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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 403

[CMS-4187-F]

RIN 0938-AT87

Medicare and Medicaid Programs; Regulation to Require Drug Pricing Transparency

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule revises the Federal Health Insurance Programs for the Aged and Disabled by amending regulations for the Medicare Parts A, B, C and D programs, as well as the Medicaid program, to require direct-to-consumer (DTC) television advertisements of prescription drugs and biological products for which payment is available through or under Medicare or Medicaid to include the Wholesale Acquisition Cost (WAC or list price) of that drug or biological product. This rule is intended to improve the efficient administration of the Medicare and Medicaid programs by ensuring that beneficiaries are provided with relevant information about the costs of prescription drugs and biological products so they can make

informed decisions that minimize their out-of-pocket (OOP) costs and expenditures borne by Medicare and Medicaid, both of which are significant problems.

DATES: This rule is effective [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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SUPPLEMENTARY INFORMATION:

Table of Contents

- I. Background
 - A. Purpose and Statutory Basis
 - B. Summary of the Rule
 - C. Problems that this Rule Seeks to Address
 - D. How the Rule Addresses these Problems-Transparency in Drug Pricing Promotes Competition and Lowers Prices by Informing Beneficiaries
- II. Summary of, Analysis of, and Response to Public Comments
 - A. Secretary's Statutory Authority to Require List Prices in DTC Advertising for Manufacturers whose Drugs are Payable under Titles XVIII or XIX of the Social Security Act
 - B. General Comments on Direct-to-Consumer Advertising
 - C. Use of Wholesale Acquisition Cost as List Price
 - D. First Amendment Considerations
 - E. Requirements in DTC Advertising other than WAC
 - F. Other Alternatives
 - G. Enforcement
- III. Collection of Information Requirements
 - A. Wage Data
 - B. Information Collection Requirements Regarding Pricing Information (§403.1202)
- IV. Regulatory Impact Analysis
 - A. Statement of Need
 - B. Overall Impact
 - C. Anticipated Effects
 - D. Alternatives Considered
- E. Accounting Statement

I. Background

- A. Purpose and Statutory Basis

Delivering better care at more transparent, lower prices is one way the Trump Administration is putting American patients first. The May 2018 Trump Administration blueprint to lower drug prices described a new, more transparent drug pricing system that would lower high prescription drug prices and bring down out-of-pocket (OOP) costs. The blueprint described four strategies: boosting competition, enhancing negotiation, creating incentives for lower list prices, and reducing OOP spending.

The blueprint called for HHS to consider requiring the inclusion of list prices in direct-to-consumer (DTC) advertising. This final rule will improve the efficient administration of the Medicare and Medicaid programs by improving drug price transparency and informing consumer decision-making, both of which can increase price competition and slow the growth of federal spending on prescription drugs.

B. Summary of the Rule

In the October 18, 2018 **Federal Register** (83 FR 52789), we published a proposed rule titled “Medicare and Medicaid Programs; Regulation to Require Drug Pricing Transparency” (hereinafter referred to as the “October 2018 proposed rule”). After consideration of the public comments received, we are finalizing this rule largely as proposed, with one modification to proposed § 403.1204(b) in response to comments, and other minor technical changes to improve clarity.

This final rule requires DTC television advertisements for prescription drugs and biological products for which reimbursement is available, directly or indirectly, through or under Medicare or Medicaid to include the list price of that product. This final rule amends subchapter A, part 403, by adding a new subpart L.

New § 403.1202 requires that advertisements for certain prescription drugs or biological

products on television (including broadcast, cable, streaming, and satellite) contain a statement or statements indicating the Wholesale Acquisition Cost (referred to as WAC or the list price) for a typical 30-day regimen or for a typical course of treatment, whichever is most appropriate, as determined on the first day of the quarter during which the advertisement is being aired or otherwise broadcast, as follows: “The list price for a [30-day supply of] [typical course of treatment with] [name of prescription drug or biological product] is [insert list price]. If you have health insurance that covers drugs, your cost may be different.”

New § 403.1200 specifies that this requirement applies to any advertisement for a prescription drug or biological product distributed in the United States, for which payment is available, directly or indirectly, under titles XVIII or XIX of the Social Security Act, except for a prescription drug or biological product that has a list price, as defined herein, of less than \$35 per month for a 30-day supply or typical course of treatment. The list price stated in the advertisement must be current, as determined on the first day of the quarter during which the advertisement is being aired or otherwise broadcast. When the typical course of treatment varies based on the indication for which the drug or biological product is prescribed, the list price should represent the typical course of treatment associated with the primary indication addressed in the advertisement. To the extent permissible under current laws, manufacturers are permitted to include an up-to-date list price of a competitor’s product, so long as they do so in a truthful, non-misleading way.

New § 403.1203 specifies that the required list price disclosure set forth in § 403.1202 must be conveyed in a legible textual statement at the end of the advertisement, meaning that it is placed appropriately and is presented against a contrasting background for sufficient duration and in a size and style of font that allows the information to be read easily.

Finally, new § 403.1204 specifies that the Secretary will maintain a public list that would include the prescription drugs and biological products advertised in violation of these requirements. We anticipate that the primary enforcement mechanism will be the threat of private actions under the Lanham Act sec. 43(a), 15 U.S.C. 1125(a), for unfair competition in the form of false or misleading advertising. Accordingly, we proposed at § 403.1204(b) that this rule preempt any state-law-based claim that depends in whole or in part on any pricing statement required by this rule. No state or political subdivision of any state may establish or continue in effect any requirement that depends in whole or in part on any pricing statement required by these regulations.

C. Problems that this Rule Seeks to Address

1. Rising Prices and Costs and Their Effect on the Medicare and Medicaid Programs and Their Beneficiaries

a) *Rise in Prices and Costs*

The cost of drugs and biological products over the past decade has increased dramatically, and prices are projected to continue to rise faster than overall health spending, thereby increasing this sector's share of health care spending. The HHS Office of the Assistant Secretary for Planning and Evaluation estimates that prescription drug spending in the United States was about \$457 billion in 2015, or 16.7 percent of overall personal health care services. Of that \$457 billion, \$328 billion (71.9 percent) was for retail drugs and \$128 billion (28.1 percent) was for non-retail drugs. Factors underlying the rise in prescription drug spending from 2010 to 2014 can be roughly allocated as follows: 10 percent of that rise was due to population growth; 30 percent to an increase in prescriptions per person; 30 percent to overall, economy-wide inflation; and 30 percent to either changes in the composition of drugs prescribed toward higher

price products or price increases for drugs that together drove average price increases in excess of general inflation.¹

This final rule is designed to address rising list prices by introducing price transparency that will help improve the efficiency of Medicare and Medicaid programs by reducing wasteful and abusive increases in drug and biological product list prices- spiraling drug costs that are then passed on to federal healthcare program beneficiaries and American taxpayers more broadly. First, it will provide manufacturers with an incentive to reduce their list prices by exposing overly costly drugs to public scrutiny. Second, it will provide some consumers with more information to better position them as active and well-informed participants in their health care decision-making. Consumers make a series of critical health care decisions related to their treatment with prescription drugs or biological products, and the list price of those drugs may inform those decisions. Even where the consumer may be insured, and therefore may be paying substantially less than the list price, the coinsurance borne by some consumers will increase as the WAC increases.

*b) Impact of Rise in Prices and Costs on Part B and Part D
Beneficiaries*

As discussed in the proposed rule, CMS is the single largest payor of prescription drugs in the nation. In 2017, CMS and its beneficiaries spent \$224.6 billion (\$166.2 billion net of rebates) on drug benefits provided under Part B (\$30.6 billion),² Part D (\$129.7 billion gross

¹ US Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation, *ASPE Issue Brief: Observations on Trends in Prescription Drug Spending*, (2016). <https://aspe.hhs.gov/system/files/pdf/187586/Drugspending.pdf>.

² ASPE Calculations from Part B Standard Analytic Files

spend, \$100.7 billion net of rebates),³ and Medicaid (\$64.0 billion gross spend, \$34.9 billion net of rebates including federal and state funds).⁴ An additional sum was spent on drugs furnished by hospitals under Part A's inpatient prospective payment system, but the precise amount is difficult to isolate because hospitals receive a single payment for all non-physician services provided during an inpatient stay (including drugs). In 2016, CMS and its beneficiaries spent more than \$238 billion on prescription drugs, approximately 53 percent of the \$448.2 billion spent on retail and non-retail prescription drugs in the United States that year. Each year overall expenditures on drugs by both the Medicare and Medicaid programs and their beneficiaries have increased at rates greater than inflation both in the aggregate and on a per beneficiary basis.⁵ These dramatically increasing costs are a threat to the sustainability of the programs and harm CMS beneficiaries every day.

*c) Impact on States Under Medicaid—Rising Prices and Costs
Adversely Affects Medicaid and Benefits Offered to Beneficiaries*

The increasing cost of drugs and biological products are a major concern for state

³ 2018 Annual Report of the Board of Trustees' of the Federal Hospital and Insurance and Federal Supplementary Medical Insurance Trust Funds

⁴ MACPAC. Fact Sheet: Medicaid Drug Spending Trends. Feb 2019. <https://www.macpac.gov/wp-content/uploads/2019/02/Medicaid-Drug-Spending-Trends.pdf>.

⁵ According to the 2018 Annual Report of the Board of Trustees' of the Federal Hospital and Insurance and Federal Supplementary Medical Insurance Trust Funds, over the past 10 years, Part D benefit payments have increased by an annual rate of 7.4 percent in aggregate and by 3.8 percent on a per enrollee basis. These results reflect the rapid growth in enrollment, together with multiple prescription drug cost and utilization trends that have varying effects on underlying costs. For example, though there has been a substantial increase in the proportion of prescriptions filled with low-cost generic drugs there has also been a significant increase in spending on high-cost specialty drugs (including those most frequently advertised via televised DTC advertisements), leading to overall increased costs. In other words, the per beneficiary cost of drugs through Part D has increased nearly 40% over the past decade, while the consumer price index has increased only 19% during this same period. Over the period 2013-2016, Medicare Parts D and B, and Medicaid expenditures on a per beneficiary basis increased by 22%, 32%, and 42% respectively. Drug price inflation accounts for some of this growth. Between 2006 and 2015, Part D brand drug prices rose by an average 66% cumulatively.

Medicaid agencies. The Medicaid and CHIP Payment and Access Commission (MACPAC) states that the “[h]igh rates of spending growth for prescription drugs have been of great concern to state and federal Medicaid officials. In 2014, Medicaid prescription drug spending experienced its highest rate of growth in almost three decades. And although spending growth slowed in 2015 and 2016, over the next 10 years prescription drugs could see the fastest average annual spending growth of any major health care good or service due to growth in high-cost specialty drugs.”⁶ States are having to balance alternatives to control drug costs,⁷ and increases in drug spending that threaten the provision of other health services are causing other states to address drug costs to keep their programs sustainable.^{8,9,10}

2. Direct-to-Consumer Advertising

Prescription drugs, by definition, cannot be accessed directly by the consumer; they must be prescribed by a licensed health care practitioner. We know, however, that consumers are responsible for critical choices related to their treatment with prescription drugs. For example, consumers decide whether to make the initial appointment with a physician; whether to ask the physician about a particular drug or biological product; whether to fill a prescription; whether to take the drug; and whether to continue taking it in adherence to the prescribed regimen. Drug

⁶ MACPAC. Prescription Drugs. <https://www.macpac.gov/topics/prescription-drugs/>

⁷ Young K and Garfield R. Kaiser Family Foundation Issue Brief: Snapshots of Recent State Initiatives in Medicaid Prescription Drug Cost Control. Feb 2018, <http://files.kff.org/attachment/Issue-Brief-Snapshots-of-Recent-State-Initiatives-in-Medicaid-Prescription-Drug-Cost-Control>

⁸ Reck J. As Drug Prices Rise, Oklahoma’s Medicaid Agency Advances Alternative Payment Models. National Academy for State Health Policy. 2018 Dec 17. <https://nashp.org/as-drug-prices-rise-oklahomas-medicaid-agency-advances-alternative-payment-models/>

⁹ Rosenberg T. Treat Medicines Like Netflix Treats Shows. NYT. <https://www.nytimes.com/2019/03/05/opinion/can-netflix-show-americans-how-to-cut-the-cost-of-drugs.html>

¹⁰ Gee R. Health Affairs Blog. Louisiana’s Journey Toward Eliminating Hepatitis C. 2019 April 1. <https://www.healthaffairs.org/doi/10.1377/hblog20190327.603623/full/>

manufacturers, therefore, spend billions of dollars annually promoting their prescription drugs and biological products directly to consumers through television advertisements and other media.

In 2017, over \$5.5 billion was spent on prescription drug advertising, including nearly \$4.2 billion on television advertising.¹¹ DTC advertising appears to directly affect drug utilization.¹² DTC advertising may increase disease awareness and facilitate more informed discussions between consumers and their health care providers. But it can also result in increased utilization through patients requesting costly drugs and biological products seen on television. This could cause problematic increases in government spending if less costly alternatives are available, or would be available through market pressures resulting from greater price transparency.

a) *Direct-to-Consumer Advertising Promotes Interaction with Physicians, But Also Is a Factor in Increasing Demand for Higher Cost Drugs*

Studies show that consumers exposed to drug advertisements can exert sufficient pressure on their physicians to prescribe the advertised product.¹³ In one recent survey, 11 percent said they were prescribed a specific drug after asking a doctor about it as a result of seeing or hearing an advertisement.¹⁴ Another study concludes that there is evidence that DTC advertising can

¹¹ Kantar Media Advertising Intelligence—2013 to 2017 Prescription Medications Ad Spend Data.

¹² Dave D and Saffer H. Impact of Direct-to-Consumer Advertising on Pharmaceutical Prices and Demand, *Southern Economic Journal*. 79 (1), 97-126; Datti B and Carter MW. The Effect of Direct-to-Consumer Advertising on Prescription Drug Use by Older Adults, *Drugs Aging*. 2006;23(1):71-81.

¹³ Mintzes B, Barer ML, Kravitz RL, et al. Influence of direct to consumer pharmaceutical advertising and patients' requests on prescribing decisions: Two site cross sectional survey, *BMJ*. 2002 Feb 2;324(7332):278-9.

¹⁴ Kirzinger A, Wu B, and Brodie M. Kaiser Health Tracking Poll – June 2018: Campaigns, Pre-Existing Conditions, and Prescription Drug Ads. Jun 27, 2018. <https://www.kff.org/health-costs/poll-finding/kaiser-health->

lead to more physician visits, diagnoses, and prescriptions for advertised conditions, though there is little evidence showing that the additional care is medically necessary.¹⁵ The same study found that DTC advertising is associated with higher prescribing volume of advertised drugs, increased patient demand, and a shift in prescribing behavior. Other studies have shown that DTC advertising increases both the utilization of pharmaceuticals¹⁶ and costs of pharmaceuticals.¹⁷

b) Physicians Lack Access to Published WAC Data or a Patient's Out-of-Pocket Costs

DTC advertising, which has been shown to increase prescribing and demand for high-cost drugs, currently provides no context for physicians and other prescribers to assess a drug's cost or compare the costs of different treatments. Although the WAC for most drugs payable under Medicare Part B is reported to CMS and the WAC for most other drugs is reported to commercial compendia for widespread use by pharmacies and payors, prescribers generally lack access to this information. In addition, prescribers generally lack information about a drug's formulary placement or the cost sharing that patients would pay. For this reason, in our recent proposed rule titled, "Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses," 83 FR 62152 (November 30, 2018), we proposed to require that Part D plan sponsors implement an electronic real-time benefit tool (RTBT) capable of integrating with at least one prescriber's e-prescribing and electronic medical record systems, to

tracking-poll-june-2018-campaigns-pre-existing-conditions-prescription-drug-ads/

¹⁵ Mintzes B. Advertising of Prescription-Only Medicines to the Public: Does Evidence of Benefit Counterbalance Harm? *Annu Rev Public Health*. 2012 Apr;33:259-77.

¹⁶ Frosch DL, Grande D, Tarn DM, Kravitz RL. A decade of controversy: Balancing policy with evidence in the regulation of prescription drug advertising. *Am J Public Health*. 2010;100(1):24-32.

¹⁷ Law MR, Soumerai SB, Adams AS, Majumdar SR. Costs and consequences of direct-to-consumer advertising for clopidogrel in Medicaid. *Arch Intern Med*. 2009 Nov 23;169(21):1969-74.

make beneficiary-specific drug coverage and cost information visible to prescribers who wish to consider such information in their prescribing decisions. This could provide an important supplement to any pricing information that is provided to patients and allow both the patient and provider to be informed when having discussions about the best overall therapy for the patient.

