AMA
AMERICAN MEDICAL ASSOCIATION

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November 30, 2016

Chad Buskirk, MPH
Health Insurance Specialist
Centers for Medicare & Medicaid Services
Medicare Drug Benefit and C&D Data Group
Mail Stop C1-24-23
7500 Security Blvd.
Baltimore, MD 21244-1850

RE: CMS-4183-N; Medicare Program; Implementation of Certain Medicare Part D Provisions in the Comprehensive Addiction and Recovery Act of 2016 (CARA)

Dear Mr. Buskirk:

On behalf of the American Medical Association (AMA), thank you for the opportunity to provide our perspective on certain topics related to the implementation of section 704 of CARA. The listening session that the Centers for Medicare & Medicaid Services (CMS) convened on November 14 was helpful and the AMA participants appreciated the opportunity to hear the perspectives of other interested stakeholders.

1. Clinical guidelines indicating misuse or abuse of frequently abused drugs.

   As the recent report from the U.S. Surgeon General on facing addiction describes in a clear and compelling manner, addiction is a chronic brain disease that needs to be diagnosed, treated, and managed like other chronic conditions. The appropriate clinicians to develop clinical guidelines for managing this condition are those who specialize in the diagnosis and treatment of addiction. It is not appropriate for CMS to seek clinical guidelines from Part D plan sponsors. In addition, the terms "misuse" and "abuse" are vague and could encompass a variety of issues associated with drugs. The Overutilization Management System currently in effect focuses on patients' use of prescription opioid analgesics. But the terms "misuse," "abuse," and "frequently abused drugs" suggest other considerations as well. For example, are there patients with Medicare Part D who are using heroin or other substances that are not prescribed to them? For clinical guidelines to address this issue, CMS would clearly need to rely on specialists in addiction medicine to advise the agency on the best methods to identify, diagnose, and treat this type of substance use disorder. In addition, <u>treatment</u> of substance use disorders is crucial; it is not enough to seek guidelines on indicators of misuse or abuse.

2. Impact of drug management programs for at-risk beneficiaries on cost-sharing and access.

   The structure of Part D formularies generally provides for patient cost-sharing to be the same for a particular medication regardless of which in-network pharmacy the medication is purchased from. If

patients become restricted to one or more pharmacies, however, and are not able to obtain exactly the same medications they were receiving before due to different supply issues, they should be able to maintain the same cost-sharing they had before the restrictions were imposed. Patients should also be fully informed about financial arrangements between pharmacy benefit managers, payers, and pharmacies to discourage inappropriate assignment to a pharmacy based on financial considerations that may not be in the patient's best interests. With regard to access, it is critical that exception processes be in place in the event that a patient who is in some type of management program has to go to the emergency department or is hospitalized, or is referred to a specialist for a new problem. Clearly care needs to be coordinated so that prescribers know what other conditions and medications patients already have, but it should not be so restricted that patients lack access to medically necessary care. The same considerations would apply for a patient identified as at-risk who travels, moves, and/or changes caregivers.

3. Use of an expedited appeals process for enrollees to appeal their status as "at risk for prescription drug abuse."

   Many physicians and patients have given up on the appeals process. CMS audits of Part D appeals show that plans have little incentive to properly handle appeals and the consequences for failing to do so are minimal. Massive failures have been cited by CMS for failure to provide adequate explanations of denials, and failure to conduct adequate outreach and provide required notice. Frequently, appeals are classified by plans as complaints with no further action taken. CARA adds a new set of duties to this already dysfunctional system. In its March 2014 Report, the Medicare Payment Advisory Commission observed:

   > Our focus groups with beneficiaries and physicians and interviews with beneficiary counselors revealed general confusion and frustration with the process. For example, the majority of beneficiaries were not aware that they could ask for an exception or appeal a plan decision, nor could they understand how the appeals process works. Physicians often found plan exceptions and appeals processes frustrating, noting that some plans' processes are particularly burdensome. Beneficiary counselors reported that they treated the exceptions and appeals process as a last option and often helped beneficiaries find alternative ways to access their medications—for example, by directing them to manufacturers' assistance programs. While the exceptions and appeals process must ensure that exceptions are granted only for clinically appropriate cases to protect the tools that plans use to manage the benefit, these findings suggest a need for increased transparency and streamlining of the processes involved so that beneficiaries and physicians are not discouraged from seeking exceptions for needed medications. (Page 369)

4. Enrollees who should be exempted.

   Patients receiving hospice or palliative care, those with a terminal condition who may not have elected hospice care, patients with cancer, patients in a hospital, SNF, long-term care facility or similar facility, and patients receiving medication-assisted treatment for substance use disorders

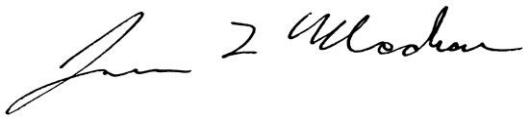
should be exempt from identification as at-risk beneficiaries.

5. Information to include in notices sent to at-risk beneficiaries.

   The best way for patients to learn about identified risks associated with their medications is from their physician(s). Notices sent by a Part D sponsor to patients or patients' caregivers who have not discussed the drug risks with their physicians will interfere with patient-physician relationships, harm trust, and potentially lead patients to abruptly discontinue therapy. Patients with substance use disorders need to be referred for treatment. There needs to be hands-on coordination of patient care which a letter from a Part D plan simply cannot accomplish. Part D sponsors have patients' prescription drug claims; they do not have access to patients' medical histories, test results, treatment plans, and progress reports. They are not in a position to communicate effectively with patients about these issues.

Thank you for the opportunity to share our views. If you have any further questions, please contact Sandy Marks at sandy.marks@ama-assn.org or 202-789-4585.

Sincerely,



James L. Madara, MD