

CENTERS FOR MEDICARE AND MEDICAID SERVICES

PRACTICING PHYSICIANS ADVISORY COUNCIL

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

Monday, March 9, 2009
8:30 a.m.

Council Members

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DR. JOSEPH GIAIMO
*DR. PAMELA HOWARD**
DR. ROGER L. JORDAN
DR. JANICE A. KIRSCH
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DR. GREGORY J. PRZYBYLSKI
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DR. ARTHUR D. SNOW
DR. M. LEROY SPRANG
DR. CHRISTOPHER J. STANDAERT
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* Not in Attendance

CMS Representatives

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Center for Medicare Management

Stewart H. Streimer, Acting Deputy Director
Center for Medicare Management

Kenneth Simon, M.D., M.B.A.
Executive Director
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William Rogers, M.D., Director
Physicians Regulatory Issues Team
Office of External Affairs

Thomas Valuck, M.D., J.D.
Medical Officer & Senior Advisor
Center for Medicare Management

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Jean Moody-Williams, Director
Quality Improvement Group
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Lt. Terrence Lew, Health Insurance Specialist
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Office of Clinical Standards and Quality

Arrah Tabe-Bedward, Director
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Medicare Enrollment and Appeals Group
Drug and Health Plan Choice

Robin Fritter, Director,
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Kelly Buchanan, Division of Provider Relations and Evaluations
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Contractor Representative

Paula Bonino, M.D., MPE, FACP
Contractor Medical Director
Highmark Medicare Services

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Public Witnesses

AMA

MS. DANA TREVAS, Rapporteur
Magnificent Publications, Inc.

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Open Meeting

2

Dr. Bufalino: My name is Vince Bufalino. I'm the Chairperson of the Practicing Physicians Advisory Council here and it's a pleasure to welcome all of you to Washington for the 67th meeting of the Council, and looking forward to some meaningful dialog today around the agenda we have outlined. I want to thank my fellow council members for making the time to come to town through your arrangements. It was a complex day of travel, as many of you know. Excuse my attire. Since my suitcase is somewhere between the airport and my hotel and HHS, and at this point in time, we're going to manage without a tie. We thank those of you that were able to make it. We do have a couple members that are coming late, Dr. Snow, and John is not coming from Cleveland. So we thank all of you for being here. Today's agenda as you have seen, is on a number of topics, including Value-Based Purchasing, the night scope of work, looking at the RAC audits, both the local and national coverage decisions, along with the medical appeal process. We're hoping to have some good discussion around that and we are looking forward to Ken's comments around our recommendations from the December 8th meeting. And so we're looking forward to all of your input today and hope to have a meaningful discussion.

15

Let me begin, and start the morning out and introduce Liz Richter, whom all of you know. Liz is the Acting Director of the Center for Medicare Management at CMS, and we're pleased to have her join us today and as you know, we have some change in the administrative side, and a number of changes that are going to happen at the agency over the next several months. And we're looking forward to that. Joining Liz today is the Acting Deputy Director for Medicare Management, Mr. Stewart Streimer, and we'd like to ask Liz to open the morning with a few comments.

21

Welcome and Opening Remarks

22

Ms. Richter: Okay thanks. I'd like to start by welcoming everybody and repeating everything Vince said about the difficulty of the travel and, appreciate your being able to be here. He asked me to talk a little bit about transitions and how that's affecting the faces that you see around, the folks you see from CMS in the Department side. So I'll start by doing that. I think Jeff Rich mentioned at the December meeting that that was his last meeting and Herb Kuhn's as well. When the administration changed, they left. We currently have a lot of people in acting roles, which is why you see "acting" in front of Stewart's and my name. One transition at a lower level that didn't have anything to do with the administration change

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1 is if any of you haven't met Robin Fritter, who, if you could stand up in the back, she's the new Director of
2 the Division of Provider Relations & Evaluations, who works with Kelly and Ken and Robin to make sure
3 that everything is done that needs to happen to make these meetings a success, so Dave Clark's taken
4 another position in the agency, if you remember him. And Robin will be here at the meetings from now on
5 to work with all of you on administrative issues. As far as the administration, the President announced that
6 he was nominating Kathleen Sebelius to be Secretary last week. Last week was the announcement. And so
7 working through that he previously announced that Bill [sp] Coor would be nominated to be Deputy
8 Secretary, and so those nominations will wind their way through the system. We don't have an
9 announcement as yet as far as who will be nominated to be administrator, or who will be appointed to be
10 Deputy Administrator or the Director of the Center for Medicare Management, and we'll keep you up to
11 date as those roll out and all of the positions start filling in, as they do throughout the spring in the first year
12 of an administration.

13 With that, the only thing I'll say other than let's get started is I was really happy on this agenda
14 that I think we could address a number of topics that have come up in previous meetings, explicitly that
15 you'd asked to have a greater understanding of the coverage process, both local and national; the appeals
16 process, updates on the RACs, everything else. So I think this will be a very responsive agenda as far as
17 questions you've asked us, as well as just us telling you what we're doing and I think with that, we should
18 take it away, because this is not about you hearing from me. This is about us hearing from you. So, thank
19 you.

20 Dr. Bufalino: Thank you. And we'd ask you to carry our invitation to the new members that get
21 appointed over the next month or two that we'd love to have them come visit with us in May or in August,
22 so if any of them would be willing, we'd be glad to get a chance to meet them. Thank you. So moving right
23 along, are the slides ready to roll? We'll invited Dr. Ken Simon, who's the Executive Director of PPAC and
24 Medical Officer in the Center to present the responses from the December 8th meeting.

PPAC Update

26 Dr. Simon: Agenda Item E, Medicare Physician Fee Schedule Final Rule, Item 66E-1: PPAC
27 recommends that CMS expand its review of the Practice Expense Geographic Price Cost Indices,
28 commonly called GPCIs beyond taking testimony on geographic localities. The response: As discussed in

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1 the calendar year 2009 Medicare Physician Fee Schedule Final Rule, CMS is conducting a study of
2 alternative locality structures. Our current study is focused on reviewing the possible alternative approaches
3 for reconfiguring Medicare Physician Fee Schedule payment localities. An interim report of the
4 contractors' research and county level data for each option is complete and posted on the CMS website. We
5 expect to receive a final report from the contractor in the summer of 2009, and when the final report is
6 received, we will post it on our website and discuss the findings at a future PPAC meeting.

7 Agenda Item 66E-2: PPAC recommends that CMS reevaluate its formula for Practice Expense
8 GPCIs to use actual practice expense data to make the determinations, reporting back to the Council on its
9 findings at the Council's second meeting in 2009. The CMS Response: The Practice Expense GPCI is
10 comprised of three categories; employee wages, rent, and medical equipment and office supplies. CMS has
11 specified that data must be available nationwide and accessible to the public to be used in the calculation of
12 the GPCIs. The employee wages component uses census data on the actual wages of the types of medical
13 and clerical workers found in physician offices. The rent category is based on HUD residential apartment
14 rental data because no acceptable national source of commercial rent data was available. The census and
15 HUD residential data are available to the public. Medical equipment supplies and miscellaneous expenses
16 were found to have a national market not varying significantly geographically and therefore, have the same
17 national value of 1.000 in all areas. The next GPCI update will be discussed in the 2011 Medicare
18 Physician Fee Schedule Rulemaking cycle, conducted during 2010. We will solicit public comment during
19 this period.

20 Agenda Item J: Value-Base Purchasing efficiency measures and physicians quality reporting
21 initiative in 2009. 66J-1: PPAC recommends that CMS provide PPAC with regular updates on planning for
22 the physician resource use measurement and reporting program. The response: CMS has and expects to
23 continue working collaboratively with the physician community on development, implementation and
24 maintenance of the Physician Resource Use Measurement and Reporting Program. In addition to face-to-
25 face sessions with individual physicians and groups of physicians to gauge reaction and gather input about
26 the reports, CMS has also engaged the American Medical Association and medical specialty societies in an
27 ongoing series of discussions about the program. We look forward to further collaboration with the
28 physician community, including regularly updating PPAC.

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1 Agenda Item 66J-2: PPAC recommends that CMS reports on its use of downstream diagnoses that
2 are not captured among the first four diagnoses in the claims database. The response: For each Medicare
3 Physician Fee Schedule claim, CMS accepts up to eight ICD9 CM diagnoses codes on the header on the
4 electronic claims format, and up to four ICD9 diagnoses codes on the header on the paper claims format for
5 billing particular items and services provided to a Medicare beneficiary on a particular date of service. The
6 diagnoses codes are placed at the claim level, and the clinician must point to the relevant primary diagnosis
7 from those claim level diagnoses on each line item on the claim. In other words, the clinician must point to
8 the diagnosis that supports the reason for the service or procedure on that line. For the Physician Resource
9 Use Measurement and Reporting Program, we are using all of the claims related to an episode of care cross
10 settings, so we have access to the ICD9 CM diagnoses codes from all of the claims within the episode,
11 including but not limited to the Medicare Physician Fee Schedule claims. The patient level risk adjustment
12 methodology takes into account all diagnoses within an episode for an acute condition or during a calendar
13 year for chronic condition. Appendix A, which is attached, lists the relevant Medicare payment systems,
14 and a number of ICD9 CM diagnoses codes we capture for claims within those payment systems.

15 Agenda Item O, Wrap-up and Recommendations, 66O-1: PPAC recommends that CMS not
16 expand the list of hospital-acquired conditions, commonly called HACs, until evaluation shows that the
17 current program to address HACs is achieving the goal's outline by CMS. PPAC requests that CMS present
18 an analysis of the program at the June 2009 meeting. The response: In the Inpatient Prospective Payment
19 System, Fiscal Year 2009 Final Rule, CMS presented candidate HACs for potential consideration during
20 future rulemaking. CMS has also discussed in various payment rules, the potential for expanding the HAC
21 concept to settings of care beyond inpatient hospitalization. CMS is pursuing an evaluation of the initial
22 impact of the inpatient HAC payment policy, subject to the availability of resources. At this time, it does
23 not appear that preliminary data will be available for the June 1 meeting, or by the end of the year.
24 However, even prior to the completion of the evaluation, we know that the HAC policy has achieved the
25 goal of heightening attention to patient safety, generally. It has specifically resulted in attention to
26 prevention of selected HACs that have been highlighted in the IPPS Final Rule. As program evaluation
27 results become available, we will share them with the Council.

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1 Agenda Item 66O-2. PPAC recommends that CMS revise its payment of nonpayment of HACs to
2 allow payment when the condition occurs despite the fact that the provider responsible for that condition
3 follow the pertinent evidence-based guidelines. The response: The statutory authority for the HAC policy
4 requires prospective selective of conditions that may be considered reasonably preventable through the
5 application of evidence-based guidelines. Reasonably preventable does not mean absolutely preventable,
6 and CMS recognizes that HACs may occur when evidence-based guidelines are followed. We note that the
7 statute does not require that a condition be always preventable in order to qualify as a HAC, but rather that
8 it be reasonably preventable, which necessarily implies something less than 100%.

9 Agenda Item 66O-3. PPAC recommends that CMS provide physicians with real time access, in
10 essence, same calendar year, to information to determine whether they are properly reporting data to the
11 Physician Quality Reporting Initiative, so that physicians have an opportunity to adjust their reporting to
12 meet the requirement. The response: CMS is unable to provided contemporaneous feedback reports at the
13 individual level. However, we have committed to provide aggregate level reports quarterly, by measure as
14 to the reasons for invalid quality data code reporting, as such information becomes available. We are
15 providing such information for the first three quarters of 2008 in February 2009. Fourth quarter data of
16 2008 in May 2009. We anticipate providing such information for the first quarter of 2009 data by August
17 2009, based on availability of claims data for the first quarter of 2009.

18 Agenda Item 66O-4. PPAC recommends that CMS delay implementation of any new information
19 technology requirements, until an independent study can assess whether doing so would have the
20 catastrophic effect of putting physicians out of business and accentuate the already severe problem of
21 patient access to care. 66O-4 Response: CMS reports the adoption of health information technology,
22 including electronic health records, and electronic prescribing. The Physician Quality Reporting Initiative,
23 and the eprescribing incentive programs provide financial incentives to physicians and other eligible
24 professionals, but do not require the use of health information technology. Congress recently passed the
25 American Recovery Reinvestment Act of 2009, ARRA, which the President signed into law on February
26 17th. Among other healthcare provisions, ARRA provides funding to encourage the adoption of health
27 information technology. For physicians, ARRA provides financial incentives beginning with 2011 for
28 eligible professionals, who are meaningful electronic health record users, followed by financial penalties,

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1 beginning with 2015 for eligible professionals who are not meaningful electronic health record users. CMS
2 will be working closely with the department and affect its stakeholders to implement these new provisions.

3 66O-5. PPAC recommends that the cost of implementing any information technology changes
4 requested by CMS be fully funded by CMS. The response: As mentioned above, in response to 66O-4,
5 recent legislation provides financial incentives to encourage the use of health information technology.

6 66O-6. PPAC recommends that CMS provide clarification of the appeals process for Recovery
7 Audit Contractor determinations. The response: CMS has included an overview of the appeals process for
8 today's meeting. Members of the CMS Enrollment and Appeals Group will provide an overview to the
9 Council on providers' appeal rights, which are the same for RAC determinations, as they are for any other
10 Medicare determination.

11 66O-7. PPAC commends CMS and strongly recommends that CMS proceed expeditiously to
12 develop medically reasonable approaches of valuing decreases in HACs instead of the unreasonable
13 approach of eliminating HACs. The response: In the Hospital Value-based Purchasing plan report to
14 Congress, CMS discussed a performance-based payment model that would adjust hospital payments based
15 on measured rates of performance. We received comments from stakeholders during the December 18,
16 2008 HAC listing session, that the use of rate-based measures of complications to adjust hospital payments
17 through the value-based purchasing model would be preferable to a claim by claim payment adjustment for
18 HACs.

19 Agenda Item 66O-8. PPAC recommends that CMS requires RACs to reimburse all providers for
20 the cost of fulfilling medical record requests. The response: CMS will take this recommendation under
21 advisement for fiscal year 2010.

22 Agenda Item 66O-9. PPAC recommends that CMS limit the number of medical records that a
23 RAC can request from a solo practitioner to three records every 45 days for each national provider
24 identifier. The response: CMS appreciates the Council's feedback on the difficulty many providers face in
25 responding to medical record requests. We believe that the request guidelines as currently established, are
26 fair and that they represent a reasonable balance between the need to supply the RACs with an adequate
27 universe of claims to review and the need to protect providers from undue administrative burden; however,

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1 we will carefully monitor the affects of the record requests during the remainder of fiscal year 2009 and
2 we'll consider the Council's recommendation for fiscal year 2010.

3 Agenda Item 66O-10. PPAC commends CMS for progress on the PQRI and recommends that
4 CMS continue to work towards greater transparency in all aspects of developing the PQRI, especially data
5 used for measure selection and implementation of processes. The response: The CMS is appreciative of the
6 commendation and is committed to engaging physician and other eligible professionals to improve the
7 program. CMS appreciates the inputs received from PPAC and others. CMS in early 2008 and in 2009, has
8 requested suggestions for measures. Selection of the measures is carried out through Notice and Comment
9 Rulemaking, as required by the PQRI authorizing legislation.

10 Agenda Item 66O-11. PPAC recommends that CMS strongly consider the ultimate use of the
11 Physician Resource Use Reports in the medical marketplace, when designing the physician resource use
12 measures and report and that plans for this effort be reported to PPAC. The response: The Medicare
13 Improvement for Patients and Providers Act, commonly called MIPPA, of 2008, requires CMS to
14 disseminate resource use reports to physicians on a confidential basis. MIPPA also requires CMS to
15 develop a plan for value-based purchasing for physicians and other professionals, and submit a plan in a
16 report to Congress. The physician value-based purchasing plan will address payment incentives and public
17 reporting of both quality and cost of care, as was discussed in a recently released issues paper that's
18 available on the CMS website. While the current use of physician resource information is for confidential
19 reporting, CMS is ultimately considering the use of information for payment incentives and public
20 reporting.

21 Agenda Item 66O-12. PPAC recommends that CMS make an effort to obtain data on the cost to
22 providers and institutions of appealing a RAC determination. The response: The requested data are not
23 currently available, although CMS will consider including this subject in the annual RAC provider survey.
24 However, the results may be of questionable validity, due to the myriad of ways that provider organizations
25 can account for appeals related expenses.

26 Agenda Item 66O-13. PPAC recommends that CMS provide data on the amounts of RAC
27 determinations that were appealed in a RAC demonstration, particularly in relation to the amounts of RAC
28 determinations of improper payments in general. The response: CMS released a variety of appeals related

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1 statistics for the demonstration project in its June 2008 evaluation report. These figures were updated in
2 September 2008, with data through June 2008, and again in January 2009, with data through August 2008.
3 Additional updates will be provided until all appeals have been completed. As of August 31, 2008, 118,051
4 claims, or 22.5% of the 525,133 RAC overpayment determinations had been appealed. Of these, 40,115, or
5 34% were ultimately decided in the provider's favor. This figure represents 7.6% of the total RAC
6 determinations. CMS has made numerous enhancements to the RAC data warehouse for the permanent
7 program, including the way that data are captured across the appeals process. We anticipate the ability to
8 provide robust appeals data upon request by PPAC or other constituencies, and we appreciate the
9 opportunity to respond to this recommendation.

10 Agenda Item 66O-14. PPAC recommends that CMS withdraw changes to the Medicare enrollment
11 process proposed in the Physician Fee Schedule Final Rule until related physician payment problems and
12 persistent delays are resolved nationwide. The response: The effective date for provisions found in the
13 calendar year 2009 Physician Fee Schedule is January 1, 2009, unless otherwise specified. Since CMS did
14 not establish a delayed effective date for any changes in the Medicare Provider Enrollment Provision, the
15 effective date of the enrollment provisions is also January 1, 2009. We are in the process of developing
16 implementation guidelines for Medicare contractors. CMS has worked with the Medicare administrative
17 contractor, commonly called the MAC, for jurisdiction one, the Palmetto GPA, to develop a plan for
18 reducing the backlog of provider enrollment applications, identified immediately following the jurisdiction
19 one implementation. Palmetto was able to rapidly resolve the issues encountered, and is meeting CMS
20 requirements for timely processing of claims, and has been successful in reducing provider enrollment
21 application inventories to workable levels within the timeframes established in the plan. We will continue
22 to work closely with our Medicare contractors, the medical associations, and other stakeholders, to resolve
23 any issues impacting provider payment, as quickly as possible.

24 That, Mr. Chairman, concludes the report from the December 8, 2008 PPAC meeting.

25 Dr. Bufalino: Thank you, Dr. Simon. While you're thinking of any questions or comments you
26 have for Dr. Simon, let me open with one. Could I go back to page 3, 66J-2. When you talked a little bit
27 about the claims in the Medicare Physician Fee Schedule, the question we had actually raised at that time
28 was will the PQRI expand beyond the initial four diagnoses that were allowed in response to calculating

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1 whether or not you met the PQRI requirements. And I guess I, reading this, I wasn't exactly sure, but does
2 this mean it will go down to eight diagnoses for PQRI? Because you didn't specifically address PQRI here,
3 unless that was under the Resource Use & Measurement Program.

4 Dr. Simon: That is under the Resource Use & Measurement Program, and I think that if we evolve
5 to episodes of care, that would capture all of the ICD9 codes.

6 Dr. Bufalino: But for now, it won't capture it until we moved to episodes of care?

7 Dr. Simon: That's correct.

8 Dr. Bufalino: Understand. Other questions? Frederica?

9 Dr. Smith: On page 4, 66O-1, the recommendation was that CMS not expand the list of HACs
10 until evaluation showed that the current program was achieving the goals, and I don't think that was
11 addressed in the response. It said it's discussed, but it didn't say whether they would or would not follow
12 PPAC's recommendation.

13 Dr. Simon: I think the agency has taken the Council's recommendation under consideration.
14 However, as listed by the legislation, the agency is challenged and charged with developing hospital
15 acquired condition measures, so it is still moving forward with doing so, with the input of all the medical
16 associations and advisory councils such as PPAC.

17 Dr. Przyblski: Same page, next recommendation, 66O-2, the question was really can CMS pay for
18 conditions when all of the evidence-based medicine guidelines were followed. The response really
19 addresses whether these have to be absolutely preventable or not. And the answer obviously is it doesn't
20 have to be absolutely preventable to be on the list. But it still doesn't answer the question, does CMS have
21 the authority to pay for the condition when all reasonable efforts were followed and the evidence-based
22 guidelines were followed. So I'm not sure that that response answered the question, either.

23 Ms. Richter: The way the statutory authority is written, once we've placed a condition on the list,
24 then it's on the list. And so there's no discretion about using that diagnosis code for DRG assignment if it's
25 a secondary diagnosis and was not present on admission, even if the evidence-based guidelines were
26 followed. So it's an all or nothing provision, right.

27 Dr. Bufalino: Other questions? Seeing none, we'll—Dr. Ross, sorry.

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1 Dr. Ross: According, I'm not sure if this is the way it was written from the last meeting, but in my
2 notes, I had a recommendation that PPAC recommends that CMS provide data of provider decrease in care
3 to Medicare beneficiaries and I asked the question is there a brown-out process taking place? Looking at
4 cuts in Medicare payment rates in 2010 and looking at the coming decade. Is that the question that was
5 answered in the last 66O-14, or was that recorded or am I missing something here from the last meeting?

6 Dr. Simon: I think all of the recommendations were transcribed and written as we have them here.

7 Dr. Ross: I don't see it. I'll have to re-introduce. But I thought that was recommended from the
8 last meeting.

9 Dr. Bufalino: Well, we could take it for a recommendation today.

10 Dr. Ross: Thank you.

11 Dr. Bufalino: Anyone else?

12 Ms. Trevas: Sorry, what was that recommendation?

13 Dr. Ross: We'll do it at the end.

14 Dr. Bufalino: We'll do it at the end, thank you, Dana. Okay, moving the agenda along, we'll move
15 to the PRIT Update. Dr. Bill Rogers, Director of Physician Regulatory Issues is here with us again today
16 and glad to have you, Bill. And looking forward to your comments. Good morning.

17 PRIT Update

18 Dr. Rogers: Good morning. Thank you for inviting me again to address the PPAC. This is a very
19 important body and we very much appreciate your input into the program. I'm supposed to be the person I
20 guess here who keeps it real and understands what the practicing physician's life is like, and in my ER
21 where I work, we have, in the past month, not only transitioned to a new company—the company that had
22 the contract for 18 years lost the contract to a new company, and all of the doctors got laid off except me.
23 And we also introduced an electronic health record, and so now I spend about 90% of my time tap tap
24 tapping, rather than talk, talk, talking to my patients. It's been an eye-opening experience.

25 Anyways, moving on to the first issue—and I love this cartoon. I don't know how many of you
26 have had this experience in your practice as when patients come in with very clear understandings of
27 disease, clearer than your understandings because they have access to the web, which we apparently don't
28 have access to.

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1 First issue, I am also on the Ambulance Open Door Forum, and actually this was an issue that was
2 initially brought up by an ambulance company in New York which found that they could not get their
3 Medicare claims automatically crossed over to Medicaid. This is a big administrative cost issue. Obviously,
4 Medicaid in most states is no generous payer anyways, and so having to manually reprocess your claims
5 and submit them to the Medicaid program really doesn't make very much sense administratively. So we've
6 asked the HBNA and MGMA to help us by surveying their members so that we can find out if this is a
7 problem nationally, and so far, it seems that New York and South Carolina are the states where there are
8 problems. It seems that the majority of states actually do automatically cross over these claims, which is
9 great. And when the surveys are finished, then we'll see what we can do to encourage the states that are not
10 currently able to automatically accepted crossover claims, see what we can do to encourage them to
11 develop that capability.

12 This is an old issue. The specialty code which somehow accidentally was dropped from the
13 enrollment form. We've now updated the online enrollment and the specialty code is now listed in the
14 online enrollment. The paper enrollment form still has to be updated, but we're making progress on getting
15 this done. And we've let the specialty society know but it is possible for physicians to write in the specialty
16 code and then they will be appropriately enrolled in the Medicare database.

17 This was an issue which was sort of tied in with this whole issue of the MA plans that were
18 enrolling physicians, the private Fee-for-Service plans that were enrolling physicians automatically if they
19 were caring for one of their patients. And the question was, are those physicians who had not signed a
20 contract with the private Fee-for-Service plan but we deemed to be participating, are they able to get paid
21 the PQRI bonuses and eprescribing bonuses. And the answer is, the long answer is long, but the short
22 answer is if you're not contracted, yes you will get those payments.

23 Still spending a lot of time running around the United States. It seems mostly, lately, talking at
24 oncology conferences. A lot of interest in the oncology community with a number of things that are going
25 on at Medicare and what the future holds. In fact, I'm going to be up in New York, day after tomorrow,
26 speaking with an old friend, Peter Bach, who used to be at CMS.

27 Website's back up now. We've had a lot of trouble with keeping the website up and I apologize
28 for any of you that have been going to check on your issues lately, but we're back up now.

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1 efficient care for Medicare beneficiaries. So one of the themes that you see here is we're not just talking
2 about clinical effectiveness. So you see use of terms like value, a factor of both quality and cost,
3 performance measurement rather than just quality measurement, to indicate a broad range of considerations
4 around performance, including performance on cost. You see that we're talking about encouraging both
5 higher quality and more efficient care. So many different aspects to Value-based Purchasing. And the why I
6 think is easy for all of you who are quality experts and interested in use of Medicare incentives. The idea is
7 that we have a big opportunity to improve both the quality and to avoid unnecessary costs in care. And
8 along the way, we'd like to use incentives to accomplish a decrease in the variation, the unnecessary,
9 unwarranted variation in care, decrease in the fragmentation, and there are a lot of stakeholder comments
10 about using Value-based Purchasing to decrease fragmentation, as we'll see when I get to the stakeholder
11 feedback. And then the idea that we know we have current incentive. Because any payment system will
12 have incentives and we understand that our current payment incentives are part of the problem that feed
13 into the fragmented system and the variation, and then of course, we've got our solvency issue, where I
14 think the latest estimate by our Office of the Actuary, is that the Part A trust fund, at least, will be insolvent
15 by 2016. That's not very far down the line and with decreasing problems, with the economy and the
16 revenue sources for the program, that is looming large.

17 So our statutory authority as I said, that darnn paper clip, it just shows up whenever you don't
18 want it. Our statutory authority from MIPPA, very simple, very straightforward. Basically, just asks for a
19 transition plan to a Value-based Purchasing program for physicians and other practitioners I think is the
20 statutory language, with a report due to Congress May 1 of 2010, so having provided some technical
21 assistance to the Hill staff who worked with their members and their legislative counsel to draft this
22 provision, we understood that they were interested in us duplicating, if you will, the hospital Value-based
23 Purchasing plan development process for the Part B payment system. You'll remember that throughout the
24 latter half of 2006 and 2007, we worked on a hospital Value-based Purchasing plan that was presented to
25 Congress in November of 2007. So the folks who were writing this legislation liked that, and asked us to do
26 the same thing for professional payment.

27 This is the process that we've undertaken. Again, a lot of parallels here to the hospital Value-based
28 Purchasing planning. We've developed an internal Value-based Purchasing work group, with cross

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1 component expertise within the agency, to staff four subgroups, and the subgroups are the topics that you
2 would expect to see in a plan that connects performance to payment. So first of all, we have our
3 foundations group. The measures group, the measures are the foundation. So I guess we could call them the
4 foundations group as well. That's co-chaired by Dr. Mike Rapp, whom you all are very familiar with,
5 directs our, within the Office of Clinical Standards and Quality, directs our Quality Measurement and
6 Health Assessment Group. He co-chairs with Karen Milgate, who works with us on efficiency measure
7 development. So again, the dual focus on both clinical effectiveness, patient safety, other aspects of clinical
8 quality, and on cost of care. Then we have a group that's chaired by Terry Kaye, who's been involved in
9 physician payment issues for a long period of time at CMS and brings insight into the incentives that we
10 would use based on the performance measures. We have a group looking at data infrastructure, because we
11 have to bring this large amount of information into the agency in order to be able to apply the incentives,
12 and then to publicly report the information. So these are all four very important subgroups that will
13 contribute to the overall plan.

14 As you would expect, we are also building on the experience that we have in our demonstration
15 projects and also our ongoing programs that are relevant to Value-based Purchasing across settings and also
16 building on what we learned from private sector VPP experience and as I've mentioned, our experience in
17 developing the hospital VPP plan. So the first deliverable for the workgroup was our issues paper, which
18 was posted a few months ago, in November, a few weeks ahead of our listening session to be the
19 background information for that listening session. It's been available on the website under the Physician
20 Center spotlights since November, and I hope that you've had a chance to at least scan that and possibly to
21 review it in more depth.