3. Direct-to-Consumer Advertising that Lacks Meaningful Pricing Information Is Potentially Misleading

As we stated in the October 2018 proposed rule, price transparency has been lacking in the case of prescription drugs or biological products, where consumers often need to make decisions without information about a product's price. Price transparency is a necessary element of an efficient market that allows consumers to make informed decisions when presented with relevant information. However, for consumers of prescription drugs or biological products, including those whose drugs are covered through Medicare or Medicaid, both the list price and actual price to the consumer remain hard to find. Third-party payment, a dominant feature of health care markets, is not a prominent feature of other markets of goods and services and causes distortions, such as an absence of meaningful prices and the information and incentives those prices provide. Because of the confusion and distortions in the existing prescription drug market, it is our view that the absence of the WAC would make a DTC television advertisement potentially misleading because consumers appear to dramatically underestimate their OOP costs for expensive drugs, but once they learn the WAC, they become far better able to approximate their OOP costs.¹⁸

a) *Studies Suggest that Patients Are Ill-Informed About Their Out-of-*

¹⁸ Garrett JB, Tayler WB, Bai G, et al. Consumer Responses to Price Disclosure in Direct-to-Consumer Pharmaceutical Advertising. *JAMA Intern Med.* 2019;179(3):435-437. ("JAMA 2019 Study")

Pocket Costs and Do Not Use Available Online Services

As we explain in further detail in section II.C.1 below, although the WAC is highly relevant to patients' OOP costs, it may not reflect what a patient actually pays. Studies show that many beneficiaries do not appropriately use existing online tools, such as the Medicare Part D Plan Finder, to find the most cost effective product^{19,20} or to determine their OOP costs. While we continue to believe that the Medicare Part D Plan Finder is very helpful and we hope more patients use it, we think the DTC advertisement disclosure provides additional information that is very useful to patients to help them understand drug pricing. In this context, the availability of readily accessible pricing data – such as what would be conveyed at the time a DTC advertisement is aired – becomes more important.

b) Studies Suggest that Patients Want to Know the List Price of Drugs

Despite the fact that a patient's OOP costs will likely differ from the list price, studies indicate that knowing the list price of a drug is important to consumers. A recent tracking poll by the Kaiser Family Foundation found that 88 percent of Americans support requiring drug manufacturers to include their list prices in DTC advertisements.²¹ The same survey found that 24 percent of Americans find it difficult to afford their drugs, and 10 percent say that it is very difficult to afford their drugs. Of those that spend more than \$100 per month on drugs, 58 percent find it difficult to afford their drugs. The poll showed broad support for policies intended to reduce prescription drug costs. The price disclosure requirements that we are

¹⁹ Heiss F, Leive A, McFadden D, and Winter J. Plan selection in Medicare Part D: evidence from administrative data. *J Health Econ.* 2013 Dec;32(6):1325-44

²⁰ Zhou C and Zhang Y. The vast majority of Medicare Part D beneficiaries still don't choose the cheapest plans that meet their medication needs. *Health Aff.* 2012 Oct;31(10):2259-65.

²¹ Kirzinger A, Lopes L, We B, and Brodie M. KFF Health Tracking Poll – February 2019: Prescription Drugs. Kaiser Family Foundation. 2019 March 01. <https://www.kff.org/8c7d090/>

finalizing in this rule will provide consumers with this important information needed to aid them in an effort to find lower cost alternatives, and improve the efficiency of Medicare and Medicaid.

c) Studies Suggest that Patients Who Know the List Price of a Drug Are Better Informed about Their Out-of-Pocket Costs than Those Who Are Not Informed of the List Price

A recent study strongly suggests that when told the price of pharmaceutical products, patients are better able to approximate their OOP costs.²² In that study, published after the proposed rule was issued, researchers asked subjects to estimate their monthly OOP costs for a drug with a hypothetical price of \$15,500 per month. When subjects were provided no information about price, they responded that their OOP costs would be, on average, \$78 per month. This finding tends to support our belief that patients seem to underestimate the true cost of drugs advertised on television. However, when subjects were told the price, they more accurately determined their OOP costs at \$2,787 or about 18 percent of the hypothetical price. The informed estimates were far closer to what one would expect to see paid at the pharmacy counter under most plans than the uninformed assessment of \$78. This finding provides evidence that patients may adjust their expectations of cost if they received pricing information.

D. How the Rule Addresses these Problems-Transparency in Drug Pricing Promotes Competition and Lowers Prices by Informing Beneficiaries

Both Titles XVIII and XIX of the Social Security Act reflect the importance of administering the Medicare and Medicaid programs in a manner that minimizes unreasonable expenditures. *See, e.g.*, Sections 1842(b)(8) and (9), 1860D-4(c)(3), 1860D-4(c)(5)(H),

²² Garrett JB, Tayler WB, Bai G, et al. Consumer Responses to Price Disclosure in Direct-to-Consumer Pharmaceutical Advertising. *JAMA Intern Med.* 2019;179(3):435-437. (“2019 JAMA Study”)

1866(j)(2)(A), 1893(g), 1902(a)(64), 1902(a)(65), 1936(b)(2). In order to enable consumers to make good health care choices, which will in turn improve the efficiency of the Medicare and Medicaid programs, it is critical that they understand the costs associated with various medications. This is especially important where consumers have cost sharing obligations that may be significant. As discussed above, DTC television advertisements that do not provide pricing information may contribute to rising drug prices. Consumers of pharmaceuticals are currently missing information that consumers of other products can more readily access, namely the list price of the product, which acts as a point of comparison when judging the reasonableness of prices offered for potential substitute products. In an age where price information is ubiquitous, the prices of pharmaceuticals remain shrouded and limited to those who subscribe to expensive drug price reporting services. Consumers may be able to obtain some pricing information by going online to the websites of larger chain pharmacies. However, there are several reasons consumers are not likely to do this. First, while consumers make many critical decisions that bring about the ultimate writing of the prescription— making the appointment, asking the doctor about particular drugs, etc.—the physician, rather than the patient, ultimately controls the writing of the prescription. Second, meaningful price shopping is further hindered because the average consumer receives no basic price information. Arming a beneficiary with basic price information will provide him or her with an anchor price or a reference comparison to be used when making decisions about therapeutic options. Triggering conversations about a particular drug or biological product 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 the 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 price information may result in the selection of lesser cost alternatives, all else being equal relative to the patient's care.

To this end, this rule requires price transparency for drugs that are advertised on television. Price transparency can be an effective and appropriate way to influence behavior and improve market efficiency. Price transparency has the potential to influence patient behavior, as well as address our increasing health care costs. Additionally, price transparency has been identified as a low-risk intervention with the potential to reduce health care costs without directly regulating health care reimbursement systems.²³

II. Summary of, Analysis of, and Response to Public Comments

We received 147 comments in response to the October 18, 2018 proposed rule (83 FR 52789). Stakeholders offered comments that addressed both high-level issues related to DTC advertising as well as our specific proposals and requests for comments. We extend our deep appreciation to the public for its interest in lower drug prices and increased price transparency, and the many comments that were made in response to our proposed policies. In some instances, the public comments offered were outside the scope of the proposed rule and will not be addressed in this final rule.

A. Secretary's Statutory Authority to Require List Prices in Direct-to-Consumer Advertising for Manufacturers whose Drugs are Payable under Titles XVIII or XIX of the Social Security Act

We proposed to use our authority under sections 1102 and 1871 of the Social Security Act to require manufacturers to disclose their list prices in DTC television advertisements. We

²³ Sinaiko AD and Rosenthal MB. Increased price transparency in health care--challenges and potential effects. N Engl J Med. 2011 Mar 10;364(10):891-4.

received comments on our use of these authorities. These comments, and our responses, follow.

Comment: Many commenters stated that the proposal is beyond the authority of CMS to promulgate these regulations under a reasonable interpretation of sections 1102 and 1871 of the Social Security Act, specifically noting that neither statutory provision says anything about prescription drugs or biological products, their prices, or advertisements about them. A commenter stated that while CMS acknowledges that it is bound both by the purposes and means specified by Congress, the agency improperly tries to mix and match various ends and means from disparate Social Security Act provisions to essentially create a new statute that this rule would “implement.” Commenters stated that CMS’s interpretation is unreasonable because sections 1102 and 1871 of the Social Security Act are general housekeeping statutes, not broad delegations of authority.

Response: We disagree with these comments. As discussed in the proposed rule, the Secretary has the authority to promulgate regulations as necessary for the efficient administration of Medicare and Medicaid. Although we acknowledge that neither section 1102 nor section 1871 of the Social Security Act specifically references prescription drugs or biological products, their prices, or advertisements, we nevertheless believe that requiring manufacturers to include list prices in DTC television advertisements is supported by the plain text of these statutes. Section 1102 requires the Secretary to “make and publish such rules and regulations, not inconsistent with this Act, as may be necessary to the efficient administration of the functions with which [he or she] is charged” under the Social Security Act. Similarly, section 1871 requires the Secretary to “prescribe such regulations as may be necessary to carry out the administration of the insurance programs under [Title XVIII].” By their terms, then, these provisions authorize regulations that the Secretary determines are necessary to administer these programs. These

statutes do not impose a limit on the means, other than to say, in the case of section 1102, that they not be inconsistent with the Social Security Act.

We also disagree with the commenters who believe that our interpretation of sections 1102 and 1871 is unreasonable. These provisions confer broad discretion upon the Secretary to determine the regulations that are necessary to the efficient administration of the functions with which he or she is charged under the Social Security Act (in the case of section 1102), and the administration of Medicare (in the case of section 1871). Thus, the text of these statutes clearly indicates that they are intended to permit requirements that are necessary to achieve those aims. Medicare and Medicaid beneficiaries have access to significant amounts of information about their OOP drug costs, such as the Medicare Part D Plan Finder, which permits Medicare Part D enrollees to look up information about their expected costs. However, beneficiaries do not use Plan Finder to the extent necessary to promote price competition. We are imposing this disclosure requirement to enable beneficiaries to make more informed decisions, as this will promote transparency, efficiency, and the responsible use of federal funds, in particular the Medicare trust funds.

We further disagree with commenters who contended that we are “mixing and matching” ends and means to form a statutory basis for this rule. In the proposed rule, we stated that the rule uses means that Congress has generally endorsed – disclosures about drug prices – to advance an end that Congress endorsed – minimizing unreasonable expenditures – and thus there is a clear nexus between HHS’s proposed actions and the Act. This statement was not intended to indicate that we believe we can piece together statutory authority from various sources; rather, it was intended to show only that the requirements we proposed are within the realm of what is necessary for the efficient administration of Medicare and Medicaid because they are consistent

with other means Congress has authorized elsewhere in the Social Security Act.

We disagree that sections 1102 and 1871 are housekeeping statutes. A true housekeeping statute, such as 5 U.S.C. 301, relates to internal agency governance. In contrast, sections 1102 and 1871 provide broad rulemaking authority to carry out Medicare and Medicaid and have been cited as authority for a multitude of regulations to implement these programs. *See Thorpe v. Housing Authority of City of Durham*, 393 U.S. 268, 277 n.28 (1969) (“*Thorpe*”).

Comment: Commenters stated that the cases cited in the proposed rule did not support the agency’s interpretation of these statutory authorities and that because the cases cited predate *Chevron U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837 (1984), they are not the correct standard under which to assess the agency’s interpretation of its statutory authorities. These commenters state that the agency’s interpretation fails under the two-part *Chevron* test.

Response: We disagree with these comments. The cases we cited stand for the proposition that a grant of broad rulemaking authority permits regulations that are reasonably related to the purposes of the programs for which rulemaking is authorized, and that the Secretary has discretion to determine which rules are necessary. *See Mourning v. Family Publ’ns Servs., Inc.*, 411 U.S. 356, 369 (1973) (“*Mourning*”); *Thorpe*, 393 U.S. at 277 n.28; *Sid Peterson Mem’l Hosp. v. Thompson*, 274 F.3d 301, 313 (5th Cir. 2001); *Cottage Health Sys. v. Sebelius*, 631 F. Supp. 2d 80, 92 (D.D.C. 2009). Even the cases cited in which regulations were struck down support CMS’s interpretation. For example, in *Food & Drug Administration v. Brown & Williamson Tobacco Corporation*, 519 U.S. 120 (2000), the Supreme Court instructed that an agency’s power to regulate must be grounded in a valid grant of authority from Congress, viewed in context of the overall statutory scheme. Viewing the Medicare and Medicaid schemes

as a whole, nothing prohibits the requirements we are finalizing in this rule. Instead, they are consistent with the overall statutory scheme under the Social Security Act given the clear nexus between this requirement and Congress's recognition throughout the Social Security Act of the importance of administering the Medicare and Medicaid programs in a manner that minimizes unreasonable expenditures. Similarly, *Colorado Indian River Tribes v. National Indian Gaming Commission*, 466 F.3d 134 (D.C. Cir. 2006), states that agencies are bound by Congress's ultimate purpose and the selected means, but in that case – similar to *Brown & Williamson* – the regulations at issue, though based on a general grant of rulemaking authority, were invalidated because they would have been inconsistent with the overall statutory scheme that called for class III gaming to be subject to state-tribal compacts rather than agency regulations.

We disagree that the cases cited in the proposed rule represent the incorrect standard under which to assess our interpretation of sections 1102 and 1871 or that this rule fails the two-part *Chevron* test. With respect to questions of statutory interpretation, “considerable weight should be accorded to an executive department’s construction of a statutory scheme it is entrusted to administer.” *Chevron*, 467 U.S. at 844. *Chevron* sets forth a deferential two-step process to review an agency’s construction of a statute which it administers. 467 U.S. at 842. First, if Congress has unambiguously spoken to the issue in question, the court must give effect to Congress’s intent. *Id.* at 843. Second, if the statute is silent or ambiguous, the court should accord deference to the agency’s construction so long as it is reasonable. *Id.* at 843–44. This rule complies with the first step of the *Chevron* test because Congress did not directly speak to the question of requiring the disclosure of the list price in DTC television advertisements, and nothing in the text or structure of the Medicare statute prohibits this rule. At the same time, consistent with the second step of the *Chevron* test, this rule is a permissible interpretation of the

Secretary's broad authority to regulate for the efficient administration of the Medicare and Medicaid programs. As noted above, *Mourning* and *Thorpe* hold that broad rulemaking authority permits regulations reasonably related to program purposes. While we acknowledge that Congress has, indeed, provided HHS with various specific authorities to address drug costs and reimbursement rates, it does not follow that the requirements we are finalizing in this final rule are unauthorized. Just because Congress has expressly authorized particular means of addressing drug costs in general by authorizing generics and biosimilars and by imposing a rebate system for Medicaid does not signify that all other reasonable means are foreclosed, particularly if the other means are not inconsistent with the Social Security Act. The commenter's argument does not consider plain language of the provisions of the Social Security Act at issue, which, as noted previously, authorize regulations as may be necessary for the efficient administration of Medicare and Medicaid, so long as they are not inconsistent with the Social Security Act. For the reasons described in the proposed rule, the regulations we are finalizing in this rule are necessary for the efficient administration of Medicare and Medicaid. The Social Security Act's prohibition of the Secretary from interfering in Part D negotiations does not make the price disclosure requirement inconsistent with the Social Security Act. Rather, the non-interference provision is not relevant to whether we may require list prices be transparent to beneficiaries. List prices already are known to payors and manufacturers, so simply requiring they be made known to beneficiaries has no bearing on payor-manufacturer negotiations.

Comment: Several commenters further stated that Congress's directive to CMS to operate the Medicare and Medicaid programs efficiently cannot reasonably be construed as giving CMS the authority to regulate prescription drug advertising and that if Congress intended

for CMS to do so, it would have expressly given the agency that authority.

Response: We disagree that explicit authority for this particular regulation is needed, because Congress has explicitly directed the Secretary to operate the Medicare and Medicaid programs efficiently and has expressly authorized regulations necessary to that purpose, so long as they are not inconsistent with the Social Security Act. Promoting pricing transparency, and thus efficient markets, for drugs funded through those programs falls within the scope of the Secretary's mandate. As we stated in the proposed rule, there is a clear nexus between the requirement we are imposing in this final rule and the efficient administration of Medicare and Medicaid. The DTC disclosure requirement is simply a way to ensure transparency of information necessary to minimize unreasonable expenditures, which is an important purpose that Congress has recognized throughout Titles XVIII and XIX of the Social Security Act.

Comment: One commenter stated that Congress has prescribed other means to address the costs of prescription drugs and biological products through federal laws such as the Drug Price Competition and Patent Term Restoration Act of 1984 and the Biologics Price Competition and Innovation Act of 2009, and that if Congress intended for CMS to have this authority it would have given it explicitly to CMS. The commenter stated that Congress also has prescribed numerous, highly detailed methods to control prescription drug and biological product costs in Medicare and Medicaid, such as the Medicaid drug rebate statute, but has expressly prohibited CMS from interfering in negotiations in Medicare Part D, which means that Congress has addressed a course of conduct for the agency that does not permit CMS to regulate prescription drug and biological product prices outside of federal healthcare programs. This commenter stated that the disclosure requirement would undermine the purposes of Medicare and Medicaid by discouraging appropriate and medically necessary use of drugs (and not just "waste" as the

proposed rule contends), which demonstrates that Congress did not empower the Secretary to adopt the DTC requirement as a cost-containment measure.

Response: We disagree with the contention that requiring a disclosure of the list price is a cost control. In implementing this rule, we are not regulating how a manufacturer sets its list price, which remains entirely in the manufacturer's control. As we stated in the proposed rule, in order to enable consumers to make informed health care choices, which can, in turn, improve the efficiency for the Medicare and Medicaid programs, it is critical that they understand the costs associated with various medications. If transparency in such pricing prompts a manufacturer to make the business decision to reduce the list price of overly costly drugs, it is a desired, but by no means a required, outcome. Instead, this rule provides Medicare and Medicaid beneficiaries with important information – namely, an anchor price – they can use to make informed decisions about their care, including whether the difference between the list price and what they actually pay out of pocket is reasonable. For this reason, as well as the reasons described above in section I.C.3. of this final rule, requiring the disclosure of the WAC improves the efficiency of both Medicare and Medicaid.

