REPORT NUMBER FIFTY-SIX

to the

Secretary

U.S. Department of Health and Human Services

═══════════════

(Re: Physicians Regulatory Issues Team [PRIT] Update, Medically Unbelievable Edits, Provider-Based Disease Management Demonstrations, Development of Pay-for-Performance Cost and Quality Measures, Practice Expense Methodology, and other matters)

═══════════════

From the

Practicing Physicians Advisory Council

(PPAC)

Hubert H. Humphrey Building

Washington, DC

May 22, 2006

SUMMARY OF THE MAY 22, 2006, MEETING

Agenda Item A — Introduction
The Practicing Physicians Advisory Council (PPAC) met at the Department of Health and Human Services' Hubert H. Humphrey Building in Washington, D.C., on Monday, May 22, 2006 (see Appendix A). The chair, Anthony Senagore, M.D., welcomed the four new members of PPAC: Vincent Bufalino, M.D.; Tye Ouzounian, M.D.; Jeffrey Ross, D.P.M., M.D.; and Karen Williams, M.D.

Agenda Item B — Welcome
Tom Gustafson, Ph.D., Deputy Director of the Center for Medicare Management, also welcomed the new members and said the Agency appreciates PPAC's efforts.

OLD BUSINESS

Agenda Item C — Update
Ken Simon, M.D., M.B.A., Executive Director of PPAC, presented the responses from CMS to PPAC recommendations made at the March 6, 2006, meeting (Report Number 55).

> 55-B-1: PPAC recognizes and sincerely appreciates the work of Mr. Herb Kuhn and CMS staff for their efforts in implementing provisions to the Deficit Reduction Act in a timely and efficient manner.
>
> **CMS Response:** CMS acknowledges the Council's comments. CMS will continue to work diligently to implement the provisions of the Deficit Reduction Act in an efficient and timely manner.
>
> 55-C-1: The Council recommends that CMS measure the costs of data collection incurred by physicians in the planned Coverage with Evidence Development program. Once data are gathered, the costs should be conveyed to Congress for inclusion in the Physician Fee Schedule. CMS should also ensure that trials conducted under the Coverage with Evidence Development program be subject to the same regulatory requirements as other clinical trials, such as Institutional Review Board participation and assurance that patients who decline to participate are not penalized.
>
> **CMS Response:** To allay the cost of data collection, CMS recommends that the Coverage with Evidence Development program take place in the context of existing data systems when feasible. CMS does not expect to provide additional financial support for data collection.
>
> The Agency recognizes that the potential value of information generated through coverage linked to evidence development must be carefully considered in the context of the burden associated with the collection of these data. To minimize the

financial and other resources required, careful attention must be paid to collecting the minimum data necessary to answer specific questions. Collecting that data should use the least resource-intensive mechanisms possible. The use of routinely collected data from administrative sources represents an important potential efficiency in the conduct of evaluations linked to coverage decisions. Finally, greater adoption and use of health information technology by providers in all settings have the potential to significantly reduce the burden associated with observational and experimental data collection. This will significantly enhance our ability to simultaneously speed adoption while developing better, more individualized evidence about new medical technologies and services.

In the coming months, CMS expects to publish a second draft of the guidance document, "Factors CMS Considers in Making a Determination of Coverage with Evidence Development." This draft clarifies many of the elements of the Coverage with Evidence Development program discussed in the Agency's April 2005 draft document, including emphasis that the application of the Coverage with Evidence Development program will be consistent with Federal laws, regulations, and patient protections.

55-D-1: The Council recommends that CMS provide an online directory of National Provider Identifier (NPI) numbers for use by physicians.

CMS Response: CMS is in the process of developing its NPI data dissemination policy. Once cleared (the Office of the Secretary and the Office of Management and Budget will need to review and approve), this policy will be published in the *Federal Register*. The Office of Management and Budget semi-annual report indicates that we will publish this notice in August 2006.

55-D-2: The Council recommends that CMS publish in its proposed and final rules the Relative Value Units (RVUs) forwarded by the American Medical Association's (AMA's) Relative Value Update Committee (RUC) for new physician services for which CMS has made a noncoverage decision.

CMS Response: CMS acknowledges the recommendation from the Council and will consider the recommendation as it prepares publication of the Physician Fee Schedule proposed rule.

55-D-3: The Council recommends that CMS withdraw the proposal to create a list of "medically unbelievable edits" and resubmit the proposal through the normal, formal rulemaking process, working closely with the medical community throughout.

