which is they believe the QIO program overall is a very valuable entity
5 and with proper redesign, it's should be kept not only for Medicare, but to help all healthcare providers.
6 The second statement is really that. It's become obvious that since we have some resources to develop
7 hospital and physician quality measures, that the Medicare QIO program could actually be of benefit to all
8 providers, not just providers that serve Medicare beneficiaries.

9 We've already talked about number 3, which is the organizational governing structure and then
10 number 4 is one of the focused recommendations coming out of IOM, that is probably going to require
11 legislative change, and that is separation conceptually between the case review functions of the QIOs and
12 the quality improvement structures and we can talk more about that in the question period if you'd like.

13 The data handling practices in number 5, we've talked about that. And that's one of the things
14 that's very close to OCSQ and we're working on that right now. The program management is actually
15 linked to number 5 and data management, but we have redesigned program management and evaluation
16 completely, compared to the 8th Scope of Work. And then we've made great steps forward in the 9th Scope
17 of Work for a better program evaluation. In contrast to the rather haphazard evaluation of previous scopes
18 of work, we're now engaging a completely independent, external program evaluation contractor right from
19 the beginning of the 9th Scope of Work that will function in parallel to us as the scope of work progresses,
20 and we've incorporated specific metrics for program evaluation, individual contractor evaluation, and then
21 specific evaluations of selected interventions within each of the themes.

22 And the final recommendation the IOM made was with respect to funding and again, we get into
23 the issue of what the relationship between the quality improvement technical assistance activities would be
24 to the case review in the discussion of the program funding.

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1 We don't have anything to report right now, since the program's still under review by OMB. So
2 how did we go about doing this then? I'm not going to go through all those in detail, but I just want you to
3 know that it's been a very different process than previous scopes of work. It's involved collaboration with
4 the QIO community, starting back a year ago, and then a work group was developed between CMS and the
5 department that worked for 6 to 8 months in terms of aligning priorities with the Secretary's priorities and
6 reviewing the evidence there was for the quality measures and the interventions that we're recommending
7 in the 9th Scope of Work. The middle bullet's a little bit out of date. We're past early discussions with
8 OMB. We expect a funding decision on the 9th Scope of Work within the next couple of weeks. I told you
9 about the cross-cutting themes and the Secretary and just so you know, the IOM was not the only set of
10 recommendations we took into account. Senator Grassley also launched a Senate Finance Committee
11 investigation of the program and those recommendations have been dealt with as well.

12 So many, many parts of the internal working and CMS management of the QIO program have
13 been revisited and redesigned and again, if anyone has questions over that, I'd be happy to address them in
14 a minute. And I just emphasize again that we've done a lot of external outreach in terms of changing the
15 QIO program, and I hope that I've been successful in starting to draw the connection between QIO
16 technical quality assistance for providers and all of the ongoing and upcoming issues in both Pay for
17 Reporting and Pay for Performance, really in every setting of care. So hospital, nursing home, home health,
18 and physician office are all impacted by these types of considerations. We're hoping by the end of the 9th
19 Scope of Work to brand the QIOs as the automatic go-to organization within Medicare for anything
20 involving performance management and quality improvement.

21 You can read a lot about the QIO program and its redesign on our technical professional website. I
22 also wanted to give you one other website, that should be up here, which is www.medqic.org. We call it
23 Medqic, [spells] and that's a technical assistance website that has most of the materials developed by the
24 QIO program in the last 2 or 3 scopes of work, and it's divided by provider settings, so that those of you
25 who wish to begin to lead and launch quality improvement initiatives in your setting of care, might find that

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1 resource very useful. It's of course available to all providers, free of charge. Again, this slide is somewhat
2 out of date, fedbiz.opps the publisher of note for large government contracts, and we're actually going to
3 try to get the QIO 9th Scope of Work published on fedbiz.opps sometime near the end of December or the
4 beginning of January 2008. So those of you who are interested in either joining or becoming part of this
5 initiative, we encourage you to watch for those announcements. And that's it. I'll be happy to entertain any
6 questions.

