

CENTERS FOR MEDICARE AND MEDICAID SERVICES

PRACTICING PHYSICIANS ADVISORY COUNCIL

CMS Single Site Location
Multipurpose Room
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Monday, August 27, 2007
8:30 a.m.

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Public Witnesses

Dr. Jonathan Myles, American College of Pathologists

MS. DANA TREVAS, Rapporteur
Magnificent Publications, Inc.

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1 Open Meeting

2 Dr. Senagore: I'm Anthony Senagore. I'm the Chairperson of the Practicing Physicians Advisory
3 Council. It's my pleasure to welcome you to Baltimore and this is our 61st meeting of the Council. I'd like
4 to extend a cordial welcome to all my colleagues and fellow council members and I appreciate your
5 willingness to adapt your schedules to accommodate this meeting. Once again, we will ask your input,
6 guidance on a variety of issues that you'll see on the agenda today that CMS staff has put together for our
7 consideration. And also would encourage your practical input on many of these issues.

8 As you look at today's issues, we have a number of I think some very interesting topics to review.
9 They include Coverage with Evidence Development, and Update of the Recovery Audit Contractors,
10 Medically Unnecessary Edits, the Physician Proposed Rule, the Outpatient Prospective Payment System,
11 and Ambulatory Surgical Center Proposed Rules, and the results of the 2007 Medicare Contractor Provider
12 Satisfaction Survey and the NPI Data Dissemination Notice, and some of the policies related to that. We'll
13 receive our quarterly PRIT Update as well, and you'll see the responses that were prepared for our prior
14 meeting of May 21st of 2007. Once again, I think we'll try, we have a fairly large agenda, so we'll try to
15 stay on mission as best we can. But I do want to encourage open discussion to explore all of the issues.

16 At this point, I'd like to introduce Mr. Herb Kuhn. Since the fall of 2006, Mr. Kuhn has performed
17 the many demanding duties of the position of Acting Deputy Administrator for the Centers for Medicare
18 and Medicaid Services, and he's joined by Ms. Elizabeth Richter in her new role as Acting Director, Center
19 for Medicare Management. Mr. Kuhn, Ms. Richter, do you have comments for us this morning?

20 Welcome

21 Mr. Kuhn: Good morning, everybody and welcome to Baltimore. I think it's been a year since
22 we've met at our campus here, the Central Office Campus, so we're thrilled that everybody could come
23 back here, and those from Washington could travel up here to spend the day with us. Once again, I just
24 want to say how much we appreciate here at CMS, the work of this committee. I think we acknowledge it
25 every time, but I think everybody understands it's worth acknowledging again that this is the Practicing
26 Physicians Advisory Council and it really does help us a great deal to get information from physicians who
27 are out there practicing to come in and spend, not only four times a year at this meeting, but in the
28 intermediate times to share with us information about not only our programs that we're doing right now,

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1 but also to help us think into the future in terms of issues that are out there. So again, we appreciate the
2 value you all bring to us and appreciate your continued service.

3 I think as you heard, in the introduction here, I think we have another good agenda for today's
4 meeting. I think, as before, we're going to focus on a number of issues as you've heard a NPI, Recovery
5 Audit Contractors, activities that are impacting us right now, and impacting your colleagues and others
6 around the country, for you all to get updates and talk to us about those issues, what you're hearing from
7 your colleagues, or perhaps personal experience with these particular programs right now and what we can
8 do. But also, it's a chance for us, again, to look a little bit into the future as we talk about at least three
9 proposed rules that are out there right now, the Annual Physician Payment Update Rules, the Outpatient
10 Prospective Payment System Rule, and of course the Ambulatory Surgical Center Rule, among other things
11 that are on the agenda, but again, I think what this agenda provides is the nice balance that we've seen over
12 the last several years and we appreciate that.

13 I also would just want to mention that I think everybody understands we're in a bit of a transition
14 here at CMS right now. I think as many of you know, Leslie Norwalk, who was our Acting Administrator,
15 and before that our Deputy Administrator for a number of years, left the agency about the third week of
16 July. And so Leslie's go on to other things right now, but I think as many of you are aware, in the spring,
17 the President nominated Cary Weams to be the new Administrator for the Centers for Medicare and
18 Medicaid Services. Cary has had his confirmation hearing before the Senate Finance Committee, and we're
19 looking forward to getting him confirmed very soon and getting him in place, so that he can take over the
20 mantle of the agency and hopefully be in a position to join this panel in the future, as previous
21 administrators have as well. I know we've talked to him about PPAC. He understands the role that you all
22 play and looks forward to coming to these meetings in the future. So, again, I want to thank you all for
23 taking your time to spend this day with us, and to, some of you because of long travel, had to spend more
24 than a day in terms of getting here and returning home, but again, thanks for your service and look forward
25 to a good day's meeting.

26 Dr. Senagore: Ms. Richter, any comments?

27 Ms. Richter: No.

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1 Dr. Senagore: Thank you. We'll move on then to the PPAC Update. Invite Dr. Kenneth Simon,
2 who is the Executive Director of Practicing Physicians Advisory Council, and medical officer in the Center
3 for Medicare Management to present the response to the May 21st PPAC meeting.

4 PPAC Update

5 Dr. Simon: Thank you, Dr. Senagore. Reflecting on the minutes for the May 21st, 2007 PPAC
6 meeting, Agenda Item C, pertaining to 60C-1, PPAC requests that CMS present timely reports that include
7 assessments of the quality and outcomes of its various demonstration projects. For example, the Gain
8 Sharing Demonstration, the Medicare Healthcare Quality Demonstration, the Physician Hospital
9 Collaborative Demonstration, and the Physician Group Practice Demonstration, specifically as they relate
10 to gains sharing across Medicare Parts A and B. The response: CMS agrees with the Council regarding the
11 importance of reviewing the analysis and outcomes of the various demonstration projects underway by the
12 agency. We recognize this information has the potential to 1) provide greater insight into ways of
13 improving the delivery and quality of healthcare received by Medicare beneficiaries, and 2) create the
14 opportunity to establish new incentives for healthcare providers and institutions that can be financially, that
15 can be rewarding financially. Once a report of a CMS demonstration project is publicly available,
16 individuals are informed of the release on a quarterly basis through the CMS Research Email list. The
17 public may access the reports as soon as they are released on the CMS website. Timely release of the
18 reports is affected by the fact that most of the CMS Demonstration Projects are Congressionally mandated.
19 Evaluation reports on these mandated demonstrations can only be released to the public after the report is
20 formally presented to the Congress. Individuals may subscribe to the CMS Research list and the Email
21 address is posted for the Council members.

22 Agenda Item 60C-2. PPAC recommends that the Secretary of the Department of Health and
23 Human Services, and CMS leadership, make it a priority this year, to work with Congress, to enact
24 legislation that will repeal the Sustainable Growth Rate and replace it with a system that adequately keeps
25 pace with the increase in medical practice cost, and establish a 1.7% update for physicians in 2008, as
26 recommended by the Medicare Payment Advisory Commission. The response: CMS is aware of the
27 concerns expressed by the medical community, regarding the use of the Sustainable Growth Rate

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1 methodology in determining the update for Medicare physician payment. Legislative action, however,
2 would be required to make the types of changes recommended by the Council.

3 Agenda Item 60C-3. PPAC recommends that drugs be removed from the SGR calculation
4 prospectively. The response: Prospective removal of drugs from the SGR calculation is estimated to have
5 no impact for the first eight years of the ten year period, beginning 2008 and ending 2017. In other words,
6 removing drugs from the SGR calculation on a prospective basis would not have any impact on the
7 physician update under the year 2016. The cost of removing drugs from the SGR calculation is currently
8 estimated to represent about 5% of the cost of eliminating the SGR and replacing it with the MEI.
9 Removing drugs from the SGR calculation on a prospective basis would, however, have the affect of
10 increasing the Part B premium paid by beneficiaries in the years 2016 and 2017.

11 Agenda Item D, the Physicians Regulatory Issues Team Update, commonly called the PRIT. 60D-
12 1. PPAC recommends that all Carrier Advisory Committees allow alternate delegates, as well as delegates
13 to attend meetings to facilitate mentoring of alternate delegates, so that they can effectively substitute for
14 delegates who are unable to attend meetings. The response: CMS concurs with the recommendation. The
15 Contractor Medical Directors now allow delegates as well as alternates delegates to attend the Carrier
16 Advisory Committee meetings.

17 Agenda Item E, under the DME Final Rule. 60E-1. PPAC recommends that CMS expand to
18 physicians the exemption from the competitive bidding process for dispensing orthotics that has been
19 proposed for physical and occupational therapists. Response: CMS does not anticipate that many items will
20 meet the definition of off-the-shelf orthotics. In addition, we believe off-the-shelf orthotics are routinely
21 used by occupational therapists or physical therapists as an integral part of their therapeutic services. CMS
22 did not receive any written comments from the medical community on this issue during the comment
23 period prior to the DME Final Rule. We only extended this exemption to occupational therapists or
24 physical therapists, however, we welcome any written comments from the physician community on this
25 issue.

26 60E-2. PPAC recommends that where the Final Rule exempts healthcare providers from
27 competitive bidding requirements for durable medical equipment, prosthetics, orthotics and supplies, that
28 CMS also consider including physicians among those providers who are exempt. The response:

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1 Exemptions have been provided in the Final Rule to allow physicians and treating practitioners to furnish
2 crutches, canes, walkers, folding manual wheelchairs, blood glucose monitors, and infusion pumps as part
3 of their professional service. Physicians who act as commercial suppliers of DME POS as opposed to
4 furnishing items as part of their professional service, are subject to all of the requirements of the Final Rule.

5 60E-3. PPAC recommends that CMS acknowledge that physicians are qualified to supply DME
6 POS by virtue of their education, training, and experience and therefore be deemed accredited for this
7 process. The response: The law did not give CMS the authority to acknowledge physicians as having
8 already met the quality standards and thus be exempt from accreditation. In general, such suppliers shall be
9 required to comply in order to furnish any such item or service for which payment is made and received, or
10 retainer provider, or supplier number used to submit claims for reimbursement for any item or service for
11 which payment may be made under Medicare.

12 Agenda Item F, under Contracting Reform Update. PPAC strongly recommends that CMS allow
13 national participation in the critical phase of the Medicare Administrative Contractor, commonly called the
14 MAC, communication and development meetings. CMS welcomes the participation of physicians and
15 national physician groups within the limits of the procurement process as defined by the Federal
16 Acquisition Regulation. Since the start of the MAC procurement efforts, CMS has held public forums to
17 engage stakeholders, including physicians, in the development of areas, such as contract performance
18 standards. Requests for information have been employed to further gain stakeholder feedback, and inform
19 the procurement process. CMS will continue to engage physicians and physician groups as additional MAC
20 contracts are awarded and lessons are learned.

21 60F-2. PPAC recommends that CMS require a performance rating of 90% or better on the
22 Provider Satisfaction Survey as the standard of performance for MAC contractors. Medicare Contractor
23 Patient Satisfaction Survey survey scores are not percentage based. Rather, the scores are based on an
24 anchored scale, ranging from one to six, in correspondent to how satisfied a provider is with their Medicare
25 contractor, with one being not at all satisfied, and six being completely satisfied. Again, in 2007, CMS is
26 pleased that the scores have shown that providers are satisfied with their contractor. The national average
27 satisfaction score was 4.56, with no contractor scoring below a 4.0 on average. However, CMS agrees that
28 provider satisfaction is a key responsibility of its claim processing contractors. All of the satisfaction scores

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1 are provided to each contractor in detail, so that the contractor may continuously work to improve
2 satisfaction levels. In the future, Medicare Administrative Contractors will, at a minimum, be held to a
3 performance standard, to ensure that their scores do not fall below 1.5 standard deviations from the
4 previous year's national mean score. Further, CMS will be exploring ways to provide incentives to MACs
5 to achieve higher rates of satisfaction.

6 Agenda Item J. Physician Quality Reporting Initiative. 60J-1. PPAC recommends that CMS
7 annually review the appropriateness of continued use of individual quality measures through a Notice of
8 Proposed Rulemaking and comment period, in which specialty societies and others can provide additional
9 analyses of peer-reviewed published data or the absence of such data that may refute the applicability of
10 individual measures and specific circumstances. Response: CMS is constantly monitoring the evidence
11 base to ensure that our measures are consistent with the current clinical evidence. CMS anticipates that it
12 will annually review the appropriateness of the quality measures and other measures used in its value-based
13 purchasing initiatives, with ample opportunity for public comment. Congress required that the measures for
14 2008 Physician Quality Reporting be proposed and finalized on an explicit timetable through the Notice
15 and Comment Rulemaking process. In future years, CMS may use the Notice and Comment Rulemaking
16 process or a more flexible process. For example, the need for timely review may not correspond precisely
17 with the Physician Fee Schedule Rulemaking timetable.

18 Agenda Item M. National Provider Identifier. 60M-1. PPAC recommends that CMS allow
19 physicians, for example, residents, who are relocating to a new area, to apply for an NPI and be enrolled as
20 a Medicare provider at least six months in advance of the anticipated service to Medicare beneficiaries and
21 other patient groups that may require an NPI for physician registration for payment. While we have
22 recognized allowed physicians additional lead time to apply, we believe that allowing physicians more than
23 30 days to apply in advance of the enrollment effective date would limit CMS's ability to verify critical
24 information during the enrollment process. Specifically, Medicare contractors are required to verify state
25 licensure, tax information, practice location, and banking information if the physician will receive direct
26 payments. By establishing an application date that is close to the effective date, we believe that we can help
27 reduce delays in the enrollment process, as well as hold our contractors to the processing standards,
28 establishing the program integrity manual. Moreover, if a physician submits a complete enrollment

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1 application, including state licensure, the National Provider Identifier, tax information, and if applicable,
2 the CMS-588 (the electronic funds transfer authorization agreement) at the time of filing, CMS's Medicare
3 Contractors will be able to process the enrollment application in a timely manner. Finally, CMS expects to
4 implement the Provider Enrollment Chain and Ownership System, commonly called the PECOS on its
5 website, an Internet version of the Medicare enrollment process, in fiscal year 2008. With the
6 implementation of PECOS web, we expect that the processing time to review and process an enrollment
7 application will be significantly reduced.

8 Agenda Item O, Wrap Up Recommendations. 60O-1. PPAC recommends that CMS partner with
9 the National Medical Association and similar groups serving underserved populations to conduct
10 pilot/demonstrations among underserved patients involving providers who traditionally serve the
11 underserved, to collect information that would enable CMS to adjust value-based purchasing and pay for
12 quality reporting initiatives, rules, and practices that affect underserved populations. Response: CMS is
13 working with the NMA and similar groups serving underserved populations to plan the evaluation of our
14 physician- and hospital-value based purchasing initiatives. We will evaluate the impact of our initiatives on
15 underserved populations and their providers, so that we can adjust our program to minimize any unintended
16 consequences related to healthcare disparities.

17 Under Old Business, there were a couple of amendments that were made. From the last meeting,
18 Agenda Item 59D-5, PPAC requests that CMS define the methodology used for data analysis related to
19 performance measure submission under the Pay for Quality Reporting Initiative. The response: CMS has
20 defined the methodology that will be used to determine satisfactory reporting under the 2007 PQRI an
21 eligible professional selects a measure as being applicable to his or her practice, by submitting at least once
22 during a reporting period, a quality code that represents the numerator for that measure. That professional's
23 claims, from the entire reporting period, will then be analyzed to determine whether the 80% threshold was
24 met for that measure. In the analysis, the number of opportunities for reporting, as defined by the presence
25 of the measure denominators, international statistical classification of diseases, commonly called the ICD9,
26 and CPT category 1 code on the claim, is compared with the number of times that the numerator quality
27 codes for that measure were actually reported on the corresponding claim. The analysis is repeated for
28 every measure on which an eligible professional reports. The professional must meet the 80% threshold for

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1 reporting on one, two, or three measures, depending upon the number of measures that are applicable to the
2 patients who were treated during the reporting period. If the professional is reported satisfactory on three
3 measures, then the bonus payment will be calculated accordingly. If the professional is selected and
4 reported satisfactorily on only one or two measures, then a validation will be performed on the claims from
5 the reporting period, to determine whether another measure was applicable to the professional's practice
6 and could have been reported. If there are no other measures applicable to the professional's practice during
7 the reporting period, then the bonus payment will be calculated. If one or more additional measures were
8 applicable to the professional's practice, then no bonus will be paid.

9 Agenda Item 59E-1. PPAC recommends that CMS provide assurance to providers that private
10 information will be secure and that access to National Provider Identifiers be restricted to only those
11 physicians and other entities with legitimate healthcare administration needs. The response: A privacy act
12 statement is part of the NPI application. The statement indicates that healthcare provider data collected by
13 the Department of Health and Human Services from the NPI application, are protected under various laws
14 and that data may be disclosed under specific circumstances to certain entities. HHS will be publishing a
15 notice that will describe the policy by which HHS will disclose healthcare provider data from the National
16 Provider and Plan Enumeration System. The notice is expected to be published soon and of course we will
17 have further comment and discussion on that topic later this afternoon.

18 Agenda Item 59E-2. The final agenda item PPAC recommends that CMS publish the NPI data
19 disclosure notice as soon as possible and allow time for public comment following publication. CMS
20 appreciates PPAC's interest in this important matter for sharing your comments and concerns with us. The
21 Department of Health and Human Services expects the public to notice in the *Federal Register* that will
22 describe our policy with respect to the availability of information from the National Provider and Planner
23 Enumeration System. We expect this notice will be published soon.

24 That concludes the agenda items from the May 21st meeting, as well as the March 7th meeting.

25 Dr. Senagore: Thank you, Dr. Simon. Are there any comments or questions from the committee
26 for Dr. Simon?

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1 Dr. Przyblski: Just one question. At the last meeting, I had asked that we get an update on the PLI
2 issue, and whether any movement between Rick Ensor’s team and PIAA had occurred between the pilot
3 project?

4 Dr. Simon: I think we may hear comments on that later this afternoon, under the Physician
5 Proposed Rule Update.

6 Dr. Przyblski: Thank you.

7 Dr. Senagore: Seeing no questions, we’ll have Dr. Rogers give us the PRIT Update. Dr. Rogers.

8 PRIT Update

9 Dr. Rogers: Thank you, Dr. Senagore. Thanks, Ken. It’s nice to be here giving my 65th report or
10 whatever it is. We’ve been doing this for a long time and you all do great work and we’re lucky to have you
11 here. It’s been actually fairly quiet the last month or two. We don’t have a lot of meetings during the
12 summer time and I think people have been so focused on the Physician Proposed Rule and the ASC Rule
13 that we haven’t gotten an enormous number of issues, but we have been working on the issues that we
14 have, so I’ll go through those issues and then take some questions.

15 These are the issues that we’ve been working on. Actually, two of these issues have been moved
16 to Old Issues, as I go through them, I’ll point those out. That’s the problem with having to submit these
17 slides early because our website does change fairly quickly. We’ve seen much less issues having to do with
18 PQRI. That seems to be working pretty smoothly and we’ve answered I think most of the questions that
19 people have. And Part B has also dropped off a lot. But we have had a big increase in calls about
20 particularly Recovery Audit Contractors. And we’ll talk a little bit about that. This, the RAC audits in
21 California issue, actually has been taken care of and we got a very good contractor, medical director out
22 there, and I think things are going more smoothly, but we do occasionally get calls, but we recently have
23 started working on a problem for a pathologist in another part of the United States who is having a
24 technical issue with the RAC and they’ve made a demand that has been overturned and we’re going to get
25 that straightened out. What we’re finding is that to the extent that we’re able to improve accessibility and
26 communication between the RAC and the providers, we’re facilitating getting these things resolved more
27 quickly and that seems to be an issue and staff in Baltimore who are writing the proposal, the request for
28 proposal, and who are dealing with the rules having to do with RAC are very aware of where the rough

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1 spots are and are being very aggressive about addressing those, because as you know, the RACs are going
2 to be a 50-state initiative, and we want to make sure that things are working smoothly as we move forward
3 and expand the Recovery Auditor Contractors.

4 The next issue, clarifying the rules concerning volunteer GME. There's been a very simple
5 methodology, which is now published. It's not going to require that the volunteer physicians submit
6 complex financial statements or anything like that, and so we're pleased with the outcome of that, and I
7 have to get, it recognizes that these volunteer physicians shouldn't be burdened by a lot of paperwork.
8 What they're trying to do is have a resident with them in their office or in their practice environment, and
9 give the resident valuable clinical experience. And we want to encourage that as much as we can.

10 The issue about can hospital provide continuing medical education? The rule is still under review
11 and hasn't been released yet, having to do with this issue and the question is what limits are there are what
12 hospitals can do to provide CME to their staff, their medical staff. We recognize the hospital's a great place
13 to get CME and a really important place to get CME for a lot of physicians, but of course, we have to be
14 sensitive to the concerns that that CME might become more than just CME and so the rule is going to try
15 and walk the fine line between what's reasonable and what's not reasonable.

16 Simplifying the work of enrollment. This turned out to be far more complex than it should have
17 been the 855 form that's on line is an Adobe form, and the one that we originally had on line, you couldn't
18 save, so if you did half of the 855 form, and then had to go do something and wanted to come back to it,
19 unless you had the full Adobe Suite, you couldn't save it, so all your work was lost. And after several
20 months, we now have a form there that you can, even if you haven't bought the Adobe Acrobat Suite, you
21 can save the form, which is partially completed. Of course, now, as we go forward with having enrollment
22 on line, this will all become unnecessary, and we've very excited about seeing that start. We're doing the
23 beta testing and I think that's going to do great for getting these enrollments completed in a more timely
24 fashion.

25 Active Military Physician ability to bill government payers. This is an issue that we started
26 working on last November, because it affects, or because it's an issue of interest to the Department of
27 Defense, to the Veteran's Administration, to US Public Health Service, to CMS, it's been laborious to get
28 everybody to the table and everybody agreeing on appropriate policy. But we now have a statement of

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1 position from HHS, which is now being reviewed by DOD and VA and Public Health Service and
2 everybody else who's interested in it, so I hope that we're going to have a resolution to this in the next
3 month.

4 Records Retention Requirements. We were asked why we have a number of different requirements
5 for the length of time that records have to be retained, and we looked at this and we have frankly decided
6 it's best we don't go here. The concern is that if we do look at this and make it a real issue, that we might
7 end up with a 10-year requirement in all arenas. So we're going to just leave things the way they are and
8 sorry about the complexity. But there's some lack of consistency across the laws, across the various
9 payment venues that the Medicare Program's involved with. There's inconsistency across the laws about
10 record retention.

11 So anyways, my requisite cartoon. My phone number and email address and we hope that you'll
12 tell your colleagues and friends that if they have issues or concerns to please contact us. Thanks.

13 Dr. Senagore: Any comments or questions?

14 Dr. Snow: Dr. Rogers, you mentioned on that 855 available on line. Can you do half of it on line,
15 save it, and then come back to it later?

16 Dr. Rogers: Yes, you can now. You can now. That was what we got fixed. It used to be that if you
17 tried to save it, it would disappear. But now you can save the partially completed form.

18 Dr. Ross: Dr. Rogers, I don't know if you're aware of this—it's in the back of the book under Tab
19 O, under AUA, and there's a several-page letter from Urology that they're having significant problems with
20 the RACs. Has that brought to your attention and you're working on resolving that?

21 Dr. Rogers: Yes, actually I got a copy of the letter a couple of days ago and we are prepared to
22 assist in that. We have actually a number of different providers in each of the RAC areas that we're
23 working on issues with. And it's primarily just sort of facilitating communication and getting people at the
24 RAC aware of the problem.

25 Dr. Ross: Thank you.

26 Dr. Senagore: Any other comments or questions? Thank you, Dr. Rogers. We'll move onto
27 Coverage with Evidence Development. Dr. RoseMarie Hakim is an epidemiologist in the Office of Clinical
28 Standards and Quality. She maintains primary responsibility for over-arching evidence issues, including the

1 clinical research policy, coverage with evidence development, and post-coverage analysis. Please welcome
2 Dr. Hakim for her presentation and some questions afterwards.

3 Coverage with Evidence Development

4 Dr. Hakim: Hi. Thanks for letting me speak here. Coverage with Evidence is a pretty simple
5 concept when we do a national coverage determination. Sometimes we're going to require patients who are
6 covered to be in some sort of study. This came about a two years ago in proposed form and now it's been
7 finalized in the most recent coverage determination for clinical trials. Anyway, the reason we came up with
8 CED in the beginning—was about four or five years ago—we did that because we wanted to promote
9 innovation and we wanted to cover services that might be still under development but had promise and
10 were safe. We wanted to improve evidence available to patients and providers, and we wanted to target
11 treatments to sub-populations, who may have not received treatment for whatever they have before. We
12 also use CED to inform future changes in coverage.

