

December 17, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: CMS—4187—P, Medicare and Medicaid Programs; Regulation to Require Drug Pricing Transparency; Proposed Rule (Vol. 83, No. 202), October 18, 2018.

Dear Ms. Verma:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed regulation to require drug pricing transparency in direct-to-consumer (DTC) television advertisements. We support CMS's proposal and encourage the agency to rein in skyrocketing drug prices for patients and the providers who serve them.

Requiring drug companies to disclose list prices of their drugs in DTC television advertisements is an important component of addressing the larger issue of unsustainable growth in overall drug pricing. We appreciate CMS's focus on this issue, and we believe this proposal represents an important first step in bringing more transparency to drug pricing. Further, the specific provisions outlined in this proposed rule are consistent with drug price solutions for which the AHA will continue to advocate.

In the proposed rule, CMS provides evidence of the challenges high and rising drug prices create for patients, providers and health care purchasers. The agency estimates that prescription drug spending in the U.S. grew to approximately \$457 billion in 2015, which equates to almost 17 percent of overall spending on personal health care services. Taxpayers finance more than half of that amount on behalf of Medicare and Medicaid beneficiaries. **These numbers continue to grow at an unsustainable rate**



far above the rate of inflation.¹ The public has been clear: more than 80 percent of the American public says that prescription drug costs are “unreasonable.”²

Despite this outcry, drug manufacturers continue to take advantage of a complicated system to extract high prices. Recent efforts by some manufacturers to implement price freezes or smaller price increases do not illustrate a commitment to addressing this issue. Price freezes have shown to be temporary, and the smaller price increases seen in 2016 and 2017 follow years of double, triple and even quadruple digit price increases. For example, after canceling its plans to raise drug prices in the summer of 2018, Pfizer announced that it would raise prices on 41 drugs in January of 2019.³ Additionally, while Daraprim has not experienced recent price increases, in 2015 it saw a staggering 5,000 percent price increase from \$13.50 a pill to \$750 a pill; however, the astounding and unjustified change in price continues to present potential access to care barriers and financial burdens.⁴ Therefore, we need policy action to achieve relief for patients and other drug purchasers.

The AHA supports CMS’s focus on DTC advertising as one place where policy changes could advance efforts to achieve sustainable drug prices. The U.S. is only one of two countries in the world that allows DTC advertising for drugs. Other countries have limited such advertising due, in part, to concerns about the lack of objectivity of information in such advertisements. For example, the European Commission in 2008 found that, “[t]here was overall consensus that there is a need to provide patients with understandable, objective and high-quality information on drugs;” however, the DTC advertising ban in Europe should remain in place, “making sure that there is a clear distinction between advertising and non-promotional information.”⁵ It is clear that DTC advertising works: drug manufacturers spend billions of dollars per year on such ads. For instance, the pharmaceutical industry spent \$6.4 billion on DTC advertising in 2016 alone.⁶ In fact, marketing, including, but not limited to DTC advertising, is so important to manufacturers that they spend more on it than on research and development of new drugs.⁷ Given that more than half of all drug revenue is from taxpayer dollars for programs administered by CMS, of which a significant portion is spent on advertising, the agency has appropriate standing to address this issue.

¹ Purvis, L. & Schondelmeyer, S.W. (September 2018) *Brand Name Prescription Drug Prices Increase Four Times Faster than Inflation in 2017*. Retrieved from <https://www.aarp.org/content/dam/aarp/ppi/2018/09/brand-name-prescription-drug-prices-increase-four-times-faster-than-inflation.pdf>

²Kaiser Health Tracking Poll – March 2018: Views on Prescription Drug Pricing and Medicare-for-all Proposals,” Ashley Kirzinger et al., Kaiser Family Foundation, March 23, 2018

³ https://www.washingtonpost.com/business/economy/2018/11/16/45831a82-e9b7-11e8-b8dc-66cca409c180_story.html?utm_term=.ce063b0e553b

⁴ https://www.washingtonpost.com/news/wonk/wp/2017/08/01/what-happened-to-the-750-pill-that-catapulted-pharma-bro-martin-shkreli-to-infamy/?utm_term=.a17f7ff19be1

⁵ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2661977/>

⁶ <https://www.usatoday.com/story/money/2017/03/16/prescription-drug-costs-up-tv-ads/99203878/>

⁷ https://www.washingtonpost.com/news/wonk/wp/2015/02/11/big-pharmaceutical-companies-are-spending-far-more-on-marketing-than-research/?utm_term=.8063a506e1f0

This proposed rule contains a series of specific provisions that we agree could help address drug price increases. Providing patients with some understanding of the price of a particular drug therapy could help make them more informed when in discussions with their doctors about the appropriate course of care. We also agree that the pricing information provided should be for either a typical 30-day regimen or typical course of treatment, as long as this information is clearly articulated in the advertisement. Additionally, we support the \$35 per month threshold as a good starting point for when such requirements would apply. The \$35 threshold would likely target those drugs that have the most significant financial impact on patients.

The AHA also supports CMS's initial focus on television advertisements, as the vast majority of DTC drug advertisements appear on television. However, over time, we recommend that the agency broaden the scope of these requirements to cover additional advertising mediums. As platforms for advertising continue to change and evolve, it is important that all potentially applicable forms of advertising be considered, including print, radio and digital media.

In addition, the AHA supports CMS's intent to require that the price stated in the advertisement be correct as of the date of publication or broadcast. This is a common sense provision that would ensure drug companies are not able to deceive consumers with outdated information or last minute changes to prices. Through this requirement, the agency would make clear its intention to protect consumers and hold drug companies accountable for their actions. Further, in addition to requiring the price be current, the AHA encourages the agency to ensure that the required font, text size, location, and duration of the disclosure provide consumers with adequate opportunity to notice and comprehend the price-related information.

Finally, we support CMS's proposal for the Department of Health and Human Services to create, manage and maintain a public list of all pharmaceutical companies found to be in violation of this rule. Drug manufacturers who are neglectful of or willfully refuse to meet the requirements of this proposed rule should be held publicly accountable. In addition, this information can support Congressional and other oversight efforts of drug manufacturer behavior.

Again, the AHA commends CMS for its work on this issue and looks forward to additional regulatory action to lower drug prices. We welcome further opportunities to engage with the agency on these issues.

Please contact me if you have questions or feel free to have a member of your team contact Mark Howell, senior associate director, policy, at mhowell@aha.org or (202)-626-2274.

Ms. Seema Verma
December 17, 2018
Page 4 of 4

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President