7 Dr. Ouzounian: Thank you, Dr. McGann. Does the Council have any questions or comments for
8 Dr. McGann?

9 Dr. Arradondo: You gave some examples on I guess it was your first prevention theme. I presume
10 you just happened to, although that may have been more purposeful. You mentioned diabetes, and you said
11 flu shots, mammography and one or two other things you were doing—what were the other two?

12 Dr. McGann: So it's the rate of influenza vaccination, the rate of pneumococcal pneumonia
13 vaccination, mammography for screening of Medicare beneficiaries for breast cancer, and colorectal
14 carcinoma screening.

15 Dr. Arradondo: OK, are there other prevention themes that use more primary prevention? One of
16 these basically or maybe two of them are primary prevention, the others are kind of secondary.

17 Dr. McGann: Of course, there are. One of the redesign principles that we were reacting to from the
18 Institute of Medicine was that in past scopes of work, the QIO program has tended to respond to all
19 suggestions that came both from the QIO community and from the surrounding area. In this scope of work,
20 we were advised to focus our energy on only a very few elements of each broad theme. And so I was
21 actually on the prevention committee that focused this in. We probably started with the US Preventive
22 Services Task Force Recommendations, and probably more than 22 separate measures when we first began
23 this a year ago. But we applied several criteria to the ones that we chose in the end. One of them was that
24 there had to be incontrovertible evidence that the measure that we had was reliable and that could indicate
25 and be correlated with provider activities, and so the measurement system is critical to all QIO work, and

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1 we chose only the measures that have the highest degree of consensus, for example, national quality forum.
2 Secondly we required that there be incontrovertible evidence that interventions that QIOs could help with,
3 to providers, resulted in changes in those measures. And when we got to that step of the redesign of the
4 QIO program, many of the measures that we'd recognize as physicians that would be desirable, fell out for
5 lack of evidence that those measures actually had been changed. And the final and probably the most
6 restrictive was that there had to be evidence at some level that QIOs had been involved in this type of work,
7 and been successful at it in the past, and that really reduced the field, considerably.

8 Dr. Ouzounian: All right. Seeing no further questions, thank you, Dr. McGann.

9 Dr. McGann: Thank you very much.

10 Dr. Ouzounian: Let's see. What we're going to do next is I would like to invite the
11 Councilmembers to make their recommendations, which we'll discuss, vote on, and Dana will then make a
12 document for us to review. So I invite your recommendations. Dr. O'Shea.

13 Dr. O'Shea: I have a few recommendations that I would like to ask my fellow colleagues to chime
14 in on. I've written a few down and I'd like to go through them and see if we'd like to collaborate on these
15 please. First of which concerns PQRI. PPAC recommends CMS report to PPAC the analyzed results of
16 data collected from the 2007 Physician Quality Reporting Initiative, at the May 2008 PPAC meeting with
17 the follow up of more final data at the August 2008 PPAC meeting.

18 Dr. Ouzounian: Is there a second?

19 [Second]

20 Dr. Ouzounian: Discussion? All in favor?

21 [Ays]

22 Dr. Ouzounian: All opposed? The motion passes. Dr. O'Shea?

23 Dr. O'Shea: PPAC recommends CMS implement a rapid and direct NPI outreach plan with a
24 special emphasis on small and rural practitioners. CMS is asked to reconsider the revalidation process that

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1 began October, until the enrollment problems associated with Medicare NPI matching problems are
2 thoroughly resolved.

3 Dr. Ouzounian: Is there a second?

4 [Second]

5 Ms. Trevas: [inaudible]

6 Dr. O'Shea: I'll do it for you, hon. CMS is asked to reconsider the revalidation process that began
7 October, until the enrollment problems associated with Medicare NPI matching problems are thoroughly
8 resolved.

