

CENTERS FOR MEDICARE AND MEDICAID SERVICES

PRACTICING PHYSICIANS ADVISORY COUNCIL

Hubert H. Humphrey Building
Room 705A
Centers for Medicare & Medicaid Services
200 Independence Avenue
Washington, D.C. 20201

Monday, May 21, 2007
8:30 a.m.

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1 Open Meeting

2 Dr. Senagore: Good morning. I am Dr. Anthony Senagore. I am the chairperson of the Practicing
3 Physicians Advisory Council. It's my pleasure to welcome all of you to Washington, D.C. and hope you
4 were able to get a cab with Digestive Disease Week in town, they're at a premium. This is the 60th meeting
5 of the Council, this morning. I'd like to extend a cordial welcome to our new members. You'll be formally
6 introduced just before we break for lunch, but Dr. Arradondo, Dr. Jordan, Dr. Rodbard, Dr. Siff, and Dr.
7 Snow are joining us for the first time, so we look forward to their input. We had a vigorous breakfast this
8 morning, so I think everyone is ready to engage. And before we break, they will be sworn in by the CMS
9 Acting Administrator, Leslie Norwalk, about a quarter to?

10 Dr. Simon: Eleven a.m.

11 Dr. Senagore: Eleven a.m.? OK. I appreciate once again all of you arranging your travel schedules
12 to make the time for this meeting. As you know, we are an important advisory committee for CMS and they
13 value our opinions. And as we look at our agenda items, I think we have a number of very interesting topics
14 for today. We'll be discussing the DME Final Rule, Contracting Reform Update, The Post Acute Care
15 Project, PQRI—Physician Quality Reporting Initiative, the Personal Health Records, and the ongoing
16 discussion of the National Provider Identifier. And of course, we'll have our rousing PRIT quarterly
17 update, and that should be available very soon, based on our recommendations for March 5th. And we'll
18 change a little bit from our last meeting. If you recall, we did our recommendations at the end. We'll try to
19 do them in turn with each presenter, and then we'll have a wrap up session in case we miss any topics.
20 There will always be a chance to catch up at the end, but we'll try to do the majority of our
21 recommendations when each presenter's still available. Well, at this time, I'd like to welcome Mr. Herb
22 Kuhn. In the fall of 2006, Mr. Kuhn assumed the position of Acting Deputy Administrator for the Centers
23 for Medicare and Medicaid Services, and he is joined today by Elizabeth Richter in her new role as Acting
24 Director, Center for Medicare Management. Mr. Kuhn, any comments to start us off?

25 Welcome and New Member Introductions

26 Mr. Kuhn: Good morning. Thanks Dr. Senagore and thank you again for your leadership and for
27 continuing to serve as chairperson of this group, and all of you, welcome back, those that are on the
28 committee before, and also the five new members. We're grateful that you're here and appreciate your

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1 willingness to serve and take on these important roles. I think as we say each time, but I think it's worth
2 remembering, that this is the Practicing Physicians Advisory Committee. You all are practicing physicians.
3 In that regard, I think you bring a unique perspective to CMS as we talk about the various issues that are
4 out there. And I can't think of a more important time than now over the last couple of years for this
5 committee as we move forward. If you think about the transition that we're in now, moving from the
6 Medicare Program and trying to think differently how we pay physicians. It's been almost 20 years since
7 the Fee Schedule has been updated, and as we begin to think about the Medicare Program moving from
8 being a passive payer to an active purchaser of care, and all the issues that are involved in that, again, I
9 think more of an important time for you all to be part of this group and helping us think through these
10 issues. We've had a number of presentations on PQRI. And we have more today to help us think through
11 those. We've had a number of questions on NPI and again, I think all of you have been very helpful in that.
12 Also the Recovery Audit Contractors, all the different things that we're grappling with now to have your
13 input, and your thoughtful input as those that are out there on the front line, dealing with these is important,
14 so for you all to come to Washington, to take time from your practice to do that is very important. At the
15 same time, I think it's equally important that we all go talk to you in your communities about these issues
16 and I'll just share with you a recent experience I had as part of that effort. One of the things that we started
17 at CMS about 3 or 4 years ago, was a preceptorship program, that is, the opportunity to get CMS staff out
18 of Baltimore, out of the central office, and out in the field, whether it's spending time with folks in
19 hospitals, ambulatory surgical centers, with physicians, whatever the case may be, but to leave this area,
20 and get out and so we can understand what it looks like from your eye level, at your ground, what's going
21 on. And for years, I've been telling staff that they need to do this program. And they have been, but they
22 also finally turned it on me and said, well, if you think it's so important, why don't you go participate in the
23 Preceptorship Program, and I did. And so 3 weeks ago, I was in Kansas City and I have the pleasure of
24 working with Dr. Snow for a day, following him around on his rounds, and unfortunately I had to cut it
25 short to come back to Washington, but I was able to spend some time in our regional office. I was then able
26 to spend a good morning and part of an afternoon with Dr. Snow. I was able to spend time with 4 states and
27 their state medical societies to talk to them about issues that they were dealing with and grappling with,
28 CMS, and other things at the time. And there were a number of other CMS staff that were participating in

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1 this effort and so I think that's equally important. And so, again, thank you all for coming here. But I think
2 it's equally important that we go out and see you all as well. And we are doing that. So Dr. Snow,
3 personally, in front of this group, I want to thank you for hosting me. I hope to come back and we can
4 continue on and follow through some of the things we did miss. But thanks for doing that. So with that, let
5 me turn it over to Liz Richter, to see if any comments from Liz.

6 Ms. Richter: I just want to echo Herb's welcome and thank you in advance for all the help you are
7 going to provide us today, as you always do, and I wanted to ask the new members if they wouldn't mind
8 taking a couple of minutes to introduce themselves, and Dr. Arradondo, you're first. Alphabetically. So if
9 you could just...

10 Dr. Arradondo: I'll just cover the lag time over here. Your first three word. I'm John Arradondo
11 from Old Hickory, Tennessee. I'm a family physician. I think it says that here. I don't know what all you
12 want to know. I'm a citizen and I'm very keen on how I spend my tax dollars, if that is of interest. And that
13 would be one of the reasons I would be interested in participating in an activity like this that is advising an
14 agency like this in a government like this. That's saying a whole lot, but I'm sure that'll come out as we
15 participate. That's enough. That's more than I usually say. [laughter] I'm John Arradondo.

16 Mr. Kuhn: Welcome.

17 Dr. Jordan: I'm Roger Jordan. I'm an optometrist from a small town in Wyoming—Gillette, where
18 we actually run the country through energy of coal and I'm in a group practice of four, and I've spent years
19 back in D.C. I'm on my 8th year serving in our association's Federal Relations Committee, so this is not an
20 unfamiliar surroundings, so I look forward to participation.

21 Dr. Rodbard: I'm Helena Rodbard. I'm an endocrinologist, not too far away from here in
22 Rockville, Maryland. I'm very pleased to be here as part of the committee. I'm particularly interested in the
23 fate of what's going to happen to access of care to patients, considering how the upcoming reimbursement
24 issues, and also the cuts. I'm past President of the American Association of Clinical Endocrinology and I
25 had been working as a representative to the AMA, so that's a concern and an issue that we've debated
26 extensively and access to care is a big deal, it's a real big issue. Something that we physicians grapple with
27 because we'd like to provide the best possible care to our patients and many of the physicians in our area

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1 are not able to continue to provide good medical care except Medicare patients at all. So that brings me
2 here and I'm delighted to participate in the committee.

3 Dr. Siff: I'm Jonathan Siff. I'm an emergency physician from Ziegler, Ohio. I primarily practice in
4 Cleveland's Level 1 Trauma Center, Inner City Hospital. And access to care are obviously near and dear to
5 my heart, and funding of the safety net hospital, and making sure that when care of all kinds is needed it's
6 there, not just for Medicare beneficiaries, but for everybody.

7 Dr. Snow: Art Snow, I'm from Shawnee Mission, Kansas, which is a suburb of Kansas City on the
8 Kansas side, for those of you who are not familiar with Shawnee Mission. I'm a family physician. I've been
9 an emergency physician, board certified in both for 20 years. Getting a little older at this point, I've given
10 up my emergency medicine practice. I do primarily geriatrics now, nursing home office, and hospital, and
11 as has already been mentioned, I'm certainly very concerned about access to care, especially with policies
12 with the SGR and CMS's system of reimbursement or nonreimbursement anymore for E&M services that
13 we, in primary care, depend upon. And I think it is something vital to the health of the elderly of our
14 country that we change. So hopefully, I can have something back on that, and I look forward to this
15 opportunity.

16 Dr. Senagore: Thank you, Ms. Richter, Mr. Kuhn. And we'll begin now with the review of our
17 recommendations from last meeting, Dr. Ken Simon.

18 PPAC Update

19 Dr. Simon: Good morning to the Council members. From our last meeting, agenda item 59C-1,
20 PPAC recommends that CMS provide the Council with a semi-annual update of Medicare beneficiaries'
21 access to physician care in America. CMS response: CMS currently can respond on an annual basis.
22 Several of the prongs of our multi-prong approach to monitor access to care involves surveys and analysis
23 of claims data that are reported annually. Surveys, such as the Medicare Current Beneficiary Survey,
24 commonly called the MCBS and the Medicare Consumer Assessment of Health Plan Survey, commonly
25 called the CAPS have a 12-month data collection and reporting cycle. Although claims data can be
26 accessed more often, the Office of Research and Development obtains a research data file every July on an
27 annual basis which is to standardize analytic file, used for computing measures of physician density, dollar
28 volume per physician and beneficiary, and a number of distinct beneficiaries per billing physician. Only the

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1 1800 Medicare monthly summaries of access problem calls are reported on a cycle of less than 12 months.
2 However, the numbers reported on a monthly basis are too small to be interpreted. We have found that at
3 least a full year of data from the 1800 system is necessary. A change in the data collection cycles for both
4 the Medicare Current Beneficiary Survey and the Consumer Assessment of Health Plans Survey is not
5 feasible due to the significant additional resources that would be required. A change in the reporting on the
6 claims data would entail using a different process than is currently employed. The MCBS and the CAP
7 survey employ a 12-month to data collection cycle. A change to a 6-month cycle for access to care
8 questions would require modifying the instruments as well as significant and costly alterations for the
9 survey process. Further, the claims-based reports uses standard analytic data file, constructed on annual
10 basis for multiple research and reporting purposes. Moreover, it typically takes several years to observe a
11 meaningful change in a measure. If we reduce the period of observation with the measure that has
12 significant variation in the short run, we can arrive at incorrect conclusions. In essence, we can interpret a
13 random fluctuation as real change.

14 Agenda Item D under the Physician Quality Reporting Initiative. 59D-1. PPAC recommends that
15 fiscal intermediaries be required to transmit claims National Claims History file within one business day of
16 receipt so that any claim received by a fiscal intermediary by February 28, 2008, is transmitted to the
17 National Claims History File by February 29, 2008. And therefore, is eligible for inclusion in the
18 calculation of the bonus payment. The CMS response: To be included in the basis for the PQRI bonus
19 calculation, claims must be submitted by professionals who are participating in a 2007 Physician Quality
20 Reporting Initiative, no later than February 29, 2008. It is possible that not all claims submitted by that date
21 will have been transmitted to the National Claims History file in time to be included in the bonus
22 calculation. The Tax Relief and Healthcare Act, Division B, Title 1, § 101, allows CMS to estimate the
23 charges upon which the potential 1.5% percent bonus for quality reporting will be based. We are reviewing
24 our authority to add a nationally applicable completion amount to each participant's charges before
25 calculating potential bonuses.

26 Agenda Item 59D-2. PPAC recommends that CMS review future models of aggregation of Part A
27 and Part B into a global system of care. The response: CMS has a number of demonstration projects
28 underway that are evaluating, among other things, options for future integration of Medicare Part A and

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1 Part B services. These demonstrations include the Physician Group Practice Demonstration, the Physician
2 Hospital Collaboration Demonstration, under MMA 646, the Gain Sharing Demonstration under DRA
3 5007 and the Medicare Healthcare Quality Demonstration, under MMA 646.

4 Agenda Item 59D-3. PPAC recommends that CMS consider the implications of simultaneous
5 implementation of the new 1500 form in conjunction with reporting CPT Category II codes and more
6 importantly, the issue of potential edits related to those submissions to ensure accurate and timely payment
7 of medical services. The response: After due consideration, CMS does not anticipate that the use of CPT
8 Category II codes for quality reporting or any other aspects of claims-based quality reporting will cause an
9 adverse impact on the accuracy or timeliness of payments for professional services.

10 Agenda Item 59D-4. PPAC requests that CMS staff explain at the next PPAC meeting the source
11 of funds that will be used to pay for bonuses for 2008 and beyond. The response: CMS statutory authority
12 to pay bonuses for quality reporting for 2008 and beyond is not clear. We will further discuss how we will
13 address the payment for bonuses for physicians who participate in the physician quality reporting initiative
14 and meet the threshold for the quality reporting measures, when the notice for proposed rulemaking for the
15 Medicare Physician Fee Schedule is published later this year.

16 Agenda Item 59D-5. PPAC requests that CMS define the methodology used for data analysis
17 related to performance measure submission under the new Physician Quality Reporting Initiative. The
18 response: CMS has defined the methodology that will be used to determine satisfactory reporting under the
19 2007 Physician Quality Reporting Initiative. 1) a participating professional selects a measure by submitting
20 at least once during the reporting period, a quality code that represents the numerator for that measure. 2)
21 that professional's claims from the entire reporting period will then be analyzed to determine whether the
22 80% reporting threshold was met for that measure. 3) in the analysis, the number of opportunities for
23 reporting as defined by the presence of the measured denominators ICD9 and CPT Category I codes on the
24 claims, is compared with the number of times that the numerator quality codes for that measure were
25 actually reported on the corresponding claims. Then the analysis is repeated for every measure that a
26 professional selects. The participating professional must meet the 80% threshold for reporting on 1, 2, or 3
27 measures, depending on the number of measures that are applicable to the patients who were treated during
28 their reporting period. If 3 measures are reported satisfactorily, then the bonus payment will be calculated.

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1 If only 1 or 2 measures are reported satisfactorily, then a validation will be performed on the claims from
2 which, from the reporting period to determine whether another measure could have been reported. If no
3 other measures should have been reported, then the bonus payment will be calculated. If another measure
4 should have been reported, then no bonus payment will be paid.

5 Agenda Item E under the National Provider Identifier Update. 59E-1. PPAC recommends that
6 CMS provide assurance to providers that private information will be secure and access to NPIs restricted,
7 including the sale of NPIs, to only those physicians and other entities with legitimate healthcare
8 administration needs. The response: Our Privacy Act Statement is part of the NPI application. The
9 statement indicates that healthcare provider data collected by HHS from the NPI application are protected
10 under various laws, and that data may be disclosed under specific circumstances, to certain entities. The
11 Department of Health and Human Services will be publishing a notice that will describe the policy by
12 which HHS will disseminate healthcare provider data from the National Planner Provider Enumeration
13 System. The notice is expected to be published soon.

14 Agenda Item 59E-2. PPAC recommends that CMS publish the NPI data dissemination notice as
15 soon as possible and allow time for public comment, following publication. The response: We appreciate
16 PPAC's interest in this important matter and for sharing your comments and concerns with us. The
17 Department of Health and Human Services expects to publish a notice in the *Federal Register* that will
18 describe our policy with respect to the availability of information from the National Planner Provider
19 Enumeration System. We expect this notice will be published soon.

20 Agenda Item 59E-3. PPAC recommends that CMS establish a one-year contingency plan for
21 implementing NPI numbers. The response: The Centers for Medicare and Medicaid Services announced
22 that it is implementing a contingency plan for covered entities other than small health plans who will not
23 meet the May 23, 2007 deadline for compliance with the National Provider Identifier regulations under the
24 Health Insurance Portability and Accountability Act, commonly called HIPAA, of 1996. Details are
25 contained in the CMS document entitled "Guidance on Compliance with the HIPAA National Provider
26 Identifier Rule" and this guidance can be viewed at our website, under
27 cms.hhs.gov/nationalproviderstand/downloads/npicontingency.pdf on our website. A press release on the
28 topic is also available on the CMS website, on the media press release webpage. CMS encourages health

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1 plans to assess the readiness of their provider communities to determine the need to implement contingency
2 plans to maintain the flow of payments, while continuing to work towards compliance. Likewise, we
3 encourage healthcare providers that have not yet obtained NPIs to do so immediately and to use their NPIs
4 in HIPAA transactions as soon as possible. Applying for an NPI is fast, easy, and free. Visit the National
5 Planner Provider Enumeration System website at nppes.cms.hhs.gov.

6 Agenda Item G, the Transparency Initiative. 59G-1. PPAC recommends that CMS promote the
7 same level of transparency for health plans as for physicians and other providers, specifically PPAC asks
8 that health plans become more transparent about pricing information, physician fees, insurance claims
9 processing, and payment practices, re: underwriting and identification of intermediaries that offer health
10 plans, unauthorized discounts, and reductions in physician payments. The response: CMS agrees that
11 greater transparency across the entire healthcare industry is important. CMS sets a positive example by
12 making quality information available in a variety of providers, including hospitals and nursing homes, as
13 well as on the health plans that provide benefits to Medicare beneficiaries. CMS also makes payment
14 information available for hospitals, physicians, and ambulatory surgical centers, via its website.
15 Beneficiaries are also able to access benefit and cost structure information, including premiums and cost
16 sharing obligations about Part C and Part D plans to enable them to make more informed choices, using the
17 CMS website.

18 Agenda Item 59G-2. PPAC recommends that to be effective and fair, CMS apply transparency
19 initiatives to all sectors of the healthcare market. The response: CMS agrees that transparency is important
20 for all stakeholders. The most effective steps to achieving lasting improvements in healthcare require a
21 critical mass of support from all stakeholders, including healthcare providers, consumers, payers, and
22 purchasers, investing their time and resources toward shared, meaningful, actionable goals. The system will
23 benefit substantially if public and private stakeholders actively collaborate to establish and support uniform
24 standards for health IT interoperability and measuring and reporting quality and costs, or price information.
25 Considerable efforts to develop more extensive uniform standards are already underway and need to be
26 reinforced. This information is necessary for all stakeholders to make effective decisions and to work
27 towards improved literacy for better care.

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1 Agenda Item 59G-3. PPAC recommends that CMS dissuade health plans from implementing
2 policies or quality initiatives that focus on cost without regard to quality. The CMS response: We agree that
3 where possible, price or cost information should be made available with relevant quality information. To
4 this end, the Department of Health and Human Services materials and speeches consistently promote the
5 importance of this concept. As well, CMS activities will increasingly link these concepts through
6 demonstration projects and release of information.

7 Agenda Item H, Recovery Audit Contractor Update. 59H-1. PPAC recommends that due to the
8 demonstrated insignificant amounts of funds recovered from physicians, RAC audits of physician practices
9 be discontinued. CMS response: §302 of the Tax Relief and Health Care Act of 2006, specifically requires
10 CMS to utilize Recovery Audit Contractors to identify underpayments and over payments, and recoup
11 overpayments for all services for which payment is made under Part A or B. The use of Recovery Auditor
12 will allow CMS to determine where policies need to be corrected to prevent improper payments in the
13 future. Paying claims correctly remains CMS's goal in the Recovery Audit Program.

14 Agenda Item 59H-2. PPAC recommends that if a RAC audit is appealed, and the provider
15 prevails, RAC reimburse the provider 25% of the requested recovered amount to offset the costs of the
16 appeals process to the provider. The response, CMS has implemented the Recovery Audit Program to
17 mirror the process used by fiscal intermediaries and carriers. This allows providers to maintain all of the
18 advantages of the administrative appeal process as well as the ability to have claims repaid by offset of
19 future payments. An appeal for an overpayment follows the same process as an appeal for a denied claim.
20 CMS is not implemented a different appeal process for RAC identified overpayments, and paying a portion
21 of the provider's appeal expenses is currently not a process utilized by CMS.

22 Agenda Item J. Physicians Regulatory Issues Team, commonly called the PRIT Update. 59J-1.
23 PPAC recommends that CMS hold a briefing within the next 10 days on the formal described in the
24 proposed rule in the *Federal Register* on February 1, 2007, about graduate medical education volunteer
25 preceptors, and transmit the information to the ACGME and all residency review committees. The
26 response: CMS has outlined the data proxies and the guidelines pertaining to graduate medical education
27 volunteer preceptors in the nonhospital setting in the long term care final rule. To view this guidance, one
28 can refer to the long term care hospital PPS page on the CMS website. This information will also be posted

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1 on the PRIT webpage, located on the CMS website and transmitted to the ACGME and all the medical
2 specialty societies, using our usual channels of communication.

3 Agenda Item K. Hospital Conditions of Participation Update. 59K-1. PPAC recommends that
4 CMS evaluate the implications of the additional documentation requirements proposed by local carriers that
5 supersede the base recommendations by CMS, in particular, PPAC recommends that CMS evaluate recent
6 determinations that require specific documentation of negative findings as part of the review of systems.
7 The response: CMS will review its current documentation requirements with the Medicare contractors and
8 relevant CMS parties to better understand the potential issues surrounding additional requirements if any,
9 the carriers have put in place.

10 Agenda Item M. Under the testimony portion of the meeting. 59M-1. PPAC appreciates the
11 legislation passed to avert the 5% cut to Medicare physician payment rates planned for 2007, but remains
12 concerned about planned cuts totally in almost 40% over 8 years. To avert the steep cuts and avoid the
13 looming crisis in healthcare access for seniors, PPAC recommends the Secretary of the Department of
14 Health & Human Services, and CMS leadership, work with Congress to repeal the Sustainable Growth Rate
15 methodology this year and replace it with a system that adequately keeps pace with medical practice cost
16 increases. If repeal of the SGR is not possible this year, PPAC recommends that CMS use its statutory
17 authority to remove Medicare covered drugs from the SGR calculation. The CMS response: The formula
18 for the SGR in the physician update are defined by statute. We're working closely and collaboratively with
19 medical professionals and the Congress on the most effective Medicare payment methodologies to
20 compensate physicians for providing services to Medicare beneficiaries. We're committed to developing
21 systems that enable us to encourage quality and to improve care without increasing overall Medicare cost.

22 Mr. Chairman, as you can see, we had a rather robust meeting on March 5. And so that concludes
23 the update from that meeting.

24 Dr. Senagore: Thank you, Dr. Simon. Are there any comments for Dr. Simon? Dr. O'Shea?

25 Dr. O'Shea: Thank you, Dr. Simon. I'd like to reply to 59C-1 for the PPAC update. PPAC
26 appreciates the difficulty CMS would incur to fulfill timely reporting and the demands of additional
27 resources. PPAC is aware that access to care will be an increasing problem as reimbursement declines and

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1 reporting demands increase the burden of providing care to beneficiaries. PPAC respectfully requests that
2 access to care remain as a focus of demonstratable quality.

3 Dr. Senagore: No motion. Comment. Any other comments for Dr. Simon on the review?

4 Dr. Grimm: Again on 59C-1, it mentioned that CMS, it said it can respond on an annual basis to
5 this question about access to physician care. It didn't say if it would. Is this a promise then that we will
6 have reporting on an annual basis?

7 Dr. Simon: I think the agency will make every effort to provide that information to the Council.

8 Dr. Grimm: I think that would be nice to have some documentation of that at one of these
9 meetings would be very helpful, too, so that we'd understand when that's going to be reported so we can
10 anticipate that.

11 Dr. Simon: Sure. And at the next meeting, what I'll do, I will chat with the Office of Resource and
12 Development and find out what their yearly cycle is, and be able to give you a time frame when we would
13 share that information with the Council, after they've been able to collate all that information.

14 Dr. Grimm: Yes, I think they mentioned July was their, in this, they said that they get their
15 information every July on an annual basis, so sometime in the fall would be reasonable.

16 Dr. Simon: So it may be ready for the December meeting.

17 Dr. Grimm: Don't want to put out a time frame. Thank you.

18 Dr. Simon: That's all right. Thank you.

19 Dr. Ross: On our last point, Dr. Simon, on 59M-1, I know that you can't come up with answers
20 too quickly and I know that this is a looming crisis in the making, but rather than waiting until let's say
21 November, December, and the Congress has to make an impromptu correction as far as the SGRs go, is
22 there a timetable that you think that we can see in this calendar year, that this SGR system may be corrected
23 or the new formula may come out? I know that you're working on it, I know that CMS is working on it, but
24 if come around December time, if we're looking at 9.9% reduction, I think the doctors need to know that
25 before the time comes so that they can start making contingency plans or maybe we can start looking at
26 how we can advise the Secretary, or for that matter, the Congress.

27 Dr. Simon: I know that the administrator and the CMS leadership is working closely with
28 members in the Department, and the Secretary obviously works very closely with the President. And we

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1 would anticipate that if in the Proposed Rule, if there are any steps that may be taken, that it could be
2 articulated at that time. So I would say at this point that we probably will have to stay tuned to see what
3 information, if any, is shared with us this summer when the Notice of Proposed Rulemaking is published.

4 Dr. Ross: Thank you.

5 Dr. O'Shea: I have one other comment on 59D-2. PPAC had asked CMS to review future models
6 of aggregation of Parts A and B. The response said that there were many demonstration group practice
7 demonstrations out there. I request, PPAC requests that CMS presents in a timely manner, the results of
8 these demonstration studies with assessment and evaluation of the data received.

9 Dr. Senagore: I think that was a motion, so I'll take a second and discussion. Is there a second?

10 [Second]

11 Dr. Senagore: Discussion? Dr. Simon?

12 Dr. Simon: Yes, I'll be able to at the next meeting provide information to you in regards to when
13 those demonstration projects will be completed. Most of them, as you may or may not know, are 3 years in
14 duration and so they're well under way, but I'll give you a time frame in terms of when they'll be
15 completed, and hopefully when we may be able to have information that we can share to enlighten the
16 Council.

17 Dr. Senagore: Maybe we should just vote on that proposal. All in favor?

18 [Ays]

19 Dr. Senagore: All against? Motion carries. Any other comments? Dr. Sprang?

20 Dr. Sprang: On 59M-1. Obviously all the specialty societies all recognize the SGR as probably the
21 single most significant issue this year to just kind of, and I know there's a response there, but just kind of
22 keep on the agenda, just like make a couple of statements. Obviously a physician's first priority is the
23 health and well being of our patients. To do this, CMS has to provide physicians with the financial stability
24 needed in 2008 and beyond. I'll make a continuing ongoing recommendation that PPAC recommends that
25 the Secretary of the Department of HHS and CMS leadership make it a priority this year, to work with
26 Congress to enact legislation to repeal the Medicare physician payment system, replace it with a system
27 that adequately keeps pace with the increases in medical practice costs, and establishes a 1.7% Medicare
28 physician payment update in 2008, as recommended by the Medicare Payment Advisory Commission.

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1 Dr. Senagore: Second?

2 [Second]

3 Dr. Senagore: Any discussion? All in favor?

4 [Ays]

5 Dr. Senagore: All against? Motion carries. You got that Dana? Great.

6 Dr. Przyblski: Just 2 comments and these were things that we had talked about but I do not think
7 were in the form of motions, so perhaps they will need to be. One was about an update on the PLI project,
8 which CMS working with PIAA and we were supposed to get a status update on that. The last time I'd
9 heard back, I think, from Rick Ensors is probably going on more than a year ago, so I'll start with that one,
10 and then there's one other following.

11 Dr. Senagore: Do you want to make that a presentation or do you want just to comment on the
12 next meeting?

13 Dr. Simon: I'll check with Rick and provide comments at the next meeting on that.

14 Dr. Senagore: OK.

15 Dr. Przyblski: The second was we had a discussion about removing drugs from the SGR,
16 according to my notes, it was thought that it could not be done retrospectively at our December 5th, 2005
17 meeting, then it was thought we could not do it prospectively at our March 6th, 2006 meeting, and at our
18 last meeting in March, Dr. Gustafson thought that this could be done prospectively, but perhaps the impact
19 would not be so great while we're currently stuck in this SGR system, since it seems that Congress feels
20 that it can be done, now CMS thinks that it can be done, why don't we just do it, and stop talking about it
21 over the last several years? So I would make a motion that PPAC recommends that prospectively, drugs are
22 removed from the SGR calculation.

23 [seconds]

24 Dr. Senagore: Any discussion? All in favor?

25 [Ays]

26 Dr. Senagore: All against. Motion carries. Thank you. We'll move on to our first scheduled
27 presentation, then, that's the PRIT Update. Once again, we have Dr. Rogers, here, who's the Director of the
28 PRIT, in the Office of External Affairs, and we look forward to his presentation. Welcome Dr. Rogers.

