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Jonathan Blum
Director
Center for Medicare
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Advance Notice of Methodological Changes for Calendar Year (CY) 2013 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2013 Call Letter

Dear Director Blum:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to offer comments and recommendations concerning the *Advance Notice of Methodological Changes for Calendar Year (CY) 2013 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2013 Call Letter* (2013 Advance Notice) issued by the Centers for Medicare and Medicaid Services (CMS). The AMA supports CMS oversight of the MA and the Medicare Prescription Drug (Part D) programs and generally applauds efforts to ensure MA and Part D sponsors have policies and practices that protect beneficiary access to medically necessary care. It is for that reason that we urge CMS to reconsider and modify provisions in the Advance Notice that will weaken beneficiary protections and create significant access barriers to clinically indicated drugs for some of the most vulnerable patients and potentially undermine quality patient outcomes as well as the physician-patient relationship.

Drug Utilization Review and Drug Utilization Management

In the 2013 Advance Notice, CMS has asserted that sponsors have not employed effective concurrent and retrospective drug utilization review (DUR) programs to address what the agency has characterized as overutilization of medications. Related to the foregoing, the agency has also stated that the sponsors have failed to properly employ drug utilization management (DUM). CMS singled out overutilization of opioids as a key area of concern, but has urged the adoption of far more intensive DUR and DUM policies **across the board**. However, CMS acknowledged in the 2013 Advanced Notice that the Government

Accountability Office (GAO) report that concluded effective concurrent DUR had not been fully implemented across the Part D program found that **two drugs** (hydrocodone and oxycodone) accounted for more than **80 percent** of the instances of potential doctor shopping. The AMA strongly agrees that combating potential prescription drug abuse and/or diversion is a pressing national priority. We, however, have serious concerns with the application of policies and programs that are designed to address prescription drug abuse/diversion to all prescription drugs and medications. This is especially troubling when the population of patients impacted will be elderly, more likely to be medically fragile, and less likely to be equipped to navigate the already bewildering array of Part D sponsor and pharmacy practices, policies, and requirements.

We strongly urge CMS to focus on the actual problem raised in the GAO report: possible prescription drug abuse or diversion of oxycodone and hydrocodone. As a threshold matter, we would urge CMS to acknowledge that physicians are best equipped to evaluate the medication needs of their patients and CMS should not promote the adoption of policies that substitute physician clinical judgment with that of sponsors. The Advance Notice states that:

Plan sponsors are in a unique position to evaluate medication overutilization. They are a central data collection point for beneficiary medication dispensing events, which may be generated from multiple providers and pharmacies, which may be unaware that a beneficiary is receiving the same drug (or therapeutic equivalent) simultaneously from different providers and pharmacies.

To the contrary, Part D sponsors are not in a position to evaluate medication overutilization. The only information they have is the various claims that are submitted for prescription coverage. Sponsors do not know diagnoses and they do not know about any other services the patient is receiving that do not involve Part D coverage. We acknowledge that there are instances where multiple prescribers and pharmacies are writing and dispensing medications to the same patient and unaware that the patient is receiving the same drug or similar drugs from other sources. **The best way to address that information gap is for the plans to share the information with the other prescribers so that these prescribers can reconcile the patient's multiple medications and ensure the beneficiary is getting appropriate care.**

To achieve the foregoing and to maintain the necessary balance between minimizing prescription drug abuse and diversion while promoting access to appropriate treatment, we recommend that CMS work with MA and Part D sponsors to partner with all of the state-based prescription drug monitoring programs (PDMP) in order to share prescribing information. We have strongly supported congressional and Administration efforts to increase funding for the adoption of PDMPs as well as for upgrades that provide real time access to physicians at the point of care.

Another effective strategy for addressing the information gap would be to require prescription drug plans to provide a copy of a patient's explanation of benefits (EOB) to all

of the physicians who have prescribed for the beneficiary. Prescription drug plans currently do not share any data or drug claims information with a patient's prescribing physicians. This would have the added benefit of increasing adherence/compliance and flag medication reconciliation needs or potential doctor shopping.

We strongly urge CMS to withdraw its proposal that, "in the event that a beneficiary's prescription drug claims for opioid analgesics cannot be established as medically necessary to the plans' satisfaction, the sponsor may implement beneficiary-level edits at point of sale (POS) at all pharmacies that result in the rejection of claims, or rejection of quantities in excess of plan established limits of opioid analgesics, for the beneficiary."

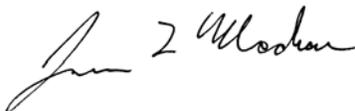
Sponsors should not be making clinical determinations and overruling physician prescribing judgments. This will engender significant confusion when beneficiaries pick up prescriptions and informed that their insurance plans have denied coverage. It has the potential to be highly disruptive to patient-physician relationships and undermine their mutual trust. Serious medical consequences would exist if Part D plans suddenly disallow legitimate prescriptions and create conditions leading to the under treatment of pain.

Accountable Care Organizations (ACOs)

In response to the 2013 Advance Notice provisions concerning ACOs, we urge CMS to provide ACOs and other innovative organizations the option of assuming responsibility for drug costs. The organizations can identify potential savings in drug costs, such as through greater use of generics, as well as areas where increases in drug costs through better adherence could potentially reduce expenditures elsewhere. At a minimum, CMS should provide Medicare ACOs with information on the Part D plans in which their attributed patients are enrolled, and provide those plans with information regarding the patients' assignment to the ACO. Similarly to our recommendation above, we recommend that prescription drug plans provide a beneficiary's EOBs to the patient's physician. Then the drug plan Pharmacy and Therapeutics Committees and the ACO physicians are in a position to collaborate and identify strategies to promote better adherence and lower costs.

Thank you for your consideration of these comments and recommendations. Should you have any questions, please contact Sandy Marks, Assistant Director, Division of Federal Affairs, at sandy.marks@ama-assn.org or 202-789-4585.

Sincerely,

A handwritten signature in cursive script, appearing to read "Jim L Madara".

James L. Madara, MD