Finally, we disagree that this disclosure requirement is inconsistent with the purposes of Medicare and Medicaid. The Medicare program provides federally funded health insurance to the elderly and the disabled. Medicaid is a federal-state program that provides financial assistance to states to furnish medical care to needy individuals. As we stated in the proposed rule, there are numerous provisions in the Social Security Act in which Congress has recognized that Medicare and Medicaid should be operated in such a manner as to minimize unreasonable expenditures. Making sure beneficiaries understand the value of their benefits is fully consistent with this goal. Congress has acknowledged in provisions such as sections 1851 and 1860D-1(c),

which require the Secretary to broadly disseminate information to Medicare beneficiaries and prospective Medicare beneficiaries on coverage options under Medicare Parts C and D, that the provision of information to promote an active, informed selection among coverage options is important. This final rule, which requires disclosure of information to promote beneficiaries' understanding of the value of their benefits and enable them to make more informed choices, is similarly consistent with the programs' purposes.

Comment: One commenter wrote that CMS is acting within its authority under sections 1102 and 1871 of the Social Security Act in proposing to require pricing information in DTC advertisements, as CMS has broad latitude to issue regulations that advance the efficient administration of the Medicare and Medicaid programs.

Response: We agree, and we thank the commenter for the support.

Comment: One commenter specifically noted its belief that CMS lacks the authority to regulate broadcast, cable, streaming, and satellite communications.

Response: We disagree with this comment. First, this rule does not regulate broadcasting. Second, as noted previously, sections 1102 and 1871 authorize regulations as necessary for the efficient administration of Medicare and Medicaid, and for the reasons described elsewhere in this preamble, the requirements we are finalizing in this rule are both necessary to that purpose, and not inconsistent with the Social Security Act. We also note that current HHS regulations address broadcast advertisements. For example, we regulate marketing by Medicare Advantage and Part D plans, including via newspapers, magazines, television, radio, billboards, the internet, and social media. See 42 CFR 422.2260, 423.2260.

Comment: Several commenters stated that Congress has given the FDA the authority to regulate DTC advertisements, not CMS. Several commenters stated that while the FDA has the

authority to regulate DTC advertisements, it does not have any specific authority to require the listing of prices. A commenter stated that CMS lacks authority to promulgate a rule that would require manufacturers to violate existing FDA statutory or regulatory requirements.

Response: The statutory authority to issue rules, whether under the Social Security Act or the Federal Food, Drug, and Cosmetic Act, rests with and can always be exercised by the Secretary, even if such authority has been delegated to the individual agencies. We take no position in this rule on whether FDA has the authority to require the listing of drug prices in DTC advertisements. Whether FDA possesses such authority is not dispositive of the question of CMS's authority to implement the disclosure requirement necessary for the efficient administration of Medicare and Medicaid. Indeed, given CMS's role as an agency that reimburses for drugs, it is appropriate that CMS impose the price disclosure requirement, as it is the Medicare and Medicaid programs that bear the cost of drugs with excessively high prices.

Comment: One commenter stated that CMS has not drawn a rational connection between its proposal and high drug prices and provides no explanation for subjecting only television advertisements to the proposal. As such, the commenter contended that the proposal is arbitrary and capricious.

Response: We disagree with this comment. As discussed in the proposed rule, HHS has concluded that the rule has a clear nexus to the Social Security Act. In numerous places in the Act, Congress recognized the importance of administering the Medicare and Medicaid programs in a manner that minimizes unreasonable expenditures. Efficient administration of both Medicare and Medicaid, therefore, encompasses federal efforts to achieve value for funds spent in the Medicare and Medicaid programs. The transparency required by the disclosure requirement will provide beneficiaries with relevant information about the costs of prescription

drugs and biological products, so they can make informed decisions that minimize costs, both for themselves and the Medicare and Medicaid programs. As discussed above in section I.C.2 of this final rule, studies suggest that DTC advertising directly affects drug utilization and exerts pressure to prescribe. The list price disclosure requirement is rational because it will require the price information to be transmitted at the same time as the rest of the advertisement; thus, it will be a seamless and meaningful way to provide concurrent, important context (i.e., the list price) in a way that is low-cost for the manufacturer, and low-burden -- but high-impact -- for affected beneficiaries. It is appropriate and rational to implement this policy for only television advertisements because television advertising makes up over two thirds of the DTC spend for pharmaceuticals.²⁴ Additionally, television is a universal medium widely watched by beneficiaries, and therefore it is an efficient and effective means to ensure beneficiaries are provided with appropriate information. Traditional television reaches about 87 percent of the adult population, with older adults spending the most time watching television (Age 50-64: 5 hours and 38 minutes per day; Age 65+: 6 hours and 55 minutes per day).²⁵

B. General Comments on Direct-to-Consumer Advertising

We received general comments on the merits of DTC advertising.

Comment: Many commenters recommended against allowing DTC advertising at all.

Some commenters noted that DTC advertisements leads to longer, less efficient patient encounters and reduced patient confidence in prescribers' advice. Commenters also stated DTC advertising increases inappropriate prescribing and drives demand for products that patients may

²⁴ Schwartz LM and Woloshin S. Medical Marketing in the United States, 1997-2016. JAMA. 2019 Jan 1;321(1):80-96.

²⁵ The Nielsen Total Audience Report Q2 2018. <https://www.nielsen.com/content/dam/corporate/us/en/reports-downloads/2018-reports/q2-2018-total-audience-report.pdf>.

not need. Many other commenters stated that DTC advertisements provide an important source of patient education by increasing disease awareness and informing patients and caregivers about new treatments.

Response: Eliminating DTC advertising is outside of the scope of this rule. We agree that DTC advertisements can both drive utilization and provide a source of patient education, and we are implementing the list price disclosure requirement so as to provide additional information as a resource to educate and inform patients in a manner that can temper the increases in demand that DTC advertising causes.

Comment: Many commenters support including the list price of prescription drugs and biological products in DTC advertising as an important step toward providing price transparency in our health care system. Many commenters note that being aware of the price of goods is essential for an efficient and competitive market to work. Additionally, many commenters note that drug cost is an important concern for patients, and this information will be important to allow them to have a meaningful conversation with their providers to select the best, most cost-effective, and most appropriate overall therapy.

Response: We appreciate the support for our proposal, and we agree that requiring a list price in DTC television advertising will provide valuable new information for patients to empower them to engage with their providers and engage in their care decisions. We agree that pricing information is essential for creating a more transparent health care system and an important element in creating a free and competitive market that will allow patients to be engaged consumers.

C. Use of Wholesale Acquisition Cost as List Price

In the proposed rule, we sought comment on whether WAC is the amount that best

reflects the list price for the stated purposes of price transparency and comparison shopping.

Comment: A few commenters expressed concern that the WAC is not standardized or well-defined enough to serve as a meaningful price point. A few commenters noted that the WAC varies by National Drug Code (NDC) and requested clarification on which NDC would be used in determining the WAC to be included in advertisements.

Response: We disagree that the WAC is not standardized or well-defined. Congress defined WAC in section 1847A of the Social Security Act, and we are finalizing a definition in this rule that parallels the statutory definition. WAC has been used in Medicare Part B drug payment policy for more than a decade without significant concern that it is not a meaningful price point.²⁶ In Medicare Part D, the negotiated price is a function of pharmacy-level charges, which are typically expressed in network pharmacy contracts as a function of the WAC (e.g., $((WAC \times 1.2) - 15\% + \$2.00)$). With respect to the commenters' request for clarification about NDCs, we note that the regulation requires the list price for a 30-day supply or typical course of treatment. To the extent an NDC reflects an amount of the manufacturer's product other than a 30-day supply or typical course of treatment, the manufacturer will need to use reasonable assumptions to determine the appropriate list price for a 30-day supply or typical course of treatment.

Comment: Several commenters supported the use of the WAC. One commenter noted that the WAC is a well understood price point that is defined in statute and applies to every drug,

²⁶ The WAC is used in Part B in two ways. First, Medicare Part B pays 106 percent times the lesser of the Average Sales Price (ASP) or WAC. See Social Security Act sec. 1847A(b)(4). Second, when a new Part B drug or biological product comes to market and has no established ASP, the Secretary may use the drug's or biologic's WAC or methodologies in effect on November 1, 2003 to determine the Part B payment amount. See Social Security Act sec. 1847A(c)(4).

and that because it serves as a starting point for negotiating prices, it directly impacts patients' costs. A few commenters noted that the full WAC is paid by the uninsured and by beneficiaries with high deductibles. Others noted that patients could estimate their out of pocket costs from the WAC if they understand the percentage coinsurance of their coverage. A few noted that due to variation in other price points, it would be administratively burdensome for manufacturers to display any price other than the WAC and that the proposal is easy for manufacturers to comply with. A few commenters noted their belief that with the proposed cost variation disclaimer, the WAC is an appropriate price point to share in advertisements. Others noted that the WAC is primarily informative for single-source drugs, which make up the majority of DTC advertisements.

Response: We appreciate these commenters' support for the use of the WAC, and agree that it is an appropriate metric for disclosure in DTC television advertisements for the reasons commenters note. The WAC is the most commonly used benchmark in the pharmacy purchasing of drugs, which means that it is a single, manufacturer-published price that excludes rebates and discounts, and therefore is the closest metric we have to a generalizable list price that applies to all patients prior to the application of insurance coverage, making this an actual list price of the drug. While insurance coverage will affect what the patient pays OOP for the drug, as stated above the WAC is an important factor for determining the final price that patients will pay for the drug. Moreover, the WAC is a real price that manufacturers set for their drugs and share with various private price compilers such as Red Book, Medispan, and First DataBank. WAC publishers sell subscriptions to their compilations, allowing pharmacies and others willing to pay annual subscription fees to access current prices. For all of these reasons, the WAC is a relevant and important price point in the drug supply chain.

Comment: Several commenters recommended that additional or different information should be required in advertisements other than the WAC. Specifically, commenters requested that DTC advertisements include detail on what a patient may expect to pay out of pocket. One commenter recommended that advertisements include both the WAC and expected out of pocket costs. A few commenters recommended that advertisements include rebate, discount and formulary information as well as details for consumers to make a coinsurance calculation. One commenter noted that patients want information about what payment support options may be available to them. One commenter expressed concern that the proposed disclosure does not give patients information about what other drug options may be available. A few commenters recommended that advertisements include appropriate explanations of what the WAC means.

Response: We decline to require manufacturers to provide pricing information in addition to the WAC of the drug being advertised because this rule is targeted to providing the minimum amount of cost information that will allow a patient to engage in shared decision making with their prescriber. We also decline to require that DTC advertisements explain what the WAC means, as the required disclosure language refers to the “list price,” and does not the term WAC. Further, the rule is targeted to require disclosure of the most essential price information, but manufacturers may include additional information if they so choose, so long as the information does not obscure safety and effectiveness information.

Comment: One commenter requested clarification on whether standard manufacturer costs would be used if the proposal were applied to the inpatient setting.

Response: The requirement we are finalizing in this rule will require DTC television advertisements to disclose the WAC of any drug for which payment is available under Medicare or Medicaid, regardless of the care setting.

Comment: A few commenters expressed concern that for drugs that lack therapeutic alternatives, disclosure of the WAC will be irrelevant because patients do not have cheaper options to choose from.

Response: We disagree. Even if a drug does not have any cheaper therapeutic alternatives, it will be useful to the patient and his or her caregivers to know its list price, as it will inform the conversation about anticipated costs.

Comment: Many commenters agree that the WAC is the best price point to include in DTC television advertisements because it is a single, easily accessible metric created by manufacturers and available to wholesalers, and is the most common benchmark used in pharmacy purchasing and reimbursement. One commenter recommended using National Average Drug Acquisition Cost (NADAC), which is a CMS-published benchmark created through a national survey of actual invoices paid by retail pharmacies to wholesalers. The commenter suggested that it is more accurate, especially for generic drugs. One commenter noted that alternative price points are more relevant to what patients pay, such as the Federal Upper Limit (FUL) and the Maximum Allowable Cost (MAC), which reflect rebates and discounts provided by manufacturers. One commenter recommended against displaying the average wholesale price (AWP), average acquisition cost (AAC), or national average drug acquisition cost (NADAC).

Response: We appreciate the feedback on alternative metrics for the list price. We agree with the commenters that the WAC is an appropriate metric to use as a list price because it is commonly used, easily available and manufacturer-developed. We appreciate the comments that noted that the WAC is not available for all drugs. However, not only is the WAC generally available for the overwhelming majority of drugs, but it is available for the more expensive drugs

that are commonly advertised on television, as shown in Table 1. All drugs that are distributed through a wholesaler have a WAC, including all of the top 20 drugs that have the highest DTC advertising spending. While we agree that other price metrics may be useful, we decline to adopt any of these other metrics as alternatives because we believe the WAC is a better metric for purposes of the disclosure requirement. As noted previously, a manufacturer sets its WAC, and therefore readily knows the WAC for all of its advertised products. In addition, generic drugs are rarely advertised on television, so the NADAC, which tracks generic prices, is not only less relevant for purposes of this rule, but is also one step removed from information – WAC – that the manufacturer already has at hand.

1. WAC is a Benchmark for Federal and Commercial Healthcare Programs

A drug's WAC has relevance as a benchmark in both federal and commercial health care programs. In the commercial sector, nearly half of all beneficiaries have high deductible plans including those with plans purchased on the Health Insurance Exchange under the Affordable Care Act.²⁷ An analysis of commercial health plans also determined that nearly half of all drug spending is subject to deductible or coinsurance.²⁸

Under Medicare Part B, after meeting the annual \$185 deductible, beneficiaries generally pay a 20 percent co-insurance for all items and services, including prescription pharmaceuticals. When a Medicare Part B drug is new, it may be reimbursed for a period of time based on its WAC rather than its ASP. After that time, Medicare pays for prescription drugs based on the

²⁷ Cohen R, Martinez M, and Zammitte E. Health Insurance Coverage: Early Release of Estimates From the National Health Interview Survey, January–March 2018. National Center for Health Statistics. <https://www.cdc.gov/nchs/data/nhis/earlyrelease/Insur201808.pdf>.

²⁸ Rae M, Cox C, and Sawyer B. What are recent trends and characteristics of workers with high drug spending? Peterson-Kaiser Health System Tracker. <https://www.healthsystemtracker.org/chart-collection/recent-trends-characteristics-workers-high-drug-spending-2016/#item-deductibles-and-coinsurance-represent-a-larger-share-of-out-of-pocket-drug-spending-than-a-decade-ago>

ASP. Sixty percent of the top 50 Part B drugs by spending have an ASP that is less than 10 percent different from the WAC.

Medicare Part D allows beneficiaries to choose a private health plan offering prescription drug benefits, and these include a standalone prescription drug plan (PDP) for those with original Medicare or a Medicare Advantage plan that includes prescription drug coverage (MA-PD). In 2018, the majority of Part D enrollees had some form of deductible, and more than 70 percent of standalone Part D plans offered in 2019 included a deductible.²⁹ The top 10 PDPs by enrollment, which represents 81 percent of standalone PDP enrollment, all charge coinsurance rather than copayments for drugs on nonpreferred tiers, charging 32 percent to 50 percent of each prescription's negotiated price (which closely resembles the WAC).³⁰ All Part D plans may charge coinsurance for drugs on the specialty tier. As such, the overwhelming majority of Part D beneficiaries are exposed to OOP costs based on the negotiated price (which closely resembles the WAC).

Table 1 includes the 20 drugs with the highest television advertising expenditures during CY2016. The average WAC for these drugs is \$3,473 (range: \$189 - \$16,937.91) per month.

Two of the drugs are covered by Medicare Part B, which requires Medicare beneficiaries to pay a coinsurance equal to 20 percent of a drug's ASP-based payment allowance for physician-administered drugs. For the two Part B drugs, the ASP of the drug closely resembles the WAC, suggesting that a beneficiary who knows the drug's WAC can easily approximate their OOP costs.

Eighteen of the drugs are covered by Medicare Part D, in which a beneficiary's OOP

²⁹ MedPAC Report to the Congress: Medicare Payment Policy. March 2019.

³⁰ MedPAC Report to the Congress: Medicare Payment Policy. March 2019.

spending is dependent on the plan benefit design. For these 18 Part D drugs, the mean per month WAC was \$3,586.44. We used the benefit design of the two PDPs with the lowest and highest premiums available to a Medicare beneficiary in Washington, D.C., to estimate the formulary coverage and OOP costs for these 18 drugs. In the low-premium plan, all 18 drugs were subject to a deductible, during which time the beneficiary pays the negotiated price until entering the next phase of the benefit, seven (39 percent) were on the preferred tier and subject to a copayment after meeting the deductible, six (33 percent) were on the non-preferred or specialty tier and subject to coinsurance after meeting the deductible, and five (27 percent) were non-formulary drugs for which no insurance benefit is available (unless the beneficiary obtains a formulary exception). Thus, OOP spending was based on the WAC for all of the drugs before meeting the deductible, and 61 percent of the drugs after meeting the deductible. In the high-premium plan, all 18 drugs were subject to a deductible, during which time the beneficiary pays the negotiated price until entering the next phase of the benefit, five (27 percent) were on the preferred tier and subject to a copayment after meeting the deductible, eight (33 percent) were on the non-preferred or specialty tier and subject to coinsurance after meeting the deductible, and five (27 percent) were non-formulary drugs for which no insurance benefit is available (unless the beneficiary obtains a formulary exception). Thus, OOP spending was based on the WAC for all of the drugs before meeting the deductible, and 61 percent of the drugs after meeting the deductible. Of note, the WAC was often less than the Part D plan's negotiated price, and the high-premium plan subjected beneficiaries to coinsurance more often than the low-premium plan for the drugs with the highest DTC ad spending.

