AMA
AMERICAN MEDICAL ASSOCIATION

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The Honorable Frank Pallone, Jr.
Chairman
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Richard E. Neal
Chairman
Committee on Ways and Means
1102 Longworth House Office Building
Washington, DC 20515

The Honorable Greg Walden
Ranking Member
Committee on Energy and Commerce
2322A Rayburn House Office Building
Washington, DC 20515

The Honorable Kevin P. Brady
Ranking Member
Committee on Ways and Means
1139E Longworth House Office Building
Washington, DC 20515

Dear Chairmen Pallone and Neal and Ranking Members Walden and Brady:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to respond to the request for comments on the Medicare Part D Prescription Drug program (Part D program) as well as to provide comments on the draft legislation that would establish an out-of-pocket cap for Medicare beneficiaries. In short, the AMA strongly supports efforts to address the high price of prescription medication as well as the growing barriers to access faced by patients and their health care team. The concerns of physicians around the nation have only deepened over the past decade as the price of prescription drugs has inexorably and often inexplicably climbed. Physicians continue to report that their patients, including Medicare beneficiaries, struggle to pay for their prescription medication and increasingly are burdened by insurer utilization management programs that also delay and block access. We look forward to working with you to develop solutions that help patients.

The AMA supports the provision of the draft legislation that would create an out-of-pocket maximum on prescription drugs costs for Medicare beneficiaries in the Part D program based on the current catastrophic threshold. The draft language would also alter Medicare's share of the catastrophic coverage from 80 percent to 20 percent over four years. The AMA underscores that it will be important to understand how these provisions of the draft legislation would impact premiums and other program policies that could affect access. We are concerned that while the intent of the draft legislation is to reduce costs for taxpayers and Medicare beneficiaries, the presumed shift of expenses to pharmaceutical manufacturers and Part D plans could have the unintended consequences of raising premiums and/or increase plans' use of utilization management restrictions. The ultimate goal should be to ensure patient access to medically necessary and affordable treatment options. The escalating cost and complexity of obtaining prescription medication undermines patient adherence, timely access, health outcomes, and increases the overall cost to the health care system. Patients who cannot afford their medication will eventually require medical interventions in more-costly care settings, such as emergency departments, when their condition is at a more advanced stage of disease or acuity. These high prices continue to occur among all segments of the market from innovator biologics to previously low-cost established generics.

Physicians see every day that costs have become a major barrier to our patients getting the right medication at the right time.

As Congress considers modifications to the Part D program, however, we would also caution that stripping out important patient protections and implementation of utilization management programs also deny patient access and increase costs to the health care system. For example: the Centers for Medicare & Medicaid Services (CMS) finalized portions of the *Modernizing Part D and Medicare Advantage (MA) to Lower Drug Prices and Reduce Out-of-Pocket Expenses* proposed rule. The final rule makes changes to the Part B drug benefit for MA plans and the Part D program. The final rule permits indication-based formulary design. The foregoing allows Part D plan sponsors to exclude protected class drugs for indications that are not protected class indications and permits variable coverage of drugs based on the condition being treated. The AMA has expressed concerns with indication-based formulary design, as it has the potential to exponentially increase confusion surrounding formulary information for both physicians and Medicare patients. For the MA program, the rule finalizes parameters of earlier policy changes allowing MA plan sponsors to utilize step therapy for Part B physician-administered drugs. The AMA continues to have pronounced concerns that these changes will negatively impact the most vulnerable patient populations, drive poor outcomes, and increase overall costs. We urge Congress to scrutinize these provisions which impede patient access to timely treatment, can fragment care, and drive higher administrative costs.

The AMA has continued to express our concern that commercial health insurers respond to high prescription medication costs by increasing premiums and cost sharing as well as imposing administrative barriers, such as frequently changing formularies, step therapy requirements, and prior authorization requirements. Physicians and their staff will frequently undertake multiple steps before their patient is able to receive their medically necessary medication, including: finding clinically appropriate but more affordable alternatives; identifying and applying for discounts or patient assistance programs; and filing appeals or exception requests. These are compounded by antiquated insurer communication methods to process utilization requirements and appeals/exception requests including faxes, non-standardized forms, and understaffed telephone call lines that can include limits on the number of requests.

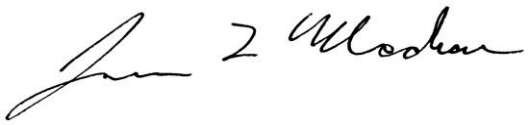
Physicians and practice staff around the nation now spend the equivalent of several workdays each week responding to prior authorization and exceptions request rejections even for common medications. As detailed in the 2018 AMA Prior Authorization Physician Survey, practices report completing an average of 31 prior authorizations per physician per week, a workload that consumes 14.9 hours—nearly two business days—of physician and staff time every week. The growing maze of insurer utilization control requirements delay treatment for patients, consume time physicians could be spending with other patients, and add costs to the health care system as a whole. As a result, finite resources are diverted away from direct patient clinical care to a large volume of paperwork, emails, facsimiles, and phone calls. Administrative burdens have led to increasing delays in medically necessary care, which can have grave consequences for patients' health. In the AMA survey, 28 percent of physicians reported that prior authorization has led to a serious adverse event (e.g., hospitalization, disability, or even death) for a patient in their care. Utilization management requirements thus not only drive up practices' administrative expenses but can also increase overall care costs when a patient's condition deteriorates during paperwork-induced delays.

In light of the foregoing, it is essential that any proposed policy to address escalation in prescription drug costs should be evaluated to ensure:

- lower price prescription drugs for patients and policies are targeted to reduce hardship for those with low-incomes and those with catastrophic costs;
- increased transparency along the pharmaceutical supply chain;
- increased competition and production capacity in all segments of the pharmaceutical and biological markets;
- a substantial decrease in administrative and red tape burdens to obtain medically necessary treatments faced by patients, physicians, pharmacists, and other members of the health care team; and
- physicians and pharmacists are not financially penalized as an indirect mechanism to lower prescription medication prices nor favor a site of service.

We thank you for the opportunity to comment and look forward to supporting the legislative efforts.

Sincerely,



James L. Madara, MD