



December 17, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Service
200 Independence Avenue, Southwest
Washington, DC 20201

RE: CMS-4187-P

Dear Administrator Verma:

The Campaign for Sustainable Rx Pricing (CSRxP) is a nonpartisan coalition of organizations committed to fostering an informed discussion on sustainable drug pricing and developing bipartisan, market-based solutions that promote competition, transparency, and value to improve affordability while maintaining patient access to innovative prescription drugs that can improve health outcomes and save lives. Our members represent organizations including consumers, hospitals, physicians, nurses, pharmacists, employers, pharmacy benefit managers and insurance providers.

Prescription drug prices are needlessly high for U.S. consumers and continue to grow at unsustainable rates. One in four Americans cannot afford their medications. Excessively high prices place significant burden on taxpayers and unfairly threaten the financial security, health and wellbeing of U.S. patients and their families every day. Too often patients are faced with the unfortunate choice of purchasing the medications they need to get well and stay healthy and buying groceries for their families. Patients should never be presented with such a choice. It is therefore imperative that actions be taken to lower out-of-control drug prices and make prescription drugs more affordable for consumers.

As such, CSRxP applauds and welcomes policies from the Centers for Medicare & Medicaid Services (CMS) that will lower drug costs for consumers and taxpayers by meaningfully improving price transparency and generating increased competition in the marketplace. We therefore strongly support the Agency's proposed rule to require disclosure of list prices in direct-to-consumer (DTC) advertising for prescription drugs and biological products (herein "drugs") reimbursable under Medicare and Medicaid entitled "Medicare and Medicaid Programs; Regulation to Require Drug Pricing Transparency" (CMS-4187-P).

CSRxP firmly agrees with CMS that DTC advertising contributes to the overutilization of prescription drugs – especially high-cost drugs whose prices are growing at a particularly accelerated pace – leading to unaffordable out-of-pocket costs for consumers and excessive, unnecessary spending by the Medicare and Medicaid programs. We strongly believe that including list prices in DTC advertising will engender more market competition and lower list prices, as well as provide critically important information to patients as they discuss with their providers the most medically appropriate and cost-effective treatment options for their individual healthcare needs. CSRxP thus welcomes CMS's proposed rule and offers comments of strong support for proposed policies that would:

1. Require inclusion of list prices in DTC television advertisements for prescription drugs and biological products available under Medicare and Medicaid;
2. Mandate inclusion of list prices for drugs payable under Medicare and Medicaid in all other types of DTC advertising including radio, magazines, newspapers, internet websites, and other forms of social media;
3. Require that DTC advertisements display list prices in a consumer-friendly manner by presenting them in an easily readable format and reflecting a 30-day regimen or typical course of treatment, as appropriate;
4. Enhance and expand drug pricing information available to consumers in the Medicare and Medicaid Drug Dashboards;
5. Potentially establish in the future a new payment code in the Medicare Physician Fee Schedule to incentivize practitioners to engage with patients about their out-of-pocket prescription drug costs once real-time pharmacy benefit information tools are validated and embedded in a prescriber's electronic health record platform;
6. Use Wholesale Acquisition Cost (WAC) as the "list price" to meet the disclosure requirements specified in the rule; and
7. Exempt drugs with a cost of \$35 or lower per month from the requirements in the rule.

CSRxP's comments reflect our strong desire to work effectively with CMS to implement bipartisan, market-based policies that improve prescription drug affordability. Without increasing transparency and taking other critically important actions to lower drug prices, consumers and taxpayers will continue to face the unsustainable growth in drug costs that are already out-of-control.

1. Inclusion of Drug List Prices in DTC Television Advertisements

CSRxP strongly supports CMS's proposal to require inclusion of list prices in DTC television advertising for prescription drugs available under Medicare and Medicaid. Mandating disclosure of list prices in DTC television advertisements will significantly enhance drug price transparency and make publicly available critically important information that will: (1) lower drug prices and costs for consumers; (2) improve and enhance healthcare decision-making between patients and providers; and (3) increase the efficiency of the Medicare and Medicaid programs.