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1 PRIT Update

2 Dr. Rogers: Thank you, Dr. Senagore. It's a pleasure to be here, giving my 2,387th PRIT
3 presentation. [laughter] And I was pleased to hear that you have a very engaged group of new members,
4 and an emergency physician, which is very important to me, personally. I'm going to just quickly go over
5 some of the issues that we've been working on lately and then take some questions. Dr. Senagore, you can't
6 cover up my cartoons.

7 Dr. Senagore: Is this one of your new quality measures?

8 Dr. Rogers: [laughter] This is one of the new quality measures. That's pathologists, they know
9 everything and they can do everything, just a little too late. So these are the issues that are really sort of
10 front and center right now for the PRIT and I apologize, as we go through the issues, one by one, that the
11 slides are a little bit out of date, but that's because we have to turn this in in time to do your briefing book.
12 The first issue that we've been working on a lot has been RAC audits and I need to praise Melanie Combs
13 and Connie Leonard. They have been wonderful on this. We have been talking to particularly practices in
14 California about issues, about demands for medical records, which are burdensome and about repeated
15 demands and things like that, and they recognizing that as this becomes a 50-state initiative, it's going to
16 need to be well thought through and organized and so they've been very, very receptive to the comments of
17 the physicians in California and have been making major policy decisions, which I think are going to make
18 the RAC much less burdensome as it goes across the 50 states. I was very pleased that recently we've
19 announced that all of the RACs are going to have medical directors. And although it's not a current
20 requirement, the RACs that we currently contract with are hiring medical directors, and in fact the RAC in
21 California has one, a former CMD, a great guy, and I think that's going to be a real plus for physicians.

22 Clarifying the rules, concerning volunteer GME, as it says there, we released a proposed rule
23 about how to avoid doing burdensome documentation of reimbursement by physicians if they want to prove
24 that they are truly volunteers, and we would hope that interested parties would comment on that proposed
25 rule. Deeming has been another issues where I think we've gone, CMS has done a good job of addressing
26 physicians' concerns about this. The two most recent initiatives being now having the private Fee for
27 Service plans appear appropriately labeled when a physician queries the common working file to determine
28 a beneficiary's eligibility for care. Before, the Private Fee for Service plan would just appear as an HMO in

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1 the common working file, and in July, it's going to actually appear as a Private Fee for Service and then all
2 of the contact information for the Private Fee for Service plans is now being listed on line, which is going
3 to make it a little easier for physicians to check and see what the fee schedules are and things like that, if
4 they're deciding whether or not to take care of a Private Fee for Service patient.

5 The issue about hospitals providing continuing medical education. I would recommend that you
6 read, the interim final rule, concerning this. It seems pretty reasonable, you know, basically says that
7 reasonable CME can be provided by hospitals without causing a problem with the regulations, but you
8 know if your hospital's taking you down to Florida or Hawaii for your CME, then that may be a problem.

9 Active military physicians' ability to bill government payers. This has been incredibly complex, as
10 it turns out. Because it impacts the DOD, it has Tricare concerns, it impact US Public Health Service, and
11 so we now have a group of I don't know how many attorneys from the various branches now, working on
12 this, trying to come up with a resolution to this. I've explained to them the importance to active duty
13 physicians who are supplementing their income and more importantly, I think, getting really important
14 experience and more busy civilian hospitals, and they understand that, but the issue is making sure that the
15 policy is consistent with the law.

16 Definition of consultation. I am assured that we're still working on this. But I can't say that there's
17 been any update since 3 months ago.

18 Simplifying the work of enrollment. The PDF form that you can fill out for the 855 is, can be
19 filled out on the line and you can't save it, and we are in the final stages of concluding negotiations to get a
20 fix from Adobe, so that you'll be able to save the 855 form if you have filled it out and then have to go do
21 something else, you won't lose your work, but I'll let you know the second that that is available on line.

22 Issuing name of the use of the DEAs by prescription drug plans. I think that problem has gone
23 away. The optometrists were sort of the straw that broke the camel's back. We were able to get policy
24 changed I don't think any prescription drugs plans now are requiring the DEA number for noncontrolled
25 substances. They're using the license number right now to identify and then once the NPIs are universally
26 available, the NPIs will be used to identify practitioners.

27 Part D prior authorization for antiretroviral medications. As you know, this is a protected class of
28 drugs. And we were, we've had a number of calls from HIV specialists about different problems they've

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1 had with different plans, most recently with a drug called Presista, and we've gotten good resolution of
2 every one of the problems that we've had, and we would like to ask for your assistance in making sure that
3 the HIV specialists out there know that we are interested in helping them if they are having problems with a
4 specific plan.

5 I'm still doing a lot of public speaking. I spoke to the American Gastroenterological Association
6 on Saturday, and my voice was even worse on Saturday than it is today. I was down speaking to South
7 Carolina Medical Association, the California Orthopedic Association, the American Academy of Nurse
8 Practitioners, and the American College of Rheumatology and we have a bunch of things coming up.

9 So anyways, as you know well, that is my phone number, and that's my email address, and thank
10 you very much for inviting me.

11 Dr. Senagore: Thank you, Dr. Rogers. Are there any comments for Dr. Rogers?

12 Dr. Przyblski: Just, I want to thank Dr. Rogers again. He visited the National Association of Spine
13 Specialists a couple of months ago and has been very proactive in engaging the physician community and
14 being very responsive, and I just want to publicly thank you.

15 Dr. Ouzounian: He also came out to California, to California Orthopedic Association I think was
16 welcome, so thank you.

17 Dr. Williams: Dr. Rogers, thank you for your presentation. I understand that there is a problem
18 with some of the carrier advisory committees in either New York or Connecticut, that the alternate
19 delegates are not allowed to attend the meetings, along with the delegates so that they can be mentored and
20 sufficiently fill in for the delegate when the delegate can't attend the meeting. Do you know anything about
21 this? And can you comment on that?

22 Dr. Rogers: I call a couple of years ago hearing a comment, something about that, but it never
23 really developed as an issue, but that sounds like that would be a problem, and you know, be happy to take
24 a look at that after the meeting and see what we can find out, and then of course with the administrative
25 contractors coming along, it would be a good time probably to get that addressed.

26 Dr. Senagore: Would you want to make that a recommendation, so that this way we can...

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1 Dr. Williams: PPAC recommends that all carrier advisory committees allow alternate delegates as
2 well as delegates to attend meetings in order to facilitate mentoring of the alternate delegate, and provide an
3 effective substitute for the delegate, should he or she be unable to attend a meeting.

4 Dr. Sprang: Second.

5 Dr. Senagore: Second, Dr. Sprang. Any comments? All in favor?

6 [Ays]

7 Dr. Senagore: All against? The motion carries. Anything else for Dr. Rogers? Dr. O'Shea?

8 Dr. O'Shea: Dr. Rogers, I'd given you a comment from one of our colleagues, I believe it was in
9 Colorado. With change of addresses, they're still having problems getting reimbursement from Medicare.
10 And I'm certainly going to follow up on that issue. I'm just going to say that thank you for being able to be
11 available to us when we need you to. And had you seen that before? This is not a new comment. I've seen
12 it again with, it used to be a programming issue, but reimbursement sometimes when you do change your
13 addresses is, I think it's not since March he's been reimbursed for Medicare beneficiaries.

14 Dr. Rogers: Yes, I'll definitely check into that. I sent, actually Carol Monaco an email this
15 morning to ask for more identifying information. I think I know why I haven't gotten an answer yet. But we
16 will definitely get on that right away.

17 Dr. O'Shea: Thank you.

18 Dr. Senagore: Thank you, Dr. Rogers. We'll move on now to the discussion regarding the DME
19 Final Rule, and we have Mr. Joel Kaiser, who is the Deputy Director for the DME POS Policy. He has
20 extensive working knowledge of the benefit, and he addressed us last December in Baltimore, at which
21 time he talked about CMS's plan to phase in competitive bidding for the program for Durable Medical
22 Equipment in 2007 and we'll hear an update this morning. Welcome.

23 DME Final Rule

24 Mr. Kaiser: Thank you. Good morning everyone. I am Joel Kaiser, I'm the Deputy Director of a
25 Division in CMS that is working very actively on developing policies and implementing the new
26 Competitive Bidding Program for DME POS. For those of you who don't know, DME POS is Durable
27 Medical Equipment Prosthetics, Orthotics, and Supplies. It's a mixture of Medicare Part B benefits for
28 various equipment and devices. We'll have to go on without the slides, since we don't know how long it

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1 will be. But that's fine, I have them here, and we have handouts, so just follow along with the handouts.
2 Basically, if you're on the second slide I'm going to give an overview of the program, and also obviously
3 give some key websites that have important information and provide regular updates on the program. Just
4 by way of introduction again, we're working very hard right now developing policies and working on
5 implementation of the Competitive Bidding Program. It's a very new and very complex program under
6 Medicare. As we speak, suppliers, durable medical equipment suppliers, are submitting bids to become
7 contract suppliers under Medicare for furnishing items beginning next year. We'll be closing the bid
8 window in the middle of July. We'll be evaluating bids this summer, and by the end of the year, we'll be
9 announcing the contract suppliers for the first phase of competitive bidding. Contracts will be effective
10 starting April 1st, 2008 for items furnished on or after that date. As was mentioned, I came to PPAC in
11 December, and gave a presentation on the proposed rule. A lot of the things that were in the proposed rule
12 were finalized in the Final Rule, which was issued on April 2nd, 2007. I believe the publication date was
13 April 11th, if you want to look up the rule in the *Federal Register*. You can also go to our website and
14 access the *Federal Register* document there. Slide 3, the Competitive Bidding Program was mandated by
15 §302 of the Medicare Modernization Act, which was signed in 2003, I believe, so it's now 4 years later and
16 4 years that went very quickly, I might add. To look in the statute, §1847 of the Social Security Act is
17 where the Competitive Bidding Program rules are located, if you want to look in the Social Security Act to
18 see the statute. The Competitive Bidding Program will replace the current payment methodology, under
19 Medicare for DME POS, certain DME POS, and that is a fee schedule methodology. The fee schedules
20 have been in effect for most DME POS items and services since 1989. And the Competitive Bidding
21 Program will be for select items of DME POS. It's not all DME POS, but it is most of the big ticket items,
22 starting out with Durable Medical Equipment, which is a Part B benefit for equipment used in the patient's
23 home. Currently Medicare spends about \$9 billion a year on DME, so it's a large percentage of the total
24 DME POS pie, which is about \$12 billion. Under competitive bidding, we'll be implementing, or phasing
25 in competitive bidding for durable medical equipment for everything except class III items. These are items
26 that are classified by the Food & Drug Administration as class III items. So there are some safety issues
27 associated with those. For example, implanted infusion pumps are an example of a class III piece of durable
28 medical equipment. Also inhalation medication is also exempt from competitive bidding. Inhalation

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1 medication that's used with certain DME. But by and large, most durable medical equipment is subject to
2 the program. The second major category is enteral nutrition, enteral nutrients, equipments, and supplies,
3 which is about a half a billion dollars in terms of Medicare expenditures, and finally the third major
4 category is off-the-shelf orthotics. Now the statute defines these items very narrowly. They are items that
5 require minimal self-adjustment and do not require expertise in fitting. So that narrow definition means not
6 a whole lot of orthotics are going to meet that definition. So it's really compared to the other categories, a
7 rounding error. It's not a whole lot of money for those items under Medicare. So it's mainly durable
8 medical equipment. Slide #4 would give you an overview of the demonstrations which were the basis for
9 the programs. The Balanced Budget Act of 1997 mandated demonstrations to take a look at Competitive
10 Bidding to see how it worked under Medicare for durable medical equipment, specifically. Under the
11 demonstrations, which occurred in Polk County, Florida and San Antonio, Texas, there was an average
12 overall savings of nearly 20%, across the different items. Items included oxygen, hospital beds, manual
13 wheelchairs, a few other items. There were also reports to Congress that were due each year of the
14 demonstration and one final report to Congress as well as surveys of beneficiaries to gauge their
15 satisfaction with the program. And the reports to Congress concluded that access to items under the
16 demonstrations was not impaired by the Competitive Bidding. Again, I mentioned, the Final Rule for the
17 national program mandated by the MMA, was issued on April 2nd. So we are busy in the process of
18 working to implement the program. We also announced the initial metropolitan statistical areas for the first
19 round of Competitive Bidding on April 2nd, and before we move on, I'd just like to give a little bit more
20 background on durable medical equipment, and on the Competitive Bidding Program and how it works.
21 There's no slide for this. I just wanted to give a little bit more detail.

22 Again, it's \$12 billion a year, currently. It's growing. DME is very labor intensive in that there's
23 lots of DME. There are a lot of HCPCS codes for all different types of varieties of durable medical
24 equipments, anywhere from canes, crutches, to complex pumps, complex wheelchairs. So there's a wide
25 variety of items, there's a wide variety of manufacturers and a wide variety of suppliers who furnish all
26 those items. So it is very complex. It's very labor intensive. The projections for Competitive Bidding is an
27 annual savings, once full implemented, of approximately \$1 billion a year. And basically, how it works is
28 that we will be bidding for different product categories. A supplier will submit a bid for a product category,

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1 for example, hospital beds and accessories. That supplier will be bidding for Medicare business in a
2 competitive bidding area and in the first couple rounds, that's linked to metropolitan statistical areas. If the
3 supplier submits a competitive bid, then and I'll define what this is a little later, then they would be a
4 contract supplier, they would be offered the contract once they know what the final payment amounts will
5 be. During the contract period, they are offered the contract, and they will either accept it or not accept it. If
6 they accept it, then they are bound by the contract to furnish the items to all Medicare beneficiaries residing
7 in the Competitive Bidding area for the length of the contract. And again, the Competitive Bidding
8 Program is designed to replace for certain items in certain areas the fee schedule amounts that we currently
9 pay. The fee schedule amounts have been in place since 1989, are based on average Medicare payments
10 under the reasonable charge methodology, which was a methodology which based Medicare payments on
11 supplier charges and updated those charged-based payments every year, or in those cases where we don't
12 have fee schedules that are based on reasonable charges for most newer items, the fee schedules are based
13 primarily on retail prices, and in some case, manufacturer suggested retail prices. So the Competitive
14 Bidding Program is a program that's designed to use market forces and competition to establish Medicare's
15 payment rate, as opposed to relying on charges, supplier charges from many, many years ago and
16 manufacturers' suggested retail prices. We would be at this point on slide 5. Which is the one before this
17 one.

18 Thank you. CMS awards contracts to the lowest bidders. Again called Contract Suppliers. They
19 must meet quality standards, which is another thing that was mandated by the Medicare Modernization Act.
20 Quality standards and accreditation are now mandated for DME POS suppliers, because there are so many
21 of them, it will take a while to phase in the accreditation for every supplier in the nation, but we are going
22 to begin the phasing in the accreditation which includes the quality standards, beginning with the
23 competitive bidding areas and the competitive bidding suppliers first. So there are suppliers, contract
24 suppliers under Competitive Bidding Program will be the first suppliers under the Medicare Program that
25 will be subject to these quality standards. Basically, the way we do the bidding. Again, I'll just elaborate
26 more on the bidding, is that a supplier will submit a bid for every item in the product category. They will be
27 required to provide every item in that product category. Every item in the product category will be
28 weighted based on past utilization, will take the weight times the supplier's bid for that item, then the sum

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1 of all the weighted bids will be what's called the composite bid for the supplier, then we will weigh the
2 composite bid for the suppliers. We are also asking suppliers to report their projected capacity for
3 furnishing items in the area and we will also be projecting the demand for the items during the contract
4 period in the areas. Starting with the lowest bidders, once we have the cumulative capacity of bidding
5 suppliers that meets or exceeds our projected demand, then we will have a range of "winning suppliers."
6 These winning suppliers will be anyone that has a composite bid at or below the pivotal bid. We'll go out,
7 we'll offer contracts to these suppliers, assuming they all accept the contracts, then payment under the
8 program will be based on the median of the bid for each item that the winning supplier submitted. If any of
9 the winning suppliers don't want to sign a contract, then we'll be moving up to the next lowest bidding
10 supplier and offering them the contract. The payment amount will still be the same based on the median of
11 the winning bidder range, we'll just offer the next supplier the contract, and they'll either accept it or they
12 won't, and we'll go from there. Incentives under the program are to provide high quality items and
13 services. Once they win a contract, of course, the competition doesn't end. They obviously submitted a
14 contract for 2 reasons; #1 was to continue furnishing items for Medicare patients in that area. #2 is they're
15 expecting to increase their volume of business. So they're going to be competing with other suppliers in the
16 area for that business. They'll want to be providing high quality items. They'll want to be doing a good job
17 so that they'll get more referrals. And again, of course, it reduces, the program is designed to reduce costs,
18 obviously.

19 Just real quickly, the law mandates phase in under the programs. Obviously we're not going to
20 jump right into the national competitive bidding everywhere across the country right away. That would be
21 mind boggling. It's already mind boggling what we're doing already. But beginning in 2007, the law
22 mandates that we phase in Competitive Bidding first in 10 of the largest metropolitan statistical areas.
23 Second round, 2009, we'll be doing 80 metropolitan statistical areas. That's bidding in 70 additional areas.
24 So 70 plus 10. Then after 2009, we have discretion, our administration has discretion to phase in additional
25 areas. And that, you know, we'll see where we go at that point. But by way of largesse, we're defining
26 largest basically to mean an MSA that has at least 250,000 people. And the MSAs are scored, based on the
27 dollars, DME POS dollars spent per beneficiary, and also the number of suppliers per beneficiary. So we

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1 gave priority to MSAs where we're spending the most money on DME POS, per capita, and also where
2 there's more suppliers that will be competing. So more suppliers per beneficiary.

3 Just a real quick run down of the first MSAs that were selected through this process. You'll see
4 them in the handouts so I won't read them all. The first 10 product categories for Competitive Bidding,
5 based on our authority in the statute, it is discretionary authority to phase in the Competitive Bidding
6 Program first for the highest cost highest volume items, or those that offer the greatest potential for savings
7 under the program. And for the first round, we have identified those items. Our initial phase in items to be
8 oxygen supplies and equipment, standard power wheelchairs, scooters and accessories, complex rehab
9 power wheelchairs and accessories, mail order diabetic supplies, enteral nutrients equipment and supplies,
10 continuous positive airway pressure devices and respiratory assist devices, hospital beds and accessories,
11 negative pressure wound therapy devices, walkers, and for just 2 MSAs for the first round support services.
12 These are mattresses overlays to prevent [unintelligible 01:03:20]. There's been a huge spike in utilization
13 in Miami and San Juan, so we felt that we wanted to phase in, at least for those areas for the first round
14 competitive bidding for sports competitive.

15 Competitive Bidding affects Medicare beneficiaries under Fee for Service. It affects the Medicare
16 beneficiary who has a permanent residence in a Competitive Bidding area. Competitive Bidding area is
17 identified by a series of zip codes, and the payment amount that we establish under Competitive Bidding
18 travels with the beneficiary. Just like today, our fee schedule amount for example, if you live in New York,
19 and you travel to Florida, as a snow bird, then if you get an item while you're in Florida, then we pay the
20 New York fee. Just the same thing will happen in a Competitive Bidding. If you travel outside of the
21 Competitive Bidding area, if somebody provides a Competitive Bidding item to you, it doesn't have to be
22 one of our contract suppliers, since you're out of the area, but we will pay the Competitive Bidding
23 payment amount to that supplier. Second bullet there, in some MSAs, we've used our authority that the
24 statute gives us to exclude low population density areas from the metropolitan statistical area, I should say.
25 For example, Riverside, California is a very large metropolitan statistical area. We don't have any control
26 over the boundaries of the MSAs. They're drawn up by OMB and they're drawn up based on a group of
27 counties, surrounding urban areas. In the West, you have some very large counties. You have some very
28 sparsely populated large counties, or at least part of them are, that are away from the urban area. For

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1 example, Riverside, California is an MSA that does have a lot of DME dollars. Does have a lot of suppliers,
2 so it was selected as the first round area, but it has also 2 of the largest counties in the United States. San
3 Bernardino County is the largest county, in terms of square miles in the United States, and also Riverside
4 County. So most of the Eastern part is desert area, very few beneficiaries, not a lot of savings to be had and
5 logistically a nightmare for someone who has a supplier location in Riverside or San Bernardino, we don't
6 want them traveling 100 miles to deliver a hospital bed to someone in the desert. So we used our authority
7 to carve out those sparsely populated desert areas. There are also a couple of other MSAs where there are
8 some low population counties that were excluded from Competitive Bidding in the first round.

9 Moving on to the next slide just briefly to describe the mail order diabetic supplies. We decided to
10 phase in competitive bidding first for mail order diabetic supplies, the supply test strips, lancets, supplies
11 that are used for the home blood glucose monitor. Right now, today, over 60% of Medicare beneficiaries
12 obtained replacement test strips and lancets for their monitors through mail order suppliers. And we
13 decided to phase in competitive bidding first for the mail order. The reason is that we want the beneficiary,
14 at least for the first couple years of the program to still have the choice of going to the local drug store if
15 they want to get their diabetic testing supplies. And for mail order, we see that once you picked out, once
16 you and your physician or you and a pharmacist have picked out the monitor that you think best meets your
17 needs, because there are many, many, many different models of monitors on the market, then we're just
18 talking about replacing the brand of test strips that go with your monitor. So, we feel that mail order is a
19 good cost effective way to do that. We believe that there will be a lot of savings by implementing
20 Competitive Bidding first for mail order items only and then later we can think about phasing in the
21 Competitive Bidding for other diabetic supplies, but initially, there's, we believe there's a lot of savings
22 potential for the mail order market. In 2010, right now, because we're mandated to phase it in in a certain
23 way, we're doing mail order in just the 10 MSAs. By 2010, when we can expand into additional areas
24 under the program, we believe that we will be, assuming that the mail order Competitive Bidding goes well
25 in the first round, we'll be phasing in national or regional mail order programs for diabetic supplies.

26 Just some of the requirements again. People who, Medicare beneficiaries who live in a
27 Competitive Bidding area must use a contract supplier for the most part. There are some exceptions. The
28 law mandated that we have a grandfathering process for rented items and for rented durable medical

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1 equipment, and for oxygen. So a beneficiary and a supplier if they both choose to continue that supplier
2 relationship, can continue to do that. The supplier does not have to be one of our contract suppliers, so
3 there's no break in service. Also, in the next slide will go into more detail on this, a beneficiary may
4 continue to get certain items from a doctor that they sometimes get while they're visiting the doctor's
5 office. Walkers is one example. And under the Competitive Bidding Program the Medicare beneficiary
6 pays 20% of the Medicare approved amount. So it's going to be obviously a lower amount than what we're
7 paying now, so savings for the beneficiary and all, so assignment is mandatory under the Competitive
8 Bidding Program, so the beneficiary is guaranteed not to have to pay more than 20% of the single payment
9 amount, which again, is lower than what we pay now, so tremendous savings potential for the beneficiaries,
10 many of which are on very limited budgets

11 Just in more detail the physician exception for certain items. We used our authority to provide an
12 exception for items that are furnished out of the physician's office. Those items primarily, well, actually,
13 it's limited to crutches, canes, walkers, forwarding manual wheelchairs, blood glucose monitors, and
14 infusion pumps. And sometimes a beneficiary will get these items from the physician's office if they're
15 going in there, and the physician says you can't walk out of here unless you have a walker. You're in no
16 shape. You need a walker, so beneficiary, rather than having contract suppliers drive out and furnish the
17 walker, the physician sometimes will provide the walker right then and there. So we're allowing that to
18 happen under competitive bidding. The physician does not have to submit a bid if they're a physician
19 supplier of those items. But they will be paid the single payment amount for the items, just like the contract
20 suppliers. And we also have an exception. It's not on the slide, but for occupational therapists and physical
21 therapists, who, as part of their therapy, they provide a brace. So an off-the-shelf orthotics, that's subject to
22 Competitive Bidding, if an OT or a PT is generally furnishes, or customarily furnishes that orthotics as part
23 of overall therapy treatment, then they would be excepted from the bidding as well.

24 The physician authorization process is something that's mandated by the statute. And we provide
25 some details in our rulemaking on what this process is. A physician or treating practitioner may prescribe a
26 specific brand or mode of delivery and the contract supplier must furnish that item. The payment is the
27 same, regardless of whether they're furnishing the normal items they furnish, or the one that is specifically
28 prescribed by the physician, we're going to pay the same amount but the law does require this process to be

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1 part of the Competitive Bidding Program. The supplier, if they get a specific brand that's prescribed by the
2 physician, generally they have to furnish the item, unless one of two things; either they find another
3 contract supplier in the area, who's willing to furnish that brand or mode of delivery, or after consulting
4 with the physician or treating practitioner, they come up with an acceptable alternative brand. But if those 2
5 avenues don't produce, the supplier must produce. They must find a way to provide that item; they may
6 have to special order it or whatever they have to do, they will be required by our contracts to furnish that
7 item, so the patient will get what the physician prescribes. And again, the law mandates that this be used
8 only for those items for which beneficiary gets a different item there would be an adverse medical outcome.
9 So there has to be some documentation by the physician that this specific model or brand, or mode of
10 delivery would prevent that adverse outcome.

11 Just to sort of wrap up, the bidding process, because it's coupled with the quality standards and
12 accreditation, will be a way to secure access to quality items. Right now suppliers don't have any quality
13 standards. Although we have lots of quality suppliers, there's no specific standards, and we're phasing
14 those in, obviously beginning April 1st, 2009, actually before that. Before you can even submit a bid, you
15 have to either be accredited or begin the process. So right now, we're, we've been accrediting all year.
16 We're going to continue accrediting for years to come. And the accreditation process, I believe you have to
17 be reaccredited every two years. Involves site visits and the normal things that go along with accreditation.
18 People with Medicare will be paying less. I mentioned that assignment is mandatory, so the beneficiary's
19 payment is limited. Medicare program obviously will save money, projected one billion dollars per year.
20 And it should reduce fraud, waste, and abuse, at least in those areas. DME suppliers who are gaming the
21 system, have a habit of picking up and moving to other areas. But at least in the high fraud areas,
22 Competitive Bidding means you have only a few number of contract suppliers furnishing those items. You
23 know who they are, you know they're legitimate. And if there's any problem, we'll have ombudsmen and
24 we'll have beneficiary surveys that we do that will highlight problems, and we'll make sure the supplier
25 does what they have to do to be a good supplier under the program. And the next 2 slides are our key
26 websites, starting with the CMS website, and that website has a lot of information, including our link to our
27 contractor website, which is the next slide, but for this slide, as the bullets points out, we have the links to
28 the regulation and any updates, notices. We have the links to the quality standards and accreditation

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1 organizations that are implementing those quality standards. And we have the link to information on our
2 program advisory and oversight committee, which is a committee mandated by the statute to provide advice
3 to us on implementation of the programs. And that committee meets periodically. The next slide is the slide
4 for our implementation contractor. The statute gave us specific authority to contract with contractors to
5 implement the program sufficiently, and we contracted with Palmetto Government Benefit Administrations
6 to be our CBIC, Competitive Bidding Implementation Contractor, and their website is the website that's
7 going to be Grand Central Station for information for suppliers. Lots of facts sheets. We have a webcast.
8 We have bidding conferences that are going to begin soon. Eventually the CBIC will have a manual for
9 Competitive Bid Contract Suppliers, that will have all the rules and the bidding process and everything in
10 that manual. But we are starting out a significant education campaign right now for suppliers, because
11 obviously they're the ones that information right now, to know how to submit a bid, to know what they
12 need to know to submit a bid. Then, later, this year, by the end of the year, we will announce the contract
13 suppliers for Round 1 and then we will start an intense education campaign for physicians, referral agents
14 and beneficiaries, so that they know who the contract suppliers are and they have information on how the
15 program works. And that will be an education campaign that will be intensive. It will be for approximately
16 3 months, once we announce the suppliers at the end of the year and up to April 1st, when we implement the
17 contracts. So just to summarize real quickly and wrap up, we're starting Competitive Bidding in 10 MSAs.
18 Bidding is underway now. In 2009, we'll start the bidding process all over again for a whole lot more areas,
19 80 total, and then additional areas after 2009. Thank you.

20 Dr. Senagore: Thank you, Mr. Kaiser. Just a couple of comments. I think you addressed it, but just
21 for clarification, the benefit will be defined by the beneficiary's zip code, is I believe what you stated for a
22 given item?