13 Here's how CED works. First there's an NCD, a request for an NCD and then we do, sometimes
14 we do a technology assessment of whatever item or service is being requested, and then we post a draft
15 decision and then we receive public comments on the NCD, and then we do a final decision. And this is the
16 time it takes to do an NCD. The kind of evidentiary standards we have in [unclear] is we look for, we do a
17 review, and if we find inadequate evidence, then we don't cover an item. However, if it's persuasive, we
18 cover it. And we probably cover it with certain restrictions in terms of patient condition and facilities and
19 providers.

20 If the evidence is promising but not persuasive enough for us to cover it, we may do CED. We
21 would only require CED if otherwise rigorous studies did not evaluate outcomes that are relevant to
22 Medicare beneficiaries. In other words, if we see studies that are very good, but don't convince us because
23 they may not have evaluated older people, or the wrong subgroups, we may see promise, but otherwise we
24 wouldn't cover it. Sometimes, we'll do CED for off-label studies.

25 We'd only do CED if there's evidence of basic safety. Usually the FDA has reviewed the product.
26 Sometimes it's a procedure, and we have to think that the item or service has a high potential to provide
27 significant benefit to Medicare beneficiaries and that for some reason there are significant barriers to
28 conducting clinical research and I can talk about that later.

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1 I'm going to give you some examples that we are currently doing. We're running a registry for
2 cardiac defibrillators, for secondary prevention. Now that NCD was passed in early 2005 and we've been
3 covering defibrillators, as I'm sure you know, for years and years and years, but we passed an NCD where
4 we're covering them for people who had less severe risk factors for cardiac arrest. And to be so, patients
5 had to be entered into a registry. In other words, they will not be covered unless providers enter these
6 patients into a registry run by the American College of Cardiology. And that's been going along for two
7 years and we have two years of data and we'll evaluate that data and probably reopen the NCD to perhaps
8 broaden coverage and not require this registry anymore.

9 The next one was PET for cancer staging and diagnostics. That was, we previously didn't cover
10 PETs for that, because there was not a lot of evidence that for certain cancers, that it did any good.
11 However, we decided to cover it for most cancers, if they were entered into another registry, run by the
12 societies. Now, this one is interesting in that first patients don't get covered for the PET unless they're
13 entered in the registry. Second of all, the societies were really aggressive in getting providers and imaging
14 centers to participate and in order to get into the registry, every provider has to pay \$50 per procedure, per
15 test. However, they won't get paid at all if they don't enter their patients.

16 Finally, we have this one that's been going on long before CED, LVADs, artificial hearts and
17 ventricular assist devices. They've been being entered into the Intermax registry. And the reason we
18 require entry into that, this is one of the barriers we have, is it wasn't a good way to do a clinical trial for
19 artificial hearts. There are very few patients who get them, maybe 20 a year at max, maybe 20 every three
20 years, I don't know. And there wasn't enough people in the world to do a good clinical trial. But there's not
21 a lot of evidence that getting these, particularly for destination therapy, meaning permanent, was doing a
22 person any good in terms of their quality of life. So we're having every patient who receives one of these
23 devices be entered into this registry that's co-funded by the FDA, us, and NHLVI and it's being run by the
24 University of Alabama Medical School.

25 OK, we've also required patients to be entered into some randomized trials, and only patients who
26 are in these trials are getting covered. The first one is cochlear implants. We decided not to cover them for
27 hearing loss between 40% and 60%, because there was no evidence that it provided any benefit for patients.
28 However, so we were requiring a clinical trial, but no one's come along to do one. So as of now, people in

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1 this category are not covered. PET for AD is a little bit different. We had an NCD for that and we did not
2 cover PETs for dementia because there wasn't any evidence that it benefited the patients, the providers, or
3 anybody or the families. However, somebody, we passed an NCD that said patients who could have a PET
4 for dementia if they were entered into a clinical trial. Well, there is a clinical trial now being run by a guy
5 from UCLA and he's getting paid for about 800 PETs to enter people into the study. And it's an interesting
6 study. He's giving everybody a PET, but then half of the PETs are going to be blinded, in other words,
7 they're not going to be read until the end of the study and he's going to see if there's any change in patient
8 management.

9 The last one is home oxygen for sort of a mid-range of oxygen deficits for people with COPD.
10 This one, again, requires a clinical trial because we don't see a lot of benefit. And NHLBI is starting a
11 clinical trial. It will be rather large, so it's going to be an NHLBI-funded study.

12 That's it. If anybody wants to read our guidance document, there is a website, and you can look at
13 any NCDs, including the one NCD on our coverage website. And that's me.

14 Dr. Senagore: Questions?

15 Dr. Williams: Thank you for your presentation, Dr. Hakim. They do, and have been performing
16 many PET scans at the National Institutes of Health, the mental health branch in particular. Do you contact
17 them about some of their programs so that you can also be a part of their clinical trials and maybe find out
18 from them front line what's happening?

19 Dr. Hakim: Well, I don't know if you've ever used ClinicalTrials.gov? But you can get into that
20 website—it's exactly what I said it was. It's being run by the National Library of Medicine, and the guy,
21 Dr. Silverman at UCLA is running this trial, if you just type in UCLA or Silverman, you'll come up with
22 his trial, and it's multi-center and he's still recruiting.

23 Dr. Williams: So that's the only one you found?

24 Dr. Hakim: It's the only person in the world who's come up to ask us for coverage, so we're only
25 covering people in that study. If somebody else designs a clinical trial, we'd be glad to consider—

26 Dr. Williams: Well I'm just wondering if the Mental Health Individuals know about your program
27 here, because as of ten years ago, they were using PET scans long before the popularity now, so it might be
28 worth contacting—

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1 Dr. Hakim: To diagnose dementia?

2 Dr. Williams: To diagnose many different things, dementia as being one of them—

3 Dr. Hakim: Then it shouldn't have been—

4 Dr. William: Might be worthwhile to contact them because maybe they don't know about your
5 program and that's why they haven't asked.

6 Dr. Hakim: I don't know how to spread the word, but I advise everybody in the world now to use
7 this Clinical Trials website. It's meant for providers, it's meant for researchers, and it's meant for patients
8 to look and see what trials are available for their particular condition. And it's pretty easy to use. It's a
9 search site, and you're not connected to the web, are you?

10 Dr. Senagore: Probably goes off the screen...

11 Dr. Bufalino: Question. Could you—thank you for your presentation. Would you mind elaborating
12 a little bit more about the process of how and when a CED applies and who designs the study? Would you
13 take a moment?

14 Dr. Hakim: OK. Well, the whole thing is in flux. For a while we weren't doing any at all, because
15 our lawyers weren't happy about the way we were doing it. But now, it's set in stone. It's a legal procedure.
16 If you would like as a physician to have something covered that you know you're not going to get
17 reimbursed for, but you think that it's worthy, you can call me, or anybody in the coverage center and
18 request an NCD, a national coverage determination. That's if you're not getting it covered at the local level.
19 And you think that it's worthy. So usually we get requests from manufacturers or societies, or we can
20 decide to open one up. For example, we have a big one open for ESAs Epo for cancer. OK, so you think
21 something's valuable, you ask us, and we say to you, as long as we're going to look to oncologists do it, as
22 long as they're associated with a major cancer center. So those would be our conditions of coverage. Or, we
23 might say, well we don't know, but we don't think it's really going to harm the patient, however we think
24 there's potential, and maybe it's an off-label chemotherapy drug and we see the potential for this drug to
25 help people, so we might say, OK, you can try to get funded for a clinical trial, and in that trial, we'll fund
26 you for giving this medication. And that would be a second way of getting covered. Or we might say, well,
27 we're just going to let it lay and if the local contractors decide to cover it, so be it. And the other thing we

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1 could do is say, no, we're not going to cover it because we don't believe that there's any net benefit for
2 patients.

3 Dr. Simon: Just to amplify that comment, Dr. Bufalino, I think that recognizing that since the
4 inception of the program in 1965, initially policy makers thought that local people knew how to make
5 decisions best, and so the local carrier process is the process that was principally and continues to be
6 principally used to cover most services by the Medicare Program, recognizing that over 90% of the services
7 covered by the Medicare Program is through the local carrier process, or the LCD process as we commonly
8 call it. But actually since April of '99, there's been a move afoot to standardize more of the coverage
9 determinations. So in April of '99, the coverage group in the *Federal Register* published a federal notice
10 outlining the process by which anyone, physicians, specialty societies, manufacturers, could submit an
11 application to the agency to seek a national coverage determination on a service product or device that
12 would be in question and of course, Dr. Hakim can comment on it, but once a completed application is
13 submitted to the agency, then the coverage group has as its responsibility to review that application
14 carefully and if the evidence is sufficient, then they usually will proceed expeditiously in making a
15 determination that would enable national coverage for it. If the information turns to be unclear or wanting,
16 they may choose to send it to one of the 12 evidence-based practice centers throughout the US to have the
17 technology assessment on that product, service, or device to determine whether it's worthy of having
18 consideration for coverage. Clearly, of course, so since 1999, the agency has taken a greater stance in
19 looking at nationalizing mainly the coverage determinations because it does provide standardization of
20 coverage across all of the 50 states as well as the District of Columbia. One of the, and that's one benefit
21 for some of the manufacturing industry. They prefer the local carrier process because if the evidence is still
22 experimental or wanting, then they try to find a carrier that may provide coverage and then have it spread
23 throughout the country through that process. So there is actually a dual process by which services are
24 covered and reimbursed by the program, which I think is just important to illuminate that for the Council.

25 Dr. Bufalino: Thank you.

26 Dr. Hakim: And can I just expand on—you opened up a can of worms. There's another policy
27 called The Clinical Trial Policy, which is what you're talking about and in that, we have a formal process.
28 If you as an investigator want your clinical trial covered, and this is outside of CED, it has actually very

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1 little to do with it. There's a process by which we will cover the usual cost of patient care in a clinical trial
2 and if we approve that study. And now that is going to, we hope, be a regulation that will have an
3 application process and it will be sent to us. You don't have to send it to NIH or anything, and we decide
4 whether—we look at the application and we decide whether that clinical trial should be covered. CED—the
5 difference in CED is you have to go through the national coverage process, and you're asking for the actual
6 investigational item to be covered. In the other case, the investigational item will not be covered but the
7 routine services will be. OK, you had a question?

8 Dr. Ouzounian: Yes, I did. I'm a little concerned—I really appreciate the work you're putting into
9 it and that you're looking at this in an objective fashion to try and cover things appropriately, but I wonder
10 if maybe you could get some input from some of the specialty societies. It would seem that if there's only
11 one ENT doctor in the whole country who thinks that something is appropriate, that maybe there might be
12 some issues with is, and if you went to the specialty society they could give you some input as to maybe
13 why nobody else has an interest in it. When there's only one ENT doctor that says this is the right thing to
14 do, maybe it's not the right thing to do. And I think you might want to look to the specialty societies for
15 some input and some recommendations.

16 Dr. Hakim: Well, we do have what we call the MEDCAC, the Medicare Evidence Development
17 Advisory, somebody else knows the name—

18 Dr. Ouzounian: Well, I'm an orthopedist, and there's issues that have come to our table, where
19 there's one orthopedist that goes to CMS and says hey, I want to get paid for this. And we've looked at it
20 repeatedly and said we don't support this—we don't think it's appropriate. Then the orthopedist
21 circumvents the specialty society and goes to CMS and says pay for it.

22 Dr. Hakim: Then we're not going to cover it. If you—

23 Dr. Ouzounian: Well, you might cover it.

24 Dr. Hakim: I doubt it. If there's insufficient evidence, then we're not going to cover it. I don't care
25 who comes. If we see some evidence, we might say OK, you have a clinical trial of 5 people, we'll pay for
26 that. But we're not going to pay outside of that. So generally speaking, if you come to us, we do an
27 incredibly rigorous evaluation. We have these evidence practice centers set up around the country and we
28 have them do evidence analyses and med-analyses and then we ourselves, have stacks and stacks and stacks

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1 and stacks of papers back there on the other side that we look at before we make a decision. So hopefully
2 that solves that problem. But there's—most of our decisions are made on a local level and we don't really
3 have any control over that, unless somebody formally applies to us.

4 Dr. Przyblski: I share Tye's concern but in the opposite direction. If an individual has an axe to
5 grind, and is concerned about a particular procedure or proliferation of a procedure, they can simply write a
6 letter, as I understand it, and have this whole process started of a national coverage decision. And is that a
7 rational way to allow entry into this process? Because I could see you becoming deluged with requests by
8 individuals who have a particular bias and then you really won't get to the meat of things, as we've seen
9 from the Quality Reporting Initiative, it's sometimes very difficult to get measures because there's not a lot
10 of great data that's based in prospective randomized studies, and so I can take about any area of medicine,
11 and request a national coverage decision, which would probably turn out to be negative based on the
12 available evidence. So I'd like your thoughts about allowing an individual to make such a request.

13 Dr. Hakim: OK, so you come to me, and you have an odd kind of thing that you want us to do,
14 before you even did anything, we would talk to you. Sort of like a counselor, and we would say, can you
15 come up with any kind of evidence even before we start the process that could make us think that you were
16 doing something that we would consider, because we can't do millions of these. So if you are adamant,
17 then by law, we have to take your request. However, I said the process takes 60 days. If we don't in a week
18 see that there's any evidence at all, anywhere, we'll just end the process right there. And we'll say no.

19 Dr. Przyblski: I'm actually thinking of the negative side of thing, meaning the bias that I want a
20 negative coverage decision.

21 Dr. Hakim: Right, so you come to us, and you say, I've been giving EPO to patients for years and
22 I think there's a problem and I don't think you should cover it anymore. We'll take that very seriously.
23 And almost, we hardly ever, in fact have we ever, said to something covered, we're not going to cover it
24 anymore. But we are starting to do that. We're doing it with ESAs and we did do it with something else and
25 I can't remember what it was. So we are cutting back on coverage of those drugs.

26 Dr. Simon: When a letter is submitted that as Dr. Przyblski has alluded to, can you articulate on
27 the process that the coverage group would use and the mechanism by which that communication would be
28 forwarded to the public at large?

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1 Dr. Hakim: Is that a question?

2 Dr. Simon: Yes. [laughter]

3 Dr. Hakim: Everything's on our website. If you come, the whole EPO process is published on our
4 website if you're interested in the coverage of website under erythropoietin stimulating agencies, it's under
5 E. We actually have a search data base. And that's been hugely controversial as you well imagine. So
6 whenever you have a concern, and you think that there should be a change, first look at that website,
7 because maybe somebody already did and we already said no. And that would make it really unlikely that if
8 you came back, that we would say yes.

9 Dr. Senagore: I just had a comment. In terms of a lot of the process measures, that are being put
10 out, is the same coverage opportunity exist and just as an example, I saw a paper recently looking at
11 administration of antibiotics within four hours for community acquired pneumonia. And in this one trial, at
12 a very large center, 35% of patients received antibiotics, and it turned out they didn't have pneumonia.

13 Dr. Hakim: Wouldn't that be nice. OK, so we don't, our—

14 Dr. Senagore: Could we request such a study?

15 Dr. Hakim: OK, well you can let's take those scenarios. Well, it's been known for a long time that
16 people are over using antibiotics. Unfortunately coverage and analysis, we don't deal with Part D drugs,
17 we're only Part A and Part B. But let's say I want to study whether children need antibiotics for Otitis
18 Media, which we know the study's already been done, but I want it to be a big study, and I want 6,000
19 pediatricians to participate, but we need coverage. So we'll say because you've asked us for coverage, not
20 an NCD, this sounds like a really good idea and we'll cover you for the costs of the medical services in that
21 trial.

22 Dr. Senagore: I guess, no I'm asking kind of a reverse question is, if you do the study, and we
23 convince you that maybe the four hours is irrational, given certain clinical criteria, that now the negative
24 would not yet, I wouldn't be hurt on my reimbursement or on my quality reporting measure, because this
25 has been proven not to be, under these criteria that the 4 hours does not apply.

26 Dr. Hakim: It's hard for me to answer that. Because it's a Part D drug, I'm trying to—

27 Dr. Senagore: But it's Part A payment though to the hospital right? Because they have their—

28 Dr. Hakim: Or let's say you give a drug in the office, then it's Part B.

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1 Ms. Richter: I think, aren't you asking a question about which quality measures we use for the
2 PQRI Program or in general rather than for a coverage determination really, how the evidence base
3 connects with when we're using quality measures to measure the quality of care?

4 Dr. Senagore: Actually, where I was going with it was tying it back to the same concept, is that
5 does the right hand not follow the left hand in this scenario? If we have a study that says the reverse is true,
6 we put out this process, and it really doesn't work under these constraints, it is not economically efficient,
7 nor is it optimal care, is this a mechanism to also be a way to vet out quality measures, rather than just the
8 NQF process.

9 Dr. Hakim: Can you answer that, Liz?

10 Dr. Simon: I think that information will clearly come to several different venues within the
11 agency. The coverage group would be aware of this information, as other sections of the agency, but I think
12 it would require collaboration between the coverage group and more importantly the quality measurement
13 group that works with a consortium, which includes the National Quality Forum, the AQA and others to
14 assist the agency in developing the quality measures as they work with the medical specialties societies that
15 submit the measures, and so as the clinical evidence changes for reflecting practice pattern changes, then
16 the consortium would receive that information and respond accordingly, and then submit that information
17 back to the quality measurement group in the agency, which is actually a different group than the coverage
18 group.

19 Dr. Senagore: Again to get at it from a financial perspective—this would be a hard study to do at
20 any of our hospitals. If you said, look, I'm going to just say under these criteria we're not going to follow
21 the four-hour rule, and then the hospital's going to say, well, I'm going to take this financial risk for doing
22 it. Could you set up a study that would guarantee compensation for the care of all those patients, even
23 knowing that a percentage of the population's not going to meet the four-hour rule? And thereby would
24 face worse—

25 Dr. Hakim: Yes, as I said, you have to come to us.

26 Dr. Senagore: OK.

27 Dr. Hakim: We don't come to you.

28 Dr. Senagore: No I understand.

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1 Dr. Hakim: We're the government. [laughs]

2 Dr. Senagore: We could come to you and explain that study—that's where I'm trying to get.

3 Dr. Hakim: OK, and let's say you apply for the clinical trial. You can only do this outside of an
4 NCD and you say I want to do a study and it doesn't matter what it is. It could be a Part D, it could be a
5 drug that we don't really deal with in coverage and analysis and you send us your application and we say
6 this looks like a good study. We'll cover your patients in your hospital. This hasn't—OK. This is not
7 occurred yet.

8 Ms. Richter: No.

9 Dr. Hakim: In October, we're hoping that it'll be broadcast to the public. We'll have an official
10 decision that something like this could happen. In general, right now, we're not covering any kind of trial
11 or study that's not being done or paid for by the government. And we're hoping to broaden that in October.
12 So...

13 Ms. Richter: And I think if you'd like to hear a discussion on sort of how the quality measure set
14 expands and contracts and changes over time, Dr. Hakim really isn't the right person to do that.

15 Dr. Hakim: That's right.

16 Ms. Richter: We'd be happy to have someone come to the next meeting to talk about that—

17 Dr. Senagore: No, I know that but since it was a new presentation, I just wanted to, if this was
18 another vehicle to use another potential revenue stream to fund a trial that otherwise would be very difficult
19 to fund. I mean the trial I outline would be a very difficult thing to go to a grant funding agency, or even at
20 your local institution to say we want to do this, because there's so many other specters that could occur.
21 This seemed to be a better vehicle within the agency.

22 Dr. Hakim: This is why we're doing the clinical trial policy. Way back when, when Clinton was
23 President, he passed a memo, he didn't pass anything. It was an executive memo saying we would like
24 more Medicare beneficiaries in trials. And immediately we put out the clinical trial policy, but it was very
25 restrictive and it was only for federal granted investigations, so what we're trying to expand it to is for
26 people like you who want to do a local study in your hospital or in your health center, or in your HMO, so
27 that we know, we need to know about the study. We need to have it put on clinical trials.gov and then we

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1 would examine whether this is a valuable thing, and we'd decide to cover it. And you would not have to go
2 to NIH.

3 Dr. Senagore: Great, because that would be a hard sell.

4 Dr. Hakim: But if you're using an antibiotic and it's already covered, we'll cover it. But if it's
5 something new that we've never seen before, that's when CED might come up as an issue.

6 Dr. Simon: Usually the principle investigators will speak with the [interruption]. The typical
7 process is that the principle investigators will speak with the leadership of the coverage group in order to
8 obtain information regarding assistance with developing the design of the project and the feasibility to
9 provide guidance to let the PIs know whether the project that's proposed would be applicable under the
10 policy, and if so, how to design and empower it so that the agency would be able to gain useful information
11 from it and also determine whether it would be eligible for reimbursement.

12 Dr. Hakim: Yes, that would be on a good day, because we have very limited resources. We have
13 three epidemiologists, which is a kind of a new thing, and we try to work with applicants to design studies,
14 but we don't have time, except in very special cases, to do the design for somebody.

15 Dr. Ross: Dr. Hakim, not getting into specifics on studies or individual studies, but if for instance,
16 there is a means to try to treat a condition for heel pain called Extra Corpal Wave Shock Wave therapy, and
17 this has been proven in the United States, the studies have been done. If you had a study that showed only
18 about a 50% success rate, or thereabouts, where do you come to a certain level of approving under
19 Medicare guidelines something that's only a certain percentage, versus a high percentage of success, which
20 may negate the need for surgical intervention at some time? This is just one example that I'm trying to
21 bring out. But I'm trying to draw attention to certain means of treatment that could be done to avoid
22 surgery in the future, which obviously runs up the costs, but has a good success rate, but may not be 90%
23 success?

24 Dr. Hakim: What you're talking about is what level of evidence do we need? And sometimes 50%
25 is better than 2% improvement.

26 Dr. Ross: Exactly.

27 Dr. Hakim: So that might be good enough for us.

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1 Dr. Senagore: Any other comments or questions? I think we'll take about a 15-minute break here
2 and then we'll reconvene.

3 Break

4 Dr. Senagore: I think we'll go ahead and reconvene. We have a bit of a change in the schedule
5 just to accommodate folks coming into Baltimore. We'll start with the Medically Unnecessary Edits
6 discussion. Our speaker is Ms. Brenda Thew, joined CMS in 1996 and is currently the Director of the
7 Division of Benefit Integrity Management Operations. And prior to her work at CMS, she practiced law
8 with a focus on state regulatory compliance issues for skilled nursing facilities. And she's joined by Ms.
9 Kim Brandt, who will offer comments and participate in the Council's discussion following the MUE
10 presentation. Ms. Brandt is the Director of Program Integrity Group in the Office of Financial
11 Management. Prior to joining the Program Integrity Group, Ms. Brandt worked for five years for the Office
12 of Inspector General on a variety of other challenging jobs I'm sure in the OIG. Ms. Thew to begin?
13 Welcome

14 Dr. Simon: And the only comment I'll make, Dr. Senagore, is that we comment this Medically
15 Unlikely Edits based on the recommendations from PPAC last year.

16 Dr. Senagore: Yes. It was better than unbelievable [laughter].

17 Medically Unlikely Edits

18 Ms. Thew: Good morning. I am new to this project. As you may know, Lisa Zoe left CMS
19 recently and Program Integrity's Acting Deputy Director, Troy Barsky and I are trying to, I won't say
20 replace Lisa, but we're trying to pick up where she left off with this project. So I'm here this morning to
21 give you an overview of the project as a whole and today's status. Medically Unlikely Edits constitutes a
22 national CMS program. The purpose is to reduce the paid claims error rate and we are endeavoring to
23 reduce a variety of errors, especially typographical errors and coding errors. MUEs are implemented at all
24 the claims processing contractors you see listed on the slide. An MUE is an edit based on units of service.
25 We are endeavoring to create an MUE for each HCPCS and CPT code that would be appropriate, and the
26 code is directed at the same beneficiary seeing the same provider on the same date of service. So how do
27 MUEs impact claim adjudication? Each line of a claim is tested against the MUE. If the unit of service on
28 the claim line exceeds the MUE, the claim line is denied at the carrier or the DME MAC facility. At the FI

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1 processor, the claim is returned to the provider with the reason code. Now there are protections in place in
2 the MUE program to ensure that appropriate claims are paid on initial submission. One of the mechanisms
3 CMS is using to ensure that medically reasonable and necessary services are paid up front, meaning
4 without having to go through the appeals process, is the use of the modifiers you see listed here. These
5 modifiers, if used properly, will allow a claim to be adjudicated with the same CPT code on more than one
6 line of a claim. Now this makes more sense to me if I think of it as an example. If we think of say,
7 procedure A that has an MUE of 1, and perhaps the physician performs the procedure A in the morning,
8 and then in the afternoon, it becomes medically reasonable and necessary to perform procedure A again on
9 the same patient, when the physician files this claim, the physician would report procedure A, without a
10 modifier for the morning procedure, and then would again claim procedure A, with modifier 76 for the
11 service performed in the afternoon. So when the claim is adjudicated, each line goes up against the MUE
12 separately, and the entire claim would be paid. I want to go over the criteria that we use for the edits. And
13 this information is included in each of our letters sent to national healthcare organizations who comment on
14 the MUEs. We look at anatomical considerations, for example, the number of eyes. We may use CPT code
15 descriptors, for example, initial service. We rely on CPT instructions where they exist, because some CPT
16 instructions might say for example, report once per day. We look to CMS policies, for example, bilateral
17 indicators. There could be a CMS policy that presumes a service is performed bilaterally. The nature of
18 some procedures and services lend themselves to an MUE, for example, and overnight sleep study, could
19 only be billed one time in a 24-hour period. Similarly, the nature of equipment, might lead us to an MUE,
20 typically only one power wheelchair would be required for one beneficiary on a particular date of service.
21 The nature of an analyte might give us an MUE. For example, if a specimen is a 24-hour sample, the claim
22 would be submitted one time per day. When none of these criteria are appropriate. We do use clinical
23 judgement. And when we use clinical judgement, we seek input from several CMS physicians, coding and
24 medical experts, carrier medical directors, and specialty societies that I'll be talking more about in a
25 moment. Clinical judgment is considered against the backdrop of data. But in the absence of reliable data to
26 the contrary, we do set the MUE on the high side. We err on the side of being too high. Now we have the
27 implementation schedule that we're following. The first MUEs were in place, January 1st, 2007. They're
28 quarterly updates, that follow the same schedule as the National Correct Coding Initiative. Our most recent

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1 update was released this past July and we have a total of almost virtually 5700 CPT HCPCS code MUEs. I
2 must say though if you visited the CMS website on MUEs recently, you will notice that it needs to be
3 updated, and we are working on that.