CMS Response: While edits are not normally addressed in rulemaking, CMS will continue to work closely with the medical community as we develop a list of "medically unbelievable edits."

55-F-1: The Council recommends that CMS use a payment methodology that uses bonuses rather than differentials to avoid damaging practices that serve patients who are socioeconomically disadvantaged or noncompliant.

CMS Response: CMS will need to be able to adjust physician performance data for important differences among physicians' patients before we can use the data for payment purposes. Appropriate adjustment should give all physicians a fair opportunity to participate in the pay-for-performance program, regardless of their patient mix.

55-F-2: Given that many pay-for-performance measures will require more Part B services, which will 1) increase the future volume and intensity of services provided by outpatient providers, 2) lower future conversion factors as calculated under the sustainable growth rate (SGR) formula, and 3) penalize providers for implementing the quality measures CMS requires, the Council recommends that CMS delay implementation of pay-for-performance measures until the SGR is replaced with a more equitable system.

CMS Response: Performance measures of both quality and cost of care are meant to encourage the appropriate utilization of services. Some services are currently underutilized, but other services are currently overutilized. The impact on the SGR of implementing a physician pay-for-performance program has not yet been determined, so it is too early to assume that performance measures will increase volume and intensity of services. Ultimately, Congress will decide the timing of pay-for-performance implementation and of any replacement of the SGR.

55-F-3: The Council recommends that that some of CMS' pay-for-performance pilots be directed toward small practices, especially those that cover socioeconomically and geographically diverse populations, and not just large, vertically integrated practices.

CMS Response: We agree. The Medicare Care Management Performance Demonstration, which was mandated by Medicare Modernization Act (MMA) section 649, is focused on solo and small-to-medium-sized practices, typically composed of 10 physicians or fewer. CMS will implement the 3-year demonstration in both rural and urban areas in the states of Arkansas, California, Massachusetts, and Utah. The demonstration proposes to promote the adoption and use of health information technology to manage and improve the quality of patient care for chronically ill Medicare patients. Participating physicians who meet or exceed clinical performance standards will receive a bonus payment.

55-F-4: The Council recommends that CMS initially focus on process measures rather than outcome measures.

CMS Response: CMS intends to focus on a mix of structure, process, and outcome measures as appropriate to encourage the desired improvements in quality and avoidance of unnecessary costs. Certain types of measures are more effective for accomplishing certain types of goals. However, we recognize that outcome measures require particular attention because they need to be valid and reliable; in addition, such risk factors need to be risk-adjusted for fairness.

55-F-5: The Council supports efforts of CMS to explore the possibility of incentivizing beneficiaries to be compliant with processes being measured.

CMS Response: As part of our long-range planning for pay for performance, we will be exploring the use of patient incentives. One option that we will be considering is use of incentives to encourage patient compliance with the processes on which their physicians are being measured.

55-G-1: The Council recommends that CMS monitor the amount of time physicians spend appealing Part D pharmacy coverage decisions and the amount of time involved with/costs of care related to substituting medications.

CMS Response: CMS has attempted to design the Part D program so that the amount of time involved with/the cost of care related to substituting medications is not a material concern. However, we remain receptive to specific physician concerns.

55-G-2: The Council recommends that CMS use the findings from evidence-based medicine and peer-reviewed journals to allow off-label use of medicines covered under Part D.

CMS Response: The off-label use for Part D drugs is allowed based on statutory language including the compendia: the U.S. Pharmacopeia Dispensing Information, the American Hospital Formulary Service, and DRUGDEX. These sources, as well as the U.S. Pharmacopeia Formulary Committee that updates the classes and categories, are supposed to take into account best evidence for all of their decisions.

55-N-1: The Council recommends that CMS establish a pilot program that gives resources for disease management, such as funds to pay for translation and social services and the costs of management fees, to primary care physicians and compare the costs of primary care physicians providing the same services with those of the disease management industry.

CMS Response: Section 646 of the MMA provides the opportunities that the PPAC has recommended. The Medicare Healthcare Quality Demonstration offers major opportunities for physician groups, integrated delivery systems, or regional coalitions of the above to restructure/redesign delivery and payment, including the

opportunity to waive the restrictions the PPAC identified. The goals of the demonstration are to:

- improve patient safety;
- enhance quality;
- increase efficiency; and
- reduce scientific uncertainty and the unwarranted variation in medical practice that results in both lower quality and higher costs.