22 The structure of the issues paper. We began where you would expect, with our goal objectives,
23 assumptions, and design principles. And I'm going to be reviewing those to give you a feel for where we're
24 headed here. The design issues were broken down into not only four subgroup major topic areas, but also
25 into overarching design issues discussion. And the appendices to this particular report are interesting. Not
26 only do we list the work group members, so you know whom to hold accountable, but we also have an
27 appendix that captures all of the relevant CMS demonstrations and other aspects of CMS's experience that
28 have been informing this particular initiative. That's a particularly complete portion of the appendix, and if

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1 you want to know all the things that are going on relevant to physician Value-based Purchasing currently at
2 the agency that will inform where we're going, that's a good place to look. And then we also captured just
3 select highlights from private sector experience. Again, another good resource, but not as fully complete as
4 the appendix about the CMS experience.

5 So again, we started with the goal and objectives. The goal is an attempt to capture several key
6 ideas; to improve Medicare beneficiary outcomes and experience of care by using payment incentives and
7 transparency to encourage higher quality more efficient professional services. Well, you see reflected in the
8 PVBP planning goal, you see then reflected our goals generally for Value-based Purchasing. The focus on
9 the beneficiary, the idea that we're moving to quality outcomes, but also other aspects of performance, like
10 the patient's experience of care, and then you see in there quality and cost, in terms of efficiency, and the
11 dual use of the measurement information for both payment incentives and for transparency or public
12 reporting. So there's a lot in that goal, but I think you'll find that it's consistent with the overall goal for
13 Value-based Purchasing. And then we have the four planning objectives that flow from the goal. They're, I
14 think, not unexpected. We obviously want to use incentive to promote evidence-based medicine through
15 measurement payment incentives and transparency. Also, this idea of reducing fragmentation and
16 duplication, so alignment, which you'll see a lot repeated in the stakeholders' comments are reinforcing,
17 and better care coordination transitions, and doing so, looking across episodes of care. The idea that we can
18 encourage effective management of chronic disease through various improvements in the incentive
19 structure. You know that our particular population, the Medicare population, is more apt to have multiple
20 chronic diseases and we feel like that's a good place to focus as we're developing the Value-based
21 Purchasing plan. And then the fourth is about accelerating the adoption of effective health information
22 technology. We got a big boost in this objective from Congress in the recent American Recovery and
23 Reinvestment Act that has a significant chunk of money now available for Medicare and Medicaid, HIT
24 incentives for physicians and for hospitals.

25 So those are the goal and the objectives. Then we also have our planning assumptions. And I think
26 in some ways, these may be more enlightening. I think the goal and objectives are probably what you
27 would expect, having been familiar with our VBP plans generally, but the assumptions really start to get to
28 what we're going to accomplish through this particular process and how we're going about it. So of course,

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1 the focus will be on performance-based payment, but we started to think more about how to really make
2 this work on the ground, and how it's very different, this planning process, for professional payment than
3 our hospital Value-based Purchasing planning. First of all, we've got to figure out how to accommodate
4 multiple different practice arrangements. Hospitals are relatively homogeneous compared to physician
5 practices, so we've got to figure out how to accommodate different practice arrangements. While
6 recognizing the contributions of all of the members of the health professional team, so you'll recall that our
7 statutory authority wasn't just physicians, but it was physicians and other practitioners, non MD DO
8 practitioners and we need to figure out how to pull the other practitioners and therapists into the Value-
9 based Purchasing model. The idea of addressing multiple levels of accountability. This is related to
10 accommodating different practice arrangements, but even within a practice arrangement, like a group
11 practice, you can have multiple different ways to assign accountability. We can talk a little bit more about
12 that. Then the idea that given the solvency issues that the program is facing, that our plan should be
13 expected to be and would be expected to be by policymakers, like Congressional leaders, to be at least
14 budget neutral, and ideally, identify program savings. Now when you think about opportunities for program
15 savings, and you think about the problems that we already are in with physician reimbursement, and
16 policymakers seem to be looking for ways to find more money for physician reimbursement, it makes you
17 wonder where those savings might come from. Well, the first item of business is of course to look for
18 greater value for what we're currently spending. So that's one way to enhance the services, through greater
19 value. But in terms of finding program savings, we are expecting to look across all of the parts of Medicare,
20 particularly parts A and B, to see if there's an opportunity to find program savings there. We would initially
21 focus on tradition Fee-for-Service Medicare, but as I said, potentially look across all parts of Medicare.
22 And the idea that we aren't going to be able to envision probably necessarily where we would want to be in
23 detail in 20 years, or even 10 years, but that we would provide more detail for shorter-term options, 3- to 5-
24 year options with more vision or framework for longer-term timeframes, with the idea that we would then
25 build in transitions; how to get there from here, without having to necessarily specify all the details of the
26 longer-term plan, and then attention to healthcare disparities. We've talked some in this group. I've talked a
27 lot in other forums about healthcare disparities in a Value-based Purchasing context. I believe that with
28 some creativity, we can actually counter disparities using Value-based Purchasing and take this potential

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1 unintended consequence of adverse selection, or cherry picking, or cream skimming, and actually turn it on
2 its head with the use of incentives, where we're actually using incentives to counter disparities, so we're
3 going to see if we can pull that into this particular plan. And then the idea that we need to include an
4 ongoing evaluation process. And this is consistent with the Institute of Medicine's encouragement to
5 Medicare policymakers, to move forward with performance-based payment, but do so in a way that
6 accounts for the possibility of unintended consequences, and so we would do that through ongoing real
7 time and in-depth program evaluation.

8 So I have five slides then, that are the heart of the presentation on our stakeholder feedback from
9 the four major topics in the overarching issues. So the first thing, which was encouraging to us is that the
10 stakeholders overwhelmingly affirmed our goal and objectives, but they also reminded us that the goal and
11 objectives are fairly 50,000-foot level, and so as we all know, the devil's in the details. And so even though
12 most agreed with the general direction, they said we want to see how the details play out. They advocated
13 for new payment approaches that cut across settings and align part A and B payment incentives. We talked
14 about the importance of that in decreasing fragmentation. This theme of alignment, you'll see, shows up in
15 all of the major topics, but again reinforcement for our idea of looking more broadly than just to part B
16 payments. They agree that we need to accommodate different practice arrangements, that it's not going to
17 be a one-size-fits-all, and praise the attention to disparities and the idea that we recognize that there could
18 be potential unintended consequences, associated with disparities and like the idea that we might think
19 about using incentives to counter disparities. And then, folks urged attention to the operational transitions.
20 The mantra was make sure that the beneficiaries don't get caught in the middle as we undergo what's
21 potentially a revolutionary change in our approach to payment for professional services.

22 Under the measures topic, then, again this theme of alignment across settings and payers. It has to
23 do with both the rational approach to use of incentives; the more payers who are using the incentives, the
24 stronger message that's going to send, and also the more consistent message that sends to the practice. It
25 also has to do with the burden of reporting, which we'll talk a little bit more about, when we talk about the
26 data infrastructure. There was a lot of input about different kinds of measures that we should be employing.
27 Currently, as you know, we have a majority process measure. And folks say we should be moving toward
28 outcomes, care coordination, measures of patient experience, and also HIT. That risk adjustment is very

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1 important to make sure that we're comparing apples to apples when applying incentives, that we ought to
2 be looking at both quality and cost measures and not just the fact that you need to look at both in isolation,
3 but the idea that they need to be looked at together, sort of this idea that efficiency or value is a
4 combination of the two, and looking at one in isolation is an incomplete picture, and then several folks
5 suggested avoidable readmissions as a good measure of both quality and cost. And this gets at the part A
6 part B coordination issue, as well, interestingly in the last couple weeks, the President's budget overview
7 has indicated that readmissions might be a focus of the new administration. And then, the commenters
8 agreed with our idea that addressing multiple levels of accountability for the performance information goes
9 along with the idea that one-size-doesn't-fit-all where you might have some different folks practicing in
10 ambulatory settings, or inpatient hospital settings. You might have folks who are wanting to be held
11 accountable as individuals, but others as a team, and others as a multi-specialty group practice. Others may
12 be an accountable care organization, integrated system, so lots of different options there for practice
13 arrangements and levels of accountability.

14 The next slide, then, has the input on incentives. So some folks have been frustrated with the
15 relatively small magnitude of the PQRI incentives and indicated that the incentives should be large enough
16 to be meaningful. They should be large enough to drive behavior. They should be timely and cover the cost
17 of participation. So there should be an upside, that the incentives should be coordinated among payers,
18 again, like the measures and the measurement data, the idea that the incentives would be coordinated to
19 give a stronger signal, that they would reward both attainment and improvement, not just the high attainers,
20 but those who need improvement shouldn't be left behind. That they should promote the use of effective
21 HIT, I talked a little bit about the most recent legislation in that regard, and that more than one structure
22 may be necessary to accommodate different practice arrangements, depending on the different goals that
23 might be out there for the use of incentives.

24 Data infrastructure. Of course, administrative burden is paramount when we're thinking about data
25 infrastructure, how to minimize that administrative burden to focus on what's more important, which is the
26 uses of the information. Some suggestions were made about use of registries and ERH reporting, as
27 superior to claims-based reporting, although there are important uses for administrative data as well, the
28 idea is that we should be using all those data sources. Folks want and felt like they deserved in participating

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1 in something like this, timely, detailed feedback, that they can actually take action on. That makes a lot of
2 sense and we would work to get to that point. And then a thing that was raised quite often was the idea for a
3 review period prior to any use of the information. And so like we have for hospitals, before public reporting
4 of the hospital quality data on hospital compare, the professionals who responded, as stakeholders here,
5 indicated that they want the opportunity to review the information prior to its use for a public reporting or
6 payment purpose. Then the last slide is on the core feedback slides is on public reporting. To a large
7 degree, the stakeholders affirmed the importance of transparency, and the various important uses of the
8 reported information, but urged caution in that even though transparency can help consumers and
9 professionals who are making decisions about referrals, for example, that inaccurate information is worse
10 than no information at all, and also encouraged multiple different approaches to public reporting, to reflect
11 the multiple different approaches to accountability, with the idea of course, that the information needs to be
12 as user friendly as possible, to all of the different audiences for the publicly reported information. So the
13 last slide here is next steps in planned development. As our new leadership is assembled, we will receive
14 direction, and at that point, be very timely, because at this point, we're moving into design options. These
15 design options reflect a discussion that was in a letter to Congress that was submitted in January as an
16 update. I believe that letter has been provided in your packets of material. And it laid out some approaches
17 that we're going to be exploring more deeply.

18 First, Physician Fee Schedule overlay, basically how to make performance-based payments,
19 within the context of the Physician Fee Schedule, perhaps with the enhancement of the medical home.
20 Another is looking at levels of accountability beyond the individual payments under the Physician Fee
21 Schedule, like group level, or accountable care entity level accountability. The idea of looking at shared
22 savings models that would build on the model that we've studied in depth through the Physician Group
23 Practice demonstration project. And there are other shared savings models that are happening in the private
24 sector that we would study as well. And then the idea of bundled payment arrangements will be under
25 consideration. You may be familiar with the accountable care episodes demonstration project that looks at
26 bundled payment for specific conditions for hospitals and physicians that have chosen to participate in that
27 demonstration. So lots of different approaches to consider and then various levels of complexity within
28 each of those is going to keep us very busy.

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1 And then we would use available resources to model and simulate these different approaches and
2 then hopefully, have opportunities for additional stakeholder input. We know that this is going to be a topic
3 in our Physician Fee Schedule 2010 rulemaking, because we're already planning ahead for the contents of
4 that proposed rule, and then there's the potential for at least one more listening session about the design
5 options and perhaps more than one listening session. We'll have to see what direction we receive from our
6 new leadership. So that's the overview of the Physicians Value-Based Purchasing plan development. I'd be
7 happy to discuss anything further with you at this point.

8 Dr. Bufalino: Thank you. Janice?

9 Dr. Kirsch: I have five quick comments. First of all, just commenting about the culture in which
10 PQRI was initially established. Pretty much it was set up to create winners and losers and to help with
11 budget neutrality. And I really think it's time to start thinking about creating a culture in which you try to
12 "float everybody's balloon up." Try to bring everybody up to the right level, and I think it's going to work
13 out a whole lot better. Secondly, when we look at the outcomes that we're doing, I really think we need to
14 be looking at outcomes and following through with processes, as opposed to the outcomes of the final
15 result of the patient, like whether their hemoglobin A1C came out good or bad. What we're going to do is
16 just create a culture in which overtly, you're going to kind of push out the patients from your practice that
17 make you look bad and not include the others. And that really isn't going to help with overall costs. You
18 really have to make it easy for that doctor to continue to work with that difficult patient and not want to
19 wish that they can make them go away. Third, are the guidelines which are being used. And I really haven't
20 heard too much complaint about the guidelines that have been established, but I encourage you to be
21 careful about your source of guidelines, and to really encourage you to look at the AMA Physician
22 Consortium for performance improvement and the guidelines that they have set, because they certainly
23 work with all the subspecialties and I think there's a fair amount of consensus with that, because when you
24 just look at any particular guideline, there can be so much variety that you just really have to be careful of
25 which ones you pick. Next, we never talk about patient accountability. I haven't seen that come up here.
26 And it's time to start floating that conversation. And lastly, with the Compare website, on the physician
27 outcomes, I'm not sure if there was ever an opportunity for public comment, which I understood that there
28 was a plan to allow public comment before it went up and my understanding is that that never happened.

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1 Dr. Valuck: Lots of food for thought as we move from current approaches to an approach under a
2 Value-based Purchasing model. So you spoke of winners and losers under PQRI, since it was characterized
3 as a bonus program, I guess there were those who didn't get the bonus, but I don't know that you could call
4 them losers. I think that there is an upside there for folks who figured out the relatively claims-based
5 reporting system. In terms of the idea of moving toward outcomes measures. That is very important. This
6 idea that if patients are sicker, we need to be sure that they aren't somehow disadvantaged under our
7 approach. And so one of the things that we're going to be thinking about is not only the adequacy of risk
8 adjustment, but how to potentially apply incentives to encourage the care of sicker folks. In other words,
9 the incentive could be larger based on the better performance for a sicker patient, than on better
10 performance for a patient that's not so sick, because apparently there would be more challenge there in
11 caring for and improving that patient's outcome. So we like that approach. We agree with that. In terms of
12 the roll for the PCPI, as you know, the great majority of current measures come out of the PCPI and I've
13 been encouraged that the leadership of the PCPI is taking an even broader view. So as we talk about all
14 these different aspects of performance measurements, I am encouraged that the PCPI is looking at all of
15 those beyond just developing more process of care measures. Patient accountability. That's an interesting
16 piece to inject here. Though we don't require a lot of patient accountability in a Fee-for-Service system,
17 and it's unclear how politically feasible adding patient accountability might be, but that's one of the top
18 things that I hear from physicians is I can't be responsible for everything the patient does, even though
19 physicians recognize that they're probably the primary reason why patients get engaged and want to follow
20 the direction from the physician. There is some role, obviously an important role for the patient as well.
21 And in terms of a compare website, I know that that's been an item of discussion. We don't yet have a
22 physician compare website. There has been some data that's been posted, but the PQRI folks would have to
23 talk with you more about that. As we're writing this plan, however, under the public reporting piece, we'll
24 no doubt be discussing a physician compare website, so when I talk about additional options for
25 stakeholder comments, that would be a place where you have an opportunity to have input. Good
26 comments. Thank you.

27 Dr. Ross: I'm glad that Dr. Kirsch brought that point up about patient accountability. I'd call it
28 also patient compliance, Dr. Valuck. I mean you and I, I think, went over that a little bit, when you first

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1 rolled out before PQRI, when we talked about those patients with co-morbidities and other problems. Just
2 as a couple of examples, today especially with our economy, we have patients who have, let's say eight to
3 ten medications, and they may be taking four or five of them because they can't afford to take a certain
4 number of medications. Many are taking generic drugs, sometimes complications with generics. We had
5 that discussion earlier. I'll share with you that privately at another time, but in my particular case, I have
6 patients all the time, who take their casts off themselves, or diabetic wounds and they're not staying off of
7 their feet, and so those wounds don't heal, and so they take much longer time to heal, and I'm sure all the
8 other subspecialties deal with this constantly. I think that's an area that we need to explore. Not just
9 accountability, but patient compliance—how well are those medications working? Are they taking their
10 medications? Are they coming in for their visits? Are they keeping their visits? With deductibles these
11 days, are patients able to afford to even come in to see their doctor? We're seeing that more and more now
12 with the new year, patients are not coming in because they can't afford to come in. So I've given you a
13 couple of points on the medication area, on the economy on patient compliance that might change some of
14 these guidelines.

15 Dr. Valuck: Couple of things. One is, it usually comes up that the patients who are more likely to
16 be noncompliant are also the ones that are more likely to be vulnerable, potentially disenfranchised by the
17 system. So I think we can get at the compliance issue through appropriate adjustments in the scores, and in
18 the incentives to reward caring for these vulnerable patients. And remember, all physicians struggle with
19 the compliance issue, so to the extent that you're being compared to peers with like patient populations,
20 that should help in making the comparison more obvious, and also should give the incentive to focus on
21 increasing the compliance, again, believing that the physician is probably the number one factor in
22 encouraging compliance, you can actually under the right incentives, be rewarded for increased focus on
23 that particular issue.

24 Dr. Sprang: Couple of comments as well. One is on patient accountability and patient compliance,
25 it does make some difference where you practice, too. I'm fortunate I practice in a more affluent, nice area.
26 When I ask a patient to get a study or do a test, they're going to do it. If somebody practices in the inner
27 city, and different circumstances, and I'll even say people around cocaine or something like that, they're
28 not anywhere near as likely going to follow through. And there are different patient populations, and

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1 different physicians take care of different populations, and those are real. I do want to absolutely
2 congratulate you on paying as much attention to the stakeholder input on that. I think it was a great
3 presentation. I liked all the slides, on really looking at issues that have to be taken into account. It's clearly
4 what you're doing has to be done. We're spending too much money, we need more cost effective care
5 without a doubt, but having said all that, there are also very complex issues and I'll go back to our first rule
6 of medicine, is first do no harm. So take the steps a little more cautiously and thoughtfully that we don't
7 harm either the patients or the physicians, because it's, as you already know, a very complex issues.

8 On some of the incentives, I'll just point to one that one of my consultants said, and just we have a
9 lot of wrong incentives now. If I order an ultrasound in the hospital and there's a question, because of
10 abdominal pain, the most common report I'll get back is there's something here—we're not sure, we didn't
11 see enough. You might also want to do a CAT scan. And then I do the CAT scan. And then the report
12 comes back with some of the information on the CAT scan that says, but you might be more thorough if
13 you do an MRI. The incentives are if the radiologist misses something, doesn't tell me to order another test,
14 they get sued. If they order another test, they get paid. And I think somehow we just have to address that
15 issue and kind of look at it, and I know there's not hard data, but I would say again, we're a Practicing
16 Physicians Advisory Council. I see what's really happening in the office, I see what's really happening in
17 recommendations. I'm not sure how we do anything about it, especially at this point in time. I'm going to
18 say defense of medicine probably accounts for about 20% in healthcare dollars. I can't prove that because I
19 don't have hard data, but it's certainly what I see in the real world. And I think somehow we have to
20 acknowledge that, and try to do something about it.

21 The third point is just kind of location of services. I was pleased to see again maybe some
22 alignment between part A and part B. I think appropriate care in the most appropriate safe setting, a
23 hospital is a very expensive place to provide care. If you can provide some of these procedures, and I've
24 said repeatedly in this room, we do a lot more things in our office, and I really do believe it can
25 significantly decrease the cost. It's actually more efficient, more convenient, certainly can be done safely
26 for the patient in the cost savings are, it's done for \$200 in the office, and \$5,000 in the hospital. And I can
27 give you numerous examples of this; doing a colposcopy, a number of relatively small procedures, where
28 the patient goes into the hospital, it literally is a \$5,000 bill. So the location of service, I think is something.

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1 And alignment of A & B. If we can save those costs by not going into part A, well then does some of that
2 money get put into part B so it makes sense?

3 Dr. Valuck: Yes, definitely things that we've been considering. The hospital is an expensive place
4 to receive care and as we've learned through the implementation of our hospital acquired conditions
5 provision, also a relatively dangerous place to receive care, and so we've used incentives in that way to try
6 to decrease the incidence of hospital acquired conditions. And some of the payment models that you've
7 seen would continue to push in that direction for the alignment and getting rid of the fragmentation,
8 focusing, for example, on preventing avoidable readmissions.

9 Dr. Sprang: Defensive medicine?

10 Dr. Valuck: Defensive medicine. You talked about giving the right incentives not to over order
11 care. Some of the mechanisms, again, that we talked about, for example bundled payment or shared savings
12 models, reward picking the right services and there would be a financial consequence to ordering services
13 that have marginal benefit. So it might cause some additional thinking about what that right bundle of
14 services for that patient might be.

15 Dr. Sprang: How do we decrease the fear factor in the physicians for getting sued?

16 Dr. Valuck: I think you have to reward them for taking on that marginal risk.

17 [laughter]

18 Dr. Sprang: Have you ever been sued? How can you reward me for being sued and going to trial
19 and being there for three or four weeks and being in a really I'll say stressful situation, and potentially, I
20 mean it would be over my policy limits and actually losing my retirement fund. Those are major issues that
21 are affecting decisions on a daily basis.

22 Dr. Valuck: Yes, and so my point is that right now, there is no, as you pointed out, no downside
23 financial consequence to really stepping back and giving a thoughtful view of the bundle of services. The
24 encouragement is actually because there's additional quantity-based payment incentives, to go ahead and
25 order to the nth degree. The financial incentives can give an opportunity to take a pause and think about
26 that correct bundle of services that would be ordered.

27 Dr. Sprang: That's from the positive side as far as maybe some reimbursement. The negative side,
28 the threat of getting sued, the risk, the stress, the possibility that every physician I know is worried about,

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1 they have a million dollar coverage, that in Illinois for sure, it easily can be a \$3 million judgment. That's
2 coming after your personal assets. That's going to way overwhelm anything else. One of my partners was
3 recently in a case where a baby's finger was cut and the question was whether it was in the delivery or in
4 the hospital later. I won't go into any of the details of that. I will go into the fact that the jury awarded \$2.7
5 million, and fortunately for us, it came from the hospital, not the doctor. But with those kinds of threats out
6 there, it is significantly impacting physician behavior. And I think if we're going to cut costs and have
7 medical care provided with just what's in the best interest of the patient and not just preventing lawsuits,
8 somehow we've got to address that. It's a significant part of the healthcare cost. And I don't think we're
9 saying that enough.

10 Dr. Bufalino: Unfortunately, I don't think Mr. Valuck's going to solve the liability crisis.

11 Dr. Valuck: Thank you, Mr. Chairman.

12 Dr. Sprang: But shouldn't it be part of what we're looking at, is what I'm saying.

13 Dr. Bufalino: But can I just pick on one thing that Leroy said, to go back to? I just wanted to make
14 clear, so is there an opportunity now for there to be a cross pollination of funding of part A and part B? Is
15 that a serious consideration in the agency?

16 Dr. Valuck: As we've indicated, we're going to be looking at opportunities to do that through the
17 planning process.

18 Dr. Bufalino: Good. Janice?

19 Dr. Hirsch: I think we all agree that radiology costs contribute significantly to the increasing costs
20 of medical care across the board and Dr. Sprang brings up a good point about the liability issues and what
21 we really need are some reasonable guidelines as far as ordering x-rays and when you can get by without
22 ordering the radiologic studies and I cringe every time I make a decision to order a CT scan, because I
23 never end up with one CT scan. Everybody in the state of Iowa has been exposed to a little bit of
24 histoplasmosis, and everybody has a little nodule on their CT and everybody gets CT scans every six
25 months for two years. There's a level of some ridiculousness to it, and it's really up to the radiology groups
26 to help set some guidelines and some standards. Because their report will say, could be monitored,
27 physician discretion, do another CT in six months. They don't order it themselves, but they make it darnn
28 clear that you're really pressed to the wall against that, and we really need some incentive for the radiology

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1 groups to come up with some guidelines as far as ordering those, if you really want to cut the radiology
2 costs.

3 Dr. Valuck: So you mentioned the Physician Consortium for Performance Improvement in your
4 first comments, and said that we should be looking to them for guidelines. I think that's a really good
5 suggestion—

6 Dr. Hirsch: You're absolutely right.

7 Dr. Simon: Just also add that this is an area that has been looked at by both the CPT Editorial
8 Panel as well as the RUC, and we don't have any radiologists here, unfortunately, but they would say that
9 they are not the ones that order the tests, and that the physicians, the primary care physicians and others are
10 the ones who order the tests, in fairness to them, since they aren't here to speak for themselves. So this
11 question has been an ongoing one, but I think that we have made appeals to all of the specialty societies to
12 consider creating clinical guidelines that would be used for those common diagnoses that people are seeing
13 and treating on an ongoing basis. And the reviews have been mixed when we've requested the specialty
14 societies to consider developing clinical guidelines. So it's certainly an area that's ripe for more discussion,
15 but there has been considerable dialog along this area, not only within CMS, but also outside of CMS.

16 Dr. Hirsch: I guess I would say the push probably needs to be from the physician community to
17 kind of push back on them so to kind of get at some changes on that.

18 Dr. Bufalino: Leroy wants a rebuttal shot.

19 Dr. Sprang: Yes, I just [off mike] but in report, they're suggesting you do it. In an environment
20 where if you are wrong and you don't do it, if you miss something, you know you're going to get sued and
21 you're going to lose because they suggested it. So they're not out in out suggesting it, but almost every
22 physician is going to order it just because of defensive medicine, because they're afraid if they don't order
23 it, and they miss something, they're going to get sued and they're going to lose. So they're in a no-win
24 position and the test is going to get ordered.

25 Dr. Ross: Clarification for osteomielitis. Suggest for the testing. They always do that, and same if
26 you pick up something on CT in the abdomen or the chest or wherever, they're always doing that. Leroy's
27 correct. I just wanted to ask a particular question on the bundling. You brought that term up and I'm just
28 trying to get an update on the bundling concept. Where are we heading with this bundling of fee service,

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1 particularly with complicated cases, with many co-morbidities? We know that surgical intervention
2 involves a 90-day fee, global fee, so how would that change or where would that come in and where is the
3 physician reward, versus the detrimental aspect of the physician with a global, if you will, bundled fee for
4 procedures and hospitals? Where are we headed?

5 Dr. Valuck: Well, that's one of the things that we're going to be addressing through the planning
6 process. There are no clear approaches at this point in time, so your questions are some of the questions that
7 we share. We do have the Accountable Care Episodes demonstration project to look to for at least early
8 partial answers to some of those questions, but there's not a whole lot of experience out there with bundled
9 payment and so we'll be trying to get at the evidence to answer some of those questions through the
10 planning process.

11 Dr. Standaert: One other angle on that, where you're talking about physicians sort of ordering
12 things, one of the drivers is certainly the defensiveness and the radiology sort of report and that sort of
13 thing, and the other is patient demand and expectation. In the midst of this, I didn't hear you ever talk much
14 about sort of the juxtaposition or conflict between physicians practicing in a marketplace where patients
15 have certain expectations they look for or things they want conflicting with restricting things with Value-
16 based Purchasing. People get MRIs, frankly [unintelligible 21:53] people want an MRI. They come in
17 saying I want an MRI of my back. That's what I want. If I don't do it, someone else will do it, so they'll go
18 somewhere else and it's a competitive marketplace for the patients. You wind up with the same thing. The
19 patients watch the marketing for a certain drug and say no I don't want this drug, I want that drug. I saw it
20 on TV. My neighbor takes it. It seems to work very well. So we're not working in a vacuum, we're
21 working a world where the patients have expectations from the outside world, and for marketing from other
22 places that come in and affect their choices and their demands and their expectations. And if we don't meet
23 them, then we get rated poorly on their expectations side. We get dinged on websites, they don't come back
24 to see us, our patient flow goes now, and just going after the physicians I don't think, you leave us sort of
25 fighting the south side force by ourselves, then. Does that make sense?