4 I want to give you an overview of the development process we use. We work with our contractor,
5 CCS, or Correct Coding Solutions. CCS reviews all HCPCS and CPT codes and assigns provisional MUEs.
6 We use the term provisional as a term of art to simply distinguish the MUE that's our initial belief as to
7 what's appropriate. But there are other players in this process as well. We enlist the four CMD work groups
8 you see listed here, and I want to note that there's a special pathologist CMD work group because we
9 believe there are special issues associated with the pathology codes, and CMS determined that it would be
10 advantageous to have a special CMD work group with this area of expertise. The provisional MUEs that
11 are reviewed by CMDs include most of the DME codes, all the MUEs based on clinical judgment, and
12 select groups of HCPCS CPT codes, like radiology and pathology. After we receive input from the CMDs,
13 the provisional MUEs graduate to be proposed MUEs. And that's the way we can distinguish where we are
14 in the process. The proposed MUEs are then reviewed by the groups you see listed here, and I want to note
15 that the AMA graciously offered to assist us by disseminating the proposed MUEs to the National Medical
16 and Surgical Societies and the National Professional Societies that participate in the AMA's CPT and RUC
17 committees. And I also want to note that CMS readily accepted this offer. And we appreciate their help.
18 The hospital interests are represented by the American Hospital Association and the Federation of
19 American Hospitals, and we take their input and then we also look to laboratory and DME organizations.
20 These organizations are listed separately because their interests would not be necessarily represented by the
21 groups that the AMA works with. Now if you will see this slide as a flow chart of the development process.
22 CCS sends the proposed MUE files to the commenters that we listed, that I listed, for a 60-day comment
23 period. When comments are received that provide alternative recommendations and a rationale for those
24 recommendations, we consider them, and CCS does provide a response to all comments received. At this
25 point, there's a collaborative effort between the contractor and CMS, to determine a final MUE. After the
26 decision is made, feedback is given to the national healthcare organizations that commented on the
27 proposed MUE and that feedback includes rationale that we used in setting the MUE, if it's set in a way
28 that's different from the comment we received. The expected outcomes go back to the purpose of this very

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1 project. We are endeavoring to reduce the paid claims errors rate and promote correct coding, and from
2 examples we've received from physicians, it appears we are succeeding. I want to stress that MUEs are set
3 to ensure payment of medically reasonable and necessary services. Some values are absolute. Like initial
4 service. But the MUE value does allow the vast majority of claims to be paid, where reasonable, medically
5 reasonable and necessary services exceed the MUE, the modifiers that I spoke about a moment ago, serve
6 as a mechanism to allow claims to be paid. We expect the use of modifiers however to only happen in
7 unusual cases. And of course, as a last resort, appeals are possible at the carrier and DMAC.

8 There are some other issues that are of general interest. One is the confidential nature of MUEs.
9 And I want to let you know that we have just begun to solicit input from stakeholders and other interested
10 parties regarding whether we should change our stance on this and disclose the MUEs. I believe the CMDs
11 were asked last week for their opinions and I expect a letter to be coming out in the immediate future,
12 hopefully this week, to the national healthcare organizations, asking for an opinion and a rationale on the
13 opinion as to whether we should release them. We will also be soliciting input from interested areas within
14 CMS and we're going to turn to our program safeguard contractors for input. We're trying to get a
15 complete and balanced perspective from everyone's perspective on our decision. FOIA requests are
16 something that we're asked about frequently. Any FOIA request that comes to the contractor is sent to
17 CMS's FOIA office here in Baltimore. I want you to know that we do have a mechanism to adjust our
18 MUEs and if you believe that an MUE needs to be adjusted, you can contact the Correct Coding
19 Solutions—the information for reaching them appears at the end of this presentation. And finally, local
20 edits and clinically unlikely edits are an area of interest. Contractors of course, claims processing
21 contractors, can have their own local edits. The rule that we follow is that if a local edit is more restrictive
22 than the MUE, the local edit applies. So the most restrictive edit is what we look for. This slide will show
23 you some differences and similarities between CUEs and MUEs. They do differ in scope. MUEs are
24 national, while CUEs are local. They share the purpose to reduce the claims error rate, but CUEs are
25 focused on preventing fraud, waste, and abuse. Both MUEs and CUEs are based on units of service. Both
26 address any HCPCS and CPT code for the same beneficiary and the same provider, but if you notice, the
27 last bullet does not show an asterisk. That's because the date of service is a little different. CUEs will look
28 at a data of service, but may look at dates of service across time. And a good way to understand this is to

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1 look at the infusion codes, the J codes that we've performed, we've prepared CUEs for. We found that
2 some unscrupulous providers were submitting claims for a unit of service of infusion and a drug for the
3 same beneficiary, obviously it was the same provider, everyday for a week, a month, maybe several times a
4 day, and the level of medication that would be given, and I understand the level of fluid that would have
5 been given would have been toxic and impossible for the human body to take in. So we're looking at the
6 unit of service, but if it's repeated multiple times in a very short period of time, we would consider that a
7 clinically unlikely edit. CUEs were developed in the combined effort of our claims processing contractors,
8 the affiliated contractors, carriers, and FIs, and our MACs. The program safeguard contractors and CMS's
9 central office, regional offices, and field offices. Like MUEs, they are implemented at all our claims
10 processing contractors. They are, CUEs are different from MUEs in that they may look at the frequency of
11 services over time, as I just described. They can be beneficiary based, especially if we know beneficiary
12 numbers have been compromised. They can be provider or specialty-based and they may actually look at
13 dollar thresholds because that may be a way for us to find potential fraud or abuse. If you have any
14 comments about the edits, or any questions you want to ask our contractor for this project, please feel free
15 to reach out to Correct Coding Solutions at this address and phone number. And if you have general
16 comments about the project itself, please feel free to contact Ms. Valerie Allen. She's on my staff and
17 perhaps gratuitously, she began her vacation today [laughter], so if you do send in a question, please give
18 Ms. Allen a week or two to respond.

19 Dr. Senagore: Any questions?

20 Dr. Sprang: Just a comment. You did say you were considering making them public or not, and so
21 I just kind of taking the position from PPAC, we'd actually make a recommendation that PPAC
22 recommends that CMS make the MUEs available to the public. Just seems more transparency, more
23 openness of providers and patients and everybody kind of know what's going on, it'll even serve a better
24 purpose. Clearly we support Medicare's attempt to decrease errors and always obviously decrease fraud. So
25 specifically, the recommendation, PPAC recommends that CMS make the MUEs available to the public.

26 Ms. Thew: Thank you.

27 Dr. Senagore: Support?

28 [Second]

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1 Dr. Senagore: Any comments, discussion? All in favor?

2 [Ays]

3 Dr. Senagore: All against? Motion passes.

4 Dr. Sprang: Thank you.

5 Dr. Senagore: Any other comments about the process?

6 Dr. Przyblski: My original understanding of MUEs was that there was a heavy anatomical basis,
7 meaning you only have so many limbs, so only so many procedures on limbs, etc. When we look at the
8 spine in particular, where you have many dozens of vertebrae if you will, in our recent interactions with
9 CCS, there's been a different tack that's been taken, meaning rather than looking at anatomically what's
10 possible, what is medically typical or what is the range of typical that may be less than what's anatomically
11 possible. So if you could comment on what truly is the intent of MUE.

12 Ms. Thew: Well we are endeavoring to make sure that claims that are necessary, medically
13 necessary and reasonable are paid. So appropriate claims are paid. At the same time, we're trying to reduce
14 errors. And if you noticed earlier, unfortunately, I'm an attorney not a clinician. So you're asking me
15 questions about anatomy without that background from my perspective [laughter]. I would however like to
16 try and get an answer for your question and I would like to take it back to our CMS physicians.

17 Ms. Brandt: And I think I can speak a little bit to that. To begin with, we did start with the
18 anatomical edits, largely because we perhaps erroneously, and naively thought that that would be an easier
19 place to start because we thought well there is a finite number of limbs that most people have, and things
20 like that. And so once we realized that our original intent was perhaps not going to work from a clinical
21 perspective, we have expanded it, but I do think it would be good for Brenda to come back with sort of
22 what the current thinking of the team. But you are right, we did have a shift from that original anatomical.
23 And that was in large part based on feedback from physicians like yourselves and from the associations that
24 we interact with. And it's been a good education process for us in that regard.

25 Dr. Przyblski: Thank you.

26 Dr. Senagore: Any other questions or comments? Very good. Thank you for coming.

27 Ms. Brandt: Thank you.

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1 Dr. Senagore: Now we'll move on to the Recovery Audit Contractor Program Update. We are
2 joined by several speakers today. Dr. Earl Berman, currently the RAC Contractor Medical Director at PRG-
3 Shultz. Dr. Earl Berman is an internist and specialist [interruption]. Yes, sir. Dr. James J. Lee is certified by
4 the American Board of Osteopathic Emergency Medicine, serves on the board of medical directors at
5 Connelly Healthcare Recovery Audit Experts, and additionally, we are joined once again by Connie
6 Leonard, Project Office for the six Recovery Auditors, and Melanie Combs, who is tasked with assisting in
7 the national implementation of the RAC Program. You are asked to consider the following questions as our
8 speakers update us on the RAC demonstration. First, do we have any suggestions for CMS about RAC
9 identified vulnerabilities and improper payment strategies, i.e., best methods to communicate these
10 vulnerabilities to individual providers? And do you have any questions about the RAC expansion plans?
11 And then we'll be open to any other open questions from the committee. Welcome all.

RAC Update

13 Ms. Leonard: Well, thank you. Thank you for having us here again today. I am Connie Leonard. I
14 am the CMS RAC project officer. I have been since the beginning, so I've learned a lot throughout the
15 demonstration. Today, we want to talk about those findings. What we're finding, not only in terms of
16 vulnerabilities, but in terms of learning about physicians and how they interact with CMS and the total
17 overpayment process and how we can improve upon that, and then also update the Council on the RAC
18 expansion. We do just list the questions again. I would almost expand that first one, not only to how we can
19 communicate the vulnerabilities we identify to individual providers, but you know how can we improve
20 that total overall overpayment process for physicians. Early on, we tried to keep it the same as what was
21 used in the carrier world, and were starting to think that maybe we need to update that. You know, maybe
22 that was antiquated and we need to update it to more individual process for these providers. And then two,
23 any questions you may have about the CMS RAC expansion plan. We list the website again, just for your
24 own knowledge. We do try to update it and keep it with the links necessary to any of CMS status reports.
25 The legislation, as you know, the most recent is the Tax Relief and Healthcare Act of 2006, Section 302,
26 and it's kind of where we're heading now to go towards nationwide RACs.

27 Ms. Combs: I'll talk a little bit about the RAC legislation, RAC tasks. Let me talk a little bit about
28 the RAC tasks. The tasks of the RAC are primarily detecting Medicare improper payments and correcting

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1 them. And by correcting, we mean if they find an overpayment, they need to collect that back. And if they
2 find an underpayment, they need to make payment to the provider. The names of the RACs are Connelly
3 Consulting in New York, Health Data Insights or HDI in Florida, and PRG Schultz in California. The RAC
4 look back period means how far back can the RACs look when they are crunching through all that claims
5 data, the paid claims, and trying to identify the overpayments and the underpayments. And the RAC
6 demonstration says that they can look back just as far as carriers and FIs can, that is four years. We have
7 had some glitches in the system. We have had a couple of situations where a RAC's computer system
8 didn't adhere to that and they actually looked back further than that, and when they identify those
9 problems, they notify the provider and they make it right. If they collected an overpayment from that
10 provider, they pay the money back. If they catch it in the midstream, in the process, they undo that demand
11 letter before it goes out. The permanent RACs will only be able to look back 3 years. This demonstration
12 ends in March of 2008, or that's when it's anticipated to end. You'll be hearing more details about that
13 from Connie in just a few minutes. And we are beginning to plan how it is that we want these permanent
14 RACs to operate differently from the demonstration RACs. This is a lesson learned for us. This four-year
15 look back period, and so we're changing it in the permanent RAC Program so that the RACs can only look
16 back three years, so that we will no longer have that problem with the RACs looking back further than they
17 are supposed to.

18 The RAC review process is something that I'm going to talk about over the next couple of slides.
19 The RACs never do prepayment review and they never do random review. They only do post-payment
20 review. They're only looking at claims that have already been paid, and they are focused on problem areas.
21 They don't do random review. They try to target in on the claims that are most likely to contain improper
22 payments. And they will not until March of 2008 or later, conduct evaluation and management reviews for
23 level of coding. They certainly can look at E&M codes if it's a violation of the global surgical window, or a
24 duplicate claim or anything like that, but in terms of level of coding, we decided to take that off the table
25 during the demonstration, and that would not be available for RAC review until March 2008 or later. In
26 addition, just for administrative simplification purposes, we chose to leave hospice and home health claims
27 off. Those claims are processed by regional home health administrators. It was a little bit harder to pull
28 those claims and get them to the RACs, so we decided just to leave that off until March 2008 or later. The

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1 RAC review process is very similar to the process used by carriers and FIs to identify improper payments.
2 The RACs use the same Medicare policies as the regular contractors. They use the same types of staff.
3 They use nurses and physical therapists and coders. They also perform the same kinds of review that the
4 carriers and FIs and MACs do, that is automated review, where the computer system can identify the
5 improper payment without having to request a medical record, and complex review, where the RAC has to
6 write to the doctor or the provider and say, please send me a copy of that medical record so I can compare
7 the medical record to the claim and see if I can identify an overpayment or an underpayment.

8 Let me just add one thing before I get into the dollars that have been identified by the RACs.
9 About the process in general, the review process. And that is, there have been some improvements that we
10 have identified during the demonstration that have needed to be made and many of those improvements
11 that we making to the process are because of folks like you. And the folks that participate in the PRIT and
12 general physicians out there that work through their specialty society to let us know where changes need to
13 be made to the program. One example has been the demand letter process. We heard from providers that
14 the demand letters were not very clear about why the overpayment was being made in some cases, and so
15 we've worked with our RACs to try to add more detail to those demand letters so that physicians and other
16 providers understand what it is that the RAC's found, what it is that was done wrong on that claim and
17 what can be done in the future to prevent those kinds of improper payments. We welcome the feedback that
18 we've gotten from physicians and other providers. We have a very close working relationship with the
19 AMA and I think I must be on Bill Rogers' speed dial, because he continuously, as soon as hears about an
20 issue, a potential problem in the RAC world, he lets me know right away, so thank you all very much for
21 all of your ideas about how we can improve the program.

22 This slide is a summary. I think you've seen it before in presentations that we've given over the
23 last year or so, summarizing what the RACs found in fiscal year '06. They collected \$68 million in
24 overpayments, and they paid back \$2.9 million in underpayments. That split of overpayments to
25 underpayments is somewhat to be expected. We generally speaking, and I random review, that's done by
26 the CERT program, the Comprehensive Error Rate Testing Program, that chooses a random sample of
27 claims, they find about a 90% overpayment rate compared to about a 10% underpayment rate. This is a
28 little bit lower. We do anticipate that we'll be watching this number and see what happens as the years

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1 unfold with the RACs. The RAC program in fiscal year '06 cost \$14.5 million, so the program returned to
2 the trust fund \$54.1 million. You'll be hearing a little bit more from Dr. Berman in just a minute about sort
3 of what the implication of returning that money to the trust fund really means.

4 This is a break down of where the improper payments occurred and as you can see, about 77% of
5 them came from inpatient hospitals, only about 6% came from physician, ambulance and lab. The next
6 series of slides really talks about some of the things that the RACs found. And I think it's really important
7 for you to understand that the RAC program does not stop with identifying the overpayment or the
8 underpayment. It goes on to include trying to prevent those improper payments from happening again in the
9 future. We at CMS are very busy looking at the data, looking at the statistics, where are these problems
10 occurring and what can we do to fix those problems in the future? Do I need to be talking to the speakers
11 who were just up here a minute ago? Do we need some medically unbelievable edits put in place? Do I
12 need to be talking to the carriers and FIs? Are there new local coverage determinations that they need to put
13 in place or maybe a place where their current LCD is unclear or needs to be clarified. Or maybe there's
14 more provider education that needs to be done either at the national level or at the local level. So the next
15 couple of slides are going to share with you two or three of the findings that the RACs came up with this
16 past year that are specific to physician claims. The first one is vestibular function tests. This is a \$7 million
17 problem in fiscal year '06 located in California. This is a medical necessity problem where the local
18 coverage determination says that these services rarely needed more than once a day, and yet the providers
19 billed for many a day. The kinds of things that we're thinking about implementing to correct this problem
20 and prevent it from happening in the future are to encourage more carriers to develop LCDs, not just the
21 one in California, but other contractors as well, and encouraging all of our carriers to educate the physician
22 community about the LCDs that they've put in place. We are evaluating the feasibility of some local edits
23 that could be put in place that would try to catch these payments before they get made and nurse review is
24 something that would not be appropriate for these. These are things that we believe could be caught
25 through automated review. The next slide talks about what CPT assistant said on this particular topic. And
26 they said in May of 2004, that the use of this code should occur only once per date of service. And the next
27 slide, I believe has some comments from the AMA which again point out that these codes should only be
28 reported once per date of service. The next slide talks about another problem. This was found in the state of

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1 Florida, and this has to do with multiple surgeries. That is where the surgeon is going is going in during one
2 operative session and performing several different procedures and the coding rules say, or the payment
3 rules say, that the physician gets paid 100% for the first surgery, and then a reduced amount for the second
4 surgery or the third surgery. And those payment reductions did not occur on the second or the third surgery
5 in a few cases. Most of the time, the payment rule works fine. But in some cases, the payment rule was not
6 working properly. When we looked at these claims and tried to figure out what the pattern was, the only
7 thing that we could find was that in a fairly large proportion of them, these were situation where the
8 physician was billing using multiple claims. The first claim was for surgery number one. A second claim
9 came in for the second procedure that was done, and a third claim came in for the third procedure that was
10 done. And because those multiple, surgeries came in on multiple claims, they didn't always bump up
11 against our claims payment edits. The RACs found this problem, and like I said, to the tune of \$1.2 million
12 got those overpayments back and returned the money to the trust fund. Things that we think that we can do
13 to prevent this problem in the future, would be to encourage the carriers to make sure that they have the
14 processes in place to implement the payment rules, even across multiple claims and to try to alert the
15 contractors in the future as soon as we find out about these problems, where evaluating whether or not we
16 can put in place an auto-deny edit across the board, nationally at the system level, and we're certainly
17 asking the carrier to think about prepayment review might be necessary if they find a particular provider
18 who always bills using multiple claims for these kinds of services and they can't get their computer system
19 set up just right, they may need to do some type of prepayment review.

20 The last issue that I want to talk about today, specific issue, has to do with excessive units. This
21 would be when for example, the physician is billing for 15 minutes of physical therapy, when the medical
22 record says that 45 minutes was done, or billing for six units of nulasto when only one unit of nulasto was
23 given. These situations added up to about \$420,000 in the State of Florida. This is clearly an incorrect
24 coding issue and we think that we can do things like issuing MedLearn Matters articles and encouraging the
25 carriers to educate the physician about the coding rules. If it's possible to put in play auto-deny edits again,
26 as MUEs or CUEs or any other type of automated edit, we will do that as appropriate and medical record
27 review is not needed in these cases.

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1 Ms. Leonard: So that leaves CMS going from 3 states to 50 states, and legislation section 302, did
2 say we need to do it by January of 2010. Luckily, we do have some time, and we don't have to go right
3 away, so we're going to be able to do that gradually, and we have planned a two-step RAC expansion
4 process. Really, step 2 probably has lots of baby steps, too. The first step we've actually completed 75% of
5 already. What we did was we added one new state to each of the current states. So for example, in New
6 York, we added Massachusetts. And in Florida, we added South Carolina. And we also added any Mutual
7 of Omaha claims that might be for providers in those states. And we have already reached out to the South
8 Carolina Hospital Association and the Massachusetts Hospital Association already had on-site meetings in
9 South Carolina, and some conference calls with providers in Massachusetts. And the data has already
10 started flowing to the new RAC or to HDI and Connelly for those new states. In Arizona, we have not
11 reached out, or we have reached out to the Hospital Association but we have not held a meeting yet because
12 CMS actually has to do some administrative contract modifications to the Medicare Administrative
13 Contractor, and so they're a little bit behind because of some of the administrative tasks CMS has to do, but
14 it is on the schedule for September. Only hospitals were affected right now in those new states. So this is
15 really just informational knowledge for the Council. Physicians will not be affected and we do not believe
16 they will be affected before the end of the demonstration. We have August 1st up there, as far as RACs
17 beginning issuing medical record requests. There have not been any that have been released in South
18 Carolina or in Massachusetts yet. We're probably another couple of weeks away before those first letters do
19 go out the door, but as I said, we're in close communication with the hospital associations in both of those
20 states, and even on some of our state medical association calls, Massachusetts and South Carolina have
21 kind of already been brought into the fold, just for information. Again, those physicians aren't going to be
22 affected yet, but we wanted them to get the background and then start learning about the RAC program.
23 The other thing that's kind of simultaneously going on is CMS is holding a full and open competition to
24 hire four RACs. We're going to have one for each region. These are the same regions as the DME MACs,
25 so everyone should be somewhat familiar with them. And in mid-August we released our solicitation notice
26 for the full and open competition. And near the end of the month, we will be actually be releasing the final
27 request for proposals, and we expect to be reviewing those sometime this fall with an award sometime
28 around the calendar year, give or take a couple of weeks or so. CMS's goal is to have the made the awards

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1 for the new RACs by the time the demonstration ends. Because while we do want to gradually go into the
2 regions and new states, we don't have to have a period of time where we don't have a RAC at least in some
3 area. We want to keep progressing with our preventer outreach that we've already started and keep going
4 on, you know, adding on new hospital associations, new specialty associations, so we can get in the fold,
5 too, with monthly or quarterly calls, so that we can hear the feedback from the provider communities as we
6 start going into these you know, new specialties that maybe haven't heard from the RAC, and I think that's
7 going to be very important in for example, home health, who know about the RAC, but you know, we're
8 not on their radar screen right now because they haven't been hearing from the RACs, so we're really going
9 to have to reach out to them and make sure they're up to speed, same thing in all these other states.

10 That kind of is time line there. In March of '08, we do expect to have our new RACs awarded.
11 Will they begin issuing letters to providers? Well you know I doubt it in March of '08. there's a lot of
12 administrative issues they need to do. They need to get data from CMS. That's probably the biggest thing.
13 They need to analyze it. They need to do their provider outreach and CMS is having a very clear transition
14 plan which we will keep the council updated with as far as going into new provider types. We're going to
15 start with hospital inpatient outpatient coding, DRG validation issues, and then move over into inpatient
16 rehab facilities, SNFs, going into physicians and DME suppliers kind of at the end, as well as medical
17 necessity issues. We want to make sure we have a staggered approach so that we can fix any issues, keep
18 them small, and that we don't have something going on in every single provider type. For example, the
19 demand letter issue; we want to make sure that's fixed before we go nationwide. We want to make sure
20 providers can understand the contents of why that overpayment was created, and so they can then go back
21 and if they need to, they can do their own quality assurance in their own physical location so they can
22 prevent that from happening in the future. Because that is CMS's goal with this RAC program; it's to pay
23 that claim right the first time. And we're trying to move toward that. I know Melanie's I think full time job,
24 as well as everything else we give her is trying to get to that point; how do we correct those issues? How do
25 we identify those vulnerabilities? How do we share that with physicians so that we can get that claim
26 coming in the first time? What edits do we need in the system? And it's a lot of communication with the
27 associations, with other components of CMS to try to fix those issues so we can pay that claim right the
28 first time.

