TAG
Treatment Action Group

The Honorable Seema Verma
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, DC 20201

Re: Docket No. CMS-2018-0123, RIN 0938-AT87, Comments in Response to Proposed Rulemaking: Regulation to Require Drug Pricing Transparency CMS-4187-P

Dear Administrator Verma:

As an organization dedicated to ensuring vital access to affordable treatment for HIV, tuberculosis (TB), and hepatitis C virus (HCV), Treatment Action Group (TAG) lauds CMS's attention to curbing drastic increases in drug pricing. While we recognize the administration's efforts, the recent CMS proposed regulation mandating the publication of the list price, or wholesale acquisition cost (WAC), in direct-to-consumer advertising for prescription drugs and biological products paid by Medicare and Medicaid will not be sufficient in providing the necessary transparency needed to adequately and meaningfully address rising drug prices. This is due to a number of realities in both private insurance and public benefit healthcare programs.

WAC simply represents where drug pricing negotiations begin before different entities have a significant hand in lowering the price for U.S. consumers. As a direct result of the uniquely high cost of prescription drugs in the United States, numerous coverage entities have been developed to ensure that patients do not pay the full list price for their medications. A cascade of public programs, private insurers, pharmacy benefit managers, and employers help reduce the overall WAC - a price that a consumer may never ultimately see. In the case of people living with HIV in the U.S., an important patchwork of systems, from the Ryan White AIDS Drug Assistance Program (ADAP) to the Affordable Care Act (ACA), work together to make affordable access to lifesaving antiretroviral medications a reality. Publishing WAC pricing alone does not give sufficient transparency on the tremendous role that these systems play in driving down the WAC pricing and making expensive drugs accessible.

Since many of these coverage and payment assistance programs vary from drug to drug and from person to person, patients could sometimes pay a smaller amount for a medication with a higher list price.[i] Without being given this necessary information through DTC advertising, consumers might wrongly believe they should switch to a drug with a lower list price in order to save themselves money. This could be misleading, cause unforeseen treatment interruptions, or misinform decision making with information that is erroneous to U.S. patients. High WAC prices might also lead some patients to believe they should avoid seeking treatment for fear of high costs. Some legislators have charged that this concern does not place sufficient faith in the consumer to make rational choices, but this seems to disregard the reality that healthcare costs continue to drive many Americans to file for bankruptcy.[ii] When a consumer with few resources is deciding whether or not to seek care, an advertisement seeming to address their illness with a high WAC price tag may just be a sufficient deterrent.

Conversely, patients with higher incomes and greater resources may have the opposite reaction to the detriment of drug pricing. Recent studies have shown that, without sufficient information about the specific differences between one healthcare option and another, consumers sometimes rely on price as an indicator of quality and choose the higher-priced option.[iii] If enough patients follow this logic, drug prices may continue increasing in response.

While efforts to promote transparency on drug pricing is important, further ambitious steps are needed to help both untangle the complexities of drug pricing and inform policy measures that meaningfully curtail rising costs. The federal government should undertake efforts to improve consumer understanding of how taxpayer money often subsidizes the creation of many prescription drugs we see in the marketplace. Importantly, there are currently no market regulations to ensure that drug prices reflect the true costs of research and development, production, public incentives, or funding received from public programs and private foundations. While pharmaceutical companies claim that drug prices must remain high to recoup losses spent during research, such research is often funded by large public grants (including those from the NIH and other federal agencies).[iv] Once a drug has been developed with public dollars and then sold for a high price, taxpayers end up paying those costs twice.

To address this issue, consumers should be able to find information about the costs associated with drug development and the funding sources used during development. This would provide much more meaningful information to the American consumer and would contribute more efficiently to a decrease in drug costs by informing policies that subsequently hold the pharmaceutical industry accountable. Requiring companies to publish their development costs, instead of or in addition to advertising their list prices, would draw necessary attention to each company's profit margin and the unreasonably high prices for most prescription medications in the U.S. marketplace. This information can be valuable to build the negotiation power of the government to meaningfully drive down the cost of prescription drugs by intervening on behalf of the U.S. taxpayers, who have underwritten the development of many of these drugs.

In addition, proposals to hold pharmaceutical companies accountable for price increases through government action have been gaining traction amongst policymakers and consumer groups. If companies are given clear guidelines and limits for determining list prices and price increases, their compliance with these guidelines can be enforced by making them the contingency for patent licenses. This would be an extremely effective approach, as companies would likely prefer more modest price increases rather than losing their exclusive license.

Another effective approach would be to introduce price regulations similar to those already used and leveraged by Veterans' Affairs, Medicaid, and the 340B drug pricing program. These programs take proper advantage of the fact that certain agencies buy medications in bulk and, similarly to other suppliers who buy in bulk from a manufacturer, they pay a lower price per unit. This model could be successfully applied to other public insurance programs, large private insurers, and pharmacy benefit management programs who could then be compelled to pass their savings on to consumers. This strategy is one already used in many other countries to effectively control drug pricing through government negotiation.

17 December 2018
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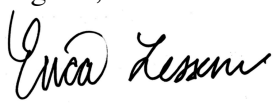
Administrator, Centers for Medicare & Medicaid Services (CMS)

In conclusion, we find that the proposed rule to publish WAC prices in DTC advertisements could be a step in the right direction, but it alone is not enough to address the fundamental root causes of high drug prices and may confuse consumers or impede health-seeking behaviors. Such rules would only be effective if implemented in tandem with other policies that build the federal government's negotiation power and establish price controls to lower the cost of prescription drugs. In addition to publishing WAC prices, more data points on drug pricing are needed and companies should be required to report their production costs to inform better understanding of how prices are determined. This would also help inform taxpayers of the ways in which their tax dollars are used to develop drugs and other public incentives received. Regulators should also then leverage this information to develop informed policy and use their power to negotiate better prices, and more broadly to determine fair pricing guidelines and hold companies accountable. Driving down costs directly will ultimately help ease strain on vital coverage entities such as Medicaid and Medicare that unsustainably attempt to keep up with rising drug costs.

Thank you for the opportunity to submit public comments on the proposed rulemaking, and we hope you commit to further action that is required to effectively control drug pricing. Please do not hesitate to contact Erica Lessem at erica.lessem@treatmentactiongroup.org for further information.

Signed,



Erica Lessem
Deputy Executive Director of Programs, Treatment Action Group (TAG)

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[i] If paying copayment, rather than coinsurance.

[ii] Dickman S, Himmelstein D, Woolhandler S. Inequality and the health-care system in the USA. The Lancet 2017 Apr 8-14;389(10077):1431-1441. https://www.sciencedirect.com/science/article/pii/S0140673617303987.

[iii] Kaiser Family Foundation. 2008 update on consumers' views of patient safety and quality information: summary and chartpack. Menlo Park (CA): KFF; 2008 Oct. http://www.kff.org/kaiserpolls/upload/7819.pdf.

[iv] Galkina Cleary E, Beierlein JM, Khanuja NS, McNamee LM, Ledley FD. Contribution of NIH funding to new drug approvals 2010-2016. Proc Natl Acad Sci U S A. 2018 Mar 6;115(10):2329-2334. http://www.pnas.org/content/early/2018/02/06/1715368115.