Thus, when drugs are purchased early in the year before a deductible has been met, or during the plan year when coinsurance applies, or at any time when a drug is not covered by

insurance, the patient often pays the WAC or cost-sharing based on the WAC, making the WAC highly relevant. Knowing the WAC may also help a beneficiary begin a conversation about less expensive alternatives, prompt them to ask their pharmacist if a lower-cost option would be available, or encourage them to choose a plan with more favorable cost-sharing requirements.

Table 1: Comparison of List Price and Out of Pocket Cost under High and Low Premium Plans for the Drugs with the Highest DTC Advertising Expenditures

Drug (Quantity)	WAC per Month	Representative Low Premium Plan					Representative High Premium Plan				
		Tier	Negotiated Price and Deductible	Initial Coverage	Coverage Gap	Catastrophic	Tier	Negotiated Price and Deductible	Initial Coverage	Coverage Gap	Catastrophic
Humira (2 pens)	\$5,174	Specialty	\$5,169	\$1,292	\$1,292	\$258	Specialty	\$5,097	\$1,325	\$1,274	\$255
Lyrica (60 tabs)	\$468	Preferred Brand	\$446	\$40	\$117	\$23	Preferred Brand	\$462	\$42	\$115	\$23
Xeljanz (60 tabs)	\$4,481	Specialty	\$4,477	\$1,119	\$1,119	\$224	Non- formulary	\$5,377	\$5,377	\$5,377	\$5,377
Trulicity (4 pens)	\$730	Preferred Brand	\$730	\$40	\$182	\$36	Nonpreferred Drug	\$720	\$345	\$180	\$36
Xarelto (30 tabs)	\$448	Preferred Brand	\$448	\$40	\$112	\$22	Preferred Brand	\$442	\$42	\$110	\$22
Otezla (60 tabs)	\$3,398	Non- formulary	\$4,078	\$4,078	\$4,078	\$4,078	Non- formulary	\$4,078	\$4,078	\$4,078	\$4,078
Eliquis (60 tabs)	\$444	Preferred Brand	\$444	\$40	\$111	\$22	Preferred Brand	\$438	\$42	\$110	\$22
Keytruda	\$4,719	Part B									
Ibrance (30 tabs)	\$16,938	Specialty	\$17,608	\$4,402	\$4,402	\$880	Specialty	\$16,686	\$4,338	\$4,171	\$834
Jardiance (30 tabs)	\$493	Preferred Brand	\$493	\$40	\$123	\$25	Preferred Brand	\$486	\$42	\$66	\$24
Rexulti (30 tabs)	\$1,109	Specialty	\$1,109	\$277	\$277	\$55	Nonpreferred Drug	\$1,093	\$525	\$273	\$55
Taltz (1 pen)	\$5,162	Non- formulary	\$6,442	\$6,442	\$6,442	\$6,442	Non- formulary	\$6,194	\$6,194	\$6,194	\$6,194
Verzenio (60 tabs)	\$12,087	Specialty	\$12,510	\$3,128	\$3,128	\$626	Nonpreferred Drug	\$11,907	\$5,715	\$2,977	\$595
Prevnar-13	\$189	Part B									
Eucrisa (1 tube)	\$633	Non- formulary	\$745	\$745	\$745	\$745	Non- formulary	\$745	\$745	\$745	\$745
Latuda (30 tabs)	\$1,223	Nonpreferred Drug	\$1223	\$562	\$306	\$61	Nonpreferred Drug	\$1,200	\$528	\$300	\$60
Victoza (3 pens)	\$922	Preferred Brand	\$921	\$40	\$230	\$46	Preferred Brand	\$908	\$42	\$227	\$45

Drug (Quantity)	WAC per Month	Representative Low Premium Plan					Representative High Premium Plan				
		Tier	Negotiated Price and Deductible	Initial Coverage	Coverage Gap	Catastrophic	Tier	Negotiated Price and Deductible	Initial Coverage	Coverage Gap	Catastrophic
Farxiga (30 tabs)	\$492	Preferred Brand	\$492	\$40	\$123	\$25	Nonpreferred Drug	\$486	\$233	\$121	\$24
Enbrel (4 pens)	\$5,174	Non- formulary	\$6,209	\$6,209	\$6,209	\$6,209	Specialty	\$5,097	\$1,325	\$1,274	\$255
Cosentyx (1 pen)	\$5,179	Non- formulary	\$4,661	\$4,661	\$4,661	\$4,661	Non- formulary	\$4,661	\$4,661	\$4,661	\$4,661

Note: In Table 1, we looked at the Top 20 drugs with the highest television advertising expenditures during CY 2016, per Kantar Media. We filled out the WAC for each of the drugs based on the common monthly package size using Analysource and ProspectoRx data. Then, we selected the plan in the Washington D.C. area (Zip 20201) that had the lowest monthly premium (WellCare Value Script (PDP)- \$14 monthly premium) and a choice plan with the highest monthly premium (Express Scripts Medicare (PDP) – Choice- \$97.20- monthly premium). We identified the tiers for the drugs based on the respective formularies for each plan. Then, we used the Plan Finder website for each plan to identify the deductible and initial coverage for each drug to estimate the OOP costs for beneficiaries before they enter catastrophic coverage phase. The WAC was obtained from Analysource and ProspectoRx data. Tiering info was obtained from Express Scripts Medicare Choice PDP 2019 Formulary and WellCare Value Script PDP 2019 Formulary. Deductible and Initial Coverage Period for Value Plan (WellCare Value Script (PDP)) OOP amounts were obtained from the Medicare.gov Part D Planfinder for an applicable beneficiary living in Washington DC (20201). Deductible and Initial Coverage Period for Choice Plan (Express Scripts Medicare (PDP) – Choice) OOP amounts were obtained from the Medicare.gov Part D Planfinder for an applicable beneficiary living in Washington D.C. (20201).

2. Absence of WAC as Potentially Misleading

Comment: Many commenters strongly opposed the use of the WAC and expressed concern that the WAC is not a meaningful measure of what a patient will pay for a drug and is instead misleading and confusing. Commenters noted that, based on insurance coverages, rebates, patient assistance programs, and negotiated discounts, consumers could pay less for a drug with a higher list price than for a drug with a lower list price and that disclosure of the WAC does not provide accurate or relevant information to patients. Commenters expressed concern that the proposal will deter patients from seeking appropriate care, as some may believe the WAC represents their out of pocket costs. Commenters noted their belief that the proposal puts the burden of increasing drug prices on consumers and stated that disclosing the price out of context will overemphasize costs. Commenters noted that the WAC is useful only if patients have a detailed understanding of the provisions of their drug coverage. Commenters stated that if information about OOP costs cannot be included, we should not require inclusion of any prices at all.

Response: We disagree that disclosure of a drug's WAC would be misleading. For the reasons stated above, WAC is a highly relevant data point with significance in both federal and commercial health care. Indeed, it is our view that the absence of a drug's WAC would make a DTC television advertisement potentially misleading because consumers appear to dramatically underestimate their OOP costs for expensive drugs, but once they learn the WAC they become far better able to approximate their OOP costs. In the 2019 JAMA study,³¹ published after the proposed rule was issued, researchers asked subjects to estimate their monthly OOP costs for a

³¹ Garrett JB, Tayler WB, Bai G, et al. Consumer Responses to Price Disclosure in Direct-to-Consumer Pharmaceutical Advertising. *JAMA Intern Med.* 2019;179(3):435-437. ("2019 JAMA Study")

drug with a hypothetical WAC of \$15,500 per month. When subjects were provided no information about price, they responded that their OOP costs would be, on average, \$78 per month or about 0.5 percent of the WAC. However, when subjects were told the WAC, they more accurately determined their (OOP) costs at \$2,787 or about 18 percent of the WAC. We do not know whether subjects used their own plans as the bases for their calculations and if so, the report does not reveal their plans' coinsurance rates. Nonetheless, the informed estimates were far closer to what one would expect to see paid at the pharmacy counter under most plans than the uninformed assessment of \$78. This study strongly suggests that advertisements without the WAC may lull viewers into a false sense affordability and may therefore be potentially misleading under the relevant state laws. *See, e.g.,* Calif. Bus. & Prof. Code sec. 17200.

We also disagree with commenters' concerns that the list price may be more confusing than beneficial to patients because it is not related to their OOP costs. As noted above, consumers may be better able to predict their OOP costs when they know a drug's WAC. In addition, the list price will be new information to patients, and a starting point for conversations among prescribers, patients and caregivers. We believe it would be too complicated to require manufacturers to try to disclose every possible cost sharing outcome in a DTC television advertisement, but requiring disclosure of the list price will help prompt further discussions that help consumers make informed decisions about appropriate treatment options. (As discussed elsewhere in this preamble, the rule also requires inclusion of the statement, "If you have health insurance that covers drugs, your cost may be different," a further disclosure that provides context for consumers.) As noted above, the list price is relevant for uninsured patients, and insured patients with deductibles and coinsurance as is frequently the case under Part D for high cost drugs advertised on television.

We disagree that disclosure of a drug's WAC in DTC television advertisements will overemphasize costs or deter patients from seeking care. As noted in the 2019 JAMA Study, the risk of patients not seeking care is mitigated when the advertisement includes a caveat that OOP costs may be less.³²

Comment: Some comments cite evidence that the disclosure of the list price may dissuade patients from discussing certain medical treatments with their prescribing health care practitioners.³³ In support of the dissuasion argument, at least one comment also cited to an article about a study that concluded that high deductibles discourage patients from seeking prompt medical care.³⁴ Another comment disagreed, asserting that companies advertising their products expend considerable resources to ensure that their advertising communicates effectively. The comment further asserts that consumers who are able to understand and make use of the information about a prescription drug or biological product described in the advertisement would have the capacity to understand and make use of the pricing information.

Response: We find the latter comment more persuasive. The article from the New England Journal of Medicine was published under the "Perspectives" heading, which the journal describes as "[c]over[ing] timely, relevant topics in health care and medicine in a brief, accessible style." See <https://www.nejm.org/author-center/article-types>. The authors opine that "a *potential* unintended consequence of price disclosure *may be* to dissuade patients from

³² Garrett JB, Tayler WB, Bai G, et al. Consumer Responses to Price Disclosure in Direct-to-Consumer Pharmaceutical Advertising. *JAMA Intern Med.* 2019;179(3):435-437. ("2019 JAMA Study")

³³ Dusetzina SB and Mello MM. Disclosing Prescription-Drug Prices in Advertisements - Legal and Public Health Issues. *N Engl J Med.* 2018 Dec 13;379(24):2290-2293.

³⁴ Gordon S. High Deductibles May Mean Poorer Diabetes Care. *U.S. News & World Report*, Nov. 20, 2018. <https://health.usnews.com/health-care/articles/2018-11-20/high-deductibles-may-mean-poorer-diabetes-care>

seeking care because of the perception that they cannot afford treatment” (emphasis added).³⁵

This statement of the authors’ opinion is not based on any data, and we do not find it persuasive.

We are also not persuaded that the study on high deductibles undermines the DTC ad requirement. That study concluded that individuals who transitioned from low-deductible to high-deductible insurance demonstrated a delay in seeking care for certain diabetes complications, as compared to peers who remained in low-deductible plans. Furthermore, the study suggests that people with diabetes should select benefit designs that are appropriately tailored to their expected use of care. But the proposition that individuals, if informed of a drug’s list price, will necessarily delay visiting a doctor and discussing treatment options (including but not limited to the advertised drug) does not necessarily follow from the study’s conclusion.

In contrast, as we discussed in section I.C., price transparency is essential to enable consumers to make informed health care choices, which will in turn improve the efficiency of the Medicare and Medicaid programs, as it is critical that beneficiaries understand the costs associated with various medications. This is especially important where consumers have significant cost sharing obligations. Increasing drug price transparency changes patient behavior, and price transparency is an accepted strategy for addressing our increasing health care costs. Additionally, price transparency is recognized as a low-risk intervention because it has the potential to reduce health care costs without otherwise affecting health care delivery and reimbursement.³⁶

³⁵ Dusetzina SB and Mello MM. Disclosing Prescription-Drug Prices in Advertisements - Legal and Public Health Issues. *N Engl J Med.* 2018 Dec 13;379(24):2290-2293.

³⁶ Sinaiko AD and Rosenthal MB. Increased price transparency in health care--challenges and potential effects. *N Engl J Med.* 2011 Mar 10;364(10):891-4.

Comment: Many commenters note that including the list price could be a psychological burden for patients, whether or not it is related to their OOP costs, because many advertised drugs are expensive, sole source drugs for severe, debilitating, or terminal diseases. This means patients often will not have the opportunity to “shop” for lower cost alternatives. Some commenters note that patients should not be the one bearing the responsibility for making cost-benefit analyses when they are undergoing active treatment for severe disease, so it is inappropriate to include the list price as an element for patients to consider as they enter active treatment. Commenters also stated that including the list price could also have the unintended consequence of patients’ electing to use higher-cost drugs, particularly if there is no difference in OOP costs, because price is seen as an indicator of quality in other categories of consumer goods.

Response: While we acknowledge that a person’s clinical needs or health condition may make it infeasible for them to seek lower cost drug therapies, we disagree that this makes the provision of list price information inappropriate. We believe providing this information regarding price is better than providing no information, even if the additional information is not considered by a particular patient and his or her providers in making treatment decisions. Contrary to commenters’ assertions, it may be more burdensome for patients and their caregivers not to have pricing information to take into consideration as they determine the most appropriate course of action. Moreover, we would not characterize any decision to prescribe a higher cost drug, based on consideration of all the applicable factors including safety, efficacy, side effects, and price, as an unintended consequence of this rule.

Comment: Commenters noted that because WAC has no relation to what patients will actually pay, it is unreasonable to assume the proposal will have any impact on treatment choices

or the cost of drugs.

Response: We disagree. As discussed above, studies show that consumer behavior is affected by DTC advertisements, and that consumers who know the list price may be better able to predict their OOP costs. This evidence leads to the conclusion that the additional data point, which, as discussed elsewhere in this rule, is highly relevant and would have an effect on treatment choices and, potentially, the cost of drugs.

Comment: A few commenters expressed concern that disclosing the WAC fails to account for the value of drugs and could lead to consumers comparing drugs based on the WAC alone, without considering important factors such as safety and effectiveness.

Response: We disagree that providing this limited price information would lead to decision making that disregards safety and effectiveness. Given that the drugs and biological products that are subject to this rule are dispensed upon a prescription, and therefore require consultation with a prescriber, the choice of an appropriate treatment option is not based solely on a drug's WAC.

Comment: A few commenters expressed concern that the proposed disclosure of the WAC in DTC advertisements undermines FDA efforts to make advertisements simple and clear to patients.

Response: We disagree. The DTC disclosure requirement we are finalizing in this rule requires simple, standardized text be placed at the end of the ad, and would not make the advertisement any more complicated. However, we remind manufacturers that they have to comply with all applicable FDA requirements and that nothing in this rule is intended to supersede any FDA requirement.

Comment: Some commenters note that providers and prescribers do not have the time,

resources, or expertise to have conversations with patients about the cost of drugs or biological products, so it may be inappropriate to provide list price information to patients encouraging them to discuss this information with their providers or prescribers. Commenters stated that DTC television advertising may actually decrease the quality of conversations between patients and their providers because it will force the provider to dedicate a portion of their limited time with the patient discussing a list price unrelated to their OOP costs that the physicians are not trained to discuss. Some commenters note that the payor or the pharmacists may be better equipped to educate the patient on the cost of therapies.

Response: This rule does not require that providers and prescribers discuss pricing or costs with their patients. Rather, this rule merely requires that relevant information be shared with patients should providers and prescribers wish to discuss drug costs with them. We believe it is important that providers discuss any barriers to medication adherence, such as cost, with their patients to determine if consideration of alternative therapies is needed. The availability of list price information will not decrease the quality of doctor-patient interaction or require any particular training or resources. In fact, it may encourage patients to discuss any barriers to medication adherence with their providers. As discussed in section F of this final rule, certain Medicare billing codes already account for the resources associated with counseling patients on therapeutic options.

3. Use of a \$35 Threshold

We sought comment as to whether the cost threshold of \$35 to be exempt from compliance with this rule is the appropriate level and metric for such an exemption. We proposed this threshold because it approximates the average copayment for a preferred brand drug. We also considered incorporating a range for exempted drugs defined as less than \$20 per

month for a chronic condition or less than \$50 for a course of treatment for an acute condition. In particular, we considered whether “chronic condition” and “acute condition” are sufficiently distinguishable to accomplish the stated regulatory purpose. We sought comment on alternative approaches to determining a cost threshold, whether or not the threshold should be updated periodically, and if so, how the threshold should be updated.