CMS is looking for provider-driven models of delivery redesign that constitute major and multifaceted improvements to the health care system. Proposals must be submitted no later than September 29, 2006. For additional information, go to: http://www.cms.hhs.gov/DemoProjectsEvalRpts/MD/itemdetail.asp?filterType=n one&filterByDID=-99&sortByDID=3&sortOrder=ascending&itemID=CMS023618

NEW BUSINESS

Agenda Item D —PRIT Update
William Rogers, M.D., Director of PRIT, said CMS recognizes that it would be helpful to include in the Physician Fee Schedule RVUs for some codes that are not covered under the Physician Fee Schedule because other insurers use the schedule as a reference (Presentation 1). CMS hopes to provide a directory of NPIs for use by physicians, but it is not possible to ensure the privacy of NPIs, because they will likely be communicated among providers through sources that are not secure, such as faxes. The PRIT believes most drugs are now available at the average sales price; CMS is evaluating the availability of intravenous immunoglobulin but does not believe the problem is related to average sales price.

Agenda Item F — Medically Unbelievable Edits (MUE)
Lisa Zone, Deputy Director of the Program Integrity Group in the Office of Financial Management, explained that the MUE program seeks to identify implausible claims submissions, such as hysterectomy performed on a man or dosages that appear grossly inconsistent with common use (Presentation 2). On the basis of public comments received so far, CMS will create a small subset of MUE that focuses on identifying anatomical and typographical errors in claims submissions. The subset will be published for public comment in the fall and implemented in January 2007. Ms. Zone said about 1.7 percent of Medicare claims paid in error relate to coding and billing errors, which amounts to billions of dollars.

Recommendations
56-F-1: PPAC recommends that CMS change the name of the MUE program to remove the term "unbelievable." Some suggestions include replacing the word "unbelievable" with the word(s) "unlikely," "unusual," "unexpected associations," or "inaccurate."

56-F-2: PPAC recommends that CMS allow modifiers for services that may be clinical outliers and develop an appeals process for claims denied under the MUE program.

56-F-3: PPAC recommends that when CMS publishes the proposal for an MUE subset to be implemented in January 2007, CMS provide background information on the context and rationale for the MUE program and specific data on the estimated percentage of errors that CMS hopes to address. The information and data should be disseminated through educational vehicles of the AMA and national and state specialty societies, as well as the usual CMS communication channels.

Agenda Item G — Disease Management: Provider-Based Models

Linda Magno, Director of the Medicare Demonstrations Program Group in the Office of Research, Development, and Information, said 31 percent of Medicare beneficiaries have multiple chronic conditions, and she described various CMS demonstrations aimed at disease management and coordination of care for such beneficiaries (Presentation 3). PPAC members suggested CMS focus on end-of-life and palliative care to contain costs. Also, CMS could help strengthen the role of the primary care provider in coordinating care for beneficiaries.

Agenda Item H — Swearing In of New Members

Alex M. Azar II, Deputy Secretary of the Department of Health and Human Services, described some of the goals of the Agency, including providing more and better consumer information tools, implementing pay for performance programs, and speeding the adoption of health information technology. He then swore in the new PPAC members.

Agenda Item J — Pay for Performance: Cost Measurement Development

Tom Valuck, M.D., J.D., Medical Officer for the Center for Medicare Management, described the Agency's efforts to identify resource measures and present them to providers in a format that is meaningful, actionable, and fair (Presentation 4). CMS has learned that simple claims data do not yield sufficiently rich information with which to create meaningful resource reports. CMS is evaluating episode grouper software, which lumps together clinically related services and procedures for a given patient over time into one episode for evaluation. A contractor has been hired to compare various software technologies and methodologies, and physicians will compare the algorithms used by the software with medical records and claims.

Agenda Item K — Pay for Performance: Update on Quality Measurement Development

Michael Rapp, M.D., J.D., Director of the Quality Measurement and Health Assessment Group of the Office of Clinical Standards and Quality, said the AMA created Current Procedural Terminology (CPT) codes to report quality measures on claim forms

(Presentation 5). CMS has already incorporated these CPT Category II codes into its Physician Voluntary Reporting Project (PVRP). The PVRP is expanding the number of measures and specialties it covers with input from the AMA's Physician Consortium for Performance Improvement and the National Commission for Quality Assurance. Some PPAC members questioned the utility of measures such as a hemoglobin A1c threshold of 9 percent for people with diabetes. Others were concerned that the program measures outcomes over which individual physicians have little control, such as patient compliance.