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1 The key points in with the expansion is that hospitals will start in these new states; Massachusetts
2 and South Carolina for now, will start to see the RAC presence in August and September. As I said, we
3 already did some on-site meetings and conference calls, that they know who to contact if they have
4 questions. So far, it's been going quite well. One of the biggest points we've learned in the demonstration is
5 that a point of contact for providers helps with the communication issues. A lot of times, fiscal
6 intermediaries and carriers don't have correct addresses. Providers receive their payments electronically
7 these days, there's necessarily no need to update that address if they move. And we do have some RACs
8 that are going to a web-based system which works really well for providers to update that contact. The
9 hospital associations have been very helpful in the Part A side, and we're trying to get the medical
10 associations on board from the state, local medical societies, to get that information on the Part B side. Who
11 do physicians want that letter to come to? Is it the billing manager? Is there a billing company out there
12 they use? Should it be going there? Do they have a medical record company that they use? Exactly who
13 should get that letter so that they can determine why and what medical record is necessary to what provider,
14 why that overpayment was determined, what is the LMRP, what is the LCD? What information do they
15 need? We want to make sure that's all at the physician's hands and at the right person's hands. And having
16 a point of contact has worked very, very well in some states. And the RACs use the same policies are
17 Medicare contractors and they should be having the same interpretations. And we have had some issues.
18 We worked those through with the associations, with the RACs, with the FIs, with the carriers. And you
19 know, we can have these open discussions that I think are very important to helping the RAC Program
20 move forward and I know, as Melanie said, we value all input. You know, we put our phone numbers and
21 email addresses out there. We hear from physicians, we talk to them, we talk to the associations, we want to
22 hear how to improve the process. We understand physicians don't like to be audited. No one does. But for
23 the most part, they're willing to work with CMS. We certainly appreciate that and they're willing to offer
24 us their feedback about how to correct the process. We all are trying to reach the same goal and the
25 physicians are the ones who can help CMS improve that process.

26 Ms. Combs: Connie has to run to another meeting. The RAC project keeps us very busy, and so
27 she and I are used to sort of dividing and conquering sometimes. But this is a good segue. Because the next
28 slide talks about the introduction of new contractor medical directors to the RAC program. Before I go any

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1 further, let me just ask, is Dr. Lee or Dr. Green in the room? No. We have put in a requirement for the
2 permanent RACs to all have a full time contractor medical director on board. So that will start sometime in
3 March of '08. Even though it was not a requirement for our current RACs, under the demonstration
4 program, all three of them have decided that they need to have some MD leadership and have hired some
5 folks that we think are going to bring some wonderful experience to the program. One of those, Dr. Earl
6 Berman, the medical director for PRG Schultz, is here with us today. And I've asked him to share from his
7 perspective a little bit about what a CMD can bring to the RAC Program. Dr. Berman?

8 Dr. Berman: So I see I have 30 second to give my presentation, so I'll indulge the chair and the
9 physicians of the PPAC to let me go a little bit over.

10 Dr. Senagore: No problem.

11 Dr. Berman: First of all, it's a privilege to be here. As a background, I'm a general internist with a
12 subspecialty in sports medicine. I practice in small towns majority of my practice life. Eight years of which
13 in Milardsville, Georgia, which is a town of 20,000. Where I did critical care, general internal medicine, a
14 five-county sports medicine clinic, and at all times was very involved in utilization management, utilization
15 review, trying to make sure that physicians, including myself, documented what we did and got paid for
16 what we did, instead of trying to somehow finagle the system to do things improperly. So the beginning of
17 the RAC Program, to me is a fascinating process and a fascinating program. Ken knows me from a Part B
18 medical carrier. I was the Georgia Part B Medical Director for five years with Kahava GBA, and in that
19 position, I was involved with CCI. I was one of the reviewers of the first phase of the MUE with Niles
20 Rosen, that you all heard about a few moments ago. I was on the fall prevention work group, trying to
21 prevent a lot of liability and exposure in the Medicare Program to a common problem that's very expensive
22 to the elderly population. I was on New Tech Workgroup, so I bring a pretty good background into the
23 RAC Program. By no means expert, but the one thing that Ken'll tell you and anybody who knows me from
24 my clinical practice, I'm available, open-minded, and try and provide the highest level of integrity and also
25 knowledge and accuracy to anything I do. By no means does that mean I'm perfect, and by no means does
26 it mean that I would ever follow blindly any opinion of someone but I am open and I take it as a privilege
27 to be here to interact with you all, because I think the feedback that we get from you and what you hear
28 from us is very important.

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1 So that being said, I'd like to get into a little bit about how we set up reviews. There's really no
2 difference what a MAC, FI, DME, Part B Contractor does. We do something called data mining. We don't
3 throw darts at a board. We don't pick out enemies if the state. We don't pick out previous partners that we
4 want to get back at. We basically look at aberrancy data. Aberrancy data does not mean something is done
5 wrong. As an example, one of the Part B audits that we're getting ready to do is direct LDLs measured on
6 the same day as a Lipid profile. So everybody knows that a Lipid profile has a calculated LDL in it, and it's
7 paid by Medicare as a panel. A direct LDL would indicated if the triglycerides are over 400, because the
8 math involved in the calculation gets thrown off when the triglycerides are over 400. So about two years
9 ago at one of the national meetings that I'm partially missing today to spend my day at CMS, was brought
10 up by a PSC, a safeguard administrator, that they noticed that there were some groups of doctors who
11 routinely ordered a direct LDL with the Lipid panel, so I said that's very interesting. Let's look and see. So
12 we started. We sent out a few letters. And Dr. Cullman said I'm a lipidologist and I've memorized the
13 national cholesterol education program and he started quoting. And I said I'm not a lipidologist, but I'm
14 pretty good internist. Can you tell me the problem you have with the rationale of our review. So at the end
15 of an hour and a half conversation, he said, you know what, I appreciate your interaction. I will no longer
16 routinely order a direct LDL, I'll make it a reflex test. In other words, I'll tell my in-house lab to look at the
17 results. If the triglycerides are over 400, and it just so happens by spectrometry, and I'm not a lab
18 pathologist or anything so the pathologists here, if I say something wrong, please yell out, but it has to do
19 with some of the calculations and stuff, that when the LDL gets very low, under 70, there's also a
20 calculation problem. So he will set up a process where there's a reflex testing as opposed to an automatic
21 testing. So this is an example of an aberrancy not being wrong as far as medical, the guy was trying very
22 hard to get his patients to go with the NCEP, but he was doing thing automatic and routine, which is not
23 paid for necessarily by the Medicare program, and we were able to pick that up by audit. And he said you
24 know, it's only \$20, what's the big deal? I said well, that \$20 goes to around \$3 million across the state of
25 California. He said, wow, I didn't know it was such a problem. So part of the problem with the RAC and
26 why I'm so happy to be here is that there's a lot of misinformation out there. So an aberrancy, as I've told
27 him, does not mean you're not practicing within the standards of care of an internist, it just means you may
28 be doing things that are outside what Medicare pays for and we need to collect that back. So an aberrancy

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1 could be justified or unjustified, but we've run reports to determine who floats to the top and who doesn't
2 and who may be identified as somebody doing things improper.

3 We also get referrals. We get referrals from the Part B, the FI, the DME, and other carrier contract
4 directors to us, saying you know, we're having a big problem here, and the post-pay folks just cannot—we
5 don't have enough post-pay people to manage, would you mind looking at it? As you are all aware, as the
6 MAC program comes into full force the payment to the carrier or the new MACs has been dramatically
7 reduced. For example, the Part B program I was involved in before I transitioned to RAC, had an average
8 cost of around \$1.80 to \$1.90 per claim. CMS said you have to get it under \$1 to be competitive. So what
9 happened? The Post-pay program, which is basically all nurses, got eliminated from that contractor. So
10 contractors in the future, as they move into MAC will only be able, because of money, to be very honest,
11 it's a business, will only be able to do pre-pay and education. So there's this huge post-pay world that is
12 now being unattended to. And as MAC goes into full process, that's going to get even worse. So I look at
13 the RAC as a collaborative, cooperating entity that interacts with the MACs in the jurisdiction to catch that
14 post-pay dollar. So that's the referrals we're talking about. We also have internal referrals. We have nurses
15 and staff that have been involved with all different aspects of care, and we get referrals from within as the
16 things that may be something to look at. Everybody knows what CERT is. We review the CERT report, just
17 like the MAC contractor does to see what are the opportunities for us and the impositions on the trust fund
18 that we can look at. And of course OIG publishes a work plan every year, called the Red Book, and they
19 have an Orange Book and we look at those just like every contractor does, to determine what the OIG looks
20 at, liabilities to the trust fund and to the proper payment world.

21 So again, I want to make it very clear we don't throw darts and go after people. It's really done in
22 a very evidentiary, scientific technologically sound fashion. The next thing we do is we do something
23 called Audit Prioritization. And that involves looking at review standards. We look at NCDs, LCDs,
24 manual language, and also evidence, just like the MAC contractor. Peer review journals, we do look at gold
25 standard of the community although it's a lower evidentiary significance, but we do look at that. We have a
26 quality assurance quality improvement program. We have something called an Internal Reviewer
27 Reliability Program, where we set up review criteria at my direction in concert with the audit manager. We
28 then provide that through education, either through conference call or in person education, we then give

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1 each nurse—we pull a sample from each nurse to determine whether or not we’re having consistent reviews
2 and if they are not consistent across the population, then we may bring in a subspecialist or a consultant to
3 come and educate, because obviously haven’t done the proper job. Or we have one nurse who’s in
4 aberrancy, I hate to use that word because it sounds so negative. But if her data is aberrant from the rest of
5 the group, we may have a little private education session with her to make sure that her education is the
6 same as everybody else. We also do outreach. We are not allowed to educate. I’m not a wordsmith, but
7 educate and outreach seem kind of similar to me, but what we do is we outreach, and we’ll call that a
8 feedback loop to the carrier. So like I said at the very beginning, we will be doing a lot of what we classify
9 as post-pay in the carrier world and then we feedback to the carrier to educate the provider world as to what
10 we’re finding and how to change things. Of course, the bottom line has been reiterated over and over again,
11 the goal is to reduce the improper payments through the Improper Payment Prevention Plan.

12 So I was taught by a mentor at the Medical College of Georgia, which is where I went to Medical
13 School, that nothing stands alone and everything has a history. So I want to show you the historical
14 perspective of Medicare, and I think that the RAC’s time has come. And if you’ll indulge me another
15 moment or two, I was not in practice in 1965. I don’t know of anybody at the table, you all look very young
16 to me, maybe you were, maybe you weren’t, but those of you who were in practice in 1965, are by my
17 mentors that I cherish, say that Medicare used to be the golden egg, because Medicare paid whatever you
18 charged. The usual and customary was truly your usual charge. It’s like when I was in August in practice,
19 we did some of the prison system, and at that time, when I first went in practice, whatever you charged a
20 prison system, they wrote you a check back. It wasn’t a check and balance, your usual and customary was
21 truly your usual charge. Then as time went on and the Medicare population grew, and LCDs and carriers
22 and policies and things of that nature came about, the usual and customer then became, I remember when I
23 was in practice, I said how did this UCR get calculated? And I was told by a mentor they throw a dart at a
24 wall and whatever number comes up that’s what they assign. And when I was in practice, that’s what it
25 would seem like, you do a flexible sigmoidoscopy that takes 40 minutes in your office and the cleaning and
26 everything else for \$65. Where I’m an internist who trained at a community program, so I was certified to
27 do my own EGDs, my own nuclear stress test, swangans, temporary pace makers, I did critical care the
28 most of the life, and EGD when I first started doing them paid \$600. An EGD is nothing but passing a tube

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1 down a hole, straight shot. Flexible sigmoidoscopy much more difficult. Take more time. Now the
2 gastroenterologist in the crowd will say, no you have to worry about esophageal perforation, and things—
3 now I'm not going to debate. It's mainly just a parallel or a point I'm trying to make that things seem not to
4 be appropriately assigned a usual and customary rate. Then as we go on, and we know that the Medicare
5 population continues to grow, we now have the reimbursement to physicians dropping at a rate that's
6 contended on how that's calculated. Some people say it should be done way another way, that's beyond
7 me, or as I always say, that's above my pay grade, someone else does those calculations. Are they fair, not,
8 it doesn't matter to me. But the bottom line is physician reimbursement continues to drop every year. The
9 last three years, it's been promoted or proposed 5, 6, 8% due to AMA, American College of Physicians,
10 FACOG everybody else. There's been a legislative halt of that, zero percent, half a percent up, half a
11 percent down, but you know what, 2012 is coming and we're all going to be out of business. So how do we
12 do that?

13 In my opinion somebody has got to collect the billions of dollars that the OIG tells us is sitting out
14 there collectible, but not being collected. So what will happen as the RAC collects those monies and
15 channels it back into the trust fund? I would not have taken this position if I did not think that the
16 reinvestment or the collection of and rechannelling of the money back into the trust fund was not going to
17 serve a good purpose. I still have an active sports medicine practice. I volunteer in internal medicine,
18 because I feel as though since I know the Medicare system so well, it's probably improper for me to bill the
19 system because I know a lot of the bypass codes and stuff, and it's really not proper in my opinion. So I
20 volunteer at a nursing home and do internal medicine, mainly to keep my skills up, but also provide back to
21 the community that has supported me for all these years. So I believe really that the return of the monies
22 that I collect through the RAC will do two things; one it will allow the Medicare Program to exist past
23 2012. The Medicare population, those who are disabled, those over the age of 65, they have to have
24 healthcare. We know what a disaster the Medicaid Program is in some states. We see how the uninsured
25 rate continues to climb. All these political things are being thrown out now in the election process. We have
26 to somehow finance the CMS process, Medicare specifically. And I really believe that the RAC program is
27 a way to do that. The other thing is it doesn't cost the government anything. The return on investment may
28 not be as high, because you have to pay me a contingency fee, but you know what 85%, 90% whatever the

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1 government ends up getting up back, minus the contingency fee is better than nothing. And the contingency
2 fee will be mandated in my opinion in the future, things progress by CMS and it'll be fair. It'll be a fair
3 wage for fair work. The other thing is it'll stabilize provider reimbursement. Taxes are not going to go up to
4 provide healthcare. That's a sure way not to get elected. So the only way we're going to provide physicians
5 stabilization of income is by refunding if you will the Medicare Program.

6 Finally, and most importantly, if the errors continue, it's like running on a treadmill with no end.
7 It's like you set the timer to end your program and the timer just doesn't go off and you keep running. So
8 the ultimate goal is to refund the program to stabilize physician income to allow Medicare Program to exist,
9 to maintain solvency, and to prevent the error rate from going up. To actually reduce the error rate through
10 close collaboration and feedback and therefore over time reduce the error rate to a point that we no longer
11 have this huge indebtedness. One last thing, and I apologize again for going over and obviously, I'll have
12 questions for everybody. You all are typing a lot of instant messages back and forth so I can't wait to see
13 what those mean, [laughter] the take home message in my opinion and our company has found this out very
14 clearly, is collaboration is always the best tactic of conflict resolution. Conflict is good. But no conflict is
15 no growth. So I'll just sit here, I was going to say stand here, but I'm sitting so it would be kind of funny, I
16 sit here in front of you saying that I am available. I want to be part of the collaboration. And if there's any
17 way that we can make the program work in a more appropriate fashion, I'm more than happy to be
18 available. So I appreciate your time. And Melanie will answer all the questions and I'll just sit here and
19 smile. If there are any questions, Mr. Chairman.

20 Dr. Senagore: Thank you very much. Comments and Questions from the Panel?

21 Dr. Berman: Don't let me off this easy. I got to earn my cab fare back, you know? Yes, ma'am.

22 Dr. Williams: Thank you very much for your comments. And both of you, they were very
23 informative. Among other things that I'm sure will come up at the table, I understand Melanie that you've
24 been working with the AMA, and the ASA, regarding an issue between anesthesia and nonpayment of fees
25 for surgical procedures. My understanding is that the surgeon determines that the procedure needs to go on,
26 the operation needs to proceed, and then after the fact, the determination is made that the surgery was
27 deemed not necessary or some likeness thereof, but the anesthesia fees are then denied. When the

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1 anesthesiologist is not the one that can make the surgery decision. I understand that you guys have been
2 talking about this. Is there any resolution to that or you know...

3 Ms. Combs: I don't know that we have anything to share with you today. I know that it's always a
4 difficult situation where the improper payment was billed by one particular provider, where it was really a
5 different provider that ordered that service, or that sort of caused that chain of services to begin, and I know
6 that's the situation that you're raising today. We will continue to work with the AMA and the specialty
7 societies to try to address those issues on an issue by issue basis and go ahead—

8 Dr. Williams: Do you have any thoughts though about how you're looking at it at least at the
9 moment?

10 Ms. Combs: I'll just tell you off the top of my head, it sounds to me like it still is an improper
11 payment. It's unfortunate that the anesthesiologist is the one that is having to pay back that money. I hope
12 it's in addition to the surgeon. I hope if it was determined that the surgery was medically unnecessary, that
13 both the surgeon and the anesthesiologist and probably the hospital all three involved entities would have to
14 refund the overpayment, but that's just what it seems to me like on the surface.

15 Dr. Williams: Can I make a recommendation, Mr. Chair?

16 Dr. Senagore: Yes, absolutely.

17 Dr. Williams: PPAC recommends that CMS continue to work collaboratively with the AMA to
18 disconnect payment denials for anesthesiology when a RAC retrospectively determines that the surgery was
19 unnecessary. Just as an aside, I think it's inhumane for a patient to have surgery without anesthesia
20 [laughter].

21 Dr. Senagore: Depends how quickly you operate, I guess, but [laughter]

22 [Second]

23 Dr. Senagore: Discussion first on that? I wonder if we might broaden that to cover multiple
24 specialties? I can see where they may be several specialties involved in a care plan, so I don't know how to
25 word smith that to get at that same discussion. Can we read that back, Dana, just see if we can figure out a
26 way to, because our issues with hospitalized patients where the primary admitting physician may have done
27 something that adversely affects a consultant, where the consultant did actually do their best to take care of
28 the situation.

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1 Ms. Trevas: PPAC recommends that CMS continue to work collaboratively with the AMA to
2 disconnect payment denials for anesthesia when the RAC retroactively determines that surgery was
3 unnecessary.

4 Dr. William: How about disconnect payment for one medical subspecialty when another
5 subspecialty was responsible for making the decision? Does that sound too broad.

6 [off mike cross talk]

7 Dr. Senagore: We're talking off line, side bar. I guess if there are no other comments now, we can
8 entertain a separate proposal then. So all in favor of the current one, as proposed?

9 [Ays]

10 Dr. Senagore: All against? Motion carries.

11 Dr. Ouzounian: Let me make a proposal that PPAC recommends, and this is what I think Tony's
12 trying to get encompassed in there, that if a rendering provider renders a service at the request of another
13 provider, that he would not need to refund payment for those services if they were subsequently determined
14 to be not medically necessary.

15 Dr. Williams: By the initial provider. By the requesting provider.

16 Dr. Ouzounian: Well, examples would be what about an X-ray, MRIs, CTs, scans like that where
17 it's ordered by one provider, it's done by a different provider. The provider that does it doesn't order it,
18 he's doing it at the request of another provider. And what if they decide it's not medically indicated. That's
19 not his fault. He's doing what the other doctor ordered. You can see it with lab tests.

20 Dr. Ross: If you would add as a friendly amendment to that—

21 Dr. Ouzounian: Please do.

22 Dr. Ross: Where appropriate or when medically necessary. In other words, the second physician
23 who's providing that service, at the request of the first, even though the first did not provide the medical
24 necessity type of care, the second provider provides that care, but as a clarification, that it should be
25 medically necessary.

26 Dr. Senagore: I think—let's have a second so we can discuss the topic.

27 [Seconds]

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1 Dr. Senagore: I think what we're kind of grappling with is that the medical necessity of the
2 original order may be questioned but because of legal issues, regulatory issues, and just good practice, the
3 consultant may follow through on assessing the information, not knowing what the preliminary reason was
4 for it. So--

5 Dr. Ross: Well, the reason I brought that up is because the second provider may be providing care
6 but it may or may not be medically necessary. So what I'm trying to say that if the second provider is
7 providing that care, it should obviously be necessary. In other words—

8 Dr. Senagore: But I think yes,

9 Dr. Williams: But doesn't that go back to—

10 Dr. Ross: So that provision should be part of—

11 Dr. Williams: If it wasn't med—if the surgery was not medically necessary, then you're
12 presuming that the anesthesia wasn't medically necessary, when that's not the case in that particular
13 situation.

14 Dr. Senagore: Tye's example is probably cleaner. Someone orders the MRI for some diagnosis
15 that it doesn't make sense, but the radiologist doesn't know that—they're obligated to read the MRI and
16 follow through on that. Should it be that they have to refund or not just because the person upstream did?
17 I'm not sure what Medicare's perspective will be on that, but it sure seems like that person's collateral
18 damage.

19 Dr. Przybiski: But I wonder whether you're taking it too far to an extreme, if I order an MRI for a
20 diagnosis that clearly an MRI is not the appropriate test for, is it not the radiologist's obligation to call me
21 and say an MRI is the wrong test. You may want this instead. But I'll do it anyway because you asked but
22 it's worthless. That doesn't make sense, either.

23 Dr. O'Shea: I think we're also misguided in that. I think each one of the things that we bill for are
24 going to be looked at, whether they initially came from a misdiagnosis. I see with anesthesia that there's
25 definitely a correlation there because the whole surgery has been disavowed or unnecessary. But I think
26 that as an internist, if after the surgery there has to be some post operative care that this was necessary
27 because it's post operative then, and within that post operative care, if I'm doing things that aren't—still

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1 always going to be looked at. So I think we're trying to litigate too much, or put too many commentaries on
2 top of that. It's going to be looked at already.

3 Dr. Williams: So, extending from what you're saying, should I tell the surgeon you can't do the
4 surgery because I probably won't get billed if it's really not an appendix.

5 Dr. O'Shea: That's not your call.

6 Dr. Williams: Absolutely. But they're saying it is my call if I'm not going to get paid for it.

7 Dr. O'Shea: And that's why we're agreeing with your recommendation to say that it's not. But
8 this further one that Tye has put forward that we're trying to put the amendment on, that if it's necessary, I
9 don't think we need to make that in there, because it's already going to be looked at if it was necessary.
10 That's partially what CMS does.

11 Dr. Ross: I would assume that we're doing it because it is, so I understand.

12 Dr. Simon: Dr. Senagore, what I think what would also be important for us to also chat with the
13 contractors and the program integrity, because I think the site of service, this is a broad issue, and the site of
14 service can be very important. You know, if the doctors own the hospital for example, and they decide to
15 collude together, they all benefit from these inappropriate activities. So we're talking in the abstract, but I
16 think we really need to look at the total picture of this before we can figure out what the appropriate actions
17 and responses should be.

18 Dr. Senagore: Yes, I guess I mean that's why I'm struggling how to phrase it. What I'm looking
19 for is something where you would have no ability to know whether or not it was valid. You were simply
20 giving—and radiology is probably the best example that you're getting a test that was ordered and the
21 clinical issue is back pain. You don't know where they are and the work up, what else was done, you're
22 really in an isolation of one instance with no way to really know if that service is done. I mean I suppose in
23 a perfect world, you would close that loop on some sort of quality panel and say these are not reasons to
24 order, these are reasons you should not order these X-rays. I guess I would ask the question, do you find
25 this a big challenge? I mean I would, using your lipid example, the pathologist may or may not know in a
26 split sample what the triglyceride level was on the first specimen.

27 Dr. Berman: As an FYI, we did not go after any pathologists. Mainly it was in-doctor labs. That's
28 a very important distinction. Almost in agreement, but not in agreement with what you all are discussing.

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1 Dr. Senagore: Yes, that's helpful.