Comment: Some commenters agree that \$35 is a reasonable cost threshold to be exempt from compliance with this rule. Many commenters recommend that we do not include a threshold price for drugs that would exempt them from including their list price in DTC advertising. They note that if one of the purposes of this rule is to improve price transparency, then it is important to provide the prices on all drugs and biological products that are subject to DTC advertising. Some of these commenters also note that it is not appropriate to assume that \$35 is a good threshold as an approximation of the co-payment of an average copayment for a preferred brand drug because \$35 may still be a financial burden for many patients, and awareness of this amount could be useful for patients. One commenter recommended that we reduce the threshold to \$25 because that is also representative of copayments for brand drugs. Another commenter recommended that we increase the threshold to \$100 to avoid inundating patients with price notifications, and potentially reducing their effect. Finally, several commenters noted that it may be confusing to patients on why some drugs and biologic products have a list price included in their DTC television advertisements, while others do not. To avoid this confusion, the price should be included in all advertisements. We did not receive any comments on whether or how often this threshold would need to be revisited.

Response: We agree with commenters that \$35 is an appropriate list price threshold for exemption from compliance with this rule. We disagree with commenters that suggested there

should not be an exemption from the list price disclosure requirement. Since patients with the traditional benefits with no low income cost subsidies can already expect to pay up to \$35 in cost sharing for a preferred brand drug, knowing the list price of low-cost drugs is unlikely to affect their drug purchasing decisions. We appreciate commenters' recommendation to reduce the threshold to \$25, but we continue to believe that \$35 is a more appropriate threshold, given that it frequently is the copayment amount for preferred brand drugs. For the same reason, we decline to adopt the suggestion to raise the threshold to \$100. Also, there are likely not many additional drugs that would receive the exemption if we move it from \$35 to \$100. Finally, we disagree that it will be confusing to patients that some drugs and biological products include prices in their DTC advertising while others do not because drugs and biological products that do not have the price displayed will be within the range of what they would expect to pay for a prescription regardless of insurance coverage or structure, or if they are uninsured. DTC advertisements that do not have prices will be just like advertisements on television today. Moreover, nothing in this rule prevents a manufacturer from including its WAC even though it is exempt. Advertisements with prices will simply provide additional information that can help beneficiaries engage their doctors and make appropriate treatment decisions.

D. First Amendment Considerations

1. Background – *Zauderer/Central Hudson*

As an initial matter, the speech here at issue does not implicate core First Amendment interests. Manufacturers already disclose the very same information at issue, their products' WACs, to purchasers as well as publishers of various pricing databases and other compendia. As the Supreme Court has explained, "Our lodestars in deciding what level of scrutiny to apply to a compelled statement must be the nature of the speech taken as a whole and the effect of the

compelled statement thereon.” *Riley v. Nat’l Fed’n of Blind*, 487 U.S. 781, 796 (1988). The key concern relating to compelled speech is having the government compel a speaker to convey a message with which it disagrees. *Johanns v. Livestock Mktg. Ass’n*, 544 U.S. 550, 557 (2005); see, e.g., *Nat’l Inst. of Family and Life Advocates v. Becerra*, 138 S. Ct. 2361, 2379 (2018) (“*NIFLA*”) (law at issue “compel[ed] individuals to contradict their most deeply held beliefs, beliefs grounded in basic philosophical, ethical, or religious precepts”) (Kennedy, J., concurring). More routine disclosure requirements are “simply not the same as forcing a student to pledge allegiance[] or forcing a Jehovah’s Witness to display the motto ‘Live Free or Die.’” *Rumsfeld v. Forum for Academic & Institutional Rights, Inc.*, 547 U.S. 47, 62 (2006). The “disclos[ure of] objective facts and statistics” about price information “is simply not the same as forcing a speaker to support or accommodate an idea, belief, or opinion.” *Beeman v. Anthem Prescription Management, LLC* (“*Beeman*”), 315 P.3d 71, 84 (Cal. 2013) (citations and internal punctuation omitted).

It is therefore well established that the government may, consistent with the First Amendment, require the disclosure of factual information in marketing commercial products where the disclosure is justified by a government interest and does not unduly burden protected speech. *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985); *NIFLA*, 138 S. Ct. at 2372. The rule’s required disclosure meets this test. The list price is a fact that is controlled by the manufacturer; it does not represent a government viewpoint or policy message. Price transparency enhances the information available in the market and allows markets to function more efficiently to the benefit of consumers. And the brief textual statement placed at the end of a television advertisement would not unduly burden the advertiser’s ability to convey its message in the remainder of the advertisement.

Many comments assert that the rule should be evaluated under the intermediate scrutiny test for commercial speech articulated in *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557 (1980). Under that test, agencies can regulate speech where the regulation advances a substantial government interest and the regulation is no more extensive than necessary to serve that interest.

Although we believe that *Zauderer* provides the appropriate framework for review, the rule also satisfies the elements of the *Central Hudson* test. The government interest is clear. Prescription drug spending in the United States has increased dramatically in recent years and is projected to account for an increasing share of the country's health care spending. This affects consumers both through their own OOP expenses and through the expenses borne by Medicare and Medicaid and taxpayers. Price transparency helps improve market efficiencies by helping consumers make informed choices and the disclosure of price information clearly and directly advances this interest. The brief disclosure at the end of a prescription drug advertisement is narrowly tailored to achieve that result and does so more effectively than alternatives that do not provide the information in the advertisement itself.

2. Application of the *Zauderer* test

Comment: Some comments assert that the *Zauderer* test applies only where the government interest relates to preventing consumer deception. In contrast, at least one comment noted that some lower court cases have recognized other interests. Another comment stated that the United States Supreme Court has not resolved the issue.

Response: The latter comments more accurately summarize the current state of the law. While some lower court decisions could be read to limit the application of *Zauderer* to matters where the government interest relates to preventing consumer deception, e.g., *Entm't Software*

Ass'n v. Blagojevich, 469 F.3d 641, 651-53 (7th Cir. 2006), other courts have held that *Zauderer* applies where other interests support the compelled speech. See, e.g., *Am. Bev. Ass'n v. City & Cty. of San Francisco*, 916 F.3d 749, 755-56 (9th Cir. 2019) (*en banc*); *Am. Meat Inst. v. United States Dep't of Agric.*, 760 F.3d 18 (D.C. Cir. 2014) (*en banc*). The Supreme Court did not reach this issue in *NIFLA*. See 138 S. Ct. at 2377. It is our view, based on current law, that the *Zauderer* test is not limited to disclosures designed to prevent consumer deception.

Comment: Several comments assert that the *Zauderer* test applies only to mandated disclosure of “purely factual and uncontroversial” information, but that the WAC, even if a literally true, should not be considered factual and uncontroversial because many patients would pay less, and therefore the WAC is incomplete, misleading, and will be misunderstood. Other comments argued that the disclosed prices “for a typical 30-day regimen or for a typical course of treatment” will often be inaccurate for certain drugs, where the course of treatment varies based on patient-specific factors such as age, weight, or baseline test results. Some comments further assert that by misleading patients, the compelled disclosure of inflated prices could dissuade patients from seeking appropriate treatment.

Response: We disagree with these comments. The rule requires the disclosure of “the current list price for a typical 30-day regimen or for a typical course of treatment.” The current list price for a prescription drug or biological product is an objective fact. As discussed above, the WAC is a manufacturer-specified metric that is commonly used, reported in compendia, defined in statute, and relevant to both federal and commercial health care programs.

As discussed in the proposed rule, price disclosure requirements are commonplace under federal, state, and local laws, and have been upheld when challenged under the First Amendment as permissible disclosures of factual and uncontroversial information. See, e.g., *Spirit Airlines*,

Inc. v. United States Dep't of Transp., 687 F.3d 403, 414 (D.C. Cir. 2012); *Poughkeepsie Supermarket Corp. v. Dutchess Cnty*, 648 Fed. Appx. 156, 157-158, 2016 U.S. App. LEXIS 8770 (2d Cir. 2016); *see also Beeman*, 58 Cal. 4th at 341, 315 P.3d at 78, 165 Cal. Rptr. 3d at 809 (upholding compelled disclosure of pharmacy fees under the right to free speech guaranteed by article I of the California Constitution, which is “at least as broad as and in some ways is broader than the comparable provision of the federal Constitution’s First Amendment”) (citations and internal punctuation omitted). The “disclos[ure of] objective facts and statistics” about price information “is simply not the same as forcing a speaker to support or accommodate an idea, belief, or opinion.” *Beeman*, 58 Cal. 4th at 349, 315 P.3d at 84, 165 Cal. Rptr. 3d at 816 (citations and internal punctuation omitted). And as the Supreme Court confirmed in *NIFLA*, “we do not question the legality of . . . purely factual and uncontroversial disclosures about commercial products.” 138 S. Ct. at 2376.

The rule further requires the disclosure to contain the following statement: “If you have health insurance that covers drugs, your cost may be different.” Again, this is undeniably a truthful statement of objective fact. Moreover, it directly addresses the issue raised in some of the comments in that it contextualizes the list price information. The assertions in the comments that consumers will misunderstand the price disclosure with this additional context are purely speculative. In addition, nothing in the rule would prevent the manufacturer from presenting additional contextual information, should the manufacturer wish to do so. However, we remind manufacturers that they have to comply with all applicable FDA requirements and that nothing in this rule is intended to supersede any FDA requirement.

Comment: At least one comment asserts that disclosure of the WAC is controversial because pharmaceutical pricing is a controversial topic, and therefore even if the *Zauderer* test

for permissible compelled disclosures did apply, it would not be satisfied here. The comment cites *NIFLA* and *Nat'l Ass'n of Mfrs. v. SEC*, 800 F.3d 518 (D.C. Cir. 2015) as support for this proposition.

Response: We disagree with this comment and the applicability of the cited cases. First, because the WAC is a truthful statement of objective fact that is not subject to dispute, it is “uncontroversial.” Indeed, all drug manufacturers provide this information voluntarily to companies who publish this information in compendia or databases available to the public, and we note that one drug manufacturer voluntarily chose to include the list price of their more commonly prescribed drug prior to the establishment of a legal requirement to do so. Second, under the case law, it is not clear that “uncontroversial” or “noncontroversial” is a legal standard that is part of the *Zauderer* test. *See Disc. Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509, 559 n.8 (6th Cir. 2012) (The test under *Zauderer* is “factual” and “accurate”; the Court in *Zauderer* used the term “noncontroversial” once to “merely describe[] the disclosure the Court faced in that specific instance.”). Indeed, some cases have not mentioned “uncontroversial” or “noncontroversial” in the course of applying the *Zauderer* test. *See, e.g., Milavetz, Gallop & Milavetz, P.A. v. United States*, 559 U.S. 229 (2010); *Spirit Airlines, Inc.*, 687 F.3d 403.

In *NIFLA*, the Supreme Court held that the *Zauderer* test applies only to required disclosures about the speaker’s own product or service, and therefore it did not apply to a disclosure about the availability of state-sponsored medical services (including, in that case, the potential provision of abortion services). *See* 138 S. Ct. at 2372. Although the Court noted that abortion is “anything but an ‘uncontroversial’ topic,” that statement does not appear to be the basis for its finding that *Zauderer* did not apply to the disclosure about state-sponsored services. *See id.* Here, by contrast, the disclosure required by the rule relates to the product being

advertised, thus falling squarely within the traditional ambit of the *Zauderer* test.

Unlike the 6th Circuit holding in *Discount Tobacco*, the D.C. Circuit held in *Nat'l Ass'n of Mfrs* that “uncontroversial” is part of the *Zauderer* test. However, the holding in that case underscores that a drug’s list price is not “controversial.” At issue in that case was a requirement that companies report to the SEC and state on their website if any of their products “have not been found to be DRC conflict free” – which the court described as “a metaphor that conveys moral responsibility for the Congo war” and “compel[s] [a company] to confess blood on its hands.” 800 F.3d at 530. A disclosure of the list price of a prescription drug or biological product is hardly comparable, and courts have upheld required disclosures similar to the one here. *See, e.g., Spirit Airlines, Inc.*, 687 F.3d 403 (upholding requirement for airlines to make total price the most prominent cost figure in advertisements); *N.Y. State Rest. Ass'n v. N.Y. City Bd. of Health*, 556 F.3d 114, 134 (2d Cir. 2009) (upholding required posting of calories on menus in chain restaurants); *Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104 (2d Cir. 2001) (upholding requirement that mercury-containing products be labeled with a statement that the products contain mercury and, on disposal, should be recycled or disposed of as hazardous waste). Thus, even if “uncontroversial” is part of the *Zauderer* test and given the meaning adopted by the court in *Nat'l Ass'n of Mfrs*, the disclosure of price information is uncontroversial.

Comment: Some comments assert that the required disclosures are not adequately justified. Some state that the government goal of encouraging the selection of cost-effective therapies cannot justify the compelled disclosure of the WAC, because the WAC is not the kind of health care economic information that would facilitate informed price-shopping and providing pricing in advertisements is too disconnected from purchasing decisions, which are often made

during physician-patient discussions. Other commenters claimed that CMS assumed, without sufficient evidence, that higher drug costs result from a lack of transparency about drug prices, and that CMS failed to explain why the disclosure of the WAC would be effective in light of the distortions in the market created by third-party payors. Commenters also stated the rule would fail to advance the government's interests because it would simply result in manufacturers shifting advertisements from TV to other forms, such as online or through social media. One comment asserts that the required disclosure is unnecessary because many prescription drug manufacturers will begin voluntarily providing this pricing information on their websites pursuant to a document issued by the Pharmaceutical Researchers and Manufacturers of American ("PhRMA"), entitled *PhRMA Guiding Principles-Direct to Consumer Advertisements About Prescription Medicines*. That document was revised in October 2018 to include a new price disclosure principle recommending that prescription drug broadcast advertisements include direction to where patients can find information about the cost of the medicine, such as a company-developed website.

Response: We disagree with these comments—the rule is more than adequately justified. The *Zauderer* test requires that compelled disclosures “remedy a harm that is potentially real [and] not purely hypothetical.” *NIFLA*, 138 S. Ct. at 2377 (citation and internal punctuation omitted). Here, the harm is clearly real. As discussed in section I.C. above, rising drug prices increase federal health care costs, threatening the sustainability of federal health care programs and the availability to care to Medicare and Medicaid beneficiaries, and are a harm to beneficiaries by increasing their health care and OOP costs.

PhRMA's issuance of a new guiding principle in October 2018 does not change the need for the rule. The PhRMA principles are voluntary; they are not binding on PhRMA members, let

alone non-members, and there is nothing to prevent PhRMA from revising its principles at any time, a fact which is underscored by the timing of the issuance of the guideline to coincide with the issuance of the proposed rule. Moreover, including direction to where price information can be found will not have the same impact as including the information in the advertisement itself. As noted in section II.E.7. of this rule, one third of adults surveyed stated that they do not frequently use the internet, making the PhRMA proposal relatively meaningless to that cohort. As to the other two thirds who do, the PhRMA proposal would require them to immediately open their browser, navigate to the URL flashed on the television screen, and then click through to find the pricing information. We believe that relatively few viewers will make use of the approach advocated by the PhRMA proposal, even assuming that its members implement the proposal.

Comment: Some comments assert that the rule would be unduly burdensome in that it would clutter the advertisement and would require monthly updates.

Response: We disagree. “[C]ompliance with most compelled disclosure laws will logically entail some expense.” *Poughkeepsie Supermarket Corp. v. Cnty. of Dutchess*, 140 F. Supp. 3d 309, 317 (S.D.N.Y. 2015), *aff’d* 648 Fed. Appx. 156, 157-158, 2016 U.S. App. LEXIS 8770 (2d Cir. 2016). Courts, however, have not found them to be unduly burdensome unless they “drown[] out the [speaker’s] own message” or “effectively rule[] out” a mode of communication. *NIFLA*, 138 S. Ct. at 2378. As we explained in the proposed rule, the requirement to add certain information to an advertisement is not unduly burdensome where, as here, the manufacturer has the ability to convey other information of its choosing in the remainder of the advertisement. *See, e.g., Spirit Airlines, Inc.*, 687 F.3d at 414 (requirement for airlines to make total price the most prominent cost figure does not significantly burdens airlines’

ability to advertise); *Discount Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509, 524 (6th Cir. 2012) (size of required warnings is not unduly burdensome where remaining portions of their packaging are available for other information). The inclusion of a brief textual statement at the end of a broadcast advertisement neither drowns out the speaker's message nor rules out broadcast advertisements as a mode of communication.

Even if economic burden were relevant under *Zauderer*, the burden here is minimal. First, most manufacturers report the WAC to compendia and databases for other business purposes. Second, we are narrowly limiting the amount of information included on the advertisements and the advertisements subject to this policy to minimize the burden on manufacturers and advertising platforms to only deliver the minimum amount of necessary information to implement the policy. Finally, the fact that one pharmaceutical manufacturer is voluntarily including list prices in its television advertisements shows that including these prices is a minimal burden to the manufacturers.³⁷ Finally, the Regulatory Impact Analysis in section IV shows that the cost to implement this change would cost less than 0.1 percent of what manufacturers spend on DTC television advertising.

Comment: Some comments assert that the rule will be burdensome on other actors in the chain of distribution such as broadcasters and cable operators, particularly in that the disclosure requirement will have the effect of diverting the advertising revenue to different media.