Agenda Item M —Practice Expense Update

Don Thompson, Senior Technical Advisor, and Rick Ensor, Analyst in the Hospital and Ambulatory Policy Group, said CMS will soon publish a final rule with a revised methodology for calculating the practice expense portion of physician reimbursement (Presentation 6). The methodology takes into account recent survey data provided by several specialties, as well as input from town hall meetings held in February 2006. CMS also plans to publish its 5-year review of practice expense methodology.

> *Recommendations*
> 56-M-1: PPAC recommends that CMS continue to evaluate and correct disparities in payment to academic anesthesia programs to bring them in line with similar payment methodologies used by other teaching physicians.

Agenda Item N — Testimony

William Hazel, M.D., of the AMA asked PPAC to urge CMS to replace the SGR system with one that recognizes the increasing costs of providing care and to support the Medicare Payment Advisory Commission's recommendation for a 2.8 percent positive update to the Physician Fee Schedule for 2007 (Presentation 7). He asked that quality measures for the PVRP be vetted through groups representing multiple stakeholders.

> *Recommendations*
> 56-N-1: PPAC recommends that CMS continue to use its influence with Congress to encourage changes in physician reimbursement, particularly the SGR, the outcome of which will enhance the Agency's ability to improve the quality of care for its beneficiaries.
>
> 56-N-2: PPAC commends CMS for using the input of the AMA's Physician Consortium for Performance Improvement in the quality measures for the PVRP. PPAC recommends that all physician measures used by CMS be developed by physician specialties through the Consortium, endorsed by the National Quality Forum, and implemented across public and private programs by working through the Ambulatory Care Quality Alliance.

The Council reviewed the written testimony of the College of American Pathologists (Presentation 8).

Agenda Item P — Wrap Up and Recommendations
Dr. Senagore adjourned the meeting. Recommendations of the Council are listed in
Appendix B.

Report prepared and submitted by
Dana Trevas, Rapporteur
Magnificent Publications, Inc.

PPAC Members at the May 22, 2006, Meeting

Anthony Senagore, M.D., *Chair*
Surgeon
Cleveland, Ohio

Jose Azocar, M.D.
Internist
Springfield, Massachusetts

Vincent J. Bufalino, M.D.
Cardiologist
Naperville, Illinois

Peter Grimm, D.O.
Radiation Oncologist
Seattle, Washington

Carlos Hamilton, Jr., M.D.
Endocrinologist
Houston, Texas

Dennis K. Iglar, M.D.
Family Practice
Oconomowoc, Wisconsin

Joe W. Johnson, D.C.
Chiropractor
Paxton, Florida

Tye J. Ouzounian, M.D.
Orthopedic Surgeon
Tarzana, California

Laura Powers, M.D.
Neurologist
Knoxville, Tennessee

Gregory Przybylski, M.D.
Neurosurgeon
Knoxville, Tennessee

Jeffery A. Ross, D.P.M., M.D.
Podiatrist
Houston, Texas

M. Leroy Sprang, M.D.
Obstetrician–Gynecologist
Evanston, Illinois

Robert Urata, M.D.
Family Practitioner
Juneau, Alaska

Karen S. Williams, M.D.
Anesthesiologist
Washington, D.C.

_____

CMS Staff Present:

Alex M. Azar II, Deputy Secretary
Department of Health and Human Services

David C. Clark, RPH, Director
Office of Professional Relations
Center for Medicare Management

Rick Ensor, Analyst
Hospital and Ambulatory Policy Group
Center for Medicare Management

Thomas Gustafson, Ph.D., Deputy Director
Center for Medicare Management

Linda Magno, Director
Medicare Demonstrations Program Group
Office of Research, Development, and
Information

Michael Rapp, M.D., J.D., Director
Quality Measurement and Health Assessment
Group
Office of Clinical Standards and Quality

William Rogers, M.D., Director
Physicians Regulatory Issues Team

Ken Simon, M.D., Executive Director, PPAC
Center for Medicare Management

Don Thompson, Senior Technical Advisor
Hospital and Ambulatory Policy Group
Center for Medicare Management

Tom Valuck, M.D., J.D., Medical Officer
Center for Medicare Management

Lisa Zone, Deputy Director
Program Integrity Group
Office of Financial Management

Public Witnesses:
William Hazel, M.D., American Medical
Association
_____
Dana Trevas, Rapporteur
Magnificent Publications, Inc.