9 Dr. Ouzounian: Discussion? It was seconded before. Seeing no discussion, all in favor?

10 [ays]

11 Dr. Ouzounian: All opposed? The motion passes. Dr. O'Shea.

12 Dr. O'Shea: PPAC recommends that CMS work with Congress to ensure an immediate action to
13 provide at least 2 years of positive updates and avert the 15% cut over 2008 and 2009; repeal the SGR
14 altogether and replace the SGR with a system that produces positive physician updates that accurately
15 reflect increases in medical practice costs as indicated by the MEI.

16 Dr. Ouzounian: Discussion? Seeing none, all in favor?

17 [Ays]

18 Dr. Ouzounian: All opposed? The motion carries. Dr. O'Shea.

19 Dr. O'Shea: PPAC recommends that CMS apply the budget neutrality adjustor to the conversion
20 factor for 2008 and subsequent years.

21 [second]

22 Dr. Ouzounian: Discussion? All in favor?

23 [ays]

24 Dr. Ouzounian: All opposed. The motion carries. You have more? Dr. Grimm?

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1 Dr. Grimm: PPAC is concerned that Medicare patients receiving brachytherapy for prostate cancer
2 at ambulatory surgery centers will be denied care as of January 1st, 2008, because of the failure of the final
3 rule to recognize payment of brachytherapy sources. PPAC recommends that CMS address this problem
4 immediately, and suggests maintaining the current methodology, or granting a temporary solution to allow
5 these patients to receive timely care.

6 Dr. Ouzounian: Is there a second?

7 [second]

8 Dr. Ouzounian: Discussion? Seeing no discussion, all in favor?

9 [Ays]

10 Dr. Ouzounian: All opposed? The motion carries. I have one ahead of you, Dr. Ross. Dr.
11 Bufalino?

12 Dr. Bufalino: Thank you. Two. One, PPAC urges CMS to not issue additional rules that further
13 complicate the Stark self-referral laws by adding more layers of confusion and regulation that discourage
14 efficient, innovative, quality healthcare.

15 Dr. Ouzounian: I believe it needs to be PPAC recommends, but with that friendly amendment, do
16 we have a second?

17 [seconds]

18 Dr. Ouzounian: Discussion?

19 Dr. Bufalino: Just trying to be creative, sorry.

20 Dr. Ouzounian: This is the government. Seeing no discussion, all in favor say Ay.

21 [Ays]

22 Dr. Ouzounian: All opposed. The motion carries. Dr. Bufalino?

23 Dr. Bufalino: The last one. PPAC recommends that CMS delay implementation of the Anti-
24 Markup provision in order to evaluate the substantial impact that these changes will have on healthcare
25 providers.

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1 Dr. Ouzounian: Second?

2 [seconds]

3 Dr. Ouzounian: Comment?

4 Dr. Snow: I would add to the end of that, especially in group practices, since they specifically are
5 looking at that exception as a possibility.

6 Dr. Bufalino: Friendly amendment, absolutely.

7 Dr. Ouzounian: Further discussion as amended? We're going to vote on the amended
8 recommendation. All in favor say ay.

9 [Ays]

10 Dr. Ouzounian: All opposed? The motion carries. Dr. Ross.

11 Dr. Ross: Yes, this is a revisit but some of them have been revisited. PPAC recommends that CMS
12 be aware of the areas of concern with the proposed DME POS's rules, including competitive bidding, and
13 the requirement to acquire assurity bond to provide the DME POS's service. It is nearly impossible
14 physicians including podiatric and all other healthcare providers to compete against much larger
15 businesses, whose sole purpose is to supply medical equipment. Physicians are trained in residency and
16 fellowships to dispense DME POS's to patients, thus providing the medically necessary convenience to
17 dispense those durable supplies in the office setting. The burden upon the beneficiary to leave the
18 provider's office, with a known medical condition or injury, would necessitate travel to a distant location
19 for dispensing of this medical equipment. Therefore the provider should be excluded from this accreditation
20 process due to their training, and should be excluded from the competitive bidding process which is another
21 financial burden to the practitioner. We urge CMS to help remedy this situation by its assistance to amend
22 the final rule in this regard.