26 Dr. Valuck: Partially, yes. As we've talked about, the patient's a very important partner in the
27 care. We've talked it about it from the patient accountability, patient compliance perspective. You're
28 talking about it now from the patient expectation perspective. I think the best way to deal with

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1 inappropriate expectations on the part of the patients is both through education at that level, the individual
2 physician patient level, but generally to have more educated patients in our society and we think about the
3 efforts that are being made to educate consumers for example, through the information that we're providing
4 in terms of transparency. It's an effort to engage them and get them to be more educated in what their
5 expectations should be. Having said that, as the Medicare program, we look to the licensed professional to
6 be the one to order the services and make the decisions. And so we're not going to hold the patient
7 accountable for the ordering of services. They're not legally able to do that in any of your states. So there is
8 a responsibility and it does ultimately come down to whoever is writing and signing that order. None of us
9 work in a vacuum. We all work in social systems, and so I understand what you're saying about patient
10 experience expectations and how that plays into the legal liability, so clearly there are other considerations.
11 But bottom line is, the physician writes the order.

12 Dr. Standaert: There's a kind of a shared risk in there. So if you're asking people to sort of say,
13 likelihood of this is low, evidence-based guidelines say I do this, because likelihood is low, the physician
14 isn't assuming the entire risk somewhere, other than talking to patients, saying you know, if we really want
15 to know, we should get this. And patient goes well, sure, just get it then. Why shouldn't I get it? And it's a
16 difficult conversation in the current structure, because it's all on the physician, and we're up against a lot of
17 external forces in education and demand that we can't do anything about.

18 Dr. Arradondo: I wanted to, I've comments about this last four piece here, in terms of what I do,
19 but my reason for holding up my hand a while ago, had to do with patient accountability. I realize that you
20 want the system to do a lot for the patient and I think you've just said there's not a lot that you can require
21 the patient to do for the patient. One of the things that, well let me back up, you referenced in your response
22 and I appreciate your detail, of the number of diagnoses, that section, where you referenced the four and the
23 eight, and then you referenced for acute conditions, so to speak. And then for ongoing and chronic
24 conditions, whatever gets reported during the course of a year, in order to adjust risk and apply risk to
25 interaction with the patient. My question and one of the recommendation that I would have, relates to how
26 thoroughly that data is collected when some of the activity is not provided by hospitals or physicians,
27 because there are other providers. One example that fits that, that gets into the business of adherence, as a
28 measure somehow of patient accountability, patient involvement, relates to the outsourcing—I call it

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1 outsourcing, of diabetes education. It's a whole code and some, a small series of codes there now. And they
2 are being treated in a fashion analogous to saying, and we had this discussion earlier, which is the reason I
3 raise it again, to saying to say, the family physician or the orthopedist, you're going to have a disincentive
4 for keeping a cast or a support gadget, joint support gadget on your shelf and giving to a patient, whereas a
5 physical therapy operation or some other operation will have an incentive, in fact, to hand out such medical
6 equipment. We had that discussion last year and again this year. And I say that because the diabetes
7 education, the code makes it simple for a person trained in health education to get the maximum payment
8 for educating a person around diabetes, whereas the primary care physician, the family physician, the
9 general internist, gets a much less of an incentive to provide the same education, use the same code, to even
10 get certified, as if they should be certified. That's one of the tenets of primary care education, family
11 medicine and general internal medicine, to have that kind of ability. You notice I use the word adherence,
12 not compliance. That's a whole attitude difference, and it's a whole skill set difference between the person
13 who thinks about compliance on part of a patient, versus a person who thinks about adherence. I said that
14 but I didn't intend to use it as an example, but it turns out, it is.

15 So that at the end of the day when the A1C's score's kept, and factored into a case of acute care to
16 relate to risk, for which you're going to say reimburse the physician or an appropriate provider at a higher
17 rate because you're taking a greater risk; or, at the end of the year, when the A1C is measured again, and
18 the physician, the A1C has not done anything, has not moved down, and so the physician gets less of a
19 reimbursement, because the physician hasn't done the right things, this gets back to the question of the
20 process. The physician's done all the right things. We talked about that in the HAC discussion, but it was
21 also referenced in just the general care discussion. In your response to the four and the seven diagnoses that
22 you would look at in the annual aggregate, I would offer the suggestion of mining the data better to get a
23 better view of the patient's overall risk, as well as a better view of the provider, particularly the primary
24 provider, on a chronic basis. But even the acute care provider, whether that's the primary provider, or
25 person operating on a person with diabetes, in the hospital, and realize that there's an excellent chance that
26 that person, who's merely say metabolic syndrome, when they go in, is going to make all the diagnostic
27 criteria—meet all the criteria for diabetes—simply because of the trauma of surgery, or for that matter the
28 trauma of a myocardial infarction or the trauma of several things associated with hospitalization. And they

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1 can carry that diagnosis of diabetes for a while. It's not quite like, we haven't figure it out like we have
2 gestational diabetes, so you have that during a period of time, and you're at risk later for a "regular"
3 occurrence, but it's almost the same kind of stress. Giving a person episode of steroid would do the same
4 thing. Put them over into a bona fide diagnosis of diabetes, but we don't have a way of capturing that for
5 long-term use when their sugar is normalized.

6 So I would recommend being able to collect all that data. You get it now, because you pay the
7 person who does the diabetes education, and you pay the primary physician for seeing the person, and you
8 pay the surgeon for operating on the person, and you pay various other people, hospitals, for doing things.
9 But if they are to get payment on an acute basis, or payment for product care basis, say using just the one
10 ear, and would get payment because they're dealing with someone who is at higher risk, in order to
11 measure that risk, all of those parameters need to be collected. Some of the insurance companies seem to do
12 that a little bit better than I here Medicare per se doing it. But then Medicare has access to much of the
13 information that the insurance companies have, and I realize I'm mixing Medicare and nonMedicare here,
14 but the process is the same, because insurance companies carrying out Medicare orders are their own
15 orders, so to speak, their own processes, in order to handle those two different classes of patients. Blue
16 Cross has for Medicare patients, Blue Cross for persons not Medicare. So I would offer some more work in
17 that area that you're already recognizing. The increased risk on an acute care basis, the increased risk on a
18 chronic basis, one year, all based upon data you collect from claims. I think if that data were collected more
19 rigorously, and in more real time, you would have a—and then you had a more responsive adjustment
20 protocol, you could ferret out the patients who are at much higher risk than those who are at just a little
21 higher or maybe average risk, and then be able to match the physicians, whether they're primary physicians
22 or whether they're the secondary, tertiary care physicians, that are often episodic care for that patient and
23 realize right away, recognize right away that this physician and this patient are dealing with a higher risk,
24 and therefore, higher level of accountability, I would pray, higher level of reimbursement for the involved
25 provide, I would recommend—not just pray—and then in the case of the patient, if we get to the business
26 of accountability for their level of adherence, then something there.

27 I will segue to the conversation just before this, Vince, and make two comments. One really, but
28 it's two parts. When my patients come to me and say, I like our first presenter's cartoons. I was looking for

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1 the second line under there. This is the way it wasn't on the web. Patient's computer in patient's lap, while
2 patient's in the hospital bed—not just a regular bed, but a little higher intense care bed, his slide showed.
3 When my patients bring that to me, it's the same equivalent of getting it from the *Redbook* 40 years ago, or
4 getting it from *Life* or some other book 10 years ago, or 15 years ago. It's just different communication. But
5 the web does allow the patient to get into much more detail, so often they know more about something than
6 I might know or would admit to. And so they ask me, or tell me sometimes, that I want this test and that's
7 fine. One of my first reactions is, my insurance company isn't paying me to listen to this patient. I just went
8 off the clock at 12 minutes. And now this is minute 15. But I usually ignore that, and my colleagues have to
9 talk to me about that, or the person who gives me the paycheck reminds me. But I ask the patient why do
10 you want this test? It's the same question I ask myself. Why do I want the MRI? Why do I want the special
11 test for serum porcelain, why do I want the [rubart? 35:05] test? And I have pen in hand, or typewriter in
12 hand, if I'm on the electronic one, and I write it down. And then I give the patient my best advice, and I
13 wrote that down. And my best advice might be fine, that's a good idea. My best advice might be, I haven't
14 run into that before. I haven't ordered that test for this before, but I'd be happy to order it for those reasons.
15 I might get my butt kicked. I'm okay with that, I know butt kicking. I'm talking to my patient. Your
16 insurance company might not pay for it. I don't usually have to follow up with do you know insurance
17 nonpayment. They know that right away. But that's how I relate to that and I don't get a lot of hassle with
18 it. Some patients want to go through with it. Payment's not issued. Most patients defer to my judgment. I
19 still have to write it all in the chart. I guess I'm happier with that because I've never been sued, but I really
20 shouldn't be happy with it, because every suit is a first time, so to speak. But that's what I do, and I do it
21 routinely. Somebody asks me something like this almost everyday, which is five or four percent of my
22 patients, given the numbers that I see. That's just my comment.

23 But I really would offer looking at that data collection that you already do, intensify, put it
24 together, and of course on the back end, I'd love the primary care providers, the general internist, who are
25 trained in the area and are pursuing primary care and the family physicians, to have an even playing field
26 on health education. Because when everything is said and done, and when the studies are done, the patients
27 say routinely that they respect identical health education coming from the physician far more than they
28 respect it coming from the best certified, CHE, certified health educator, and we have both in our practice.

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1 And why not pay the physician, or make it just as easy for the physician to do that? It would almost be
2 mini-counseling for us, because we seldom register counseling if it's under 30 minutes, although there are
3 some forms that we can register at five, or ten, or fifteen minutes. But this kind of counseling tends to be in
4 that 15- to 30-minute range, the diabetes education programs pay for, and yet it doesn't get attached to my
5 patient when it's done. And one little caveat for your watching: I've noticed that our carriers, who contract
6 and outsource and unbundled the diabetes education, tend to have diabetes educators, that take the patients
7 with the lowest, or the best A1Cs, and I have routinely decided to refuse agreeing that they will see such a
8 patient, and see what kind of payment the insurance company will give them. Because half the time, I have
9 helped to get that A1C down. I suggest routinely to the insurance company, have them take the patient's
10 A1C when the patient's A1C is in the double digits. I don't have many takers. I don't know if that's a
11 pattern, it just could be with us. But I'm trying to look at one or two data points and make conclusions,
12 revise if I need it later with more data, and that's what I've found. And some of our carriers have, in fact,
13 stopped pushing their diabetes education program on our practice. We still invited the program to see our
14 patients, but routinely, it's the people with nine and above. They're the ones that have difficulty adhering.

15 Dr. Bufalino: Thank you, John. One last question for the break. Greg?

16 Dr. Przybalski: Sure. CMS has made a choice to incentivize physicians and hospitals for certain
17 behaviors, positively and negatively; PQRI, HACs, I would think that CMS might consider doing the same
18 thing with patients as well, running along this theme of patient accountability. For example, you do not
19 have access, other than through claims data, any information about the patient. No outcome data at all,
20 clinical outcome data. Would there be ways to incentivize patients to fill out and share that clinical
21 outcome data with CMS. For example, their proportion of payment of reduced or changed based on that.
22 That might be a way to get more robust data beyond claims data that gets patient participation. In terms of
23 something that was mentioned about getting an MRI, I'll give the simple example of low back pain. Patient
24 with low back pain comes in, wants their MRI, even though guidelines would suggest that unless that's
25 been present for six to eight weeks, without some red flags, it should be done. CMS can have a negative
26 incentive; we won't pay for that MRI unless you've been symptomatic for 6 to 8 weeks. That doesn't
27 change the patient's option to get it. They're more than welcome to pay for it out of pocket if they want, but
28 CMS should look at ways to control this ever growing problem of imaging growth.

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1 Dr. Valuck: There are certain programs that private sector payers and employers are using with
2 their members and their employees in order to accomplish some of the things that you laid out there. And
3 also compliance on the back end. There's one approach that uses something called an information
4 prescription, in order to reward patients for going on line and following up with the things that they need to
5 do from a perspective of getting educated and being compliant. And then there's some rebate to them, some
6 of their cost sharing. Other private sector plans use tiering, or pay differentially for different value of
7 services, so to speak. There are some things that are going on that could potentially support that, like for
8 example, comparative effectiveness research. Right now it's a little hard to know the value of the MRA in
9 one instance versus another, but there are some studies and there are likely to be more with the new push
10 toward comparative effectiveness research. What it will boil down to in terms of our ability, our authority
11 to use those incentives will be a political determination. So you can imagine the discussions around that.
12 But Medicare of course will not be able to act without the statutory authority to do so.

13 Dr. Bufalino: I'll take the chairman's prerogative and end 40 minutes of grilling [laughter]. Thank
14 you for joining us. We'll take a ten minute break, and resume at 10:35.

15 Break

16 Dr. Bufalino: We can follow the presentation in the books if we don't have the slides. Let me
17 introduce our next speaker. Ms. Jean Moody-Williams is the current Director for CMS Quality
18 Improvement Group and has the responsibility for the Quality Improvement Program and we are interested
19 to hear your report on the 9th Scope of Work and what impact it's likely to have going forward. Thank you.
20 Good morning.

21 9th Scope of Work

22 Ms. Moody-Williams: Good morning. And thank you for having me here, to be able to provide
23 this opportunity to update you I think on the 9th Scope of Work. I believe that several months ago, you did
24 get a brief overview before we actually implemented the program, by Dr. McGann. I've now been with the
25 program about four months now, and brought on as the permanent director for the Quality Improvement
26 Group, and am looking quite forward to continuing the work for the 9th Scope, as well, we've already
27 started to give thought to what will occur in the 10th Scope. As we don't have the slides up front, I
28 understand they are in your packet, and hopefully they are numbered, and so I'll just refer to them as I walk

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1 through, starting with slide 2. And just a refresher, the purpose of the Quality Improvement Program: It is
2 mandated by law, and our mission is really to improve the efficiency, effectiveness, economy and quality of
3 services, delivered to Medicare beneficiaries. So our goal is to work directly with Medicare beneficiaries,
4 the provider groups that work with them, physicians, their families, to improve the care that's received. We
5 worked, we have three things that primarily we focus on. One, being focus quality improvement activity,
6 related to perhaps in the area of technical assistance or focus projects, as well as protecting the integrity of
7 the Medicare Trust Fund. Traditionally, this has been done in the past by way of efforts such as utilization
8 review and certain types of case review. We've moved away from that somewhat from prior years. And
9 there's some case review that we still do as we look at higher way to DRGs and other areas, but I think that
10 as we develop and evolve, we're going to be moving back to that area, more as it relates to efficiency
11 within the healthcare system, and we'll probably move in a different direction than just looking and
12 counting the number of services, but more the effectiveness of those services and how they interact in the
13 health market place.

14 The next thing that is required by our statute is protection of beneficiaries, by expeditiously
15 addressing their complaints. And whenever the term "protection" is used, particularly among practicing
16 physicians, it sometimes becomes a little bit offensive in that why do you need to protect the beneficiary
17 from me? And in reality, it's protecting or looking at the system that the beneficiary must navigate,
18 protection from what's become a fragmented system in many areas, and one of the things that I'll talk about
19 relates to more care transition. Protection from even government bureaucracy, or protection from
20 themselves, so it can take on a number of different meanings where we talk about beneficiary protection.

21 As far as our contract activity, on August 8th, 2008, CMS publicly announced the awards of the 9th
22 Scope of Work contracts. There were 53 contracts awarded to QIOs, to perform the work of the 9th Scope
23 of Work. They were all awarded on August 1st, which was a little bit of a departure from how we used to
24 award contracts. We used to stagger them, but in response to the Institute of Medicine Report, we changed
25 a lot of the procedures and processes that we used in the 9th Scope of Work. Thus, everybody started
26 primarily at the same time, with the exception of two states in which we had to renegotiate contracts. We
27 also introduced more of a competitive nature into this scope. Thirteen of the contracts were awarded
28 competitively, based on some criteria that we had on prior performance, and the other 40 were negotiated

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1 for their renewal based on the criteria that they met. If you look at slide four, you'll note that we moved
2 from—in prior scopes we tended to work more based on settings, and so we had areas particular for nursing
3 homes, for hospitals, for home health agencies, and was more a little bit more of a siloed approach.
4 Obviously as we move forward, and we want to have more of a coordinate care process, we wanted to
5 move more into themes. So we've moved away from the setting-specific themes to other themes, and you'll
6 see them related here.

7 First Care transitions which I'll talk—I'll talk a little bit about each one of these, but as an
8 overview, we have a core prevention where we're looking at health and wellness, a chronic kidney disease
9 theme, focus disparities theme, and particularly where we have a project that's focused on disparities, but
10 we really try to integrate the reduction of disparities throughout all of the themes. Beneficiary protection,
11 and then within our patient safety theme, we have a number of what we're calling projects, that deal with
12 various areas, such as pressure ulcers in both the nursing home and the hospital setting, physical restraints,
13 surgical infection improvement, Mersa, which is a brand new area that we've been looking at, nursing
14 home need and medication safety. So I just want to give a real brief overview of those themes, where we
15 are currently with the 9th Scope of Work, how the QIOs are doing and how we move forward.

16 I'll start with the Care Transitions theme. And you can see on slide five, I did want to mention that
17 some of our themes are what we call national, and every QIO is responsible for performing that particular
18 theme. And then we have some others that are subnational whereby we had a competitive process, the QIO
19 submitted their proposal, we ranked them based on what they placed in their likelihood of success, and
20 based on that, for at least three of our themes, we chose not to award them to every QIO for this scope of
21 work. Now, our hope is that we learn a lot from these particular themes, and if indeed they prove to be
22 successful, they would be expanded in the 10th Scope of Work. Well, care transitions, we received 14, what
23 we thought to be exceptional proposals to work in this particular theme. And you see the areas that we have
24 listed them. Slide five gives a really brief snapshot of how we're working with care transitions. And when
25 we talk about care transitions, we're looking at the care as the beneficiary moves from setting to setting, so
26 again, trying to break down some of these silos, and look to see how we can improve care and move the
27 patient from one setting to the next, as seamlessly as possible. One of the things that we noted when we
28 were looking at the evidence, and each of these themes have been based on available evidence, and they all

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1 have metrics, which was a requirement of the Office of Management & Budget, that we come up with
2 measurable objectives for these, but we noted that one of the areas when beneficiaries completed the CAP
3 survey that they rated the lowest, was dissatisfaction with their discharge process. And so we began to look
4 at that as a part of our care transitions from the time that they're leaving acute care facility and they move
5 out into wherever setting that they're going, there was some dissatisfaction there. We also noted that 17%
6 of the Medicare beneficiaries are often rehospitalized within 30 days of discharge and MedPac did an
7 estimate that perhaps as many as 76% of these readmissions may have been preventable. And we then went
8 a step further to look at what's happening in between the time that the beneficiary leaves the facility and the
9 time that they are readmitted, and we found that 64% of these beneficiaries receive no post-acute
10 intervention or interaction with a provider. So based on all of that, we came up with a project where we
11 would begin to look at how we could facilitate transitions in the community, with an overall goal at this
12 point, a metric of reducing readmissions. So you have an example of one community, small community,
13 and that's what we're calling these groups or teams that we've put together, because indeed we do believe
14 this is a local issue, and so in Tuscaloosa, they have the QIOs work to recruit their community, which
15 consists of seven hospitals, 13 skilled nursing facilities, and 12 home health facilities in a certain zip code.
16 They're working with 42,000 Medicare beneficiaries. The rate of readmission for this particular group was
17 18.9%, so it was pretty much consistent with others, and the number of 30-day readmissions were 1500. So
18 that's just one example. I could give you the statistics for all those communities that we've mentioned.
19 Slide 7 gives more a national overview and you can see that we are in awe with this particular project,
20 looking at about a million beneficiaries, and if we estimated their readmission rate, we would see that, and
21 we wanted to avoid 2% of them, we'd be looking to reduce about 2500 readmissions.

22 So in this project, it's new. It's exciting. The communities are excited to work together, working
23 with a physician groups, the home health agencies, the hospitals, we're looking to see how, between
24 readmissions to be sure that beneficiaries are getting contacts, getting their discharge planning, that they are
25 having questions answered, that their medications are being monitored, and it's again, too new to have the
26 results yet, but we will be happy to come back to you as this project moves forward to see if, indeed, we
27 have seen any reductions in readmissions, and to the extent that we can, what that's attributed to and
28 feedback from the provider community on how they would like to see this project go forward.

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1 Moving on to our next project, core prevention. Obviously, we want to try and institute wellness
2 and prevention wherever we can. And this project really builds off of a docket which we had in our 8th
3 Scope of Work, and that project was focused more on adoption of electronic health records, and what we
4 wanted to do in this particular project was move more from adoption to what we are now looking at as
5 meaningful youth of the electronic health record. How do you use the data that you're collecting in order to
6 improve patient care, to facilitate the practice efficiency, to be a help to both the provider and to the
7 beneficiary. So we began to focus our attention more and that's what we've done in most of this Scope of
8 Work, instead of casting such a wide net, trying to do all things for all people, we've tried to narrow it
9 down to see what are those areas in which people needed the most attention. So in the case of nursing
10 homes, for example, what were the nursing homes that were having the most problems. And we focused
11 our attention on those instead of doing all nursing homes in the state. In this particular area, we focused our
12 attention to physician practices that already had electronic health records, they primarily participated in the
13 docket project in the 8th Scope of Work so they had some familiarity with them. And then they were
14 willing, and this was, the QIOs had to go out and recruit a participation, and they had targets. We set targets
15 of how many practices they had to recruit, and they met all of those targets effective January 31st of their
16 participating practices. And then, as well, in addition to recruiting, they had to provide education to the
17 practices on how to glean the information that we were looking for. And our preliminary report said that we
18 would expect that the QIOs would give two hours of training in the physician's office, in order to look at
19 metrics related to colorectal screening, mammography, immunizations, vaccinations for pneumonia, and
20 preliminary report is that two hours is not enough, because the equipment that's being used, it's all
21 different. We do require that it be certified, that many of the functions that are being, the EHRs are being
22 used for may not necessarily coincide with trying to pull this out for clinical data purposes. And so in some
23 regards, that's exciting because I think we're showing that there's a need for this, and as we move forward
24 with the acts that are coming out now with the Recovery Act, we'll have some information by which we
25 can draw upon to see how we can best help the provider community use these EHRs in a meaningful way.

26 Moving on, I just want to note to slide 11, again, I show here the recruitment targets. We try to
27 stratify those based on the various areas that the QIOs were practicing on, so you can see that the larger

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1 QIOs had to recruit anywhere from 35 to 100 participating practices, physicians to work with this, and in
2 total we were trying to get 1500, and we are well on our way to doing that.

3 Once we get away from, right now, most of our metrics and all of our goals are geared toward
4 recruiting providers and beneficiaries for the first couple of quarters. As we move on, we'll be looking
5 more toward what are the outcomes. So we are looking for reductions or improvements, actually
6 immunizations in this case, when the rates of screenings in this particular case, and we're looking to extract
7 that from the electronic record, versus claims-based data.

8 On slide 13, it goes into another one of what we call our prevention theme. That was our core
9 prevention theme, where we're looking more at our screenings, and we move into a more focused area of
10 prevention, in which we are trying to have an early impact in the area of chronic kidney disease, so as to
11 delay or prevent where possible, the treatment that occurs with end stage renal disease. We did again, put
12 out for broad brush of QIOs that would be interested in working on this project and found that there were
13 10 states who put forth an excellent project that we wanted to fund, and so this became a subnational
14 theme, and once we're learning a lot actually from this project, as far as establishing the baselines, looking
15 at the interventions, and we anticipate that this would be one of our themes that would indeed continue on.
16 So there are 10 states and then the Virgin Islands, because of the nature, the culture in the island, we're
17 working just a bit differently as well with them. But our goal, as really noted on slide 14, is to improve the
18 statewide detection of chronic kidney disease in diabetic patients, using certain tests, and using metrics,
19 primarily some measures that we had developed at CMS, as well as [HETUS? 18:23] measures. We would
20 also like to prevent the progression of CKD to end stage renal disease. And we want to improve the
21 frequency of the use of fistulas in this population. And so this is a focus area here, as well as the reduction
22 of disparities. Again, we try to incorporate, because of the importance of this issue, reduction of disparities
23 in all of the themes to the extent that we could do so.

24 Slide 15 you will note that we have a part of our prevention theme, a focused disparities theme.
25 While we are trying to move for integration, we wanted to ensure that there was indeed a focus in this
26 particular area, we again, put out for competitive proposals, and there were five states that demonstrated a
27 capacity to really get a good start on this particular project, and we're learning a lot, again, from this
28 project. We've formed a national steering committee to help us with this. We want to get this right, and

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1 we've been working with a number of renowned experts across the country as we shape this particular
2 theme.

3 This one gets into some of the discussion that you had just in the previous panel related to patient
4 activation, motivation, as well as diabetes education. And so we're trying to learn what we can from here
5 and indeed make progress as we move along. But we understand that diabetes continues to be a growing
6 problem in the African American population, Latino population, there are socio-economic issues involved,
7 as well as geographic issues, and so while we are starting with a small project, we hope to be able to
8 expand this as we move along. Here, we are trying to have physicians and patients come together, identify
9 patients that would benefit from activation and motivation and education, and then pair them with people in
10 the community, community workers, and through a diabetes self-management education program, helping
11 them to get the tools that they need. Again, we're early in this project. We started with our recruitment
12 phase and we have all the QIOs that you see listed here have met their first and second quarter recruitment
13 efforts, so we do have the practices that we need that are saying, yes, I would like to participate in this
14 project. And now we're in the process of getting the beneficiary to sign up to participate in this project as
15 well, and currently, we're doing quite well with recruiting the beneficiaries. They will go through training.
16 There are training goals that have to be met and then, again, these are our process measures that we have
17 now, but at the end of this project, or actually midcourse in many of these projects, we'll begin to look at
18 the outcome measures; looking at the reductions in Hemoglobin A1C, looking at various other tests that
19 will, as far as clinical, but also satisfaction, we'll be looking to see do the beneficiaries find this helpful?
20 Are they managing their disease processes better? And it has implications for other chronic diseases. The
21 other exciting thing about this particular project is that it started as a CMS project where we were working,
22 and one of the things that the IOM noted is that the QIOs need to be able to show that their work, there's
23 some attribution to the work that they're doing, that they really are helping the project. So while we started
24 this project of primarily trying to keep it insular to the QIO, there's just so many areas going on. We don't
25 want to be fragmented in our approach while we're trying to improve and show attribution, that we have
26 now partnered with the NIH and we work with CDC, and we're working with Area Agency on Aging,
27 because we all have programs, and we don't want to trip over each other, and so we're trying to coordinate
28 where we can in this particular area.