2 Dr. Berman: So we only went off after inpatient labs, in doctors' offices. That's very important,
3 because obviously if you received something, if I may be so bold as to speak to the radiology issue, when I
4 was a care and medical director, we used to get comments all the time from the radiologist—the chest X-
5 ray's ordered, but no diagnosis. We just do it because we're a service-oriented profession. So my statement
6 back was set up a screen, either at the ordering clerk's station or the receiving station, not to let it get
7 processed until a diagnosis is put on. Because if a chest X-ray is ordered, that diagnosis, the radiologist is,
8 excuse the pun, in the dark. And it hurts patient care, and also it's not a Medicare billable service. The
9 anesthesia thing I'm not going to comment on because I don't know enough of the background information
10 because it wasn't part of our state's issue. But the disconnect between properly ordered test and the
11 receiving physician is sometimes difficult. I don't know what specialty you are over here, but the back
12 pain's a perfect example. When I was in practice in a small town, there were no neurosurgeons,
13 rheumatologists or anyone else, so the internists did all that work, and my subspecialty in sports medicine, I
14 would call the radiologist on my own and say I've got a kid with back pain. I need to work it up. Do I need
15 a bone scan to see if it's acute or chronic? Do I need an MRI? Do I need a CT? What is it that I need as a
16 general internist with sports medicine background to make this test useful and allow me to make a clinical
17 decision? Can he play football on Friday night? So I'm going to make a comment that sound bold, and this
18 is not as my position as a RAC Medical Director, it's my position as a practicing physician, unfortunately
19 in this world of through-put, we have lost the skill of communication. Now when I first went in practice,
20 there was a lot of time in the doctor's lounge having a cup of coffee, discussing in a proper sense how to
21 handle certain problem patients. And that collaboration and communication, that clear, concise, considered,
22 and correct, the lack of that is why we're having this discussion. And I guess as an outsider talking to
23 PPAC, I'd love for you all to go back to your organizations and say let's reinstate communication. I don't
24 know if I helped you in this problem.

25 Dr. Senagore: There's, I mean we see it for screening colonoscopy, where patients don't really
26 meet the criteria. I mean we've, our default position unfortunately in the scenario has become to use the
27 ADM process as a way to communicate at least to the patient that you know, there are rules. Maybe not
28 everyone understood the rules, but these are the rules, so that doesn't always completely medicate the

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1 conflict, but at least you have something in writing that says you broached the topic. I'm not sure that I
2 have a clear solution to this current proposal.

3 Dr. Snow: I'd suggest we put it off a vote on that until the wrap-up session. Maybe we could have
4 some time over lunch and til then to think about it.

5 Dr. Senagore: That be—want to come back to that Dana at the end, then?

6 Dr. O'Shea: First off, I think I want to say that some of our discussion might have been able to be
7 done over dinner last night, because I think I remember seeing you and your family over some crabs at
8 O'Brinsky's last night? [laughter]

9 Dr. Berman: You didn't see me over crabs, because I'm an orthodox Jew and we don't eat that. It
10 wasn't me. I travel business alone. My seven children wouldn't want to come to this meeting.

11 [chat]

12 Dr. Berman: But thanks for recognizing me.

13 Dr. O'Shea: I have another recommendation. PPAC recommends that CMS Recovery Audit
14 Contractor Program create clear and uniform notification and demand letters. In composing these
15 communications the objective should be to decrease confusion and inefficiency and to increase clarity and
16 compliance.

17 [second]

18 Dr. Senagore: OK, now we can have discussion, that's fine.

19 Dr. Berman: I'm going to make a brief comment. I know Melanie has a—I agree with you. And I
20 will tell you one of the things that we have come under fire for is not being the most friendly demand letter
21 or medical record review request letters, and we have recently entered into a collaborative effort with the
22 AMA, Mari is here, she's our point person, and we have also changed our letters under the direction of
23 CMS prior to that, and we have basically put several things on hold until those letters are exactly what you
24 just said. Clear, not only what do we want to receive back from the medical record, but once we make that
25 determination, why we have a free text box now that every nurse must fill out on a complex. They just
26 can't say B17 and have it automate. They must free text with examples from the clinical record, for every
27 complex review. So these are lessons learned. Without feedback, we think we're perfect. So this is the kind
28 of feedback that we're—I got one extra gray hair from it, but it has ended up in a much better product. And

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1 between CMS's input, AMA's input, you will see from PRG Schultz a dramatically different and better
2 letter and appreciate you bringing that into the record and allowing me to respond because I agree
3 wholeheartedly with you and you will see a change, because we're not doing business really until the letters
4 change, and CMS signs off on them. And AMA will be a consultant in that and we appreciate their
5 involvement.

6 Dr. Senagore: I think Ms. Combs asked one of the questions earlier about who should the letter go
7 to. I think if it were clearer and didn't have coding jargon and code numbers to go to the physician would
8 be the most helpful because it would explain what the perceived issue is, what was done and what the
9 correct action should have been.

10 Dr. Berman: Right, one problem that we have and we have recently, someone commented earlier
11 about web-based updates and that kind of stuff, on every demand letter, every MRR medical record request
12 letter, there will be a statement saying Please update your address and contact person. When I was in the
13 carrier world, you'd be amazed. A lot of doctors used billing services, so our letters would go to the billing
14 service and the doctor was in the dark. And would have no clue that we were auditing them. So contact
15 people, updates, all that stuff is very important, and you'll see that we're much more aggressive in that
16 area.

17 Dr. Senagore: Any comments on the current proposal? I'll call the question. All in favor?

18 [Ays]

19 Dr. Senagore: All against? Motion carries with that.

20 Dr. Ouzounian: I'd like to use this just more for discussion than actually a motion. But I appreciate
21 the comments you've just made and the willingness to want to learn and move forward. There's a letter in
22 the back of this book. I don't know if you've seen it, but it's from a urologist in California. It's a fairly well
23 written four-page letter, specifically indicating the difficulties that he's had with the contractor, PRG
24 Schwartz. So your position seems in direct conflict to what he's stating in the ease with working with that
25 particular contractor. I'm also wondering if in the '60s there was the golden egg and maybe now you've
26 found it again, because you've got a lot to gain and nothing to lose. And I think it would be appreciated by
27 the physician community if things could be a little more focused and maybe there are providers out there—
28 I'm sure there are, who do things repeatedly, inappropriately, but it's a burden on their offices when they

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1 get a request for 50 records, and I don't know the time frame, but there's got to be a different way of
2 dealing with it.

3 Dr. Berman: And I'll say that you're exactly right. We've had a teleconference with this provider
4 in concert with AMA and I believe the resolution at the end of that conversation other than their contention
5 that they owe no money back, but the other issues that they discussed in that letter were all resolved. For
6 example, we have the opportunity to send out 50 medical requests. But after a conversation with this doctor
7 and some others, we have voluntarily in our future corrective action plan reduced the number, probably
8 more in the line of 20 to 30 depending on the size of the practice, to reduce that burden. Number two, we're
9 using a variety of assessments to look at financial burden on the small provider, and also looking at the
10 impact of our audit on even bigger providers. It's not our intent, nor is it CMS's intent to put anybody out
11 of business. And we are doing assessments and our corrective action plan is in progress and being reviewed
12 by CMS to reduce the burden on the practice, to reduce the burden on the hospital. A lot of the things that
13 we have done have been in direct response to input from practicing doctors, not only on committees such as
14 this, but the individual doctor who calls up and says we have a problem. For example, for drugs, let's say
15 that you're getting an injection once a month, and it's an injection that we have audited and we're going to
16 collect money back. We do things in waves. We try to do things in waves to limit the burden on the doctor
17 as far as making records copied. So what we're told is, we store our records from three years ago in Iron
18 Mountain. Or we have a private shed off site that we have to go to and find these things. So when you send
19 us for three months and then three weeks later or a month later, you send us for an additional three months,
20 we've got to send somebody out to the middle of nowhere and unlock the shed. If you know that you're
21 going to audit this drug for the entire course of therapy which may be nine months, ten months or a year,
22 please tell us up front so we can collect those records all at once. Well, you know, unfortunately, when
23 you're working through computers and stuff, you sometimes you lose sight of that. So we now have what
24 we call a consolidated request, where we're auditing a course of treatment request all that up front. To be
25 very honest, we didn't even think of off-site records, and Iron Mountain and these kinds of things. So that
26 kind of input made such tremendous sense to us, and we changed it. So I'll be more than happy to continue
27 going down this physician's letter, but I think it suffices to say that we did have a teleconference with him,
28 and Melanie and/or AMA can comment, but my feeling at the end of that conversation was very positive,

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1 and I think most of the contentions, other than the fact that he doesn't think he owes us any money back,
2 but the other contentions all have been handled and I think you'll see before we ramp back up, they'll all be
3 checked off on by CMS and AMA to make sure that we're in compliance and we're user friendly. And as
4 another example of feedback working.

5 Ms. Combs: I'll just add that CMS recognizes that it's really critical for the RAC Program to
6 balance identifying and collecting and paying back improper payments with hassling providers. It's a tough
7 balancing act to do. We've had to walk carefully through this mine field during this demonstration, but
8 we've learned a lot of lessons, and we think that we have a really good plan for going forward. So thank
9 you for bringing that to our attention. We are certainly working with every specialty society that brings
10 issues to our attention.

11 Dr. Senagore: Any other questions or comments on this situation? Dr. Ross?

12 Dr. Ross: I would just like a clarification on that letter that was sent. I'm very curious. What
13 happens if there is an error, that your request for those records dealing with cases to a physician, and it
14 happens to be the wrong physician? Where do you come into this whole play as far as HIPAA regulations
15 go and how is the patient protected against mistakes and errors on those cases to the wrong physician?

16 Dr. Berman: Right. So first of all we take HIPAA allegations extremely seriously. My recollection
17 there was one doctor who had that complaint. So if you look at the number of audits that we've done since
18 we've been in business, a one doctor out of thousands and thousands of audits, even though HIPAA
19 allegations are very serious, that's not bad. OK. So let's just put that on the table. That's not bad. I'm sure
20 it's human error. You know we have thousands, and hundreds of thousands of phone numbers and fax
21 numbers and it was a human error that this doctor got the wrong patient request. So how do we handle it?
22 We would hope it would be handled by the doctor calling saying this patient isn't mine. And we would say,
23 huh, well the patient name data base says such and such, would you please—what was your name and your
24 provider number or your NPI, we can make that disconnect and just not go after that patient anymore. Same
25 thing, I mean Melanie made a comment—this 3-year, 4-year thing. OK. We're allowed to go back 4 years.
26 Let's say we go after a chart that's three years and ten months. It's amazing the process that the chart has to
27 go through, or the letters and the data files and the CDs. I mean I barely know how to turn on a laptop, so I
28 don't really understand how it does, but the exchange of things is just unbelievable. So we could very

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1 easily go over the four-year threshold, and you know what, we may even have requested letters that were
2 four years and a day. I'm not pleading innocent on that, we may have done that. So we basically have
3 rescinded and refunded anything over four years. So once a problem's identified, we address it, hopefully
4 to the satisfaction of all people involved. And I think the important thing to take home is we're not perfect.
5 I make a comment all the time about clinical practice. I never miss a diagnosis in retrospect, none of us
6 have. So I guess I'll ask you to be tolerant of us as we go through this demonstration project, and by
7 defining this demonstration, it means it's a work in progress, and we require feedback to perfect it, to just
8 be a little tolerant. If we have a problem, address it with us. We'll do our best. We've had a few things
9 escalated to CMS and AMA level and we have responded, and feel assured CMS is not going to allow us to
10 continue to operate if we're not satisfying the regulations. You know, and we want to be in business. As far
11 as golden egg and contingency fees and all those kinds of things, that's beyond my pay grade to discuss. I
12 just do my job.

13 Dr. Snow: I think one of the charts that was shown earlier indicated that the RAC refunds for
14 physicians, ambulance and lab was 6%. Any breakdown on how much of that is physicians?

15 Ms. Combs: I don't have statistics on what percentage of the improper payments identified or
16 collected. I just don't have it. It's just not the way that we have collected it last year. We are trying for our
17 annual report that will come out this November, to break it down that way, and I certainly can probably go
18 back to the statistics and see if I can gather that and maybe the next time that I come, it seems like you guys
19 are now having me on a regular basis. I can see if I can find that statistic and get that to you. That is a
20 knowable number, I just don't know it here, today.

21 Dr. Ouzounian: I have a question and maybe you presented it, maybe you don't know the answer,
22 maybe I was asleep. It could have been any of the above. The last meeting we tried to address the issue of
23 refunds from facilities, versus refunds from physicians and it's come up again, but the question when I ask
24 is a little different. And I'm a physician, and this is a Practicing Physicians Advisory Council, so that's
25 where the question is directed, and if you want to give the 6% with the ambulance and the nursing or
26 whatever it was, also, that's fine. But of the numbers of physicians that you audit, you send out the audit
27 request, what percentage of those do you then find that there is a request for a payback? Is it 100%? Is it
28 10% or is something in the middle?

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1 Ms. Combs: Is your question of what percentage of the medical records that are requested from a
2 physician end up having an underpayment or overpayment on them? Is that your question?

3 Dr. Ouzounian: Yes.

4 Ms. Combs: I'll first start that answer and then I'll let Dr. Berman answer if he wants to. We were
5 very clear in the statement of work that we were anxious to find Recovery Audit Contractors who were not
6 casting a wide net and randomly choosing records, but instead were targeting their medical record request
7 letters to problem areas.

8 Dr. Ouzounian: Right, so what's that number?

9 Ms. Combs: I don't know what that number is, but I can tell you that I would expect it to be very
10 high. We have met with certain provider groups, and we have done studies on particular specialties or
11 particular provider organizations and sometimes that number is over 90%. We see that as a good thing.
12 That means that the RACs are not sending out medical record requests letters to providers that aren't
13 submitting claims that contain improper payments. I'll ask Dr. Berman if he knows any specifics to
14 physicians. But I can tell you that CMS is hopeful that that number will be very high at each one of the
15 RACs.

16 Dr. Berman: My statistical back up is on another call. He just stepped out I think about a half hour
17 ago. I'll be more than happy to send it to you if you'll give me contact information. We do have that, I
18 would say, as Melanie was saying, it's very high. And that's what we're challenged to do is try and pick
19 things that we know are going to be a problem and that we're able to go at a very high rate of confidence.
20 But the exact number I'll be more than happy to get to you, I don't know how long you're in session, but
21 our statistical person's upstairs. I can get it for you.

22 Dr. Ouzounian: Can we get it today?

23 Dr. Berman: Sure.

24 Dr. Senagore: We'll be here in the afternoon.

25 Dr. Bufalino: Could I ask you to elaborate on that—can you help us define who are these groups
26 that you're concerned about and where are the problems that you folks have already identified, and can we
27 communicate that back to the physician community, that if there are areas that you think are clearly
28 problematic that are being over-billed, can we learn from this over the next couple years, so that we can

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1 provide back feedback so that maybe someone is innocently doing that and be able to give them that
2 information, be able to say, hey by the way, this isn't Kosher, this doesn't work, let's get you to change that
3 behavior pattern.

4 Ms. Combs: Absolutely. That's what we call the Improper Payment Prevention Plan. And what I
5 did on the slides earlier was share with you three of the very specific topics that the RACs are finding. It
6 was multiple surgeries, stibular function tests, and billing for too many units of service. And what we plan
7 to do is share that information with all of our carriers and fiscal intermediaries, because the majority of it
8 does happen in inpatient hospitals. We are sharing it with people throughout CMS, you know, we continue
9 to be a bureaucratic organization and there's one group of people that does the payment policy and another
10 group of people that does the Medically Unbelievable Edits, and another group of people that does the
11 Outreach and Provider Education, so we're sharing it with all the right people in CMS. Sharing it with all
12 the contractors and we soon will be putting the information up on our website so that any provider specialty
13 organization who wants more information can certainly come to us and say gee, we want to write an article
14 for our newsletter, or we would like to have you come and talk, or any kind of outreach or education that
15 the provider community would like us to do, we're certainly more than willing to come and talk.

16 Dr. Senagore: Any other comments or questions? Thank you very much.

17 Dr. Berman: Who should I provide that number to? The statistical? To you?

18 Dr. Senagore: To me would be great.

19 Dr. Ouzounian: Thank you.

20 Dr. Senagore: We'll move on to the Physician Proposed Rule. I think we have Ms. Amy Bassano
21 here today to provide us the latest information on this year's fee schedule. Some of you recall Ms. Bassano
22 has addressed the Council several times over the last two years, and she is the Director the Division of
23 Practitioner Services in the Center for Medicare Management. Prior to joining the Center for Medicare
24 Management in March of '05, Ms. Bassano worked for four and a half years in the office of Management
25 and Budget as the lead analyst for both Part B and Part D. Prior to 2000, she was a Part B issue analyst in
26 the CMS Office of Legislation and welcome.
27

1 Physician Proposed Rule

2 Ms. Bassano: Morning. Thank you. I'm pleased to be here with you, today, and talk about the
3 2008 Proposed Physician Fee Schedule Rule, which came out earlier in the summer on July 2nd. It's
4 currently in a 60-day comment period, which closes the end of this week at 5 pm, August 31st, and we
5 really anticipate everyone's comments on that, so we can review those and anticipate putting out the Final
6 Rule by November 1st deadline of the Rule. The Rule, as has been in previous years, continues to be more
7 than just the fee schedule, physician issues, there's also other related Part B and other Medicare policy
8 issues in there as well. I'll focus primarily on the physician issues, but I just want to quickly run through
9 some of the other issues there are in there. There's also, as I mentioned, it's all of the Physician Fee
10 Schedule, establishing the rates for all the services, or proposed rates for services next year. There's also
11 several Part B drug issues, regarding the Average Sales Price methodology, and the Competitive
12 Acquisition Programs, and tweaks to those to make those more efficient, clinical lab fee schedule, having to
13 do with reconsideration of new tests and date of service on certain tests, ESRD payments. This is
14 something that's in there generally every year, having to do with their updates on their payments.
15 Independent Diagnostic Testing Facility standards. This is something that builds upon provisions that were
16 in the Rule last year, having to do with what entails to be an IDTF and requirements for enrollment and that
17 must be met, in order to function as an IDTF. There's a variety of physician self-referrals, STARK issues in
18 the rule, that get into a variety of different issues to clean up things. The Tax Relief and Healthcare Act of
19 2006 implementation. A lot of those issues were implemented last year, at the legislation passed at the end
20 of the year, most notably the Update to the Physician Fee Schedule but there are some other issues that
21 require, had later implementation dates and required rulemaking, so this rule addresses this. There's also
22 ePrescribing Exemption in there, that's for a Part D plans, and doesn't necessarily address the Fee for
23 Service Program, but there are some issues in there about the computer generated FAX exemption. So it
24 does cover a broad spectrum of issues and so it has a little bit of everything. A little bit of something in
25 there for everyone.

26 Moving on to the specifics of the physician issues, this is sort of a, I'd like to think of it as an
27 extension of many of the proposals we started the last year, most notably it completes the third 5-year
28 review of the Work to Value Update, I'm sorry Work to Value Units, and had some changes in there. The

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1 most notable one was a significant increase to anesthesia services, that came to us as a recommendation
2 from the RUC, has the result of increasing payment for anesthesia services by about 25%. There are some
3 other codes that RUC had reviewed that we accepted their recommendations for. A lot of these had been
4 deferred from last year, based upon the other E&M changes that were being in place, that either we asked
5 to defer to make sure that they were consistent with the E&M changes, or had the RUC had put some things
6 to CPT or sort of deferred business on that. So we are completing that 5-year review, and discussed all
7 those different codes that were changing there.

8 Also builds upon the New Practice Expense methodology we implemented last year. This is year
9 two of our four-year transition, and that we didn't make any changes of the methodology but we do show
10 what the rates are going to be in 2008 and then also for reference the full implemented rates for the new
11 methodology in 2010. One of the areas, it's not a specific proposal, but has been an area of great interest is
12 the utilization rate we use for equipment services. We currently assume it to be 50%, MedPac and others
13 have recommended that it be higher, so we have a discussion in the rule, looking for more information on
14 that, looking for data to support a potential change in the future, to get to a more accurate utilization rate.
15 That has generated lots of discussion and interest from variety of parties, so we look forward to reading all
16 the comments on that and considering how to potentially address any changes in the future. This also has
17 our statutorily required updates, the Geographic Practice Cost Indices, which adjust the payments for the
18 across the localities, across the country, these are updating to the Work, Practice Expense, and Malpractice
19 GPSIs based upon more recent data for the PE and the Malpractice. The work generally stays the same
20 because it's based upon Census data, but it comes out every ten years, so we're still using the same Census
21 data, but we do have updated information for certain components in the PE and the malpractice, so as I
22 mentioned, that's a statutorily mandated change that happens every three years, and so this is our third year,
23 year to do it, although the changes are by law phased in over a two-year period. So the Rule lays out what
24 they would be 2008, and then the full year, 2009. Related to that we have a discussion about California
25 localities. There's been a number of issues there. We've been working with the CMA over the past several
26 years trying to address some issues in certain counties and localities in California. We don't have a specific
27 proposal. We have three options that we discussed. The first two options are similar to each other, and they
28 take out the certain counties that have the largest differences between the existing locality they're in and

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1 dealing with certain counties in northern California and the option really difference is if the counties you do
2 take out, you give them each their own locality or do you take the ones out and make it one separate new
3 locality? The third option is a complete reconfiguration of all of the localities in California, where you
4 would array them and they're within 5% of each other. Ends up in six new localities that are sort of
5 different than we've had before because they don't have to be geographically contiguous. It's really based
6 upon the putting their costs together, so that would be sort of a big departure from what we've done in the
7 past, and there are significant impacts up and down for that type of option and any of these changes we do
8 we have to do in a budget neutral fashion? So we lay out all what the impacts would be for those. Another
9 issue we have in the rule—it's a discussion, not a specific proposal, and it's the treatment of the
10 malpractice RVUs for the technical component of services. This is something the RUC PLI workgroup has
11 brought to our attention that there are quite a few codes where the technical component, malpractice RVUs
12 are higher than the professional component RVUs. Comes from a couple different places, but mostly
13 because the professional component are resource-based, and the technical component are not. We've never
14 had the data or ability to go to make them resource-based, so we have a discussion in there about laying out
15 the issue and options we're thinking about or considering to address the problem, some suggestions from
16 the PLI work group, and looking for data on how we could approach on actually making these resource-
17 based.

18 Some other related things to the fee schedule are therapy services, which are paid off a fee
19 schedule. We talk about the qualifications for providing therapy in Part A settings, trying to achieve the
20 goal of having quality therapy across all of the settings, regardless of the payment methodology so we lay
21 out some settings here, updating some standards and other issues about grandfathering in those who were
22 providing services through home health because they are already at a different level, and updating for
23 military and foreign trained therapists, and trying to make them consistent with the requirements we have in
24 the Part A setting. The second therapy-related issue is the certification for the plan of care. Right now, a
25 physician must certify within 30 days of the therapy beginning and certify every 30 days thereafter. We
26 want to provide some more flexibility to the physicians and the therapists, allowing the physician to
27 determine the appropriate length of the plan of care. They still need to require to certify within 30 days, but
28 have the flexibility to certify up to 90 days. Our data suggests that most therapy is complete long before 90

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1 days, I think it's even less than 45 days, so instead of having to have the burden of doing it every 30 days,
2 giving the physician some flexibility to work with the therapist and the patient to determine what the most
3 appropriate length would be. That is something though that's a 2-year trial period, wanting to see what sort
4 of impact that has on our therapy utilization data, so we are proposing to do that for a two-year period.

5 Semi-related to therapy is the comprehensive outpatient rehab facilities. These were going back to
6 BBA, so ten years ago, moved from a cost-based reimbursement to a fee schedule, and these are some
7 technical changes allowing, we've been paying off the Physician Fee Schedule for quite a few years now
8 and updating the regulations to reflect the services that can be provided in the course and make sure we are
9 all in alignment on our regulation for those services as well. We had our annual process for updating the list
10 for telehealth services. This year, we're proposing to add neurobehavioral status exam, in that it's similar to
11 other exams that are already allowed under the list of services and there are several, there are 2 other
12 services which are not going to accept at this point, but want more information on how they are similar and
13 how they meet our process for doing services and if we could potentially add them in the future, so we
14 asking for some comment there.

15 I talked about the Tax Relief and Healthcare Act earlier. The implementation of the Physician
16 Assistance and Quality Initiative Fund comes from there. It's \$1.35 billion for in 2008, for physician update
17 or quality programs. We are proposing to use that to extend the PQRI Program into 2008, where the bonus
18 would be paid on a retroactive basis, at the end of the year, once all the claims are submitted. And we had a
19 sense of how much the participation level was and we could pay the bonuses. We anticipate they still would
20 be in the range of what this year, the 1.5 to 2, 2 and a half percent. One of the issues here is this is a unique
21 program because it is an appropriated amount, an entitlement program, so the law says you have \$1.35
22 billion and doesn't allow us to spend a penny over that. And you know Medicare, being an entitlement, we
23 pay whatever the claims come in, whatever the benefits are, so it's hard for us to cut things off, so we are
24 proposing this. It also continues our important quality programs, but doing it this way on a retroactive basis
25 allows us to determine what the claims are and then split up the \$1.35 billion after the fact.