Response: Spending on DTC pharmaceutical commercials increased 62 percent between

³⁷ Johnson and Johnson. What Cost Information Helps Patients in a TV Ad? We Asked Them. <https://www.jnj.com/our-company/what-cost-information-helps-patients-most-we-asked-them>

2012 and 2017.³⁸ Studies estimate that every dollar spent on DTC advertising increases sales on the advertised drug by \$2.20-\$4.20.³⁹ Because of the value and return on investment related to DTC advertising,⁴⁰ it is unlikely that adding the list price of pharmaceuticals to DTC television advertising will significantly affect the amount spent by that sector on television advertisements (i.e., \$4.2 billion in 2017).

In addition, we disagree that this type of alleged impact is properly part of the First Amendment analysis. The undue burden that the *Zauderer* test contemplates is an undue burden on “protected speech,” not the economic impact on other actors. *See NIFLA*, 138 S. Ct. at 2377.

Comment: Some comments assert that government-scripted speech is always burdensome.

Response: We disagree. There are many products and services regulated under federal, state, and local laws for which disclosures are required. *See Reed v. Town of Gilbert*, 135 S. Ct. 2218, 2234-35 (2015) (Breyer, J., concurring); *Beeman*, 58 Cal. 4th at 366-67, 315 P.3d at 96-97, 165 Cal. Rptr. 3d at 830-31. And the Court in *NIFLA* confirmed that “we do not question the legality of health and safety warnings long considered permissible, or purely factual and uncontroversial disclosures about commercial products.” 138 S. Ct. at 2376. Thus, the fact that many of these disclosures are “government-scripted” does not make them unconstitutional.

Moreover, disclosure of price information is fundamentally different from the viewpoint discrimination that lies at the heart of First Amendment protections. “Required disclosure of

³⁸ Kantar Media. Pharma ups the ante on DTC advertising. <https://www.kantarmedia.com/us/newsroom/km-inthenews/pharma-ups-the-ante-on-dtc-advertising>

³⁹ Ventola CL. Direct-to-Consumer Pharmaceutical Advertising: Therapeutic or Toxic? P T. 2011 Oct; 36(10): 669-674, 681-684.

⁴⁰ Garrett JB, Tayler WB, Bai G, et al. Consumer Responses to Price Disclosure in Direct-to-Consumer Pharmaceutical Advertising. *JAMA Intern Med.* 2019;179(3):435-437. (“2019 JAMA Study”)

accurate, factual commercial information presents little risk that the state is forcing speakers to adopt disagreeable state-sanctioned positions, suppressing dissent, confounding the speaker's attempts to participate in self-governance, or interfering with an individual's right to define and express his or her own personality.” *Nat’l Elec. Mfrs. Ass’n v. Sorrell*, 272 F.3d 104, 114 (2d Cir. 2001).

The disclosure required by the rule is:

The list price for a [30-day supply of] [typical course of treatment with] [name of prescription drug or biological product] is [insert list price]. If you have health insurance that covers drugs, your cost may be different.

The bracketed language will be drafted by the company and the list price will be incorporated by the company. The few remaining words that constitute “scripted” language do not unduly burden First Amendment values.

Accordingly, we conclude that this final rule is constitutionally proper under the *Zauderer* test.

3. Application of the *Central Hudson* test

Comment: Most comments did not dispute that the government interests described in the preamble to the proposed rule are substantial. Some comments affirmatively assert that HHS has a substantial interest in reducing Medicare and Medicaid costs. One comment, however, asserts that the proposed rule failed to establish that HHS’s interest in the efficient administration of both Medicare and Medicaid programs was substantial.

Response: We agree with the comments that affirm the substantial government interest in reducing prescription drug or biological product costs generally, as well as the costs borne by Medicare and Medicaid. As discussed in section I.C.2.a. above, DTC advertising increases both

utilization and costs of pharmaceuticals. Because DTC advertising has a direct impact on the utilization of prescription drugs or biological products, and the drugs most frequently advertised on television are high-cost drugs, the link between DTC advertising and efficient administration of the Medicare and Medicaid program is clear. In our view, there is no question that this interest is substantial.

Comment: Some comments assert that the rule will not advance any substantial government interests. Some of these comments assert that disclosure of the list price to consumers would not be helpful to consumers because of the disparity between the list price and the price actually paid by most patients.

Response: We disagree. As discussed in section I.C.1., there is a substantial government interest in reducing list prices because list price is directly linked to a number of factors that directly tie to how much Medicare Part D patients will pay for their drugs. Increased spending on high-cost drugs harms CMS programs and CMS beneficiaries. Additionally, as discussed in Section II.C., the WAC is a good price metric to use to represent list price.

Comment: Some comments assert that disclosure of the list price will not reduce drug prices. Other comments assert that the record is not sufficient to support the conclusion that the rule will be effective and that further study is necessary. At least one comment asserts that the rule will directly advance the government interest in reducing the high cost of prescription drugs or biological products including reducing Medicare and Medicaid costs.

Response: We agree with the latter comment. As discussed in section I.C., it is well accepted that price transparency helps improve market efficiencies by helping consumers make informed choices. Disclosure of price information clearly and directly advances this interest. *Cf. Spirit Airlines, Inc.*, 687 F.3d at 415. Including the price of pharmaceuticals in DTC consumer

advertising does change patient behavior, as discussed in section I.C. above. At the same time, any potential risks of being a barrier to access can be mitigated by notifying patients that the price may not reflect what the patient will pay OOP. Instead, it will create an opportunity for conversation between the patient and provider.⁴¹

Comment: At least one comment asserts that the rule could cause companies to withdraw their television advertisements in favor of other media.

Response: We find this scenario highly unlikely. As discussed, above, the health care and pharmaceutical industry spent over \$4.2 billion on DTC advertising in 2017,⁴² up to a 4 fold increase in spending on the advertised drug for every dollar spent on DTC.⁴³ Given the popularity of TV among potential purchasers of a manufacturer's drugs as discussed in Section II.A, we have no basis to conclude that manufacturers would stop advertising on TV in favor of other media.

Comment: Some comments assert that the rule is not appropriately tailored to advance the government interests. At least one comment asserts that it is underinclusive in that the media is limited to television advertisements and drug products are limited to those reimbursed by Medicare and Medicaid. The comment also opined that rule is overinclusive in that it would cover drugs for which there is no alternative.

Response: We disagree with these comments. The *Central Hudson* standard does not require the government to employ "the least restrictive means" of regulation or to achieve a

⁴¹ Garrett JB, Tayler WB, Bai G, et al. Consumer Responses to Price Disclosure in Direct-to-Consumer Pharmaceutical Advertising. *JAMA Intern Med.* 2019;179(3):435-437. ("2019 JAMA Study")

⁴² Kantar Media. Pharma ups the ante on DTC advertising. <https://www.kantarmedia.com/us/newsroom/km-inthenews/pharma-ups-the-ante-on-dtc-advertising>

⁴³ Ventola CL. Direct-to-Consumer Pharmaceutical Advertising: Therapeutic or Toxic? *P T.* 2011 Oct; 36(10): 669-674, 681-684.

perfect fit between means and ends. *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 556 (2001). Instead, it is sufficient that the government achieve a “reasonable” fit by adopting regulations “in proportion to the interest served.” *Bd. of Trustees v. Fox*, 492 U.S. 469, 480 (1989) (citation omitted). As long as the regulation is “[w]ithin those bounds” of reasonable fit and proportion, the agency may determine “what manner of regulation may best be employed.” *Id.* The final rule starts with television advertising because we want to define the rule as narrowly as possible to achieve the goal improving price transparency and reducing the costs of prescription drugs and biological products. Since DTC television advertising makes up the majority of DTC spending, this is a good place to start to have the largest impact with the smallest burden. We reserve the right to expand the rule to include other media formats through future rulemaking.

As discussed above, the rule targets television advertisements for drugs because television advertising makes up the largest portion of DTC spend and has an outsized impact compared to other forms. As we try to educate as many patients as possible with this valuable information, as manufacturers do with their advertisements, we want to focus on the most commonly used and broadest reaching medium. This will allow us to maximize the number of patients educated while minimizing burden on manufacturers. The scope is limited to Medicare and Medicaid because we can directly link the lack of information and transparency on drug pricing to harm to those programs and their beneficiaries.

We disagree with the concern that providing the price for drugs or biological products that have no alternatives is overinclusive. As discussed above, the purpose of this rule is to provide valuable information about the drugs and biological products to the patient facilitate conversations and shared decision-making with their providers. The purpose is not to deter patients from using high cost prescription drugs and biological products. In the case of drugs and

biologic products that have no alternative, the price will still be an informative talking point.

Comment: Some comments assert that the preamble to the proposed rule incorrectly cited *Red Lion Broad. Co. v. FCC*, 395 U.S. 367, 390 (1969) because the “fairness doctrine” at issue in that case is inapplicable here.

Response: We agree that the fairness doctrine is inapplicable to this rule. The preamble to the proposed rule cited *Red Lion Broadcasting* for the much more limited proposition that the Supreme Court has recognized that broadcast advertisements can be a particularly powerful means for conveying information to listeners.

Comment: Some comments assert that there are better alternatives that would be less burdensome on speech. Some comments assert that HHS should encourage companies to institute voluntary price disclosure measures, which the comments assert are preferable to compelled speech. At least one comment disagrees and asserts that, since corporations owe duties to their shareholders, not to the public, they should not be allowed to self-regulate.

Response: Since the issuance of the proposed rule, some manufacturers have made more pricing information, including list price, available on websites, and one manufacturer has begun to disclose list price information in some of its television advertisements. While we applaud these measures, we have concluded that voluntary measures will be insufficient to ensure the continued commitment of all of the relevant companies. We address the issue of manufacturer websites further below in section II.E.7.

4. Heightened and Strict Scrutiny

Comment: Some comments suggest that content-based compelled speech and speaker-based regulation should be subject to strict scrutiny or at least heightened scrutiny, citing *Reed v. Town of Gilbert*, 135 S. Ct. 2218, 2226 (2015), *Sorrell v. IMS Health Inc.*, 564 U.S. 552 (2011),

and *NIFLA*.

Response: We disagree with these comments. As discussed above, HHS believes that this rule is properly reviewed under *Zauderer*. In *Reed v. Town of Gilbert*, the Court applied strict scrutiny to content-based restrictions on non-commercial speech in public fora. In that opinion, the Court stated that, “[c]ontent-based laws – those that target speech based on its communicative content – are presumptively unconstitutional and may be justified only if the government proves that they are narrowly tailored to serve compelling state interests.” 135 S. Ct. at 2226. However, as Justice Breyer explained in his concurring opinion, many regulatory programs “inevitably involve content discrimination”; applying strict scrutiny to those programs would “write a recipe for judicial management of ordinary government regulatory activity.” *Id.* at 2234-35 (Breyer, J., concurring). Lower courts have subsequently held that *Town of Gilbert* does not apply to the regulation of commercial speech. *See, e.g., Sarver v. Chartier*, 813 F.3d 891, 903 n.5 (9th Cir. 2016). And the Supreme Court has not applied strict scrutiny to the content-based regulations in decisions issued after *Town of Gilbert*, namely *Matal v. Tam*, 137 S. Ct. 1744 (2017), *Expressions Hair Design v. Schneiderman*, 137 S. Ct. 1144, 1151 (2017), and *NIFLA* itself.

The Supreme Court in *Sorrell* suggests that content- and speaker-based restrictions would be subject to “heightened scrutiny,” but nevertheless continued to apply the “commercial speech inquiry” as outlined in *Central Hudson*. *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 571-72 (2011). That led to debate in the lower courts about whether heightened scrutiny is a different standard from *Central Hudson* and, if so, what the test is and when it is applied. *See, e.g. Retail Digital Network, LLC v. Prieto*, 861 F.3d 839 (9th Cir. 2017) (en banc) (“*Sorrell* did not mark a fundamental departure from *Central Hudson*’s four-factor test, and *Central Hudson* continues to

apply.”); *Wollschlaeger v. Florida*, 848 F.3d 1293 (11th Cir. 2017) (en banc) (applying “heightened scrutiny” to a content-based restrictions); *1-800-411-Pain Referral Service, LLC v. Otto*, 744 F.3d 1045, 1055 (8th Cir. 2014) (Because *Sorrell* did not define heightened scrutiny, *Central Hudson* applies to restrictions on commercial speech that are content- or speaker-based). Thus, the legacy of *Sorrell* remains unclear.

In addition, there have been suggestions that heightened scrutiny should be connected to viewpoint discrimination, and not more broadly to content-based regulation. *See Sorrell*, 564 U.S. at 565 (law under review “goes even beyond mere content discrimination, to actual viewpoint discrimination”); *Matal*, 137 S. Ct. at 1767 (Kennedy, J., concurring) (“the viewpoint based discrimination at issue here necessarily invokes heightened scrutiny”). This distinction may be particularly important given that many regulatory programs necessarily involve both content- and speaker-based restrictions. *See Sorrell*, 564 U.S. at 589 (Breyer, J., dissenting) (“Regulatory programs necessarily draw distinctions on the basis of content. . . . Nor, in the context of a regulatory program, is it unusual for particular rules to be ‘speaker-based,’ affecting only a class of entities, namely, the regulated firms.”).

While the First Amendment jurisprudence continues to evolve, one thing is clear – the disclosure required by this rule does not implicate the concerns underlying *Sorrell* and many other cases – that is, the government’s “regulation of speech because of disagreement with the message it conveys.” *Sorrell*, 564 U.S. at 566. Here, the rule requires merely the disclosure of price information regarding prescription drugs or biological products in television advertisements – objective, factual information that will help inform consumers and improve market efficiencies.

E. Requirements in DTC Advertising other than WAC

1. Medium to Include List Price

We sought comment on whether we should apply the proposed regulation to other media formats and, if so, what the presentation requirements should be.

Comment: Some commenters recommended that list price be included on all DTC advertising, such as radio, magazine, and online communication. Some commenters asked CMS to explain why this rule only applies to DTC advertisements on television. Including the prices on all media formats would support the goal of this rule in increasing transparency and informing patients. Several commenters recommend providing the list price to the patient and provider at the time of prescribing, which would require expanding beyond just television advertising, because this is when the provider and patient would best be able to use the information when making care decisions.

Response: We appreciate recommendations to include the list price on all forms of DTC advertising. We intend to only apply this rule to television advertising because we want to apply this rule as narrowly as possible to achieve our goal of promoting price transparency and reducing drug costs, with minimal burden on those providing the information. We appreciate commenters' recommendations to make the list price available at the time of prescribing. In our recent proposed rule titled "Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses," 83 FR 62152 (November 30, 2018), we proposed to require Part D sponsors to implement an electronic real-time benefit tool (RTBT) capable of integrating with at least one prescriber's e-prescribing and electronic medical system to provide complete, accurate, timely and clinically appropriate patient-specific real-time formulary and benefit information, including cost, formulary alternatives, and utilization management requirements.

2. Typical Regimen—30 days or Course of Treatment

We sought comment on whether 30-day supply and typical course of treatment are appropriate metrics for a consumer to gauge the cost of the drug.

Comment: Many commenters agreed that 30 days is an appropriate quantity for the purposes of providing a usable list price in a television ad, especially for chronic medications. One commenter suggested providing the cost for a 90-day supply because many payors prefer that patients fill their prescriptions for a 90-day supply. Some comments, including those that support using a 30-day supply, recommend including the annual cost instead of, or in addition to, the cost for 30-day supply.

Many commenters also agreed that the price for a typical course of treatment would be appropriate for drugs that are not taken chronically or do not have standard 30-day supply. Commenters note that it is important for CMS to provide specific guidance on the definition of a typical course of treatment, as this could be an opportunity for gaming to provide the cost for the minimum possible treatment.

Some commenters note that it is difficult for manufacturers to calculate a WAC or list price for a 30-day supply or a typical course of treatment because doses can vary dramatically for individual patients based on characteristics such as weight, gender, pharmacogenomics, renal and liver function, or severity of disease.

Response: We appreciate commenters' feedback. We are finalizing the requirement as proposed. While we understand that including the WAC for a 90-day supply or the annual cost may be useful for some patients, we believe that our requirement to include the WAC of a 30-day supply will provide sufficient information for patients to assess their costs on a monthly, or even a 90-day or other basis without being burdensome to manufacturers. In addition, we

understand that payors generally cover chronic medication in monthly increments, which makes the 30-day price most relevant. In response to comments seeking further guidance on what constitutes a typical course of treatment, we decline to impose specific requirements for determining the typical course of treatment at this time. The manufacturers will be in the best position to determine what a typical course of treatment would be for their drugs, and therefore will be in the best position to determine the appropriate list price for a typical course of treatment, consistent with the disclosure requirement set forth at § 403.1202. We will monitor compliance and take appropriate action if warranted.

3. Other Information

We also sought comment on the content of the proposed pricing information statement as described herein, including whether other specifications should be incorporated.

Comment: Some commenters agreed with the general disclosure, “If you have health insurance that covers your drug, your cost may be different” because, while it does not provide the specifics of how different the OOP cost may be from the list price, it provides enough information for the patient to expect a different price based on his or her insurance. Other commenters believe that this is not enough of a stipulation, and that patients need additional context for the information to be meaningful.

Response: We appreciate commenters’ support for the general disclosure about OOP costs. Although a general statement might not provide detailed information about each patient’s OOP cost or address the potential confusion between list price and OOP cost for a patient, we believe it is sufficient because, as noted in section II.C.2., DTC advertising is a source of information for patients from which to start a conversation patient and provider or payor. This rule encourages such conversations by promoting price transparency without unduly burdening

manufacturers. We therefore decline to require a more specific disclosure about a patient's OOP costs.