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1 Moving on to beneficiary protection, this is one of the areas that is statutorily mandated that a QIO
2 must do certain types of this review, and it involves being the place where a beneficiary can come to lodge
3 a quality of care concern, if they have one. We also of course look at hospital discharges in this area and
4 appeals can be launched here. And there are other types of reviews that can be done as well. But by and
5 large, by many reports, that we've had commissioned internally through CMS, as well as the Institute of
6 Medicine, as well as the Office of Inspector General, many Congressional oversight committees, and the
7 beneficiaries themselves, find this process to be problematic. It's not one that's easy to use. They don't feel
8 that the information that they get back is particularly useful. They feel that the process takes much too long
9 to go through for them to even get information. Many of the providers feel it's a bit onerous in the amount
10 of information that's provided. There are concerns about what happens, how this information is used for
11 malpractice. I mean I could probably just spend the rest of this time going on and on with the things that
12 have been identified. However, that said, it is one of the most important things that we do. It is to me, one
13 of the most person-centered things that we do, so then how do we bring this together to come up with a
14 process that everyone can feel meets the needs of what we were, the QIO program was started for? And so
15 one of the things that we are looking at in our current Scope of Work slide 17, lets you know that we have
16 established some very basic metrics to monitor our work, and we feel that these are just basic metrics, just
17 what they say, and they look at how the beneficiary feels about the complaint process. How did they feel
18 working with the QIO? And we do fairly well with this. It's 80% and it's mainly looking at did you get
19 your phone call answered on time, those kinds of things. And then we also look at was the QIO able to even
20 get the beneficiary to complete a satisfaction survey. And then once you found a problem, what kind of
21 activity occurred? We also look at timeliness of review. So those are some process measures that we have,
22 that we are looking at and again, we had to approach this particular scope of work. It had to be very
23 measurable and we had to be able to show attribution. But what we really have is a vision and we've started
24 a redesign process, a beneficiary protection redesign process, to try and address all of the things I
25 mentioned just a bit earlier. And the vision here is to whatever part that we can play to lead a national
26 beneficiary initiated quality of care concern process, and I didn't even use the word "complaint" there,
27 because we want this to be anything that they feel within their healthcare system, that they need to come to
28 talk to all of us that there's a mechanism by which they can do so. And we say to lead a national

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1 beneficiary, again it's a vision, because each payer has their own particular type of system out there. I was
2 a former Director of the Medicaid Quality Program, and we had our own system and every state has their
3 own system, and most insurers have their own system, and quite frankly, the person in the [person center?
4 26:54] gets a bit confused as to what it is that they are to do. If they want to get information, provide
5 information, and so to the extent that we can, we've engaged all of our external partners, or we are going to
6 engage them as we move forward in this process. Some of the things that on slide 19, for Beneficiary
7 Redesign, we want to have beneficiary input, and we've had a number of Open Door Forums to get input.
8 Again, Institute of Medicine has given some very concrete examples of things they think we should look at
9 and then those other things I've mentioned, input people have already given recommendations for. We find
10 ourselves in the predicament of now prioritizing all the recommendations because we can't possibly get to
11 them all. On slide 20, what we've done, we've begun to facilitate a multi-stakeholder redesign workgroup,
12 and that will obviously be interagency. We work with the Office of Civil Rights, the Area Office on Aging,
13 our Partners in Medicare, other groups, we will work with the quality improvement organizations who've
14 been doing quite a bit of work in this area, and beneficiaries. One of my goals is to have really focus
15 beneficiary groups, as I said, we've had Open Door Forums, but to be able to bring them together from the
16 professional community, your input is extremely important there in order for us to get a system that's going
17 to be workable. We are executing a redesign study. Now we've had studies and studies and studies, so the
18 particular focus of this study that we're commissioning is the Now What? We have kind of the As Is, these
19 are the problems. Now What are we going to do and how should we go about formulating our plan? And so
20 we've already worked with the contractor and we have that in place. We're going to look to see what are
21 some things we can do right now in the 9th Scope of Work. Our 10th Scope of Work doesn't begin until
22 August 2011, so there are some quick things that we think we can do right now. For example, every QIO
23 gets information a little bit differently, and they work with it a little bit differently. Thus you have different
24 feelings from across the country of satisfaction from our beneficiaries. So we've looked and we've gotten
25 some of the best practices from the various QIOs and we're trying to cull that together, and within the next
26 several months, we hope that we can at least get that out, standardize that process to the extent possible. We
27 have, I have noted here, Chris Redesign, which is actually our information system, our case review
28 information system, and it's been kind of a patchwork system across the years. We want to redesign that so

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1 that we can put good information in, get good information out, and really move toward more transparency
2 with the entire process. Again, the themes come back to reduction in disparities. We want to be able to have
3 a system that we can determine areas of disparities, again, be that socio-economic, geographic, whatever
4 the disparity is, and our challenge here is that these are things that you're not likely to find in a medical
5 record, and so how is it that we cull this information out? And the other challenge that we have is that we
6 want to be able to link case review to quality, looking at a case here, case there, case there, what does that
7 really mean? How do we really change the system of care, based on the findings that we have? And so
8 that's another one of our goals. And many of these things will require regulations or even perhaps changes
9 in legislation, and so we will go through a formal process there. There will be plenty of opportunity for
10 public comment, rulemaking and those kinds of things, so the whole process we hope to be very transparent
11 with that. I spent a little bit more time on beneficiary protection because we see that one as the one that
12 needs work going forward, and intense scope of work, but moving now onto slide 21, this is another of our
13 theme, the last them in the current 9th Scope of Work, which is patient safety.

14 And again, we are looking at this, all of the QIOs are working on this particular theme. This is one
15 where we put a lot of emphasis, given the importance of it, but it is also one probably where we had the
16 least amount of experience, as far as the metrics that we wanted to work with, so we view this 9th scope as
17 very important and to seeing where we go next. We've used the metrics that were available for the 9th
18 scope. The nursing home and hospital pressure ulcer—this is one that was basically a carry over from the
19 8th scope, and we continue to look for reduction here. The SKF measures, the hospital, the infection
20 measures, we wanted to again, not duplicate efforts. These are measures that are being used with Hospital
21 Compare. Facilities are accustomed to using them, so we tried to incorporate them in the 9th Scope of Work
22 as well.

23 The last three that you see listed there are fairly new. Mersa, we've been working closely with the
24 CDC to see how we can, our goal, obviously is to reduce, but we also, our first step was to increase the
25 reporting in this particular area, and this one CDC has produced a module that hospitals can report on and
26 we're just starting to collect that baseline information there and look for a reduction. The nursing home
27 needs, our Survey and Certification, they identify nursing homes that are having a great deal of difficulty.
28 They're called Special Focus Facilities, and they notify CMS and we notify the quality improvement

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1 organizations that these particular nursing homes are in need of help. And so the QIO will go out, work
2 with that nursing home, do a root cause analysis, see what assistance they can provide them in order to
3 provide better care in those areas and then they establish a plan of action. And so this is just an example of
4 how we're trying to, again, even in the federal level, break out of our silos and work with Survey and Cert,
5 quality improvement, and our state agencies as well. And the Medication Safety, this came about as also a
6 statutory requirement, and we're looking at some of the drug-drug interactions and potentially
7 inappropriate medications and working with providers who have agreed to work, that signed up to
8 participate in this particular activity to see what we can do with the multiple medications that beneficiaries
9 are on to improve care in this area.

10 So just to summarize, we, through the 9th Scope of Work feel that we've been able to address
11 many of the items that were pointed out to us that needed improvement in the program. The QIOs are
12 embracing this work. They have met, with the exception of a few, met the criteria, the targets. Each quarter
13 for the most part, we have targets we've established, and 18-month evaluation. The QIOs that have not met
14 those targets have developed performance improvement plans, so there's close monitoring in that area. And
15 that was one of the things that the IOM wanted. We've developed a rapid corrective action, even internally,
16 within CMS, if we feel that we're not doing what we need to within our contract monitoring and
17 improvements efforts, we do a root cause analysis, we report that out, and we've developed electronic
18 management information system to give us more real time information about how are we doing. The first
19 part of our Scope of Work again is more process measures, and then the second part will be more outcome
20 measures. As far as next steps, we are reviewing our baseline data that we're collecting. We are again,
21 going to be checking outcomes. And we've already started to look at the 10th Scope of Work and your input
22 here will be helpful. And we've already of course, started to look at the American Recovery Investment
23 Act. How is it that we can help put forth the administration's agenda to get electronic health records and
24 use health information technology in a meaningful and useful manner, and we feel that the quality
25 improvement program can play a very vital role in both this area and in the area of wellness and prevention.

26 So that was a very quick overview of a lot of work that's going on. But I'd like to take this time
27 for questions.

28 Dr. Bufalino: Thank you. Did you want to address the questions you had for the Council?

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1 Ms. Moody-Williams: Yeah, well one of the areas was, I spent a bit of time talking about
2 beneficiary protection and the need to have it transparent and open, so I'd be very interested in any
3 feedback that you have, your experience with the process, or things you think would be better, and ideas, as
4 I mentioned, for the 10th Scope of Work as well as thoughts that you have about using the electronic health
5 records, or other questions that you have.

6 Dr. Bufalino: Thank you. Let me open that for discussion.

7 Dr. Williams: Thank you for your presentation. It was very informative. As opposed to your
8 questions, I guess I have a question as a former physical therapist in another life, and currently a caretaker
9 of elderly Medicare beneficiaries, you talked about the discharge planning or maybe lack of discharge
10 planning and how it may result in readmission rates, I think. Can you talk a little bit more about the detail
11 of how better discharge planning might prevent readmission rates? And how that's related to the silos that
12 you're trying to get out of. Because I do find that when a patient transfers from the acute care facility, to
13 either the nursing care facility and/or home, there is a slight bump in the road when it comes to the
14 transition of that care, and in my personal experience, it might be during that time that the person then ends
15 up back in the hospital. Is that what you find in your statistics?

16 Ms. Moody-Williams: Exactly. That's what we built this particular project on, was some of the
17 findings both through the literature, the evidence, and anecdotally that what we're finding, and specifically,
18 where I talked about the dissatisfaction with the discharge planning. This was through the beneficiary
19 survey, so the beneficiaries themselves provided this information and some of it, I think, has to do with the
20 timing that the information is provided, who it's provided to, and how we can have it repeated back, or the
21 best way to find to get a true understanding that when the beneficiary leaves the hospital, they know what
22 to do next, or who to see when they leave, which is often the question. They may get called for follow up
23 on such and such a date, but it's not always clear to them exactly who they are supposed to follow up with.
24 So these are the kinds of interventions that the QIOs are working on. Again, this project is just in its fourth
25 or fifth month, and so I think if you invite me back, I'm going to have a lot more information to share about
26 exactly what we're finding and which interventions are most effective. But as far as the silos, I think that's
27 probably one of the more exciting things about this particular project, because we are getting people in the

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1 community where those bumps occurring, sitting at the tables and talking now, because they all want to see
2 this work in a more coordinated fashion.

3 Dr. Williams: It may help that the patient actually has an advocate when they leave that actually
4 sort of helps to smooth the transition, because patients are often handed a slew of information, appointment
5 dates, etc., that I think is hard for them to coordinate when they first get out and they're trying to recover
6 from their illness.

7 Dr. Hirsch: [off mike] ideas on after the care. My question was about the physician contact after
8 they leave the hospital. I guess I've been hearing some things that when the keys is that they get back to the
9 primary care doctor, not just to the subspecialist, and I was wondering if your project looked at who the
10 follow up is with?

11 Ms. Moody-Williams: Yes, we're in the process of right now gathering that data and finding the
12 best way, but we are getting information on between the time of these discharges, of exactly who the
13 patient came into contact with, and whether it's the primary care or the subspecialist, home health, and we
14 will be able to—we call them transitions—we will be able to determine how many transitions that
15 beneficiary had between readmissions.

16 Dr. Hirsch: I guess my point is that they may have a follow up with the subspecialist, but in
17 maintaining continuity of care, and knowing that someone knows who all the balls in the air are, not to
18 forget the primary care doctor in that.

19 Ms. Moody-Williams: Right and we'll be looking for that.

20 Dr. Arradondo: I have a question that relates to one of the themes you were using in your
21 protection section. You referenced, I guess diabetes is getting a good play here, today. I don't mind that
22 since it's such a preventable epidemic. You mention in your goals in your slide 14, following chronic
23 kidney disease and diabetes, by using micro albumin. What process is used to make that determination?
24 How are you going to follow, determine the goals in one of your themes? Is that internal? That's not
25 Congressional, clearly.

26 Ms. Moody-Williams: No, it's more related to identifying our denominators and our numerator in
27 the specific measure that we're using, because we're trying to make sure we identify the beneficiary that
28 hasn't already—we initially, when we were measuring it, we were getting the beneficiary that already had

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1 chronic kidney disease, they were already on the [HNR? 42:34], they were already on this. What we're
2 trying is to get to that group who hasn't had the intervention, and how we can impact on them quicker. So
3 this is just one of our measure specifications what we're looking at. If they are, have a problem with their
4 macro [altmeria? 42:55] and then beginning to work with them at that point, and eliminating those that
5 have already had the full range of intervention, so getting a smaller population to work with.

6 Dr. Bufalino: Frederica?

7 Dr. Arradondo: Let me—I haven't finished this line of questioning—I have a recommendation
8 actually. How old is this particular goal? The one dealing with chronic kidney disease and diabetes? Is that
9 something that's been revised in the last five years?

10 Ms. Moody-Williams: This is a new project for us, but the information that we're working with,
11 we have a technical expert panel, so it's fairly new information that we're working with. I would say, as a
12 matter of fact, we just had a panel a couple of months ago to look at the data, but is there something that
13 you would like us to take a closer look at?

14 Dr. Arradondo: Well, yes. Chronic kidney disease tracks reasonably well with microalbuminuria if
15 you start it at stage three. And so preventing end stage six dialysis. Starting at stage three is not bad, but
16 starting at stage zero when the kidney is normal is probably a little bit better, particularly if the person has
17 diabetes, has something that you know is going to cause kidney disease, just a matter of when, how much,
18 how fast. And there have been data around, they were first approved a little over a decade ago, that
19 employs the use of estimated [provarial? 44:38] filtration rate based upon a serum creatinine level, which
20 we get all the time with the comprehensive metabolic panel, the CMP, the chem. 25, chem. 26, those so-
21 called routine tests that we get, so many people get, hospitals, everybody, and the estimated [provarial?]
22 filtration rate tracks better with stage one and two and even early stage three, the microalbuminuria. In fact,
23 micro might not show up until stage three or four, although it might show up earlier. But I mention that
24 because so many people, the theme of patient accountability has been coming up today, and you use very
25 great words, patient activation, education, motivation. I mean that's all necessary for patient adherence.
26 And it would be kind of nice since we get these tests all the time, you pay for them, to put in a goal of
27 tracking the estimated [provarial ? 45:47] filtration rate, or estimated creatinine clearance, since the data for
28 estimating it was there, it was its own line, wwwkdoqi.com, patients see it, lab people are even on it a little

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1 bit now, various people. But so starting at stage one or two would be a better deal. And so many people
2 take NSAIDs that hurt their kidneys and move them from stage one to three and if we're just picking them
3 up at stage three, or picking them up with microalbumin, we've missed all the opportunities for patient
4 activation, education, motivation, and adherence to know a low NSAID diet if they have diabetes. Since we
5 know that diabetes is going to hit the kidney, that's one of the job descriptions of diabetes, hit your kidney.
6 Hits everything else, too, but you're paying for kidney disease, I mean what, \$15 billion just on dialysis?

7 Ms. Moody-Williams: Right.

8 Dr. Arradondo: A billion dollars maybe on this prevention side could save eight or nine on the
9 dialysis side. There's been some data on that. So I would advise looking at, and when I said advise, I didn't
10 mean loop advice, this just technical advice—

11 Ms. Moody-Williams: No as we look at our next Scope of Work, which we're doing right now,
12 these are the kinds of comments that are very useful. Thank you.

13 Dr. Arradondo: Yes, I'd recommend doing the estimated [provarial ?] filtration rate. It's
14 increasingly known in various circles, and I mentioned a number of the labs, major national labs are
15 adopting it, although they're adopting only half of it, starting at stage three with a GFR of less than 60.
16 They're saying above 60 is normal, when we know that less than 90 is not normal. But that's a start. I
17 would advise that. You pick up people earlier, give people more to do.

18 Dr. Bufalino: Great. Frederica?

19 Dr. Smith: I think in a sense I'm turning back to you a couple of the questions that you have for us
20 here. One is on the Beneficiary Protection program, and I'm, you gave us a lot of information and
21 technically it was clear, but whether I'm putting the right question with the right program, I'm not sure, but
22 I heard you say things about surveying patients to see how well their needs have been met and things like
23 that. I don't know how you do it quantitatively and accurately. And qualitatively is not usually good
24 enough. If you ask the specific question, I think you mentioned, was the patient's phone call was returned
25 promptly. Well, one patient's definition of promptly is very different from another's. One wants it back in
26 30 minutes because she's going shopping and won't be home the rest of the day. And the next is perfectly
27 comfortable to sit there not able to breath very well for 24 hours. So as you're looking at that, I would urge
28 you to try to think through the maze of designing something that provides you accurate information, just

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1 saying was it returned promptly or not returned promptly is not accurate. Was the discharge information I
2 was given sufficient or was it not? What Karen was saying a little, people were told, only remember 10% of
3 what their fed. So if they're fed a huge number of, or huge amount of information in the 30 minutes before
4 they're discharged, it isn't that it wasn't given to them, it was that it was somehow overwhelming them. So
5 there needs to be, as you're looking at this, someway to capture it accurately, and I would urge you to run it
6 by physicians, especially organizations, AMA Council, PPAC, something like that before you put it out in
7 the general domain of getting information back from patients.

8 The other thing is, and you've asked us, what's the meaningful use of electronic health records? I
9 don't think I can answer that unless I know what it is you want to get from them. If you're asking very
10 simple thing like how many patients did I see with rheumatoid arthritis and on [sounds like: Dmards 50:02]
11 well that's information that's very easy to extract. If you're asking how many people have seen me as the
12 5th consultant because they didn't like the diagnosis the first four gave them, that's very different, but it's a
13 very pertinent question to cost and quality of care. I mean if a patient is using excessive resources to get the
14 same information. So before I can address your question of the recommendations your way to meaningful
15 use, I kind of need to know what your goals are for that.

16 Ms. Moody-Williams: Okay, thank you. As it relates to the first question, we do use a tool that's
17 been tested quite a bit through the agency for healthcare research and quality, funded as well by CMS, to
18 try and solicit what we call Patient Experience of Care versus satisfaction of care, and so there have been a
19 number of focus groups and trial tests in those kinds of things to make sure that there's some validity and
20 reliability to the questions that we asked to patient to try and solicit the information. And so from the
21 perspective, it has been tested. But I think, as with any tool such as this, there's always room for
22 improvement, because sometimes the tools, especially as we get more and more sophisticated about the
23 type of care that we want, we don't always want to know about well was the waiting room comfortable?
24 Well, yes, that's important, but I want somebody to ask me a meaningful question as well about the care
25 that I received. So we are looking at continually improving those tools to get back the information that we
26 need and then realizing that what's important to one person is important to that one person. So then how do
27 we use that type of information that's going to give us the high level? This may be a problem area, to
28 feedback to the provider so that they can then use that to drill down to their beneficiary population to see

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1 what indeed that means. That's just another tool that a provider can have to talk with their patients. As a
2 matter of fact, we've been seeing some things where they're developing these systems, touch screen
3 systems, that the beneficiary can fill out before they leave the physician's office. It's fed back real time and
4 that's meant for dialog between you and the beneficiary.

5 Oh and the EHR- actually I wasn't really expecting an answer to that, but more throwing that out,
6 that we all need to start really thinking about that quickly. What is it that is most useful to you in your
7 EHR? What is it that CMS needs from their EHR? It has to be, it needs to be something that's satisfying to
8 both of us or else, it's just going to be burdensome to both of us, or else it's just going to be burdensome to
9 both of us.

10 Dr. Bufalino: Thank you. I think we'll just cut it off because we're about 15 minutes late, if you
11 don't mind. Thank you, Ms. Moody-Williams. We appreciate your spending the morning with us.

12 Ms. Moody-Williams: Thank you.

13 Dr. Bufalino: Let's move on to the Recovery Audit Contractors and we have a panel of three of
14 our CMS representatives with us today. Let me introduce Commander Marie Casey, Lt. Terrence Lew, and
15 Amy Reese. Commander is Adjunct of CMS in the Commission Corps of the U.S. Public Health Service in
16 2002, initially serving as a health insurance specialist in the Division of Medical Review and Education in
17 2005. She assumed the role of technical advisor for the division. And Commander Casey currently serves
18 as the Deputy Director in the Division of Recovery Audit Operations. Joining her is Terrence Lew, who
19 was with us in December. He's a lieutenant in the Commission Corps of the Public Health Service. He's
20 been with the RAC program since June. He joins CMS, before he joined he was a healthcare administrator
21 at the U.S. Navy. His duties at the RAC include primarily establishing medical record requests limits and
22 insuring the RAC data warehouse is fully supportive of the program. Amy Reese joins us again. She has
23 been at a number of these meetings in the past, representing the RAC audit from the Office of Financial
24 Management. Good morning everyone. Thank you for joining us. Who's starting?

25 RAC Update

26 Ms. Reese: Good morning, and I thank you for inviting us here to speak today. My name is Amy
27 Reese. I am the Project Officer for the RAC in Region C, which is currently Connelly Consulting. Actually
28 Marie won't be presenting with us today, since our presentation isn't terribly long, but she's up here, and

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1 she'll be available to help out with questions as well. Just to go over a little bit what we're going to be
2 talking about, some background on the program, what is a RAC, who will they affect, why do we have
3 RACs, what do they do, what have we identified as our keys to success, and what can providers do to get
4 ready for them?

5 To explain what a RAC is, we think one of the best ways to go about this is to talk about our RAC
6 program mission, which is that the RACs will detect and correct past improper payments, so that CMS,
7 carriers, FIs and MACs can implement actions that will prevent future improper payments, and by doing
8 this, providers can avoid submitting claims with improper payments. We at CMS can lower our error rate,
9 and the trust fund will be protected for taxpayers and future beneficiaries. As far as who will the RACs
10 affect, if you submit a claim to the Fee-for-Service Medicare program, those claims may be subject to RAC
11 review. RACs don't look at managed care or Part D, only parts A and B, and as of the beginning of
12 February, the protest for the RAC contracts have been resolved and we are starting our provider outreach as
13 we speak. The map kind of shows our RAC jurisdictions as well as some time frames for when the reviews
14 will be started. Like I said, we're starting our provider outreach now, and as far as when you may see some
15 correspondence from the RAC, the RACs are just starting to receive their data, so they'll have to do some
16 analysis on that data, and then as long as we have gone into a state and completed our outreach, then you
17 may start seeing some requests for medical records from the RAC. And to kind of backtrack, now we're
18 going into why we have the RACs, and even though our error rate at CMS has kind of been steadily
19 decreasing, in 2007, we still had almost \$11 billion in improper payments, so Congress wanted to give
20 Medicare another tool to combat those improper payments, and just as an aside, if you look at that box, our
21 error rate in 2008 decreased from 3.9 to 3.6% and we estimate that that saved over \$400 million, so we're
22 looking forward to continued savings in the program.

23 As far as the legislation, the Medicare Modernization Act required the demonstration, which was
24 three years, ran from 2005 to March of 2008, and then the Tax Relief and Healthcare Act of 2006 required
25 that the program be made permanent and expand nationwide by no later than January 1, 2010, and both of
26 these statutes did give CMS the authority to pay the RACs on a contingency fee basis.

27 The next few slides go into more of the details of the RAC review process. The RACs only review
28 claims on a post-payment basis and the use the same Medicare policies as our claims processing contractors

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1 do. They use NCDs, LCDs, and our manuals. They utilize two types of review; automated review, which
2 does not require medical record, just the review from the face of the claim. And complex review, which
3 does require them to request a medical record from the provider. The RACs will only look at claims that
4 were paid after October 1, 2007, and as the program starts expanding and moves forward, they will only be
5 able to look at claims from three years back from the date that it was paid. And we do have requirements as
6 far as the staffing of the RACs. They are required to have a fulltime physician medical director. They are
7 also required to use certified coders as well as nurses or therapists. And the collection process for the RACs
8 is generally the same as for the collection processes for the claims processing contractors, except that the
9 RAC is the one that will issue the demand letter and their reviews. The claims processing contractor will be
10 the one to issue the remittance advice, and we do have a new remark code that they'll be using, which is
11 N432. That means that the adjustment was based on a Recovery Audit. We hope that that will help
12 providers in their tracking of their RAC claims. And as with the usual process, the claims processing
13 contractor will recoup the money by offset unless the provider has submitted their payment or filed a valid
14 appeal within the appropriate time frame.

15 A few differences between the RAC process and other claims processing contractor processes is as
16 I said before, the demand letter is issued by the RAC, and the RACs are going to offer a discussion period
17 to the providers after they've made their determination. This is outside the normal appeal process and kind
18 of outside those time frames, but if the provider wishes to discuss that improper payment determination
19 with the RAC or submit some new information that they think may help their case, the RAC will be open to
20 doing that. Also, CMS will approve all new issues that the RAC wishes to review on a widespread basis,
21 and those approved issues will be posted to the RAC websites.

22 I think later on in the agenda, there's someone here to speak specifically about the appeals process,
23 but just some general information about what to do when you receive a RAC determination if you want to
24 appeal, if you don't, and here are some options if you agree with their determination. You can pay by check
25 on or before day 30 and you won't need to pay any interest and not appeal, you can allow the recoupment
26 to happen on day 41, which will include the overpayment plus any interest, and not appeal, or you can
27 apply for an extended repayment plan, which will again include the overpayment and any interest, and not
28 appeal. If you disagree with the RAC's determination, you can again, pay by check on or before day 30 and

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1 you won't have to pay any interest and file your appeal by day 120, you can allow the recoupment to
2 happen on day 41 and again that will include the overpayment and interest and file your appeal by day 120,
3 or you can stop the recoupment from happening by filing your appeal prior to day 30, or you can request an
4 extended repayment plan which will include that overpayment and any interest, and file your appeal by day
5 120. And now I'm going to turn it over to Terry Lew to continue the presentation.

6 Lt. Lew: Great. I'd like to thank the Council again for having us back to discuss the RAC
7 program. My name is Terry Lew I'm a lieutenant in the Commissioned Corps. I've been with the RAC
8 program since last summer. Three keys to success under a RAC program, the permanent RAC program:
9 Recognizing that success is defined differently for different individuals and different organizations, three
10 things that we see as very important are minimizing provider burden, and sharing accuracy and maximizing
11 transparency. We heard loud and clear on the demonstration program that providers were upset with the
12 burden that was placed upon them in working with RACs during that process. And so we've taken a
13 number of steps to try and minimize that burden on providers. I'm sure and actually, it serves no one to
14 have bad information out there, us or the RACs and then to have to go back and correct it, bad information,
15 make bad calls, so we're doing the best we can to ensure accuracy throughout the program, and we've
16 made a number of requirements on the RACs to ensure that accuracy. And also, to maximize transparency.
17 Tim Hill is the CFO of CMS, the Director of the Office of Financial Management, and one of his big goals
18 for the program is to have an open transparent, knowable, process, and accountable. And again, we've
19 made a number of changes to the program. I'm looking forward, that we hope will maximize transparency
20 and share accuracy, and minimize provider burden.

21 So some details on minimizing provider burden. We're going to limit the RAC look back period to
22 three years. Amy mentioned earlier that the earliest a RAC will be able to review a claim will be October 1,
23 2007. Another step we've taken, the RACs will accept imaged medical records. Now those are imaged
24 medical records, we are not currently set up for electronic data interchange. That will hopefully come
25 somewhere down the road. But right now, RACs will accept images from providers. TIFs, PDFs, we're still
26 working on some of the exact details of how that will work, but the bottom line is that providers will not
27 have to print and mail stacks and stacks of papers. They can submit them on CD or DVD. And limit the
28 number of medical requests. That's also very important. There are almost an infinite number of ways that

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1 providers can be organized, and so we've done the best we can to establish limits that are fair to the
2 provider community. We know that this is somewhat controversial. CMS will revisit the limits periodically.
3 We have the limits for the remainder of FY, we're in 2009. We have the limits for the remainder of the
4 current year, and FY 2010 we may change them. We'll have to see how the next few months go. Actually,
5 just this morning, we've started sending the data to the RACs, the claims data. We're still doing some tests.
6 So we haven't started our major push yet, but we have begun the transfer process and so they'll start
7 mulling over the data, and we'll see what happens over the next few months.

8 Now this I believe we had in our last presentation in December. This is a summary of the medical
9 record limits again for this fiscal year. For inpatient care, that limit is going to be 10% of the average
10 monthly discharges, with maximum of 200, per 45 days, per NPI. Home health, 1%, versus 10%; for
11 professional services, the limits are based on the size of the practice, solo practitioners, small partnerships,
12 large groups, medium groups as well. Then there's other part B billers, DME suppliers, labs, outpatient
13 hospital services, 1%. Now, if a facility has multiple NPIs, offers the full range of services, there is going to
14 be a facility cap in addition to the per service cap. Our goal is not to slam a facility with thousands and
15 thousands of records per 45 days, that is something we'd like to prevent. Again, as I mentioned, there is an
16 almost infinite number of ways that facilities can be organized. Unfortunately, we're not entirely sure how
17 this is going to work. We are encouraging the RACs to work with providers, let's say there's a provider
18 that's got a number of part time providers, a small practice has a number of part time providers, and they go
19 to the RAC and say, hey, we only have one FTE, despite the fact that we had 10 NPIs come through last
20 year. We'd encourage the RAC to consider that. We're encouraging the RACs to be reasonable in dealing
21 with providers. In the first medical record request letter, the RACs are instructed to tell providers your limit
22 for the current fiscal year is X. And if the provider disagrees with that, again, we encourage them to contact
23 the RAC, discuss it, explain any extenuating circumstances that would justify a different limit. We are
24 hoping that the RACs will work with that provider to come up with something that's fair. We don't want an
25 arbitrary system. We expect that provider A will be treated fundamentally the same as provider B and
26 provider C, but our overarching goal here is to be fair. We want to give the RACs a good universe of claims
27 to work with, but we don't want to overwhelm providers in the process. That is our goal.