26 There's also discussion in the rule just of the varying spiring provisions, such as the therapy caps,
27 the physician scarcity areas, and some other changes that have been extended over the years, through the
28 difference pieces of legislation, but just as a reminder to the community that these will be expiring the end

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1 of this calendar year unless Congress acts. I think that's the highlight of the major provisions of the rule,
2 and I'm happy to answer any of your questions and go into more specifics if you like.

3 Dr. Senagore: Comments or questions?

4 Dr. Przyblski: You addressed one of the PLI issues that the RUC work group is looking at and will
5 be looking at in September, but one issue that hasn't been addressed is a proposal that CMS had looked at
6 in a select group of states, PIAA data, which is an alternative source to the data that CMS has been using,
7 and we really haven't had an update for a while as to that pile of projects and where it stands and where it's
8 going.

9 Ms. Bassano: Sure. We've had our contractor, who did the update to the GPSIs take a look at that
10 data and sort of on an informal basis, it seems that there's no real difference they can determine based upon
11 the look they've taken at it. So it's looking like it's consistent with the recent data they acquired from their
12 sources at the state level, it's very similar to what was provided.

13 Dr. Przyblski: A follow up then, does that imply that that data may be potentially used as an
14 alternative source?

15 Ms. Bassano: It's something we can consider, and but I think that since we have a source we use
16 that sort of has been working for us, if it's finding the same thing, we'd, we'd have to look at which is the
17 most timely set of data.

18 Dr. Przyblski: That was the whole issue, exactly what you're raising is that the timeliness of the
19 data sources that you were using were 3 to 4 years old, whereas as PIAA could provide it within a year.
20 That was our concern.

21 Ms. Bassano: Is that available nationwide?

22 Dr. Przyblski: It is a national company. Yes.

23 Ms Bassano: OK.

24 Dr. Sprang: I was just going to discuss the same issue and I am involved in PIAA and go to their
25 annual meetings. And they do represent all physician liability insurers throughout the United States and
26 have very good data, so I guess I'd actually go so far as to say that PPAC recommends that CMS consider
27 using the PIAA data because it is more timely.

28 [seconds]

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1 Dr. Senagore: All in favor, except [inaudible/laughter] All in favor?

2 [Ays]

3 Dr. Senagore: Anyone against? Motion carries. Any other issues? Thank you very much for
4 coming.

5 Ms. Bassano: You're welcome.

6 Dr. Senagore: We'll adjourn for lunch. We'll reconvene at 1:15. Thank you.

7 Lunch

8 Dr. Senagore: We'll go ahead and start this afternoon's portion of the meeting. We have Don
9 Thompson here to discuss the Outpatient Ambulatory Surgical Center Proposed Rule. Don is the acting
10 Deputy Director of the Hospital and Ambulatory Policy Group. His work at CMS has included physician,
11 hospital, and ambulatory surgical center issues. Mr. Thompson would like us to consider the following:
12 Dissemination of information to physicians and ASCs regarding the revised ASC payment system,
13 particularly with respect to new ASC procedures in efforts to encourage quality ASCs including
14 suggestions for appropriate quality measures. Welcome, Mr. Thompson.

15 Outpatient Ambulatory Surgical Center Proposed Rule

16 Mr. Thompson: Thank you. Today we'll talk about the Outpatient Prospective Payment System
17 Propose Rule and the Ambulatory Surgical Center payment system Final Rule and proposed rule for 2008.
18 There are two major proposals in the Outpatient Prospective Payment System for 2008. One has to do with
19 quality measures. I'll touch on that a little bit. And also a proposal for expanded packaging under the
20 Outpatient Prospective Payment System and then a whole host of new policies for ambulatory surgical
21 centers and those are all in conjunction with a revised ASC payment system that's going to go into place,
22 January 1st, 2008. We're going to talk a little bit about the revised payment methodology. Talk about the
23 expansion of the procedures that can be performed in ASCs, talk a little bit about device-intensive
24 procedures, covered services, ancillary services to a surgery in an ASC, the transition to the new system
25 from the whole system, and then how we're going to update the system over time.

26 So a little background on the OPSS. These are based on relative payment weights. They're
27 calculated for groups of services. They're called APCs, and the APCs are similar in terms of clinical
28 characteristics and resource costs, and we look at that each year about what CPT codes and HPCPS codes

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1 should go into the APC payment buckets and then we annually update the APC groups again based at
2 looking at claims data, the cost reports, the cost to charge ratios from the hospitals come into play here. We
3 look at what the hospitals charge for the services, convert that to cost, and that's who we use to examine the
4 cost similarities for the procedures that are in the ASCs and then also the wage index. We use the hospital
5 wage index to geographically adjust the Outpatient Prospective Payment System.

6 So again as I mentioned, one of the first, the larger initiatives in the Outpatient Prospective
7 Payment System rule was to expand the list of quality measures, or actually propose implementation of a
8 list of quality measures of the Outpatient Prospective Payment System. And some of the reasoning behind
9 that when we looked at this Outpatient Prospective Payment System has been growing quite robustly over
10 the last few years, 10 and a half percent in '08 is what we're expecting, and that will take it up to about 35
11 billion, and that was about 1/3 of the Part B premium increase for last year. These are kind of the first
12 step—these reporting standards are a first step towards value-based purchasing and there were ten measures
13 that we proposed and those were surrounding emergency department AMI transfers, some surgical care
14 improvement measures, heart failure, acquired pneumonia and some diabetes measures. And hospitals that
15 failed to report would get a 2% point reduction to their payment update beginning in 2009. And if this
16 sounds somewhat similar to the way the world looks under inpatient, you would be right. This is kind of a
17 very similar system, there are less measures. It's in earlier stages, but it is somewhat patterned after the
18 inpatient system.

19 Another significant proposal has to do with expanded packing under the OPPS. If you look at
20 since the implementation of the OPPS in 2000, there's been a bit of an evolution towards smaller payment
21 groupings over time, and we decided to kind of take a step back and also MedPac did look at this as well
22 and kind of recommended that we examine larger bundles under OPPS, and some of the rationales for that
23 being that it encourages efficiency to have a larger bundle. Hospital can decide what it is they want to do
24 within that bundle. So larger payment bundles provide hospitals more flexibility to manage their resources,
25 and it's also an expansion of some of the bundling that we have now, where we package low costs, drugs,
26 and supplies. It's one of the packaging policies that we have now.

27 So our 2008 proposal was to extend the current packaging to supportive ancillary services. And
28 that included guidance services, image processing services, interoperative services, imaging supervision

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1 and interpretation, diagnostic radio pharmaceuticals, contrast agents and observation. Those were the areas
2 that when we looked at this we said OK these might be good candidates for packaging, so we've put those
3 out in the proposed rules, so we'll be put that out for comment and we look forward to getting comments on
4 all of those. And you know, seeing in again, the Final Rule will be coming out at some point towards late
5 October, early November, and that's where we'll respond to all those comments, and a little later on, I'll
6 give you more information about the comment period which closed on September 14th and some of the
7 scheduling involved with both ASC and final OPSS policies. So this was our packaging proposal. Again
8 it's significant increase in packaging and bundling under OPSS.

9 That brings us to ASCs. Again as I mentioned, we have revised payment system that's going into
10 effect January of 2008, that was required by the Medicare Modernization Act. Under the current system, we
11 have about 2500 surgical procedures that are shoehorned into nine payment groups in total. It's the current
12 system is a little old, a little long in the tooth, the last three dates are March, 1990. Using '86 data, and a
13 relatively narrow range of payment buckets there as you can see under the current system, 333 to 1339. So
14 we first issued a proposed rule on this of August of last year and then just this past July, we adopted the
15 final methodology that I'll be talking about here. So the way the new methodology works is that it's pretty
16 much patterned after the Outpatient Prospective Payment System. So we take the Outpatient Prospective
17 Payment System, kind of relativity, the relative relationships between the surgical procedures, and we
18 multiply that by an ASC-specific conversion factor. So the proposed payments are much broader than
19 under the old system from a low of \$3.15, up to \$24,000, so a much broader payment range for those
20 procedures, and the conversion factor that we've proposed is about \$41.40 that translates for 2008 into
21 about 65% of the Outpatient Prospective Payment System rates. So when I mentioned we take the OPSS
22 kind of relative payments, and then we adjust those for the efficiencies that you would find in an ASC, and
23 also that a law requires us to have the new system be budget neutral, and so by setting the payment rates at
24 65% of the Outpatient Prospective Payment System, that allows us to keep budget neutrality with the
25 current system as required by the law. In terms of the geographic adjustments, we are going to pattern that
26 after the IPPS, again using the pre-reclassification wage index, and the portion that we will adjust under the
27 ASC system is 50% so we'll be adjusting 50% of the ASC payments for the geographic differences using
28 the IPPS wage index. We've also with the list expansion, included procedures that also be performed in a

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1 physician office, more so than we had in the past, and as part of that policy for these new procedures, that
2 are currently performed in the office will be capping the payment to the ASC at the Physician Fee Schedule
3 rate. We don't want to provide any financial incentives for a case to move from the physician office to the
4 ASC and so we'll be paying the same amount for the physician office and the ASC for those office based
5 procedures. The beneficiary co-insurance will be 20%. The only exception to that is by law, for screen
6 flexible sigmoidoscopies and colonoscopies which will be at 25%, and as a general statement, the final
7 payment policies are paralleling the OPPS, and we want to have kind of uniform payment policies across
8 settings, and so that's generally speaking, if you looked at the final ASC rule, that's what we've done.

9 And as I mentioned, it's a budget neutral system compared to the old, so that's why we ended up
10 at 65% of the Outpatient Prospective Payment System conversion factor. And we looked at shifts in site of
11 service, so we expected procedures to kind of migrate from the hospital outpatient department to the ASC
12 and also some migration from the physician office to the ASC. We took that into account when setting the
13 budget neutrality and kind of looking at the, as I mentioned, the lower costs in the ASCs, we relied on some
14 GAO Report recommendations as well. In adopting the OPPS system. And then in subsequent years,
15 similar to what we do in other payment systems, we'll be updating those. We're going to use the OPPS
16 weights every year and then we will just make sure we have a budget neutrality adjustment so that the
17 expenditures don't go higher or lower in ASCs, and that will be an ASC specific budget neutrality
18 adjustment, to make sure that payments don't go up or down as a result of the adoption of the new OPPS
19 weights each year. And that's very similar thing about the Physician Fee Schedule, very similar process.
20 RVUs change. We budget neutralize that each year, same concept here.

21 Again, the other significant thing we did was expand the ASC procedure list. We've added almost
22 800 additional surgical procedures to the list and the only thing, when we looked at, we looked at pretty
23 much everything in the surgical range of CPT, and the only things that we excluded were things that pose a
24 significant safety risk or were expected to require an overnight stay. So that brings up the total procedures
25 that can be done in ASC up to about 3,300 for next year.

26 We also looked at device-intensive procedures. There are certain high cost devices that are
27 packaged into the associated procedure payment, and that will be the same under OPPS and ASCs where
28 those kind of high-cost devices will be packaged. One thing we did look at and received some public

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1 comments on this, and when we examined it we decided that it would not kind of apply that 65% factor to
2 the device portion of the procedure, the concept here being the ASCs can't get the device for 65% of the
3 cost of the hospital, so when we looked at these, we said that we would make the device payment the same
4 between the OPSS and ASC and we would apply the budget neutrality to the service portion. Covering
5 ancillary services, there are services for example, some radiology services and also some drugs, that are
6 kind of integral to the provision of the surgical procedure. And we would allow those to be paid in the ASC
7 if they're separately paid under OPSS and we have a list of those in the proposed rules, the services that we
8 would consider to be covered ancillary services if they were provided before, during, or after a covered
9 ASC procedure.

10 We are in transition to the new system. We are taking this over four years for the procedures that
11 were in the current system and those blends are 25-75, 50-50, 75-25, and then 100% in 2011, a linear
12 transition not heard of in some of our other payment systems when we've had large changes like this. And
13 that was also in response to public comment that we received requesting a longer transition than we had
14 proposed, so we went to four years from our initial proposal.

15 Again, the updates will be published around November 1st. That's in the OPSS, ASC Final Rule,
16 on or about, updated annually. We're going to again take public comment each year on any of the changes
17 that'll be again, OPSS ASC rulemaking cycle similar to what we do every year for the OPSS currently.
18 And the conversion factor will be updated beginning in 2010 based on the CPIU, the reason why there's no
19 update in 2009 is that the law does not provide for an update in 2009, explicitly. And then beginning in
20 2010, we'll be updating that conversion factor, the ASC conversion factor by the CPI.

21 Again it went on display July 16th, it was published August 2nd in the *Federal Register* and we will
22 be accepting public comments through September 14th, 2007. There's also an APC Panel meeting in early
23 September, which is a panel where they give us recommendations on different aspects of the OPSS and so
24 we'll be taking those comments as part of the public comment period as well. Some key websites for you
25 on our website if you just even did a search if you just went to our website and did a search on hospital
26 outpatient. You'd see hospital outpatient PPS and that has a whole host of information about the proposed
27 rule and supporting files and ASC similar, has a website where you can get further information.

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1 And again, the questions for the Council, as mentioned earlier, I will take questions on any of this,
2 but two of the things we were looking at were kind of how you do education. We have kind of an expanded
3 list of ASC procedures, how to kind of get the word out that those could now be performed in an ASC, any
4 thoughts there, and also about quality in ASCs. We did talk about in the proposed rule where we discussed
5 the outpatient measures, we did say that we, through future rulemaking, we wanted to address quality in
6 ASCs, quality measures, and reporting quality measures in ASCs and were going to kind of seek comment
7 on how to do that, so any thoughts that you might have, either now or in the future, on appropriate
8 measures or where to look at ideas for quality measures in ASCs would be appreciated. And so with that,
9 that's my contact information. If anybody has any questions or wants to follow up, but we can take
10 questions now on anything I discussed either in OPSS or in ASCs.

11 Dr. Senagore: Dr. Sprang?

12 Dr. Sprang: Just an area I'm very interested as far as kind of doing more procedures I'll say in the
13 office setting, as opposed to the ambulatory or hospital. And I just you were commenting on you expected
14 some transition obviously from hospital procedures to the ambulatory. But you also said from physician
15 offices to ambulatory. Why would you think that?

16 Mr. Thompson: Well, even in spite of the capping of the procedures from the physician office,
17 when the Office of the Actuary looked at the procedures that were predominantly performed in an office
18 now, it was in fact the case that about 15% of those procedures were also performed in an ASC. So even
19 where you had under the current list, where you had procedures, that could be performed in the office, and
20 in fact, the vast majority of time were performed in the office, it was still 15% of the time that they went to
21 the ASC. So when we were looking at this, we thought, well similar to what exists under the current
22 system, where you have 15% of the procedures done at ASC, it seems like that even for office-based
23 procedures that 15% of those might end up in the ASC for similar reasons, so that's what's happening
24 under the current system and we expected that would happen under the new system.

25 Dr. Sprang: OK, so you mean for the new procedures that are now being performed?

26 Mr. Thompson: That's correct.

27 Dr. Sprang: OK, yeah, just in looking at it, I'll say it's more and more procedures are clearly being
28 done in the office in my office, for instance, we do coplastopy and LEAP and cervical biopsies. We also do

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1 D & Cs, endometrial ablations, and tubal ligations, which is kind of a, some people would be amazed at
2 that, but we can do that in the office with the new equipment and the new procedures and clearly the
3 advantage, maybe not as much for Medicare, because there are not that many patients that are getting those
4 procedures, but if you perform them in the office, it's safer and more convenient and significantly less
5 expensive than to walk into an operating room in the hospital that's \$10,000 when you walk into the
6 operating room. How does, as far as this goes, as far as where we're going now as actually payment to
7 physicians, if they're saving that much money from Part A and doing things in the office, does it affect
8 what the physicians are getting paid for what site of service?

9 Mr. Thompson: Are you saying do we take that into account?

10 Dr. Sprang: Are you now in I guess going forward, I'd like to obviously see more of this on that
11 because it's saving so much money from Part A.

12 Mr. Thompson: Oh and part of the Physician Fee Schedule in general each year, you know there's
13 obviously a payment differential between the facility and the nonfacility, and each year that gets
14 reexamined for procedures that we may not have costed out in the physician setting in the past, so as it
15 appears through the practice of medicine, you might have a situation where things were migrating into the
16 physician office and if we felt that was appropriate, yes, we would look at the inputs under the Physician
17 Fee Schedule, and we have in the past, and created payment rates for services that were prior to that, not
18 available for office-based payment that we might have considered strictly facility. So that's an ongoing
19 process that would continue in the future where we look at, as the practice of medicine changes, and also
20 the AMA's Relative Value Update Committee would make recommendations where perhaps in the past
21 they hadn't given us inputs under the Physician Fee Schedule for a service because it was predominantly
22 performed in a facility. As that changes over time, certainly they give us inputs on those and they become
23 valued under the Physician Fee Schedule.

24 Dr. Sprang: The thing about actually rewarding physicians for doing it in that setting, which is a
25 safe and appropriate and cost effective.

26 Mr. Thompson: It is difficult sometimes from a budget neutrality perspective to determine kind of
27 when you look at growth of a procedure in any given setting and it talks about migration between different
28 sites of services, it's difficult sometimes to isolate kind of the reasons for that and budget neutralize it. In

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1 other words, we don't have a system where we look at site of service shifts between inpatient and
2 outpatient and ASCs and offices and attempt to attribute causality to that. Was it because of a new payment
3 system or was it because of a specific policy to do that on a code by code basis, is quite a Herculean task.
4 So that's not something that we normally attempt to do when we look at budget neutrality. We usually stay
5 within a system and this particular issue for the ASCs we did look across and make some global
6 assumptions about migration between an outpatient hospital and an ASC and also some kind of global
7 assumptions about migration between physician offices and ASCs, but that wasn't done necessarily looking
8 by code by code and saying we think this procedure is going to migrate X % of time and this procedure will
9 migrate X% of time, doing that across 3,300 procedures, with any degree of accuracy would be quite a task
10 and I haven't seen anybody who has actually done that even in the public comments that have been
11 received on the system. So inherently difficult, even with ASC which one might argue in this arena is a
12 low-lying fruit, compared to looking at shifts across all our payments over time, that's not an easy task
13 from a budget neutrality perspective.

14 Dr. Sprang: I realize it's not easy, but I guess what I see as a very positive aspect to it. I'll use the
15 endometrial ablation for somebody who's having heavy periods prevents a hysterectomy and that's
16 something you do in the office. You're obviously looking going forward with more and more of that kind
17 of thing will be done, so you're actually going to see savings in other major surgical procedures, which are
18 being done more economically, more efficiently and in the best interest of the patient; much, much simpler
19 surgery solves the problem.

20 Dr. Senagore: Any other comments or questions? Very good. Thank you. We'll move on the
21 Medicare Contractor Provider Satisfaction. I believe we have a change in game plan. I think Mr. David
22 Clark will be speaking to us due to an unexpected illness. Dave is the Director of Provider Relations and
23 Evaluations, with DPRE, as such he oversees a variety of CMS initiatives designed to allow provider
24 feedback. One such initiative is the MCPSS, that we will talk about today, which measures provider
25 satisfaction with the service provided by Medicare in Fee for Service. Welcome, Mr. Clark.

26 Medicare Contractor Provider Satisfaction

27 Mr. Clark: Thank you, Mr. Chairman. Good afternoon and again thank you for allowing me to
28 share with you what we're doing with the Provider Contractor Satisfaction Survey. This afternoon, I'm

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1 filling in for my manager, Gerry Nicholson, who is recuperating right now, and I'm sure she would like to
2 be here doing this instead of what she's challenged with right now. This afternoon, what we're going to do
3 is to share with you basically two pieces of the survey, along the lines of the responsibilities of the two
4 groups that are involved with the Contractor Satisfaction Survey. For us, in the provider communications
5 group, I'll be talking about the administration of the survey, and the results that we achieved in 2007 which
6 is our second national administration of the survey. Karen Jackson will be talking about what will happen
7 as a result of the survey, and with respect to the Medicare contractors. And as mentioned in the outline
8 there, I'll go over the methods for administering the survey. I'll talk a little bit about the results and the
9 analysis of the scores that we received, as well as talking about the survey, with respect to the Medicare
10 administrative contract environment. And a little bit about next steps.

11 As I say, this was our second national administration of this survey, and in preparation for that, we
12 conducted extensive testing of the survey with the providers and physicians that would be participating, or
13 that would be affected by the survey, as well as inhouse what the subject matter expert's responsible for
14 each of the business functions that the survey covers. It's mentioned that we made a couple changes in the
15 instrument for 2007, that rather than look at 6 months prior services by the contractor, in 2007, we changed
16 that to a 12-month period. We also through the cognitive testing, we were able to reduce the length of the
17 survey by 10 questions. In terms of the methodology for 2007, we sampled some 36,359 providers. This
18 was a statistically valid sample across all of the Medicare contractors. We used the Medicare claims history
19 to identify our sample frame which was then matched against various CMS files for contact data for our
20 various providers. We also used an outside source in terms of validating some information for providers in
21 terms of contact information. For 2007, we challenged ourselves with one of the two things that we were
22 trying to do with the survey and administering it. First of all, wanted to shorten the cycle time. From 2006,
23 we administered the survey starting in January, but reports were not out to the public until October sort of
24 beginning, middle of October 2006, so for 2007, we wanted to shorten that time to get the survey results in,
25 complete the data collection period and turn that around for the public and more particularly for the
26 contractors, in terms of the results of the 2007 survey. To that end we were successful. We were able to get
27 the reports out in July of this year.

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1 The other activity that we took on was to try and increase the awareness of the survey. This is a
2 fairly new responsibility for CMS, and fairly new responsibility for physicians and providers. So that we
3 see it as a particular challenge to increase the awareness and understanding of the survey as an opportunity
4 to provide feedback in terms of how contractors are performing in terms of serving Medicare providers so
5 that takes quite a bit of work and we were particularly appreciative of the endorsements that we received
6 from various provider and physician organizations. We think that's very important in terms of our being
7 able to get and enjoy the sort of 65% response rate that we received this year in 2007.

8 As I mentioned the data collection period started January 2, 2007 and extended through April 20th
9 of 2007 and already mentioned, we received a 65% response rate. This is similar to the response rate that
10 we achieved in 2006. In scoring the survey, physicians and providers have an opportunity to score one
11 through six, where one indicates that an individual is not at all satisfied with a particular function or
12 service, and six represents completely satisfied. The national average for the survey in 2007 is 4.56.

13 On this chart, we're just trying to show how that 65% response rate breaks down. And looking at
14 the completed surveys, the non response rate, ineligible, and unable to contact, which was subtracted from
15 the base of our, or the net result was 65% response rate that we achieved with the survey.

16 For the response rate by contractor type, you can see through this chart, a comparison of the
17 response rate from 2006 to 2007. Going back please, and just basically with the fiscal intermediaries and
18 the RHHI contractors, there was a slight increase in the response rate while the contractors, the carriers and
19 the DME, there was a slight decrease in the response rate, looking at the two years. This next slide gives an
20 indication that the mode of administration that for 2006, there was a slight decrease in the number of
21 respondents to the survey by telephone and mail and Fax, where an increase in the use of the web and
22 Internet for 2007. This next slide, just again, shows the average score by contractor type. The line going
23 across just above 4.50 represents the national average score and as you can see, for fiscal intermediaries
24 and RHHIs, they were slightly above that average, and carriers and DMEs were below. And this next slide
25 is just a different way of showing similar information. The scores across the bottom represent the individual
26 scores for a contractor type. Going up the side is just a numeric count of the number of contractors that had
27 similar scores and while it's a little bit difficult to tell but if the colors were a little bit clearer, you would be
28 able to see that at the right side of the chart that the carriers and the DME suppliers, their scores were a

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1 little bit lower than what the fiscal intermediaries achieved, whereas on the left hand of the chart, with the
2 carrier scores, they scored a little bit lower, in the 3.9 range to 4.1, whereas the fiscal intermediaries and
3 RHHI were scoring much higher at 4.5, 4.9, 5.2 and so on. So carriers are on the left side of the chart, and
4 the fiscal intermediaries are on the right side of that chart.

5 And this chart we're attempting to show the scores by provider types by carriers and DME
6 contractors. And you'll see that the physician suppliers, their scores were 4.27 and that's on the far left side
7 of the chart, whereas the other Part B providers that were billing carriers on the extreme right, scored the
8 highest at 4.66. And I won't read through each one of those, but it's sort of a break out of how the carrier
9 and DME results or scores were by provider type.

10 This chart is attempting to show the scores by business function. There are seven business
11 functions in the satisfaction survey. Those are listed on the left side under benchmark. It again shows the
12 different contractor scores, but the last column we tried to emphasize what physician scored each of the
13 business functions, say as compared to the carrier. And just for example, with inquiries, the carrier scored
14 4.42 as did the physicians, when there's a difference say the appeals, which is sort of the middle of that
15 chart, the carriers scored 4.23, whereas physicians scored 4.27 and FIs scored 4.50.