First, CSRxP believes that making drug pricing information more transparent will result in increased competition in the marketplace, ultimately lowering drug costs for consumers and taxpayers. We share the Agency's view that requiring list prices to be publicly available in the widely used format of DTC advertising "will provide manufacturers with an incentive to reduce their list prices by exposing overly costly drugs to public scrutiny."¹ We further agree with CMS "that when better price information is available prices for goods sold to consumers fall."² Taken together, these two elements will drive increased competition and have the significant potential to meaningfully lower list prices over time. This critically benefits patients who take the expensive medications, as their cost-sharing typically derives from a drug's list price. This also importantly benefits all consumers – even those not taking a specific medication – by slowing the rate of growth or reducing their insurance premium amounts allocated to prescription drug coverage.

Second, CSRxP strongly concurs with CMS that making publicly available drug list prices will substantially improve healthcare decision-making between patients and providers and better facilitate the selection of treatment options that best meet the patient's individual healthcare needs in a cost-efficient manner. While DTC advertising can make patients aware of treatment options that they otherwise may not be aware of, DTC

¹ 83 FR 52792

² 83 FR 52790

advertising also very problematically can lead to the over and unnecessary utilization of prescription drugs, particularly high-cost drugs. CSRxP agrees with the Agency that expanding price information available to patients will help limit the unnecessary drug use, as patients will be much more aware of their medical costs and potentially consider more cost-effective treatment alternatives as a result. Indeed, CSRxP concurs that “[a]rming a beneficiary with basic price information will provide him or her with an anchor price, in other words, a reference comparison to be used when making decisions about therapeutic options. Triggering conversations about a particular drug or biological and its substitutes may lead to conversations not only about price, but also efficacy and side effects, which in turn may cause both the consumer and prescriber to consider the cost of various alternatives (after taking into account the safety, efficacy, and advisability of each treatment for the particular patient). Ultimately, providing consumers with basic information may result in the selection of lesser cost alternatives, all else being equal relative to the patient’s care.”³ In other words, making consumers aware of drug list prices through DTC advertising importantly can drive more meaningful conversations between patients and providers that can result improved patient health outcomes at a lower cost.

Finally, CSRxP strongly agrees with CMS that the combined impacts from including list prices in DTC advertisements – both pressure on manufacturers to lower list prices over time and encouraging more active healthcare decision-making between patients and providers – ultimately will lead to the improved efficiency of the Medicare and Medicaid programs. Federal health programs and the many U.S. taxpayers that fund them cannot afford – and should not continue to bear – the burden of the unsustainable growth in prescription drug costs at the expense of the profit-gouging pharmaceutical industry. Taxpayers simply should not fund unnecessary and unreasonable spending by the Medicare and Medicaid programs on prescription drugs that are unfairly priced too high just to sustain the excessive profitability of the pharmaceutical industry. We could not agree more with CMS that “price transparency will help improve the efficiency of Medicare and Medicaid programs by reducing wasteful and abusive increases in drug and biological list prices—spiraling drug costs that are then passed on to federal healthcare program beneficiaries and American taxpayers more broadly.”⁴ Hence, CSRxP agrees with the Agency that requiring the disclosure of list prices in DTC advertisements for drugs paid for by Medicare and Medicaid “advances the government’s substantial interest in the efficient administration of both Medicare and Medicaid programs by minimizing unreasonable expenditures.”⁵ We therefore urge CMS to mandate that manufacturers disclose list prices in DTC advertisements for all drugs paid for by Medicare and Medicaid.

2. Inclusion of Drug List Prices in All Other Forms of DTC Advertising

CSRxP strongly supports extending the requirement to include list prices for drugs paid for by Medicare and Medicaid to all other forms of DTC advertising beyond television, including radio, magazines, newspapers, internet websites, and other forms of social media. Many consumers view DTC advertisements from a variety of sources beyond television and some consumers may not watch or own a television, but still purchase prescription drugs. The more drug pricing information patients have, the better able they are to make more informed decisions about the most medically appropriate, cost-effective treatments for them and the greater the likelihood that drug costs decline over time. As such, CSRxP urges that CMS require all forms of DTC advertising – in addition to DTC advertisements on television – include list prices for prescription drugs reimbursable by Medicare and Medicaid.