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1 Ensuring accuracy. The RACs are required to employ a certified, qualified staff. Certified codes,
2 nurses, therapists, also to have a physician medical director. We have a New Issue Review Board. Before
3 the RACs can go out and issue widespread medical record request letters, or conduct widespread automated
4 review, they have to come to CMS and request approval for whatever that issue is. Our new issue team will
5 review the information submitted by the RACs, and make a decision. Are they allowed to move forward or
6 not? They may request more information from the RAC. They may say that looks great. Move forward. But
7 the idea here is to make sure that the RACs aren't issuing medical record request letters willy nilly,
8 otherwise going out and issuing request letters or connecting automated reviews for topics that are not
9 perhaps as clear cut as they might think they are. We're establishing the new issue review board as a sort of
10 a check and balance on the RAC. We also have a RAC validation contractor. And they'll be providing an
11 annual accuracy score for each RAC, connecting random and targeted rereviews of claims that the RACs
12 have looked at, again, to validate those reviews, and ensure that the RACs are conducting business properly
13 and accurately. And last, if a RAC loses at any level of appeal, providers have a number of options. The
14 appeals process is always available, and if the appeal is found in the provider's favor, the RAC will have to
15 return its contingency fee.

16 Maximize transparency. The New Issue Review Team, once they've approved an issue, once
17 they've signed off on it, and the RAC has permission to do widespread review, that issue will be posted to
18 the RAC's website. So the RACs will basically have out there for the world that we'll be looking at X, Y
19 and Z, and providers in that RAC's region can go to that website and see what the RAC will be looking at,
20 potentially. Vulnerabilities will also be posted to the web. Once we start having reviews and we start seeing
21 patterns, and we identify common vulnerabilities, those will be posted to the web as well. New issues will
22 be RAC-specific and posted to each RAC's website. Vulnerabilities will be posted to the RAC's websites
23 as well as perhaps the CMS website. We haven't quite determined how that's going to work yet, but our
24 goal, again, is transparency. If there are common threads, we intend to get them out there so the provider
25 community is aware. Also a RAC Claims Status website. By 2010, each RAC is required to have a web
26 functionality where a provider can log in and see the status of record requests. If you, as a provider, have
27 sent 20 medical records last week, you'd like to know where they are last month, you can log on and see
28 the status. It's been forwarded to the reviewer, it's in X, Y, and Z, you can always call the RAC, but also in

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1 2010, that website will be available for you to see the status online. Another step to maximize transparency
2 is a detailed review results letter. Any time the RAC conducts a complex review, one where they've
3 requested medical records, they're required to send out a results letter, whether they've found an
4 overpayment, an underpayment, or there's been no finding at all, that letter will go out to notify the
5 provider that the review is concluded. So they're not just hanging out there indefinitely.

6 So what can providers do to get ready? We have a number of suggestions here. Some of them are
7 generic, some of them are specific, but we feel that these are things that will help providers prepare for
8 RAC audits. Number one, know where previous improper payments are found. The RACs will be drawing
9 from published reports, the demonstration project findings, OIG reports, CERT reports, providers can do
10 the same thing. Take a look at what's out there. What's been found in the past. Chances are, the RACs will
11 be looking for many of the same things. And again, permanent RAC findings will be listed on the RAC's
12 websites. Things they're looking at, things they've found, those vulnerabilities.

13 Also you can know if you're submitting claims with improper payments. We encourage providers
14 to conduct internal assessments, look at your practices, look at your processes, ensure that you're in
15 compliance with Medicare rules. If you have, if you're doing everything right, there's nothing to be
16 concerned about if a RAC comes knocking. Identify corrective actions to promote compliance, assuming
17 that most organizations aren't 100% perfect, we all have opportunities to improve, your audit will probably
18 turn up something. Identify corrective actions to ensure that whatever that problem was is mitigated, is not
19 a problem in the future. Also, appeal when necessary. The Medicare appeals process is available in RAC
20 identified overpayments. We encourage providers to not appeal everything, but if a provider disagrees with
21 a RAC's conclusions, or if a provider does choose to appeal everything, that's certainly their right. And
22 also, learn from past experiences. If you have been subject to RAC audits in the demonstration, or several
23 months down the road, if you've been subject to RAC audits in the permanent program, look at the results
24 letters. See what they've found, merge that with the information from your internal audit, and again,
25 identify corrective actions that can prevent future audits. Also learn from the experience of your
26 associations, medical societies, hospital associations, there's a lot of information out there and plenty of
27 people who are happy to share it.

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1 Another thing that providers can do is prepare to respond to RAC medical record requests. The
2 RACs will receive the provider name and address files from the claims processing contractors, but those
3 may not be exactly where you want the RAC letters to go. So you should contact the RACs and say, we're
4 hospital X, Y, Z, or practice X, Y, Z, please send any correspondence to our practice administrator, our
5 health information management department, or whatever works for your facility. The sidebar on the right
6 are some specific suggestions, some questions that you may want to ask yourself. Who will be in charge of
7 responding to RAC medical record requests? A good idea is to identify a single point of contact for RACs,
8 and then communicate that to the RACs. Yes, the claims processor should deal with this person for any of
9 their issues, but the RAC audits, work with this side of the house. Pass that information on to the RACs,
10 call them at first, and by 2010, those websites will be up, and providers will be able to enter their contact
11 information online. Also, speaking of the websites, check on the status of your medical records. If you've
12 submitted a record to the RAC, they have 60 days to respond with the outcome of their review. If it's day
13 45, 46, 49, 59, and you're wondering what's going on, call the RAC. Or check with their website by
14 January 2010. Other questions: Who, what address, and also tracking. You may want to have the requests
15 go to one place, and then have another department assigned follow up. Each organization will determine
16 what works best for them and then we encourage them to communicate that to the RAC. Again, appeal
17 when necessary. The appeal process is exactly the same. The Director of the Division of Appeals Policy
18 will be coming this afternoon for a brief on the appeals process. We encourage organizations to decide who
19 will be in charge of deciding what will be appealed and how will those appeals be tracked? Also, you want
20 to track the outcome of those appeals, overturn rate, if there are any trends, things that you've noticed in the
21 claims that you've appealed and that sort of thing. Also, the RACs offer a discussion period. But that does
22 not take the place of the appeals process. If you as a provider, disagree with a RAC's decision, certainly
23 take advantage of the discussion period. But also, if you object, take advantage of the appeals process.
24 That's what it's there for. And learn from your past experiences. Keep track of your denied claims, keep
25 track of the outcome of your appeals, keep track of the outcome of any discussions you have with the
26 RACs. Look for patterns, identify any corrective actions that you can take. Once you see a pattern, what
27 can you do to make sure there's no longer a problem in the future? And questions will be in charge of
28 tracking and how we avoid making similar improper payment claims in the future?

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1 A couple of contacts: The RAC website, this is CMS's website. We post information there
2 frequently. And also our email address: RAC@CMS.HHS.GOV. Feel free to email us. We're happy to take
3 questions.

4 These are the project officers for each of the four RACs, Region A, B, C, and D. DSC, CGI,
5 Connelly, Healthy Insights, the four CMS project officers, one for each RAC and their phone numbers.
6 And on the next slide, these are the names and specialties of the RAC medical directors. I believe, Dr.
7 Przyblski, you had requested that last time. We didn't want to put the RAC medical directors' phone
8 numbers and email addresses out there for the world, but if you would like to contact one or more them,
9 please feel free to be in touch with us and we'll get that to you. That's the last slide. We'd be happy to take
10 any questions.

11 Dr. Bufalino: Thank you. Open for discussion. Frederica?

12 Dr. Smith: Four things. One is that you're heavily discriminating against the small and solo
13 practice. You're asking a solo practitioner to provide 10 records for 45 days, you're asking a small group of
14 two physicians to provide 20 records per 45 days. You're asking a large group, one group in Albuquerque
15 is 250 physicians, to provide one-fifth record every 45 days. I think that's very unfair. I think it ought to be
16 evenly distributed across all sizes of groups.

17 Second thing is that I didn't see anything in the material you presented—[off mike remark by
18 committee member 14:46 4th mp3 file] —I can make that a recommendation certainly. We had that
19 recommendation at the last meeting. I will point out that we asked not to discriminate. Second issue is that
20 there are a lot of studies out there, a number of studies anyway, that show that even certified coders don't
21 always agree on the correct coding for a given level of service. So a physician may code it as say a 99214
22 or comparable levels for inpatient or emergency room or whatever the coder might think it's a 213 or a 215
23 and I hope that the RACs are being instructed not to take a difference of one level in coding as an error for
24 which they should recover money. Four level difference, certainly, if the RAC thinks it's a 212 and the
25 coder billed it as a 215, that's a very clear disagreement of opinion, which could be appealed, but a one-
26 level difference, I don't think should be picked up at all.

27 The next thing is that in terms of your appeal, and this again is a burden on the small practices.
28 You're saying 30 days from the date received. You take a solo practitioner, who has, for some reason, the

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1 misfortune to land in the hospital for three and a half weeks. He's not in the position, or she's not in the
2 position to respond within 30 days, or if said solo practitioner is incredibly lucky and gets to take a three-
3 week vacation and the letter happens to come right on the first day of that, it does not mean that the office
4 staff couldn't respond. But the office staff is not always in a position to write a good appeal letter. So I
5 think that should be relaxed in some way.

6 And then the last thing is I think it would be fairer to allow PPAC or physician groups to see the
7 language in the letters that the RAC proposes to send out. Certainly, the one request that I had, which was
8 for verification of a lab order for a CBC and a urinalysis, on a patient which seemed to me incredibly petty,
9 like they weren't going to pay \$4 on something, so they were going to recover this. The letter was, it was
10 really not nice. I looked at that thing and kind of was taken aback. And so I hope that somehow that
11 language has been modified. I know that examples have been given to you all that might make it very clear
12 what's needed and why it's needed without sounding threatening or aggressive, and I hope that that has
13 been approached. So those are my four concerns at the moment. I may have others.

14 Commander Casey: I just wanted to address your issue about the certified coders and the fact that
15 there may be some discrepancies whether it's a level one or a level two. And honestly, our thought is as
16 moving forward with the national RAC program, that the RACs are really probably not going to look at
17 those type of claims just because there's one level differences, because there's too much risk for them to
18 lose on appeal, and it's too resource intensive for them to deny things for one level. So at least as we start
19 this initial program, we really don't foresee that being a problem. We hope that they will use good clinical
20 judgment. We hope that they will talk to their medical director, if there is a discrepancy, that the certified
21 coder has a question about, but we really don't see them looking at the one-level differences. We do also
22 have a requirement in the RAC statement of work, that in the event that as you mentioned, you mentioned
23 about the 30 days seems like an unreasonable amount of time sometimes if a provider goes out of town or
24 whatever, to get those medical record requests in. All you need to do is pick up the phone and ask for an
25 extension, and that is something that they should be granted by the RAC, and it is something that's in the
26 RAC statement of work. And lastly, the question about the language on the medical request letters, we have
27 been working primarily with the AMA and AHA on those letters. We actually owe them opportunity to
28 look at those letters. We are actually providing a sample letter that should go out to the RACs hopefully in

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1 the next two or three weeks, that will require them to find things like a detailed explanation as to why the
2 provider was even put on review in the first place, to answer the questions as whether this is something that
3 falls under the reopening regulation, and also in their information letters that go out to the providers after
4 they do the review, they are required to have a detailed reason for why they are denying the claim, and that
5 rationale for that particular issue, CMS will approve that language as part of our new issue process.

6 Lt. Lew: None of us will be pleased if the results letter is not medically necessary. We are
7 instructing and expecting them to go into greater detail than that.

8 Commander Casey: And we even expect them to have even greater detail than what we tell them
9 we're approving by the new issue review board. We want page 10 of a medical record did not support this
10 service because of X, Y, and Z. In this issue, normally, CMS will only pay for the service because of these
11 four things being present.

12 Dr. Smith: And then the first question, pretty heavy burden of discrimination against the one- and
13 two-physician groups?

14 Lt. Lew: Sure. We certainly appreciate your comments, and we did take it under advisement after
15 the last meeting as well. You raise valid points. The enormous practice does bear a different burden than
16 the two-provider group. With that said, the limits are set for the current fiscal year for the balance of the
17 year. I don't mean this to sound hollow. We will take that under advisement for FY10. We do intend to
18 review the limits and adjust them if they are unfair for any particular groups. We are attempting to be fair to
19 everyone. It is walking a tightrope at times. We realize that we are not going to please everybody, but we
20 do value input.

21 Dr. Smith: You're unlikely to please anybody, unfortunately.

22 Lt. Lew: But we do value input. And we will definitely take it under advisement.

23 Dr. Ross: Thank you for your testimony. Again, two meetings ago, we looked at the error decrease
24 rate and as you reported, it went from 3.9% to 3.6%, saving \$400 million. I asked a question at the last
25 meeting or two meetings ago, dealing specifically with what of that 3.6% error rate, what percentage are
26 the physician RACs, versus the hospital, because we saw that pie shape and we saw the hospital and then
27 there was a durable medical provider, and then I also would like to know the home healthcare provider

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1 percentage as well. So basically if you could report back to us, as I was hoping, where the percentages are
2 coming from, versus the physicians, and how low the physicians' percentage may be.

3 Ms. Reese: Sure, we are working, I mentioned to Terry, he is our data warehouse project officer,
4 that when the RACs put in those improper payments, the separation between DME supplies and DME
5 physicians and the RACs haven't been doing reviews for a year, so we don't have any data on that, but
6 we're hoping to collect that data when they do start doing the reviews. And what we're trying to figure out
7 is how the RACs will know that information. I spoke to a few of the DME folks that are in our office, and it
8 seems like whether it's a supplier or a DME physician, isn't on the actual claim that the RAC would be
9 reviewing, so we're still trying to look for some information on how the RACs would know that. Because
10 we'd be more than happy to report on that. So—

11 Dr. Ross: That might be a recommendation that we make in the future; to distinguish between the
12 durable medical physician, versus the durable medical provider, so that you can audit your numbers a little
13 bit better and report back to us, because that's one of the areas of concern that we have as far as durable
14 medical equipment, that physicians still may be required to be "accredited." And so that's an area that still
15 may be of contention in the future as well, and this might provide the data showing that the physicians are
16 not really the nemesis behind this problem.

17 Ms. Reese: Sure, yes, I do remember that conversation two meetings ago. And we're working on
18 getting that information to be able to report. Also, the home health you spoke about. The RACs didn't
19 review any home health issues in the demonstration. Now those are open to review and we will be reporting
20 those separately in our warehouse as well.

21 Dr. Ross: I'd like to just continue the conversation from Dr. Smith. I know that even in my own
22 particular practice, I'm sure everyone around this table, deals with the E&M coding and with the
23 discrepancy that you may find versus where we're coming from, from various specialties, from decision
24 making, from the age of the patient, from the condition of the patient, how much time may be spent,
25 whether or not a phone call is involved to another physician, whether lab testing or radiological evidence is
26 necessary, so there is a really, the factors that go into how to determine an E&M can vary from one office
27 to another, from one practitioner to another, and from one case to another, so the question really is, how do
28 you choose a RAC supervisor, or a RAC auditor to determine what we see as a physician made decision on

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1 what level that E&M should be? I think that was Dr. Smith was asking a few minutes ago, but I wanted to
2 elaborate on that, and show that there are wide variations that may occur. And so now the physician's being
3 penalized because this is in their expert opinion what the E&M should be according to what they feel their
4 time and their effort was involved with the care of that patient. I'd like to—can we make recommendations
5 now or are you going to wait until afterwards? So, the recommendation that I would like to make, Mr.
6 Chairman, is that PPAC recommends that the RAC report to CMS and to PPAC procedures that are being
7 conducted that minimize the occurrence of the E&M error in the future. Did you get that, or do I need to
8 reread it? Okay. And Dr. Smith made a couple of other comments and I would like to continue—

9 Dr. Bufalino: Can I have a second for that?

10 Dr. Ross: Oh, I'm sorry. I apologize.

11 [second]

12 Dr. Bufalino: Second. Discussion?

13 Dr. Przyblski: Can it be reread? Because I don't understand what it's asking.

14 Dr. Ross: What I'm asking is for them to report back to us the occurrences of the E&M errors that
15 are taking place, and how we can minimize those errors in the future. How often those errors are occurring.

16 ??: What errors?

17 Dr. Ross: Coding errors, on the E&M.

18 Dr. Standaert: And if they come up in the RAC is recovering, recovering or putting out demand
19 letters for coding errors. Isn't that too, what you're asking?

20 Dr. Ross: Correct.

21 Dr. Bufalino: Maybe I misunderstood. We're not going to bicker over one level coding error?

22 Commander Casey: I think any RAC that bickers over one coding error is going to find himself in
23 trouble on the appeals level and this is something that those companies are not going to want to do. They're
24 not going to want to waste resources to have a claim overturned on appeal. And our experience in the
25 demonstration was that they did not look, they have part B claims data available to them. They did not
26 focus their resources on E&M coding. They looked at larger dollar inpatient reviews, and larger dollar part
27 B claims.

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1 Dr. Bufalino: I guess one of the confusions we had, just to kind of close this loop, that we
2 discussed earlier was we were just trying to understand, and obviously you referenced to go to the website,
3 where are the areas of focus at physicians? I think we understand the hospital side in terms of where the
4 RACs are focusing on issues of debate over the determination of the reimbursement, but on the physician
5 side, I guess a lot of us are a little confused.

6 Commander Casey: I'll be honest with you, our RACs just got the data, so we're not sure what
7 areas they're going to focus their reviews.

8 Dr. Bufalino: So we don't even know.

9 Commander Casey: Right. We don't even know at this point in time. I think we'll have a better
10 understanding, probably in about three or four weeks where they might be with what type of part B reviews
11 they want to—

12 Dr. Bufalino: I guess that confuses me. So why isn't CMS providing direction to the RAC around
13 areas that they're concerned about?

14 Commander Casey: Well, we will through the new issue review process. As part of their proposals
15 to the agency as to what they want to review, I mean we could give them lots of recommendations on what
16 to stay away from and what not to, but what we want them to do is we want them to mine their data. We
17 want them to identify for us how big of a problem they believe in their particular jurisdiction a particular
18 issue is, and then come in with their plan for review and then we will assess the Medicare rules and
19 regulations regarding that particular issue, and then render a decision whether we want them to just conduct
20 maybe a limited review, or we want them to do a review across all their jurisdictions, so until we get them,
21 give them the data to really know what they're looking at, there's many things we can look at throughout
22 the Medicare program. We're really letting them come into us and let us know what they want to look at.
23 Because we don't want to tell them how to best utilize their resources. They only know the skill sets of the
24 clinicians they have on staff. I wouldn't want to tell them to review home health claims and they do not
25 have appropriate home health nurses to review those claims. I think that would be a big mistake.

26 Dr. Bufalino: Understood. So your recommendation?

27 Dr. Ross: Still want to hold that recommendation with the friendly amendment?

28 Dr. Bufalino: I guess we don't understand the recommendation.

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1 Dr. Ross: My recommendation was, PPAC recommends that the RAC report to CMS and to the
2 PPAC, procedures that are being conducted to minimize the occurrence of E&M errors in the future.

3 Lt. Lew: Do you mean the steps that the RACs and CMS are taking to avoid the type of it's a 214,
4 no it's a 213 type errors?

5 Dr. Ross: Correct.

6 Dr. Hirsch: Could we revise that to ask for feedback on what types of errors they did find and
7 what request they made for payback at the next meeting? Rather than just focus on the E&M, just find out

8 [chat]

9 Dr. Bufalino: ...deal was what Commander Casey talked about, which is we don't really
10 understand the scope of what their even aiming at at this point in time, so I guess my recommendation
11 would be that you bring to us at least the first review of the concerns or the areas that might be focused,
12 because I guess we don't understand what they're aiming at at this juncture.

13 Commander Casey: Right, and we don't know yet either.

14 Dr. Bufalino: And you don't know either. Right.

15 Dr. Przyblski: Well, perhaps where Dr. Ross is going, most of the data that we saw from the
16 demonstration projects was aggregate, meaning hospitals. I think Dr. Ross is saying can you separate out
17 E&M errors specifically, and provide us data if it is looked at, as to what is the number of E&M claims,
18 number that were found in error, number that were appealed, etc., and then we can sort of determine based
19 on that information either how to instruct the physician community on not to make those errors or find a
20 problem with how it was discovered in the first place.

21 Commander Casey: I believe our plan is, as we get more sophisticated data, we will include in that
22 yearly report that we put out, I think that the detailed level information that you're looking for, I think it'll
23 be fairly similar. I don't know if you've seen the comprehensive error rate testing program. They identify
24 specific codes and problems. Terry maybe you can address it more as to what we may be able to get out of
25 the warehouse.

26 Lt. Lew: Sure. The RACs are required to put every claim they review in the warehouse, whether
27 it's automated review, complex review. We do have provider types, and we've had the distinction between
28 DME supplied by provider and DME supplied by supplier. I was under the impression that the data can

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1 support making that distinction, although I'm not positive on that. But that would be hopefully available
2 through the warehouse, as well as the specific service, whether it be E&M or whatever service the RAC is
3 looking at. They do assign an error code, which are sort of a super set of the CERT codes. We're looking at
4 merging our lists, but those will be a four-digit error type and those get fairly specific on the nature of the
5 error that the RAC found that led to the improper payment and so we'd certainly be willing to present the
6 findings. I'm not sure how many findings we're going to have at the next Council meeting. I'm not sure if
7 the end is going to be particularly meaningful, but we certainly can present at that and future meetings what
8 RACs have found.

9 Dr. Bufalino: Great. Roger?

10 Dr. Jordan: Just two quick questions. During the demo, didn't the RACs do some physician
11 offices? So didn't they have some direction at that point about what we're trying to talk about here? And
12 then my second question is on slide 21, where you're telling me what to do as far as calling the RAC and
13 giving the right contact, will that, as a provider, target me, flag me quicker than other offices that do not
14 contact?

15 Ms. Reese: I would say no, the RACs do their reviews differently than the claims processing.
16 They're not provider-specific. They'll look at service areas, so if they decide to look at a certain drug code,
17 if you're data's in there then you'll be subject to that review, but they're not looking at anything provider-
18 specific. And also just as an aside to that, each RAC kind of has their own way of gathering that data. I
19 know for Region C, when we're going out to our, for our provider outreach, the providers that are in the
20 room, they can fill out a form that we'll have available for them right then, to fill out. There might be
21 something in another RAC's initial request for a medical record that if this isn't the correct place to send
22 that request, here's a little spot to revise, or here's some instructions. So that's going to be something that a
23 provider will need to work with their individual RAC on. But nothing like that is going to target you.

24 Commander Casey: And just to answer your other question, regarding the demonstration.
25 Actually, if you recall, basically the demonstration was only run in initially three states, and then we added
26 a few states. But the purpose of the demonstration was to see if this was a viable tool for Medicare in terms
27 of finding improper payments. So at the time of the demonstration, we did not provide them with a lot of

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1 direction as to what areas CMS believed there was a lot of error. So to answer your question, no there was
2 not that much oversight.

3 Dr. Bufalino: Dr. Simon had a follow-up comment.

4 Dr. Simon: I think my recollection serves me well, during the demonstration, there was no, E&Ms
5 were not part of the demonstration project. So to go back to Dr. Ross's question, there is no E&M data. So I
6 don't understand his recommendation based on that background.

7 Commander Casey: Well, I guess maybe going forward.

8 Dr. Standaert: One, when I was here last time, I asked for more information. You did send me
9 some information on a link to the 2006 data, and one of the things that we've just talked about here. Clearly
10 we're concerned about the impact on physicians and what's going to happen to our offices. In the data you
11 have, the Florida RAC focused on physicians. The other two RACs focused on hospitals in the
12 demonstration project. And if you look at the appeals and numbers, and the gross number of appeals was
13 way higher for the Florida RAC than any other RAC. I don't know how many claims they filed, but the
14 appeals number was much higher, and so the data wasn't in the demonstration report I could read to tell me
15 sort of what that meant. But there clearly is data from that RAC on what they were after with physicians
16 and what the appeals rate were, which was then washed out in an aggregate sort of numbers of the whole
17 thing. So I could probably pull that fairly easily if it's germane.

18 Commander Casey: You are 100% correct, that unfortunately our appeals data was not able to
19 break it out by what type of physician or what type of service was being appealed. However, in the future,
20 we do plan on being able to break out the appeals statistics so we believe that that will also help you as we
21 move forward with the national program. But I can tell you that one of the reasons why Florida appeared a
22 little bit different than the other RACs was not all the part A data was available to Florida initially. There
23 was a lag in when we got part A data and I can't remember exactly what the reason was. But they didn't
24 receive as much part A data initially, so I think that's why their focus was on part B services initially. And
25 we did have some problems in the Florida jurisdiction that we did actually, actually I had several providers
26 call me and I actually worked through the issues with those providers and we ended up having, it had to do
27 with [FACEP? 36:46] joint injections at the time, and we really did work with the provider community
28 down there to get those claims overturned and get them paid.

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1 Lt. Lew: We built what we believe are fairly robust appeal reporting capabilities into the data
2 warehouse that we didn't have in the demonstration, so with any luck, we will be able to report that in
3 greater detail.

4 Commander Casey: I'll tell you, we lucked out with a little bit of time, because the RACs, because
5 of the protest, so we were able to get a lot more of these improvements put in place so that we can move
6 forward with national expansion.

7 Dr. Standaert: Which is good, we appreciate that. I guess my other, that is very helpful actually.
8 My other questions are points where one, when you look through this whole thing, your suggestions are
9 somebody's in charge of monitoring requests and this is an enormous administrative burden on the
10 physician practices to do this. They almost have to have somebody who's going to read the RAC website
11 every week, track all your record requests, track all your appeals things. I mean there could be a lot of stuff,
12 here. A group of 50 cardiologists, you could have a lot of work here. And that's a big administrative burden
13 and they're going to have to hire people just to do this. And there's no, it's probably not in the RUC for any
14 sort of compensatory mechanism to cover that cost for physicians. So there's a fundamental problem, there,
15 I just want to point out.

16 My other question is sort of use the word vulnerabilities on slide 18. What does that mean? Said
17 vulnerabilities are posted to the web. And does this mean that—I guess my question would be, when people
18 file appeals, you can put new issues posted on the web, saying these are the things we have decided are
19 recoverable, and you're going to put them on the web. If people appeal things, and that decision is reversed
20 and you say, you know what? These really aren't recoverable, is that also going to go on the web, so other
21 people who see oh wow! That go overturned by those guys in New Mexico, I can probably do that, too. Is
22 that going on the web? Is that what you mean by vulnerabilities?

23 Commander Casey: No. Actually what we will probably do is we will have a particular issue, the
24 widespread issue that will be posted to the RAC website, and we can ask them to include their appeals
25 statistics for that particular issue, because you know, we might have an issue that really was true for the
26 LCD that was written in jurisdiction C, but then when we applied the same standard to jurisdiction B, the
27 language in the LCD wasn't exactly identical so it really wasn't maybe an area that we should have because
28 the policy wasn't as strong, that stated that CMS should be denying those cases, and we may lose on appeal

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1 unfortunately on some of those. And we can ask the RACs to post their appeals statistics to the website.
2 When we talk about vulnerabilities, the term “vulnerabilities” as CMS is utilizing that to mean, something
3 we find across the country, a national, high-dollar problem. Like we saw a lot of things in the demo that
4 were maybe 500,000, but we really only looked at and included in the status document anything that was a
5 million or above. Those are the type of things across the country that we will post, or even if it’s
6 jurisdiction specific, but it’s high dollar, we’ll post those to probably the CMS website and the RAC
7 website, that says these are high dollar problems that were identified and we will include in the report to
8 Congress, the yearly report, the status report, that goes up on the web, the appeals overturn rates for those
9 issues. So does that answer your question?

10 Dr. Bufalino: We’re going to try to cut it off with two more questions, so Karen, you haven’t
11 asked yet.

12 Dr. Williams: I work in an acute care hospital, level one trauma center. I had a patient last week
13 who came in with severe vassal spasm in her brain. She was on a number of vassal active medications in
14 the ICU, intubated, her brain was subsequently lacking oxygen, and because of this vassal spasm. The ICU
15 put her on a balloon pump in order to help continue to profuse the rest of her brain, and then the
16 neurosurgeon wanted to bring her down to our very aggressive interventional radiology department with
17 anesthesia involved in order to try to open this woman’s brain. This is just an example. We spent hours in
18 this intensive care setting with this woman on this balloon pump, with anesthesia, radiology, the
19 neurosurgeon, etc. It was a request that was implemented within about 15 minutes of the surgeon asking us
20 to participate in the care. Ultimately the woman was not able to be re-vascularized. She went up to the ICU
21 and ultimately expired the next day. My question is, when a primary care physician requests services of
22 another physician, radiologist, anesthesiologist, pathologist, or any of my other colleagues here, as
23 secondary providers, and if Medicare decides for whatever reason to deny the care of that particular
24 patient—let’s say they said you shouldn’t have gone down to interventional radiology in the first place. The
25 woman was already dead, she had multi-organ system failure, I don’t know what else this woman had
26 because there was no time for me to evaluate all that. I’m running to the interventional radiology
27 department. Subsequently, the physician that requested my services gets denied payment and ultimately all

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1 the downstream consulting services also don't get paid for the intensive care that they gave to this woman.

