AMA
AMERICAN MEDICAL ASSOCIATION

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November 22, 2011

Sherry Glied, PhD
Assistant Secretary
Office of Planning and Evaluation
U.S. Department of Health & Human Services
200 Independence Avenue, SW
Washington, DC 20201

Sherette Funn Coleman
Reports Clearance Office
U.S. Department of Health & Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Agency Information Collection Request; Multi-Payor Claims Database, FR Doc. 2011-24442

Dear Dr. Glied and Ms. Funn Coleman:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide comments on the proposed Multi-Payor Claims Database (MPCD) that the U.S. Department of Health & Human Services (HHS) indicates will be used for comparative effectiveness research (CER). The Paperwork Reduction Act of 1995 (PRA) provides that the collection of information by the agency should advance the proper performance of the agency. We continue to have unaddressed questions as they pertain to the necessity and utility of the MPCD to undertake CER and promote the proper performance of HHS. There remain additional questions as to whether the MPCD will improve the quality and use of federal information, whether it will strengthen decision-making, accountability, and openness in government and society. In brief, MPCD could have sweeping implications for CER and the practice of medicine, yet the decision to establish the MPCD, which pre-dates this notice by over a year, and development of the MPCD has not involved organized medicine or the public in an open manner. **We strongly urge HHS to place the development of the MPCD on hold until a transparent and public process is developed to engage health care stakeholders, particularly physicians and organized medicine, in the development and governance of the MPCD.**

We agree that the American Recovery and Reinvestment Act (ARRA) included funding to support the development of a CER infrastructure. We strongly supported (and publicly defended) the ARRA CER funding to advance research and infrastructure development that focused on clinical data (such as registries and randomized clinical trials). However, when we first learned of the MPCD, after HHS had already decided to create such a database and awarded a contract of $16 million for its development to a private company, we had concerns that the MPCD would require significant ongoing funding that would siphon funding away from CER that utilized clinical data. Further, the database presents significant risk of misuse if not properly designed, and is being developed without the active engagement of organized medicine and practicing physicians in a decision-making role. Currently, the physician role is limited to an advisory body that expressly has no decision-making authority. Although assurances were provided that the MPCD would be developed utilizing an open and transparent process, activities proceed apace with the development and funding of MPCD without public notice, without any effort to involve organized medicine, and with meetings of the MPCD advisory board that bar public attendance and participation. **We are incorporating the concerns we raised in the March 22, 2011, letter that we sent to the then HHS Medical Officer and Senior Program Manager of the Comparative Effectiveness Portfolio within the Office of Planning and Evaluation. Most of the questions and concerns we raised in the letter at that time remain unanswered or unresolved.**

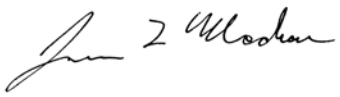
We believe strongly in the CER enterprise and know that building the evidence base of medicine is essential in order to improve quality patient outcomes. We do not want the fledgling efforts to scale up CER to fall short of its promise because of confusion, misinformation, or lack of stakeholder engagement. CER will only improve clinical practice if all of the end-users (physicians and patients—not only payors) agree that the findings are based on data and information that they trust.

We would welcome the opportunity to discuss the concerns that we have raised previously as well as our concerns that this notice and the agency's information collection request have not met the minimum requirements of the PRA. In brief, the notice does not provide a cogent or clear justification of why CER research has been hindered without a MPCD. Currently, HHS supports a large and broad portfolio of CER without a MPCD. In addition, other CER infrastructure development such as clinical registries could provide far richer source of data as well as opportunities to identify research priorities, engage practicing clinicians, and speed adoption of research findings. Registries could also provide longitudinal data, provide insight into demographically representative populations, and avoid the tendency to reach conclusions about clinical care based on claims and payment data.

In addition, the estimated burden specified in the Federal Register notice of 437 burden hours—about two months of eight hour days—is neither credible nor accurate based on the little public information that is available about the MPCD. The MPCD represents a monumental undertaking as evidenced by the reported number of HHS personnel already engaged in meetings related to the MPCD. **Opening up the process for developing the MPCD to the public, consistent with this Administration's emphasis on open and transparent government, would enhance the agency's efforts to construct a CER infrastructure that accurately reflects the anticipated burden, but more importantly incorporates strategies that enhance the quality, utility, and clarity of information to be collected.**

We would welcome the opportunity to discuss the above issues with the HHS Office of Planning and Evaluation at greater length and to discuss strategies moving forward that would produce meaningful participation of all interested practicing physicians and organized medicine in the development and use of all-payer databases for research. The AMA appreciates the opportunity to provide our views on these critical issues, and we look forward to working with you collaboratively. It is from this perspective that we would like to arrange a conference call or meeting to discuss these issues. Please contact Jennifer Shevchek, jennifer.shevchek@ama-assn.org, (202) 789-4688, with our Washington, DC office if you have any questions.

Sincerely



James L. Madara, MD

Enclosure

AMA
AMERICAN
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Michael D. Maves, MD, MBA, Executive Vice President, CEO

March 22, 2011

Amol Navathe, MD, PhD
Medical Officer and Senior Program Manager
Comparative Effectiveness Portfolio
Office of Planning and Evaluation
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: American Recovery and Reinvestment Act funding for an All-Payer, All-Claims Database to Conduct Comparative Effectiveness Research

Dear Dr. Navathe:

On behalf of the physician and medical student members of the American Medical Association (AMA), we thank you for the opportunity for AMA staff to discuss with you the funding awarded from the American Recovery and Reinvestment Act (ARRA) appropriations for comparative effectiveness research (CER). As you know, we had questions about the process utilized to develop an all-payer, all-claims database for CER as well as substantive concerns. We look forward to continuing the discussion and working with you to address these concerns.