23 Dr. Ouzounian: Dana, did you get that?

24 Ms. Trevas: No

25 Dr. Ross: I have it written down and can give it to you.

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1 Ms. Trevas: The recommendation is not [inaudible]

2 Dr. Ouzounian: How do you have that Dr. Ross?

3 Dr. Ross: I'm sorry?

4 Dr. Ouzounian: Do you have it written down?

5 Dr. Ross: Yes.

6 Dr. Ouzounian: Can you get that to her?

7 Dr. Ross: Sure.

8 Ms. Trevas: Do you want the entire thing as the recommendation?

9 Dr. Ouzounian: I believe that was his recommendation. Do you think you could shorten that?

10 Dr. Ross: I could shorten it to the first paragraph. And then to the final conclusion. I was just
11 trying to be a little more explicit as to why. But I can do that.

12 Dr. Ouzounian: Why don't you rephrase your recommendation without the discussion, as we've
13 heard the discussion?

14 Dr. Ross: PPAC recommends that CMS be aware of the concerns, with the proposed EMS rules
15 including competitive bidding and the requirement to acquire assurity bond to provide the DME POS
16 service. It is nearly impossible for physicians, including podiatric and all other healthcare providers to
17 compete against much larger businesses whose sole purpose is to supply medical equipment, therefore the
18 provider should be excluded from this accreditation process due to their training, should be excluded from
19 the competitive bidding process. We urge CMS to help remedy this situation by its assistance to amend the
20 final rule in this regard.

21 Dr. Ouzounian: Do you have that? Second?

22 [second]

23 Dr. Ouzounian: Discussion? Seeing none, all in favor?

24 [Ays]

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1 Dr. Ouzounian: All opposed? The motion carries. Further recommendations from the
2 Councilmembers? Dr. Snow.

3 Dr. Snow: Little prelude, the Medicare Physician Payment updates are based in part on the
4 Medicare Economic Index, which is reduced by CMS so PPAC recommends that CMS reevaluate and
5 reduce this 1.4% productivity adjustment to the 2008 MEI and that reduction for future years.

6 Dr. Ouzounian: Second?

7 [second]

8 Dr. Ouzounian: Discussion? All in favor ay?

9 [Ays]

10 Dr. Ouzounian: All opposed? The motion passes. Any further recommendations from the Council?
11 OK, seeing none, we're going to take a 15 minute break until 2:30. It's my understanding we'll get the
12 recommendations back in writing at that time. We can review them during AMA testimony and wrap up
13 after that. Thank you.

14 Break

15 Public Testimony—American Medical Association

16 Dr. Ouzounian: Is Dr. Dolan available? Now I invite Dr. William Dolan to present testimony on
17 behalf of the American Medical Association on topics presented here today. Dr. Dolan.

18 Dr. Dolan: Thank you, Mr. Chair, and members of the Council. My name is Bill Dolan. I'm a
19 practicing orthopedic surgeon from Rochester, New York and a member of the board of trustees of the
20 American Medical Association. First and foremost, I want to thank you for a number of the resolutions that
21 you just passed. Dr. O'Shea, Dr. Bufalino, Dr. Ross, Dr. Snow, Dr. Sprang, you don't good work. I'm
22 proud of you. As you all know, a number of critical issues face Medicare today and the future. Many of
23 these issues as recently addressed in the Physician Fee Schedule final rule are of great concern to the AMA.
24 First, the AMA urges CMS to work with Congress to avert the more than 10% Medicare physician pay cut
25 that will take effect January 1st, 2008. Many of my remarks here as you know from your resolutions, are

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1 going to be redundant, but as an Irishman, I have to go ahead anyway [laughter] and repeat. And that's not
2 all, physician payments are expected to be cut almost 40% by 2016, with physician practice costs
3 increasing nearly 20% during that period of time. Now this make an unsustainable business model for
4 physicians and other practitioners. Only physicians and other health professionals face these steep
5 Medicare cuts. Other providers, such as nursing home and hospitals have payment updates that reflect the
6 cost of inflation. Further, Medicare Advantage Plans are paid 112% on average above the cost of traditional
7 Medicare, and a significant number of these plans are paid from 120% to 150% of traditional Medicare Fee
8 for Service. MedPac has said that Medicare spends far per beneficiary for Medicare enrolled senior
9 Advantage Plans than it does for those in the original Medicare. And MedPac has called for these subsidies
10 to be eliminated.