2 Can you comment on that, and then I would like to make a recommendation about that.

3 Commander Casey: I don't know whether the RACs will review those subsequent physician
4 services. They may. We don't have any examples of the demonstration in your instance to provide you with
5 any information on whether they'll look at the other services. They might decide, you know, I'm just
6 looking at this particular issue. I'm not going to look at all the subsequent issues, so at this point it's too
7 soon to tell.

8 Dr. Williams: Well, my understanding from colleagues across the country, as well as when I
9 brought this up a few meetings ago, is that I think there is consideration for denying of payment for all
10 downstream services if that initial evaluation was decided to not be paid for, so can I make a
11 recommendation or do you want me to wait? Okay. Whenever a particular—I have this in writing by the
12 way—Whenever a particular procedure or service has been questioned as unnecessary by a RAC
13 contractor, after service has been delivered, all downstream medical services, including consultant services,
14 have been called into question. Request for repayment during the period of investigation have been made of
15 consulting physicians, such as, but not excluding, pathologists, radiologists, and anesthesiologist. These
16 hospital-based specialists have rendered their service in good faith in response to a request from another
17 physician and have no way of determining at the time that they are asked to participate in the care of a
18 patient, whether or not the underlying procedure or service may be questioned or determined to be
19 medically unnecessary by a RAC contractor at some time in the future. Therefore, PPAC recommends that
20 the RAC process be modified to exclude extending demands for repayment to consulting physicians for an
21 index case for a particular surgery or procedure.

22 Dr. Bufalino: Second? We'll give it to you so you can type. Second, I'm sorry. Yes? Any
23 discussion?

24 [off mike comment/chat]

25 Dr. Arradondo: Besides a surgical opinion or another medical opinion would cover that also.

26 Dr. Bufalino: Okay.

27 Dr. Williams: So you can modify that last sentence, thank you.

28 Dr. Bufalino: All in favor?

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1 [Ays]

2 Dr. Bufalino: Thank you. One last comment before we break?

3 Dr. Smith: I wanted to make a recommendation also. PPAC recommends that RAC only be
4 allowed to review and request records on three patients per physician, and that the number of records
5 requested and reviewed be the same, whether the physician is solo or part of a group of any size per 45
6 days.

7 Dr. Bufalino: Second?

8 [Second]

9 Dr. Bufalino: Any discussion? Leroy?

10 Dr. Sprang: What are the rates now for large groups?

11 Dr. Smith: Large group is 50 for a large group, so if you had 250 physicians, that'd be a fifth of a
12 record. For a solo practitioner, it's ten.

13 Dr. Sprang: But then, for a large group of 200—

14 [crosstalk/chat]

15 Dr. Kirsch: She's saying it's an undue percentage put onto the lower

16 [crosstalk/chat]

17 Dr. Smith: A fifth for the solo practitioner or a fifth for the large group, or it should be the same
18 across the board.

19 Dr. Sprang: But I don't think we want to increase the burden on that group of 200.

20 [crosstalk/chat]

21 Dr. Kirsch: The burden to the large group would be the same, and a lower burden to the small
22 group.

23 Dr. Smith: I mean if they were testing records on every physician in a group of 250 people, then
24 the group has a problem in terms of compliance, but the numbers should be the same. But the RAC be
25 allowed to review and request records on only three patients per physician per 45 days and that the number
26 be the same whether the physician is solo or part of a group of any size, so it's per physician. So they
27 couldn't request 600 records on one physician saying it's part of the 250-person group. They couldn't do
28 that. It would be per physician.

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1 Dr. Bufalino: All in favor?

2 [Ays]

3 Dr. Bufalino: Thank you. Any other recommendations? Jeff?

4 Dr. Ross: PPAC recommends to CMS that RACs reimburse physicians for copies of requested
5 medical records prior to the commencement of the RAC audit.

6 [second]

7 Dr. Bufalino: Second. Okay, any discussion?

8 Dr. Standaert: Haven't we already done this? We've already made a recommendation—

9 [crosstalk/chat]

10 Dr. Bufalino: All in favor?

11 [Ays]

12 Dr. Bufalino: Thank you.

13 Dr. Smith: PPAC recommends that CMS direct the RACs in writing that the 30-day deadline for
14 filing an appeal should be flexible if there are extenuating circumstances, and should include that
15 information in the letter sent to the physician.

16 Ms. Reese: Can I just add something?

17 Dr. Bufalino: Please.

18 Ms. Reese: The 30-day, the time frame for filing an initial appeal is actually 120 days—

19 Dr. Smith: It's 30 if you don't want to pay interest.

20 Ms. Reese: 30 days is the limit, right, right.

21 Dr. Smith: So it's 30 days functionally if you don't want to write them a check and don't want to
22 pay interest, it's 30 days.

23 Dr. Kirsch: What is the interest rate?

24 Lt. Lew: It changes I believe it's quarterly. Last time I looked, it was something unpleasant. I
25 believe it was around eleven and a half.

26 Dr. Smith: It's not the same as your bank is currently paying you.

27 Dr. Bufalino: Other recommendations?

28 Dr. Smith: Did somebody second that one?

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1 [second]

2 Dr. Bufalino: It was seconded? All in favor?

3 [Ays]

4 Dr. Bufalino: Thank you. Sorry. Anyone else?

5 Dr. Simon: What's the status of our first recommendation?

6 Dr. Bufalino: Dr. Ross's first one? I think he removed it.

7 Dr. Ross: I rescinded it because it—

8 [crosstalk/chat]

9 Dr. Ross: I did say that I rescinded it because when I heard your testimony that it hadn't come out
10 in the demonstration, then I said I would rescind it. I addressed it to the chair.

11 Dr. Bufalino: Thank you for joining us. Have a nice afternoon. We'll take a quick lunch and be
12 back here at 1:00.

13 Lunch

14 Local Coverage Determination Process

15 Dr. Bufalino: Why don't we all get a seat and we'll get started. Thank you. So our next topic is
16 local coverage decision process. We're welcoming Dr. Paula Bonino, who has accepted our invitation to
17 provide some insights around this process. Dr. Bonino is an internist, geriatrician, contractor medical
18 director with a local contractor for Medicare Administration Contractors in jurisdiction twelve, the
19 Highmark Medical Services. She's been involved in LCD per traditional part A and part B. She's also
20 worked with Medicare Advantage dual eligibility for Special Needs programs, part D prescription drug
21 formula. Highmark Medical Services has just completed a major transition into the MAC environment, and
22 will be involved in local coverage decisions of multiple outgoing contractors. Accompany her today is
23 Patrick Kiley, who is President of Highmark Medical Services, and someone else who I don't have in my
24 little list. [chat] Thank you, good afternoon. And welcome.

25 Dr. Bonino: Thank you for the invitation to come. Can you hear me all right? Okay. We're going
26 to talk a little bit today, we're going to talk primarily about the LCD development process, both in the
27 regular world and in this new MAC environment, through the transitions that are occurring in the last
28 phases here. One of the last reasons why LCD work in the Fee-for-Service Medicare program has become

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1 so high profile is because of course, these LCDs often set the coverage, or do set the coverage for all other
2 Medicare programs in the jurisdiction, including the Medicare Advantage programs. The Medicare
3 Advantage programs must provide at least what the LCDs of the Fee-for-Service contractor provide plus
4 more if they choose to. The other issue is that our coverage determinations are often used as a template by
5 everybody else and that's a little bit odd when you look at how we do them and why we do them, as
6 opposed to how the commercial world does them. Highmark is again our, the MAC J12 jurisdiction we'll
7 talk about a little bit toward the end.

8 Basically, local coverage determinations tell us the clinical circumstances under which a service,
9 item, or procedure is considered to be eligible for coverage. According to the Social Security Act, Section
10 1862A1A requirement, are reasonable and necessary. It must be consistent with all statutes rulings,
11 regulations and national coverage payment and coding policies. This is where one of the major differences
12 is with the commercial world. In the commercial world, the assumption is that often made that unless there
13 is a medical policy, there is no coverage. And that's clearly not the case in the Medicare program, but
14 manufactures, folks often come to us asking for a policy because they want to know if it's covered when
15 that's not necessarily the driver for coverage in Medicare. The detailed instructions we currently have for
16 LCDs in the development process are in the Medicare Program Integrity Manual, Chapter 13. So then how
17 do we choose where to focus our efforts? How do we decide what to do LCDs on? We look for where we
18 found problems, where we validated through medical review, through our data analysis, that there is a
19 widespread problem that presents a risk to the trust fund, either at a dollar level or a volume of service
20 level. An example would be of course, many radiation therapy services while wonderful are extremely high
21 dollar, so things that are new like IMRT, when it first came out, lent itself to the need for a medical policy.
22 Things that are high volume, chest x-rays, the number one volume item in order to automate an edit to
23 approve or deny claims, one must have either a statement from CMS on a national level or on a local level.
24 What else do we look for? We truly do look for a need to assure beneficiary access to care. There are some
25 treatments that are either orphan, small numbers of people, but perhaps in the Medicare population, it's a
26 larger population subset of the group that would need that care, and do do policy to assure beneficiary
27 access to that care. Items for which frequent claim denials are issued or anticipated is another driver of our
28 efforts. Again, we very, very much look at our data, and not just our data locally, but our data locally in

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1 comparison to the national data. And we look for aberrancies. We look for things that are being used in a
2 different fashion in our jurisdiction or reimbursed in a different way, as compared to the neighboring
3 counties, the neighboring jurisdictions. New technology, any service or procedure that is new, often at a
4 local level, we're able to move quickly to put out some guidance on what's eligible for coverage. A need to
5 specify certain circumstances under which an item or service is never covered. There may be an item that
6 we would cover for nine things and the tenth item we would never cover it for, so that would be a driver of
7 policy. And then more recently, of course, problems identified through the CERT Program. The
8 Comprehensive Error Rate Testing Program, or CERT program of course, was established to support the
9 requirements of the government Performance and Results Act from 1993, and CMS manages it with
10 Advance Medic—it's other contractor. And we get data on a monthly basis. We're graded and watched
11 very carefully on this, but it is important. It is a major driver of where to focus our efforts. We are limited
12 as well in what we can focus on. So where we're finding errors is a place that sometimes will drive
13 development of LCDs.

14 So what are the requirements. And Tamara and I were talking earlier. We're going to have a little
15 bit of overlap between the two, because coverage is coverage, but for the LCD, we have to do the same
16 thing as for an NCD. We have to look for a benefit category existing in Title 18 of the Social Security Act.
17 Among the most obvious examples that contractors have been struggling with over the past decade or so,
18 there was a time where finally there was a benefit for cardiac rehab as a program services. But not until
19 very recently was there a benefit for the program of services of pulmonary rehab. Those services were
20 independently or individually allowable for coverage. We could cover PT, we could cover respiratory
21 therapy, but we couldn't pay for a pulmonary rehab program as such, so there has to be a benefit category
22 available for us to allow payment under the law. The service can be excluded by some other section of the
23 law. We can't at the moment, pay for routine physical exams, of course, except for the new Welcome to
24 Medicare physical. We don't cover cosmetic surgery, except, not, we don't cover cosmetic surgery. We
25 may cover surgery in repair of an injury. Hearing aids, eyeglasses, except for after cataract surgery and
26 most dental care of course non covered. What else? The service can't already be covered as a specified
27 Medicare benefit, as an exception to the requirement. I am a geriatrician. Earlier in my career, I couldn't
28 order screening mammograms for my elderly women because there was no benefit under Medicare—I

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1 could order them. Medicare wouldn't pay for them because there was not such a screening benefit. And
2 most of what we deal with on the local level then, after we get through these considerations is what, how do
3 we define that this particular item or service is reasonable and necessary? Well, first it must be safe and
4 effective. It can't be at this point still experimental or investigational, except as defined for the routine cost
5 of clinical trials, and it must be appropriate, both in its duration and the frequency that it's considered
6 suitable for that service. We also have to look at the accepted standards of medical practice and the setting
7 in which the service is provided. I think it's been a challenge with the change of so many inpatient
8 procedures to the outpatient setting and so forth. It takes a little time to get all these things moved to the
9 right setting. What kind of supporting evidence do we need? We want the best, we want the strongest
10 evidence of course, and published scientific literature is always reviewed first for the available evidence
11 pertinent to that item or service. The order preference is also defined by the program integrity manual for
12 us. Of course, a definitive, randomized clinical trial is what everyone wants, or another definitive study. We
13 don't always have those for the new technology, but that's the preference. General acceptance by the
14 medical community is a standard practice as supported by some medical evidence. One of the issues on the
15 local level is that sometimes things are more common on a local level. I currently come from Pittsburg. I
16 know the transplant folks in the room will know that that's Tom [Starzels SP? 10:54] home town, so liver
17 transplantation was of course first in Pittsburg and big in Pittsburg, but that's now covered on a national
18 level. So we don't have to deal with that one on a local level, but there are these local variances. So we may
19 have a different standard of practice for liver transplant in Pittsburg, or may have had a different standard
20 of practice 20 years ago than was in another part of the country, and so those local determinations often
21 come and then they may not need to stay for 20 years. That's one of the differences with the LCDs also, is
22 that we do retire them. We do move them on. We update them, and when they're no longer necessary, they
23 move on. We have to look at the sound medical evidence based on scientific data, research studies and peer
24 review medical journals, consensus of expert medical opinion and then consultations with medical
25 associations or other healthcare experts. Again, this is the order of evidence.

26 We put our draft local coverage determinations out for a minimum 45-day comment period, and
27 that's for any new LCD, for any LCD that we've revised that has even the appearance of restricting an
28 LCD, and for any revised LCD that makes substantive corrections to an existing LCD. And we timed this

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1 to occur both before the open session, which I'll speak about in a moment, and the contractor advisory
2 committee meeting. All of this information, the drafts themselves, the status page saying where in the
3 process the draft is, information on how to comment and a form actually to comment directly through the
4 website are out on the website. The draft LCDs are also provided to our contractor advisor committee
5 members, to appropriate groups of healthcare professionals, and provider organizations to specialty society
6 representatives, other contractors to the quality improvement organizations, and of course to CMS.

7 The open session. I actually worked in Medicare before these came into being and they are now a
8 meeting that is scheduled prior to the CAC meeting. And the intent is to provide an opportunity for
9 interested parties to make a formal comment, and to present pertinent scientific information on issues
10 related to the draft LCD. What happens is that they present this information. We ask that they provide us
11 with a one-page summary of their information, which is then given to each CAC member, so that the CAC
12 members don't generally have time to come to both an open session and to the meeting itself, but they get
13 that information directly at the CAC meeting. The Contractor Advisory Committee provides that formal
14 mechanism for the physicians and other providers to be informed of and participate in this development in
15 an advisory capacity. The CAC does review all the draft LCDs, but the final decision on the
16 implementation does rest with the contractor medical directors. Now, our Contractor Advisory Committee
17 really works with us in many ways. Their formal purpose is for the CAC meeting, but we work with them
18 throughout the lifespan of the policy, even before that draft LCD is finalized and posted, we speak with our
19 subspecialists in that area to get a feel for the community standard of care. We'd like to put out a policy
20 that makes sense. We'd like to put out a policy that is consistent with the standard of care and that's how
21 our CAC members work with us. They work with us on other issues as well. Sometimes on pricing issues,
22 on questions about appropriateness of the item that we're putting, a criteria that we're in the LCD.

23 Once we have all the comments in, we do the revisions that are necessary and we post the final
24 LCD again for another notice period for 45 days. We will at least have it out there for 45 days. We also
25 post as do all contractors, a summary of the comments received and our responses to those comments on
26 the website. And then when everything is final, those LCDs are not just on our website, but they are also
27 entered into the CMS Medicare Coverage database. One of the things that we talked a little bit about,
28 whether to have NCD or LCD first and it really didn't matter, but one, I'm going to give you one example.

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1 I thought afterward that as physicians, we do cases, and so one perplexing example of a difficult LCD, but
2 a necessary LCD was our current LCD on arthroplesis stimulating agents. And why was this so difficult?
3 Well, we have several things going on. We have a Medicare benefit for ESAs in the treatment of end stage
4 renal disease patients. So we had to deal with the statute of course on ESRD patients receiving EPO in
5 relation to their dialysis and their renal disease. We have also now an NCD for the use of arthroplesis
6 stimulating agents in cancer patients, so that's another piece that we have to carve out to that, and then
7 there's left all the rest to contractor discretion, [the anemias 16:26] basically of chronic disease. So we have
8 not just the LCD, but we also have a billing and coding article. Because LCDs used to be policies, the
9 LMRPs. They are now LCDs. And they are to contain only coverage information; only information about
10 what's reasonable and necessary, not really about coding and billing. The coding and billing information is
11 now, because of the Benefit Improvement and Protection Act, the coding and billing information is to be in
12 these coding and billing articles. So we have sort of a lot of information and this is another place where we
13 differ from commercial insurance, because we may need to direct providers to more than one document, to
14 not just look to the medical policy for coverage, but also to these accompanying billing and coding articles
15 for additional information about how to code that claim to get it into the system electronically.

16 So just a word or two about the Medicare Administrative Contractors. Could you go back one
17 slide please? Of course you know contract and reform was mandated by Section 911 of the Prescription
18 Drug Improvement Modernization Act, and the previous carriers and fiscal intermediaries are being
19 replaced with Medicare Administrative Contractors, creating a smaller number of contractors with larger
20 territories. It was a, it has been a competitive bidding process with several waves. We are in the last wave
21 now. Jurisdiction 12 is the largest jurisdiction in the country. We have in this jurisdiction about 4.2 million
22 beneficiaries, 137,000 some physicians and other healthcare professionals, over 400 hospitals, and it's
23 about 11% of the national volume of claims for Medicare. Our jurisdiction includes part A and part B
24 providers in Delaware, DC, and for DC, for part B, we have the Metropolitan area, including northern
25 Virginia, Maryland, New Jersey and Pennsylvania. We were not required at the time, and I will not take
26 credit for it, it's when I was away doing Medicare Advantage, my immediate supervisor, Dr. Blastachek,
27 created the method that within the MAC process, we wouldn't just go with making choices, we actually put
28 57 draft LCDs out for comment and went through a full comment and notice period, met with all of the

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1 outgoing CAC committees, met with all the outgoing CMDs, went through every policy that we hadn't
2 chosen that they thought might be necessary and added some in and in fact, we think that it was a better
3 process because it allowed for that input. We were lucky to just have enough time to fit in and get our full
4 45 days in but we were able to do that and it has, I think, been a very helpful thing in the transition to have
5 that community voice in these policies.

6 So we started out with 57, we finished transition mid-December, so we actually just had our first
7 business as usual contractor meetings about three weeks ago. We're in the middle of our first comment
8 period. We did have a full comment period in MAC J12 in the transition, and did, as I said, do conference
9 calls with all of the outgoing contractors. How we implemented these were that the dates of service, it was
10 by [sounds like: FEDMIC ? 20:03] cut over date of course the policy couldn't apply until you transitioned
11 in, and as always, in the absence of any LCD or NCD, we still review services based on reasonable and
12 necessary. But that also means that the CAC has changed. The CAC used to be a carrier advisor committee,
13 and I used to work in our intermediary, and we had an intermediary advisory committee, but the
14 intermediary advisory committees were never funded for face to face meetings as the carriers were, so ours
15 were more through telephone, through mail, through email, and now our contractor advisory committees
16 are truly jurisdictional and have members from both part A and part B, and members from all states
17 involved.

18 This is just a quick snapshot of our website, these web addresses are at the end of the presentation,
19 and we keep trying to simplify the medical policy center. We have links to the actual policies themselves,
20 and of course to the national coverage determinations, you can click out there and go to the draft LCDs, all
21 of the above. I know that was kind of whirlwind. I realize that there may be questions that you have related
22 to these or unrelated to these that are more based on the national coverage determinations. And I guess my
23 question is, would you like to do questions now, or should Tamara talk first. How would you like to go
24 from here?

25 Dr. Bufalino: Maybe we should wrap it together since they're obviously very connected. Why
26 don't we follow it, Tamara Jensen's presentation and then we'll open it up for discussion. Ms. Jensen is
27 currently the Deputy Director of Coverage Analysis Group in the Office of Clinical Standards and Quality,
28 and at the end of this month, she will take over the role of Acting Director for Coverage and Analysis.

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1 Congratulations. So we're here to compliment the local coverage decision conversation with the national.

2 Thank you.

3 National Coverage Determination Process

4 Ms. Jensen: Thank you. As Paula said, the NCD process and the LCD process work very closely
5 together. And in my presentation, what I first would like to do is go over how we make a decision, that is,
6 what does "reasonable and necessary" mean to us, and then the second part of the presentation, I would just
7 go through the process of how we actually make an NCD. And I think you will see as I go through it, where
8 LCDs will fit within the NCD process.

9 Regardless of anything I say, I think this is the most important site, at least for NCDs. On this
10 particular homepage, on our coverage homepage, this lists all of our NCDs, all of the LCDs, any guidance
11 document that we put out and how we define reasonable and necessary, any meetings that we have with the
12 Medicare Evidence Development and Advisory Committee, or MEDCAC, basically any event that we are
13 going to have or any policy we develop will be on this particular website.

14 As Paula had mentioned, most coverage is local. Very little comes to us. It has crept up a little bit
15 in the last couple of years, I now say about 10 to 15% of the policies that come to my shop are national, but
16 most of the stuff is really at the local level. I think a number, I think there are over 5,000 LCDs and there
17 are less than a thousand NCDs. And again, just to support what Paula said, as I said, most coverage
18 decisions are local and a lot of the reason for that is because when they first wrote the statute, they said that
19 there'd be variation in medical policy throughout the country, and so the local decisions are better able to
20 adapt to that than the national side.

21 So here are what we, when we summarize, the steps to come to Medicare payment, or to a positive
22 coverage decision. The first thing, the first dot up there, regulatory approval, generally what I mean by that
23 is FDA approval. Whether the particular item or service has been cleared or approved by the FDA for
24 marketing and so that it is safe and effective for the general population.

25 And then the next step we look at is can CMS pay for it? As Paula said, basically, is there a
26 statutory, or did Congress give us a statutory determination that these particular items or services fall under,
27 and that's under 1861, and generally, that determination is made by the payment folks, Liz's group. And if
28 they decide that something does fall under one of these very broad categories, it will then come to my shop.

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1 And that is the cover shop, and we decide whether that particular item or service is reasonable and
2 necessary and there's the statutory cite there. And when we say whether something is reasonable and
3 necessary, the things that we can make decisions on are generally for the diagnosis and the treatment of an
4 illness or injury. Until recently, we didn't even get into prevention type services, but with Congress just
5 passed MIPPA, so now reasonable and necessary in certain circumstances could apply to some prevention
6 services as well.

7 And how we define reasonable and necessary. CMS, historically, has tried to actually define this
8 in rulemaking. We have not been very successful in doing that, but how CMS has publicly defined
9 reasonable and necessary is whether something improves the health outcomes for our beneficiaries. A lot of
10 times, we are asked, well if FDA approves something for marketing, why aren't you just covering it in
11 Medicare? Well the FDA does approve something for the general population, for the safe and effectiveness
12 for the general population. When it comes to us, it's whether that particular item or service works in our
13 population, the Medicare population or the disabled. So when we look at that, we want to have enough
14 confidence in the evidence that we review that it does improve the health outcomes for our population. And
15 then we're always asked, well why do you base this on evidence? Why don't you just take a look at the
16 experts, and just take their opinion and move forward with that? What we have found through experience is
17 that generally opinions differ, and we have a lot more confidence in a high quality studies. Those are
18 generally more reliable and those we can reproduce in a very confidence way. And also, I think most
19 importantly, when we use evidence-based medicine, I think it's a very open discussion. In all of our NCDs,
20 if you read them, and also in the LCDs, you will see our thought process throughout that document; what
21 evidence we reviewed, what we thought about that evidence, and how we came to our conclusion. So I
22 think at least in the Medicare world, when we use evidence, I think it's an open, and it's a generally
23 consistent coverage process, and I think you can generally predict what our decisions will be when you
24 come through the national decision. And I just also just went over this.

25 Regardless, we realize that there are some evidence deficits. It is not a perfect world. A lot of
26 times when someone comes in to ask us for a coverage decision, there's no evidence. So what do we do
27 with something like that? Or there's only short-term safety data only, so do we want to cover that when we
28 don't know what's going to happen in the long term. Or there are clinical trials out there, and they're very

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1 good clinical trials, but they only do the, they only have the clinical trial in patients that are quite a bit
2 younger than the Medicare population. So the question is, can I generalize that particular data to the
3 Medicare population? And then obviously, evidence is always changing, so it's improving, or maybe new
4 evidence came out that this particular item or service is no longer a safe item or service and so we need to
5 go back in and non cover it. And so this is generally how we get to the reasonable and necessary decision.
6 This is a good overview of the process. And the preliminary discussion, the benefit category
7 determinations, that happens outside of my shop. So once both of those are checked yes, it then comes to
8 the coverage group. And we open up a coverage decision. We have six months to come up with a proposed
9 decision, and it's during that six months where we look at the evidence; where we look at all the clinical
10 trials that may have been done, all the peer review literature, we talk to the experts. Anybody can come in
11 and talk to us about a particular decision. We are also, we are very public when we open an NCD. It's
12 always on our website, and the dates are there; the date we open it, first, and the date that we will issue a
13 proposed decision. So generally six months after we open it, we then have a 30-day, we post it, and then we
14 have a 30-day public comment period, and 60 days after that public comment period is closed, we issue our
15 final decision. When we issue a final national decision, that is the date it is effective. There's no delay in
16 implementation. This has been a big challenge for CMS. So while we have the decision as effective, and
17 that service can now be provided and paid for by Medicare—or not—it is difficult to get all of our systems
18 in line to also pay for that on that same day. So usually the implementation is delayed between three and
19 four months.

20 Ninety-five percent of all our NCDs are open are generally by an external party, generally the
21 manufacturer comes in and asks us to pay for their item or service. There are internally generated NCDs,
22 ESAs does a good example of an NCD that we opened internally, and CPAP was another one that we
23 internally generated. So we do internally generate certain NCDs. Generally, it's new evidence has come to
24 light and we need to take another look at that. ESAs the new evidence that came to light, is that it was no
25 longer safe so we wanted to take a look at that very quickly.

26 When we finalize our decision, these are the five decisions we can come up with. Clearly, we can
27 say yes, outright, and cover the entire item or service. That is generally not what happens today. We
28 generally don't outright cover something, we generally cover something with a few caveats. We can say no,

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1 a national non coverage, and when we say no to a particular item or service, the LCD process can't come
2 in. At that point, it's a national no, and so there will be no LCD on anything we have a national non
3 coverage on. That is true with a national coverage as well. Or, more often than not, we'll have a national
4 coverage with restrictions. So we can either have a population restriction. So we'll cover something where
5 we reviewed the evidence and the particular population was in that trial. We thought that was reliable and
6 we had a lot of confidence in that, so we will have an NCD just to that population that was studied. I think
7 an example of that was lumbar artificial disk. In those particular trials, they didn't have anybody in the
8 Medicare population. It was a much younger population. So what we did was we covered lumbar artificial
9 disk, but we covered it at the 65 and under and we didn't cover it for the older population. Facility
10 standards. This is becoming more and more popular in a coverage determination. Basically, we'll cover a
11 particular item or service, but the facility has to meet certain standards. For lung volume reduction surgery
12 and left ventricular assist devices, right now, we've allowed the Joint Commission to come in, certify these
13 particular facilities. If you are certified by them, we will pay for those particular procedures. Bariatric
14 surgery we did something similar to that, and the two institutions are slipping my mind of who we required
15 to do something like the joint. For carotid stenting, it's a little bit different. They must send us a letter that
16 they have met those particular facility standards, and they also have to do some extra data collection. When
17 they send us that letter, we post that particular site on our website and the carotid stenting procedure, as
18 outlined in our NCD is paid for. And this is one of our newer concepts: Coverage with evidence
19 development. And with this particular, we have a coverage decision and we are encouraging that more
20 evidence should be developed. We think that this particular item or service is a very promising item or
21 service. We think the basic safety question has been answered, but we think that it would be beneficial to
22 the Medicare population. However, we want to put some parameters around this particular item or service,
23 so we either, so what we have done is either you need to be enrolled in a registry, depending on the NCD
24 and so the data will come in here so we can make sure that this particular item, ICDs is a good example, is
25 being used on the appropriate patients and we take a look at that data. Or we require that the Medicare bene
26 would be enrolled in a clinical trial, and we would have approved that particular clinical trial, and if you're
27 enrolled in that trial, we will pay for those items and service and the related services in that trial.