23 Mr. Kaiser: Yes. Starting with the first 10 MSAs and 80 MSAs and then additional areas, the
24 Competitive Bidding area will be the series of zip codes for the area we define for implementation of the
25 program and if the beneficiary has a permanent residence in that area, then a Competitive Bid item that's
26 furnished to them must be furnished by the contract supplier.

27 Dr. Senagore: So, where I'm going with this, is so if you're in a higher service area, higher charge
28 area, is there a provision against balanced billing or everything has to be at the site of origin? And would

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1 that potentially hurt access if you're in a site that's used to be reimbursed at a higher level? Would they just
2 refuse service?

3 Mr. Kaiser: Well, it's contracts, they're contracted suppliers, so they can't refuse service...

4 Dr. Senagore: No, but if you live in Michigan and you go to Florida for 4 months out of the
5 winter, you need to go get your pick out your glucose monitor or your wheelchair overhauled, or whatever,
6 and you're in Florida, that might be a higher reimbursement area. Would the Florida provider say well,
7 we're used to getting X plus, so you need to pay the balance between those two?

8 Mr. Kaiser: Well, we have a similar situation today with the fee schedules. The fee schedules
9 range from a ceiling to a floor, it's 15% variation, so it's not significant, but you could have a situation
10 where someone from New York, obvious example, they go to Florida in the winter, and in New York, the
11 fee is at the floor and Florida's fee is at the ceiling. We've never had a problem in 20 years of paying based
12 on the fee schedules of suppliers stepping up and providing those items. We don't expect that to be a
13 problem under Competitive Bidding. It's not going to be that extensive. Most items, oxygen concentrators,
14 things like that, you know, they will rent when they're on snowbird status, but a lot of items, like diabetic
15 supplies, if we're phasing in for mail order, so if you need while you're down there, you can get through
16 the mail, and we do allow suppliers to ship 3 months of supplies in advance, but for those items, where they
17 are obtaining them from a supplier that's off site, we have had, again, similar things happen under fee
18 schedule all these years and there's never been a problem. But of course, we will closely monitor it, and if
19 there is a problem, you can believe we will do whatever we need to address it.

20 Dr. Senagore: And then a follow up comment. If there and I think there are in some of the CPT
21 codes, if a physician has an orthotics or something that's included in the practice expense component, are
22 those excluded from this process, if that's already part of their professional service, that is included?

23 Mr. Kaiser: Well, yes. Anything that's paid for under the Physician Fee Schedule and not paid for
24 under the Durable Medical Equipment benefit or the Orthotic benefit or whatever the benefit is, would
25 continue to be paid bundled into the CPT procedure payment.

26 Dr. Ouzounian: Tony, in response to your question, I think that was addressed by the PE and I'm
27 not sure of any specific instances where that would come up.

28 Dr. Senagore: I just wanted to be sure. I don't know if we caught them all, but...

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1 Dr. Ouzounian: We were pretty careful. Let's see, I have a comment and then would like to make
2 a proposal. You've made an exception for physical therapists and occupational therapists to provide
3 orthotics. And there's a variety of items that fall under orthotics and there's several professional groups that
4 do provide those, which include orthopedists, podiatrists, neurosurgeons, and probably primary care, and
5 these are commonly dispensed for treatment and patient care and patient convenience so they don't have to
6 go elsewhere. So you've made an exception for the PTs and the OTs, and we feel that it's important that
7 you also make that exception to include physicians, which our understanding is, according to your
8 definition, would include podiatry. So we'd like to make a motion that PPAC recommends that the
9 exception for the orthotics dispensing and exception from Competitive Bidding be extended to physicians
10 also.

11 Dr. Senagore: Second?

12 [Second]

13 Dr. Senagore: Any discussion?

14 Dr. Arradondo: This thinking would, should go beyond the orthotics as you make exceptions for
15 use say by allied health personnel, since primary care providers and some specialty providers would do
16 precisely the same thing that any of the allied health people might be doing, whether it's providing a brace
17 or a tens unit or some other durable medical equipment. So that thinking needs to, should in fact be implicit
18 in this motion. And should be given some priority. Now I just mentioned those two complementary—

19 Dr. Senagore: Doctor, I wonder if Tye would accept a favorable amendment from Dr. Arradondo
20 to include any orthotics and any other classification of DME.

21 Dr. Ouzounian: I'm not sure the impact, Dr. Senagore. Could we make it as two motions and just
22 vote them separately, please?

23 Dr. Senagore: Sure. Can we get that phrasing back, Dana? And we'll just use the same
24 terminology and Dr. Arradondo will just put in that definition.

25 Dr. Arradondo: Adding it won't matter discussion and suggestion, we could certainly do that as a
26 motion, but in the pain area for instance, the allied health personnel, in fact might do that, the DME
27 company might do it, but also the paying people whomever they might be, anesthesiologist, [unintelligible]
28 physicians, whoever might be the paying professionals.

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1 Dr. Senagore: Dana, I think what we're going to do is if you could read that back, we'll just
2 replace orthotics with some other terminology that would cover more expansively.

3 Ms. Trevas: OK, you ready? PPAC recommends that CMS expand the exception currently for
4 orthotics that's being, I'm sorry I'm working on this as I go. The exception applied to physical and
5 occupational therapists for dispensing orthotics from the Competitive Bidding process be expanded to
6 include physicians. I'll work it out.

7 Dr. Ouzounian: Right. As defined by CMS or whatever the guideline is.

8 Dr. Senagore: Right, so I'm just trying to craft this in my head here. PPAC recommends that CMS
9 consider including physicians as dispensers of any DME product that is excluded by the current contracting
10 language for other healthcare providers. Does that cover it?

11 Dr. Ouzounian: I'm sorry, Tony, is that the second recommendation?

12 Dr. Senagore: Yes, that's the second one. We already, we're going to vote on yours. We haven't
13 voted yet, sir. We'll get them both on the table and then we'll vote.

14 Dr. Simon: Would it be those that would be excluded by the Final Rule

15 Dr. Senagore: Yes, by the Final Rule. Yes.

16 Dr. Senagore: Could you read back what I think I said there, Dana? [laughter]

17 Ms. Trevas: PPAC recommends that CMS consider including physicians as dispensers of any
18 DME product that is excluded by the Final Rule for other healthcare providers.

19 Dr. Senagore: Why don't we craft that off line if we could. I mean I think you get the spirit of
20 what we're going for here. Any other health care providers that are allowed to dispense now, outside of this
21 Final Rule that's approved, the terminology should allow physicians if that's a matter of their practice as
22 well. And that'll be the spirit of the motion. Is that?

23 Mr. Kaiser: Yes, I hear you. Yes, we received similar comments as part of the rulemaking process,
24 so we did decide as part of the rulemaking process not to extend it beyond where it's extended now, but of
25 course we can continue to consider that recommendation for the future.

26 Dr. Senagore: Thank you, so we'll wordsmith that off line and I'll call the vote if there's no more
27 discussion. And Dr. Ouzounian's recommendation. All in favor?

28 [Ays]

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1 Dr. Senagore: All against? Motion carries. And I think we'll take a 10-minute break now, Dr.
2 Simon.

3 Break

4 Dr. Senagore: I think if we can go ahead and find our seats please for the committee folks. I think
5 there's one more comment if not a question, so maybe we should in the spirit of full disclosure have you
6 state [alissa?]. Dr. Ross, I think you had another recommendation for us, Sir?

7 Dr. Ross: Yes, Mr. Chairman. After discussion, the process I think that we dealt with before
8 beside the Competitive Bidding Program was also about accreditation. So I'd like to propose this at this
9 time, if I may, that PPAC recommends that CMS acknowledge that physicians are qualified to supply DME
10 POS by virtue of education, training and experience and therefore should be deemed accredited already in
11 this process.

12 [second]

13 Dr. Senagore: Any comments. All in favor?

14 [Ays]

15 Dr. Senagore: And then we'll clarify the one since we have it here. Dana was kind enough to
16 wordsmith for us. PPAC recommends that where the Final Rule exempts healthcare providers from the
17 Competitive Bidding process for DME POS, that CMS consider including physicians among those
18 providers who are exempt. Second?

19 [Second]

20 Dr. Senagore: Any discussion? Comments? All in favor?

21 [Ays]

22 Dr. Senagore: All against? Motion carries. Thank you, Mr. Kaiser. I think we're all set. I
23 appreciate your discussion. So we will move on now to the Contracting Reform Update and I believe we
24 have Ms. Karen Jackson is the Director of the Medicare Contractor Management Group in CMS with the
25 responsibility for Program Management of the current fiscal intermediaries and carriers as well as
26 implementation of the Medicare Administrative Contractors under section 911 of MMA. Ms. Jackson,
27 welcome.

28 Contracting Reform Update

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1 Ms. Jackson: Thank you, thank you. Good morning and thank you for inviting me to speak to the
2 PPAC this morning. It's my first opportunity to address this group and it's a real pleasure to be here. I'm
3 here to give you an update on the status of implementation of Medicare Contracting Reform and I'll tell
4 you when we're ready to switch slides. OK, very good. And I understand that you have a much more
5 important speaker coming on immediately after me, so I will try and be brief in my remarks and make
6 plenty of time for questions and comments. Why are we talking about Medicare Contracting Reform to the
7 PPAC? Well, we tried very hard as we implement these major contracting changes in the Fee for Service
8 environment to make it unnoticeable to the practitioner community, that really is the objective of myself
9 and my staff and the contracting staff in the agency as we both make award on these contracts as well as
10 implement these contracts. What we expect to have happen is physicians and other practitioners have
11 knowledge that there is a change in our infrastructure, a change in our administrative environment, that you
12 have an opportunity to opine on the quality of the entities that are processing your claims and providing
13 services to you in the payment of your claims, and that you respond when we ask for information on
14 surveys about provider satisfaction so that we can use the information that you supply to us as one of the
15 aspects in assessing the performance of the contracts. So that's part of the reason why it matters to you. The
16 other reason as a taxpayer is as we change our infrastructure for Fee for Service operations, we are doing so
17 to achieve better efficiencies in governments of the Fee for Service Medicare Program, and also to achieve
18 some savings in the cost of administering the program. We have not had access to the competitive
19 environment and the fiscal intermediary interior environment ever since the start of the program, and our
20 first experience with the competition of contract awards has been pretty successful so far. So that's why
21 I'm here to talk to you today. And I will go very quickly into my slides. Speaking more broadly than
22 contracting reform implementation, I think all of you are quite aware of the numerous changes that are
23 occurring within the Fee for Service environment and contracting reform became almost an afterthought in
24 the Medicare Modernization Act that passed in 2003. The agency and multiple administrations had been
25 making efforts almost for about 20 years prior to the passage of the legislation for changes in our
26 contracting authority so that we could take better advantage of competition and performance management
27 that we've not been able to avail the government and the Medicare program of over the history of the
28 program. One of the aspects of contracting reform, that was very clear in the intent of Congress was that

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1 spend a lot of time working with the provider communities, both on the institutional end on the practitioner
2 side, getting your input on how we structured the contracts, how we assessed the performance of the
3 entities who are awarded the contracts, and taking that performance assessment into any kind of award fees
4 or any kind of incentive structures that we place within those contracts and we are well on our way to doing
5 that.

6 Just a little bit of additional context for you. Another aspect of the business case for contracting
7 reform passage and implementation is the continued projection of presence of the Fee for Service program
8 in Medicare overall. We are building the new contracting structure both for claims administration as well as
9 for the other contracts that serve the Fee for Service program with the intent of being able to serve a
10 growing Medicare Fee for Service population as well as better interfaces and interaction with the Medicare
11 Advantage benefits. For the context for you, based on current projections in spending, Fee for Service
12 obviously continues to be a major aspect of the Medicare program. Correctness, accuracy of payment is
13 very important to us as we select the new entities and administer the contracts that we are awarding. So
14 where are we? Well, we're making very good progress. We're in the first full phase of acquisition of the 15
15 A/B MAC jurisdictions that we described in our report to Congress in 2005. We have implemented a full
16 AB Medicare Administrative Contractor in the first jurisdiction that was awarded in July of last year, and
17 we are fully implemented as of about a week and a half from now, the DME MAC environment. Those
18 were the first of the Medicare Administrative Contracts that we awarded. We had intended to have those
19 contracts fully implemented by July of last year, but one of our first outings with full and open competition
20 and full usage of the Federal Acquisition Regulations government contracting rules, we had our first
21 experience with contract protests, and have been through that process and have a lot of experience with that
22 now as we go into the large awards that we're going to be making later on this year. So contracting reform
23 in a nutshell, I think all of you know, integrates the administration of Medicare Part A and Part B under a
24 single contracting authority. It does away with the legacy carrier and fiscal intermediaries contracts that
25 have been a cornerstone of Medicare claims administration since the inception of the program. It moves
26 those contracts and those contract award and review processes fully under the Federal Acquisition
27 Regulations, Federal contracting rules that apply to practically all other contracting across federal
28 government. And with the implementation of the Contracting Reform legislation, we are reengineering our

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1 Fee for Service platform. There is no question about that. And we'll talk a little bit further about that as I
2 get further into my slides. We're not just recompeting or competing the fiscal intermediary and carrier
3 contracts to simply move into or maintain that environment in a new contract instrument. We are doing a
4 massive restructuring of the administration of claims processing and claims payment as we implement
5 contracting reform. And one of the ways that we're doing that carefully and to maintain stability in the
6 claims payment environment is we are using incentives and award fees and other kinds of reward
7 mechanisms for the contracting entities who are involved in implementing so that we are moving forward
8 with stability in the current claims payment environment. Next slide just gives you a very quick sample, or
9 example of all of the other entities that are being implemented, or are in operation with the implementation
10 of the Medicare Administrative Contractors. And you may be wondering why we have this slide in this
11 slide presentation. What I would say to you is that practically every one of the functions that are on this
12 slide were functions that were performed by fiscal intermediaries and carriers historically and in the past 5
13 to 10 years, as we have sought ways to improve the administration of the Fee for Service benefit, to achieve
14 better efficiency and cost savings on the administrative side, we have implemented specialized entities with
15 focuses on specific areas with Fee for Service administration. Those entities are all entities that perform
16 specific functions. Because of the integration of those functions, into Fee for Service benefit payment
17 though, every one of those entities has a line to a Medicare Administrative Contractor, so those entities are
18 all entities through which joint operating agreements are administered, Medicare Administrative
19 Contractors, as they are implemented, have very important working relationships with each of these
20 contracts. But the Medicare Administrative Contractors are the entities with whom the physician, the
21 practitioner community, the institutional provider community will have their primary interfaces. Moving on
22 to the next slide, what we're seeking to achieve with implementation of Medicare Administrative
23 Contractors—already talking about single point of contact for providers in our very complex administrative
24 environment, the provider satisfaction survey, which we are in the 3rd year of administration, is a very
25 important measure that we use for assessing a Medicare Administrative Contractor's performance and
26 fiscal intermediaries and carriers are also taking that very seriously and looking very closely at the survey
27 results. We have implemented performance incentives in the first round of Medicare Administrative
28 Contractors that have become operational. It's a little bit early to see the cost benefit on those, but we are

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1 seeing some program and performance improvements in the original, in the initial Medicare Administrative
2 contracts that are implemented. We have a great deal of work underway within the agency and with very,
3 with a multitude of contractors to improve our information technology platform. We're in the process of
4 consolidating all of our data processing into two enterprise data centers that will secure our data and make
5 it more securely accessible to appropriate partners that will be fully implemented in the Fee for Service
6 environment by the end of next calendar year. And we are expecting to and so far have seen significant
7 operational savings in moving into the new contracting environment. Competition, it works. It really is
8 helping us to achieve some efficiencies and savings as we implement these contracts. And a key measure in
9 measuring performance of the Medicare Administrative Contractors and also in measuring performance of
10 bidders for Medicare Administrative Contract awards is payment accuracy. The Comprehensive Error Rate
11 Testing Program is something that we use those outcomes and results are something that we look at very
12 closely in looking at a full complement of factors and making contract award.

13 So so far what we've found, administrative costs for these contracts, we do expect to achieve some
14 reductions in cost. For the Medicare Administrative Contracts, with some distribution of that cost into the
15 new contract entities around enterprise data centers, around some of the other consolidation of IT
16 framework, so that we can hopefully become more Internet ready over the next couple of years. So what
17 we're trying to do is take the savings that we generate out of the MAC awards and implementations and put
18 that into some of our IT modernization efforts. We are very pleased that we've seen a number of the legacy
19 carriers and intermediaries form business relationships, and form new corporate entities to bid and compete
20 for MAC contracts, so we expect that we will continue to have the level of expertise that's been very
21 important to us over the past 40 years of administration of the program, carrying into the MAC
22 environment. And we've been very pleased so far with the level of innovation that we've seen in
23 collaborative business arrangements in terms of finding better efficiencies in the actual operation of the
24 business enterprises that process Medicare claims.

25 Just where we are on this—we issued our report to Congress with our plan for implementation in
26 February of 2005, about a month after that, we launched our first acquisition. We made 5 contract awards
27 last year and we have a solicitation out and in review for the 7 MAC jurisdictions that are part of the first
28 cycle of procurement and we're scheduled for release of the next round of MAC solicitations for the

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1 remainder of the MAC jurisdictions in September of this year. Very quickly, the next couple of slides are
2 really reference slides for you all. The DME MAC jurisdictions are on your slide 11. The names of the
3 entities who were awarded and have implemented those contracts are listed as well. What I would say is
4 that we are pleased with the smoothness of implementation that we have had, in the DME MAC
5 environment. We've taken a tremendous amount of administrative lesson out of this implementation and
6 are applying it to those implementations that we will have underway later on this year. It is very critical to
7 us that we have early communications with the provider communities affected by these implementations,
8 certainly in the DME environment. There is a tremendous amount of change occurring in the DME
9 environment concurrent with the DME MAC implementation, and I suspect that it may have taken some of
10 the attention away from the DME MAC implementation, but that said, we accomplished that
11 implementation with minimal delay in payment and very quickly got back on track in terms of timely
12 payment to suppliers. We have adjusted some of these MAC jurisdictions a bit, and you will see in later
13 slides, what we have tried to do and what we are doing with the implementation of the DME MACs and
14 other specialty MAC jurisdictions, is aligning those directly to the A/B MAC jurisdictions that we have put
15 in place for the large Part A Part B Medicare Administrative Contractors. If you move on to the next slide,
16 what you see is the schedule for award and implementation of the 15 A/B MAC jurisdictions. What you
17 don't see here and I think we have, we certainly have this on our website, and if I don't have slide with me,
18 I'll make sure that you have the map to it, the 15 A/B MAC jurisdictions sit within those shaded states. All
19 of those jurisdictions though are assigned to MAC acquisition cycle I and MAC acquisition cycle II. We
20 have 7 A/B MAC jurisdictions up for procurement currently. They include the states of California, Nevada,
21 Hawaii and Oregon, Idaho, Alaska, and Washington along with Texas, Oklahoma, Colorado, New Mexico,
22 Kansas, Iowa, Nebraska, and Missouri, Arkansas Louisiana, and Mississippi are also up for procurement
23 right now and then the other states that are up for procurement right now are Pennsylvania, New Jersey,
24 Connecticut, New York, the DC Delaware Maryland areas, and those awards are all scheduled to be
25 completed by either the end of this fiscal year or a month or two shortly after that. And then, the remainder
26 of the MAC jurisdictions will be put up for procurement in September of this year. So as we make those
27 awards, we are looking at carrier and intermediary performance at current MAC performance in making
28 award, we have regular annual performance review cycles that pull in both error rate performance as well

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1 as provider satisfaction and as we get through the implementation of all of these contracts and some of the
2 stabilization that we need to achieve as we move states and move workloads into the MAC jurisdictions,
3 we will then be tying award to performance in those areas as well as in a number of other areas. Moving on
4 to the next slide, this is the last slide about jurisdictions, and this slide will look a little bit like the DME
5 MAC slide in terms of the state alignments, we recently did a public notification that announced that we
6 were incorporating the award of home health and hospice processing as an optional activity into 4 of the
7 A/B MAC awards that we'll be making next year. Originally we had planned on maintaining a separate
8 procurement schedule and award schedule for the home health and hospice entities, but as we looked a bit
9 further into that, we found that home health and hospice processing is very closely integrated into fiscal
10 intermediary operations and processing and we want to continue that close linkage while we maintain that
11 special relationship that home health and hospice fiscal intermediaries have with that community. So that
12 will be an optional activity that is part of an A/B MAC award, but the jurisdiction lines up directly to the
13 DME MAC specialty jurisdictions, and I think that you will see that this becomes a geographical alignment
14 for many of the other specialty contracts that we end up awarding on a jurisdictional basis.

15 What we have up for procurement right now, we have about 45% of our national claims volume is
16 up for procurement right now. Next year, we'll have a slightly higher percentage of that. I have that on
17 there just so that you can see the size and breadth of change that we are implementing in this environment
18 and I just want to assure you that we look at this with all seriousness in terms of maintaining operational
19 stability as we move this very, very large volume of claims workload and claims payment into the new
20 administrative environment. We will be reporting to Congress on our progress in 2009 that had been
21 expected to be an interim report, because we actually by legislation have until 2011 to complete the
22 implementation. We're moving a little bit faster than had originally been laid out in the legislation in part
23 because of some of the inherent instability in the environment, once you start competing work loads and
24 having contract entities lose work. We want to make sure that we move as quickly as we can into this
25 environment so that we have the companies that are committed to serving as Medicare Administrative
26 Contractors, with fast responsibility for completing all of the claims administrative work.

27 What we've done over the past couple of years to try and seek out as much provider input as we
28 could get has been using open door fora, we are regular participant, we frequently update the Provider

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1 Communities on specific of the open door fora calls and we've used that and had very good luck in getting
2 good comments and good feedback from those calls. We've also had a number of townhall meetings over
3 the past couple of years as we have rolled out the MAC jurisdictions and the performance metrics and some
4 of the other measures that we're using for assessing contract performance. We've also used the federal
5 contracting communications vehicles. Fed Biz Op is the federal contracting communications mechanism
6 for communicating both about proposed acquisition activity as well as communicating about measures and
7 metrics related to those acquisitions. We have issued I think close to 20 requests for information relating to
8 various of our implementations and our acquisitions, and that's been a very useful mechanism for us to get
9 input from both the bidding community and also from the provider community.

10 The next slide talks a little bit about how we have used and intend to use the contractor provider
11 satisfaction survey. We're in the third year of issuance of that survey. I think we're in collection, currently
12 of results and thank you and your colleagues for the work that you all have done to encourage participation
13 by the provider community in those surveys. It's very important to us to, it's important to OMB that we get
14 a good survey response rate. It's very important to me as a responsible fed for administering these contracts
15 to get good input from the provider community as stakeholders in the satisfactory performance of these
16 contracts, and we use those, as I meet with contractor executives to talk about performance. One of the very
17 most important metrics that we use is the provider satisfaction surveys. And you can be assured that
18 contractors look at those survey results; they look at the data that they can get from the surveyors to match
19 that to what's happening within their operation, correlating it to claims payment system changes, and other
20 operational initiatives that are underway so that they can understand what's happening in terms of the
21 perception of their performance in their provider communities. This will take on greater importance for us
22 as we start to tie contract performance awards, both the award of a contract, as well as the award of
23 incentive fees to survey results. So we have a little bit of work to do to make sure that that's a good
24 instrument for us to use given the importance of the award fees and the awards themselves to the bidding
25 community, but that is the path that we are headed down within CMS. This is a very important tool to us.

26 It's hard to be in front of this kind of a group without thinking about what you might be able to tell
27 me. These are questions that I think you've heard from me and from Herb Kuhn and from others speaking
28 to you about contracting reform. It continues to be very important to us to get your input and your feedback

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1 and insights on these questions. The aspects of the operational environment as it currently exists, the things
2 that you value in terms of in your constituents' value, in terms of your relationships with the carriers and
3 intermediaries to the extent that we can, we want to carry that forward and to the new MAC environment.
4 We have seen a number of letters coming in from local practitioners in various jurisdictions that are up for
5 bid. Those letters are letters that come in in support of various contract entities who are bidding on work
6 load. Those do go into our files as we're looking at past performance. We'd be very interested in
7 continuing a dialog with you on those aspects of your interaction with the Medicare Administrative
8 Contractor that you consider to be the most important. And I think I can guess what some of those are, but I
9 don't want to guess without getting some input from you. And then the other thing, we do a lot of
10 benchmarking. We try to do benchmarking on an annual basis, with other entities who have relationships
11 with practitioners in the health insurance industry generally, very interested in getting any insights or
12 thoughts from you about things that work on the private side that we might be able to incorporate into the
13 government health insurance side. And I'll leave you with some resources. We have a couple of pretty
14 robust websites of information. We have a contracting reform page that's on the CMS website, that has a
15 lot of information, specifically about the individual jurisdictions that are up for procurement, what
16 characteristics those jurisdictions have from a beneficiary, provider standpoint, claims standpoint, payment
17 standpoint, what states are in each of those jurisdictions, we are very happy to supply information to
18 anyone who has specific questions about any of the jurisdictions that are up for procurement, and also Fed
19 Biz Ops is the federal contracting site that has all of the federal procurement activity, but when you get into
20 the CMS area on that website, you can get a very good sense of the number of requests for information and
21 the projected requests for information that we will be issuing as we continue through the implementation of
22 the MAC contracting authority. I will leave you with one last thought and that is, we aren't doing this just
23 once. As we move into fuller implementation of the Medicare Administrative Contractors, Congress made
24 it very clear and in order to fully gain the benefits of competition, we are on a 5-year procurement cycle for
25 these contracts. We look at every contractor's performance on an annual basis, taking into consideration
26 error ratings, and provider satisfaction and other important metrics to us in performance of the contracts,
27 award of those next year options are made on the basis of performance, and then every 5 years a
28 jurisdiction will be up for reprocurement. So we do expect to continue to see consolidation in the

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1 environment, continued efficiencies in the claims administration environment, and we will be looking to
2 adapt the claims administrative environment to the many changes that we expect to be made on the Fee for
3 Service payment side, so that the administrative infrastructure is capable of supporting the changes that are
4 happening on the benefit payment side. And with that, I'll stop and see if there are any questions.

5 Dr. Senagore: Thank you, Ms. Jackson. Questions? Dr. Grimm.

6 Dr. Grimm: First of all Karen, thank you very much for a very clear presentation. That's very
7 refreshing to have it very clearly stated. I think this MAC contracting is extremely important to all of us.
8 And a couple of issues I face, I think are for all of us, is that the ability of CMS to understand how effective
9 these contractors are will be the ability to evaluate their performance. So the satisfaction survey is going to
10 be a very important tool, and you know, you also mentioned this payment accuracy tool that you're also—
11 so those things I think extremely important. I think the 75% that was presented to us at the last meeting was
12 abominable, to tell you the truth, in any of us that deal with business, that accepts 75% as a—so in setting
13 goals for our contractors, already up front, you have to put something in front of them saying, this is, we're
14 not going to accept this by the way. 75% is not OK. And you're going to have to say, and we're going to
15 want something about 90%. I think the other aspect in this process that we're concerned about is physician
16 participation in this process. It was mentioned earlier in some of the presentation I think will come later, is
17 that the implementation of this is the stakeholders. And one of the biggest stakeholders here is the
18 physicians and that I think we feel strongly that physicians have a very important role in these surveys and
19 tools to measure the performance of these contractors, and that they should be part of the process. I know
20 you mentioned the calls and things like that, but that's kind of a—that's not really part of the process
21 whether we actually get in and say, OK, look, these are the specific things within your, so I would, if I
22 could—can I make a proposal Anthony?

23 Dr. Senagore: Sure, absolutely.

24 Dr. Grimm: I've written them out here, so PPAC or CMS has indicated that the MAC
25 communications and development meetings include only those who have a stake in its implementation.
26 PPAC feels strongly that physicians have a primary stake in the development and is concerned that the
27 current MAC development communications meetings have excluded physician participation. PPAC
28 strongly encourages CMS to allow national physician participation in this critical phase.

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1 Dr. Senagore: PPAC recommends rather than strongly encourages?

2 Dr. Grimm: Yes. And I have this all written out, too, Karen—or Dana.

3 Ms. Trevas: Did you want the whole thing?

4 Dr. Grimm: We can truncate it a bit.

5 Dr. Senagore: Just make it shorten it out to the recommendation.

6 Dr. Grimm: PPAC strongly recommends that CMS allow national physician participation in the
7 critical phase of MAC communication and development meetings. Would that be adequate?