Comment: A few commenters recommended that CMS not expand the proposed disclaimer in such a way as to allow manufacturers to state the price of a drug after the consideration of a coupon or discount. Commenters noted that this would allow manufacturers to mask the true cost of their drugs.

Response: We are finalizing the standard disclaimer as proposed. We also note that this rule requires the inclusion in DTC television advertisements of the drug's WAC, which we have defined – consistent with section 1847A of the Social Security Act -- to exclude prompt pay or other discounts. Thus, the pricing information that must be disclosed will not be obscured by the application of coupons or discounts.

4. Combination of Drugs

We sought comment on how to treat an advertised drug that must be used in combination with another non-advertised drug or device.

Comment: A few commenters recommended that, in the cases of drugs that are typically used in combination with other drugs, DTC television advertisements include a standardized statement, such as “Note: this drug may require use in combination with another drug or device, whose price is not reflected in this cost.” These commenters also recommended against trying to estimate or include costs associated with the other drugs that are typically included in combination.

Response: We appreciate commenters' recommendations to include a standardized statement alerting patients to the fact that this drug is often used in combination with other drugs. Although we decline to require inclusion of such a statement at this time, we encourage

manufacturers of drugs typically used in combination with other drugs to include such a statement in their DTC television advertisements. We similarly decline to require that such a statement, if included in a DTC television advertisements, estimate or reflect costs associated with the other drugs, as we agree that may be confusing for patients.

5. Placement of Information/Content of the Statement (Including Use of Competitors' Prices)

We sought comment on whether the final rule should include more specific requirements with respect to the textual statement, such as specific text size, contrast requirements, and/or duration and specifically what those requirements should be.

Comment: Many commenters recommend that the information is displayed clearly in a way that is easy to see and easy for the average reader to read. Some commenters recommend that CMS specify requirements on font, size, location, and duration because without a clear, readable, and understandable standard format, manufacturers may intentionally make the information difficult to read or understand. Commenters also recommend reading the list price as part of the audio in addition to printing the price on the ad to further make the information available.

Other commenters recommended against specific requirements on how to display the list price in the ad because advertisements are extremely limited in time and space and recommended flexibility in order to develop an understanding of the best way to display this information. These commenters recommend that manufacturers be able to test different methods and details for displaying the information to best educate patients

Response: We appreciate these comments. We will finalize § 403.1203 as proposed because we believe it provides a sufficiently detailed standard for how the information must be

conveyed in the advertisement, while still allowing manufacturers flexibility to develop a format that – consistent with the regulatory standard -- best conveys the required information. We will monitor compliance with the regulation and provide guidance as necessary. We also will consider adopting more detailed requirements through future rulemaking if warranted.

Comment: Two commenters recommended against allowing manufacturers to include an up-to-date competitor product's list price because they believe that manufacturers will always list the highest competitor price available, which may confuse patients if other cheaper alternatives are available. Other commenters support the option to provide the list price of a therapeutic competitor, because the list price is not useful to the patient without additional context.

Response: We appreciate these comments. Although we recognize commenters' concerns about gaming, we are finalizing this provision as proposed. Allowing manufacturers to provide an up-to-date competitor product's price, so long as they do it in a truthful and non-misleading way, will provide additional information that the patient can use to manage his or her care. We believe that providing information about the prices of therapeutic alternatives provides valuable context for the patient. However, we remind manufacturers that they have to comply with all applicable FDA requirements and that nothing in this rule is intended to supersede any FDA requirement.

6. Effective Dates of Price

We proposed to require that the list price be current as determined on the first day of the quarter during which the advertisement is being aired or otherwise broadcast. We sought comment as to whether a statement expressing an expiration date of the current price reflected in the advertisement should be incorporated into the required disclosure language so that consumers are informed that drug prices are subject to frequent changes and a drug price may differ from

the date the advertisement is broadcast to the date that the drug is dispensed.

Comment: Many commenters recommended that DTC advertisements include a list price's expiration date to ensure that patients are acting on accurate information and to prevent manufacturers from intentionally providing misleading information. Commenters noted that, due to the frequency of prices changes, advertisements should specify the dates that the price is valid or when the price is expected to expire or change. Some commenters recommended specifying how timely the manufacturer must be in updating prices in the advertisements. A few commenters recommended that CMS require that the price always be up-to-date when they appear in the advertisement. Finally, one commenter suggested that as an alternative to updating list prices, the advertisement could include the WAC over some look-back period to approximate what the current price may be.

Response: We appreciate these comments and are finalizing § 403.1202 as proposed, with minor technical modifications described below, meaning that the list price must be current, as determined on the first day of the quarter during which the advertisement is being aired or broadcast. As we anticipate that manufacturers update their WACs twice per year, we do not believe advertisements will need to be changed with significant frequency. We decline to require inclusion of a price's expiration date in the advertisement because we want to minimize the burden on manufacturers and because we do not think that the information would helpful to patients beyond what is already required. However, a manufacturer may specify the effective dates of its prices, should it choose, so long as the price listed is current (as determined under § 403.1202). As noted above, we are making technical changes to the regulation text at § 403.1202 to refer consistently to a typical course of treatment and to remove the quotation marks that do not pertain to the required text.

7. Use of Manufacturer Websites

Comment: Commenters suggested that in lieu of requiring the WAC in the advertisement, the government could require that advertisements include a reference to where price information can be found, such as a company website that would include the list price and other context about the potential cost of the medicine. Specifically, many commenters recommend the alternative of encouraging voluntary price reporting in DTC advertising, pursuant to the PhRMA Guiding Principles-Direct to Consumer Advertisements about Prescription Medicines. These guiding principles now recommend that prescription drug broadcast advertisements include direction to where patients can find information about the cost of the medicine, such as a company-developed website. Commenters note that this would provide the flexibility to include the most important information in a method that is most appropriate for patients. Commenters note that this approach would avoid some of the potential adverse consequences associated with the requirements of the final rule, and would meet the overall objectives of the policy of providing promoting price transparency for patients.

Response: We appreciate the commenters' recommendation to promote a program of voluntarily listing drug prices. However, we disagree that voluntary price disclosure would adequately meet the goals of providing price transparency. If price disclosure were voluntary, some manufacturers would decline to provide the list price to the patient, and the patient would therefore lack that valuable information. For the reasons stated elsewhere in this rule, we believe it is necessary to the efficient administration of Medicare and Medicaid that this information be disclosed in DTC television advertisements. In contrast, referring patients to other resources, such as company-owned websites, would not serve this purpose. First, it is likely that there would be a very low conversion of patients going to a website that is referenced in a TV ad that

they see when they are not at their computer. More importantly, as noted in section II.D., 33 percent of adults surveyed say they do not frequently use the internet; as to the other, requiring them to open a browser, navigate to a site they saw on television, and click through to find pricing information creates additional burden and uncertain outcomes. Thus, manufacturer websites are not an adequate alternative to the price disclosure requirement we are finalizing in this final rule.

8. Use of Plan Finder

Comment: Some comments assert that CMS should develop its own database of list prices for the public to access.

Response: We continue to believe that the Medicare Part D Plan Finder is a valuable tool for patients, and we will continue to improve the tool over time through efforts such as the eMedicare Initiative.⁴⁴ We think the DTC television advertisement requirement provides additional information that is very useful to patients' understanding of drug pricing and provides important supplementary information to the Plan Finder tool.

Comment: Some comments stated that steps should be taken to encourage practitioners, plans, and payors to provide more information on prices and coverage.

Response: We agree that it is important to encourage health care practitioners, health plans, and payors to provide more information about prices and coverage. Price transparency is an important aspect of Medicare's most recent payment rules. In a recent proposed rule titled "Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket

⁴⁴ CMS News Room. CMS announces new streamlined user experience for Medicare beneficiaries. 2018 Oct 01. <https://www.cms.gov/newsroom/press-releases/cms-announces-new-streamlined-user-experience-medicare-beneficiaries-0>.

Expenses,” which appeared in the **Federal Register** on November 30, 2018 (83 FR 62152), we proposed to require Part D sponsors to adopt Real-Time Pharmacy Benefits Tools (RTBT) and enhanced Explanation of Benefits (EOB) forms to provide beneficiaries and their prescribers with more drug price information. We continue to encourage all patient-facing stakeholders in the drug supply chain to educate their patients and incorporate the cost of drugs and biological products into all of the shared-decision making conversations to identify the best overall therapy for the patient.

F. Other Approaches

We also considered additional solutions to provide beneficiaries with relevant information about the costs of prescription drugs and biological products so they can make informed decisions that minimize not only their OOP costs but also expenditures borne by Medicare and Medicaid. We sought comment on whether the following approaches could support price transparency and informed decision making, either in addition to or in lieu of the measures proposed in this notice of proposed rulemaking: (1.) an enhanced CMS drug pricing dashboard, (2.) intelligent plan selection or use of intelligent assignment, and (3.) a new payment code for drug pricing counseling. We are also interested in other approaches to price transparency and informed decision making that we have not contemplated.

1. Enhanced Drug Pricing Dashboard

Comment: Many commenters supported the development of a tool that could provide real-time information on drug costs, formulary, and cost-sharing that is easily accessible to patients. Some commenters pointed to useful examples in the private sector. Other commenters noted that PBMs and payors already have this capability. One commenter suggested that an enhancement could be to highlight drugs with excessive price increases or high prices, and list

lower cost alternatives. Other commenters expressed general skepticism that a dashboard would be a useful tool for patients. First, commenters noted that there are existing private tools, such as GoodRx, that provide similar information. Next, commenters noted that dashboards, no matter how they are configured, are going to be complex and difficult for patients to use. While the information will be useful and interesting to researchers, it would likely provide limited value to patients.

Response: We appreciate these recommendations and agree that online information is no substitute for pricing information in the DTC ad itself. As discussed in section II.E.8., we recently proposed to require Part D sponsors to adopt a real time benefit tool (RTBT) that would provide information about drug costs, formulary placement and cost-sharing. In addition, we also recently enhanced the Medicare and Medicaid Drug spending dashboards⁴⁵ to identify the manufacturers of drugs with price increases and highlight year-over-year pricing information. We appreciate feedback sharing concern about the usefulness of the drug dashboard for patients. We will take this feedback into consideration as we continue to improve and enhance the drug dashboard.

2. Intelligent Plan Selection

Comment: Some commenters generally supported the development of a tool to support intelligent plan selection that is voluntary for patients, and recommended it as a general improvement. One commenter was concerned that such a tool would be difficult to implement. One commenter expressed concern that intelligent plan selection could lead to adverse selection of patients and potential market instability.

⁴⁵ Available at: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/index.html>

Response: We appreciate these recommendations and concerns. There are likely various operational issues that would need to be addressed as a threshold matter for such a tool to be feasible. If CMS were to pursue development of such a tool, we would need to consider and address such issues, as well as consider how to address commenters' concerns. We will continue to consider this concept.

3. Counseling Code

In an effort to incentivize provider engagement with patients on their prescription drug and biological product OOP costs, CMS could create a new payment code, in a budget neutral manner, for doctors to dialogue with patients on the benefits of drugs and drug alternatives. This would likely decrease the number of prescriptions that go unfilled because of unexpected high OOP costs, thus improving adherence, but also could increase provider awareness of drug pricing which may influence prescribing when appropriate cheaper options are available.

Comment: Some commenters recommend creating a new payment code for counseling on drug pricing to appropriately reimburse providers for the additional time that they will need to spend on discussing the cost of therapies for patients. One commenter supports creating a new code, but recommends that the code be broad enough to also reimburse providers for care planning and navigation, shared decision making, developing a plan of care, and fostering a care coordination process, which would include counseling patients on the potential costs of their drugs and biological products. A couple commenters that supported the creation of the new payment code recommended making this code available to pharmacists, who may be one of the best resources to provide this information to the patient. One commenter noted that providers will need real time access to cost data if they are expected to counsel patients on cost, so we should keep this in mind if we plan to create the code.

Other commenters recommend against creating a new payment code. One commenter noted that providers are not necessarily the ones that should be having these conversations because they do not always have access to the relevant drug pricing information. Instead, they recommend that payors provide this information to patients. Another commenter noted that most providers already counsel their patients on their OOP costs and the importance of filling their prescription, so it is not necessary to create a separate code. Another commenter notes that current E&M documentation guidelines are broad enough to cover these conversations as part of the risk and benefits of treatment options. Finally, many commenters, including those that generally support creating a new billing code are concerned where the resources would come from based on the budget neutral element of the code.

Response: We agree that services such as patient counseling, care planning and navigation, and shared decision making are valuable to patients and important for delivering high quality care. We also agree that pharmacists may be able to provide information on drug pricing and patient coinsurance to patients and advise patients on the availability of less expensive drugs in the event cost is a barrier to medication adherence. While we are not finalizing in this rule, we will consider a counseling code for future rulemaking in the appropriate benefit categories as allowed by statute.

G. Enforcement

We proposed in § 403.1204(a) that the Secretary will maintain a public list that will include the drugs and biological products identified by the Secretary to be advertised in violation of this rule. We expect that this information will be posted publicly on a CMS internet website no less than annually. No other HHS-specific enforcement mechanism was proposed. However, we anticipate that the primary enforcement mechanism will be the threat of private actions under

the Lanham Act sec. 43(a), 15 U.S.C. 1125(a), for unfair competition in the form of false or misleading advertising. *See, e.g., POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2234 (2014); *In re McCormick & Co., Inc., Pepper Prod. Mktg. & Sales Practices Litig.* 215 F. Supp. 3d 51, 59 (D.D.C. 2016). Since Lanham Act cases normally involve sophisticated parties doing business in the same sector, the likelihood of meritless lawsuits is acceptably low. We sought comment on the primary enforcement mechanism and other approaches to enforcing compliance.

Under principles of implied preemption, to the extent State law makes compliance with both Federal law and State law impossible or would frustrate Federal purposes and objectives, the State requirement would be preempted. *See, e.g., Murphy v. NCAA*, 138 S. Ct. 1461, 1480-81 (2018); *Mutual Pharm. Co. v. Bartlett*, 570 U.S. 472, 480 (2013); *Geier v. American Honda Motor Co.*, 529 U.S. 861, 872-86 (2000). Obstacle preemption is not limited to examining the *accomplishment* of certain objectives; the *execution* is relevant as well. *Geier*, 529 U.S. 881-82. A state law is therefore preempted “if it interferes with the methods by which the federal statute was designed to reach that goal.” *Gade v. Nat’l Solid Wastes Mgmt. Ass’n*, 505 U.S. 88, 103 (1992) (quoting *Int’l Paper Co. v. Ouellette*, 479 U.S. 481, 494 (1987)).

Because this proposed rule is part of a broader initiative to reduce the price to consumers of prescription drugs and biological products, it would be counterproductive if this rule were to increase transactional costs in defending meritless litigation. We believe that the existing authority cited above, namely the Lanham Act, is the appropriate mechanism for enforcing against deceptive trade practices. Accordingly, consistent with our not proposing any HHS-specific enforcement mechanism, we proposed at § 403.1204(b) that this rule preempt any state-law-based claim that depends in whole or in part on any pricing statement required by this rule.

1. Lanham Act

Comment: Several commenters were concerned that private actions under the Lanham Act would not be an adequate enforcement mechanism for the requirement that manufacturers include the current list price of a prescription drug or biological product in all DTC television advertisements. In particular, these commenters were concerned that standing to enforce this requirement would be limited to competitors, and that consumers, who have the greatest interest in receiving this pricing information, would be precluded from taking action against violators. A few commenters added that the high costs of pursuing an action under the Lanham Act would discourage companies from bringing claims, while one commenter expressed concern about the potential for higher drug costs due to drug manufacturers having to internalize the costs of Lanham Act litigation. Several commenters noted it would be difficult to prove a claim under the Lanham Act for false advertising solely on the basis of the omission of information regarding the list price of a prescription drug or biological product, which they assert differs from the price paid by most consumers. Some of these commenters also expressed concerns that a competitor would be unable to demonstrate commercial injury.

Response: We disagree with the comments asserting that the threat of private actions under the Lanham Act for unfair competition in the form of false or misleading advertising is not an appropriate mechanism to enforce the price disclosure requirement in § 403.1202. We acknowledge that standing to bring suit under the Lanham Act is limited to competitors and others that can allege an injury to a commercial interest, and consumers would not be able to challenge the omission of pricing information. *See Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 132-134 S.Ct. 1377, 1390 (2014). We considered this limitation when proposing to rely upon the Lanham Act as the primary enforcement mechanism for the requirements of this rule. We continue to believe that competitors are best positioned to

identify and act upon advertisements that violate this regulation. Furthermore, although consumers lack standing to bring an action under the Lanham Act, we note that a fundamental premise of the rules in section 43(a) of the Lanham Act is the strong public interest in protecting consumers from false and misleading advertising. *See Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharm., Co.*, 290 F.3d 578, 597 (3d Cir. 2002) (“[T]here is a strong public interest in the prevention of misleading advertisements”) (citations omitted); *Vidal Sassoon, Inc. v. Bristol Myers Co.*, 661 F.2d 272, 277 (2d Cir. 1981) (recognizing “the clear purpose of Congress in protecting the consumer”). *See also*, Lillian R. BeVier, *Competitor Suits for False Advertising Under Section 43(a) of the Lanham Act: A Puzzle in the Law of Deception*, 78 VA. L. REV. 1, 3 (1992) (“[T]he proper perspective from which to view the rules in section 43(a) cases is that of the potentially deceived consumer rather than the possibly injured competitor.”); Ross D. Petty, *Competitor Suits Against False Advertising: Is Section 43(a) of the Lanham Act a Proconsumer Rule or an Anticompetitive Tool?*, 20 U. BALT. L. REV. 381, 395 (1991) (“Most courts recognize that there is a ‘strong public interest’ in using the Lanham Act to prevent misleading advertising and presume that consumers’ as well as competitors’ interests are to be protected under the Act.”) (citations omitted).