11 Now ladies and gentleman, continued Medicare Fee for Service cuts will impact access to all our
12 patients. In 2007 AMA Survey, 60% of physicians have told us that next year's cut will force them to limit
13 the number of new Medicare patients they treat. And this number increases to 77% if Medicare rates are cut
14 40% by 2016, as it is projected. Time is running out. CMS must work with Congress to enact this year, at
15 least 2 years of positive updates and pave the way to replace SGR with a system that produces payment
16 updates that accurately reflect increases in medical practice costs. CMS can also help Congress reduce the
17 cost of SGR in a number of different ways. As you know from one of the resolutions you passed, Congress
18 previously allocated to the Secretary of HHS \$1.35 billion for physician services in 2008. CMS is using
19 these funds for quality reporting only. We urge PPAC to recommend that CMS use these funds to avert the
20 negative physician payment update in 2008, as you have made the resolution. In addition, CMS is
21 increasing work RVUs for certain CPT 4 codes, and by law must implement these under a budget neutral
22 basis. To do so, CMS will adjust the physician work RVU instead of applying the budget neutrality across
23 the board through the conversion factor, which would be far easier and more neutral. The AMA urges
24 PPAC to recommend that CMS apply budget neutrality adjustor to the conversion factor for 2008 and all
25 subsequent years. Finally, CMS can help Congress reduce the cost of SGR by reducing or eliminating the

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1 productivity adjuster to the Medicare Economic Index, or the MEI. Medicare physician payment updates,
2 as you know are based on changes in the MEI, CMS will adjust downward by 1.4% in 2008, to account for
3 assumed physician productivity increases. However, the President’s budget proposal for 2008
4 recommended a .65% productivity adjustment for payments for inpatient and outpatient hospital services,
5 hospices and ambulance services. There is no reason for this disparity. There is no rationale for it. The
6 AMA therefore urges PPAC to recommend that CMS either reduce, or preferably eliminate the productivity
7 adjustment to the MEI.

8 Now let me turn to the Stark self-referral regulations as you have addressed in your resolutions. In
9 the final rule, CMS made changes to what is called an Anti-Markup provision of a self-referral law. Under
10 this provision, if a physician orders and bills for a diagnostic test, purchased from an outside supplier or
11 performed at a site other than “the office of the billing physician” restrictions on the marking up of the
12 charges for the test apply. Physicians will struggle to comply with this new, confusing and restrictive
13 requirement by January 1st, 2008, especially since this change was not included in the proposed rule. We
14 therefore urge PPAC to recommend that CMS delay implementation of the provision in order to evaluate
15 the substantial impact that these changes will have on physicians in group practices. Further, we are pleased
16 that CMS declined in the Final Rule to address many other changes in the physician self-referral law. We
17 are disappointed however, that CMS expects to publish a rule on these issues at a future date. We ask
18 PPAC to urge CMS not to issue these additional rules to the Stark self-referral laws. This will only add
19 layers of confusion and discourage, efficient, innovative, and quality healthcare.

20 Other provisions in the Physician Fee Schedule final rule are also of great concern to the AMA
21 and these are discussed at length in our written statement, which you obviously have read in detail, and I
22 think you for that. For example, we believe that CMS is unnecessarily precluded a number of quality issues
23 from being included in the final rule for use in the 2008 Physician Quality Reporting Initiative, or PQRI.
24 We urge PPAC to recommend that CMS include these measures in the 2008 PQRI. In another matter, we
25 also urge CMS to recommend that CMS reinstate the FAX exemption to the eprescribing requirement.