8 Dr. Senagore: OK. Second?

9 [Seconds]

10 Dr. Senagore: Discussion? How you doing there, Dana?

11 Ms. Trevas: Good.

12 Dr. Senagore: Any comments, questions? All in favor?

13 [Ays]

14 Dr. Senagore: All against? Motion carries.

15 Dr. Grimm: I have a second one.

16 Dr. Senagore: OK.

17 Dr. Grimm: PPAC recommends that or feels that the current contractor performance rating of 75%
18 is unacceptable, and that a performance rating of 90% or better should be considered the standard of
19 performance for MAC contractors.

20 Dr. Senagore: Second?

21 [Seconds]

22 Dr. Senagore: OK, comment?

23 Dr. Ouzounian: Would you consider revising that to “requires” as opposed to suggest?

24 Dr. Grimm: Mmhmm. Sure.

25 Dr. Ross: I’d like to make a friendly amendment. I don’t think 10% to satisfaction is good enough.
26 I think 95% would be better at least. That’s my personal feeling.

27 Dr. Grimm: Anybody else have a feeling about the percentage? I think we at least—we’re at 75%
28 now. 90%, we can always change it later. Increase it up. But I think 90% is at least reasonable.

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1 Dr. Ross: 10% acceptable?

2 Dr. Senagore: Better than 75. How about a minimum of 90%.

3 Dr. Grimm: Minimum 90%, yes, 90% or better. Do you want to repeat what we cobbled together
4 here, Dana?

5 Ms. Trevas: PPAC feels that the current contractor performance rating of 75% is unacceptable,
6 and recommends that CMS require a performance rating of at least 90%, well, 90% or better as the standard
7 of performance for MAC contractors.

8 Dr. Senagore: Just to kind of put it, wordsmith it a little more clearly for a recommendation, I
9 would leave out the first bit and just start with PPAC recommends that, and then leave off that first part and
10 start with the 90% where that phrase starts.

11 Ms. Trevas: [off mike]

12 Dr. Senagore: Right. 90% or better.

13 Ms. Jackson: Can I just offer one clarification?

14 Dr. Senagore: Sure.

15 Ms. Jackson: Speaking as the responsible government employee for performance management, we
16 measure performance along a number of metrics and I think it's important to be specific, and I assume here
17 that you're speaking to the customer or the provider satisfaction survey we saw.

18 Dr. Grimm: That's correct.

19 Ms. Jackson: And I would suggest that you clarify your language so that you include that.

20 Dr. Grimm: Thank you.

21 Dr. Senagore: Did we not say that? I thought that was at the end of it. OK then that'll be of
22 provider satisfaction. Is that OK, Ms. Jackson?

23 Ms. Jackson: Yes, that's certainly clear enough for us.

24 Dr. Senagore: So, Dana, one last time, so we know what we're voting on?

25 Ms. Trevas: PPAC recommends that CMS require a performance rating of 90% or better on the
26 provider satisfaction survey as the standard of performance for MAC contractors.

27 Dr. Senagore: OK. Any other comments? Is that clear?

28 Ms. Jackson: That's very clear to us. Yes, thank you.

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1 Dr. Przyblski: Just a question. So what happens when that 90% is not achieved.

2 Dr. Grimm: That's another question, that's another issue.

3 Dr. Senagore: Well, it'll be part of the global scoring, as Ms. Jackson alluded to, so it would only
4 be one component of the overall scoring.

5 Dr. Grimm: But I think we've got to, I think right now, we have to set a benchmark for these
6 MAC contractors.

7 Dr. Senagore: I mean as a corollary, we're going to hear this afternoon about one through five
8 stars and it's not clear how the stars are allocated. We want to have some sort of transparency and clarity on
9 how this evaluation process will be done and what if someone performs well, where they are and where
10 they're falling down, what the issue is. So at least this is one start. In fact, maybe at some point, we could
11 invite you back and maybe more globally how you do grade providers of the MACs.

12 Ms. Jackson: Absolutely. I'd be very happy to do that. I would, just one additional piece of
13 information. We talked a little bit about the schedule for implementation of the Medicare Administrative
14 Contractors, and I don't want you to think that we are being unresponsive. One thing that we do have to be
15 careful of is we are implementing these contracts over the next two years by moving a number of claims
16 administration workloads into those Medicare Administrative Contract entities and it takes a little bit of
17 time to actually complete that implementation. We don't expect to be assessing that MAC's customer
18 satisfaction performance during that implementation period, because they can't really influence the results.
19 And so that's something that we'll be very careful of in terms of when we begin to use this as a
20 performance measure, but it is something that we intend to be benchmarking and assessing our own
21 performance on.

22 Dr. Grimm: Just one more comment about that in terms of the power of this satisfaction survey.
23 When you presented that, you folks presented that to us several meetings ago, I brought that satisfaction
24 survey to my carrier because we had an issue in terms of their performance and I said, by the way, you're at
25 the bottom of the list. I got a call in 15 minutes to my office, to correct whatever problem we had, and
26 within a day, we had that correction problem, so these surveys are incredibly powerful in terms of how they
27 understand—they realize that they're being graded. And this is the first time that they've been graded as
28 you know, and I think it's going to be a powerful tool for us to improve their performance.

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1 Ms. Jackson: I agree.

2 Dr. Senagore: So if no more discussion, I'll call the question, all in favor?

3 [Ays]

4 Dr. Senagore: All against? Motion carries. Thank you, Ms. Jackson.

5 Are we ready, Sir? Or do you need a few minutes? You can talk amongst yourselves until we're
6 ready to go for that. Well this is always one of the enjoyable parts of the meeting when we have the
7 opportunity and that's to swear in new members of our committee. I guess all the new members are back in
8 their seats, so that's good. It's my distinct pleasure to welcome the Acting Administrator of CMS, Ms.
9 Leslie Norwalk, Esquire. Ms. Norwalk we appreciate your joining us I know you have—

10 Ms. Norwalk: Please call me Leslie [laughter]

11 Dr. Senagore: Leslie. Fine. It's Tony. So, I will let you lead off with the swearing in and any
12 comments you have beforehand.

13 Conversation with Leslie Norwalk Preceding Swearing In of New Members

14 Ms. Norwalk: Well, I think before hand it would be nice to do two things. First of all, welcome all
15 of you here and just how much we appreciate your service at CMS and how critical it is that we get the
16 perspective from the outside practicing physicians. As much as we tried to appreciate what goes on in the
17 world around and as much as we read and so forth, there is nothing like people coming in and keeping us
18 honest, and that's really what all of you do and we greatly appreciate that, and the, all the hard work you
19 put into it to make sure that we get things as right as we possibly can. Often there are other issues that we
20 have that you may not appreciate, but we hope to educate you on those while you educate us on what's
21 going on in the outside world. And if you wouldn't mind, I'd be very interested to hear a little bit more
22 from the 5 new members just quick introductions and so forth, is that all right? Where shall we start?

23 Dr. Senagore: Start on this side. We'll give Dr. Arradondo a break since he went first last time.

24 Ms. Norwalk: I'm sorry if you're doing it twice, I apologize.

25 Dr. Senagore: No, that's fine.

26 Dr. Snow: I'm Art Snow. I'm a family physician from Shawnee Mission, Kansas, suburb of
27 Kansas City. Practice primarily geriatrics. I've done emergency medicine. Been board certified but I have

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1 to slow down a little bit, getting too old to stay up all night like these ER docs. Bill Rogers can still do it,
2 but I can't. [laughter]

3 Ms. Norwalk: Is that why he's so crazy? [laughter]

4 Dr. Rogers: I can't believe I have to.

5 Ms. Norwalk: Is there anything in particular that you are looking forward to either learning more
6 about or teaching us?

7 Dr. Snow: Well, first of all, I thought you are all very honest. I was surprised that that's our task
8 here [laughter]. I've always made that assumption. But I'm very concerned about the SGR as a primary
9 care physician. Access I think of our patients, the seniors that I take care of, almost 99%, is very important
10 to me.

11 Ms. Norwalk: You're concerned about the 9.9% cut and the 41% cut over 10 years? I can't
12 imagine. [laughter] I am going to presume that all of you feel that way. At least from my perspective, from
13 PPAC, well I appreciate that. That will be something I'm quite sure that Congress will be reviewing well,
14 already are, really in short order. And would be interested generally when you're giving remarks, I know
15 that off the top of my head. But if there are other things more specifically that you think, then I'd be
16 interested in getting my hands into that, separate from the SGR. But you're right about the access concerns.
17 I hear you.

18 Dr. Snow: Well, there's a multitude of concerns. You know, Bill Rogers, through his PRIT
19 certainly takes care of I think many of the concerns that we bring to him on the regulatory burdens, the
20 unfunded mandates that primary care physicians and all physicians have placed upon them, but again, I
21 think without and I know you don't want to talk anymore about that SGR, but without some help there,
22 there's not going to be primary care physicians around and it's going to take too darn long—

23 Ms. Norwalk: I don't want to minimize the impact of SGR. I only want to point out that as PPAC
24 members, you're going to have—that your influence will be greater in other areas, only because it's really
25 led by Congress.

26 Dr. Snow: I understand, I understand. But I am pleased to be here.

27 Ms. Norwalk: Good. Glad to have you. Thank you, Sir.

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1 Dr. Siff: Jonathan Siff. I'm an emergency physician from Cleveland, Ohio. I practice at
2 Cleveland's inner city level and Trauma Center. A million things I'm looking forward to hearing and to
3 hopefully educating some of you on is access to care, not just in terms of beneficiary access, but emergency
4 access, access to specialists, the need for the government as a whole to consider the safety in all its decision
5 making. It is assumed at this point that we'll always be there and I think it's a dangerous assumption that
6 needs to be addressed both by CMS and by Congress.

7 Dr. Rodbard: I'm Helena Rodbard, an endocrinologist. I'm very local here in Rockville, Maryland.
8 I have been in private practice for the past 25 years, formally in academia. Had been at NIH, GW,
9 Georgetown, so I bring the perspective of a practicing endocrinologist as well as someone who has been in
10 research and involved in organized medicine, working with the American College of Endocrinology with
11 the AMA and obviously, I have to echo all of the concerns that were just shared. Access to care is
12 something that patients in my community are starting to feel the pinch, because physicians are not
13 accepting new patients, contrary to all the statistics that we hear. That's not the case. It's not the case in my
14 own practice, either. And this is the current status, only to get worse with the predicted cuts. So that's one
15 of the reasons I'm here. I'm very happy to be here and the regulatory burdens are not an issue that we are
16 very concerned about.

17 Ms. Norwalk: No?

18 Dr. Rodbard: Yes, we are. They are. A major issue.

19 Ms. Norwalk: I'm like, not concerned? Surely I misheard you. [laughter]

20 Dr. Rodbard: Regulatory burden's a big deal; not only is the compensation decreasing, for
21 specialty in which there aren't that many physicians to start with, there are only 4500 practicing
22 endocrinologists throughout the country. So we are talking about a shortage of endocrinologist in a
23 situation in which we need more of us, considering the burden of diabetes. So that's important, burden of
24 diabetes as well as other endocrine disorders, osteoporosis, things that happen to the aging population. So
25 we'll have more patients, fewer physicians, less reimbursement for physicians, so it's not a very good
26 situation. So I'd like to try to do whatever we can.

27 Ms. Norwalk: Glad to have you with us.

28 Dr. Rodbard: Thank you.

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1 Dr. Senagore: Let's see, Dr. Jordan I think is next.

2 Dr. Jordan: Roger Jordan. I'm an optometrist from Gillette, Wyoming, and being the only kind of
3 non MD, on the panel here, I am kind of looking forward to getting into the area that they've been stating
4 before is the access issue, and in my situation, being very, very rural and having to do all primary eye care
5 there is just to be able to keep that ability for our beneficiaries. My closest referral is actually about 130
6 some miles away regarding other surgical eye care. So we have to do what is necessary right there. So I just
7 am looking forward to participating as an allied healthcare, and keeping their concerns our concerns, in
8 front of the committee.

9 Ms. Norwalk: Good. Thanks.

10 Dr. Arradondo: I'm John Arradondo. I guess I'm the last of the new members. I'm a family
11 physician. I also have training and experience in public health and systems health and systems medicine. I
12 guess my, if I were to even attempt to influence CMS it would be to try to get you to use your existing tools
13 to increase the percentage of eligible patients who access and receive acceptable care that you pay for
14 already. That would be my hope.

15 Ms. Norwalk: How do you define acceptable?

16 Dr. Arradondo: Well you know access isn't just access. It relates to availability, acceptability,
17 affordability, accountability and all of those. And one of those As is acceptable so that if I go to a physician
18 and receive services, and I go out of there feeling worse than when I went in, maybe psychologically,
19 socially, or maybe even physically, if that's where I'm going, then that probably isn't acceptable care, just
20 to use that broad way. And then there are comparisons. I could compare Medicare recipients to Blue Cross
21 recipients, as an example, to see the difference. And some people are in the same family who have that
22 comparison. That's the short answer. But that would be my hope. And not just Medicare eligible people,
23 but Medicaid. Because the disconnect there is even greater in terms of the proportion of providers who
24 don't even accept it. All kinds of providers, not my colleague physicians, but other entities that provide
25 care and might be listed as a provider, but functionally shun patients who have Medicaid and secondary
26 Medicare. So I would and part D enrollment could be a Mediform for that. I realize that Dr. McClellan
27 thought it was successful and relatively speaking it was, but even with all the scars that he got for doing it,
28 had the system been doing more to include eligible people, enrolling all those part D underserved people

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1 would not have been as difficult. And by way of getting at that, it seems to be useful to utilize some of the
2 providers who are already out there trying to serve some of the underserved people. And when I say
3 underserved, I'm not just speaking of income, so the business of acceptable gets at that. I mean there are
4 some people who have Blue Cross but don't get acceptable services because of who they are or where they
5 are etc. So that acceptable of those 5 or 6 As to access.

6 Ms. Norwalk: Sort of a cultural competency.

7 Dr. Arradondo: Is the kind of a good metaphor for the best part of access. So if I were to even in
8 my best dreams try to influence the agency that you had, it would be that.

9 Ms. Norwalk: That's why you're here. That's why you're here. We would otherwise not be
10 wasting your time and our time, so we're very glad to have you, because we actually, we find your input
11 very important. So without question, and I often will ask, Oh, what did PPAC say about this or that, and it's
12 very common in briefings in my office and Liz is very good to bring it, Liz and Ken both are very good to
13 bring it to the forefront of whatever it is that we discuss in terms of what PPAC thought about something.
14 So we don't, you shouldn't minimize your own participation, because I think it's very important. And with
15 that, should we do the oath?

16 Dr. Senagore: Thank you, Leslie.

17 Ms. Norwalk: Thank you.

18 Dr. Senagore: We're going to go ahead and get started with our afternoon session. Our next
19 speaker should be familiar to at least the previously existing members of the Council, as Dr. Michael Rapp
20 has served formally as chairperson of the PPAC. He's currently Director of the Quality Measurement and
21 Health Assessments Group in the Office of Clinical Standards and Quality, at CMS. And Dr. Rapp will
22 share with us, the developments of one of the newest uniform assessment instruments and the 3-year
23 demonstration that's set to begin in 2008. Welcome Dr. Rapp.

24 Post Acute Care Project

25 Dr. Rapp: Thank you, Dr. Senagore. Well, thank you. I want to start off by introducing my
26 colleague, Dr. Joanne Lynn, who's a Medical Officer within our group, and she has distinguished
27 background in geriatrics and end of life care and so forth, and she's been actively involved in the details of
28 this particular instrument. So I'm going to start off and give you the background, and then I'm going to turn

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1 it over to her to give you some details about the instrument. So let's see, first of all just let me give you
2 some general background and that is that what we're going to talk about today is an issue that's been
3 around for quite a while and there's been interest in tackling this problem for probably 20 years and that is
4 that there are several post acute settings that patients who are discharged from the hospital go to. And when
5 they're in those settings, the current requirements for Medicare payment are that these patients undergo
6 assessments and the different instruments are used to assess the patients, depending on whether they're in a
7 nursing home, a home health agency or in an inpatient rehabilitation facility. So because of that, since
8 they're different instruments, the ability to compare patients in those settings is quite limited, just because
9 you have the different data that's being collected. So this issue has caught the attention of Congress and
10 people within CMS to try to in terms of how to deal with it. And there have been different approaches that
11 have been tried in the BPPA Legislation a few years ago, Congress was interested in knowing CMS would
12 deal with that, and then most recently, in the Deficit Reduction Act of 2005, Congress asked that well, the
13 approach that they would like us to look at and implement a demonstration for would be to have a common
14 instrument that starts as hospital discharge and then can be used throughout the subsequent settings,
15 whether it be a nursing home, home health, or inpatient rehabilitation facility. So that's basically what
16 we're going to talk about, which is to develop that instrument, how we're tackling that problem, and Joanne
17 Lynn will go through the details of that. And then we have a number of questions for you at the end, after
18 we've completed the detail, and the questions that we're going to pose to you are: What are the highest
19 priority items to collect on the care instrument, which is what this instrument is called, at hospital
20 discharge, upon transfer to a home care setting? And then, assuming EHR adoption, would it be desirable
21 to be able to download the information in this assessment instrument, or upload EHR data to the
22 instrument and finally, would you be interested in providing small group feedback on the instrument,
23 because this is something that we're definitely interested in, is having broad stakeholder input and Dr. Lynn
24 will explain that to you, what we've done so far. So basically you have here, the outline of what we're
25 going to talk about today. Talk about the Deficit Reduction Act, the contracts that we've awarded to
26 support this, the background, the existing instrument, previous efforts, OCSQ's role, that is, Office of
27 Clinical Standards and Quality role, that I serve within because this instrument involves a number of other
28 centers and offices in the agency, what opportunities we see from this instrument, the importance to

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1 physicians, details of the instrument development, challenges, timeline, and a summary. So as I mentioned,
2 the Deficit Reduction Act of 2005 requires CMS to develop a uniform assessment instrument to measure
3 and compare Medicare beneficiaries' health and functional status across provider settings over time. And to
4 test the instrument's usefulness in a 3-year demonstration starting in early 2008. As we've awarded 3
5 contracts to support this, the Office of Clinical Standards and Quality is responsible for development of the
6 instrument itself, that is the questions that will be asked. The items on the assessment instrument, that's the
7 assessment instrument itself. The ORDI is the demonstration office, and they will have awarded a contract
8 to the same Research Triangle International, RTI, who has our contract to do the demonstration and
9 analysis. And finally, Office of Information Systems has awarded a contract to Northrop Grumman, to
10 develop an Internet platform for this. And I just want to mention that of course you could have a different
11 platform that this instrument would rest upon, paper based would be the simplest, just give me a
12 questionnaire and I'll fill it out and check off the boxes, but in today's world, of course, that doesn't sound
13 very satisfying. And so the goal here is to have an Internet based instrument where the data can be entered
14 through the Internet interface and that data go directly to CMS. As I mentioned, the background. There's
15 been a long standing interest in trying to evaluate several things and that's what these current instruments
16 and this future instrument will deal with. Assessment instruments are used for a variety of purposes. They,
17 but basically, they assess a clinical status, needs of patients, and do that over time, so this is what the goal
18 has been, but as I said, it's been complicated by the fact that there are different settings. So to date, the
19 Medicare Benefits and Payment Policies have focused on the phases of illness defined by the specific site
20 of service rather than the patient characteristics and care needs. So as I'll discuss a little bit more, the
21 instruments have several different purposes, but since the way things tend to get developed is by the site of
22 payment. So if you've got something to do with hospital payments, you develop rules and instruments and
23 so forth dealing with hospitals, and physicians, something else, and nursing homes, something else. And
24 home health, something else. And so that's how we end up in the situation that we find ourselves, today.

25 So as mentioned here, payments across the post-acute care setting differ considerably because as I
26 mentioned, you have the different payment settings, different rules, different policies that are set up, so that
27 but on the other hand, the patients may not differ that much. So a patient with a knee replacement, for
28 example, might end up in a nursing home, might end up in inpatient rehab facility, or might end up in a

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1 home health. Those patients, if we're going to assess them in those different settings without having the
2 same instrument, you just can't, can't do it. And you also can't evaluate the appropriateness of the
3 payment, should the payment differ with the same basic patient, same basic characteristics, same
4 complications or lack thereof in the different settings. And that's one of the things that a common
5 instrument will help us tackle. So currently, as I mentioned, in the skilled nursing facility, in patient rehab
6 facility, and home health are different federally mandated instruments to collect health status data. In the
7 SNF, you use the MDS. In home health, you use OASIS. In inpatient rehab facility uses an instrument
8 called the IRFPAI Inpatient Rehab Facility Patient Assessment Instrument. And these instruments are used
9 for different purposes, which I think is a particularly critical point to this. First of all, the assessment data
10 that comes off the instrument is used for payment, so as you're aware, the payment for all these settings are
11 prospective payments. So prospective payments tend to group things in payment groupers. And in the
12 rehabilitation facility, you have the so-called RUGs and in the home health, you have the so-called HUGs.
13 You have these groupers and you get that data that are used in those groupers from these assessment
14 instruments. But in addition, the same data that's collected through these instruments are used for our
15 publicly reported quality measures. So you're aware that we have nursing home compare, home health
16 compare, the data that is posted on those websites, similar to hospital compare, come from these assessment
17 instruments. In the hospital arena, they come from chart abstracted data. But in the nursing home in home
18 health arena, the data that goes on our compare sites comes from these federally required assessment
19 instruments. In the instruments also, there is care planning that if a certain event occurs, a person no longer
20 swallows, for example, there's a care planning algorithm that has to be dealt with at that point. And finally,
21 these same instruments, the data that comes from there, are used for the Survey and Certification Purposes
22 that all, there's a periodic survey and certification that has to take place for these different payment settings
23 and so this same data is used for that.

24 As I mentioned, the problem with these is their incompatible data format. It's different scales,
25 different assessment periods, and so you cannot compare outcomes across settings, can't compare them
26 over time. And so how to deal with that? There have been previous efforts. The Uniform Needs Assessment
27 Instrument was proposed 15 or 20 years ago and the different other possible ways of tackling this problem

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1 of being able to compare patients in these different settings with equivalent conditions has been a long-
2 standing interest, as I mentioned.

3 And so, what we're doing now, again, is in response to the Deficit Reduction Act and the
4 requirement to introduce, to develop an instrument and to have a demonstration project which would
5 implement this instrument. We are developing electronic standardized patient assessment instrument to
6 identify patient's characteristics and needs, and that would deal with the 6 IOM aims for health care
7 quality. And now, at this point, I am going to turn it over to Joanne Lynn and she will go with you through
8 a number of items which will be the details of the assessment instrument, what we hope to achieve from it
9 more specifically. And at the end, I ask for your feedback. So here's Dr. Lynn.

10 Dr. Lynn: Thanks, Mike. This is a really exciting project and I hope you'll all pay attention to it
11 and weigh in and help us make it really good. All of us who have taken care of these patients know that
12 these are really sick people that tend to go in and out of the hospital most of Medicare is spent on a small
13 proportion of the population that are at least at that time very sick, and they end up getting an MDS here
14 and an OASIS there, and nobody has access to them and they really don't help clinical care and this will
15 allow all those to come together over time, and be available to you so if you're the nursing home doctor,
16 you'll get the hospital one, and if you're the home care doctor, you'll get the upstream couple of
17 assessments and see how the patient's been doing. What we've been trying to do is make it a continuity of
18 care record, that will really support clinical excellence. Now it's not a whole record. It's not a progress
19 notes, and it's not all kinds of judgments and it's not discussions and so forth, but a sort of backbone
20 elements, the functions, the medications, the patient's diagnoses, allergies and that sort of things. Things
21 you need right away will be there. We'll optimize efficiency by being on an Internet platform which has
22 become more and more available. Five years ago, you couldn't have required that nursing homes have
23 available Internet platform, but by now they're all using it. So with proper authorization, downstream
24 providers can get upstream information through this vehicle. We're trying to build it in the most interactive
25 of formats, so that hospital and other system electronic records will be able to upload and download
26 smoothly. We'll move us forward toward electronic health record, because there'll be this chunk of
27 information that will already be in the right language and in the right packaging so that it can be used and it
28 will help CMS and others predict outcome and resource utilization so we can check on quality and payment

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1 in a much more efficient way. We're trying hard to reduce provider's data collection burden, now. Any
2 time you change things, there's going to be a period of time where it seems like a lot more because things
3 are unfamiliar, but once this gets underway, well, it ought to be heavily electronic, heavily able to be
4 carried forward and corrected, feel much more like the kind of efficiencies the VA's gotten used to. In
5 addition, it may well be possible to tie in to some of these other things that CMS is doing and make it
6 plausible to reduce overall data collection burden by moving more and more of our data collection into
7 these electronic formats. The QIO initiatives, the PQRI, which we'll be talking about shortly, and the
8 hospital quality measures are obvious targets downstream. So in developing the instrument, we wanted to
9 develop something first off that was clinically relevant. The instrument was put in the Office of Clinical
10 Standards and Quality. It's the clinician anchor of CMS work and we try to make it useful, efficient,
11 available in real time and so the anchor point has been is this what's necessary for patient care as patients
12 move from one setting to another. Our partners in the instrument development process have been RTI, and
13 they have a clinical group in Chicago that has been willing to test out elements of the instrument and in
14 fact, today, the second pilot went into practice in the Chicago area, about 10 facilities, figuring out if the
15 pilot instrument can work well in which things cause trouble and that sort of thing. Now obviously, we've
16 developed this on the background of MDS and OASIS and lots and lots of work and patient assessment. So
17 it's not as if this is falling from the sky. This had a lot of prior work, and a lot of the instrument elements
18 are known pretty well. We've been trying very hard to get lots of public and provider input. We had a
19 remarkable Open Door Forum, right before Christmas, with over 2200 different people on the line. People
20 have been writing in and calling in and sending things in, and this being developed very fast. Congress
21 mandated that it go in the field of January next year, so we're especially trying to make sure people can
22 kind of catch up with the process, because there won't be the usual long lag times of waiting for lots and
23 lots of different input. So we had the Open Door Forum. There was an initial expert panel that was mostly
24 what we call industry representatives, but that's all kinds of providers involved in how will this impact us,
25 and how can we make use of what we already do, then there was a second expert panel that was much more
26 the subject matter experts, the researchers, the people concerned about the validity of items and that sort of
27 thing. There will be further Open Door Forums and involvement of experts as we try to get this into shape,
28 and then obviously, this is going out in demo mode next January, and it will continue to be developed, so it

1 will not be a fully baked good at that point. It will be a prototype. It will be the Model T and we're still
2 working on the Lexis, you know.

3 NIH has a very interested data bank called Promise, which has developed a highly interactive set
4 of items that we are building from and trying to use some of the more, most of us who think about a survey,
5 think about it as you know, sort of a whole list of questions, and maybe an occasional skip, you know, if
6 you answer yes, here, skip to Item 8. Well, there are much more interactive possibilities in these adaptive
7 testing and idea response theory in which if you can highly predict the answer to a question, they don't
8 bother to answer the question, whether the question would be a yes or a no, if it's highly predictable on the
9 basis of things you've already asked, you don't ask that. If on the other hand, this person has a problem in
10 this arena, you ask in more depth, so you can hone in fairly quickly, on which arenas need much more close
11 questioning and which ones you can skip over, so we're trying to reduce the burden, using these, the very
12 first version will not have very much of this but we're more building it in the background as an expansion
13 as the science catches up with it so that the electronics can handle it right off.

14 Care obviously will build on the things we're already doing. MDS 3.0 is under development and
15 we've had a lot of testing so the 2.0 is the version that's out now, so we're building on basis of the
16 experience with 2.0 and the learning that's gone into 3.0. OASIS is the home care instrument and IRFPAI
17 is the instrument for rehab facilities, so these have all been out there for a while and been in broad use, and
18 we're obviously building from those. But then we're also trying to crosswalk those instruments into the
19 new instrument as extensively as possible. Sometimes, it's not really possible but most of the time, we
20 think we're going to be able to make this transition relatively seamless, as care gets out there and becomes
21 matured to be able to have a planned transition from the other instruments into a coherent instrument that
22 goes across settings, assuming it works well. Care has items in these 5 domains. Obviously, you could
23 reclassify these some, but just to give you some idea of the kinds of things we're taking up, the medical, the
24 diagnoses, medications, allergies, treatments, that sort of thing. Function includes motor function, ADLs,
25 IADLs, the symptoms and so on. Social environmental includes the caregiver situation, the patient's living
26 arrangements, what kind of support is going to be necessary, cognitive, obviously deals with the questions
27 of delirium and dementia, depression, and continuity of care is sort of a subset in a sense of many of the
28 others that's essential for immediate care as the patient transitions, so things that you have to have right at

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1 your fingertips to take care of the patient, in the next hour. In the demonstration starting in January, Care
2 will be implemented at hospital discharge and admission and discharge from each of these post-acute care
3 settings. Skilled nursing facilities, rehab facilities, home health agencies and long-term care hospitals, if
4 just like MDS does now, or OASIS, if the patient has a substantial change during care in one setting, then
5 they also get an assessment, and if they go a very long time in a setting, they would get an interim
6 assessment. So if a patient goes from a hospital, say to a rehab facility, to an S&F, to a home health agency,
7 they would end up with 6 or 7 assessments that in some future time, you'll be able to portray graphically, or
8 in tabular form so you can see progress over time. That won't be in the Model T version in January.