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1 Here are some examples of the recent CEDs, Coverage with Evidence Development decisions that
2 we have made. As I mentioned, ICDs, a particular population. Their data needs to be put into a data
3 registry. The registry that we approved was ACCNCDR and there are specific questions they need to
4 answer and that is sent to ACCNCDR, and we take a look at the data for the Medicare population.
5 Colorectal cancer drugs we partnered with NCI, and there are nine trials out there that are open, and if
6 they're in the those trials, we pay for the drug and the related services. This is the same for PET scans for
7 oncology indications. That is a current open decision. We are reexamining that decision now, with all of the
8 data that we received from the original one, and the proposed was submitted about a month ago, and we are
9 outright covering a lot of the initial PET scans, and then continuing CED in the follow ups. The final is due
10 in the beginning of April. And similar home oxygen is also another trial that we require.

11 Dr. Bufalino: Thank you, Ms. Jensen. Questions. Greg?

12 Dr. Przyblski: Couple questions. How often do you rely on Hayes or Blue Cross Tech Assessment.
13 You mention that you sometimes go to external technology assessment groups in your flow sheet. How
14 common is that?

15 Ms. Jensen: In the flowchart, when I'm referring to external technology groups, it's generally
16 through ARC. And so we have four EPCs that they contract with, and those external TAs go to them, and
17 that's generally when something is very controversial and we really need an outside group to weigh in and
18 most of our decisions, we give to ARC now, so even if we don't give ourselves the extra three months, a lot
19 of our decisions have a TA with them.

20 Dr. Przyblski: My understanding is that a request for an NCD can be done by an individual. Is
21 there any requirement of burden of proof of that requesting individual or a request for their potential
22 conflicts of interest when they make that request, because of concern I've observed for the past couple of
23 years, where a biased party tries to stimulate over a controversial issue, an endpoint that they would like to
24 see that may or may not be supportable.

25 Ms. Jensen: Is that for me or for Paula?

26 Dr. Przyblski: That's for you. [laughter]

27 Ms. Jensen: You're right. Anybody can come in and request an NCD. Per the statute.

28 [chat/laughter] There are no conflict of interest statements that we need to see. Generally, the evidence is

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1 what the evidence is. An individual, unlike some of the experts or manufacturers or academia have a more
2 difficult time demonstrating what type of evidence there is out there to support a coverage decision. We
3 encourage anybody that wants to do an NCD to come visit us first. We won't tell them what our decision is,
4 but if there's not a heck of a lot out there, there's nothing out there, we may encourage them to wait a little
5 while. But if they want to open up a coverage decision and they have all the appropriate documentation and
6 it's there, we will open it. They just will risk a national non coverage.

7 Dr. Przyblski: My last question for Dr. Bonino. How do you choose the physician members of the
8 jurisdiction advisory committee?

9 Dr. Bonino: They've been in the past, on the CACs, they've been determined by CMS, sorry. In
10 the past, the membership has been dictated by CMS in the program integrity manual in the different
11 specialties. Primarily we use our state specialty societies to nominate their members. The other difference,
12 some contractor advisory groups only allow the member and never the alternate. We're very open. We
13 allow either the member and the alternate, whoever can come, and we're so thankful that they come. It's a
14 nonpaid day out of their time that we will take either the member or the alternate or both if they can attend.

15 Dr. Ouzounian: I'm having a little trouble with the LCDs. There's more of them. I think they're
16 less carefully looked at, and it's a little arbitrary and its regional. And it's hard for us as a society to help
17 our members when some of them may be somewhat arbitrary. You cite an example of liver transplants and
18 one could certainly see where if there's a high incidence there, maybe you're going to pay for it there but
19 they're not going to pay for it nationally, I think that's what you were implying. But most of the LCDs I've
20 seen are to not pay for services because for some reason you believe there's a local abuse, and I think that's
21 a problem. Things from our members end up on, I'm sure a lot of people in this room's desk, just like it
22 ends up on my desk, and a lot of times we look at it and say well that's inconsistent with what we
23 understand to be medical policy. I'm sorry, Medicare policy. It is a local issue, that's your problem. I can
24 think of at least two; one involved the state of Florida, and it was of course brought to my attention, and
25 when it came to my desk about six times, I talked to Bill Rogers and he fixed it with a phone call. And
26 another one in the state of California, again, came to my attention and through connections that I developed
27 here and elsewhere I was able to resolve that with one phone call and the person said, that's an obvious
28 misinterpretation; that's an error, that is not what was intended. So I have concern about these 4,000 LCDs

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1 and the freedom of your things. I respect that you need to control things, but I think it should be done
2 uniformly through a national policy.

3 Dr. Bonino: Well let me speak from the contractor viewpoint and ask the coverage to speak from
4 the national viewpoint, since we don't write the regulation. We're following it. And I could be, let me tell
5 you what happened with us in MAC J12. When we were given the go ahead to work on this contract, we
6 were told to review all of the existing policies in the area and choose the best but at the time, our instruction
7 was to choose the least restrictive policies. That has subsequently changed to be the most clinically
8 appropriate. We had over 900 policies in our area. I think 939. We have 57 now, because we did go through
9 the process that I spoke about today in our jurisdiction and we had the work before us of looking at where
10 the evidence is, what the data told us and we looked at the data for this jurisdiction, not just the state of
11 Pennsylvania, where our earlier contracts, or Maryland and DC part A, but we looked at the data for the
12 five-state area and looked at again, where the pockets of aberrancy were, but also looked at the evidence to
13 see where we found that we needed policy. But we were given the task of, at that time, putting forth the
14 least restrictive policy. So I will tell you that in our most recent coverage advisory, contractor advisory
15 meeting, we did take two of those policies back out for comment, to put a little bit more information in. An
16 example was, we had an intraoperative neurophys testing policy, but we didn't have any ICD9 codes in it.
17 Because there was no way when we went through the jurisdiction transition that we could make it least
18 restrictive. So we took that to our contractor advisory group to get that best coding information. I realize
19 that I'm not answering your question. I can't speak to how Florida or California or the other contractors
20 have done their work. What I can tell you is there is a now a smaller group of contractors with only 15
21 MACs, as opposed to the 30 to 40 contractors there were before, so there is a little more smaller group of
22 people, and there will be, not the 5,000 policies, because it's coming down.

23 Dr. Ouzounian: I guess what I'm really having trouble understanding is—and I understand the
24 need to control, I mean I do understand that. Why isn't it national? Why are there local coverage decisions?
25 Why don't you say, hey, we identified a local problem, let's make a national coverage decision?

26 Dr. Bonino: We sometimes do. We pushed [naceratide's role? 42:44 5th mp3], and asked for a
27 national, a number of CMDs did ask.

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1 Ms. Jensen: Well, I mean, first place you need to start is Congress. In the statute, it says there are
2 local decisions—they define LCDs and they define what LCDs are. I think what you're saying, you are on
3 one side that there shouldn't be any LCDs, that all the coverage decisions should be national and certainly
4 you have a lot of support for that and then there's the other side where they say there should be LCDs out
5 there. It's a way to test new technologies. It's a way for small companies to get into, to see if this particular
6 item or service can be paid for out there before they come to us. Does the national decision have a higher
7 bar of evidence? I don't know if we do or not. I think the CMDs do a wonderful job reviewing the LCDs. I
8 think a lot of folks don't want everything to be at the national level, because what they risk when they come
9 to us is a national no, and once it's a no, it takes a while to revisit that. But you certainly have a lot of
10 support to have everything national. I'm not so sure that I want to take it all on.

11 Dr. Bufalino: Other comments? Roger?

12 Dr. Jordan: I read in the realm, LCDs all year round from around the country from my association,
13 and some of the procedures that come through from different regions are procedures that have been around
14 for years and what I've noticed, which I think can be a huge problem for providers is inconsistency as far as
15 diagnoses. I can look at one LCD, for Florida, Georgia. And I can pull up another one from Utah,
16 Wyoming, Montana, and I can come up with 20 or 30 diagnoses that are missing out of one that are going
17 to be paid for in the other. And that's where I see a huge, huge trouble with the local is that inconsistency
18 as far as how they read on the local level and also the diagnoses that are omitted basically, from so many of
19 them.

20 Dr. Bonino: Having gone through 939, I can echo that sentiment, we did find variation in ours, and
21 having a larger jurisdiction with the least restrictive, we were able to add those in. I think one point that one
22 of the issues about the policy is that we do put coding information in. Now if the PIM does read that we
23 don't have to put any codes in, but I'll tell you that everybody that doesn't go to her comes to us at the local
24 level, because they just—I had one last week. We don't want to go national because we don't know
25 whether they'll say yes or no, and it's too big a risk, so we're coming to you locally. And they will go to
26 enough contractors, and then when they have enough contractors, then they may go nationally to get
27 something more, but I agree with you. There has been inconsistency. I think smaller groups, small group of
28 contractors may make this a little less inconsistent, but it's not nationally, you're right.

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1 Dr. Jordan: Because I was wondering if there were some way that these contractors could, I know
2 it's local, but share almost LCDs, once they've been reviewed and say hey, look at what we've got. We're
3 missing here. We have this. You don't. Let's, which I know is becoming almost like a national LCD then—

4 Dr. Bonino: Well, I did omit the piece and I apologize. I did omit the fact that as we're developing
5 LCDs, we do look at other contractors' LCDs. We are even able within the contractor and the coverage
6 database to take another contractor's LCD and make it ours. We're encouraged to do that. So we do do that.
7 The degree to which different ones come out the same may depend on the local input received.

8 Ms. Jensen: And for DME, they do, there's only four contractors for DME and all of their LCDs
9 are exactly the same, unlike part A and part B. But DME, it is basically a de facto national policy. But the
10 LCDs are not binding on ALJs, unlike NCDs, which are binding on ALJs, that's why the ALJs can't rule
11 on them. If somebody wants to appeal it, it goes directly to the DAB, or the courts.

12 Dr. Standaert: You might have mentioned this, but if you look at what we do. I mean we have this
13 dilemma that the absence of evidence isn't the evidence of absence, and there's a ton of things we do for
14 which we have no proof whatsoever, and if you took everything I did in a day and put it up for an NCD, I'd
15 be sitting around not doing a lot, a lot of days. And so is it, I understand people can bring things to you, but
16 how do you deal with that dilemma on a practical basis? I've read some of the NCDs you've done, like the
17 [IDIT? 47:59 5ht mp3] ones and the [unintelligible] and I thought they were actually very well done. But
18 you get into some other things, is it a dollar thing? Is it sort of this is a huge cost to the system, or is it a
19 there's been harm to patients? Or what, how do you drive, from this huge list of things we don't have proof
20 on, how do you pick them?

21 Ms. Jensen: Sometimes we get them from, because there is such a large variation in the LCD
22 world, some of that comes to us, so we'll open them there. Dollars generally don't drive us. We have
23 publicly said that we don't take cost into account. Generally, but it is usually the bigger ticket items that
24 come to our attention. And generally the stuff that comes to us, really it is the manufacturers that come to
25 us. It is not your everyday physician or expert that comes to us and says, we really think you need to do an
26 NCD on this. It's really the manufacturers that want something to be paid nationally by the Medicare
27 program.

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1 Dr. Bufalino: Other questions? Comments? Thank you. Have a good afternoon. Thank you for the
2 information. Appreciate it. We're scheduled to take a break, but since we've done very well on time, we
3 might move to the next presentation if you don't mind. Ms. Arrah Tabe-Bedward is Director of the
4 Division of Appeals Policy, in the Division of Medicare Enrollment and Appeals. This division is
5 responsible for the development and implementation of the appeals process under the original Medicare
6 Advantage program, and Medicare prescription drug benefit. The division also has primary responsibility
7 within the agency of Beneficiary Notice Policy, including provider-issued notices, such as important
8 message from Medicare in advance, beneficiary notices of non coverage. Ms. Bedward will detail the
9 review of the five levels of the Medicare Fee-for-Service administrative appeals process, which is available
10 to providers, physicians, and other suppliers And take a quick look at the Medicare Advantage and part D
11 appeals process.

Medicare Appeals Process

12
13 Ms. Tabe-Bedward: Thank you, and I appreciate your inviting me to participate in today's
14 meeting. And as the title indicates, I'm going to be talking mainly about the Fee-for-Service claim appeals
15 process, but toward the end of the presentation, I'll also be going over very briefly, the MA and the part D
16 appeals process as well. For many years, beneficiaries and providers complained about the Fee-for-Service
17 claim appeals process. They complained that it was too confusing, it was too cumbersome, and it was too
18 unresponsive to some of the unique situations that presented themselves, and so it came as no surprise to us
19 in December of 2000, when Congress enacted a major piece of legislation that essentially revamped the
20 appeals process, and it was really the first significant piece of legislation to affect the appeals process in
21 about a decade. And it was called Medicare Medicaid and SCHIP Benefits Improvement and Protection
22 Act of 2000, also known as BIPA. And then a little less than three years later, Congress further refined the
23 changes it had made through BIPA, through the Medicare Prescription Drug Improvement and
24 Modernization Act. So just to give you a little sense of what each of these pieces of legislation did, BIPA
25 really laid the foundation for the appeals process that's currently in place. It created a uniform appeals
26 process for part A and part B claims. It established a new second level of appeal, called a "reconsideration."
27 And it created the entities that have responsibility for adjudicating those second levels of appeal. The
28 qualified independent contractors were QICs. BIPA also, for the first time, put in place establish decision-

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1 making timeframes for each level of the appeals process, and it allowed appellants to elect to skip to the
2 next level of appeal if adjudicators failed to issue decisions within those established timeframes. It's worth
3 noting that Congress also took this opportunity to put into place a process on the Fee-for-Service side that
4 had existed on the MA side, and essentially it's an expedited review for beneficiaries who are facing a
5 termination or loss of certain part A services. The MMA, as I noted, was geared more toward fine tuning
6 the changes that had been put in place by BIPA. And it also codified some of the policies that we put in
7 place through the proposed rule, and Congress was able to do this because we actually published the
8 regulation implementing BIPA prior to the passage of MMA. And some of the changes that MMA put in
9 place include requiring transfer of the ALJ function from SSA to HHS. It also required CMS to create a
10 policy outside of appeals that would allow providers to correct what they called minor errors or omissions
11 in the claims that they filed. MMA put in place also a new requirement that evidence, necessary to support
12 the appeal, be filed with the appeal or no later than the reconsideration level. And this was in essence a
13 codification of a provision that we had put into the regulations implementing BIPA. The MMA also
14 codified the provision that we dropped into the proposed rule that allowed CMS or its contractors to take
15 part in the ALJ hearings. And the agency and its contractors had the option of either joining the hearing as a
16 participant, or joining the hearing as a party.

17 As I mentioned, in November of 2000, we published regulations implementing BIPA and
18 Congress, subsequently, passed MMA and so in May of 2005, rather than publishing a final BIPA rule, we
19 published what is called an interim Final Rule with Comment. And we elected to use that vehicle so that we
20 could role in some of the provisions that we needed to implement the MMA without having to create an
21 entirely new reg. And so the regulation that's in place now includes provisions that implement both BIPA
22 and the MMA. It includes provisions that transition to the single claims appeals process. It created a
23 transition schedule that brought the QICs on board, and it created a transition schedule for moving the ALJ
24 process from SSA to HHS. CMS used this opportunity, the new regs to incorporate certain improvements
25 above and beyond what was required through BIPA and MMA and I'll note some of them for you a little
26 bit later. The Final Rule, which we obviously have to do, is currently pending clearance and we hope that it
27 will be cleared this year and so that the Final Rule regarding the Fee-for-Service claims appeal process will
28 be in place, and it largely incorporates the process that is being used currently.

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1 The next slide lays out for you really the changes that were put in place by the MMA and by
2 BIPA. And on the right side, you see is the current process, the single process for part A and part B claims.
3 And the first level of appeal is with a contractor. It's called a redetermination. And the next level is the
4 reconsideration by the qualified independent contractor, and you'll see that the subsequent levels of appeal,
5 the ALJ hearing, appeals council review, and federal district court review, are essentially the same as they
6 were prior to BIPA and MMA. Before I go into detail about each of these levels, I do want to note that
7 there are some important time frames that are associated with the appeals process, and you'll see that in the
8 next slide. At each level, there are two time frames that have to be considered; the filing time frames and
9 the decision making time frames. And these are statutorily created time frames. The filing time frame is the
10 number of days that a party has in order to request an appeal from an adjudicator. And it's based on the
11 date of receipt of the previous determination. So for example, a physician would have 120 days from the
12 date of receipt of their remittance advice, to request that first level of appeal. And it is our assumption in
13 this process that the transmission of determinations or decisions takes no more than five days, absent
14 evidence to the contrary from a party. And if there are delays in fact in receiving a decision or a
15 determination, or if a party experiences delays in filing an appeal, it is possible to request an extension to
16 the filing deadline and that can be done at the same time that the appeal is requested and it must be done in
17 writing. The other timeframes that I noted that you should pay attention to are the decision making time
18 frames. And these are the time frames that Congress put in place and that an adjudicator must meet when
19 issuing its decision. There are certain circumstances, situations, that would allow an adjudicator to extend
20 these time frames. One example would be a case where an appeal has been filed, and subsequent
21 information or evidence is provided. The adjudicator may, if they think it's necessary, extend the decision
22 making time frame by up to 14 calendar days. Adjudicators also have the option to toll the decision making
23 time frames for certain circumstances. An example of that would be a case where a party has failed to
24 notify any other party to the appeal that they have requested a review at the next level. In that case, the
25 adjudicator would essentially stop the clock and request that the party requesting the appeal notify everyone
26 else of the request. And once that's done, they would move forward.

27 So now as I begin to get into sort of the nuts and bolts of the appeals process, I want to make sure
28 that I define a couple of terms for you. The Medicare statute gives a very specific definition to the term

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1 “provider” and I’m not going to be using it in the same way. I’m going to be using the term “provider” very
2 generically to refer to physicians and other healthcare providers who file appeals. Another term that you’ll
3 hear me use is appellate and that simply refers to the party who is bringing the appeal. So the question, first
4 question is who can bring an appeal? And physicians who participate or accept assignment on a claim
5 obviously have appeal rights to the same extent as beneficiaries. But even where a physician does not
6 participate or does not accept assignment on a claim, there are some rare instances where they may still
7 have appeal rights, and I have noted the two instances for you on the slide, but I would note that they are
8 very rare and not at all the type of thing that we see with any sort of regularity in the appeals process.
9 Beneficiaries of course, can be parties to appeals, unless they have transferred their appeal rights to a
10 provider. And part A providers, in certain circumstances, may also be parties to these appeals, as are state
11 Medicaid agencies that have liability, or may have liability for certain services that have been denied. And
12 they can establish their appeal rights by filing a timely, first-level appeal, and they would remain parties
13 thereafter to the appeal. And these last two changes are examples of what I mentioned earlier in terms of
14 certain refinements that CMS had built into the regulations above and beyond what was required by BIPA
15 and MMA and these were intended to address some long-standing questions and issues that we had had in
16 the appeals process.

17 IPA and MMA did not alter the range of issues or decisions that are subject to review under the
18 claim appeals process. And so the same types of issues that could be appealed prior to BIPA and MMA
19 continue to be subject to the appeals process. Coverage determinations, overpayment decisions, MSP
20 determinations, all of those things are still appealable issues under this process. What we did do, however,
21 in the implementing regulations is offer some clarifications about the types of things that can not be
22 appealed through this process. And some examples of new issues or new items that we identified in the regs
23 would be the denial of paper claims, if a provider is an electronic biller. A determination around that issue
24 is not considered to be an initial determination and it is not subject to appeal through the claim appeals
25 process. The same is true for any decisions regarding the application of an NCD or LCD or LMRP, and I
26 think the previous speakers mentioned this. There is a separate appeals process and adjudicators in the
27 claim appeals process do not have the ability to review these coverage policies as part of a claims appeal.

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1 So let's be looking at the individual levels of appeal. The first level is the contractor
2 redetermination. And these reviews are performed by the affiliated contractors, the FIs or the carriers, or
3 the Medicare Administrative Contractors, and redeterminations must be filed in writing, within 120 days of
4 receiving the initial determinations of the remittance advice or the MSN, and a standard redetermination
5 request form that includes all of the required elements can be obtained from either CMS's website, or from
6 any of our contractor websites. And it's possible to also simply use a writing of your own in order to
7 request this first level of appeal. You would just need to make sure that it includes all of the necessary
8 elements that it's dated and signed as well. To the extent that a contractor receives an appeal request that is
9 incomplete in some way, they will notify the appellant of the deficiency and afford them an opportunity to
10 correct that deficiency. If the time frame that they've allotted comes and goes without the deficiency being
11 addressed, the contractor will in most cases dismiss that appeal request and the party would be able to refile
12 as long as they are within those filing deadlines that apply. Once the contractor has a complete request, it'll
13 process the appeal and generally issue a decision within 60 days of receipt of the request. And if the
14 decision is fully favorable, and payment can be made in full, then the appellant would receive either
15 remittance advice, or a new MSN outlining the revised decision. If the decision on the other hand is not
16 fully favorable, then the contractor would issue to the appellant a letter explaining why payment cannot be
17 made, and they would explain the appeal rights if any that apply to that decision. One thing to note is that
18 unlike our previous appeals process, with respect to overpayments, those decisions no longer skip the initial
19 contractor review. Under the old process, on the part B side, they went straight to a contractor fair hearing.
20 In the new process, they begin as do all appeals, with the contractor and progress through the
21 redetermination, reconsideration, ALJ levels. In addition to the formal appeals process, there is also a
22 reopenings process. And as I noted, Congress required that we create a separate process for addressing
23 minor errors and omissions. And we elected to use the reopenings process to do this so it's possible for
24 providers to seek correction to claims through the reopenings process, rather than appealing those issues to
25 the contractor and these requests can be made any time within 12 months of the claim, and beyond that,
26 they can only be made if the provider can establish good cause for making the request after the 12-month
27 period.

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1 The next level of appeal is the QIC reconsideration. And this is the new level of appeal which was
2 created by Congress, and the QICs are the entities that were created by Congress to adjudicate these
3 appeals and there are currently six Fee-for-Service QICs, there are two part A QICs, two part B QICs, one
4 DME QIC, and an administrative QIC. And the administrative QIC actually serves all of the QICs. It
5 provides data analysis for all of them, it conducts trainings for all of the QICs, it also handles all of the
6 MAC referrals that are done and serves as a clearing house for the ALJ case files and they will also work
7 with the contractors to ensure that the ALJ decisions are being effectuated properly. The next two slides
8 demonstrate the jurisdictions for the QICs. And for the part A, you can see that Maximus Federal Services
9 serves as the QIC for both the east and the west jurisdictions, and for the part B QIC jurisdictions, they're
10 split between First Coast Service Options and Q2A, and for First Coast Service, as the QIC for the north
11 jurisdiction, with Q2A serving as a QIC for the south jurisdiction. And, as with the first level of appeal, all
12 reconsideration requests must be made in writing, and they must be submitted to the appropriate QIC. The
13 redetermination letter will explain to the appellant exactly what must be provided in order to request that
14 second level of review. It will tell them where to send the request. There is also a standard request form
15 that's included. And that can be used to make the request, or again, if you choose you can use a writing of
16 your own, as long as it includes all of the necessary elements. Once the QIC has all of the information that
17 it needs, they will generally issue a decision within 60 calendar days. And at the QIC level, there is no
18 amount in controversy threshold that is the amount that the claims would need to meet in order for them to
19 qualify for appeal. This is something that existed in the prior process on the part B side. At the QIC level,
20 there is the start of what we call the "escalation option." And this is available to appellants when an
21 adjudicator fails to issue a decision within the required time frame. So beginning first at the QIC level, if
22 the adjudicator does not issue its decision within the 60 days, then an appellant could notify the QIC that
23 they want the case escalated to the next level, and that next level would be an ALJ hearing. Although the
24 QICs have been adjudicating appeals for nearly four years now, they are still fairly new entities, and so it's
25 worth noting some of the differences in their adjudicative process. A key feature of the QICs is that they
26 are required to use medical panels in adjudicating cases or claims that involve medical necessity
27 determinations. That is something that is new. It isn't a requirement at any other level of the appeals
28 process, and it was stipulated in MMA and again, sort of refined, or stipulated in BIPA rather and again

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1 refined through MMA. The QIC review is also an on-the-record review. There is no option as there were
2 under Care for Hearings for an in-person hearing. Or for a telephone hearing. And the QICs are required to
3 follow Medicare statutes, regulations, CMS rulings, and NCDs. They, however, do not need to follow; they
4 are bound by LCDs or CMS manuals. What we do require is that the QICs give what we call substantial
5 deference to these policies, and essentially that means that the QICs are required to follow these policies
6 unless they are either challenged by the appellant, or the QIC can find good reason not to apply them to the
7 particular facts of the case. If the QIC elects not to follow an LCD or a manual provision, we do require
8 that they explain in their rationale in their decision, why they've elected not to follow that policy. So they
9 do have to explain to the appellant and essentially to the agency, why they are not following or applying the
10 LCD, LMRP, or manual provision.

11 One of the goals that Congress had in revamping the Fee-for-Service claim appeals process was to
12 ensure that the process was a speedier process for appellants, and so in addition to escalation, Congress also
13 required that appellants submit all the necessary evidence associated with their appeal as early as possible,
14 and as a way of enforcing this requirement, MMA provided that evidence not submitted by the time the
15 QIC issues its reconsideration could be excluded by subsequent adjudicators. So if an appellant fails to give
16 a piece of information as part of their reconsideration and they get to the ALJ level, and they would like the
17 ALJ to consider that information, the ALJ has the ability to deny the admission of that information, unless
18 the appellant can give good cause for filing the information late. For example, it wasn't available, it was
19 information that was maintained by a third party and they were not able to secure it in time to produce it to
20 the QIC. And so the hope is that this provision will encourage the early presentation of evidence so that
21 adjudicators at the very lowest levels of the appeals process have all of the same information that
22 subsequent adjudicators are using to review a particular appeal. If the QIC reconsideration is appealed, or
23 the appellant escalates the case, as I said, the next level of review is with an administrative law judge. And
24 currently, it is the Office of Medicare Hearings & Appeals, or OMHA that has responsibility for the ALJ
25 function, and there are four OMHA field offices. There's one in Arlington, another in Cleveland, one in
26 Miami, and the last one is in Irvine. The headquarters for OMHA is in Arlington, although their Chief ALJ
27 does sit in the Cleveland office. In general the ALJ hearings are being conducted either by phone or by
28 video teleconferencing; however there are situations in which ALJs will grant appellants in-person

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1 hearings. You have 60 days from the date of receipt of your reconsideration to request an ALJ hearing. And
2 the QIC reconsideration, again, will give you all of the information that you need in order to make that
3 request. It will tell you which office to submit the request to, what information to provide, and the deadline
4 by which that information needs to be submitted. At the ALJ level, there is an amount in controversy
5 threshold that applies and its \$120 for 2009. And that amount, by the way, is adjusted annually. And we do
6 post or publish a notice in the *Federal Register* around October or November of each year, announcing the
7 new threshold amounts.

8 Many of the procedures that OMHA is using to adjudicate these claims are the same procedures
9 that were in place and we used by SSA. But there were some changes and refinements that were made by
10 BIPA and MMA. Most significantly is the 90-day decision making time frame that applies. If you'll recall,
11 in the previous process, there was no time frame that applied at the ALJ level, so often cases languished at
12 the ALJ level and appellants had no recourse in terms of moving the case along. After MMA and BIPA,
13 appellants have now the ability to as I said, escalate, again, if the ALJ misses that 90-day window, they
14 have the ability to request that the case be moved up to the next level of review, which is with the Medicare
15 Appeals Council. As with the QICs, the ALJs are bound by the Medicare statute and regulations and by the
16 NCDs and CMS rulings. And they too, must give substantial deference to LCDs, LMRPs, and manual
17 provisions and to the extent that they decide not to apply those policies, they, too, are expected to provide
18 rationales in their decisions for not following these policies.