3. Presentation of Drug List Prices in DTC Advertising in a Consumer-Friendly Format

³ 83 FR 52793

⁴ 83 FR 52792

⁵ 83 FR 52793

CSRxP believes that the presentation of list prices in an easily understandable, consumer-friendly format will best enable patients to benefit from, and take advantage of, the critically important drug pricing information made available to them under the requirements in the proposed rule. Hence, we strongly support CMS's proposal to require that DTC advertisements present list prices in a consumer-friendly manner that best reflects a patient's typical use of a medication. In particular, we support:

- **Clearly presenting list price information in an easily-readable format:** CSRxP supports displaying the drug list price information “against a contrasting background for sufficient duration and in a size and style format that allows the information to be read easily.”⁶ This type of format will better ensure that consumers actually see the price of a product rather than, for example, having list price shown in fine print during a limited timeframe in the advertisement.
- **Having the list price reflect a 30-day regimen or typical course of treatment:** CSRxP supports presenting the list price as either the price of a 30-day regimen or typical course of treatment for a product, as appropriate. Reflecting list price in this manner makes the price information more understandable and meaningful for consumers as they choose the most medically appropriate and cost-effective medications for their individual healthcare needs.

4. Enhancement of the Information Available in the Medicare and Medicaid Drug Dashboards

CSRxP appreciates CMS's work to date to develop and update the Medicare and Medicaid Dashboards, which contain important pricing and spending information that can help consumers better understand the cost of the medications. However, expanding of the amount and type of drug pricing information available to consumers on the Dashboards will substantially improve their ability to more actively engage in their healthcare decision-making and place pressure on manufacturers to lower drug costs. As such, CSRxP urges that CMS enhance prescription drug price transparency by including any meaningful information in the Dashboards it can obtain from manufacturers and others on prescription drugs, including, but not limited to list price, therapeutic alternatives, pharmacoeconomic research, and other germane data.

Furthermore, CSRxP would welcome announcements from CMS when new information becomes available on the Medicare and Medicaid Dashboards, as well public service announcements to draw consumer attention to the Dashboards. Any effort to better educate consumers about drug prices, drug costs, and therapeutic alternatives will help to improve prescription drug affordability for consumers and taxpayers.

5. Future Potential Establishment of a New Payment Code in the Physician Fee Schedule to Incentivize Practitioner Engagement with Patients on Out-of-Pocket Drug Costs

CSRxP believes that informed discussions between patients and providers about out-of-pocket drug costs can increase the likelihood that the most medically appropriate, cost-effective therapies are selected for the treatment of individual patient conditions and diseases. Currently, health insurers and pharmacy benefit managers are developing and testing processes and tools to embed real-time pharmacy benefit information in a prescriber's electronic health record platform. Once these real-time pharmacy benefit processes and tools are adopted and validated by prescribers, CSRxP believes CMS could revisit its proposal to establish a new payment code in the annual Medicare Physician Fee Schedule rulemaking process.

6. Use of WAC as List Price for Disclosure in DTC Advertisements

CSRxP supports use of Wholesale Acquisition Cost, or WAC, as the appropriate price metric to disclose in DTC advertisements. WAC – the reported list price for sale to wholesalers and distributors – is advantageous for

⁶ 83 FR 52794

multiple reasons. WAC is the most widely accepted benchmark for a drug's market price. The vast majority of brand drugs have a WAC, which is not always true of other price metrics. WAC is defined in federal statute and reported regularly in a transparent manner, which helps ensure consistency and reliability in WAC price information. Thus, compared to other metrics, WAC prices provide dependable and comparable pricing information, and are also easier for CMS to monitor and verify for enforcement purposes.

7. Exemption of Products with a \$35 Monthly Cost

CSRxP supports exempting drugs with a cost of \$35 or lower per month from the requirements in the proposed regulation. We agree with CMS that consumers generally face this level of out-of-pocket cost for their medications and the largest impact from the requirements of this proposed rule likely will be on those drugs with particularly high prices.

Conclusion

In conclusion, CSRxP again wishes to express our strong support and thank CMS for the opportunity to comment on CMS-4187-P. Prescription drug prices are out of control and must fall. U.S. consumers and taxpayers simply cannot continue to pay for needlessly high drug prices that just increase the profitability of the brand drug industry at the expense of patient needs and taxpayer funding. Including list prices on DTC advertisements for drugs paid for by Medicare and Medicaid will significantly improve drug pricing transparency and increase competition, ultimately lowering costs for consumers and taxpayers and better enabling patients to become more active participants in their healthcare decision-making. CSRxP looks forward to continued work with CMS in developing market-based policies that promote competition, transparency, and value to make prescription drugs more affordable for all American patients and their families while at the same time maintaining access to the treatments that can improve health outcomes and save lives.

Sincerely,



Lauren Aronson
Executive Director
The Campaign for Sustainable Rx Pricing