9 So anyway, there's a lot complex developments tasks. We are taking on probably for the first time
10 an instrument that goes across, at least many of our provider settings, trying to put it into fully 21st Century
11 technology, trying to balance the interests of the burden of people carrying it forward and the clinical
12 excellence that it will help support. And we are trying to integrate 3 contractors, and probably half a dozen
13 pieces of CMS as well as you know, thousands of people in the provider community, who are clearly
14 interested in helping us out with this. It's highly interdependent across major CMS components. The four
15 listed there are the major ones, weighing in it all the time, but it gets out to many others, too. And it's on a
16 very tight timeframe. Congress gave us the privilege of doing this and also the mandate to do it very fast.
17 So it's, which is a good thing, because otherwise, this is the kind of thing that could drag on for a long time,
18 but it does mean that decisions have to be made right away on exactly what we're going to ask on any
19 particular item. It can't go out for 3 months of being batted around or 3 months of procurement and 6
20 months of contracting and a year of analysis. There's got to be something in there this week.

21 So timeline right now is instrument development is in progress. There's a test, as I say, starting out
22 today and we'll be going for a few weeks. We will go through the OMB process starting in the summer.
23 There'll be a *Federal Register* notice and a comment period that will happen in the fall. The demonstration
24 will be started in January. We'll actually start registering providers for the 10 markets in December and
25 then go live in the first market in January and then progressively add others. When we say a market, we
26 mean an interrelated group of providers who serve the same patients. So a hospital, maybe a couple of
27 nursing homes, and rehab facility, long-term care hospital, maybe 4 or 5 home care agencies. So we try to
28 get enough of that group that lots of patients will be followed through their whole post-acute stay,

1 obviously, there's always some bleed around the margins where a patient will go to be with their daughter
2 in some other place, but trying to get most of a market so that you can have coherent data. All the markets
3 will be up and running by this time next year, and the demonstration will include payment items as well as
4 the Care instrument. And there'll be data collection and analysis for a couple of years. Undoubtedly some
5 ongoing improvements to the instrument as well. Report to Congress is due in 2011 and we'll make plans
6 for how to develop this and how to move toward consolidation toward this instrument over those couple of
7 years.

8 So we're looking to standardize the assessment instrument for Medicare, make sure it's useful,
9 relevant to high quality care, grounded in the evidence and actually being a stimulus to developing better
10 evidence, very flexible, interactive with the electronic records that various parties are putting in place so
11 that it capitalizes on efficiency. Interoperable across setting, easy for doctors and other clinicians to use,
12 and we actually manage to have the aspiration that this will be very much welcomed by the stakeholders;
13 that people are annoyed enough at this point that this wonderful MDS that they can't get to, or there's this
14 terrific OASIS that isn't available and for the patient to have an online record of those assessments that are
15 available to the downstream providers, we think, lots of providers will really welcome, especially if we can
16 make it no more burdensome and with any luck, even less burdensome than it is now.

17 So here were the couple of questions we thought to ask you, but we would be delighted to take
18 comments or have you ask us things as well. As you think about how to coordinate care for this very sick
19 group of elderly persons, what are the highest priority items that you want to be sure are on the Care
20 instrument? Are there special considerations at hospital discharge where we haven't been collecting this
21 sort of thing before? Or when the person actually goes home out of institutional care. A second was
22 assuming electronic health records get more and more adopted over time, we obviously think it's desirable
23 to upload and download from Care, but do you see any special considerations we should be bearing in mind
24 and do you have any special advice for us on that. And would you be interested in providing any feedback
25 on the instrument itself, or its deployment? So with that, Mike and I will be glad to take questions.

26 Dr. Rapp: And just to sort of go back again, to where we're starting from and where this would
27 potentially take us—so currently we have an instrument that the different settings are required for the
28 specific setting to fill out, it comes to and used in different purposes for payment, for posting on our

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1 compare sites, and for Survey and Certification, but you don't have access to that. There is no instrument
2 filled out at hospital discharge currently. There's discharge planning that is required for the hospital to do,
3 but there is no data that is collected at that point. This of course is a demonstration, so it doesn't mean
4 implementation or anything like that, but those of us that are involved in this work dream to the future and
5 think well how could this potentially be used? But if you think about it, first of all, you would have a data
6 collection at the hospital level. When they get to the nursing home, the nursing home would have access to
7 that information, even such things as simple as what medications were they discharged from in the hospital.
8 You know how difficult it is sometimes to get straight just things like that. When they would go back to the
9 hospital, or when they would go from the nursing home to the home health, each time that instrument
10 would be filled out, and we're not talking about different instruments, we're talking about the same
11 instrument. In addition it would be on an Internet platform, therefore, if you dream to the future, it could
12 potentially be something that not only is capable of the data being entered, but providers of health care
13 would be able to have access to that information as well, so when Joanne referred to as possibly a form of a
14 medical record, that would provide that. So that's sort of a dream to the future, and it's also the ability to be
15 able to compare across those settings so that insofar as a patient ends up in one setting versus another
16 setting with the same basic condition, one would be able to tell that. So that's sort of the dream for the
17 future. There is no implementation plan like that. There is, it is at this point a demonstration, but the
18 instrument is being developed with that sort of possibility in mind.

19 Dr. Senagore: Dr. Bufalino then Dr. Williams.

20 Dr. Bufalino: My only comment to you in terms of your questioning is that I would ask for a plea
21 for simplicity. From our world, I think there's probably only 3 things that are important when someone
22 moves from a hospital to a skilled nursing and back, in the clinical side, and they are: the problem list, the
23 medication list, and what procedures were done in that hospitalization and back and forth, and more
24 particularly the problem list and the drugs. We find that to be the single most valuable 2 entities that drive
25 the connection of care between those facilities and if those are accurate, and it's all about the accuracy of
26 that list that really drives our ability to take better care of those folks.

27 Dr. Williams: [off mike] five or six instruments that you did starting 15 years ago. What were their
28 downfalls, what items were included in those lists, and how is this different than those 5 or 6 things?

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1 Dr. Lynn: There have been these various endeavors, and they mostly, as best I can tell sort of ran
2 out of steam and they ended up getting applied in one setting. So MDS got applied in nursing homes.
3 OASIS in home care. Some of it was over rather academic fighting of whether there's one way of
4 measuring function that you could make work across settings, so your nursing homes maybe wanted to
5 have a one-week lookback period and home care wanted to have 3-day lookback period. One wanted to
6 have actual performance and one wanted to have the therapist's reported performance. Those sorts of
7 things. And rather than kind of drive them through to a resolution, the resolution was to go ahead and do
8 what CMS at the time could get implemented in one setting. I think the very first effort, which was the
9 uniform patient assessment effort back in '87 was just too early. There was no way to do anything
10 electronically. It was all on paper. It was just was too overwhelming. So if you read the transcripts, they
11 raised all the same questions and issues, but they didn't have the same kinds of solutions we now can really
12 make quite available, where people can go on the Internet. We didn't have the Internet available back then.
13 So I think some of it was just a little before its time. Things hadn't matured enough and I think maybe we
14 also really thought these were separate providers. We weren't noticing as much that the patients you know
15 were going, maybe it didn't back then go as much across settings. But I think more, we just didn't notice
16 them going across settings this much. So now that you have the usual patient coming into home care will
17 not have come straight from the hospital, they will have gone through some other setting. So you routinely
18 have people who have been through multiple settings and providing continuity has just become such a
19 pressure that I think more and more clinicians are ready to back it because they can see just how disabled
20 they are when they don't have even the medication list. Or the problem list or whatever it is that you really
21 need. So I have not been a survivor of all those battles, so I don't know all of them well, but I think it's
22 something like that.

23 Dr. Senagore: The concern I would have with this approach is that there are a number of well-
24 validated quality of life measures and the issue always is they're disease specific. And there's not one tool
25 that really works across all of the patients that you're going to see, so the reason for a joint replacement to
26 go to a rehab facility would be completely different from a stroke. And if you're going to look at quality
27 measures, the quality measures of outcome would be completely different for a stroke patient than a total

1 hip patient. So as you look at these tools, I think it's going to be optimistic that one tool will be sufficiently
2 granular to be able to provide quality data that's useful and risk adjusted and be usable by the providers.

3 Dr. Lynn: We aren't working against of course the background of perfection. We've been working
4 with the MDS and OASIS. And so we have that granularity to start with, but the computer adaptive testing
5 and the computer based programming really allows over time for us to develop the ways that you can get at
6 the things that are really important. Some things really are quite generic. I mean function is pretty generic.
7 But very fine points of function may well be something that you would really want to know about the knee
8 replacement and not the stroke patient or maybe it would be a different one. You would want to know
9 range of motion on the knee replacement, but you would want to know swallowing ability on the stroke
10 patient. But with a computer assisted testing, you can go deeper into the ones that really matter, for that
11 patient.

12 Dr. Senagore: But who would be doing that computer testing? The patient?

13 Dr. Lynn: At the present time, the respondent in nursing homes and home care and inpatient rehab
14 facilities are usually one or two staff in the facility. In the hospital, one of the things we're trying to work
15 out is how would you best get reasonably reliable data? Is it going to be the discharge nurse or are you
16 going to pull it from the record? That's one of the things we're really trying to work out. But it doesn't
17 seem implausible. It doesn't seem to be a problem of granularity as much as respondent burden.

18 Dr. Senagore: Doing trauma surgery, I'm going to tell you one of the big things we look at for
19 head injuries is glass glaucoma scale on mission on discharge. That's not routinely transmitted. That's a
20 very granular piece of information, one that's been well vetted out for recovery, and there's a simple tool
21 that you could already add in right away. You don't need to do a whole lot of added investigation there.
22 And it's one that would fit in the rehab facility.

23 Dr. Lynn: That's the kind of thing I'm sure that will go round and round continue to be developed.
24 In that particular example, glass glaucoma score under certain score for a certain number of hours is yes or
25 no on sort of the patient status on the medical history and the time of discharge, function, delirium, ability
26 to respond are measured. At this point, we have asked for a formal glass glaucoma score, but if the
27 ideology was head trauma and that was something that was important to do, in the future, you could have a

1 subscale for head trauma and go deep in that. It's not, it didn't rise to the level of putting it in this tool,
2 because it's relatively rare in Medicare—

3 Dr. Senagore: That's where I'm confused. There are already excellent tools, that have been well
4 vetted, well validated, risk adjusted. Why develop another tool that realistically will take 5 years to vet out
5 and have true risk adjusted data? These are difficult things to do as I'm sure you're aware. I mean it took us
6 5 years to do a quality of life for one operation.

7 Dr. Lynn: We are caught of course between the claim of Dr. Bufalino and Dr. Senagore. You want
8 fine granularity, and you want 3 items.

9 Dr. Senagore: He just wanted to take care of the patient and I'm worried about the quality—

10 Dr. Lynn: And we're trying to draw the line in the middle. So whatever we come out with,
11 somebody will somewhat more precision and others will say actually you could lump patients much more.
12 And I'm sure it will be a living vibrant document over time, because there will be these pressures—

13 Dr. Senagore: I'll pass it along to other folks, but my concern as a practicing physician would be
14 when you're going to grade me for quality, then I want a well-documented tool. If we're just going to take
15 care of the patients, where Dr. Bufalino said is enough to take care of the patients.

16 Dr. O'Shea: My comments were that I feel like this mirrors in a large way the dialog that's going
17 on in many of our societies; that is that the primary care wants to be the medical home, and I see that dialog
18 going on, and then I see this, and I see it as one of the instruments that will actually maybe work with that
19 very, very well, but I want to hear that more—that this really is for the primary care use and that it can be
20 added to by the adjunct workers that are working with the primary care, but it really is to feed back so that
21 when they come back, from a specialty, say hospitalization, or an out patient facility, that that will always
22 be transmitted to or have primary care input during that same time, and when you asked about different
23 specific risks, what I'd like to see that it included was definitely pre-admit and post-admit drug use. The
24 changes in the drugs should always, always be there. We're working on that tool at my own hospital. The
25 other is critical risks. After a hospitalization, what is the risk that this patient has? Whether it's for infection
26 or whether it's for falls, or whether it is nutritional, as in difficulty swallowing. Identify the risk factors and
27 that gives you the milestones that you want to make. And again, milestones. Milestones that have to be
28 recommended to see whether they actually are on a healing path or not.

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1 Dr. Rapp: I just want to sort of go back to something that Dr. Senagore said about if I'm going to
2 be judged on this. This is an instrument for the different provider settings. Home health, nursing homes,
3 and inpatient rehab facilities. This is not an instrument designed to quantify or qualify anything about
4 physicians. So it'll be data collected with regard to the assessment of the patient in these different settings.
5 That's being done today. The only difference is, it'll be a common instrument, instead of a—

6 Dr. Senagore: So if a patient comes back from the home care facility with a DVT 10 days after
7 discharge, now it's theoretically preventable complication, under the proposed terminology, the hospital
8 will take the ding for that, and I, as the physician, who may or may not have done all of the performance
9 measures for DVT prophylaxis will get drawn into that. That's my concern is that it should be one tool
10 across all the spectrums of care, if that's what we're going to do. There should be one medical record and
11 you know, if you have a different vendor now, someone is going to have to do the interfaces between Dr.
12 Bufalino's EMR and my EMR, and Dr. Snow's EMR to get those to feed into that document. That's going
13 to be a huge hurdle nationally to do that, if this is how this all plays out. So my caution would be how much
14 information are you going to use, and when you say "quality" what does that really mean now? Don't say,
15 we'll figure it out later, because you have to design the tool with that outcome in mind.

16 Dr. Rapp: The instrument though has multiple purposes, as I mentioned one's the payment, the
17 functional assessment, the care planning and data elements. So it's basically a data base and data elements
18 are used. For example, pressure ulcers, for example is something that's used as a quality information with
19 regard to nursing homes. So the importance for the physicians is at this point, it really doesn't, you don't
20 have particular access to it and so forth and so it seemed important to us for you to be kind of aware of this
21 and it does impact you in certain respects, but it's not a tool to grade or evaluate physicians.

22 Dr. Arradondo: The, I don't know how we operate, but I noticed you were out of town 3 minutes
23 ago, according to the agenda, are we still on?

24 Dr. Senagore: That's OK. Chair has discretion.

25 Dr. Arradondo: Because this is a topic that needs to be related to in ways. So I'll try to be real
26 short. I was going to ask some questions. But maybe I'll just make a couple of statements and make it much
27 simpler. I was going to ask you if you're having any interactions with the Quality Care Cancer Committee,

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1 the DHHS has been operating for about 7 years? Have you sent people over or had people come over to
2 you?

3 Dr. Lynn: Yes, we've been in touch with them.

4 Dr. Arradondo: I say that because when I first started hanging with them 4 or 5 years ago, there
5 was no CMS representative. I told them they were crazy to be talking quality of care without talking CMS,
6 so we got Duga Rollo over and a couple other people. I don't know what your hierarchy is to know who
7 should have been there, but I do know that they and you should have been hanging together. That's a tax
8 dollar question. Have you done anything with VA in the query thing? All the stuff they're doing with
9 quality? They have people inside the hospital, outside the hospital, clinics and stuff? Are you doing
10 anything with them?

11 Dr. Lynn: I can't answer your question on whether we have formal representation on the Cancer
12 Quality Committee at this point. I've been there twice in the last year, so we're certainly in touch with the
13 right people. But whether anybody's officially assigned, I don't really know. But the VA obviously is a
14 step ahead of most of the country on electronic records, and also on assessing evidence base for, as you
15 know, for various—

16 Dr. Arradondo: That's the reason I asked the question as to whether you're hanging with them,
17 yes. But you have 10 times as much money as they do, that's the reason I'm asking the question. So I guess
18 the answer's no, right?

19 Dr. Lynn: We're riding their coat tails on health services—

20 Dr. Arradondo: The answer's no, you aren't hanging with them yet?

21 Dr. Lynn: Oh, we're hanging with them, but we're hanging on their coat tails.

22 Dr. Arradondo: OK, clearly CMS ought to be looking at VA, why do with \$300 and that's just one
23 piece of your money, what the \$30 billion guys have been doing with theirs until we know what the good,
24 the bad and the ugly is, was, and is going to be in their little program? These are all tax dollars. So I think
25 it's, I don't even want to mention DOD. Kaiser has a follow up plan to mention one system, that might be
26 instructive, and I don't know if there are any Kaiser people around the table, but to get back to the kind of
27 more specific stuff. It seems to me that the people who have been through this before with smaller systems,
28 the \$2 billion systems, the \$5 billion systems, have looked at general instruments and specific instruments,

1 and the conversation here kind of got at that. And it seems to me that a general instrument will be needed to
2 keep up with the patient in various sites, various conditions, various status. But at the same time, when you
3 get to a particular status, or a particular condition, or even a particular site, it's very specific tool that's
4 going to be needed. And the necessary change or the necessary status, or the necessary function with a leg
5 or a hip or a head or a psych injury might differ significantly. Well, it will differ significantly, so it might
6 be up to the people who are up to the experts in that area to say for stroke, as you correctly pointed out, it
7 might be the ability to swallow. For joint replacement, it might be the range of motion, passive or active.
8 For a person who comes in because they can't get their pills, it might have to do with their financial status,
9 or their connection to some social service. So it's going to be different among your different domains that
10 you properly laid out and the ability of the general instrument to relate to the specific instrument is going to
11 be critical. And of course, all of these instruments, and I'm, you're all the experts in here, I just read it to
12 use it as a manager from time to time will need to be validated before they're used to go out and measure
13 quality. Because if you go out and measure quality with the instrument that you'll have at the end of this
14 year and next year, then your 535 bosses are going to say, aha, that's what we're going to use to go out and
15 fiddle with the \$500 billion that we're spending for this whole system. So the instruments are really going
16 to have to be validated, I mean, really out the gazoo, so to speak, before they actually go out and demo
17 programs for management or measurement of quality. So that's going to be very, very, very important. I
18 have a lot of other things to say, Mr. Chairman, I just don't want to touch it. But whatever the status change
19 is, the site changes, or we start looking at a different condition, we need to have different pieces that that
20 particular site expert, condition expert, function expert has validated, that then fits into this larger one that's
21 going to collect them all together. And as you point out, this is no piece of cake.

22 Dr. Przyblski: I want to echo some things that Tony brought forth and that's the fact that there are
23 outcome measures that exist and you're trying understandably to create one, for 3 different settings so you
24 can make comparisons. Theoretically in the future, say I can get this patient most effectively through this
25 type of setting to get the best kind of outcome. I suspect that that's a future direction that this may go. Why
26 would you create a new instrument and then go through the process and the expense of validating that
27 seeing that it's reproducible inner observer, intra-observer etc., when you may be able to just adopt
28 something that already exists. And I understand the issues of how granular versus not, the first thing that

1 came to my mind was the short form 36 outcome measure, which basically looks at how is the patient
2 doing in general? Psychologically, functionally, are they able to walk a certain distance, and they may not
3 be very specific, but we may not need that degree of specificity. What was mentioned was range of motion
4 of a hip. Now, I'm not familiar with that area, but does a ten-degree range of motion of the hip more or less
5 change the functionality of that patient? Do we know that it does? What are really interested in? How is the
6 patient better functioning in life? And if there are instruments that already exist, why reinvent the wheel?

7 Dr. Lynn: Just say the direction that you all are going is the direction that we've gone. And I think
8 you'll find it quite comforting when you look at the instrument. As you say, what matters is can the person
9 walk? Or can they turn themselves in bed? Or can they transfer? And which ideology it is that makes them
10 unable to walk is less important, not unimportant, but less important than whether they can. And so almost
11 all of the instruments, the items that we're using have been validated before. Not necessarily in exactly this
12 format, and exactly this setting, but we have not gone out and developed a lot of wholesale new things. I
13 mean these are more bringing together the best of what's out there and making them applicable across all
14 these different settings so that the time frames and that sort of thing can match and then being very
15 sensitive to the respondent burden, trying to say well, is this really worth enough to make the therapist fill it
16 out or make the doctor fill it out or make the patient fill it out. Or can we leave it more open that multiple
17 parties can fill it, that sort of thing. So I'm sure you'll still find it to be a problematic instrument. It always
18 is, but I think you'll also find that some of the things that you're thinking of are in exactly the same
19 directions as we did. I mean went to query, we looked at what the VA's been using, we used the things they
20 swept free for us already in terms of things like copyright and so forth and all these instruments have to be
21 available in the public domain, so it's moving I think the right directions, and I think you'll find it to be a
22 welcome relief in some ways from the, the sort of scribbled, someone gave me a transfer form from a
23 hospital to a nursing home in New York City about a year ago that said, new left nephrostome tube. That's
24 it. That was the history. Patient came in on 22 drugs and clearly was at death's door and that was it. This
25 would make that very unlikely, and I think you'll find it to be really very positive. Undoubtedly, there'll
26 still be things you very much want to fix, and I expect it'll be an ongoing evolution, as we fix it.

27 Dr. Sprang: I'll just say less is more. Obviously a lot of internists who get information from the
28 hospital, especially when it's off the computer, it's a stack of paper like this, and they push it off to the side

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1 and never look at it. So if you want it to be succinct enough for it to be useful for people to read it. Some of
2 the things in medications are clearly being done, like practice in the hospital, it's totally electronic. Before
3 any patient's discharged you have to put all the meds they were on when they came in and all the meds they
4 were on when they go out, unless you can't write the discharge order. And a lot of the systems actually,
5 once the information's in there, it pre-populates the next questionnaire, and so if you can set the
6 questionnaire up any way that some of it fits with that system, half the questions will get pre-populated just
7 as soon as you put it in.

8 Dr. Lynn: The demonstration mode, the pre-population will be more limited than it is in full
9 clinical implementation when we actualize this vision. There are multiple ways to pre-populate. One would
10 be to pre-populate but ask the question, make you reaffirm that. Sometimes some things can just be pre-
11 populated, I mean the date of birth doesn't change. So the idea would be to be able to upload as much from
12 the records as much as you can in pre-populating, and once it's done once, to have a lot of things that
13 would either come up automatically that you could just reaffirm, or that would ask you the question, but
14 then tell you what a previous answer had been so you could see if there had been any substantial change.
15 But yes, we aim to be able to do what's called carry forward in a way that's responsive to the patient's real
16 situation.

17 Dr. Sprang: Again, less is mess. [laughter]

18 Dr. Snow: Working primarily in a nursing facility, I certainly appreciate your comments about the
19 patients that come in, we have no information currently. We certainly don't get discharge summaries and
20 many times no history, physicals, or just the medication list filled out and we don't know why they're on
21 those medications. But to expect I mean I see a multitude of problems with the provider being expected to
22 provide all that information before the patient can be transferred, load it onto the Internet, so that when I
23 see him 2 hours later at the nursing facility, I'll have that information assuming I can get onto the Internet.
24 My hospital has medical records. I've made at least a dozen sets of rounds in the last year where I have
25 zero information about a patient because the computer's down and the nurses don't know anything. They're
26 just key punch operators. So you can't get—I feel their forehead like we used to do back in the '50s and
27 '60s and talk to the patient if they're able to talk, to get information, so just because we can do this
28 theoretically, does not mean it's going to improve and be available to the providers of care, unfortunately.

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1 Dr. Grimm: Who's going to pay for this and how is it, is Medicare going to pay for this?

2 Dr. Rapp: First of all, this is a demonstration. The instrument is being built for this demonstration
3 that was funded by Congress, so that's taken care of. The rest is a vision. There's no implementation plan,
4 there's no funding. It's an idea and we're interested in the comments that you've given us. But it's just an
5 idea. No implementation. But we are going to build, we are building the instrument for the demonstration.
6 And a report will be given to Congress based upon the results of that demonstration. That's it. No further
7 than that. But you can dream like us, or you can say that's not a dream, that's a nightmare. [laughter]
8 Whichever. But we're interested to hear what your thoughts are.

9 Dr. Senagore: OK, well, Dr. Rapp gets to stay for the next session as well, so we'll move on. I'd
10 like to bring up Dr. Tom Valuck. Dr. Valuck has been in front of the Council before. Last quarter he is
11 newly appointed as the Director of the Special Program Office for Value-Based Purchasing, established
12 under the direction of the Acting Administrator, Leslie Norwalk, that we met earlier. Tom leads the agency
13 on this important program and is here today to bring us up to date on the current status, and your colleague,
14 Dr. Susan Nedza. Welcome.