16 At this point, I'd like to turn it over to Karen.

17 Ms. Jackson: Thank you, David. Good afternoon, my name is Karen Jackson, I'm the Director of
18 the Medicare Contractor Management Group, and work frequently with David and Gerry Nicholson in
19 assessing the results that come out of the Medicare Contractor Provider Satisfaction Survey. This has
20 turned into a very interesting tool for CMS and for my function in particular, both as we assess current
21 carrier and intermediary performance, as well as during the time that we're preparing the scopes of work
22 and the quality assurance surveillance program for the Medicare Administrative Contractors that we're in
23 the process of implementing and I will say that the chart that you saw on slide 11, those results that you see
24 on that chart, we also see by contractor and the carriers and intermediaries see those specific by contractor,
25 they ask for and have asked for a tremendous amount of detail into the questions and the responses specific
26 to their own contracts. They're looking at this, they're looking at where they fall out among their peers and
27 their competitors and we are certainly using this as a tool, one of many, to look at individual contractors
28 and their overall performance of their contracts. And it will become an even more important tool in the

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1 future and you can just switch back to that later slide, thank you, as we start to incorporate it into the
2 surveillance program that is tied to award fees under the MAC contracts.

3 Let me talk for just a minute about what we're doing with the current carriers and intermediaries
4 and those Medicare Administration Contractors that have been implemented in terms of sharing with them
5 their results and looking to them to provide some further detail in terms of specific functional
6 improvements that they would be tying off of their survey results. As I mentioned earlier, carrier
7 intermediary staffs are very interested in the contract specific results that are coming out of the provider
8 satisfaction survey. And David and his team as well as my team spend a lot of time on the phone with the
9 contractors and in on-site visits with the contractors, looking at not so much the specific question responses
10 but the overall rolled up responses and tying those to other performance measures that we use to assess
11 performances. The carriers and intermediaries, some historically have performed their own provider
12 satisfaction surveys and in some instances, we have made some small adjustments to the question set to try
13 to assist us in assessing specific contractor performance, particularly as we're implementing MAC
14 jurisdictions. One of the very critical areas obviously for the practitioner community is the consolidation of
15 local medical review policies, and the way in which we have approached that in the first implementations
16 very clear was conveyed back in terms of the provider satisfaction survey results for jurisdiction 3 that has
17 helped us to adjust the processes that we'll be using for consolidating local medical review policies for
18 future implementations,

19 This just gives you a bit of detail on what the carriers and intermediaries see in terms of the
20 specific questions that come in and where an individual carrier, and in this instance, a carrier scored both
21 on the specific questions and then also in terms of the mean score. We, I think any statistician or analyst
22 would know this, but I'll state the obvious, carriers focus their attention on those questions where the
23 responses are falling in the lower right hand corner, where they have been indicated as being of high
24 importance and lower satisfaction rating, and those are the areas where we're focusing in terms of our
25 oversight and our ongoing performance monitoring in assuring that the carriers and intermediaries are
26 focusing their outreach and education activities and to some extent some of their operational activities to
27 address these issues. Moving on to the next slide, another one where there's no real big surprise, this is the
28 coefficient assessment. Satisfaction is more strongly correlated when you have an interaction with the

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1 carrier and intermediary and very clearly, the provider inquiry and outreach and education area is a critical
2 area for the practitioner community. And one that very clearly ties satisfaction to the function itself.
3 Slightly lower correlation to claims, and I think in the other functional areas, you see an even slighter
4 correlation so obviously we're looking very closely at that coefficient inquiries. That's an area that we're
5 really focusing in in terms of assessing the elements of the Medicare Administrative contractor scopes of
6 works and performance assessment plans, as well as making sure that we're adequately staff, and the staff
7 and the provider education and the inquiries management area, the carriers are well educated in terms of
8 contractor training on Medicare policies and claims processing requirements.

9 As we look at this tool, in our very significantly changing operationally environment, this
10 becomes a very important factor for us, as we're implementing Medicare contractor reform. So you all
11 know it was a legislative requirement. We are using this in a couple of different ways. We do expect that as
12 a result of the competitions, we will see some continued improvement in scores, for a couple of reasons;
13 one, this is a factor that we assess, as we're looking at past performance for bidders. For the Medicare
14 administrative contracts, and those of you who have seen our maps know that we're intending a very
15 significant amount of consolidation as we implement the MACs, both in terms of the number of entities and
16 also the consolidation of A & B, fiscal intermediary and carrier operations, so this is an important tool for
17 us during the competitive process, and the carriers and intermediaries who are intending to bid for MAC
18 workload recognize that and I think that that's part of the reason why they're paying such close attention to
19 it in addition to our expectations for performance. In addition, the current data that we're getting from last
20 year and this year's survey results are helping us to develop and establish some baselines for the larger
21 MAC jurisdictions that we're implementing over the next couple of years. Both in terms of what we would
22 expect scores to look like as we're approaching this implementation which will necessitate some changes in
23 claims submissions as contractor front ends are changed, changes in transmission of claims are local
24 medical review policies are consolidated, we want to get a good sense of what the baseline satisfaction
25 levels are within a given MAC jurisdiction so we know how we're doing as we're implementing the
26 contracts as the MACs are coming online and completing their first year of performance. Before we begin
27 to implement this into the award fee plans.

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1 Contractor Oversight. This is an important tool for us. It gives us a formalized and very structured
2 mechanism for getting provider input and giving us some comparative performance information across the
3 carrier and intermediary community and we expect that to continue as we implement the Medicare
4 administrative contracts. I indicated already we're using the current data to establish a baseline. We will be
5 using that to correlate to the ongoing system changes that are being made, but also the consolidations that
6 occur with the consolidation of contracts. And after we get through the first year of MAC contract
7 performance, we would be expecting to incorporate the satisfaction survey results. Some metric for
8 consideration in determining an award fee for Medicare administrative contractor in a given jurisdiction.
9 We don't expect to do that in the first year of operations, just because the amount of change and the amount
10 of work that an individual Medicare administrative contractor would be going through to actually
11 implement the contract in these very large jurisdictions. But although despite the fact that we won't be
12 incorporating into the award fee plan for the first year of performance, it is a strong indicator of overall
13 satisfaction with that company's performance and the agency's performance in the implementation of the
14 MACs and so we intend to use it in that regard.

15 I think these are all familiar websites for you and your constituents and colleagues. We have
16 appreciated very much the input that we've gotten from the practitioner community, both as we've
17 developed the award fee measures for the Medicare administrative contractors, as well as the input that
18 we've gotten on the provider satisfaction survey and improvements that we've made over the past couple of
19 years. And would expect to receive your input and feedback over the next couple of years as we continue to
20 refine this model.

21 There is also a final slide that gives you last bit of information where as you're completing the
22 response to a survey, if something's not working, this is the place to go. Westat is the contractor that has
23 worked with us to develop the survey instrument and the analysis tools, and they have a specific help find
24 for you and your constituents as you're completing your surveys. We are very gratified with the strong
25 response rates that we've gotten. A little bit disappointed that we didn't see an increase in overall response
26 rates from last year to this year, but hope that with your assistance we'll be able to make sure that we get
27 good response rates in this year's survey.

28 Thank you and we're certainly ready to take any questions or comments that you have at this time.

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1 Dr. Senagore: Comments or questions, regards the survey data? I know we had some questions
2 last time?

3 Dr. O'Shea: Will we be continuing this because I saw it was between, it was about 3 and a half
4 months that this was taken from. Will this satisfaction survey be continued?

5 Mr. Clark: Yes, it'll be conducted annually.

6 Dr. O'Shea: Annually, with the same kind of time frame?

7 Mr. Clark: Yes. In fact I didn't have a slide in terms of next steps, but we are already beginning
8 the development of the sample frame for 2008. Between now and the end of the year, we will do 100%
9 validation of the sample frame and then begin a roll out toward around December with data collection to
10 begin in January. And that's sort of the cycle that we will continue for each year, January completing the
11 data collection by the end of April, and hopefully reports out by beginning of July.

12 Dr. O'Shea: I have a recommendation I'd like to make. PPAC requests that CMS continue the
13 Medicare Contractor Provider Satisfaction Survey with capability of consideration of physician satisfaction
14 with who have participated with the Recovery Audit Contractors. So what I'm asking is that in this
15 satisfaction, could you be able to give another query of have you worked with a Recovery Audit
16 Contractor? Since that's going to be rolled out across the country, it wouldn't just be California or Florida,
17 but if you can actually do that in your satisfaction to see if physicians are satisfied by the way they've been
18 treated by the Recovery Audit if that's possible.

19 [Second]

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

21 [Ays]

22 Dr. Senagore: All against? Motion passes. Any other comments for our guests? Thank you very
23 much. Best wishes to your boss.

24 Mr. Clark & Ms. Jackson: Thank you.

25 Dr. Senagore: We'll take a 10-minute break here and we'll reconvene for the NPI discussion.

26 Break

27 Dr. Senagore: The last major presentation that we have today is the NPI Data Dissemination Notice. This
28 will be of some interest to the group. Our presenters will share the most recent on that issue and we have

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1 Mr. Jim Bossemyer, who is the Director for the Division of Provider and Supplier Enrollment in the
2 Program Integrity Group. Previously, Jim held various management and technical positions within the
3 Centers for Medicare and Medicaid Services and the Social Security Administration. And his is joined by
4 Ms. Patricia Peyton, a health insurance analyst in the Division of Provider and Supplier Enrollment,
5 Program Integrity Group. And Pat is responsible for developing a national plan and provider enumeration
6 system data, dissemination notice. Prior to assuming her duties, she led the Regulatory Development for the
7 Standard Unique Healthcare Provider Identifier. And I guess you can decide amongst yourselves who will
8 go first.

9 NPI Data Dissemination Notice

10 Ms. Peyton: I'll go first. Hope I'm not too loud. This presentation is about the NPPES and BPE
11 Date of Dissemination Notice. These slides will go over the notice, what providers should be doing, or have
12 been doing all summer to get ready for data to be disseminated. A little bit about the NPI Registry, the
13 downloaded file, and then our contact information. These are some websites that we've given out in other
14 and probably have on the CMS NPI webpage. That's the first website up there. That's where CMS makes
15 available all of our information about the NPI, whether it's, how to get enumerated, what Medicare is doing
16 to implement the NPI, data dissemination. The next website, the one HTTPS: that's the NPPES website.
17 That's where providers go to apply for NPIs, furnish updates, they can view and edit their data from that
18 website. And the NPI registry, which I will talk about in a minute, starting September 4th, that'll be a look
19 up table, like a look up data base, and that's its URL right there. And then the last bullet is the
20 downloadable file, which will be ready the second week in September and that's the location of the file. Of
21 course if you try to get to the registry now, or go find the file, you're not going to find either one, because
22 they're not there yet.

23 The Data Dissemination Notice was published on May 30th and that notice listed all the data
24 elements that CMS is going to be making available. They are all disclose-able under the Freedom of
25 Information Act, that's what the FOIA stands for, and we will make them available in two ways, on the
26 Internet in the NPI Registry, and on the downloadable file. And each of those, like when you view data in
27 the registry, you'll see all the FOIA disclose-able data for the provider you selected and all that same
28 information will be in the downloadable file. And anybody who wants like data only on providers in New

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1 York, for example, or only a certain type of provider or more or less data that what we'd be making
2 available ordinarily, would have to request that information under the general FOIA procedures.

3 This is the information that we're not going to be disclosing in the registry or the downloadable
4 file. Most of this pertains to individuals. Social Security Number, also the ITIN, which is the number
5 assigned by the IRS to individuals who aren't eligible for Social Security Numbers. We're not making
6 those available either. There aren't that many of those in there actually. The date of birth, the state of birth,
7 or the country of birth of individuals. We're not going to make available the contact person information for
8 either providers that are individuals or organizations because I mean the contact person really isn't the
9 provider in most cases. In the cases where it is, you will already have the necessary provider data out there.
10 And we're not going to make available any data for providers who have deactivated their NPIs, whether
11 they're individuals or organizations, and this is because nobody should be using deactivated NPIs in any of
12 the HIPAA transactions.

13 Now we have delayed for most of the summer the disclosure of this data in order to give providers
14 time to look at their data and edit what we're going to be disclosing. We're sure that all providers want
15 their data to be accurate, and while they have always been able to furnish updates, I think a lot of them
16 probably didn't really think about it. You know you get your number and then you kind of don't think
17 about it anymore, but it is important that information be accurate, and then for some of the data elements
18 that we're going to be disclosing, some providers, particularly individuals, might want to go in and remove
19 what they might consider to be sensitive data. Some of them I know consider their DEA numbers sensitive
20 and they may have reported them in the other provider identifiers field, which is an optional field when you
21 apply for an NPI. Also quite a few individuals reported their Social Security Numbers under that other
22 provider identifiers field because some health plans do use the SSN as an identifier for a provider. So it
23 would be a good idea if they you know, took anything like that out of there. We did put a guidance
24 document on the CMS NPI webpage on June 20th, that was designed to assist providers, and here are the
25 data elements, here are the ones you can't change, like your NPI, here are the ones you can completely
26 remove and here are the ones you can just update if you want. And then we have also been going behind
27 the scenes to ensure that we don't release somebody's SSN or ITIN in any of those FOIA disclose-able
28 fields, like the other provider identifiers. So even if a provider maybe never got the word, never looked at

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1 the data, but put their SSN some place where it shouldn't be, you won't see that SSN out there when this
2 information comes out.

3 The NPI Registry, like I said, is the first thing that's going to be available and that's coming up
4 soon, September 4th. And this is where anybody with a computer and Internet access can go on and query
5 by the provider's name, by NPI, by zip code or state, then they're going to get back a screen with the
6 results of their search, and then they can select the providers by the results page that they want, because it
7 might pull up more than those that they really want. And then it will display all the FOIA disclose-able data
8 for whatever provider was selected. Now if you do query by an NPI, the first thing you see is Organization
9 or Individual. So if you put in an NPI under either one, like say you made a mistake, the NPI will, the data
10 will show up whether it's an individual or an organization, just not to waste anybody's time. And then the
11 downloadable file will come shortly after the registry. We expect the second week in September, that will
12 be out on the Internet. And what it is is going to be a snapshot at a certain point in time of all the FOIA
13 disclose-able data for all the providers in NPPES except those who have deactivated their NPIs. This is a
14 very large file. And embedded in it will be a Read Me document that talks about the file, a code value
15 document because there are some codes in this file, whereas in the registry, everything's spelled out, the
16 header file, and then the data file itself. And we have made available the Read Me document, the code
17 value document and the header file on the CMS NPI webpage because a lot of people wanted to see that
18 beforehand, and then each month the file's going to be fully replace with another file for download.
19 Initially in the notice, we said there'd just be update files each month, but we thought the people who
20 download those files might have a hard time tracking the updates with the providers in that initial file, so
21 this way if you come in late and you just download the file, you get the whole thing. So any given month
22 there's only one file for download and it has everything in it. And then the people who download those files
23 are going to have to be technically qualified to do so because they've very large, because once they
24 download it, they'll have to know what they're doing in order to manipulate the data. I mean these people
25 know who they are, but it wouldn't be for somebody like me to sit there and try to download that file. I
26 don't think it would work too well.

27 There's no charge or fee to use the registry or to download the file. Don't need user IDs or
28 passwords to do either and CMS is not and the NPI enumerator out in Fargo are not going to be able to be

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1 providing assistance to people who want to download that file or manipulate the data. Like I said they will
2 know how to do it, if they're the right people for the job.

3 And that's my contact information if anybody has any questions.

4 Dr. Senagore: Comments or questions?

5 Dr. Bufalino: I had a question. So if I went to the data base now could I call up and say give me all
6 the cardiologists in the state of Illinois and it will generate it by specialty?

7 Ms. Peyton: You could go in on the state of Illinois, but you couldn't fine tune it far enough, I
8 don't believe for the cardiologists. I mean if that's what you really wanted, you could send a FOIA
9 request—

10 Dr. Bufalino: Well let's just say I needed it for the primary care referral data base in my
11 community and I wanted their NPI numbers. I couldn't just call up family practitioners and internists.

12 Ms. Peyton: It's not going to be that fine tuned at this point in time anyway, the registry.

13 Dr. Bufalino: So I'd get Illinois, I'd get sort of all comers in Illinois.

14 Mr. Bossenmeyer: What you'd get is on the look up registry that's going to come back in terms of
15 you'd make request by name or NPI number, so it's for the simple search. What you're looking at is a more
16 complicated search and you'd need to be able to look at the larger downloadable file to obtain that
17 information and manipulate the data so you'd cut it down to Illinois, then maybe you'd look at something
18 like taxonomy codes and so that would further give the data that you'd want, so you can't do that on the
19 NPI registry, but you will be able to do that manipulating the downloadable file.

20 Dr. Bufalino: So Taxonomy, I'm not sure—

21 Ms. Peyton: Well, that's like the specialty. When the providers apply for NPIs they choose a
22 taxonomy code, but it is the Medicare specialties plus many, many more. It goes down three levels.

23 Dr. Bufalino: So you could ultimately get someone sophisticated enough to play with the file, they
24 could pull out and pull out all the urologists in that community.

25 Ms. Peyton: I'm sure you'll see many things out there once people download that file and create
26 all kinds of nice things that people will want. Yes, they would be able to do that.

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1 Dr. O'Shea: You said that there will be a forward placement file available. Do you have an idea—
2 is that going to be the first of the month, the 15th of the month, if I want to look up a new one, if I want to
3 see if my information has been changed, and is correct, when will that be available?

4 Mr. Bossenmeyer: Well, actually, as your information becomes available, or as you make a change
5 to your information, we release the look up file. The data that we have on the NPI Registry is real time. So
6 once it changes, it will change on the NPI Registry.

7 Dr. O'Shea: But you also said a full replacement will be coming out monthly—first, 15th, 30th?

8 Ms. Peyton: It'll probably be more like the 11th or 12th. It's going to be based on when we get that
9 first one out. And then I mean it would be around that same date. We'd be putting information on the CMS
10 NPI webpage. I mean it would be nice if it could be the first or the last, but it...

11 Mr. Bossenmeyer: But for an individual, wouldn't she receive an approval that your NPI has been
12 updated, you can go on look at the NPI Registry and you'll be able to look that up and you'll be able to see
13 the changes and that'll happen in a real time environment.

14 Dr. Przyblski: About how big is the file and do I need a new hard drive?

15 Ms. Peyton: 670—

16 Mr. Bossenmeyer: Well, you're looking at 2.3 million records, so it's going to be an extremely
17 large file, it's probably not something you're going to be using on your PC.

18 Ms. Peyton: It's too big for Excel.

19 Mr. Bossenmeyer: Yes.

20 Dr. Ross: Just wondering how many did not sign up for their NPI numbers, and what's the
21 recourse for those who let the time expire, who have not gotten NPI numbers, and what do they do, or how
22 do they contact CMS or what's the protocol now?

23 Ms. Peyton: Well the regulation required covered providers to obtain NPIs and of course covered
24 and non covered have NPIs. We estimated that there were about 2.3 million covered providers in the
25 country and another 3.2 million non covered, like mainly nurses was the biggest. I think there's 2 million
26 nurses that probably aren't covered providers because they work in hospitals and things like that, but not
27 being a covered provider and not getting an NPI could subject somebody to the penalties and fines under
28 HIPAA itself. So but of course they're all based on a complaint, so somebody would have to file a

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1 complaint with CMS that so and so or such and such is a covered provider and doesn't have an NPI and
2 then that would follow through.

3 Mr. Bossenmeyer: If an individual organization has not obtained their NPI to date, it's a very
4 simple process. They can do one of three ways; they can go onto the website and obtain their NPI. Generally
5 that can be obtained in a few days. They can use a paper application and submit that information today and
6 that will get processed by the enumerator. Or, for larger organizations that are obtaining lots of NPIs either
7 for their own organizational subparts or for practicing physicians within or other individuals within their
8 organization they can use the electronic file interchange process. I guess it's more what we'd refer to as
9 bulk enumeration. But to obtain an NPI for an individual or an organization, the easiest process is use the
10 Internet. You can have NPI either later that day or within a few days.

11 Dr. Ross: Good.

12 Dr. Arradondo: You mentioned that you opened the registry for edits. Did you close it, or is it
13 going to remain open?

14 Ms. Peyton: That's the NPPES that's open for edits, well not open, but the NPPES is always there
15 for edits. Somebody can edit their data at any point, but not on the registry. That's just a display.

16 Mr. Bossenmeyer: And by regulation, individuals and organizations are required to update their
17 information. If there's a change, within 30 days of that change.

18 Dr. Arradondo: I was asking this actually from the perspective of the disclose-able data, which
19 you've spelled out now, and it includes most of that that had been objectionable among the various letters
20 and statements that associations made, etc., but that edit can be made at any time is what you're saying
21 now, is that right?

22 Mr. Bossenmeyer: Individuals and organizations can update their information at any time.

23 Dr. Arradondo: Yes, right, sure. That's good.

24 Dr. Ouzounian: This is kind of a follow up to Dr. Ross's question, but actually gets off on a
25 different tangent and I don't now if it's particularly your expertise, but probably involves you people. In
26 California, I think there's some providers that are solo or that might be incorporated and somehow they got
27 NPI numbers as a solo practitioner, but because they're incorporated they've created some sort of problem

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1 with their NPI number and they have to re-enroll in Medicare and get a new NPI number. And are they
2 going to be given adequate time to get all this fixed?

3 Mr. Bossenmeyer: There's actually—you've got a couple different questions that you're asking.

4 Dr. Ouzounian: I think so. [laughter] With a lot of confusion, and it sounds like you know the
5 answer.

6 Mr. Bossenmeyer: For a few of them maybe. The first step would be knowing what types of NPIs
7 that you need to apply for. If you are an individual practitioner that has a solo, you're a sole proprietorship,
8 you only need one NPI. But practice of medicine today, many physicians are incorporated or they have a
9 corporation also, in that case, it's like that they're going to need two NPIs; one for their individual purposes
10 because they may work in multiple settings, as well as having one for their own personal practice. So they
11 may need a second NPI. So obtaining an NPI in and of itself doesn't convey any billing privileges. That is
12 conveyed by the health plan that you are seeking to receive reimbursement from. So in the case of
13 Medicare, the first step would be obtain your NPI. We request that you include all the Legacy identifiers, so
14 for that particular NPI that you're requesting, so if it's an individual, you take the UPINs that are associated
15 with that individual practice and include those in as the other identifiers. If it's an organization, you'd do
16 the same, include the other identifiers in that process. We are encouraging providers to submit their
17 enrollment applications, claims processing in most cases will work fine. But there will be cases where
18 claims will not process because we can't make the associated match and in which case you may need to re-
19 enroll in Medicare and update your enrollment information with Medicare.

20 Dr. Ouzounian: Will there be an adequate notification time for the provider to do that if he has to
21 do that?

22 Mr. Bossenmeyer: We're certainly encouraging people to test early and so that testing process has
23 begun for many people. We've been issuing NPIs since May 2005. The testing period has been ongoing for
24 more than a year now, so we encourage people to first and foremost obtain their NPIs, use those in a
25 testing process, and if necessary make changes in their enrollment information or in many case, physicians
26 or other practitioners have not submitted enrollment information to Medicare more than five years, so they
27 can update their enrollment information by completing the appropriate enrollment applications.

28 Dr. Ouzounian: Thank you.

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1 Dr. Sprang: I think you did go into significant detail on it, but just because of the concerns so
2 many of the members of PPAC and obviously the medical community on sensitivity of some of the
3 information, I just want to make sure that I understand it clearly. Social Security Numbers and home
4 addresses will not be put into the public domain?

5 Ms. Peyton: Social Security Numbers will not be disclosed. I mean they're, the only place they
6 really should have been reported is in the identifying information section you know, name, SSN, and not in
7 these FOIA disclose-able fields. But like I said, CMS is going behind the scenes and say on Dr. John
8 Smith's NPI record, he has his SSN in there where it's supposed to be and if those 9 digits show up any
9 place out, they'll be blanked out, I mean it won't be there. Home address we expected when we designed
10 the application to get the business mailing address and the business practice location address. We found out
11 after we published the notice that quite a few providers put their home addresses down as the mailing
12 address, so we tried to put on our website information that hey, if you want to go in there and change it, you
13 can. You can always change your address, so presumably they have gone and changed the addresses from
14 their residences.

15 Dr. Sprang: OK, even as a PPAC member, really didn't see those notices and would not have gone
16 in and changed it, so but I will have my office do that.

17 Ms. Peyton: And they can be changed at any time.

18 Mr. Bossenmeyer: It's a very simple process for updating or changing your information and CMS
19 is conducting an awful lot of outreach through the NPI website, through the list serve articles, partnering
20 with other organizations, so we're trying to reach out to all segments of the medical community about the
21 importance of first obtaining the NPI and then updating that information.

