AMA
AMERICAN MEDICAL ASSOCIATION

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The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
Attention: CMS-3346-P
P.O. Box 8010
Baltimore, MD 21244

Dear Administrator Verma:

On behalf of our physician and medical student members, the American Medical Association (AMA) appreciates the opportunity to provide comments on the proposal to require drug pricing transparency. As you know, patient access to affordable prescription medication is a top priority for AMA members and their patients. With drug prices reaching unaffordable levels for many patients, drug price and cost transparency play a key role in not only helping policymakers make sound drug pricing policy decisions, but in helping patients understand their potential costs so that they can make the best treatment decisions for themselves and their families.

We applaud the Administration for prioritizing drug pricing and cost issues and taking steps to help improve transparency in this area. The AMA supports action that would require pharmaceutical manufacturers to disclose the wholesale acquisition cost, or "list price," of their products in any advertisements. Disclosure of the list price to consumers will provide patients with a new level of information and transparency previously unavailable that can assist patients in making treatment decisions. While we understand that the list price of a particular drug does not necessarily represent the actual cost of the drug to the patient, it can provide patients with a financial baseline to consider and can assist them as they work with their physician to determine their best course of treatment. It can also empower them to take the first steps to contact their health plan to find out more information about their drug coverage and potential out-of-pocket costs, helping to avoid "sticker shock" when arriving at the pharmacy or physician's office.

We are concerned, however, that the proposal does not include a valid enforcement mechanism for the proposed requirements. Inclusion on a published list of violators or the threat of lawsuits from competitors is insufficient to ensure compliance. As pharmaceutical price and cost transparency is a key component of creating a healthy and functioning marketplace, we urge the Centers for Medicare & Medicaid Services to consider additional enforcement mechanisms that can better compel compliance with the proposed transparency requirement.

<u>Improving Prescription Drug Price and Cost Transparency</u>

The AMA encourages prescription drug price transparency among all key players in the pharmaceutical market, including pharmaceutical companies, pharmacy benefit managers, and health insurers. While the

reasons for prescription drug price increases are complicated and varied, manufacturers, pharmacy benefit managers, and payors all contribute to prescription drug price increases that have negative impacts on patient cost-sharing, drug tiering decisions, prior authorization policies, mid-year formulary changes, and medication adherence by patients. In addition to the proposal requiring disclosure of drug list prices, the AMA urges the Administration to consider additional policy proposals aimed at increasing prescription drug price and cost transparency, such as:

- Require pharmaceutical manufacturers to provide public notice before increasing the price of any drug (generic, brand, or specialty) by ten percent or more each year or per course of treatment and provide justification for the price increase;
- Require pharmaceutical manufacturers to publicly disclose a variety of information, which could include research and development costs; clinical trial expenditures; total costs incurred in production; and marketing and advertising costs;
- Improve transparency in formularies, prescription drug cost-sharing, and utilization management requirements;
- Make formulary requirements and restrictions easily accessible by patients and prescribers;
- Unless made for safety reasons, prohibit mid-year formulary changes;
- Increase transparency at the point of prescribing by providing physicians with timely, accurate, and complete information on drug formularies and drug utilization management policies at the point-of-care in electronic health records, without imposing additional health information technology costs or burdens on physicians; and
- Provide additional education regarding formularies, cost-sharing, utilization management policies at the time of plan enrollment, including the use of online prompts and the provision of examples of patient cost-sharing responsibilities for prescription drugs.

The AMA applauds the work of the Administration to increase transparency in the pharmaceutical marketplace, and urges the Administration to finalize the proposed rule with additional consideration given to bolstering enforcement mechanisms for manufacturers not in compliance. We also urge the Administration to consider taking additional steps to ensure transparency across the pharmaceutical marketplace to help provide policymakers, patients, and providers with the information they need to make the best decisions and be good stewards of health care financial resources.

The AMA looks forward to continuing to work with you to address this critical issue. If you should have any questions regarding these comments, please feel free to contact Shannon Curtis, Assistant Director, Federal Affairs at shannon.curtis@ama-assn.org or 202-789-8510.

Sincerely,

James L. Madara, MD