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1 Next, I'd like to address the ambulatory surgical center, or ASC final rule. The AMA is pleased
2 with CMS's efforts to implement the ASC payment system, and we applaud a 4-year transition for
3 implementation. We have concerns however that various aspects of the revised ASC payment system may
4 result in payments that do not cover the cost of the procedure. This will reduce patient access to care and
5 shift care to higher cost, outpatient hospital settings, thereby increasing beneficiary and program costs.

6 Finally, I'd like to say a word about the NPI, National Provider Identifiers. To better prepare for
7 smooth compliance with the May 23, 2008 deadline, the AMA urges PPAC to recommend that CMS do 4
8 things. First, implement a rapid and direct outreach plan with special emphasis on small and rural
9 providers. Thank you, Dr. O'Shea. Two, follow carriers' flexibility to ensure enrollment applications. Do
10 not stall a result in the unnecessary rejections, especially given that the untold member practitioners have
11 already been asked to re-enroll. Number 3, reconsider that the revalidation process that began in October,
12 until the enrollment programs associated with the Medicare NPI matching problems are thoroughly
13 resolved. And finally, 4th, carefully monitor the industry's overall ability to use only NPI numbers by May
14 23, 2008, particularly the readiness of Medicare and those billing Medicare. We thank you for the
15 opportunity to be here today and I'll be very happy to answer any questions you may have.

16 Dr. Ouzounian: Thank you, Dr. Dolan. Any questions or comments? Dr. O'Shea?

17 Dr. O'Shea: On the AOA, MEA, AMA are fighting very hard for physician rights throughout the
18 United States, and we just want to say that as part of your arm, we here want to thank you for the leadership
19 that the AMA continues to have and we hope that we can also continue here at PPAC to continuing serving
20 the physician population in respect to our Medicare patients. So thank you very much

21 Dr. Dolan: Thank you.

22 Dr. Ross: Just a thank you again, for being here and for offering your testimony and knowing that
23 your group may be the only one to help us in terms of the SGR in the final analysis when it comes to the
24 legislature, and I think we can only provide advice to the CMS and the Secretary, but it's going to take a lot

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1 more to prove our worthiness when it comes to getting the providers the reimbursements that we so deserve
2 in order to continue to provide that service.

3 Dr. Dolan: Thank you, we are doing everything we can to get rid of the SGR, come up with a
4 rational formula as so spoken.

5 Dr. Bufalino: Dr. Dolan, thank you for being here, also, and just wanted to send a message back to
6 the AMA that we'd love to have your help in engaging the seniors in this country and in bringing the
7 message to them that Medicare access and Medicare service have already been affected and are going to
8 continue to be affected as we go forward, unless they bond with the medical community to try to fight this
9 fight together with us. The affect on many of us as we enter Medicare age bracket is going to be that we're
10 all going to have less opportunities to have access. So, we'd ask you to take that message back to the AMA
11 and maybe engage AARP or whoever you all think would be an efficient partner, to try to help us reach the
12 seniors in this country.

13 Dr. Dolan: Thank you. We already have bonded with AARP to make sure that the Champ Law
14 was passed. As you know it was stopped in the Senate, but this will provide help to the neediest art of our
15 population. The young people who are uninsured under SCHT and the seniors under Medicare, and AARP
16 and the AMA have gone out and will continue to do a large PR program, telling the Medicare community
17 exactly what's going on; the access problems that they will have in the future. Thank you.