15 Physician Quality Reporting Initiative

16 Dr. Valuck: Well, thank you, Mr. Chairman. And thank you for the opportunity to be here again to
17 address PPAC on the Physician Quality Reporting Initiative. The way that we're going to deliver the
18 presentation today is that because it's been 3 months since our last meeting and because there are some new
19 faces, I would take the opportunity to bring everyone back onto the same page with the first 16 slides. I'll
20 move through those relatively quickly, and then I will ask Dr. Nedza to talk about the outreach and
21 education effort for PQRI that she's been leading and specifically some of the strategies that we've been
22 sharing with you and your colleagues and the professional organizations who represent you, and then that
23 will take us through slide 36 and then Dr. Rapp is going to finish up with a discussion of the measures and
24 measure issues with particular focus on where we're headed for 2008 and beyond. The last 4 slides, 45
25 through 48, were simply included for further information about some of the most frequently asked
26 questions that we're getting and that have been answered on our website along with over a hundred others,
27 but they give you a taste of the kind of information that we are disseminating as well as the kinds of
28 questions that are being asked. You see on slide 2 then the way the organization or the overview of this

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1 breaks down. I'll cover the first two bullets, Dr. Nedza will cover the second two. And then Dr. Rapp will
2 finish with measures and considerations for 2008. On slide three, to remind the group of the purpose of
3 what we're trying to accomplish here, that value-based purchasing is a key mechanism that we're using to
4 transform Medicare from its role in its first 40 years as a passive payer, to a new perspective of that of an
5 active purchaser, meaning that we no longer simply will pay based on quantity and resources consumed,
6 but we'll also be looking to quality and value of those services provided. The value equation that you see
7 on the slide then is what we're looking to enhance and that would be both to encourage quality and to take
8 unnecessary costs out of the system, using incentives. On slide 4, just a reminder that CMS is not out on a
9 limb with our efforts in value-based purchasing, but that many policy makers and those who are responsible
10 for setting Medicare policy have weighed in. The President's budget for the last 3 years has indicated that
11 Medicare will be moving toward value-based purchasing for all of our payment systems, including the
12 physician payment system. Certainly Congress has shown interest in their last several Acts related to the
13 Medicare program, and those who advise Congress and the Administration on the future of Medicare,
14 including MedPAC and the Institute of Medicine have all weighed in in support of value-based purchasing
15 for our payment systems. And then last, you see there that the private sector is also moving in this direction
16 and we have practices that we're adopting from the private sector as well. On slide 5 then another overview
17 slide, background slide. My intention is not to talk indepth about all of these demonstrations and pilots that
18 are going on at the agency that are related to valued based purchasing, but to show you in a very dense slide
19 that there is an enormous amount of activity, effort, investment of time, energy and resources, in figuring
20 out how to do value-based purchasing right. So this slide represents all of that activity. Some of you will be
21 involved in or will know of demonstrations like the Premiere Hospital Quality Incentive demo or the
22 Physician Group Practice demo. Others coming on line like the Medicare Managed Performance
23 demonstration for small to medium-sized physician group practices and so on down the slide. You'll see
24 other payment settings, care coordination, gain sharing, all part of value-based purchasing and the tools to
25 support value-based purchasing. So what's the tie-back to quality? I mentioned that quality and cost are
26 both factors of the value equation. The tie-back to quality that you see on slide 6 is really based in the
27 measures that we are using. These are evidence-based measures that we've discussed over the last several
28 PPAC meetings that Mike will discuss further today, but they have been developed through groups like the

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1 physician consortium for performance improvement and the National Committee for Quality Assurance
2 and vetted through consensus groups like the AQA Alliance and the National Quality Forum, and that's the
3 evidence base for quality that we're trying to accomplish. And of course, we'll be collecting data through
4 our reporting mechanisms and that measurement should enable improvements in care, but remembering
5 you have to keep in mind that the reporting, this pay for reporting program is a simple first step toward
6 what we believe we'll ultimately be able to accomplish through the promise of value-based purchasing.
7 Another way to look at the link between quality and PQRI is demonstrated on slide 7. I'm sure that most of
8 you, if not all of you, have been involved in the Performance Improvement activities of entities that you're
9 affiliated with or within your own office setting, where you follow an improvement cycle based on best
10 practices and developing measures out of best practices, collecting data, reporting results, so that you can
11 understand what's actually happening so that you can make improvement. We're starting at the top, here in
12 the measure definitions in simple data collection and recording tools. We hope to continue to push deeper
13 into the performance improvement cycle through subsequent iterations of this program and then of course
14 the idea is to enhance the value of the Medicare dollar. On slide 8, then, this is a slide that we've been using
15 with you colleagues as we're out in outreach and education efforts because we get a lot of questions about
16 so what is the PQRI going to mean to me as an individual practitioner and we emphasize that it's not just
17 about what's there in the second bullet, it's certainly not simply about the bonus incentive payment,
18 although there is a lot of focus on that, a lot of focus on how can I be successful in earning that bonus
19 incentive payment, but it's also about professionalism, it's about accountability, it's about improvement
20 within the practice, and that's what that first bullet is about. That if you can't, if you don't have the
21 information, then you can't use that for improvement. And then the third bullet is also about the future,
22 which is making an investment in the future of the practice. All signs are that we will continue to move
23 toward Pay for Performance again this support for value-based purchasing that I was mentioning that
24 Congress and the Administration will together continue to advocate for value-based purchasing, and that
25 would mean larger bonus incentives over time and ultimately, likely, public reporting of the information
26 from the physician practice setting over time. Let me quickly review as well, the sections or the provisions
27 in the §101 of the Tax Relief and Health Care Act that outline the parameters for our program, or the
28 skeletal structure and then some of the things that Dr. Nedza and Dr. Rapp will be commenting on, will fill

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1 in that skeletal structure. I'd also like to remind you that the Act was signed on December 20th, so all of the
2 activity that we've done toward implementation, has taken place in about the last 5 months, so please keep
3 that in mind. On slide 10, then, you'll see that the statute opens the program to the whole team of providers,
4 basically. The MDDO physicians, as you would expect, but also the other physicians as defined under the
5 Social Security Act for Medicare, the 3 categories of therapists that you see listed there and 9 other
6 categories of practitioners other than physicians. On slide 11, then, the just briefly on the quality measures,
7 as Dr. Rapp will cover that more in depth, we have 74 now posted on our website, along with the
8 specifications for those measures, and we will be following, as Dr. Nedza will be commenting on, with
9 instructions and further tools to support the successful reporting of those measures. On slide 12 then, the
10 form and manner of reporting as we've discussed previously is claims-based reporting, using CPT Category
11 II quality codes, and temporary G Codes where those CPT Category II codes have not yet been developed
12 and the reporting period is July 1 through December 31 and that's for dates of service on and between those
13 dates. On slide 13, then the reporting thresholds are set by statute, up to 3 measures are required to be
14 reporting 80% of the time, depending on how many are applicable to the practice, during the reporting
15 period, and then the bonus payment is also set by statute, that's discussed on slide 14, basically a 1.5%
16 bonus may be earned on total allowed charges during the reporting period, subject to a cap. That bonus will
17 be paid to the holder of the taxpayer identification number in a lump sum in mid-2008. On the next slide, as
18 we discussed in depth, at the last meeting of this group, there is a cap calculation that could apply for those
19 who report relatively fewer instances of the measures and also provides some rough equity between those
20 who are reporting fewer and those who are reporting more. If you'd like to review the discussion that we
21 had at the last meeting about the cap calculation, we can do that during the question and comment period.
22 The last slide that I'm going to cover this afternoon is two other provisions in the statute that we're required
23 to implement. One is a validation in situations where a participating professional has chosen to report only
24 one or two measures, we'll have to validate to determine whether or not an additional measure or two
25 should have been reported, and then also there will be a simple appeals process, though no formal
26 administrative or judicial review is required for the program under the statute, we'll have to be able to
27 reconcile the reporting rates and the payments that we distribute with those who take exception. So that's a
28 quick review of what we're trying to accomplish, and also the skeleton of the program. I'm now going to

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1 ask Dr. Nedza and Dr. Rapp to fill in that skeleton a bit and then we'll look forward to your questions and
2 comments. Thank you.

3 Dr. Nedza: Thank you Dr. Valuck, and thank you Dr. Senagore for the opportunity to be here. And
4 I'd like to start by expressing my gratitude for all of the work that many of you personally and a lot of your
5 organizations have done in support of the program already for both education and outreach. We have been
6 reaching out quite frequently and attempting, as you'll see in the slides I'm going to present to take your
7 comments thoughtfully and to develop the program in our outreach based upon those comments. So we've
8 got some goals. We started very early in the program with engaging eligible professionals, if you will, an
9 awareness campaign. You saw the number of people that are eligible and using all of our various tools that
10 we have at CMS and our various networks to engage all the communities for these eligible professionals'
11 practice and care for patients. In addition, we've now moved into a phase where we're helping people
12 prepare for reporting so if you will, the decision to participate has been made by many and we've been very
13 gratified by what we've seen in that area and finally, we are going to be working to support successful
14 reporting and some of the tools I'll finish talking about this afternoon will enable that. So in the next slide,
15 you'll see our main source of communication is the CMS.hhs.gov/PQRI website, which I can say changes
16 daily or every other day. We are actively adding FAQs. On Friday we announced our national provider call
17 that we'll be doing this Thursday, that's specifically related to implementation. We also announced our
18 testing strategy that I'll mention at the end of the presentation, that will allow practices to see how ready
19 they are to submit data through the claims process so that we're referring everyone to that as the first site
20 for any PQRI information, and as Dr. Valuck mentioned, we have over 100 FAQs and continue to add to
21 that weekly at least. We are working with our carriers and the MACs that you heard Karen Jackson speak
22 about earlier. They are the area we are asking professionals to call if they need additional information, and
23 I'll be doing a presentation with them today to update them on the information for our call on Thursday, so
24 that they'll be prepared to answer questions that all of the Medicare professionals will have. And then
25 finally, we're asking people to join the list serves, not just particularly for this program, but we look at this
26 as an opportunity to build awareness of other issues around Medicare and so every outreach opportunity we
27 have, we are extending it beyond PQRI.

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1 So here's a list of what you can see on the website. One physician in Ohio has told us if you spend
2 an hour on the website, you can become a PQRI expert and so I have been very actively referring people to
3 that and the website's not just a site for physicians but our work with practice managers, and also coding
4 and billing professionals, we've been told that there's a lot of valuable information there. So I'll switch
5 now to talk a little bit about our preparation strategies, and this is where we are focused and I think that this
6 is where most of the pay-off will be for people that are going to implement the program successfully. The
7 first key decision is to select measures, and these measures are appropriate for the practice and the patients
8 they care for. This is a very patients-centric program, and we didn't go out and say, you're a
9 gastroenterologist, here's your measures. You're an emergency physician—we've got how many
10 measures? Going through that, we said, who are your patients and what are your quality improvement
11 goals? So pick your measures based on that in context of the statutory requirements. So in some instances,
12 there may be only one or two measures that are appropriate for the practice. And other people may have
13 more than 3 and they can choose to do 3, or they can choose to do extra to improve their chances of
14 successfully being eligible for the bonus. This is about quality improvement, as Dr. Valuck mentioned, and
15 we are working to help people define their team roles. Who in the office is necessary? We've recognized
16 that it's everyone from the person that pulls the charts in a practice to those that design preop standing
17 orders. So in each care setting it's a little bit different, and I've actually visited some physician practices
18 recently to see how their implementing to inform our process, and then modifying work flows and billing
19 systems. So this is very big product transformation if you will. On the next slide, these are the detailed
20 instructions that we give people as how to get to the measures and to review the specifications for each
21 measure, and then finally this third goal is the one we'd really like to emphasize. This really needs to be
22 integrated in your quality improvement goals already going out in practice. We recognize that the private
23 payer community and other entities are already asking physicians to submit data, or measuring physicians
24 and other professionals on the type of quality improvement they do and the care they provide. So having
25 seen this program, the PQRI, be part of that process makes more sense than having it be something
26 different.

27 So in the next slide, in defining the team roles, it's just like any other quality improvement project.
28 Getting people together to plan the approach, to make sure that everyone who is accountable is held

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1 accountable for those particular pieces, and then also assigning responsibility and providing education. So a
2 lot of the calls we're doing with the specialty societies, we're doing national, webinars and calls for some
3 of our colleagues, where we are concentrating at 7:00 in the morning on practice managers, or at different
4 times of the day based on whom we would be trying to reach with our message.

5 So we've identified that there's a need to modify work flows and billing systems for PQRI. And
6 we know that in a prior demonstration project, that the oncologists undertook, one of the things that we
7 heard back from them was that it was the improvement in their processes that was of great benefit to the
8 practice, not just the associated gain for the financing associated with that demonstration. So we asked
9 them to walk through and determine the system changes they need to put the quality codes on the charts.
10 The next slide you see it says consider using worksheets—oh, I'm sorry, that was one bullet. The
11 worksheets we are going to be highlighting tomorrow afternoon, and I'll also be talking about them on our
12 call on Thursday, we had a contract with Mathematical Policy Research, who is working with the AMA to
13 design worksheets for all 74 quality measures that will be available electronically on the web prior to the
14 start of the program, so people don't have to develop their own sheets. We know a lot of the specialty
15 societies have but there will be tools that can be slipped in a chart, taken to the OR, taken to the GI lab,
16 carried to the long-term care facility that allow for the physician to document the kind of quality care
17 they're giving, and then that can be crosswalked to the codes that will be placed on the claims. And so one
18 sheet, one process, and we're very excited about rolling those tools out. In addition, we recognized, through
19 our efforts in PVRP and input that we've gotten that we need to make sure that at the practice the software
20 vendors and third party billing vendors and clearing houses can handle PQRI codes. So we held a call with
21 the clearinghouses. The testing process that we've put in place, where there is a G code, a G 8300 is the
22 code number, and I'd refer to the website for the actual information about how to do this. And people can
23 put on any claim between now and July 1st. That code will be retired on July 1st and they'll be able to tell
24 when your coding professionals code that at either zero dollars or one cent, they'll be able to see if it gets
25 through the process to the carrier. So you'll know that your front end processes work. And that we're going
26 to really encourage people to participate in because it will give them a sense of how well prepared they are
27 in these administrative processes.

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1 In our participation strategies, reporting quality data, I'll spend a couple minutes on that and then
2 I'll finish with the last 2. So the measure specifications. Now, I've been involved in measure development
3 for a lot of years, so I find this stuff relatively easy to read, but it's not always that way for everyone else,
4 and you go to the website—so one of the things that we're going to be posting, two more documents that
5 will be coming out with the final specifications that I think Dr. Rapp will mention, will also have a code
6 master, that will be put out with all the PQRI codes to help for implementation into electronic record
7 systems, and in practices, and in addition to that, we've got a handbook for coding for quality that will have
8 detailed instructions in how to use all the various items that you see here including modifiers.

9 We're using CPT Category II codes and I implore all of you to get our colleagues to look at these
10 codes so they understand that quality really is the basis of the program. CPT II codes have existed for a
11 while and have been growing in number, and we believe that using these in the program is going to be very
12 beneficial. There's also information on the website of how to code for these particular codes through the
13 billing process, for those that are using the paper based 1500 system, and those that are billing
14 electronically. And here are a few more details about how to do it. You can't put a blank line item on our
15 submission, so people either has to, the practice has to charge, put a zero dollar charge, or a small amount
16 like 1 cent on the line, so if they put the G 8300 code, put this on and it goes in through the process that will
17 prove to be a good test, but when these CPT II codes are placed on the charts, they'll be having either a
18 zero dollar or a small charge associated with them. It's concurrent reporting. You can't report these a
19 month later after the service was provided. In order for us to determine if there was quality, for instance, if
20 a patient's maintained on anti-platelet therapy or has coronary artery disease, we have to know who the
21 patient is, we need their age, and we need to know that they have coronary artery disease and that they were
22 seen, and all of that information comes from the normal claim form, so the CPT II codes have to be on the
23 same claim. So therefore, any claim that would be submitted later just with the CPT II code with a 0 charge
24 will be rejected. The other important nuance in the program is that the quality data code line items are
25 going to be denied for payment, so there'll be a remittance advice that will go back to the practice about
26 that, but they will be passed through the NCH, the National I've just forgot what it's called—

27 [??] National Claims—

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1 Dr. Nedza: National Claims History, I almost came up with another acronym, it was the wrong
2 one. For PQRI analysis, so the carriers are not doing the analysis. The carriers are working on our
3 education strategies and helping us with the FAQs but they are not doing the actual analysis for PQRI.
4 That's done at the back end of the process. So I'll give you one quick example about Mr. Jones, Mr. Jones
5 has become quite familiar to a lot of people because he's showing up in a lot of our presentations. We have
6 some other patients we'll be rolling out some things on Thursday. He does have coronary artery disease, so
7 as Dr. Bufalino mentioned earlier, you know, you have to know the patient's problem list and what his
8 problems are, so he's been identified. So when he comes into the practice that's managing his coronary
9 artery disease, the first situation would be that he's receiving anti-platelet therapy so the medication list is
10 reviewed, so again we're back to important things that we need to have information about and then there's
11 CPT Code 4011F, is put on the claim form, either by the physician, by the office practice, or coding billing
12 professionals in the beginning of those three. In the second situation, there's a contraindication. So I think
13 one of the great things about the program is that there are modifiers for physician judgment. So in this
14 augmented claims data, you can attach a 1-P modifier that says, well, Mr. Jones is allergic or has in this
15 case a bleeding disorder, so the physician chose to vary from an evidence-based guideline based on clinical
16 decision making, clinical judgment, so the 1-P modifier is placed. There's a 2-P modifier for patient
17 reasons, and a 3-P for system reasons. And finally situation 3: There's no documentation. Dr. Thomas or
18 other eligible professional addressed anti-platelet therapy. And this is the most, it's a different kind of a
19 modifier. It's a reporting modifier. It's called AP, so in this case, the person who's doing the PQRI coding
20 didn't see any evidence in the chart either that the patient's on anti-platelet therapy or that there was an
21 exclusion. At that point in time, the practice or the coding professional can code 4011F with an 8P modifier
22 and successfully report on this particular claim. So again, this is a, these are mutually exclusive so in every
23 instance, there is a code that can be placed and so that's one that we're going to be spending a lot of time
24 talking to practices about in about and the coding billing professionals.

25 Get your claims in early and I think I've already hit the second point, prior to this. Another critical
26 point, the statute requires us to make the payments at the tax ID number, but the analysis is going to be
27 performed at the NPI, so everyone needs to have their NPI and use it, and I know there's going to be
28 discussion about NPI later this afternoon. Participating professionals have to have it and correctly use it and

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1 we will be, analysis, as I mentioned, will be performed at the level at the NPI. I'm only going to touch on
2 validation. We will be posting the validation plan prior to the July 1, 2007 deadline, and Dr. Valuck
3 mentioned this in his comments. One of the points that has been one of confusion is one of our favorite
4 FAQs and we are going to have an FAQ of the week. The potential bonus is not just on those charts where
5 there's a quality code attached. It's for total allowed charges paid under the Physician Fee Schedule. So if I,
6 as an emergency physician were to submit a hundred claims with PQRI codes or quality data codes, 90 of
7 which have the appropriate codes on them, I qualify. But it's on all of my total billing, not just on those
8 particular claims for the 6-month period for 2007.

9 The cap just report, pick measures where you can report a number of times and that are
10 appropriate for the practice, because as Dr. Valuck mentioned last presentation and then again, now we're
11 going to talk a little bit about the cap in the question and answer if you'd like to. It is a fairness factor and
12 really to overcome the cap what one needs to do is report on measures where you can report frequently.
13 The bonus payment will be to the TIN. We've received a lot of questions about what that will look like and
14 it's anticipated it will be a report that will go back with the individual NPIs and their reporting percentages
15 on that particular document that will accompany the payment. So this is what it looks like. The visit
16 encounter form. Everyone uses something like that. It goes through the carriers, into the National Claims
17 History file, our analysis contractor determines successful reporting, the all important feedback report that
18 allows for the completion of the quality improvement loop, and then finally, the bonus payment, which is
19 generated at the end of the program in 200—in the end of 2007's program which we're anticipating will be
20 in mid-2008, the bonus payments will occur.

21 And I think with that, I'll just give you one additional comment related to some of the other
22 documents you'll be seeing. I mentioned the specifications that will be posted. Dr. Rapp will talk about
23 those. The code master will be coming out. The coding handbook also, and the worksheets. So please visit
24 the website early and often and we look forward to your questions and your comments here today and to
25 working with you to make the program successful. Thank you.

26 Dr. Senagore: Dr. Rapp?

27 Dr. Rapp: Yes, thank you. So now I'll move to the measures and I want to go a little bit back
28 historically. When we started the Physician Voluntary Reporting Program in 2006, we initiated a somewhat

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1 innovative form of data reporting, and I refer to it as an augmented claims data source for measures. We
2 adapted existing ambulatory and facility measures. We sought to make sure that they were measures that
3 were consensus based, in that they were NQF endorse, AQA adopted, and also we looked forward to the
4 possibility of having these measures reported electronically and the doctor's office quality IT project, were
5 measures that had been specified for electronic submission. We were able to cover 19 of 39 Medicare
6 designated physician specialties with our 16 measure starter set in 2006. And so as mentioned, the
7 augmented claims data methodology uses G Codes or CPT II Codes to report quality data as part of claims
8 submission. Alternatives to that for us would have been straight claims data. Straight claims data would just
9 be your CPT and ICD Code. The problem with that is in particular, attribution to the physician; what
10 physician is responsible for a woman's getting a mammogram or not getting a mammogram or other types
11 of quality information. Administrative data provides you some additional data streams like lab and
12 pharmacy, but that's complicated chart abstraction; has its obvious disadvantages and is really a nonstarter
13 for trying to collect physician information, and EHRs weren't available to us. So this augmented claims
14 data methodology has significant advantages, particularly the flexibility in terms of developing measures, a
15 single data stream, and notably, self-attribution by the physician. The way this program works is there's a
16 presumption in the statute that if the physician reports the measure, it applies to the physician, and
17 conversely, it would appear that not reporting a measure does not lead to any assumption or presumption
18 that the measure applies to the physician. So for 2007, the measures are quite expanded beyond our 2006
19 PVRP, up to 74 measures, as Dr. Nedza mentioned. This covers some 35 of the 39 physician specialty
20 categories applying to specialty categories for over 95% of physician Part B services. It's not to say that the
21 measures apply to 95% of Part B services, but those specialties that account for 95% of the Part B services.
22 As Dr. Nedza also mentioned, the applicability of the measures depends on the services rendered, not a
23 designated specialty. So one would look to the services that, a physician would look to the services
24 provided, rather than what their specialty designation is. The specifications were originally developed with
25 physicians in mind, MDs, DOs, principally, however, Congress expanded that in the PQRI legislation such
26 that it was expanded to the list that you have in your slides, going to including to such providers of care as
27 physical therapists, and speech and language pathology and so forth, so Congress had quite an expansive
28 idea of what they wanted covered by the measures, and we sought to address that by—most of these

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1 measures were developed through the AMA physician consortium, and we requested that they look at them
2 in that light, and they have done that and expanded the specifications in certain instances. So the way the
3 PQRI specifications work, and the way you look at reporting is the denominator population is based upon
4 ordinary billing processes, which is the CPT and ICD9 Code. So whatever you would ordinarily bill and
5 put down on the claim form, that defines the population, then once that happens, it's the job of the
6 physician to report the quality data, and that's what the CPT II or G Code in a few instance, relates. So
7 these are the quality data codes, to successfully report under the PQRI program, it is necessary in each
8 instance to report a numerator code, a CPT Category II Code or G Code which may be appended by a
9 modifier, that Dr. Nedza referred to, the 1-P, 2-P, or 3-P, which is really an exclusion modifier. You report
10 the code, but you say that we didn't do that service because of a medical system or patient exclusion. Or in
11 the instance that there is no identified reason for not performing the service in those first 3 exclusions don't
12 apply, then one would put the 8P modifier. But the basic idea is to get credit for reporting. This is a pay for
13 reporting, not a Pay for Performance program. One has to report a CPT II Code or G Code in all instances,
14 or it won't be considered to have been reported. We get questions frequently about how frequently should a
15 measure be reported. It differs according to the measure. Certain measures are saying such as aspirin in a
16 heart attack, which should be done each and every time, or antibiotic prophylaxis for particular surgical
17 procedures. On the other hand, diabetes hemoglobin A1C, for example, is something that should be done
18 periodically according to the way the measure works. And there are a number of measures like that, so one
19 has to look at the detailed instructions for each measure to know whether or not the reporting is periodic, or
20 in each instance if the patient is seen. We also get questions, frequently about well, I am an oncologist, for
21 example, or I am some certain specialty, but I don't do primary care. Should I have, do I have to report a
22 measure for fall screening, for example, or advanced care planning that could apply to me? And the answer
23 is really you have to look at the measure yourself. And apply the instructions to your particular situation
24 and decide whether it applies to you. Remember the presumption in the statute, that if the physician reports
25 it, it applies to the physician. So really fundamentally, it's up to the physician to determine whether the
26 measure applies to him or her.

27 Here are basically a list of the information that we include in the PQRI measure specifications. All
28 of those items are covered for each measure. The specifications to the measures were posted around April 1

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1 in quite detail, but the statute gives us the authority to update or modify the specifications as need up to
2 July 1. Obviously we're trying not to do that but there are a lot of questions we get asked and the measure
3 owners, particularly the AMA, is an owner of many of the measures. They seek to update some of these
4 measures and so they go through their process and give us that information. So in certain instances like
5 that, we will soon be coming out with what we believe and hope to be the "Final" specifications in order to
6 allow the practitioners to prepare for the program, because we can't be changing specifications at the last
7 minute. But we don't look at it, it's our—we do frequently get questions from practitioners or others, well,
8 we'd like to change these specifications. Well, in most instances, these are not CMS measures, these are
9 measures that are owned by the AMA or NCQA in certain instances, so in instances where we get asked
10 those questions, we send it back to the measure owner or developer and it's really up to them to decide
11 whether that measure should be expanded or not. And in the physician arena, particularly, sometimes
12 there's differences of opinion among the different specialties as well. We would like to get this code set
13 expanded in terms of specifications so we can report the measure and the other specialty will think that
14 well, that measure doesn't really apply to that particularly. So that's something for the measure
15 developer/owner such as the AMA to work out and CMS doesn't step in and try to basically referee that
16 difference of opinion and leave it to the measure owner. As far as the PQRI health IT considerations, we
17 did take that into account in the original PVRP and in particular, there were six measures that could be
18 reported through electronic health records under the DOQ-IT measures specifications. That was not
19 utilized. That opportunity was not actually utilized at all, and in the 2007 PQRI, we do not provide for that
20 option. However, that is definitely a goal for the future that certainly electronic health records are the future
21 and we need to make that available. But that is not available for 2007. The rule for 2008 will, we haven't
22 been asked to address in the statute EHR particularly, but registry-based quality data reporting, which I'll
23 talk about a little bit more in a second, we have been asked to address and we will. For 2008, the way that,
24 for 2007 the measures were incorporated by reference by the statute and added to through a consensus
25 process, but for 2008, they come by rulemaking, which means that we propose measures and then we
26 accept public comment after that, and then based upon the public comment, and consideration of that, then
27 a final set of measures will come out. So we will propose measures in our rule, at which point you'll have
28 the opportunity to comment on that, the public at large will, and perhaps suggest other measures, or perhaps

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1 suggest that the measures that we are proposing should be used. There are some particular statutory
2 requirements, and in particular, we do have people come to us and say, well, we have some measures which
3 we would like you to include. That's fine, however, we're limited on what we can do by the requirements
4 of statute that they be consensus endorsed or adopted such as by the AQA alliance or the National Quality
5 Forum, so basically CMS doesn't have in the statute the authority to just OK, let's put these measures in
6 because they've been suggested to us. So they have to go through the consensus process. They do have to
7 include measures that have been submitted to a consensus body by a physician specialty. They have to have
8 used a consensus based process for development and the measures have to include structural measures,
9 such as the use of electronic health records or eprescribing and the measures have to be those determined
10 appropriate by the Secretary. So as we go forward, we are up to 74 measures now, you can imagine that
11 there will be a time when you would not want it to be like 2000 measures, but where that stopping point is,
12 it's a little hard to say.

13 As far as registry-based reporting, many of you may or may not be familiar with what clinical data
14 registry is, but basically it's a clinical data base. Number of organizations have these clinical data bases,
15 particularly the Society for Thoracic Surgeons, the American College of Cardiology. CMS uses these
16 clinical data registries for coverage with evidence development, such as for defibrillators, implantable
17 defibrillators to make coverage determinations where the evidence is not all in, then that's how that works.
18 So there is a lot of hope for clinical data registries in terms of being able to track outcomes, watch patients
19 over time, learn something new from the use of these registries. And with that in mind, Congress said that
20 we should address that in our 2008 rule, which we will do. The understanding here is that currently we are
21 asking for this 1.5% incentive, physicians to report quality measures. So if they're already reporting that
22 same data to a registry, it would undercut the registries if we don't take that into account. So that is a
23 potential problem. For example, the Society for Thoracic Surgeons registry, there are 2 measures that we
24 have in our program. They have a lot more, but the data's already being collected. So it will be at least for
25 2007, duplicative, or duplicate reporting obligation for the thoracic surgeons in order to be able to get the
26 1.5% incentive payment. So hopefully in the future, there'll be a way to address that. So that is basically it
27 for 2008, and I'll be happy to answer any questions. I'll turn it back to Dr. Valuck.

28 Dr. Senagore: Any comments or questions from the Panel?

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1 Dr. Ouzounian: I just have a little, I guess a comment. You're asking physicians to voluntarily do
2 a lot of work to get 1.5% bonus incentive, and we have another example, which is coming upon us where
3 you're giving physicians 100% incentive to put a number down on a form and the way things seem to be
4 evolving is that it's not going to be too successful, and that's the NPI number. And if physicians can't
5 report their NPI number to get 100% incentive, I'm concerned that a 1.5% incentive that involves a whole
6 lot more work is not going to be a project that succeeds.

7 Dr. Valuck: In terms of the amount of the incentive, I've had some discussions with Congressional
8 staff about this, and I won't speak on behalf of Congress obviously, but I think that the idea was that we
9 want to pick an amount that would engage physicians, but that wouldn't be overly disruptive to payments
10 and potential cash flows in physician practice, so Congress could charge a larger number like 5% or 10% or
11 15% or 20% and at some point, it would sufficiently compensate for the cost of participation, but you might
12 begin to wonder how much that might be disruptive in digging in to money that would otherwise be
13 available for reimbursement. So you have to of course as a policy maker, find a balance there. The 1.5%
14 wasn't necessarily intended to simply be directly correlated to the cost of participation. The 1.5% is I think
15 an indication that payment incentives will be used in the future to try to increase the value of the Medicare
16 dollar through encouraging quality improvement and avoidance of unnecessary costs and care. So as you
17 can expect over time, I believe, to see increases in the amount, maybe in the way that your comment may
18 be seeking, increases in the amount that would be tied to those incentives. I think you could also, if you're
19 simply thinking about return on investment, also think about the future, the future of our payment system
20 reforms, think of this potentially as sort of a practice year as the stakes do get higher as we move toward
21 true pay for reporting, as we move toward public reporting of this information, I would encourage you and
22 your colleagues to take advantage of this first year for those purposes.

23 Dr. Bufalino: Two points. Just one to track on that, so can I assume by your comments then, that
24 we can be optimistic about 2008 funding since there is some concern that there is a lot of effort being made
25 for a project that could have limited life if it doesn't get funded in the next round. Are you encouraged by
26 what's coming from the Hill that this is going to continue?