The AMA supported the ARRA appropriations for CER. We worked with Members of Congress and publicly supported the funding. We again offered our support during the health system reform debate to invest long-term in CER. We are in agreement that CER findings derived through a scientific process using valid and rigorous methodologies are needed to expand the evidence base of medicine and improve health care. The AMA, however, firmly believes that it is critical to engage practicing physicians in a meaningful way in every phase of CER. Physician participation in the CER enterprise should not be limited to the physicians associated with academic medical centers or large research institutions, but should include physicians in medium-to small-practices in geographically diverse areas. This is essential in order to promote a learning health care system that rapidly adapts to changing needs and health challenges. The foregoing goal will remain simply an aspiration if physicians question the validity or accuracy of CER findings. Practicing physicians play an essential role in health care delivery. Rapid physician uptake and trust in the quality of the evidence and methodologies used to produce CER findings are the keys that will unlock the promise and transformational dimension of CER at the point of care.

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At present, concerns remain among certain stakeholders and even some physicians who believe that CER is a Trojan horse designed to solely cut costs and ration health care. We have invested significant time in the effort to disabuse organized medicine of these inaccurate characterizations promoted by opponents of CER. In light of the foregoing, we have strongly supported efforts to build CER capacity rooted in clinical data as opposed to claims or administrative data that is primarily relied upon by public and private payers. As shared with you during your meeting with AMA representatives, the all payer, all claims database as currently proposed could inflame opponents and diminish our ability to continue our vigorous support for CER. We do believe there are opportunities to work together to address some of the most significant shortcomings of an all payer, all claims database going forward.

We appreciate that you have provided us with a copy of "Multi-Payer Claims Database/Task 12: Summary Report and Recommended Design Option," prepared by Avalere. (Incidentally, we would be interested in any additional related documents since it appears to be an Appendix and is designated as "Task 12.") It appears that the Avalere report was completed in May 2010, but this was the first opportunity that the AMA has had to review the report's contents since it was not publicly posted. We appreciate the opportunity to review this report and have three general comments summarized below and additional specific questions/issues that we would welcome the opportunity to discuss with you in further detail.

Survey of Key Stakeholders. The report states that key stakeholders were surveyed, but does not identify the stakeholders other than in broad categories. As you know, the AMA, despite being a key stakeholder that worked to advance CER as part of ARRA and the Affordable Care Act (ACA), was not surveyed. In addition, it is not evident from the report whether medical specialties were surveyed. We would be interested to know beyond broad categories what stakeholders were surveyed. As outlined below, the report does not identify concerns or input that organizations representing practicing physicians have regularly expressed concerning such databases. The report indicates that a key recommendation includes ensuring stakeholder support and we agree. See page 3. This, however, should include organizations that represent practicing physicians. Given the importance of this issue, the AMA believes that it is critical that practicing physicians should have an opportunity to participate in assessing salient strategic issues related to the development of an all payer, all claims database at every phase of development, deployment, and operation.

Claims Databases Cannot Produce Clinical Conclusions/Findings. The report does not include any qualifying language that clarifies that claims and administrative databases are limited to identifying variations, but do not provide valid information on the clinical appropriateness of such variation. During the meeting with AMA representatives, it was our understanding that you agreed that a claims database would identify variations and serve as a basis for generating hypothesis that could be tested to account for variation using clinical data. The report appears to suggest otherwise. As we shared during our meeting, claims data will identify variations, but will not explain the clinical implications of the variation (good, bad, or what the appropriate clinical intervention should be). Despite the foregoing, the report makes the following assertion:

> Based on this work, we found that a [Multi Payer Claims Data] MPCD would have an incremental advantage over existing claims data sources due to its ability to link disparate sources, enabling research on broader populations that better reflect real-world clinical settings than do clinical trials. Not every comparative research question of importance is appropriate to answer via clinical trials. A MPCD presents a viable option for exploring a subset of those questions. Furthermore, because several payers already have efforts underway to collect claims data and have thus evaluated the benefits and limitations of using such data for research, the opportunity exists for the broad use of a MPCD in the short term, relative to other data sources such as patient registries and electronic medical records. (Emphasis Added.)

Additional Details Needed on the Database Architectural Schema. The report does not include a discussion of a number of issues that the AMA believes should be addressed as part of strategic planning. We welcome the opportunity to review the database architectural schema to ensure that the appropriate data elements are accommodated and are linked in a coherent and logical fashion. We also are interested in a discussion or analysis of how the data would be validated, depending, of course, on the data sources.

We have noted previously that clinical registries represent far richer and clinically relevant data sources for reaching valid, scientifically based conclusions. Nonetheless, we support the collection of all valid and useable data, and making that data available to physicians in meaningful ways that would help them improve efficiency and quality. However, for the above reasons and others, we continue to have significant concerns that done improperly, an all payer, all claims database will create widespread suspicion of the true purpose of this database and by extension CER.

We would welcome the opportunity to discuss the above issues with you at greater length and to discuss strategies moving forward that would produce meaningful participation of practicing physicians in the development and use of all-payer databases for research. The AMA appreciates the opportunity to provide our views on these critical issues, and we look forward to working with you collaboratively. We would like to set-up a conference call to discuss these issues. Please contact Jennifer Shevchek, jennifer.shevchek@ama-assn.org, (202) 789-4688, with our Washington, DC office if you have any questions.

Sincerely,

Michael D. Maves, MD, MBA

cc: Sherry Glied, PhD