18 Dr. Ouzounian: Thank you. Do we have the recommendations printed? Could we get those passed
19 out? Dr. Sprang?

20 Additional Recommendations

21 Dr. Sprang: I'd like to make one more recommendation.

22 Dr. Ouzounian: Certainly. Actually I apologize. Are there any more recommendations from the
23 Council? Dr. Sprang.

24 Dr. Sprang: Specifically related to the FAX exception for e—

25 Ms. Trevas: I'm sorry, Dr. Sprang could you lean forward please?

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1 Dr. Sprang: Specifically related to the FAX exception for eprescribing, actually my group is going
2 on electronic healthcare records right now and just added a Zeta FAX so that our prescription can get to the
3 pharmacies by FAX, so it's something we're just putting in and obviously if they eliminate it now, we will
4 no longer do it, and so they're trying to say we should be doing more of it, yet they're going to eliminate
5 something that many doctors are just starting and many are using and don't have the other systems that
6 they're requiring. So it seems counter productive if they actually eliminate something that is helping
7 accomplish their goals and we would recommend that, PPAC recommends that CMS reinstate the FAX
8 exception and work with Congress to provide financial incentives to physicians to facilitate wider adoption
9 of eprescribing.

10 [Second]

11 Dr. Sprang: Do you need that again, or...you got it?

12 Dr. Ouzounian: Discussion? All in favor?

13 [ays]

14 Dr. Ouzounian: All opposed? The motion passes. Are there any further recommendations or
15 discussion from the Council? Dr. Snow?

16 Dr. Snow: PPAC recommends that CMS report to PPAC its plan of action to correct the patient
17 access cuts forecast by the AMA do to the unsustainable continuing cuts in continuing physician Medicare
18 reimbursements.

19 Dr. Sprang: Second.

20 Dr. Ouzounian: Discussion? All in favor say ay.

21 [ays]

22 Dr. Ouzounian: All opposed? The motion passes. Any further recommendations from the Council.
23 Dr. Snow?

24 Dr. Snow: Let me look at, if somebody else has one, because I think we've got part of this already
25 and I want to see what else we need. [to Ms. Trevas] Are you ready? PPAC recommends that CMS work

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1 quickly to implement a rapid and direct outreach plan with special emphasis on small and rural
2 practitioners regarding the NPI.

3 [off mike comments/crosstalk]

4 Dr. Snow: OK, next PPAC recommends that CMS allow its carriers flexibility to ensure
5 enrollment applications do not stall or result in unnecessary rejections, especially given the fact that an
6 untold number of practitioners are being asked to re-enroll.

7 [second]

8 Dr. Ouzounian: Discussion? All in favor?

9 [Ays]

10 Dr. Ouzounian: All opposed? The motion passes.

11 Dr. Snow: PPAC recommends that CMS consider the revalidation process that began in October,
12 until the enrollment problem associated with the Medicare NPI matching problems are thoroughly resolved,
13 now do we have that one?

14 [Yes]

15 [off mike discussion]

16 Dr. Snow: So we've got that one, we're OK? How about the carefully monitor the industry's
17 overall ability to use—PPAC recommends that CMS carefully monitor the industry's overall ability to use
18 only NPI numbers by May 23, of 2008, particularly the readiness of Medicare and those billing Medicare.

19 Dr. Sprang: Second.

20 Dr. Ouzounian: Discussion? All in favor?

21 [Ays]

22 Dr. Ouzounian: All opposed. The motion carries.

23 Wrap-up and Recommendations

24 OK. I'd like the Councilmembers just to take a moment. Let's just look through the recommendations one
25 by one and mark them off. Agenda Item D. Physician Fee Schedule final rule. Any changes to that? Seeing

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1 none, Agenda Item E, E-1. No recommended changes? Agenda Item 62-E-2. Seeing no recommended
2 changes, Agenda Item 62-J-1, seeing no changes. Item 62, J-2. Seeing no recommended changes, Agenda
3 Item P-1, seeing no changes, Agenda Item P-2. Should reevaluation be reenrollment process? Who made
4 that recommendation?

5 Dr. O'Shea: I did, yes, actually it's not a problem—it's the enrollment programs associated, so
6 problems should actually be programs.