27 Dr. Valuck: That's a very good point. It is unreasonable to ask you and your colleagues to make
28 an investment in something that might only be a 6-month flash in the pan. I can't speak with certainty about

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1 what Congress will do in terms of the future of PQRI or similar reporting system, but I can tell you that
2 there is a lot of interest in continuing the value-based purchasing trend. I can tell you that we will be
3 making further statements about our position relative to having value-based purchasing be a part of
4 physician payment for the future in our proposed Physician Fee Schedule rule and we are engaged in active
5 discussions with Congressional staff on this issue.

6 Dr. Bufalino: Second point, I'm sorry. Could you shifting gears entirely, there were some
7 concerns that were raised by a number of folks about the disconnect between the inpatient side and the
8 outpatient side and the difficulty we're having kind of mixing those two big worlds, which, for a lot of us
9 are very separate worlds, and is there any interest on your part at teasing these apart and having separate
10 buckets, so to speak, or maybe one bucket or the other bucket, but not both buckets?

11 Dr. Valuck: That's an excellent question. We've been talking about how value-based purchasing
12 in the physician setting and the hospital setting and where they jointly come together would be addressed,
13 and I'm going to ask Dr. Rapp to comment on that as well, because the measures really are the foundation
14 for this, and the measures could potentially pull together the kind of alignment that you're talking about.
15 Several of the demonstration projects that I mention on that one slide, address opportunities for looking at
16 parts A and B, the future of parts A and B together, such that in a situation where a physician were able to
17 prevent a readmission for example that some of the savings for that might accrue to what had traditionally
18 been thought of as the Part B side, so we are considering opportunities there, thinking about that for the
19 future, but we need to align measures, starting now and moving forward so that we're using our payment
20 incentives to maximize the promise of value-based purchasing and not sending like our payment system
21 currently does, sending the physicians and hospitals in different directions.

22 Dr. Rapp: Yes, with regard to the problem that you pose, it goes back a little bit to the comments
23 made on the other presentation in that one has different payment settings and sort of sets up a construct in
24 one payment setting versus another. So the hospital measure development is something that anti-dates the
25 physicians and so the measures are developed for the hospital setting. However, most of the work is done
26 by the physicians, the decisions for antibody cues or any kind of pharmaceutical administration, so forth,
27 those are orders given by the doctor, and not the hospital. So there needs definitely to be more work to
28 align those measures and bring them together, because it doesn't make sense for the physician to have to

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1 report one thing and the hospital have something slightly different. So there's a lot of people interested in
2 that. We're going to make some—we're definitely going to address that.

3 Dr. Bufalino: Because you can see the difficulties of us having 2 electronic records here. We got
4 the hospital-based system, that many times is not connected to the physician end of the world and so we
5 may have the diagnosis in the ICD9, the CPT Codes, but we're not going to have the quality piece coming
6 out of the hospital as easily as we will in our office setting, where it's easier for us to control the data along
7 with the quality measures together.

8 Dr. Rapp: Right, so I think there are two issues—it's most critical for physicians that practice in
9 the hospital setting. So the ones that practice in the hospital setting, if they have to report the same measure
10 as the hospital reports, there's a duplication of effort, for one thing. And second of all, it could be that the
11 measures are not completely aligned, so we need to address both.

12 Dr. Senagore: Unfortunately our next speaker has an engagement that they have to get to, so if
13 you, do you folks have to leave right away, or if you do, then will it be OK if we make recommendations
14 after you leave?

15 Dr. Valuck: Yes, I'll be able to stay around. I don't know about Dr. Nedza and Dr. Rapp, but I'd
16 be happy to come back to answer further questions.

17 Dr. Senagore: There's obviously more interest to discuss, but unfortunately, we have to get our
18 next speaker on. Thank you. So we're going to move on to the personal health records, here. Tony Trenkle
19 is the Director of the Office of E-Health Standards and Services, OEES, which is responsible for the overall
20 coordination of CMS's E-Health initiatives, including personal health records. OEES also handles the
21 nonprivacy administrative simplification provisions of HIPAA, as well as the Medicare Modernization Act
22 E-prescribing program. Tony works closely with the Office of the National Coordinator on a number of key
23 departmental initiatives, including the American Health Information community. Before joining CMS in
24 2005, Tony served as a Deputy Associate Commissioner in Social Security Administration, as an office
25 director at General Services Administration, and welcome.

26 Personal Health Records

27 Mr. Trenkle: I'm going to speak about several different areas today. One is to give you a little bit
28 of an overview of PHRs and what we're doing at CMS over the last several years and what we're planning

1 to be doing over the next couple years, get in some challenges and then get your feedback on the whole
2 personal health record area, and some advice you can give us as we continue to move along to support our
3 beneficiaries' and others' use of personal health records. I really had 3 different questions I wanted to get
4 your feedback on. One is the use of PHRs will increase the patient's involvement in their care, and what
5 concerns does the provider community have that CMS should be aware of? I'd like to get your feedback on
6 that. The second one is the expectations that patients will begin to use the PHR as a source of registration
7 and medical history provided to the physician, and I want to get feedback on the impact you feel it will
8 have on the business flows and data integrity concerns, legal implications, and other issues. And the third
9 one is within the next year, actually within the next several months, we're going to begin to start PHR
10 outreach and education for beneficiaries. How can we best work to provide our community to support and
11 complement these efforts? So we'll get back to those questions after I just give you a couple minutes of
12 background.

13 These are the key websites at CMS, the PHR home page and then the American Health
14 Information community, which is a group, a FACA committee, a federal advisory committee, that's headed
15 up by Secretary Leavitt, that has done a lot in the personal health record area as well. PHR just a little
16 background. It's a collection of information of an individual's health or healthcare services. Originally
17 paper-based, but more and more being provided via the web and more and more being provided not only by
18 plans, but also providers and other organizations are not covered entities under HIPAA and what they allow
19 people to do is to gather, store and manage their health data with family members and care providers.
20 Basically, it's 3 separate sources of data. One is official medical information that may be derived from an
21 EHR or other sources of official information, second would be information imported by the person
22 themselves, in our case, the beneficiary, and third may be other information provided by the PHR vendor or
23 holder. And of course this information is controlled by the individual as opposed to an electronic health
24 record, which is more the official health record.

25 Over the past several years, we've looked at potential CMS roles to meet beneficiaries needs for
26 Personal Health Records. The one we've concentrated on is making Medicare data available to PHRs.
27 We've also been working with the standards organizations and with the Office of National Coordinator at
28 HHS to support standards development interoperability between PHRs and EHRs. We've also been

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1 working closely with the Office of National Coordinator on certification efforts, and of course looking at
2 this whole issue of educating beneficiaries in the uses and benefits of PHRs. Over the last several years,
3 we've done a number of efforts to begin moving in this direction. In 2005, we did a request for information
4 where we solicited feedback on our role with regard to PHRs. We got over 50 responses to it and basically
5 the questions we asked were what should be the role of CMS with regard to PHRs? Should we bill at our
6 own personal record? Should we be taking a leadership role in enforcing the standards, providing
7 certification criteria, and the feedback we got was mainly asking Medicare to provide data, whether it be
8 claims data, screening reminders, benefit information, other types of information we had that would support
9 PHRs that are out there today and will be out there in the next several years. The other major role that they
10 wanted CMS to play was the privacy and security assurance. We had a major role in doing that, and that we
11 should not bill it our own personal health record, but support personal health records that are out there.

12 In 2006, we awarded 2 contracts to Medicare contractors to test the feasibility of using Medicare
13 claims data. Those 2 efforts used a small number of beneficiary records. They were actually gave us over
14 70 use cases, and successfully tested the transfer of Medicare claims data to a group of beneficiaries. Now
15 these beneficiaries were not part of the effort. This was basically data that was part of the Medicare
16 contractor and what we were testing was the feasibility of converting it into an Internet-based PHR. One
17 contract was BPS, which uses the existing web MD tool, and then Capstone Government Solutions, used an
18 existing tool as well. And it was very successful. It showed the applicability of using claims data and it also
19 showed the capability of taking claims data to help populate a large amount of the PHR and we followed it
20 up with several other efforts that we're doing now. In 2007, we will be putting out what we called a
21 Medication History & Registration Summary Study. This is in conjunction with the Office of the National
22 Coordinator's American Health Information Community Consumer Empowerment Work Group. What
23 we're doing is actually allowing beneficiaries to go through MyMedicare.gov, which is our Medicare portal
24 on the Medicare website, and we have a number of plans that have agreed to work with us. We've allowed
25 them to go through MyMedicare, and actually get access to their medication history and registration
26 summary if they're actually enrolled in these plans. That study will begin next month. There will be a roll
27 out in the next several weeks. Later in 2007 calendar year, we plan on doing a Medicare Fee for Service
28 pilot, which will actually in this case, enroll beneficiaries to actually test the adoption and use of PHRs. So

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1 the first one will be people who already have a PHR with a plan or could get it through a plan. The second
2 one will be actually working through the Fee for Service program. In April we did a source of sought in the
3 Federal Biz Ops. We had 25 different vendors who responded to that. So we have a lot of interest in the
4 community in doing this particular pilot.

5 The third area we're looking at is really to build a business process and infrastructure design,
6 which will lay out the requirements over the next several years to support large scale PHR efforts. And
7 when I say that, I mean the infrastructure, not only the technical infrastructure, but dealing with some of the
8 policy and operational issues involved with disseminating Medicare data on a large scale. And when we get
9 to the next slide we'll talk about some of these, but you can think of some of the issues in terms of consent,
10 in terms of how do we actually get this data out to large numbers of PHRs? I'm not sure exactly how many
11 PHRs there are out there, but there's hundreds of different ones actually out there today and conceivably,
12 even if we had 10% of our beneficiaries using them, that's 4 million beneficiaries over the next several
13 years. The other thing I want to point out is that a number of the private sector firms' employers are
14 actually really moving to implement personal health records. The Verizon recently announced that they
15 would provide personal health records to 900,000 employees and retirees. Intel, Walmart, and others have
16 joined in the consortium, called Dossier, that are actually planning to provide their employees also with
17 personal health records. A number of other organizations are continuing to build out as well, so we're
18 seeing a lot of growth in this area over the next several years. And the fact that Verizon is actually going
19 after retirees as well suggests that in the near future, these retirees will also be looking for Medicare data as
20 well as their own personal data from Verizon plans. So over the next several years, after we complete these
21 3 projects we're doing this year, we're going to really build the technical and policy infrastructure, and also
22 begin extensive beneficiary outreach. The other effort that is going on is there is a lot of work in the
23 standards area. In the HL7, they produced a lot of work tied in with personal health records, the CCHIT, the
24 commissioned certification commission, that's partly sponsored by the Office of National Coordinator, will
25 be doing work with PHR certification over the next several years. The Office of the National Coordinator is
26 also working with the HISBE, which is the Health Information Standards group that the X12 is managing.
27 They have several use cases dealing with personal health records, so you can see over the next several years

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1 this is really going to begin to take off, so we want to be in position in Medicare to really begin to support
2 this on a large scale basis.

3 We have a lot of issues to deal with over the next several years. The infrastructure development,
4 we're developing an integrated data repository at CMS that will bring together the various data sources we
5 have, that will hopefully support large scale personal health record dissemination. We have issues in terms
6 of protecting beneficiary data. A number of these personal health records are not covered entities under
7 HIPAA, so we have to deal with a lot of issues related to that. There's still a lot of work as I mentioned, the
8 standards area. In the certification area, the CCHIT as I mentioned a moment ago is going to begin to look
9 at personal health records, but we may be in a position to start disseminating data over the next several
10 years that will be there before the certification commission gets done. So we have to look at what type of
11 certification requirements we will need to do in the short term as well as support the work they're doing in
12 the longer term, and then finally with beneficiary education, how do they utilize these personal health
13 records to improve their health? How do they deal with some of the issues regarding populating them? How
14 do they deal with legitimate data sources? How does this change the whole issue of the relationship
15 between the provider and the beneficiary? These are some of the issues I'd like to discuss and get some of
16 your feedback with today. I think we've gotten a number of feedback from the provider community, but I
17 would appreciate getting more of yours as well.

18 Dr. Senagore: Any answers for Mr. Trenkle's questions? I'd be happy to start off. I think number
19 one is going to be a challenge since I see that my own mother-in-law has trouble reading the ELB as it
20 stands now. When she gets her bill back, I think it's going to be somewhat problematic to have her embrace
21 her PHR electronically, but I think it'll be a growing process obviously as the new beneficiaries come in are
22 more computer savvy.

23 Mr. Trenkle: I think you're right. I think the over 75 category will not be big users of the personal
24 health records, although their family members may be. I mean your mother might not, but you might want
25 to utilize the personal health record to look at her medication history and other attributes.

26 Dr. Senagore: It does bring up some HIPAA issues, though, that tension there.

27 Mr. Trenkle: It does. Absolutely. That's one of the key issues, is how do you deal with the whole
28 issue of providing others access, including the provider, to your information, and how do you deal with the

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1 whole issues of some of this information being on this record? How do you deal with questions of validity
2 and information like that? But the next phase of beneficiaries are now in their early 60s and by the time
3 these begin to hit mainstream, will become users of personal health records. That's what we're really
4 looking at down the road.

5 Dr. Senagore: In terms of work flows, Dr. Ouzounian and I were talking earlier about having the
6 patient come in with the CDs of their X-rays and having us try to figure out how to boot up the CD, if it
7 works with our computer, to get through with that, so the only caution I would have here is interoperability
8 for how these things work and how you're able to access them and last question is—I think with providers,
9 just a matter of that. That's probably our biggest concern is can we easily tap these into our business system
10 so it will fit with my billing system, and Dr. Bufalino's system. Dr. Bufalino.

11 Dr. Bufalino: The only area I'd raise that data integrity. I guess my concern would be if the patient
12 has personal control over the record, the manipulation of that information and then providing it to walking
13 into my office and being able to take that diagnosis of depression off the list, or whatever diagnosis they'd
14 like to take off, or adjust the meds at will. I guess I'd be concerned about the ability of the patient to, so
15 now we have a piece of data that doesn't have integrity. I'm assuming that it got sent from John's office to
16 my office, that I can assume it was accurate. And if in between that patient was able to tinker with the
17 information, I guess I'd be concerned about how do we deal with that?

18 Mr. Trenkle: So I assume that what you're recommending is that there is certain types of data that
19 would not be allowed to be tinkered with by the patient?

20 Dr. Bufalino: I think some of it has to be secure so it can't be changed from his system to my
21 system on their own.

22 Dr. Ross: I was going to lead into that question I know you asked earlier about medications, you
23 know, going from an office setting to a nursing home or from a hospital to a nursing home and the same
24 thing that I see, and I'm sure many of us see. Patients come to the office and they've got a multitude of
25 medications that they're taking but the question is, when was the last time that they saw their PCP? And
26 have those medications been changed and is the medical record accurate? Not is it valid necessarily but
27 how accurate is it and how timely is it, because let's say they are on Plavix or they're not, I need to know
28 that ahead of time before I'm about to embark upon any procedure. Well, the patient could have been on

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1 Plavix and maybe not be on Plavix anymore, or was just placed on Plavix and it's not on the medical
2 record. So now we're at risk for any procedure that we may perform if that patient is on a medication that's
3 not on their personal health record. So beside validity, I think also keeping up to date with the record is
4 very, very important, and not necessarily in the patients—it's in their best welfare, but the question is, from
5 their PCP or their internist or their family practice physician or whoever, are they keeping up with the
6 record or not? Are they being compliant?

7 Dr. Bufalino: And just to follow that one more time, is then the ability for us to manipulate that
8 information, so now Mrs. Jones comes and sees me, and I change two drugs and I could flip her disk back
9 into my computer, fix her medication list, so that when she goes back to see John again, he's got the most
10 accurate set of data because it walked out of my office into his.

11 Dr. Ross: Exactly, because we did a more up to date evaluation of their meds, or their surgical
12 procedures even for that matter.

13 Dr. Senagore: Yes, I think the logistics will be the biggest problem. Is it going to be, we do it on
14 the web on the fly, or do we get a disk back or USB or what is that vehicle going to be for the information
15 is really I think the challenge, because you don't want to be handling multiple extra things now in addition
16 to your chart to communicate.

17 Dr. Grimm: Yes, I think the issue for me when I look at this issue is how is this going to change
18 the way I practice? A patient walks in the door. Am I going to stop asking them the same questions I'd
19 always asked him anyway? Mr. Jones, what medications are you on? Am I going to take this medical
20 record and say that's, I'm going to trust this or I'm going to trust Mr. Jones? But I'm still going to ask him
21 the same questions. So is it going to save me time? If it's not saving me time, I'm not going to use it. So the
22 only way that I see that I would use it is in a situation in which I needed critical information that in the past,
23 that I needed to compare with now. So maybe his laboratory test in the past or his CT studies or something
24 like that. That's where I would find it to be useful, but in terms of the medication stuff, there's nobody in
25 this room who's going to trust that record for managing the patient today. Does anybody believe that?

26 Dr. Bufalino: Well, let me give you a concrete example, what we've gone to now is that every
27 patient walks in and gets a new current list today of their medicines, and we adjudicate that list at every

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1 single visit. So if he, now brings in with him his personal record, that is, his most up to date record, it's still
2 your obligation to verify that.

3 Dr. Grimm: Oh sure.

4 Dr. Bufalino: But I mean for us a lot of our patients are on 12 to 15 drugs.

5 Dr. Grimm: Your nurse is still going to ask him the questions.

6 Dr. Bufalino: They still have to go over that list, did it come from them, or did it come from you, I
7 guess is really what the question is.

8 Mr. Trenkle: You're still going to need to ask the questions.

9 Dr. Grimm: So you're putting up a lot of energy to make this thing happen. We all know how
10 much energy we put into information systems and then what I always look at, what value am I getting out
11 of this, all this energy that I'm putting into this information system, and you realize a lot of times with
12 information systems that you get, you got that much input, that much output.

13 Mr. Trenkle: Right.

14 Dr. Senagore: I think it would be most useful to the beneficiary. For us it would only really be
15 helpful if it would populate our demographics, our other data that we would need and then it goes into our
16 former, we could edit it appropriately for our account. But other than that, our benefit would be more
17 suspect. If it gave us bad data in.

18 Dr. Sprang: [off mike] living studies and stuff where you had the actual report. You can compare
19 that and have to retest it if you have something you compare it to, but the other question I really had is I
20 was at an information technology program and the speaker of that who was an international speaker said
21 that we will have our health care records on our cell phone in two years. What do you think of that?

22 Mr. Trenkle: I think that brings up a lot of privacy and security issues, because cell phones aren't
23 the most private—

24 Dr. Sprang: But apparently some of the cell phone companies are working in that.

25 Mr. Trenkle: In fact, Nokia has come in and talked to us several times. They've been doing a lot of
26 work in that area.

27 Dr. Sprang: Because he was an international speaker and he gave us his impression.

28 Mr. Trenkle: Yes, it's true.

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1 Dr. Przyblski: I would suggest that in addition to written information that imaging information in
2 some select way should also be included in personal health records, and a lot of things for example,
3 incompletely resected tumors and seeing what they behave like over time, a lot of hard copy imaging is no
4 longer done. It's done on CD format. Sometimes the patients have it, sometimes they don't and to be able
5 to have a snapshot over time of very relevant images obviously to have all of their imaging would be too
6 large to have on something simple and transportable, but select images is something that should also be
7 considered as part of this.

8 Dr. Senagore: Great, thank you very much.

9 Mr. Trenkle: OK, thank you.

10 Additional Discussion of PQRI

11 Dr. Senagore: Let's see, do we want to, Dr. Valuck is still here. If we want to go back to the prior
12 discussion, are there any issues that we need to pick up on? Yes. Dr. O'Shea.

13 Dr. O'Shea: Dr. Valuck I know that you didn't particularly go over this slide, but on slide 17, Dr.
14 Nedza had said that PQRI outreach and education had goals. And that it was to engage eligible
15 professionals, and she said at this point, there were many professionals who had already applied to be or
16 put in some information on using the G Codes, using the codes II. Does you have an estimate of how many
17 is "many?"

18 Dr. Valuck: No, and I'm not exactly sure what she was referring to. You know, there's no
19 registration required to participate in the PQRI. Simply begin submitting the quality codes on the
20 appropriate claims for payment on dates of service July 1st through December 31st, so there's no way to
21 estimate that, as far as I know.

22 Dr. O'Shea: I know that you are well aware of it, but that nebulousness that is there, that the
23 physician will not know if the coding is valid, they won't know how many physicians are participating to
24 know if this going to be a valid study to know which of the subsets of the coding are being used, lends itself
25 to again, I feel a stumbling block in the ways that I can report back to my colleagues as to why you should
26 participate. We're not going to hear anything about this until it ends. Nothing at all can be done, and it
27 actually suggests that we're not quite sure how you can actually manage all this information, if you cannot
28 look at it, gain any insight into it before the whole thing is completed.

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1 Dr. Valuck: I'm not certain that we won't have any interim information that might be useful from
2 a management perspective, and I'm talking about program management. For example, we might find that
3 nobody from a certain region of the country is reporting and we might be able to intensify our education
4 efforts early on in the first few months, those kinds of things. What we won't know, because of the
5 implementation time that we've been given, the very short implementation time we've been given, we
6 don't have time to bring up all of the analytics to be able to do any interim processing, to tell you or your
7 colleagues that you've been successful in reporting. We just won't have that capacity. The algorithms are
8 still be written, the hardware's still being purchased, that's going to process that up to 500 million claims—

9 Dr. O'Shea: So some of it is just that the analysis won't be able to be done, and you have to get
10 the codes—

11 Dr. Valuck: That's correct.

12 Dr. O'Shea: in and then it can be worked on after that.

13 Dr. Valuck: Yes, it's just not going to be possible given the short implementation time that we
14 have. We need the time, including the time during the reporting period to continue to develop the analytics
15 and the capacity for doing the analysis to determine the successful reporting.

16 Dr. O'Shea: May I again ask one other question, that you were saying that if you are in fact
17 successful in completing the 3 measures in 80% that you will in fact gain, again there's going to be a
18 minimizer and a maximizer in that number, but you will gain 1.5% of all of your billing for Medicare?

19 Dr. Valuck: During the 6-month period.

20 Dr. O'Shea: During the 6-month period.

21 Dr. Valuck: Mmhm. Total allowed charges under the Physician Fee Schedule.

22 Dr. O'Shea: So it really, and there will be a minimum, there will be a maximum to that. Because
23 you were—there is a bonus calculation that says there's a modifier on there.

24 Dr. Senagore: Less whatever you would be exposed to with the cap.

25 Dr. O'Shea: OK.

26 Dr. Senagore: So it would be 1.5% [inaudible]

27 Dr. Valuck: No, no minimum max in the calculation of the 1.5%. Now the 1.5% could be limited
28 by the cap calculation, and that's a separate calculation.

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1 Dr. Senagore: Yes. One thing Dr. Rapp said that I wasn't sure about. Under the statute, do you
2 have latitude to move between process measures and risk adjustment measures or is it all process measure?
3 I didn't quite understand what he was saying.

4 Dr. Valuck: He mentioned structural measures, specifically. We do have latitude to pick among
5 various types of measures. We would like to see in fact, a more balanced mix. As you know, we're heavy
6 on process measures for reasons that we've discussed in this group before. In the future, I would expect to
7 see more movement toward outcomes measures. And of course you'd get the risk adjustment issue that
8 mentioned. The focus on structural measures that Dr. Rapp mentioned in his presentation is a statutory
9 requirement. The statute actually mentions as examples of structural measures, capability or use of
10 electronic health records, and/or e-prescribing, so those are things that are under consideration and you'll
11 see a discussion of that in the Physician Fee Schedule proposed rule.

12 Dr. Przyblski: A comment, then a recommendation. I'm please to see that registry based reporting
13 is being considered for 2008. As you know, I and others have commented about the lack of applicability in
14 surgery for even the two measures that have been identified antibiotic prophylaxis and DVT prophylaxis
15 for many of the things that we do and I'm still bothered, and would be remiss if I didn't make a comment
16 that on slide 6, where you say the foundation of PQRI's evidence-based measures developed by
17 professionals, a lot of that has been extrapolated to many more CPT Codes than actually there is scientific
18 evidence to support. So although the basis may have been in evidence-based medicine, actual measures as
19 currently constructed for specific CPT Codes may not be based in evidence.

20 Dr. Valuck: And could I just ask for you to expand further, because as Dr. Rapp commented, when
21 there are requests to expand the denominators, as I think you're referring to, to include either other
22 procedures or other types of professionals including non physicians, that evidence is brought to the same
23 group that originally considered and developed the measure. I think Dr. Rapp spent a little bit of time
24 making that point, so if you're aware of situations where the denominators have been expanded that have
25 not been reconsidered by the measure developer, I'd be anxious to know about that.

26 Dr. Przyblski: It's specifics in spine surgery and in cranial surgery, DVT prophylaxis. There's
27 actually very little data to support yet, there are CPT Codes on the list that entail those. In spinal cord
28 injury, however, for DVT prophylaxis, there is some good prospective, randomized data. So I actually look

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1 at it the other way, that there are too many codes in there now for which application is not really
2 scientifically based, so my—

3 Dr. Valuck: OK, well, thank you for that. I just, I do want to remind the group that those decisions
4 are not being made by CMS. They're being made by either the physician consortium or one of its colleague
5 groups. And we are relying on you and your colleagues for the development of those measure sets. So we'll
6 transfer your concern to them.

7 Dr. Przyblski: But as an example, NQF, if your society is not willing to pay the membership fee,
8 you have little voice in that process, so they can make measurements and recommendations that you cannot
9 affect. And this is the genesis of my recommendation if I may make it.

10 Dr. Senagore: I think we've one more comment, and then you can make one.

11 Dr. Przyblski: Thank you.

12 Dr. Arradondo: I got part of my question answered. And I talked to Dr. Rapp in the meantime, but
13 and I wanted to, I looked at your slide 5, the BBP demos and pilots, when the handout was sent out to us to
14 see if any of those were from sites whose patients were primarily underserved patients and I didn't see any
15 of those. And/or served by people who traditionally serve underserved patients, or for that matter, managed
16 by people who traditionally manage people who serve underserved patients. And he confirmed that, he
17 said, yes, those were not set up that way.

18 Dr. Valuck: Neither of us are closely enough involved with the demos and pilots to probably
19 completely address that question. Those are primarily run out of office of research demonstrations and
20 information and at some point and I understand there may have been some interest earlier on in getting
21 somewhat of a deeper dive into like the Physician Group Practice demo or the MCMP demo, and so I
22 would address that question to those folks when they come to present.

23 Dr. Arradondo: Well, I'm satisfied with my research and with his lack of one way or the other. My
24 suggestion is to, I really wasn't going to bring this up since I'd gotten Dr. Rapp in the meantime, but Greg
25 just shared one of the flaws in expanding new things, based on narrow data to begin with, and then it's
26 getting extrapolated to populations for which it does not apply, and this is a problem for many people and
27 some organizations who look at providing whatever the services might be across all population groups of
28 extrapolating data gleaned on one population group to all population groups, and I'm particularly and

1 keenly interested in the notion of population groups that have multiple co-morbidities for virtually any
2 problem you wish to address. And those multiple co-morbidities affect the outcome of intervening for that
3 particular problem or those particular two problems, let's say, if we look at the average patient, versus
4 certain subsets. So I would be keenly interested in CMS in a sense filling that gap before it goes worldwide,
5 so to speak, nationwide. Because it's one thing to define all as 90% or 80%, however we might define that
6 from time to time when we say all the people, all the services, and we're really meaning 80 or 90%, we
7 corrected, attempted to go this morning from 75 to 80 or 90 or 95 as a standard question, and that's a
8 common matter. But if you happen to be in the 10% or the 20% and all is fulfilled at 80 or 85, or 90%, then
9 you get left out. So that's one of the things that including other groups would be able to address, so I just
10 bring that up in that context.

11 Dr. Valuck: That's an excellent point. We have been concerned about that same issue and in our
12 evaluation of PVRP, last year's experience, we had one of the 3 major tasks for Mathematic and Policy
13 Research, our program evaluator, was to look at the potential impact on professionals who treat vulnerable
14 or underserved populations. One of their first threshold questions was to figure out how to define that since
15 there's no real disproportionate share provider definition for physicians, but that led to a larger study that
16 we'll be doing in the evaluation of the actual first year of PQRI. Now in the interim as part of the
17 evaluation that NPR did for 2006, they had a technical expert panel that turned up a number of the kind of
18 questions and concerns that you've had, which has led to us, me personally, following up with Dr. Albert
19 Morris of the National Medical Association and Dr. Gary Puckrein of the National Medical Quality Forum.
20 And we found that they had a number of important and interesting ideas for evaluation along the lines of
21 what you've brought up, so we if you'd like to have further conversations about this off line, I'd be anxious
22 to do that.

