American Thoracic Society

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Alex Azar
Secretary
Department of Health and Human Services
200 Independence Ave.
Room 600E
Washington, DC 20201

RIN 0991-ZA49

Dear Secretary Azar:

The American Thoracic Society (ATS), an international medical society of 16,000 specialists in pulmonary, critical care and sleep medicine, appreciates the opportunity to submit comments on the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. We have the following comments on the Blueprint:

Section A. Biosimilar Development, Approval, Education and Access. What types of information and educational resources on biosimilar and interchangeable products would be most useful to health care professionals and patients to promote understanding of these products?
In respiratory medicine, measures that help encourage cross coverage between biosimilars are educational materials disseminated by professional societies on specific therapeutics such as inhalers. An issue that impacts interchangeability of biosimilars for patients in respiratory medicine is specific delivery devices. For example, dry inhaled powdered inhalers can be very difficult for patients with severe obstructive lung disease to use, so patients need access to a bio similar. The Department, through the Agency for Healthcare Research and Quality, should continue working with professional organizations to support the development and dissemination of patient educational materials on biosimilars and interchangeable products.

Section B. Better Negotiation: **Proposal to change Part D plan formulary standards to require a minimum of one drug per category or class rather than two**
The ATS is concerned that this proposal could create access barriers for patients with rare or uncommon diseases for which few therapeutic options exist or for conditions in which biomarkers can be used to optimize treatment.

Under the first scenario, patients who fail to respond to one drug or who experience adverse events may find it difficult (either in access or expense) to obtain an alternative. In the second, a biomarker may identify patients who respond more strongly to one therapeutic agent than another. In both of these instances, if the more effective drug is not on the formulary, patients may experience an access barrier to medically necessary treatment. For example, patients with severe asthma who have high levels of peripheral eosinophils respond well to some of the new immunologics. Although these medications can be costly, they have a steroid sparing effect that reduces adverse consequences from the treatment. Examples of other conditions where access to more than one drug per category is beneficial are cystic fibrosis and lung cancer.

Proposal to permit participating states to determine their own drug formularies, coupled with an appeals process to protect beneficiary access to non-covered drugs based on medical need.

The ATS is concerned that under this proposal some states would craft drug formularies with differential impact by race, sexual orientation, gender, or disease condition (e.g., HIV/AIDS) with the result that some access to critical drugs would be more difficult for some historically disadvantaged populations such as people living with HIV/AIDS and people with Hepatitis C.

Proposal to Evaluate options to allow high-cost drugs to be priced or covered differently based on their indication.

The ATS believes that this proposal could be potentially impactful for patients who are prescribed medications “off label” such as children. The ATS is concerned, however, that utilizing indication-based pricing could result in sub-optimal care for some patients with respiratory and other illnesses, including young children who rely on medications that are age-limited to adolescents to adults. We believe that in order to prevent financial access barriers for patients who rely on higher-cost drugs off-label, criteria for utilizing indication-based drug pricing would need frequent safety and cost-effectiveness evaluations of individual medications and flexibility in adjusting pricing structure. If these measures cannot be ensured by payors, the ATS would recommend against implementation of this proposal.

Proposal to Require Site Neutrality in Payment

Some patients with chronic respiratory illness may need to receive care at hospital- based facilities due to the complexity of their diseases and/or co-morbidities. Additionally, some patients are referred to hospital-based clinics because they require other healthcare services at the same time as another treatment. Utilizing hospital-based facilities can improve patient compliance with therapy because it is more convenient for patients to visit one point of care rather than several different facilities at different locations which may require more time from work and school. The ATS is concerned that a blanket site neutral payment policy may push patients that require care from hospital-based facilities to receive medications at a less expensive but less optimal setting.

Proposal to Reform Medicare Part D to give plan sponsors significantly more power when negotiating with manufacturers.

The ATS believes that providing the Medicare and Medicaid programs with additional authority to negotiate drug prices with manufacturers could be an effective mechanism to lower some prices for drugs for life-threatening conditions. However, increased negotiation between federal program payors and manufacturers should not result in significantly increased drug prices for consumers with private insurance. The ATS recommends that the Department study the issue of increased negotiation with manufacturers for the Medicare and Medicaid programs.

Section C. Creating Incentives: Proposal to exclude manufacturer discounts from the calculation of beneficiary out-of-pocket costs in Medicare Part D Coverage Gap
Currently, allowing drug manufacturer discounts to apply to the Out-of-pocket (OOP) spending limit in the Medicare coverage gap (known as the "Donut Hole") accelerates patient passage through this gap and lowers the OOP spending. However, it ends up costing the federal government more because the drug has a higher list price when patients exceed the catastrophic spending limit and Medicare takes on a larger share of the costs. Under the Affordable Care Act (ACA), the Medicare Donut Hole is scheduled to be closed in 2020. But the ATS is concerned that if this proposal is implemented prior to 2020, it could potentially increase OOP costs for some patients.

Proposal to Evaluate Requiring Manufacturers to Include List Prices in Advertizing
Although this proposal may appear to be a good price transparency measure, in reality, only a consumer, who is self-paying for a medication without any health insurance, or Medicare or Medicaid coverage, will pay the list price for a drug. The ATS has a concern that listing drug list prices in advertising may deter some consumers from securing needed medications for serious life-threatening conditions**.**

Section D. Reduce Patient OOP Spending. Proposal to prohibit Part D plan contracts from preventing pharmacists from telling patients they could pay less if they do not use health insurance to pay for a drug.
We believe that permitting pharmacists to inform consumers that purchasing drugs out-of-pocket rather than through insurance coverage may be cheaper may lower drug costs, such as older off-patent antibiotics, for some consumers. The ATS supports proposals such as this to promote price transparency and related information about insurance drug coverage for consumers and urges the Department to move forward with implementing this proposal as policy.

Other Feedback: What other policies or legislative proposals should HHS consider to lower drug prices while encouraging innovation?
The ATS believes that state initiatives - such as one being tested by New York whereby the state sets spending growth caps for Medicaid prescription drugs and if the cap is exceeded, opens pricing negotiations with the drug manufacturer - could provide useful models.

The ATS appreciates the opportunity to comment on the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs.

Sincerely,

Polly Parsons, M.D.
President
American Thoracic Society