7 Ms. Trevas: [off mike] it's revalidation [inaudible].

8 Dr. O'Shea: Yes, it is revalidation. Yes.

9 Dr. Ouzounian: Could you just read it back, please, Dana?

10 Ms. Trevas: PPAC recommends that CMS implement a rapid and direct NPI outreach plan with
11 emphasis on small and rural providers and reconsider the revalidation process that began in October, 2007,
12 until the enrollment program's associated with NPI Medicare matching are thoroughly matching problems
13 [laughter] Oh, I see. Enrollment programs associated with NPI Medicare matching problems are thoroughly
14 resolved.

15 Dr. Ouzounian: Are you happy, Dana? OK. 62-P-3. OK. 62-P-4. 62-P-5. That's fine? Fine. 62-P-6.
16 Dr. Simon would you like Dana to read back the final ones that so that we can OK them? So what I'd like
17 to do Dana is I believe there was 4 recommendations at the end. Could you read those back for the Council
18 to give final approval?

19 Ms. Trevas: OK, this would be 62-M-1: PPAC recommends that CMS reinstate the FAX
20 exception and work with Congress to provide financial incentives to facilitate wider adoption of the
21 eprescribing; Yes? 62-M-2. PPAC recommends that CMS report to PPAC its plan of action to correct
22 patient access cuts forecast by the American Medical Association, due to the unsustainable cuts to the
23 physician Medicare reimbursements.

24 Dr. Ouzounian: I think that was OK.

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1 Ms. Trevas: OK. 62-M-3, PPAC recommends that CMS allow carriers flexibility to ensure
2 enrollment applications do not stall or result in unnecessary rejections, especially given that untold numbers
3 of practitioners are being asked to reenroll.

4 Dr. Ouzounian: That's OK.

5 Ms. Trevas: OK, and 62-M-4, PPAC recommends that CMS carefully monitor the industry's
6 overall ability to use only NPI numbers by May 23, 2008, particularly the readiness of Medicare and those
7 billing Medicare.

8 Dr. Ouzounian: I believe that's OK. Dr. Simon do you have the meeting dates for next year?
9 Could we—I'm sorry, Dr. Sprang?

10 Dr. Sprang: 62- When I read it—I do have a change. It's not exactly what I said. 62-E-1, PPAC
11 recommends CMS develop a simpler better approach, everything up to the 2008. Is fine. Then it should say
12 such as paying ASCs, a defined flat percentage of what is paid to hospitals for each procedure that would
13 not vary every year. It does change the meaning. So getting the same amount every year, you rely on it, you
14 know what you're going to get.

15 Dr. Ouzounian: Can you read that last part back, please?

16 Ms. Trevas: PPAC recommends that CMS develop a simpler better alternative approach to the
17 ASC payment system planned to take effect in 2008, such as paying ASCs a defined, flat percentage of
18 what is paid to hospitals for each procedure that would not vary every year.

19 Dr. Ouzounian: OK, Dr. Sprang? Thank you. Dr. Simon, the meeting dates for 2008.

20 Dr. Simon: The scheduled meeting dates for 2008 is March 3rd, here at the Humphries Building in
21 Washington, D.C., May 19th, the Humphries Building in Washington, D.C., August 18th, in Baltimore,
22 Maryland, and December 8th, Humphries Building in Washington, D.C. That's March 3rd, May 19th, August
23 18th, and December 8th.

24 Dr. Ouzounian: All right, seeing no further discussion from the Council, in closing I want to thank
25 all of you for your participation here today. I believe we've had a full and productive meeting. CMS staff

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1 members have worked very hard in preparing their presentations and sharing their concerns and requests
2 with the Council. Our hope is that the recommendations will enhance the Medicare program and enable
3 CMS to move forward with its mission and goals to provide quality care and services to its beneficiaries.
4 And a wide variety of customers and providers. We extend our appreciation to all of the CMS staff. As
5 you're aware, our next scheduled meeting is going to be March 3rd, again in Washington, D.C., and on
6 behalf of myself and CMS, I wish to wish all of you a safe holiday and trip home.

7 [applause]

8 So concludes our meeting.

9 Adjournment