23 Dr. Arradondo: Well, actually, I wasn't going there, but after talking with those two people that
24 you just referenced, my specific question is are you going to do a demo at NMA or are you going to do a
25 demo, a pilot or two, or are you going to do a pilot or two who are similar to the people NMA represents? I
26 mean if you just want to bottom line the question, I wasn't necessarily going there.

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1 Dr. Valuck: Oh sure, thank you for giving me a bottom line question. There's no demo that's
2 planned in that direction. What we would expect to do would be to use the experience that we have and use
3 the evaluation to do a lookback and learn in that way.

4 Dr. Senagore: If there are no more comments, we have a recommendation.

5 Dr. Przybalski: The recommendation I have, and then I'll give the 2 rationales. PPAC recommends
6 that CMS annually review the appropriateness of continued use of individual quality measures, through a
7 national proposed rulemaking comment period, in which specialty societies and others, provide additional
8 analyses of peer-reviewed published data, or the absence of such data, that may refute the applicability of
9 the individual measure in specific circumstances. The rationale for that is one, that all of us know that EBM
10 guidelines are a living process and that they need to be revisited with the most recent data and experience
11 and so to assume that because the quality measure exists now that it's still applicable two years from now is
12 not appropriate use of EBM. The example that I would give for that is spinal cord injury, and use of methyl
13 prednisolone, where there was purportedly class I data that supports that and subsequent other randomized
14 control studies as well as analysis of the mathematics and statistics behind it, have led to some societies'
15 recommending that it is class III rather than class I evidence. The second rationale is that the timeline that
16 we've had to develop measures was quite short. It took our society two and a half years to develop
17 guidelines for cervical spinal cord and spinal vertebral injury, and yet, in a matter of months, we were
18 supposed to review the appropriateness of antibiotic prophylaxis and DVT prophylaxis for a set of CPT
19 Codes which was too short a time line. And by having this revisited annually, it gives folks the opportunity
20 to do a careful scientific analysis and make comments about it.

21 Dr. Valuck: Are you interested in my comments at this point, Mr. Chairman?

22 Dr. Senagore: Sure. That'd be fine.

23 Dr. Valuck: Certainly the genesis of your recommendation is well founded. Obviously the agency,
24 the measure developers, the measure adopters, endorsers, that being AQA, NQF, as well as NCQA and the
25 physician consortium, who are the developers, who we would be referring these issues back to for changes
26 in their measures, should be constantly reviewing the new evidence. We've made a significant investment
27 in a measure monitoring tool, called measure manager, that's housed in our Arizona QIO, that actually
28 follows not only the physician setting measures, but all of the measures, many of which we've talked about

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1 related to post-acute care, but also the hospital setting and matches the, follows the evidence-based and
2 raises issues and red flags to us. So we all need to be vigilant. I'd be a little bit cautious about pointing to
3 the rulemaking process as the right place for addressing what could be a potentially urgent issue around the
4 need to make a change relevant to a measure. We found for example, this year, in being required to go
5 through rulemaking for the 2008 measures, that actually we started clearance in April for a rule that's likely
6 to come out in July or August that will be finalized in November. So we've got a year lag time on the
7 process that you're talking about recommending for reviewing measures that is rather laborious and doesn't
8 seem to fit well with the kind of flexibility and nimble change that we need to make in order to have a
9 robust and evolving measure set.

10 Dr. Przyblski: Can I respond?

11 Dr. Senagore: Sure.

12 Dr. Przyblski: There was actually a rationale, it's not meant to be the only way to do this but a
13 way, because I can tell you that there are specialty societies who are frustrated with the current clearing
14 house system and their responsiveness to comments that they get. And so there really needs to be a public
15 alternative way to be able to get this information to CMS so that it is heard.

16 Dr. Valuck: I guess I'd forgotten the nuance in the recommendation already that would make that
17 differentiation.

18 Dr. Senagore: Was that seconded? I'm not sure that, OK. No, I think that is one of the questions
19 for example, my subspecialty society doesn't belong either to the NQF. We're a small society and it's very
20 expensive to play in that, so if the only venue is to send some to NQF and have them look at it over a 6-
21 month period to rescind it, and then not know where the hospital measures are when something's in
22 conflict, I see a lot of potential lack of ability to perform that you may try to do one thing in one arena and
23 hurt yourself in another arena, and you're trying to do a good job based on your own published data even,
24 and you can't do what you've published that works for you. It's a tough place to be, I think, where we're
25 into this individual measure by consensus process.

26 Dr. Valuck: Yes, well, you've certainly hit on one of the difficulties in making measures through a
27 consensus based process, on the other hand we have to consider the alternatives, which would be to either
28 have the government or some other body setting measures for the profession. So my feeling is that the

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1 measure development adoption endorsement process is all something that's maturing. I think we're
2 certainly not to the ideal place where we would all like to be in terms of having a well laid out and well
3 understood, and fully transparent process from everyone's perspective. I would like to make sure though
4 that we don't move away from a couple of things; one is consensus, well first is being professionally
5 driven, second would be consensus, and the third would be maximal flexibility, which we've been arguing
6 for with the Hill to address the various kinds of things that are being brought up here today. So if this
7 routine revisiting of the measures through a rulemaking process would be seen as supporting the consensus
8 approach, it may well fit into the approach that we've taken. If it takes away flexibility to have an evolving,
9 nimble, robust, measure set, I certainly wouldn't be for it. I would also just point out that NQF isn't the
10 only organization that we're able to work with as a consensus based organization, just as the physician
11 consortium isn't the only measure developer, but that's part of maintaining the flexibility and making sure
12 that we're producing measures that fit the need for the program moving forward.

13 Dr. Senagore: Any other comments or questions? I'll call the question on Greg's proposal. All in
14 favor?

15 [Ays]

16 Dr. Senagore: All against? OK. Move on to our last presentation. Thank you, Dr. Valuck. Last
17 issues is the NPI, and as you recall, our next speaker addressed us in the March meeting and is here to
18 provide an update. Ms. Carter has 30 years of experience at CMS, working in Information Technology,
19 both Managed Care and Fee for Service operations, she is currently the Director of the Business
20 Applications Management Group in the Office of Information Services, and she manages the systems used
21 to process Medicare claims as well as the systems that house Medicare beneficiary data. It'll go on the
22 personal health record. Welcome, Ms. Carter.

23 NPI Update

24 Ms. Carter: Thank you. I also have Marlene Biggs with me.

25 Dr. Senagore: Welcome.

26 Ms. Carter: Marlene's been working on all of the systems work and the change requests and all of
27 the implementation of NPI for Fee for Service Medicare. So you all ask me questions, she may have to
28 answer them for me. The outline here, this is just what I'm planning to cover, just a little bit of background

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1 on issuance and use of NPI, some statistics that I'll give you and these should look familiar for those of you
2 who were at the last meeting when I was here in February, I believe it was. Medicare Provider Outreach
3 message and we're going to be stepping up that considerably as we move forward from this week on. What
4 we're calling Control Testing of the Medicare NPI Crosswalk Process, and I'll explain what that means,
5 focus testing with contractors, which is what we're recommending that the providers go forth and do, and
6 we'll talk a little bit about the Medicare Fee for Service NPI Contingency Plan, and some of the issues and
7 questions that were raised at the Fee for Service NPI Roundtable that was held the week before last.

8 CMS began accepting applications for NPIs and issuing NPIs on May 23, 2005, that's very nearly
9 2 years ago. In the Final Rule, we estimated that 2.3 million NPIs would be issued and we now have 2.1
10 million are issued, so if we were right with our estimates, that would be about 91% of what we were
11 assuming what would be issued, so we're in fairly good shape with those statistics. If you look at the chart
12 on the next page, that top line is blank, and I apologize. We do our statistics every week and so at the time I
13 sent this forward, we still did not have the most recent weekly statistics. So I can give you the numbers to
14 fill in there. The total claim volume for the week of 5/11 was 21.3 million claims. Claims with Legacy only
15 is 14 million. Claims with NPI only showed a little bit of increase, we're up to 152,000 and claims with
16 both NPI and Legacy is up to 7 million. The statistic for the overall percentage of claims with NPI, that
17 would include both those with the Legacy number coming in as well, or with NPI only is 33.9 something
18 percent. So 34% rounded. That means that we have gone up 3 percentage points in the last 2 weeks. That's
19 a little bit more of an increase than we have been showing over the last few weeks and I was hoping that
20 that was as a result of the contingency plan that we announced, which said as early as July, we could be
21 requiring NPI on claims, and rejecting any that don't come in with an NPI.

22 The next slide, slide 5, just gives an explanation of the chart on the following page, which is slide
23 6, and this chart also might be familiar from the last time. The most important number on this chart is
24 actually the one at the lower right hand corner, the 12.6%. Which is actually now down to about 12%, I
25 think it's 12.1, and what that says is according to the statistics that we're showing, when you look at all of
26 the Medicare Legacy numbers, and that's all the Oscars and PINs and all the numbers that we use prior to
27 NPI, and we try to match those with NPIs and if you exclude all of the terminated providers, it means that
28 we have not been able to match about 12% of those Legacy numbers. Now if you look at the statistic that

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1 was early on in the slides that showed 91% of all of the NPIs had been issued, those numbers are fairly
2 close together. What we don't know about this 12% is how much of that 12% means that providers don't
3 have their NPI, and how much of that is because we haven't been able to match. And that'll be the
4 important statistic.

5 Dr. Senagore: I'm sorry, just a question on that number. Is that numbers that have been a Medicare
6 claim?

7 Ms. Carter: No, this chart, I'm sorry has nothing to do with claims.

8 Dr. Senagore: So I wondered would that be a test—

9 Ms. Carter: No, the previous chart I showed you that had the statistic, the 34%, that is the number
10 of claims that have come forward in the previous week with an NPI. This statistic is exclusively related to
11 our provider file. It has nothing to do with claims. And what this shows is a separate effort that we have had
12 underway to actually match up Legacy numbers with NPIs. Our process for Medicare involves using the
13 Legacy number to actually do the processing of the claim. So when the NPIs exclusively come in in the
14 future, and even now on some of them, we are going to crosswalk it to the Legacy number.

15 Dr. Senagore: I guess what I'm asking is have these Legacy numbers been used in the last 12
16 months for Medicare claim or are they truly inactive and for one reason or another they haven't gotten
17 around to filing, they're inactive, or withdrawing or whatever.

18 Ms. Carter: When we say that it excludes the one down at the bottom, the critical number the 12%,
19 that is active providers, which according to the instructions that we've given to the contractors, those are
20 supposed to be the providers that have been active in the last 12 months, and that's why there's a difference
21 between the 12% and the 18%. The difference being those providers that have not billed and therefore are
22 either, have been terminated or are not considered to be active. On the next slide, we are talking here about
23 what our outreach message is. We have done an extensive outreach campaign, both for NPI generally
24 speaking for the entire healthcare industry, and also dealing with Medicare specifically, and I'm just
25 reiterating here a few of these points. We have been encouraging providers to ensure that their claims are
26 submitted both electronically and on paper with a valid NPI. And we are still getting many invalid NPIs.
27 We're getting NPIs that are all zeros, we're getting some that are all letters. We're getting some—and those
28 are being rejected upfront, or should be being rejected. Second point, ensuring that all information in the

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1 National Plan and Provider Enumeration System is correct, and specifically the date of birth, the social
2 security number, and the Legacy number that you have been assigned by Medicare, making sure that
3 information is up to date. We've been encouraging providers to look into this enumeration system because
4 you can do that via the web. It does not cost the agency anything. It doesn't presumably cost the providers
5 anything except some effort to go there and look. There's no paper form to fill out. There's no delay. And
6 you can look in there and see what information is shown for you and make sure that all of those data
7 elements are actually correct. What you can't do at this point is look into Medicare's Legacy provider file
8 and determine for sure what information is in there. The Medicare contractors are the only ones that can
9 look in there. But you at least can look into this data base and determine whether or not these pieces of data
10 are actually correct. If you're information is all correct, but you're having problems with a claim's being
11 rejected, then you are going to need to contact your contractor, the one that you submit your claims to and
12 determine whether you really need to submit an 855, which would be to update, the purpose of which
13 would be to update your provider information in Medicare's system.

14 We are working on campaign, this 2 days from now will be the compliance date for NPI, and we
15 are going to be sending out an outreach message on that date, which is going to be sort of the kickoff to an
16 increased outreach campaign, moving away from get your NPI, to actually use your NPI. We're planning to
17 have information in that message as well as following messages that will show you precisely which
18 elements we are looking to match, give providers more specific information than we've done in the past
19 about which data elements need to be exactly correct to match from those 2 systems. So you should be
20 seeing even more messages than you have in the past. On the next slide, we are also recommending that
21 providers work with their trading partners. All of their health plans that you deal with in addition to
22 Medicare, as well as your vendors and your other partners to make sure that everybody is ready to use the
23 NPI and also to use, obviously, your own NPI. We are also going to be doing some outreach to the vendor
24 community, to ensure that they're actually ready to be submitting NPIs. We've heard some anecdotal
25 information about vendors removing NPIs from claims, even though the provider is actually submitting
26 them and of course that's not doing anyone any good. So we are going to be doing some outreach to those
27 communities. You know we don't have any specific legal relationship with them, but we can at least have
28 forums to listen to them and hear what may be their concerns are and see what the state of readiness is

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1 there. The next slide, we talk about controlled testing of the Medicare NPI crosswalk process. We started
2 out using our crosswalk process back last October, but we were concerned about whether or not we were
3 really ready to go live with it 100%, and so since that point in time, any claims that have come in with an
4 NPI only, which you can see by the statistics is still a fairly low number, we are fully utilizing that logic,
5 because we have to. The only number we're getting in is the NPI. Any claims that come in with an NPI
6 plus a Legacy number which up until this point, we have been recommending that providers submit both of
7 those numbers, we are using this controlled process where we're removing, using that logic in a controlled
8 fashion across the country, rather than doing it everywhere all at once. The claims with Legacy only, we're
9 obviously bypassing that logic because the Legacy is the only number that's coming in and we're not doing
10 a crosswalk backwards. We are only doing it from the NPI to the Legacy number. We are not trying to
11 crosswalk the other way. On the next slide, I'm listing the contractors that we have been working with. In
12 this testing process, Signa in the Tennessee and Idaho region, has been doing some detailed reporting for
13 us, and we have what was the date that they were—

14 Ms. Biggs: 5/29?

15 Ms. Carter: OK, next week, I believe it is, that Signa B will be doing, we say extensive testing.
16 What they're really going to be doing is going live, if you will, with the crosswalk process. And their
17 numbers they have been reporting to us over these last couple of months actually, and we're hopeful that
18 that will all work out well. NGS, National Government Services, has been working with us extensively in
19 all of their areas. Indiana and Kentucky on the B side, but we started out with Wisconsin back in February
20 and we now have actually by the end of this month, by the end of May, we will have all of the
21 intermediaries, not just NGS, but everywhere, should be fully utilizing crosswalk logic. And if you look
22 actually at the next slide, that's what it says on slide 11, that based on the results of this controlled testing
23 on the intermediary side, about 1% of the claims are being rejected because we cannot find a match on the
24 crosswalk and so we are expanding that crosswalk use throughout the intermediary community and we're
25 expecting at this point, July 1st, the 4 DME contractors will be using the crosswalk exclusively and
26 throughout the month of July is our current target for all of the carriers to be using the crosswalk logic, and
27 again, we would do that on a phased approach with not every contractor moving forward at the same time,
28 but I'm hoping that throughout the month of July is when we will be doing that full implementation.

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1 The next slide talks about Medicare's contingency plan, which I am assuming that you all have
2 heard about and saw some of the outreach that was associated with that. Back on April 20th, we announced
3 what our plan was, which basically said that through the next year, through May of 2008, we are going to
4 continue to accept these transactions, all of them, both the claim and other claim status, and the 270, 271
5 and other kinds of transactions, with a Legacy number. But that at some point, we are going to require that
6 incoming claims must have an NPI, even though they can still have the Legacy number on them. And we
7 had said that our date could be as soon as July first, that we're going to be looking at our statistics and some
8 other measures and determine what that date is. We're going to be giving everyone notice, both the
9 provider community as well as our contractors on what that date should be. After May 22nd of next year, we
10 will no longer be accepting Legacy numbers, either on things coming inbound to us or on what we produce
11 on the outbound side. Now one critical point on this slide is which fields on the claim must have an NPI, at
12 the point where we determine that all incoming claims must have an NPI, there are 3 fields that are
13 considered primary for this purpose. The billing field, the billing provider, the pay to provider, and the
14 rendering provider. Those are the 3 that will have to have an NPI at the point when we dictate that
15 sometime over the next few months.

16 Dr. Senagore: For consults, when will that field have to be populated?

17 Ms. Carter: You're talking about referring?

18 Dr. Senagore: Mmhmm.

19 Ms. Carter: We at this point are planning on accepting Legacy numbers through 2008, through
20 May of 2008 for those fields. Now at that point in time, though, it's not good to wait until May of 2008,
21 because at that point in time, we are going to require an NPI. However, at this point, we're looking at the
22 primary provider fields and these are 3 that we're actually going to be doing our crosswalks so these are the
23 3 that are important to get in place soon.

24 Dr. Senagore: I'm sure there will be a recommendation about that, but will there be a national
25 clearing house prior to May 2008 for those numbers?

26 Ms. Carter: You mean the data dissemination process?

27 Dr. Senagore: Yes.

28 Ms. Carter: Prior to 2008, I would hope the answer is yes to that.

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1 Dr. Senagore: I'm sure that there'll be somebody that would think about making a
2 recommendation about that. So...

3 Ms. Carter: Right. And as you can guess, I can't really tell—I mean I don't have any further
4 information about that. I know everybody's waiting for it.

5 Dr. Senagore: Dr. Simon will at our next meeting—[laughter]

6 Ms. Carter: Well, you see the folks from that area didn't come to this meeting [laughter]. Maybe at
7 the next one. On the next page, on slide 13, all other providers, we are considering those as secondary
8 providers for this purpose. There are actually 13 you all might know this, but there are 13 I believe on 13
9 places on the claim where the NPI goes. On one of the claims, and 12 on the other. And I forget which is
10 which, on the institutional versus the professional, so all those other ones are considered secondary and
11 Legacy numbers will be acceptable up through May of 2008. And again, once we make a decision then we
12 are going to notify everyone. Our goal, Medicare's goal is really to implement NPI and require NPI on
13 those primary fields as soon as possible. We are not intending at all to wait anywhere near until May of
14 next year. On slide 14, it's just some information about the Roundtable that we just held. We had 4,000
15 participants on that call and we've listed some of the main questions. People seemed very concerned about
16 the paper forms. There seemed to be a lot of confusion about that. Medicare has chosen to treat the paper
17 forms and the electronic forms the same; that is, whatever date we come up with where an NPI will be
18 required on a claim, it'll be required on the paper claim as well, so we are not distinguishing between those.
19 We don't have to do that for HIPAA purposes, but we are requiring that for our purposes. We will begin
20 rejecting the old paper forms this week. Anything that comes in on May 23rd and after on an old paper Part
21 A form, the UB-92 is going to be rejected. Only the new UB-04 will be accepted and there is space on that
22 new form for the old number as well. It's not like you can only submit an NPI on that. You can still use that
23 with Legacy numbers. And on the 1500, we had originally hoped for an earlier date, but because of the
24 snafus on the version, when the new version came out, there were some issues there and some unusable
25 versions of that form were distributed, and so we have moved our date to July 1st, so any forms that come
26 in, the old 1500, after July 1st, we will reject those forms, and we'll keep accepting the old one up until that
27 point in time. In terms of how to start testing, that was one of the major questions that we heard from
28 providers. If I'm going to see how it's going to work, what should I do, how would I test? And we had said

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1 of course to start testing with small claim volume, but one of our new messages, and this is something that
2 you will be seeing in coming weeks, is that the best way to actually test is to submit a small number and
3 you can determine what's small for your own billing situation. A day's worth, one file's worth, you know
4 25 claims, it doesn't really matter, but start with a small volume of claims with NPI only. Where you do not
5 have the Legacy number on the claim. Because if that NPI only comes in, regardless of where we are in
6 terms of our crosswalk testing, regardless of anything, we will have to use the NPI on that claim because
7 that's all that will be available to us. So that will be the best way that you can determine whether or not
8 we've been able to match your specific numbers in our system. So that's what we are advocating and you
9 will be hearing a lot about that message. Up until this point in time, we had been recommending that
10 providers submit both the Legacy and the NPI and that's still OK, that's not a problem, we're not going to
11 reject them, but we would suggest that if you really want to make sure that the data in these two systems
12 are matching, the best way to do that is to just submit the NPI.

13 Dr. Senagore: I may have missed earlier, do you have any data on numbers of rejections when
14 only an NPI was used?

15 Ms. Carter: I don't have anything that's specific to that, and again, the volume of claims is very
16 small. The next question there that was a popular question is what parts of a facility and practice need to be
17 enumerated and I'm not really going to be able to address questions in that area because we don't have
18 enumeration people here, but there seemed to still be, after all of the outreach and all of the information, a
19 lot of questions about using the group versus the individual and things like that and which parts need to be
20 enumerated and which number did they use for which instance. And then finally, the NPI on the remittance
21 advice, when is it going to be used? When will they see the NPI on a remittance advice, and it lists here on
22 this slide, that beginning October 1, 2007, if you submit an NPI on a claim, the NPI is going to be returned
23 on the remittance advice and if both are sent in, only the NPI is actually going to be returned. For DME,
24 that's actually going to happen on July 1st, rather than October 1st. And that has to do with the fact that only
25 one identifier is able to be put on the remittance advice in certain, I think it's the header level of the claim.
26 So that's why we're doing it that way because only one will be available. And this the end of the slides. If
27 people have questions, I would be glad to answer them or Marlene can help answer them.

28 Dr. Senagore: Comments or questions? Dr. Grimm?

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1 Dr. Grimm: I have one question. This question came up because it's a concern of one of my
2 colleagues in my own practice, is that could you explain the issue about timing of applying for this? And
3 I'm specifically referring to residents, other physicians that are coming from one location to our location,
4 now, and when they can apply and what that, my understanding, am I incorrect that they cannot change that
5 data or apply for that data until they physically arrive at that location? Is that true or do you have any idea
6 about this?

7 Ms. Carter: I don't know. That's an enumeration question, and I would guess there's a rule
8 associated with that. I don't know what that is. I mean I would be glad to take a question back and get an
9 answer. The folks that would be able to answer that would be the people that work on the actual data base
10 and deal with enumeration, Jim Bossemyer and Pat Payton and those folks, and they're the ones that could
11 come to talk about data dissemination when we have something further to report. But I mean if you want to
12 give me your card, I can take that specific question back and ask them. I'm sure there's a very specific
13 answer, because we must have a rule that says you can apply as of a certain point, I just don't know what
14 that is.

15 Dr. Grimm: Yes, the issue if you want to take this to your enumeration people, the issue for us is
16 that to get all these things in place, when that person starts on day one, they need to have that number on
17 day one. They can't start the process on day one to get that number. So if I can make a recommendation,
18 Anthony, if that's OK.

19 Dr. Senagore: Dana already handled the form [laughter]

20 Dr. Grimm: PPAC strongly recommends that CMS allow physicians who are relocating to a new
21 area to be allowed to apply for the NPI numbers at least 6 months in advance of that relocation. I think that
22 may address that issue.

23 Ms. Carter: When you say relocating, they didn't have an NPI at—

24 Dr. Grimm: Yes, these would be resident physicians that do not have NPI numbers, or other
25 physicians who are coming from some other program or something, maybe straight out of medical school
26 for that matter.

27 Ms. Carter: OK, because if they had an NPI, I mean if they already had an NPI they don't need to
28 get a new one, they can use the other one. But you're saying in their previous world, they didn't have one.

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1 Dr. Grimm: We're talking about residents, basically. That's the issue.

2 Ms. Carter: OK, again, I'm sure there's an answer and I don't now if you'll like the answer.

3 Whether it's possible to change that, and have it be—

4 Dr. Senagore: The only reason, important in the old days with UPIN, you couldn't actually apply
5 for other commercial verification without a UPIN number, so it became chicken and the egg. If you're
6 starting a practice, now you won't be able to be on any of the plans until January, that's a problem. So I
7 need a second, is that—

8 [Seconds]

9 Dr. Senagore: Call the question. All in favor?

10 [Ays]

11 Dr. Senagore: All against? Motion carries, Dr. Bufalino.

12 Dr. Bufalino: Obviously you don't have control over the other payers, but in light of the fact that
13 you have announced your contingency plan, as you can imagine if the individual players out there are doing
14 their own thing, it's pretty disruptive to the practicing physician community, simple anecdote in Illinois,
15 Blue Cross & Blue Shield said as of Wednesday, it's NPI only, period. United, on the other hand, said by
16 the way we're only taking Legacy until June 18th. I got a headache thinking about [laughter] who's and in
17 which box. So obviously you can't control that, but we'd love to have you encourage you to continue to
18 lead the pack in trying to be a little more compliant about bending the rules.

19 Ms. Carter: Is Tony still here? [laughter] No, I mean I hear that message. I hear the message.

20 Dr. Senagore: Any other comments or questions on this issue? If not we can excuse our guest. Are
21 there any other comments then for the committee?

22 Ms. Carter: Could I ask a question of the folks here?

23 Dr. Senagore: Sure, absolutely.

24 Ms. Carter: I guess, I would like any feedback that you all are willing to share, and I didn't submit
25 this ahead of time and I apologize, but on I heard what you just said about other plans and how they're
26 dealing with this. Are folks having trouble dealing with NPIs? Are you having trouble with vendors? Is
27 everybody in this room already using their NPI?

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1 Dr. Senagore: I had a small DME and I said well I'll give you my NPI number and he said, no,
2 we're really not interested. Do you know your UPIN? [laughter] So they might not know their deadline
3 now, but...

4 Ms. Carter: Any other feed—we're really very interested in hearing from providers directly or
5 from the vendors directly about whether or not you all are experiencing problems, because like I said, at
6 some point fairly soon here, we are going to be sending out a message that says as of some date, Medicare
7 will require the NPI, although we'll allow the Legacy to continue, which hopefully should help with some
8 of those other plans, as long as they can deal with both. Then if they're still not ready—

9 Dr. Senagore: What Dr. Bufalino said, I think, is the biggest problem for our billing offices.
10 They'll be some that want this, some that want that, and different transition dates. So it'll just be a problem
11 for whatever period of time. Dr. Snow?

12 Dr. Snow: [I'm?] still doing paper claims and probably always will be and my vendor's been
13 unable to print the NPI and the Legacy number. We're trying to do one or the other. My hope is that we'll
14 have it by July 1st. We may not.

15 Ms. Carter: OK, well the new form you can still use, Legacy only, you can use NPI only, you can
16 use both, I mean the form accommodates that, but again, if you're using a vendor then they would have to
17 be ready.

18 Dr. Senagore: Any other questions? Great, thank you. Any other comments, questions, from the
19 Council? Then I'll entertain a motion—

20 Dr. Simon: Did Dana get Dr. Grimm's recommendation?

21 Dr. Senagore: Dana got it.

22 Dr. Simon: You got it.

23 Dr. Senagore: And I think we voted. We voted on his? So. I'll take a motion to adjourn. Oh, wait,
24 Dr.—

25 Dr. Arradondo: We down to finishing up—I had one. It was relating to an earlier presentation. I
26 want to make a motion. [chat] I wanted to move that PPAC recommends that CMS partner with the
27 National Medical Association and similar groups that serve underserved populations to conduct
28 pilot/demos among underserved patients (involving providers who traditionally serve the underserved), to

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1 collect information that would enable CMS to adjust VBP and PQRI rules/practices that affect the
2 underserved populations.

3 Dr. Senagore: Second?

4 [Second]

5 Dr. Senagore: Assuming Dana will transcribe it as you suggested.

6 Dr. Arradondo: Could you hear it?

7 Dr. Senagore: Yes, no I did, that's fine. Comments? Call the question, all in favor?

8 [Ays]

9 Dr. Senagore: All against? Motion carries. Any other issues from earlier presentations today.

10 Motion to adjourn.

11 Dr. Simon: That the Panel agree with the recommendations.

12 Dr. Senagore: Yes, we did, yes sir, we did that already. Good to go.

13 Adjourned