AMA
AMERICAN MEDICAL ASSOCIATION

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Ms. Amy K. Larrick
Acting Director
Medicare Drug Benefit and C&D Data Group
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244-1850

Re: Draft Revisions to Medicare Prescription Drug Benefit Manual – Chapter 6

Dear Ms. Larrick:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to submit comments on the Centers for Medicare & Medicaid Services (CMS) draft revisions to Chapter 6 of the Medicare Prescription Drug Benefit Manual. Although the AMA is not a drug plan sponsor, the Association has worked with senior officials at CMS for a number of years to improve Part D program policies and has commented on Part D issues included in proposed rulemaking and annual Call Letters.

Several of the proposed revisions address longstanding physician concerns and we welcome their adoption by the agency. Foremost, among these is the proposed revision to the transition fills policy, 30.4.10.1. Prescriber Notification of Transition Fills. The AMA strongly urges CMS to finalize this proposed revision. One of the major weaknesses of the Part D program is that physicians receive little to no information from prescription drug plans about their patient's experience filling their prescriptions. With just a 30-day transition fill available in the first 90 days after a patient changes plans, it is important for physicians to receive timely notification if their patient needs to obtain a formulary exception, satisfy a drug utilization management requirement, or switch to a different medication within the class. The proposed prescriber notification represents a much stronger beneficiary protection than exists in the current program and can help to lessen the number of problems that arise when patients change plans.

The AMA also urges CMS to finalize the new language in the manual concerning non-allowable practices on prior authorization forms. This manual revision would prohibit prescription drug plans from imposing: requirements more restrictive than CMS-approved prior authorization criteria; limited access or step therapy restrictions inconsistent with the CMS-approved formulary; quantity limits inconsistent with maximum dosing approved by the Food and Drug Administration (FDA) or inconsistent with the CMS-approved formulary; prior authorization criteria not submitted for CMS approval; as well as steering of physicians or patients to drug plan's own mail order or specialty pharmacy. These are excellent revisions which the AMA supported when originally proposed and the AMA applauds their implementation.

There are also two areas where revisions are proposed in Chapter 6 that are problematic. The AMA understands that CMS efforts to address overutilization of opioid analgesics may lead to coverage limitations for these drugs for particular beneficiaries. In previous comments, the AMA has opposed the imposition of coverage limits based on daily morphine equivalent doses (MED). The statement in the proposed revision that sponsors may apply quantity limits to opioids even though there is no clearly defined maximum dose in the approved labeling is therefore concerning. Patients with cancer and other conditions that can cause severe pain, for example, may be prescribed a rescue dose for flare ups that would cause them to exceed the MED limits set by the sponsor. An additional drug in the opioid class also may be prescribed because of an adverse reaction to a previously prescribed drug, or due to increased tolerance and corresponding need for opioid rotation. A conversation with the patient's prescriber or a prior authorization requirement for doses above a certain MED would allow the plan to learn whether or not the dose was appropriate for the patient. In the absence of an accepted standard from the FDA, however, quantity limits tied to MED would essentially be arbitrary and could leave medically fragile patients without access to critically important medications.

In addition, the AMA recommends that CMS withdraw the draft directive that Part D plan "should consistently utilize prior authorization (PA) for drugs with the highest likelihood of non-Part D covered uses." Unfortunately, Medicare is a very fragmented program. It simply is not possible to use a rule-of-thumb approach for when a drug will be covered under Part A, B, or D. Confusion about Part B vs. D coverage has existed since the program began. Prior authorization is extremely burdensome for physician practices. The proposed rule-of-thumb approach is likely to place a particularly heavy PA burden on physicians who are managing care for the sickest Medicare patients: those with cancer and other conditions who may be treated with chemotherapy agents that could be covered under either Parts B or D, those who may be in and out of Part A nursing home stays, and those entering hospice care at the end-of-life. Neither these patients nor their physicians should have to be burdened with excessive PA requirements. It should not be difficult for plan sponsors that have questions about the patient's care to contact the prescriber's office for additional information.

The AMA appreciates the opportunity to offer our perspective on the draft revisions to Chapter 6 of the Medicare Prescription Drug Benefit Manual and we look forward to continuing to work with CMS to improve Part D policies. Should you have any questions, please feel free to contact Sandy Marks, Assistant Director, AMA Federal Affairs, at sandy.marks@ama-assn.org or 202-789-4585.

Sincerely,

James L. Madara, MD

cc: Jeffrey Kelman, MD