APPENDICES

Appendix A: Meeting agenda
Appendix B: Recommendations from the May 22, 2006, meeting

The following documents were presented at the PPAC meeting on May 22, 2006, and are appended here for the record:

Presentation 1: PRIT Report
Presentation 2: Medically Unbelievable Edits
Presentation 3: Disease Management Provider-Based Models
Presentation 4: Pay for Performance: Cost Measurement Development
Presentation 5: Pay for Performance: Update on Quality Measurement Development
Presentation 6: Practice Expense Update
Presentation 7: Statement of the American Medical Association to the Practicing Physicians Advisory Council
Presentation 8: College of American Pathologists Statement to the Practicing Physicians Advisory Council on Medically Unbelievable Edits

Appendix A

Practicing Physicians Advisory Council
Hubert H. Humphrey Building
Room 705A
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201
May 22, 2006

08:30-08:40	**A. Open Meeting**	**Anthony Senagore, M.D. Chairman, Practicing Physicians Advisory Council**
08:40-08:50	**B. Welcome**	**Herb Kuhn, Director Tom Gustafson, Ph.D., Deputy Director, Center for Medicare Management, Centers for Medicare and Medicaid Services**
08:50-09:15	**C. PPAC Update**	**Kenneth Simon, M.D., M.B.A. Executive Director, Practicing Physicians Advisory Council**
09:15-09:45	**D. PRIT Update**	**William Rogers, M.D., Director, Physicians Regulatory Issues Team, Office of Public Affairs, Centers for Medicare and Medicaid Services**
09:45-10:00	**E. Break (Chair Discretion)**	
10:00-10:45	**F. Medically Unbelievable Edits**	**Lisa Zone, Deputy Director, Program Integrity Group, Office of Financial Management**

10:45-11:30	G. Disease Management- Provider-Based Models	Linda Magno, Director, Medicare Demonstrations Program Group, Office of Research, Development and Information
11:30-12:15	H. Swearing in of New Members	
12:15-1:15	I. Lunch	
1:15-2:00	J. Pay for Performance: Cost Measurement Development	Tom Valuck, M.D., J.D. Medical Officer, Center for Medicare Management
2:00-2:45	K. Pay for Performance: Update on Quality Measurement Development	Michael Rapp, M.D., J.D. Director, Quality Measurement and Health Assessment Group, Office of Clinical Standards and Quality
2:45-3:00	L. Break (Chair Discretion)	
3:00-3:45	M. Practice Expense Update	Don Thompson, Senior Technical Advisor, Carolyn Mullens, Deputy Director, Division of Practitioner Services, and Rick Ensor, Analyst, Hospital and Ambulatory Policy Group, Center for Medicare Management
3:45-4:15	N. Testimony- American Medical Assoc. (AMA);	William Hazel, M.D.
4:15-4:45	O. Wrap Up/Recommendations	

Appendix B

PRACTICING PHYSICIANS ADVISORY COUNCIL (PPAC) RECOMMENDATIONS
Report Number Fifty-Six
May 22, 2006

Agenda Item F — Medically Unbelievable Edits (MUE)
56-F-1: PPAC recommends that CMS change the name of the MUE program to remove the term "unbelievable." Some suggestions include replacing the word "unbelievable" with the word(s) "unlikely," "unusual," "unexpected associations," or "inaccurate."

56-F-2: PPAC recommends that CMS allow modifiers for services that may be clinical outliers and develop an appeals process for claims denied under the MUE program.

56-F-3: PPAC recommends that when CMS publishes the proposal for an MUE subset to be implemented in January 2007, CMS provide background information on the context and rationale for the MUE program and specific data on the estimated percentage of errors that CMS hopes to address. The information and data should be disseminated through educational vehicles of the American Medical Association (AMA) and national and state specialty societies, as well as the usual CMS communication channels.

Agenda Item M — Practice Expense Update
56-M-1: PPAC recommends that CMS continue to evaluate and correct disparities in payment to academic anesthesia programs to bring them in line with similar payment methodologies used by other teaching physicians.

Agenda Item N —Testimony
56-N-1: PPAC recommends that CMS continue to use its influence with Congress to encourage changes in physician reimbursement, particularly the sustainable growth rate, the outcome of which will enhance the Agency's ability to improve the quality of care for its beneficiaries.

56-N-2: PPAC commends CMS for using the input of the AMA's Physician Consortium for Performance Improvement in the quality measures for the Physician Voluntary Reporting Program. PPAC recommends that all physician measures used by CMS be developed by physician specialties through the Consortium, endorsed by the National Quality Forum, and implemented across public and private programs by working through the Ambulatory Care Quality Alliance.