19 After the ALJ hearing, appeals as I said may be made to the Medicare Appeals Council. And the
20 Appeals Council is a body of administrative appeals judges within the Department of Health and Human
21 Services, Departmental Appeals Board. And generally, the same procedures that were in place and were
22 used prior to BIPA and MMA continue to be used by the MAC in adjudicating Fee-for-Service claim
23 appeals. There are a couple of policies that were included that are worth nothing. One would be that now
24 when parties request MAC review, they are required to stipulate the particular aspects of the ALJ decision
25 that they disagree with. And the MAC will then conduct a Genova review of those very specific issues.
26 That was not a requirement under the previous process. Parties have 60 days to request MAC review.
27 Again, it must be a written request, and as with previous levels, the ALJ decision will explain how, where
28 when, how and where and when to do that, and will provide the necessary elements to be included. The

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1 MAC is required to issue its decision, again, within 90 days. And to the extent that they miss that, a party
2 would have the right to escalate the decision up to Federal District Court. If the MAC is reviewing a case
3 that's been escalated from the ALJ decision, the applicable decision making time frame is 180 days. And
4 the reason that that time frame is a little bit longer is because we expect that when a case is escalated up to
5 the MAC, it is likely to have not been developed at the lower levels and we recognize the need to ensure
6 that the MAC has an adequate opportunity to develop that case and issue a decision.

7 At the Federal District Court level, if a party wishes to appeal to that next level, there is an amount
8 in controversy threshold that applies, and for 2009, that amount is \$1,220. So now we've gone through the
9 Fee-for-Service claim appeals process and before I go briefly over the MA part D processes, I just want to
10 mention that while the NCD and LCD processes are completely separate from the Fee-for-Service claim
11 appeals process, there is some overlap between the two when it comes to effectuating those decisions. And
12 I won't go into any more detail, but if that is something that you have questions about, I'd be happy to
13 answer that.

14 The MA appeals process, and the part D appeals process which are the next two slides, aren't
15 included—I don't have diagrams of those processes included in the PowerPoint presentation, but you
16 should have, I hope, a side by side of those three processes; the Fee-for-Service MA, and part D, and if you
17 do, I would encourage you to take it out as I walk you through this process so that you can follow. Like
18 Fee-for-Service, the MA process includes four levels of review, four levels of administrative review
19 followed by review by Federal District Court. There are AIC thresholds, again, at the ALJ level, and
20 Federal District Court levels, but this is really where the similarities between the processes ends. An
21 enrollee under the MA process is always a party to an appeal. And providers may be parties, if they sign a
22 waiver of liability. Providers also have the ability under MA to request initial determinations or expedited
23 first level appeals on behalf of their patients; on behalf of an enrollee. We recently published a new rule,
24 CMS 4131, which will actually expand the provider's rights in this respect, and allow them also request
25 first level standard appeals. So in addition to the expedited and initial determinations, they'll now be able to
26 make requests for standard appeals. In addition, in the MA process, any time a plan makes the decision to
27 continue to deny coverage for an item or a service, they are required by statute to automatically forward
28 that denial to the next level of review. So in the part C world, there is 100% review of all unfavorable first

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1 level decisions, and that's again by statute. The MA process also includes an expedited process, which is
2 different from Fee-for-Service and that expedited review is available at the first level of appeal, and at the
3 second level of appeal, and it's generally used where applying the standard time frames would in some way
4 jeopardize or harm an enrollee's health. The next level of review in the MA process is with an entity called
5 the Independent Review Entity and that function is currently being performed by one of our QICs,
6 Maximus Federal Services. And the IRE decision can then subsequently be appealed to an ALJ, and if that
7 is done, the MA plan is automatically made a party to the appeal and that is a statutory requirement. And
8 the plan would thereafter remain a party to the appeal at any other level, the MAC level or Federal District
9 Court level. The filing and decision making time frames are laid out in the diagram that I provided, so I
10 won't go through those in the interest of time, and I'll just move on to the part D process.

11 The implementing statute for the part D appeals process required that we use a process or create a
12 process that was very similar to the MA appeals process and so if you're looking at the diagram, you'll
13 notice that they look very similar. They include the same levels of review. The filing and decision making
14 time frames are very similar. The part D process, like the MA, includes expedited review at the initial
15 determination, and level one and level two of the appeals process. The beneficiary, again, is always a party
16 to the appeal, and the provider is never a party, but can again request those initial decisions or the expedited
17 first level of appeal and again, the new regulation, CMS 4131, will also affect a provider's rights under part
18 D and allow them to request standard first level appeals on behalf of their patients. Issues involving
19 coverage and reimbursement are appealable through the part D process. The differences really that exist
20 between C and D have to do with the auto forwarding provision. That is not a feature of the part D process.
21 What is in place instead, is a requirement that plans that fail to meet the decision making time frames that
22 apply to the initial decision or that first level of appeal must auto forward those cases to the second level, to
23 the independent review entity, and again, in part D, we have one of our QICs, Maximus Federal Services,
24 serving as the IRE for the appeals process. Under part D, also, CMS can refer cases to the MAC. This is not
25 an option under MA and this is actually a policy that was put in place through a CMS ruling. Last year, we
26 published a proposed rule aimed at establishing final regs regarding how reopenings, ALJ and Federal
27 District Court hearings would be handled under the part D process. And we are in the process of clearing
28 and finalizing the Final Rule for that process.

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1 I've tried to cover what I think are the key pieces of information related to the Fee-for-Service and
2 MA and part D appeals processes, but there's certainly a lot more information available. And the resources
3 that I've included on the next two slides include links to sites with more detailed information about all of
4 these processes. Some of the things that you'll be able to find on these sites are the particular statutory and
5 regulatory provisions. We've published fact sheets on each process. And so if you're interested in work
6 load data, there's some of that available. And there are also links to our contractor site, so links to the IREs
7 that perform those second levels of review. And at this point, I'm happy to answer any questions you have
8 or hear any feedback that you have on the question that I posed regarding the electronic submission of
9 appeal requests.

10 Dr. Bufalino: Thank you very much for that comprehensive review. Okay, comments?

11 Dr. Smith: I have one quick question. I'm not going to ask you to go back, but you lost me in
12 alphabet soup about six times there and so it would be an enormous help with things like this that are
13 unfamiliar, if the first time you use things like a what was it, an MSP or something, write out what it is,
14 because I don't know what they mean, and then they get repeated and I'm done for in terms of making
15 sense of it.

16 Dr. Snow: A couple of questions. You mentioned the 120-day deadline for filing the first level of
17 redetermination and you indicated that you are assuming there is a 5-day, I assume for my case, I'm a paper
18 filer, so five days from the date of the check, I assume, although I just might comment. I have found,
19 looking at it over the last six months, there are as many as six days from the date of the check 'til the date of
20 the postmark on the envelope that they are put in and in many cases, it's a minimum of three days before
21 we receive it, and sometimes as late as seven days from the date of the postmark. So there could be a
22 potential two-week problem there. Maybe that's specific with my contractor and we can talk to them. Who
23 does the appeals at that first level of appeals or redeterminations at the contractor level? Is there anybody
24 specified to do that, system-wide?

25 Ms. Tabe-Bedward: Yes, there generally are appeals units within the contractors that handle that
26 first level of appeal, and they are different staff than the folks who make the initial determinations. So it's a
27 different group of people making the initial determination.

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1 Dr. Snow: Is it customer service representative typically an individual who can make that first
2 level redetermination?

3 Ms. Tabe-Bedward: I don't know about the specific qualifications that are put around the staff
4 who adjudicate those decisions. I can make some inquiries and get back to you, but I don't know about
5 specific parameters. There's nothing in the regs that specifies the type of qualifications in the way they lay
6 out the qualifications for say, the panel that do the medical necessity reviews for the QIC.

7 Dr. Snow: Okay, well, I've got several at our contractor, several examples of a CSR who normally
8 answers our questions when we call them on the phone, who's been making those determinations and her
9 lack of knowledge has caused tremendous problems. You've mentioned in the last comment having to do
10 with things you cannot appeal and those are rejected claims. I know in my own practice, the most common
11 reason that I have non payment of a claim is it is rejected. And the most common reason, 95% of the time it
12 is rejected is, Medicare, my contractor makes an error in scanning in that paper claim and they change
13 some of the numbers on it whether it's my NPI, whether it's the place of service or whatever. The claim is
14 absolutely correct. But it is an error on that part, and I cannot appeal. I cannot. I've been told by the
15 contractor have them reprocess it. I have to go through the process of refilling another correct claim in
16 order to try to get payment and I think there should be a better system set up to handle that kind of very
17 common problem, especially with paper claims.

18 Ms. Tabe-Bedward: And I'm not sure if paper claims are perhaps handled differently, but the
19 process that I described for correcting minor errors or omissions, the reopenings process is really the way
20 we intend for those types of things to be corrected. I think previously it was necessary to have providers use
21 the appeals process because there was no other mechanism for making those corrections. But as I said,
22 MMA required that we establish a process outside of the appeals process for making those corrections. So I
23 can follow up or I would encourage you to follow up with your contractor, and find out if the reopenings
24 process is an option for you, because that's really what it's intended to correct.

25 Dr. Snow: I appreciate that.

26 Dr. Bufalino: Other questions? Comments?

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1 Dr. Standaert: You're very good with the acronyms, I have to say. You're up there with Dr.
2 Simon. I followed most of them, but the same thing holds for the RACs, then? The same appeals process
3 holds for the RACs what they told us earlier? It's the same process?

4 Ms. Tabe-Bedward: Yes, they come through the claim appeals process.

5 Dr. Standaert: But then your first appeal with a RAC is the same RAC appeals—you just said
6 when a contractor appeals, the contractor does the first level of appeal.

7 Ms. Tabe-Bedward: Yes, when a contractor issues an initial determination, that first level of
8 review is with the contractor, but it has to be with a different group of folks within the contractor.

9 Dr. Standaert: So if it's a RAC, the RAC issues the decision. So the RAC does the first appeal?
10 They have their own appeals branch sort of thing—

11 Ms. Tabe-Bedward: I don't think that the RACs do the appeal. I'm not sure about that. I think that
12 it goes back to an FI or a carrier or a MAC. I don't think it's a RAC that's doing the first appeal.

13 Dr. Bufalino: Hearing no one else, thank you for your presentation. We appreciate having you this
14 afternoon. So we could wrap things up here if you all of the mind, and I would point out that there's a 14-
15 page written testimony by the AMA which is in your packet, and I'd actually like to just go backwards to
16 the start of the day and take a few minutes and talk about recommendations. So maybe we could kind of
17 begin back at the each of these presentations, and if you have a specific recommendation to put on the
18 table, let's kind of walk through these so we have some organization for Dana. So PRIT? Value-based
19 Purchasing? Jan, start?

20 Dr. Kirsch: Well, [inaudible 1:30:09] is physician and Value-based Purchasing planning, so I
21 thought it was important to put out some sort of statement of where we recognize they should go in the
22 future. This is a relatively lengthy one, and I've got it written out for you, Dana, but I don't make a
23 comment in this particular statement on feedback and how quickly we're paid back, but let me kind of go
24 through this.

25 PPAC recommends future physician, value-based programs should include the following:
26 measurement of physician participation and quality enhancement processes, a recognition that patient
27 population bases have an impact on the feasibility of achieving ideal patient outcome goals, a recognition
28 that a patient's co-morbidity has an impact on the feasibility of achieving ideal patient outcome goals, a

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1 continuation of use of recognized reasonable consensus guidelines (the best source at this time is the
2 physician consortium for performance improvement), and lastly, initiation of a discussion on enhancing
3 patient participation and care.

4 Dr. Bufalino: You want those all in one box, or would you like to break them up.

5 Dr. Kirsch: I'm okay with all in one box.

6 Dr. Bufalino: Okay.

7 Dr. Kirsch: If everybody else is, I think it's—and really, it kind of goes along with what's already
8 being done. I know it's not really that controversial, but I think...

9 Dr. Bufalino: Sure. Second?

10 [Seconds]

11 Dr. Bufalino: Any discussion? All in favor?

12 [Ays]

13 Dr. Bufalino: Thank you. Any others, Jan? No? Leroy you had one?

14 Dr. Sprang: [inaudible 1:32:02] physician consortium that's been around since 2000, obviously
15 recognized by [inaudible] CMS's knowledge [inaudible] make a recommendation that PPAC recommends
16 that the physician consortium for performance improvements, PCPI, should be recognized as the leading
17 developer of physician led measures in CMS's plans to transition to the VBP.

18 Dr. Bufalino: Once again?

19 Dr. Sprang: Okay. That PPAC recommends that the Physician Consortium for Performance
20 Improvement, PCPI, be recognized as the leading developer of physician level measures in CMS's plan to
21 transition to VBP, Value-based Purchasing.

22 Dr. Bufalino: Second? Second, thank you. Any discussion? All in favor?

23 [Ays]

24 Dr. Bufalino: Thank you. Others?

25 Dr. Sprang: Second, another recommendation. And this is obviously the importance VBP is going
26 to have, and clearly done right, I think it's going to be a very significant improvement and we all need an
27 I'll say improve the quality in cost and value, but we also need appropriate incentives to have physicians do
28 that so the recommendation:

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1 PPAC recommends that value-based payments should be funded with new money and should not
2 be made on a budget-neutral basis within the Medicare physician payment system.

3 Dr. Bufalino: Second? Thank you. Discussion? All in favor?

4 [Ays]

5 Dr. Bufalino: Thank you. Others on Value-based Purchasing. I'd like the Council just to consider
6 something since I can't make a recommendation. Public reporting is a concern of mine and I'd like them to
7 provide us information on the initial public, confidential physician public reporting initiative around cost
8 data. They're going to provide individual cost data around our individual performances, which initially is
9 proposed to be confidential, and then ultimately will be used to provide true public reporting. So I think it
10 would be interesting for us to be able to look at that before it becomes—

11 Dr. Standaert: This is one of the things they talked about last time, the physician report thing, is
12 that what you're talking about?

13 Dr. Bufalino: Yes, the physician report cards that are coming out.

14 Dr. Standaert: Didn't we have something about that, and having them come back to us with what
15 this data is and all that? I thought we had something last time—

16 Dr. Bufalino: Well, we didn't have it in this time's recommendations, so I don't know.

17 Dr. Sprang: PPAC recommends that physicians and other providers involved in the treatment of a
18 patient, must have the opportunity for prior review and comment and the right to appeal with regard to any
19 data that is part of the public review process.

20 Dr. Bufalino: Second?

21 [Second]

22 Dr. Bufalino: Comments?

23 Dr. Arradondo: In the motion, we discussed this a time or two before. Are you going to include in
24 the motion that any comments that the provider might have be included in the ultimate listing?

25 Dr. Sprang: Addition to that recommendation, amended: And such comments should also be
26 included with any publicly reported data.

27 Dr. Bufalino: Okay?

28 [Second that]

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1 Dr. Bufalino: Any other discussion? All in favor?

2 [Ays]

3 Dr. Bufalino: Thank you. Anything else on Value-based Purchasing? 9th Scope of Work? RAC
4 Update? We had a number of RAC recommendations at the end. Any other RAC recommendations that we
5 have—we had a number of those just before lunch. Okay, and then on the coverage decisions, anything on
6 LCDs or NCDs that the Council would like to make a recommendation? Or the appeals process is the last
7 of the presentations? And then let's wrap up with General Recommendations. That could be the shortest list
8 of recommendations in the history of the Council, so maybe we could add one or two.

9 Dr. Ross: As the expression goes, I hate to kill a dead horse, but here we go again. CMS has made
10 several indications that they do not plan on exercising the authority granted to them by law to exempt
11 physicians and licensed professionals from DME POS accreditation standards. While the law permits CMS
12 to exempt the accreditation standards, they are permitted to develop separate accreditation standards, which
13 are different from existing requirements for non office-based suppliers. So we're revisiting the same
14 situation where accreditation is still going to come in the future and so I would like to propose that PPAC
15 recommends to CMS that physicians and licensed healthcare professionals should not be subjected to costly
16 and burdensome accreditation as they are already licensed and trained to provide these items to their
17 patients. So I'd like to go on the record again, opposing the accreditation to the licensed healthcare
18 professionals at this time.

19 [second]

20 Dr. Bufalino: Second thank you. Discussion? All in favor?

21 [Ays]

22 Dr. Bufalino: Thank you. Others? Last chance at general recommendations.

23 Dr. Snow: Not a recommendation, but we are going to get a copy of the recommendations? I
24 thought we talked about that at our last meeting—that it was going to be emailed out in a few days so we
25 could look at them just to make sure there were no thoughts, changes, whatever, and I know I never got
26 them until I saw your report.

27 Dr. Simon: That has to be done here and now.

28 Dr. Snow: Here and now.

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1 Dr. Simon: No revisions after this meeting.

2 Dr. Snow: Well, are—

3 ??: Not revisions, clarifications.

4 Dr. Simon: There are no revisions. Transcripts are taken, so this is the time.

5 Dr. Snow: Are we going to get a copy of the recommendations before our next meeting?

6 Dr. Simon: Yes, as always. The recommendations are sent out.

7 ??: I guess if you made a recommendation, keep a copy of what you wrote and make sure it got
8 transferred completely, I guess.

9 Dr. Bufalino: Tye?

10 Dr. Ouzounian: Ken, there was a discussion that somebody thought they had made a
11 recommendation that never made it. So that's a little different than what you're saying.

12 Dr. Simon: Well, we always send out a copy of the recommendations and I sent a copy out
13 separately, one goes to the group and one goes to the chairman and we ask for everyone to review, but a
14 copy always goes out, within a week after the meeting.

15 Dr. Bufalino: So we'll make sure that everyone gets that. Dr. Ross?

16 Dr. Ross: Just in case the recommendation that I thought I made the last time did not get in for
17 publication, I'm going to reintroduce it again. Seeing that we are facing, physicians are facing the 21% cut
18 in Medicare payment rates in 2010, with cuts totally 40% in the coming decade, PPAC recommends that
19 CMS provide data of provider decrease in care to Medicare beneficiaries, if there is a "brown-out" process
20 taking place.

21 Dr. Bufalino: Could you just describe "brown out" process because I think—

22 Dr. Ross: Brown out process means those doctors that are now seeing less Medicare beneficiaries
23 per week, per month, per year, rather than those that are de-listing from Medicare.

24 [Seconds]

25 Dr. Bufalino: Any discussion of that motion? Hearing none, all in favor?

26 [Ays]

27 Dr. Bufalino: Thank you. Would you like an open review of the recommendations as they sit since
28 they will end with us leaving the room?

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1 Dr. Arradondo: Yes, that's what we should do. We just didn't do it the last time, we asked for that
2 later thing. But yes.

3 Dr. Bufalino: So Dana, can you read them? [laughter]

4 Ms. Trevas: I would prefer the previous process where we had about 15 minutes for me to compile
5 them and print them, which is what we have done in the past, if you want to take a 15- or so minute break,
6 and then you will have them all in writing in your hands.

7 Dr. Bufalino: Yes, sure. Fine. Let's take a 15-minute break and then we will close the loop.

8 Wrap Up and Review of Recommendations

9 Dr. Bufalino: So we're being handed out the draft of the recommendations so you want to just take
10 a few minutes and read these and jump right in if there is a correction.

11 Ms. Trevas: Please bear in mind that there are probably some typos. I'll fix them.

12 Dr. Bufalino: Typos are always excusable.

13 Ms. Trevas: Thank you.

14 Dr. Bufalino: Karen, the first item under Agenda H is yours, and we modified that. Do you want to
15 add to that?

16 Dr. Williams: Well, it seems like the Preamble needs to be in there because this, standing by itself,
17 doesn't really explain the rationale behind the request. That ends up making it kind of lengthy, but I think,
18 assuming it's being reviewed by people who are not in this room, I think that whole preamble needs to sort
19 of be in there, and then the recommendation after that.

20 Ms. Trevas: Can the preamble be in the report? Or does it need to be part of the recommendation.

21 Dr. Bufalino: The written testimony of the day.

22 Dr. Williams: I think it should be with the recommendation.

23 Ms. Trevas: Okay.

24 Dr. Bufalino: Okay, we'll add that in.

25 Ms. Trevas: I'd be happy to read it again if you want to hear it.

26 Dr. Williams: Okay, go ahead.

27 Ms. Trevas: Do you all want to hear it?

28 Dr. Bufalino: Sure.

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1 Ms. Trevas: Okay. Whenever a particular procedure or service has been questioned as unnecessary
2 by a RAC contractor after service has been delivered, all downstream medical services, including
3 consultant services have been called into question. Requests for repayment during the period of
4 investigation have been made of consulting physicians, such as pathologists, radiologists, anesthesiologists.
5 These hospital-based specialists have rendered their services in good faith in response to a request from
6 another physician and have no way of determining at the time they are asked to participate in the care of a
7 patient, whether or not the underlying procedure or service may be questioned or determined to be
8 medically unnecessary by a RAC contractor at some time in the future. Therefore, PPAC recommends that
9 the RAC process be modified to exclude extending demands for repayment to consulting physicians for an
10 index case for a particular surgery, procedure, or consultation.

11 Dr. Williams: Sounds right.

12 Dr. Przyblski: I would wonder in that recommendation whether it should be to subsequent
13 consulting physicians, because I could interpret that as the original consulting physician that did the index
14 surgery, procedure, or consultation. Because I think that's your intent.

15 Dr. Williams: So at the last part—

16 Dr. Bufalino: Subsequent

17 Dr. Przyblski: Repayment to subsequent consulting physicians for an index case. It was in the
18 preamble but it's not in the recommendation.

19 Dr. Bufalino: Repayment to subsequent consulting physicians. Okay.

20 Dr. Williams: Or you could put downstream. Is that sound better?

21 Dr. Przyblski: Assuming that the consultants are salmon [laughter].

22 [chat]

23 Dr. Arradondo: I was just going to say that there are several times that we might want to put in
24 what could be called a preamble, just by putting whereases in front of those sentences, therefore the
25 recommendation would make it in line with the usual resolutions that other bodies make. All these
26 whereases are relevant. Therefore, we recommend, all of that. And it would be clear that that's all
27 preamble, that the recommendation's here, but the preambles and those whereases would be informing.

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1 Dr. Bufalino: Although the testimony's always there, and the ability to go back and look at the
2 meeting notes from the discussion are part of what gets typed up. I mean part of this is also the brevity of
3 trying to get the meat of the answers. I mean there's a balance of providing some discussion so there is
4 some conversation and preamble to the recommendation, but ultimately, we probably have some obligation
5 to be precise. So it's a combination of those things, I think.

6 Dr. Arradondo: In this instance, I was agreeing with if someone just looked at it cold, and wasn't a
7 party to—

8 Dr. Bufalino: Wasn't part of the conversation.

9 Dr. Arradondo: Yes, in that instance, yes, whereas most of the time, just flows straight.

10 Dr. Bufalino: Other comments. Jan?

11 Dr. Kirsch: Are we [off mike 6:40 6th mp3] Dana, you brought that up about the patient
12 population. I think I will clarify that. So under my second bullet point, let's just fix that to: recognition that
13 patient population, socio-economic factors have.

14 Dr. Bufalino: Okay. So modified. Greg?

15 Dr. Przyblski: In that same listing but in the fifth bullet, would you be uncomfortable not just
16 saying "enhancing patient participation," but also incentivization?

17 Dr. Kirsch: I'd like that.

18 Dr. Przyblski: So participation and incentivization, if that is a word.

19 [chat]

20 Dr. Arradondo: You might use the word that our presenter used, patient education, activation,
21 motivation, participation.

22 Dr. Kirsch: I couldn't remember her quote and so I—

23 Dr. Arradondo: It was still a good statement and it's what the professionals in that area use.

24 Dr. Kirsch: And it's in the testimony.

25 Dr. Bufalino: Say it again?

26 Dr. Arradondo: I changed the words around, but she had them all in, professional patient
27 education, activation, and motivation, and I finished up with our sentence here, for participation.

28 [chat]

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1 Dr. Kirsch: I couldn't remember the quote, so I tried to come up with something else, so I'm cool
2 with that.

3 Dr. Bufalino: Okay, all right. Other modifications. Jeff?

4 Dr. Ross: In mine, my page two, the last item, item O. In the subjective, subjunctive portion of the
5 sentence; burdensome accreditation already licensed, and I stated and trained.

6 Ms. Trevas: Oh, I'm sorry. Thank you.

7 Dr. Ross: You can keep accredited, that's fine, but I think it's licensed and trained to provide these
8 items for these DME POS is fine.

9 Dr. Standaert: You want to take accredited out, right?

10 Dr. Ross: Accredited out and use the word licensed, and trained, excuse me.

11 Dr. Smith: Already licensed and trained to provide...

12 Dr. Bufalino: Okay. Any other wordsmithing?

13 Dr. Sprang: on mine, the third one, especially, the PPAC recommends to CMS, can I reread it, or I
14 should just give you the typed copy. It doesn't really say quite what I said.

15 Ms. Trevas: Okay. The typed copy does not exactly comport with what was added in?

16 Dr. Sprang: What you typed doesn't really...

17 Ms. Trevas: Right, but there were some additional comments and I was trying to accommodate the
18 additional comments, the amendments made, or the discussion, so perhaps you could...

19 Dr. Bufalino: Go ahead.

20 Dr. Simon: Dr. Ross, on the last sentence there, should it be as they are already licensed and
21 trained to provide DME supplies to patients.

22 Dr. Ross: I put these items, but that's

23 Dr. Simon: It has DME POS here, and it's not DME POS.

24 Dr. Ross: That's correct, I didn't say that, I had written these items.

25 Ms. Trevas: DME supplies?

26 Dr. Standaert: DME supplies.

27 Dr. Ross: So you can say DME items to their patients, or supplies.

28 Dr. Simon: So how do you want it?

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1 Dr. Ross: I would say DME items, DME supplies to their patients.

2 Dr. Bufalino: Anyone else? Leroy, we want you to be happy. You want to read what you're
3 missing?

4 [chat off mike]

5 Dr. Sprang: On the first one where it says, PPAC recommends that CMS Value-based Purchasing,
6 what I said is that PPAC recommends that the Physician Consortium for Performance Improvement, the
7 PCPI, be recognized as the leading developer of physician-level measures in CMS's plan to transition to
8 VBP. But it says CMS's Value-based Purchasing program, and it really is supposed to say Physician
9 Consortium for Performance.

10 Dr. Bufalino: I guess we all knew it was Physician Consortium Performance Improvement. Isn't
11 that what PCPI stands for?

12 Ms. Trevas: Yes, that's what I intended it to stand for. I'm sorry I don't understand.

13 Dr. Sprang: You're fine. I was just reading it differently, because I was reading it as if Value-
14 based Purchasing would be recognized. No, that's fine. She just put it differently than I did. No, it's fine.

15 [chat]

16 Dr. Bufalino: Anyone else while he's working on that? You want to read that last one when you're
17 done?

18 Ms. Trevas: PPAC recommends that CMS provide data of a decrease in care to Medicare
19 beneficiaries, to determine if a brown out process is taking place.

20 [chat]

21 Dr. Bufalino: Read it one more time.

22 Dr. Smith: How about decreased access to care, would that work? Instead of brown out?

23 Dr. Arradondo: Or you could put a little asterisk in and define brown out—decrease of
24 participation being below some percentage, you're on.

25 Dr. Ross: Percentage, did we describe per week, per month, per year? That's what I, that's how I
26 clarified it.

27 Dr. Arradondo: Give her some numbers to clarify it.

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1 Dr. Bufalino: I mean the issue is that people are not ripping up their Medicare contract, but they're
2 decreasing access to Medicare beneficiaries, less new patients, or less follow up visits per provider. I mean
3 that's what we're talking about in terms of brown out, right?

4 Dr. Ross: That's the essence of what we're trying to say by the world brown out.

5 Dr. Simon: Well, we want it clear. We don't want the essence. We want it clear so that we can
6 answer the request, so 90 days from now we don't have confusion.

7 Ms. Trevas: What I just wrote is I, whether a brown out process is taking place, i.e., whether
8 providers are seeing beneficiaries, as opposed to opting out of Medicare. Is that clear enough? My question
9 is about the first part. Is that CMS provide data of a decrease in care?

10 Dr. Ross: If there is a trend, or if there is a decrease in provider care?

11 Dr. Standaert: If there is one or whether or not there is one.

12 Dr. Smith: It's to provide data to determine whether.

13 Dr. Arradondo: Care, you're really talking about visits.

14 Dr. Bufalino: Okay, we've had enough English reviews today. I used to go down first in the
15 spelling bees, so a little science I'm okay, but spelling [laughter]

16 Dr. Arradondo: Jeff can now take the blue tarp off of his recommendation. [laughter]

17 Dr. Bufalino: All right. Thank all of you for your time today. I want to thank the staff for
18 organizing and structuring the meeting and making sure we got here and took good care of us today. I'd
19 actually like to thank all of the presenters today. We had some really in depth presentations of details that
20 things that we have asked for and responded to. So we appreciate that. The next meeting is June 1st. We
21 will be here for a warm day in Washington and we will start the morning with a morning jog prior to 8:00
22 breakfast. So we will be here. Thank you all, have a good day.

23 Adjournment

24

25

26