22 Dr. Sprang: Because of the sensitivity of it, and concerns about identity theft, I thank you for not
23 including that information.

24 Dr. Senagore: Any other comments or questions? Thank you very much. Now I believe we have a
25 little bit of testimony before we circle back and review our recommendations. I think we only have one
26 individual today, and that is Dr. Jonathan Myles to present testimony on behalf of the College of American
27 Pathologist. Dr. Myles is a pathologist at the Cleveland Clinic. Welcome.
28

1 Public Testimony—College of American Pathologists

2 Dr. Myles: Good afternoon. My name is Jonathan Myles and I'm presenting the College of
3 American Pathologists' concerns regarding CMS's Medically Unlikely Edits or MUEs and the most recent
4 proposed physician payment regulation. We applaud CMS's efforts to reduce fraud and abuse in the
5 Medicare program and we recognize that MUEs are intended to lower Medicare's paid claims rate through
6 identification of billing and typographical errors. We do, however, have concerns about the process under
7 which these MUEs are being developed. These concerns center around three areas; one, movement toward
8 nonanatomic MUEs, based on clinical judgment; two, reliance on ad hoc data; and three, inconsistency in
9 communications on MUEs. First we are concerned that while the first four releases of MUEs have largely
10 focused on anatomic edits, instructions for phase 5 have clearly stated that CMS is beginning to develop
11 MUEs based on clinical judgment. Determining medical necessity based on clinical judgment represents a
12 great degree of complexity, and it is not clear that in the current review process, adequately provides for an
13 open and transparent discussion, regarding the maximum units of service that are medically necessary for a
14 given code. Relying on clinical judgment potentially encroaches into the realm of payment policy, rather
15 than pure enforcement of existing rules. Yet MUEs are currently being implemented without the safeguards
16 of the rulemaking process. A key concern is that the practice of pathology is complex, and spans many
17 subspecialties that each has its own knowledge base. We endorse the creation of an MUE work group that
18 includes expertise from pathology and appropriate clinical specialties as well as CMS and their contractor,
19 that would enable edit development that accurately reflects current practice of laboratory medicine. An
20 MUE work group would also provide an appropriate venue for recourse to address concerns about lack of
21 clinical evidence. If an edit is based on a misunderstanding of current practice it is imperative that there be
22 a transparent opportunity for its resolution, prior to implementation. We ask PPAC to request that CMS
23 facilitate this discussion through the development of a work group or advisory committee of all
24 stakeholders. The idea of a work group composed of CMS officials, the MUE contractor, and various
25 pathology and laboratory medicine stakeholders was originally suggested by Kim Brandt, CMS's Director
26 of Program Integrity at a meeting with the College's representatives last summer. When the creation of
27 such a work group was formerly requested, however, CMS first responded by stating that the agency
28 expects provider groups to utilize their own internal advisory committees to review MUEs developed by

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1 the contractor. We appreciate CMS's subsequent agreement to meet with the college and further discuss
2 this issue and we urge PPAC to endorse this proposed creation of a pathology and laboratory MUE work
3 group.

4 A second concern is CMS's reliance on ad hoc claims data to assist in setting MUE limits. Ad hoc
5 data requests, like an open and transparent discussion about what data should be used, how it is to be
6 collected and on what statistical basis these limits should be set. Instead, data requests are being made
7 informally by the MUE contractor. Reliance on ad hoc data unaccompanied by any statement of statistical
8 representation of the Medicare population is inappropriate and should not be acceptable to CMS. The only
9 reliable data to determine MUEs must come from CMS itself, whose data sets represent 100% of billed
10 services provided to our Medicare beneficiaries. Publicly available data only represent a 5% sample and is
11 insufficient to develop MUEs. In fact, at the PPAC meeting last year, Lisa Zone stated that CMS would
12 provide access to Medicare data to evaluate appropriate levels for MUEs. Yet the MUE contractor has said
13 that he does not have access to the data, and that is why he is seeking it informally. The College believes
14 that development of MUEs based on statistical analysis of claims data requires an open and transparent
15 discussion about the specific data to be used and the statistical basis on which to base these edits. The data
16 must also be shared with medical societies. The development of an MUE work group, as discussed above,
17 would help facilitate that process. The College asks that PPAC recommend that CMS provide data from a
18 100% Medicare sample to both its MUE contractor and to medical societies reviewing the proposed MUE
19 edits.

20 A third issue of concern regarding MUEs is the inconsistencies in communications with respect to
21 modifiers' usage. Over the past year, there's been conflicting information regarding MUEs. For example,
22 CMS officials have made contradictory statements on both the use of modifiers and the intent to
23 communicate the MUEs. On one hand, CMS has stated that MUEs will not be published, to avoid
24 providers' gaming the system. On the other hand, the MUE contractor has clearly stated that for certain
25 CPT codes, if necessary, a modifier 59 can be used for units of service that exceed the MUE limit. These
26 two statements are incompatible. How will a physician know how to use a modifier to override the MUE
27 without knowing the MUE limit? Even more baffling is the latest evidence from the contractor, which

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1 state's that the College is to alert their membership that a modifier cannot be used to override an MUE for a
2 certain code, but we cannot tell our membership the actual MUE for that code.

3 An additional concern, which highlights the need for transparency is that most private payers do
4 not recognize modifiers, but have, and will continue adapt MUEs as released. In our submitted testimony,
5 we urged PPAC to recommend that CMS fully disclose to providers all MUEs that are being applied to
6 Medicare claims. And we thank you for having taken that action.

7 Finally, I would like to comment on the 2008 Proposed Physician Payment Regulation. We
8 believe that the Practice Expense Methodology unduly penalizes hospital-based pathologists who bill only
9 the professional component, or modifier 26 services. The proposed rule continues the revised practice
10 expense methodology phase in, which bases the measurement of indirect costs on the magnitude of direct
11 costs. This method does not fairly compensate PC only billers, mainly hospital-based pathologists for their
12 indirect costs. Since PC only billers by definition have no direct costs, their allocation of indirect expenses
13 under CMS's revised methodology, is limited only to the work RVU, which is further reduced by the 5-
14 year review budget neutrality adjustment. While no changes to the practice expense methodology
15 implemented for 2007 were proposed for 2008, CMS acknowledges in the proposed rule that they will
16 continue to evaluate their new methodology. Last year's Final Rule also stated that they would welcome
17 further clarification of our proposed indirect allocation recommendations. Specifically, while many PC
18 only billers are hospital-based pathologists, there is an assumption that many of their overhead costs are
19 covered by the hospital. In fact, a relatively small share, about 10%, are actually employed by the hospital.
20 Instead, the majority, or 67%, those working at the hospital are part of a group who contracts with the
21 hospital. Because they are not directly employed by the hospital, many of these pathologists are responsible
22 for directly paying their overheads costs, including rent, utilities, billing, and administrative support. We
23 will be presenting data to demonstrate to CMS that their current approach does not adequately compensate
24 these physicians for their indirect expenses. The data also show the magnitude of these indirect costs for PC
25 only billers relative to Part B receipts that support our alternative approach to allocate indirect costs. We
26 request that PPAC urge CMS to seriously consider proposed revisions to the indirect practice expense
27 methodology.

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1 In conclusion, we'd like to reiterate our request that PPAC 1) recommend that CMS move forward
2 with the creation of an MUE work group that includes members of the pathology and clinical communities,
3 CMS medical staff, and their officials and the NCCI MUE contractor to ensure that CMS receives the best
4 broad based advice prior to further development and implementation of these edits; 2) recommend that
5 CMS provide data from the 100% Medicare sample to both its MUE contractor and medical societies
6 reviewing proposed MUE edits; and 3) to recommend to CMS to seriously consider proposed revisions to
7 the indirect practice expense methodology.

8 And again, we thank PPAC for recommending that CMS make MUEs available to the public.
9 Thank you for consideration of these comments.

10 Dr. Senagore: Questions or concerns? I think with the MUEs, we addressed some of the issues
11 earlier and we appreciate the input. And I think for the fee schedule, we'll take that under consideration.
12 Thank you for your time.

13 Dr. Myles: Thank you.

14 Dr. Senagore: OK, Jon, did you want to make your suggestion there and then we can review all of
15 the recommendations.

16 Dr. Siff: This goes back to what Tye had brought up to kind of generalize Karen's
17 recommendation for downstream denied services provided after a service is denied, and we tried to
18 wordsmith this as best I can. I apologize if it's a big run on. But PPAC recommends that CMS and its
19 contractors consider the medical necessity of each service provided downstream of denied service on its
20 individual merits based on the information available to the provider at the time the downstream service was
21 performed.

22 [Seconds]

23 Dr. Senagore: Any discussion about that? I think that kind of captures what we were grappling
24 with.

25 Dr. Bufalino: Can I ask a question? What, in a detailed, just to take an example, like how much
26 information has to be, I mean how is Medicare going to know how much information we got, at least at a
27 certain level, sort of how do we determine how much information we got—OK, we get sent, a primary care
28 doctor sends us a nuclear stress test for performance, and so we had nothing to do, just did the service,

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1 much like Tye's talking about. And all we had was a guy came for a chest pain or came for a screening and
2 they're looking at now appropriateness criteria and to decide who should appropriately get a nuclear stress
3 test and who shouldn't get a stress test at all? How would you accommodate that?

4 Dr. Siff: Well, I think that the chart would have to demonstrate medical necessity for your service.
5 I think—

6 Dr. Bufalino: So you as the provider of the service, so since I did the test, it's my responsibility to
7 collect the data to make sure it was appropriate?

8 Dr. Siff: I think the imaging one's a hard example. I think a better example is—

9 Dr. Bufalino: Well take a CT scan, I mean you order—

10 Dr. Siff: Well again, imaging is tough.

11 Dr. Senagore: Well, I think there are issues because we deal with this all the time in our field with
12 screen colonoscopy. I think the onus with what you said, Vince, the onus is on the person providing the
13 service to truly judge under current regulations and what not to truly judge whether it's an appropriate
14 procedure. So before you do the stress test, you would have to collect that data off the current regulatory
15 issues.

16 Dr. Bufalino: And so in that environment, just the track for one more second, so somebody sends
17 you a screening colonoscopy. It doesn't meet the criteria, you'd turn down that procedure and send them
18 back?

19 Dr. Senagore: We do, or we have them sign an ABN for it, yes. And we tell them we don't, we
20 can't tell for sure based on the criteria we have that you need—

21 Dr. Ross: Yes, but he described, he gave two scenarios there. One where just a screening and two
22 he said chest pain—

23 Dr. Senagore: No, he has, if it's chest pain, he's saying someone comes up to your door and just
24 wants a stress test. No clinical—

25 Dr. Ross: But you had mentioned a symptom.

26 Dr. Bufalino: A symptom, you're right. I think it's really screening I was concerned about, not
27 symptoms.

28 Dr. Senagore: Symptom disease, that's easy.

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1 Dr. Ouzounian: I don't agree that's it's his responsibility to do all that. He was sent the patient by
2 the primary care doc, with the order. And all it needs to say is chest pain. If you step back—

3 [multiple voices]

4 Dr. Senagore: That's different. If you have symptom-based evaluation—

5 Dr. Ouzounian: Yours was screening only?

6 Dr. Bufalino: Yes. In our world, it's a lot of people screening.

7 Dr. Ouzounian: OK, but you can't be responsible for what the primary care doc put in his chart. A
8 lot of us in this table are consultants and you're sent a patient from a primary care physician, and the
9 patients says Oh, Dr. so and so says to see you in consultation for such and such. Well, theoretically, he's
10 supposed to have that in his chart or I can't bill for a consultation. Now, I don't have access to his chart. I
11 don't know what he wrote in his chart. But if he didn't write, "See Dr. Ouzounian for a consultation," I'm
12 not supposed to bill for a consult.

13 Dr. Senagore: No, but the better analogy in your field, Tye, would be to do a screening
14 arthroscopy.

15 Dr. Ouzounian: Well, no orthopedic's going to do that. Well I take that back [laughter] I'm not
16 going to do that!

17 Dr. O'Shea: I think we're kind of getting a little bit confused, because I think we started off by
18 having definitely an instance where something was being denied but it had adjuvant modalities with it that
19 were not able to be privy to the knowledge that it was going to be denied to begin with. But when we took
20 it a step further just to say that same thing but not with as many specifics on it. I think you got back to
21 basics. Basics of you, the primary care refers to you, and those, whether its screening tools, or whether they
22 have appropriate symptoms, you're covered. Those things are covered. If somebody walks out of the street
23 and just says my friend came to you, so I want to come to you for a screening, now there's you haven't had
24 the referral. But if you had the referral done—

25 Dr. Senagore: If you do screening and they don't meet criteria, you don't get paid.

26 Dr. O'Shea: But the referral was done appropriately is all I'm saying. I have a referral to you to do
27 a screening colonoscopy and they're 65 and they've never had a screening colonoscopy.

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1 Dr. Senagore: But no, this would be the better analogy. They're 70, they had a normal one at 65,
2 you send them for a screening colonoscopy, I won't get paid.

3 Dr. O'Shea: That's very true. Then it's wrong. But that actually is just doing due diligence, I
4 might say. It's not this one that you don't know that it's wrong after something else has been done, and my
5 example I think before was just a little bit better guys, when I'm asked to consult on somebody that
6 somebody else admitted that shouldn't have been admitted, but I've been asked to consult as an internist in
7 the hospital. I'm asked to do that, but I don't know that the initial admit is felonious. That's where I should
8 be protected.

9 Dr. Senagore: I agree. What we're trying to capture with this is that scenario. Where get called to
10 see somebody for [inaudible 39:53] and you say, nope they didn't have pneumonia,

11 [multiple voices]

12 Dr. O'Shea: But I should get paid for the consult.

13 Dr. Senagore: Yes. That's what we're trying to catch.

14 Dr. Ross: I'd like to revisit back to the beginning of this discussion again. And I think there have
15 been a couple of scenarios that have kind of raised this onus of responsibility of do we have that
16 responsibility of going back to the initial consultation to determine if that was indicated or not or do we just
17 worry about whether our consultation is indicated or not. I mean that's really what the letter of this
18 discussion is practically all about is should we worry about ourselves and whether or not its applicable, or
19 do we go back and do we have to do our research. Like you used the term "due diligence," well, do we
20 have to go through due diligence on the primary care side, or the initial visit, to determine if that was
21 appropriate or not, as you said when you go into the hospital and you've got a written order that says
22 consultation to see this patient.

23 Dr. Siff: No, I don't, I think if you're coming to a consult, then the consult's be for something
24 that's appropriate for you, so if you're a surgeon and the consult for onset of abdominal pain during the
25 hospital stay, then that's [definitely? 41:17] necessary for a surgeon to see that patient. It's a reasonable
26 consult. You shouldn't have to worry about whether the patient was admitted for a valid reason to begin
27 with.

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1 Dr. Senagore: See, where these things blur, is where the physician work piece is serving like a
2 device. I mean not to put down anesthesia, but for the unnecessary operation, the whole anesthesia
3 component is simply the device, that holds the patient still while you do the procedure. And the procedure
4 was deemed unnecessary, so they're not really in a position to judge the appropriateness of the surgical
5 procedure or not and you're using that tool to do the procedure. So the consult I think is not the big issue.
6 The bigger issue is something that gets denied, but you have performed a service, like Vince was talking
7 about with the cardiac scans. You don't really know if it's screening—how that fits in, if they have the
8 appropriate criteria or not. And if you're doing it, one argument would be to say and it gets into a service
9 related issue, you could say no I don't see any patient without a consult first, to determine if it's appropriate
10 or not to do that scan. But then your primary care colleagues wouldn't be so excited about that and you
11 know there would be other issues with how that would play out. But that would be a way to solve that
12 situation. No one gets in the scanner without seeing Dr. Bufalino first.

13 Dr. Bufalino: But unfortunately, practically, that's not how the world works. The world works
14 primary care guys write an order and say stress echo, send it over to be done and so we're at that receiving
15 point of saying no to that patient because they didn't meet criteria, or having them sign that they may not be
16 covered.

17 Dr. Senagore: See, where the guidance should come on that, and I mean laboratories see this all
18 the time, radiologists see this all the time, where there's no, it's a cryptic diagnosis that doesn't meet coding
19 guidelines is that there really needs to be a better educational tool to say that these diagnoses are covered
20 for this intervention and this diagnosis is definitely not covered.

21 ???: But as providers of testing services and minor procedures, somebody's got to take
22 responsibility for it, and I think we as physicians should, and it is not uncommon for at least in the past, for
23 us to get a call from the radiologist that says you've ordered this test, the diagnosis that you've given me
24 does not allowed me to get paid for it, therefore I can't do this test, would you give me one of these
25 diagnoses? So for us to bill anything, we have to give an ICD9 code, why would we not then ask whoever
26 is the requester you either need to give me an ICD9 code and if it's not the right code, then we need to
27 communicate. I don't think that's unreasonable.

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1 Dr. Williams: I think this whole scenario is complicated and it seems like maybe CMS should
2 develop a small finite working group to sort through the algorithm of this whole thing. I don't think there
3 are any clear cut answers to each one of these situations that we're talking about. And I don't think we're
4 going to be able to give them a scripted scenario of if this, then that, because they're all different. I think
5 what they should be made aware of is that you can't deny the downstream services based on this one
6 decision that you made and let them figure it out.

7 Dr. Senagore: I think that's what we're asking for here. I don't think we're trying to provide the
8 solution—

9 Dr. Williams: Exactly.

10 Dr. Senagore: ...expand on the question you asked.

11 Dr. Bufalino: We're also concerned that there's some bounty hunters for the golden egg. And you
12 made a proposal earlier that we supported and tried to separate out.

13 Dr. Senagore: It gets at that transparency piece that we talked about with MUEs and some of the
14 other issues, that as long as the rules are clear, and defined then we have to learn the rules and follow them.
15 It's where the rules are hard to get your arms around and figure out what really applied, but retrospectively
16 you're going to take the downstream disadvantage for participating. That is the problem.

17 Dr. Bufalino: So can we ask for some guidance from Ken or Liz, what direction should we take or
18 where would be the most productive way for us to get this looked at?

19 Dr. Senagore: Does our proposal give guidance in that direction Ken?

20 Dr. Simon: I think I made some comments earlier this morning that the scenarios can be different
21 based on the site of service and some of the scenarios that are referred to are office-based practice patterns.
22 Clearly in the hospital, one of the reasons we have QIO is that they come around as soon as patients are
23 admitted to make sure that they meet the interqual criteria for admission for those very reasons. And so we
24 don't have those type of, we don't have that type of oversight necessarily in the outpatient setting, in ASCs
25 or in the offices and so perhaps we can chat with program integrity to gain background information on how
26 they have been addressing this in those different sites of service. But each site of service is different with
27 different boundaries and rules and regulations that people are bound by. And so I think it would be very

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1 difficult to develop one recommendation or one set of rules that's going to fit all of the different sites of
2 services where we all practice.

3 Dr. Ross: I think that's a good point. I was trying to think about all the scenarios that can occur in
4 the hospital where somebody was admitted and yet didn't meet the criteria, but if you've got the hospital
5 being basically your CMS guide, they're following the guidelines of CMS right there and then, so they
6 wouldn't be admitted in the first place if they didn't meet the criteria. So that scenario probably is not going
7 to typically happen.

8 Dr. Senagore: OK, Dana can we review, so we have a few extra minutes. Want to review the
9 recommendations?

10 [multiple voices]

11 Dr. Senagore: Oh yeah, we'll call that motion. All in favor?

12 ???: Can we reread it?

13 Dr. Siff: PPAC recommends that CMS and its contractors consider the medical necessity of each
14 service provided downstream of the denied service on its individual merits based on the information
15 available to the provider at the time the downstream service was performed.

16 Dr. Senagore: Any questions? All in favor?

17 [Ays]

18 Dr. Senagore: All against? Motion carries. OK. Dr. O'Shea.

19 Dr. O'Shea: PPAC requests that CMS provide the geographic practice expense data that will be
20 sued to calculate the proposed geographic adjustment factor changes so that PPAC can verify the agency's
21 calculations. PPAC recommends that CMS update the payment localities every three years, using the five
22 percent threshold. PPAC further recommends that CMS maintain reimbursement in counties remaining in
23 the original payment localities by establishing a geographic payment floor at current levels.

24 Dr. Senagore: Support?

25 [Second]

26 Dr. Senagore: Discussion? This is related to the GPSI changes. All in favor?

27 [Ays]

28 Dr. Senagore: Any others?

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1 Dr. Ouzounian: On Tab G on the RAC audits, we were told that they could give us a percentage of
2 physician chart audits that were positive and they were supposed to give that number back to the Chair this
3 afternoon. I'm told that they told our Chair that they don't have that data readily available, and they will get
4 it to us, so with that in mind that we don't have that information, I'd like to make the following
5 recommendation. PPAC recommends that the RAC auditors provide to the PPAC data reflecting the
6 percentage of physician chart audits that result in a payment modification.

7 [Seconds]

8 Dr. Azocar: Maybe you should consider charts or [inaudible] What I'm trying to say is that when
9 you made the recommendation, do you want to present how many became positive, so to speak? Charts or
10 individual audits? No matter how many charts there was in the audit.

11 Dr. Ouzounian: I tried to word it as charts, so if one physician got a request for 50 charts, and
12 there was 25 hits on that, that's only a 50% positive hit, and if there was one out of that 50, it's way low.

13 Dr. Williams: PPAC recommends—

14 Dr. Senagore: Wait. I'm sorry I thought you had a comment.

15 Dr. Przyblski: Tye, do you think that they should report to us physicians specific, separated out of
16 ambulance and whatever the other one was?

17 Dr. Ouzounian: Yes, it says my recommendation was physician chart audits.

18 Dr. Senagore: That 6%, as a part of that 6%.

19 Dr. Przyblski: Is the recommendation clear that they should separate out the data in the future
20 when they present it to us? As long as CMS understands the intent.

21 Dr. Williams: As distinct from ambulances and ...

22 Dr. Ouzounian: So add to that, as distinct from, what are the others—

23 Dr. Przyblski: We essentially want physicians specific data reported, separated out. I would think.

24 Dr. Ouzounian: Let's make another recommendation for that.

25 Dr. Senagore: Let's vote this one. All in favor?

26 [Ays]

27 Dr. Senagore: All against. OK.

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1 Dr. Ouzounian: PPAC recommends that the RAC auditors provide audit data for physicians only,
2 not combined with any other provider group.

3 [second]

4 Dr. Senagore: All in favor?

5 [Ays]

6 Dr. Senagore: Now, Dr. Williams?

7 Dr. Williams: OK, thanks. PPAC recommends that CMS increase the awareness and education of
8 the medical specialty communities regarding the availability of coverage with evidence development and
9 the funding of clinical trials.

10 [Seconds]

11 Dr. Senagore: Discussion? That was from our presentation earlier today. All in favor?

12 [Ays]

13 Dr. Senagore: Dr. O’Shea?

14 Dr. O’Shea: PPAC requests that CMS strongly protest—recommends? PPAC recommends that
15 CMS strongly protest the cessation or curtailing of PPAC activities and continues to support quarterly
16 PPAC meetings.

17 [Second]

18 Dr. Senagore: At the risk of looking self-serving [laughter]

19 [chat]

20 Dr. Senagore: I’ll call the question. All in favor?

21 [Ays]

22 Dr. Senagore: OK. Greg?

23 Dr. Przyblski: Although I think from the presentation on MUEs, it looked like there is an out
24 using modifiers, I think a positive statement from the group would probably be useful and hopefully allay
25 some of the comments that we heard. So I would say PPAC recommends that modifiers including 59, 76,
26 77, and 91 need to be permitted when medically necessary and appropriate services are provided that
27 exceed MUE limits.

28 [Seconds]

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1 Dr. Senagore: Discussion? All in favor?

2 [Ays]

3 Dr. Senagore: Any others? Now could we ask—

4 Dr. Ross: In addition, I don't know how to phrase it exactly, but it's just a compliment to Dr.
5 O'Shea, not just protesting, but asking if CMS, that PPAC recommends or proposes that CMS give us some
6 type of information as to the process that's taking place and to the possible ramifications of this body in the
7 future as well. So not just a protest, but give us updates as to the progress whether or not this body will
8 continue on a quarterly basis, or on an annual basis.

9 Dr. O'Shea: I'd accept that as a friendly amendment or addition.

10 Dr. Ross: I appreciate that. Great. Thank you.

11 Dr. Senagore: All in favor—we'll have to vote that in, since we voted previously. All in favor?

12 [Ays]

13 Dr. Senagore: Now, Dana, I think you can run through the recommendations for us?

14 Ms. Trevas: You want me to read them? Or would you like a 15 or 20 minute break in which—

15 Dr. Senagore: We would like a 15 or 20 minute break for you to be able to organize the
16 recommendations.

17

18

19 [end of audio]