Although several commenters objected to our proposal to rely on Lanham Act actions by competitors to enforce the requirements of this rule on the grounds that such actions would be too costly, no commenters provided specific evidence that it would be prohibitively expensive to bring a Lanham Act suit. Indeed, if a competitor is able to establish a violation of section 43(a) of the Lanham Act, 15 U.S.C. 1125(a), and demonstrates that it has been injured as a result of that violation, it may be entitled to recover not only its own damages, but also the defendant’s profits and the costs of the action. *See* 15 U.S.C. 1117(a). Furthermore, as we indicated in the

proposed rule, because Lanham Act cases typically involve sophisticated parties doing business in the same sector, the likelihood of meritless lawsuits is acceptably low. As a result, the use of this enforcement mechanism is unlikely to force drug manufacturers to raise prices to account for the heavy costs of defending against meritless litigation.

Nor do we agree with those commenters who believe it will be impossible to demonstrate competitive harm from the omission of the required pricing information from a drug manufacturer's advertising. As noted by the commenters, a successful suit under section 43(a) of the Lanham Act, requires a "false or misleading description of fact, or false or misleading representation of fact." 15 U.S.C. 1125(a). However, it is also well-established that a statement can be actionable under section 43(a) if it is "affirmatively misleading, partially incorrect, or untrue *as a result of failure to disclose a material fact.*" See 5 J. Thomas McCarthy, *McCarthy on Trademarks and Unfair Competition* sec. 27.65 (5th ed. 2018) (citations omitted) (emphasis added). Failure to disclose the list price in a DTC advertisement, if required to do so by § 403.1202, makes that advertisement false and misleading. The disclosure requirements under § 403.1202 apply to all prescription drugs and biological products distributed in the United States for which payment is available, directly or indirectly, under titles XVIII or XIX of the Social Security Act other than "excepted pharmaceuticals." Excepted pharmaceuticals are defined in § 403.1200(b) as any prescription drug or biological product that has a list price less than \$35 per month for a 30-day supply or typical course of treatment. These excepted pharmaceuticals are exempt from the requirement to disclose pricing information in their advertisements. As a result, when an advertisement does not include pricing information, it would be reasonable for a consumer to conclude that the prescription drug or biological product is an excepted pharmaceutical, with a list price of less than \$35. Thus, the omission of pricing

information from an advertisement for a higher cost pharmaceutical is inherently false and misleading.

Finally, we disagree that it will be impossible for a competitor to show harm arising from the omission of information regarding the list price of a prescription drug or biological product from an advertisement. Commenters asserted this would be the case because the list price does not reflect the actual purchase price that will be paid by all consumers for all purchases. However, as discussed above, there is a direct link between the WAC and the price paid for the majority of patients, including any uninsured patients and patients with high-deductible health plans, or co-insurance, including Part D. Disclosure of the list price substantially affected consumer interest in high-priced drugs. In contrast, price disclosures had little influence on consumer interest in low-priced drugs.⁴⁶ Thus, it is reasonable to believe that the omission of list price information for a particular prescription drug or biological product, which would imply that the drug or biologic is in the low-priced category of excepted pharmaceuticals, could be material to a consumer's decision to choose that prescription drug or biological product, rather than a competing product that includes a higher list price in its advertising, as required under § 403.1202. See *McCormick & Co, Inc., Pepper Prod. Mktg. & Sales Practices Litig.*, 215 F. Supp. 3d 51, 57 (D.D.C. 2016) (“[I]t is the stuff of the most elementary economic texts that if two firms are offering a similar product for different prices, the firm offering the lower price will draw away customers from its competitor.”) (quoting *Am. Soc’y of Travel Agents, Inc. v. Blumenthal*, 566 F.2d 145, 157 (D.C. Cir. 1977) (Bazelon, C.J., dissenting)). Furthermore, the Lanham Act can be an effective enforcement tool even in the absence of direct evidence of lost

⁴⁶ Garrett JB, Tayler WB, Bai G, et al. Consumer Responses to Price Disclosure in Direct-to-Consumer Pharmaceutical Advertising. *JAMA Intern Med.* 2019;179(3):435-437. (“2019 JAMA Study”)

sales or other competitive injury. Courts have held that there is no requirement that a competitor prove direct injury in order to bring an action to enjoin conduct that violates section 43(a) of the Lanham Act. *See, e.g., Porous Media Corp. v. Pall Corp.*, 110 F.3d 1329, 1335 (8th Cir. 1997) (“A plaintiff suing to enjoin conduct that violates the Lanham Act need not prove specific damage.”); *Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1145 (9th Cir. 1997). Thus, even if a manufacturer were unable to prove direct injury from the omission of accurate pricing information from a competitor’s advertisement, it would not be precluded from bringing an action under the Lanham Act seeking to enjoin the competitor from continued use of that false or misleading advertisement.

2. State Preemption

Comment: Three commenters had comments on proposed § 403.1204(b), preempting the exercise of State laws based on the pricing statement required in the proposed rule. One commenter stated that remedies under State law, particularly those that could be accessed by consumers, should be available as a supplement to the Lanham Act remedy cited in the proposed rule with respect to information revealed as a result of the pricing statement required in the proposed rule. Two other commenters supported the transparency provisions of the proposed rule, but asked that CMS clarify that these provisions represent a “floor,” such that State laws that impose transparency requirements that go further than those in the proposed rule should not be pre-empted.

Response: As noted in the preamble to the proposed rule, we believe that the Lanham Act is the appropriate mechanism for addressing improper drug manufacturer practices that may be revealed as the result of the reporting required by this rule. We remain concerned that the pricing statement required under this final rule could give rise to the use of State law

requirements or remedies in a manner that could result in litigation costs involving potentially meritless cases that could defeat the goal of this rule of lowering drug prices. We appreciate the comment for highlighting a potential ambiguity in the proposed preemption provision. We do not intend for this rule to create an environment where states would impose varying disclosure requirements on television advertisements that may air in each respective state. We did not intend that the rule would create a regulatory “floor.” To ensure that prescription pharmaceutical advertisements on television would not have to vary from state to state, we have modified the preemption language at § 403.1204(b) as set out in the regulatory text at the end of this rule.

3. Alternative Enforcement Mechanisms

We sought comment on whether compliance with this rule should be a condition of payment, directly or indirectly, from these federal health care programs.

Comment: Several commenters suggested that CMS consider additional enforcement mechanisms, including ones the government could initiate, to ensure compliance with the requirement to disclose drug pricing information. Some of these commenters also responded directly to our request for comments as to whether compliance with this rule should be a condition of payment, directly or indirectly, under Medicare and Medicaid, by asserting that such a requirement would be more effective than either the public list or the threat of lawsuits under the Lanham Act. One commenter agreed that making compliance a condition of either coverage or payment would be a stronger enforcement mechanism, but noted that pursuing either of these options would require a change in law.

Response: We thank the commenters for their suggestions. For the reasons explained previously, we continue to believe that posting a list of drugs and biological products identified by the Secretary to be advertised in violation of this final rule on the CMS internet website,

coupled with the threat of private actions under the Lanham Act for false or misleading advertising, is the most appropriate approach to enforcing the requirements of this final rule. In reaching this conclusion, we carefully evaluated the alternative of making compliance with this rule a condition of payment under Medicare and Medicaid, including the comments recommending this approach. At this time, we do not believe that more stringent regulation is warranted, but will continue to assess compliance. If there is absence of robust compliance, then the Secretary will re-evaluate potential options and consider further rulemaking in this area.

In summary, we are finalizing this rule as proposed, except for the technical changes to § 403.1202 described above to improve clarity, the modification at § 403.1204(b) in response to comments, and technical changes to §§ 403.1201(d) and 403.1204(a) to use defined terms.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 et seq.), we are required to provide 30-day notice in the **Federal Register** before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. We solicited public comment on the issues in this document that contain information collection requirements (ICRs).

Comment: Some comments assert that the rule would be unduly burdensome in that it would clutter the advertisement and would require monthly updates.

Response: Please see the response to comments on the burden of the rule in Section II.D.

A. Wage Data

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' (BLS') May 2016 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents the

mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

Table 2. National Occupational Employment and Wage Estimates

BLS Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Adjusted Hourly Wage (\$/hr)
Office and Administrative Support Occupations	43-0000	\$17.91	\$35.82
Marketing and Sales Managers	11-2020	\$66.52	\$133.04
Lawyers	23-1011	\$67.25	\$134.50

B. Information Collection Requirements Regarding Pricing Information (§403.1202)

Section 403.1202 requires that advertisements for certain prescription drug or biological products on television (including broadcast, cable, streaming, and satellite), contain a statement or statements indicating the Wholesale Acquisition Cost (referred to as the list price) for a typical 30-day regimen or for a typical course of treatment, whichever is most appropriate, as determined on the first day of the quarter during which the advertisement is being aired or otherwise broadcast. The presentation of this information must appear in a specific format. As stated in this final rule, the notification must be presented as follows, “The list price for a [30-day supply of] [typical course of treatment with] [name of prescription drug or biological product] is [insert list price]. If you have health insurance that covers drugs, your cost may be different.”

We estimate that 25 pharmaceutical companies will run an estimated 300 distinct pharmaceutical advertisements that appear on television each quarter and will be affected by this rule. For these advertisements, we estimate that administrative support staff and marketing managers will need to verify the prescribed language and that the correct price appears in each

advertisement each quarter.

We estimate that this will require 10 minutes and \$5.97 ($\$35.82/\text{hr} \times .167$) per advertisement for administrative support staff. We also estimate five minutes and \$11.09 ($\$133.04/\text{hr} \times .083$) per advertisement for marketing managers, for a total of 15 minutes (0.25 hours) and \$17.06 ($\$5.97 + \11.09) per advertisement per quarter or 300 hours per year across all pharmaceutical companies running affected televised advertisements ($(300 \text{ ads/quarter}) \times (4 \text{ quarters/year}) \times (.25 \text{ hours/ad})$). As a result, using wage information provided in Table 2, we estimate costs of \$20,472 ($1200 \text{ ads} \times \$17.06/\text{ad}$) per year in each year following publication of the final rule after adjusting for overhead and benefits.

We are in the process of obtaining OMB approval for the aforementioned information collection requirements. Subsequent to the proposed rule, we published a separate 60-day **Federal Register** notice announcing the proposed information collection activity and soliciting comments. The 60-day notice published on April 8, 2019 (84 FR 13929) and also instructs the public on how to obtain copies of the information collection request (ICR) for review and comment. We will also publish a separate 30-day notice to announce the formal submission the ICR to OMB. At that time, the public will have an additional opportunity to review and submit comments on the ICR. These requirements are not effective until they have been approved by the OMB.

IV. Regulatory Impact Analysis

A. Statement of Need

This final rule aims to improve the quality, accessibility and affordability of the Medicare and Medicaid programs and to improve the CMS customer experience by providing transparency into drug prices with the goal of reducing the price to beneficiaries of certain prescription drugs

and biological products. Currently, consumers have incomplete information regarding the cost of pharmaceutical products. As a result, they lack important information needed to inform their decisions, which likely leads to inefficient utilization of prescription drugs or biological product. This rule requires disclosure of prices to the general public for prescription drug and biological products advertised on television. This may improve awareness and allow the general public to respond, potentially increasing the efficiency of prescription drug or biological product utilization. While we expect this rule to put downward pressure on the list prices of drugs, we cannot quantify the level of this impact because there is not data or examples that we can use.

B. Overall Impact

We acknowledge that examination of the impact of this final rule is required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the (RFA) (September 19, 1980, Pub. L. 96-354), Section 1102(b) of the Social Security Act, Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (March 22, 1995; Pub. L., Public Law 104-4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

The Regulatory Flexibility Analysis (RFA), as amended, requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. HHS considers a rule to have a significant economic impact on a substantial number of small entities if at least five percent of small entities experience an impact of more than three percent of revenue. As discussed in the

impact analysis, we calculate the administrative costs (excluding opportunity costs of screen time newly dedicated to displaying pricing information) of the changes per affected business over 2020-2024. The estimated average administrative costs of the rule per business peak in 2020 at approximately \$2,900, and are approximately \$1,300 in subsequent years. We note that relatively large entities are likely to experience proportionally higher costs. As discussed below, total administrative costs of the rule are estimated to be \$5.2 million in 2020 and \$2.4 million in subsequent years. According to the US Census, 1,775 pharmaceutical and medicine manufacturing firms operating in the US in 2015 had annual payroll of \$23.2 billion. Since the estimated administrative costs of this proposed rule are a tiny fraction of payroll for covered entities, the Department concludes that the rule will not have a significant economic impact on a substantial number of small entities and the Secretary so certifies.

In addition, section 1102(b) of the Act requires us to prepare a regulatory analysis for any rule or regulation under Title XVIII, Title XIX, or Part B of the Act that may have significant impact on the operations of a substantial number of small rural hospitals. We are not preparing an analysis for section 1102(b) of the Act because the Secretary certifies that this rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of UMRA also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending that may result in expenditures in any one year of \$100 million in 1995 dollars, updated annually for inflation. In 2018, that threshold is approximately \$154 million. This rule is not anticipated to have an effect on State, local, or tribal governments, in the aggregate, of \$154 million or more. Going forward, we believe that this rule will not impose mandates on the private sector that would result in an expenditure that exceeds the UMRA ceiling.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirements or costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since reviewing this rule does not impose any substantial costs on state or local governments, under the requirements threshold criteria of Executive Order 13132 are not applicable, we have determined that this rule would not significantly affect the rights, roles, and responsibilities of State or local governments.

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). The Office of Management and Budget has determined that this is an economically significant regulatory action. In accordance with the provisions of Executive Order 12866, this rule was reviewed by the Office of Management and Budget.

This final rule is considered an Executive Order 13771 (January 30, 2017) regulatory action. We estimated that it will impose \$2.45 million in annualized costs at a seven percent discount rate, discounted to a 2016 equivalent, over a perpetual time horizon.

Comment: One commenter stated that the proposed rule's impact analysis was flawed because it did not show that consumers lack adequate information about list prices for prescription drugs or biological products and overlooked costs to consumers and manufacturers. The commenter recommended that CMS more clearly identify a market failure that would be addressed by the rule; more thoroughly assess the rule's costs; more thoroughly review available literature on the effects of mandatory price disclosure in pharmaceutical markets; and conduct its

own studies of the rule's potential effects on consumer and manufacturer behavior.

Response: We disagree that consumers currently have adequate information on list prices for prescription drugs or biological products, because they do not have readily available access to prescription drug or biological product prices. Though some variation of drug prices are available online, we have shown that consumers are not currently effectively using these online resources to find this information or identify health insurance products and treatments that are most cost effective for the patient.⁴⁷ We have also shown that including the price in DTC changes patient behavior, showing that making the information easily available provides valuable information that patients would use for decision making.⁴⁸ Finally, we have seen that 88 percent of Americans (i.e., consumers) want the prices to be listed in DTC advertisements, showing that even though the prices may be available through other sources, such as online, it is important to them to have the prices listed on advertisements to have the valuable information readily accessible.⁴⁹ We believe that we have identified a market failure and assessed the rule's cost. We believe that it is unnecessary to pilot the intervention in this rule because a recent study previews the potential impact of the rule. Furthermore, one pharmaceutical company conducted their own research and ultimately decided to proceed on their own in the absence of regulation. It is unclear how a small-scale pilot would provide additional information that would support changing the policy. As discussed above, studies have shown patient responses to list prices being included in DTC television advertisements and shown that many effects (including adverse

⁴⁷ Zhou C and Zhang Y. The vast majority of Medicare Part D beneficiaries still don't choose the cheapest plans that meet their medication needs. *Health Aff.* 2012 Oct;31(10):2259-65

⁴⁸ Garrett JB, Tayler WB, Bai G, et al. Consumer Responses to Price Disclosure in Direct-to-Consumer Pharmaceutical Advertising. *JAMA Intern Med.* 2019;179(3):435-437. ("2019 JAMA Study")

⁴⁹ Kirzinger A, Lopes L, We B, and Brodie M. KFF Health Tracking Poll – February 2019: Prescription Drugs. Kaiser Family Foundation. 2019 March 01. <https://www.kff.org/8c7d090/>

effects) can be mitigated through disclaimers such as the one included in this rule. Additionally, manufacturers are free to add additional statements to their advertisements addressing these concerns.

C. Anticipated Effects

This rule will affect the operations of prescription drug or biological product manufacturers. According to the US Census, there were 1,775 pharmaceutical and medicine manufacturing firms operating in the US in 2015.⁵⁰ We estimate that this rule will require individuals employed by these entities to spend time in order to comply with these regulations. We estimate the hourly wages of individuals affected by this rule using the May 2017 National Occupational Employment and Wage Estimates provided by the US Bureau of Labor Statistics. We assume that the total dollar value of labor, which includes wages, benefits, and overhead, is equal to 200 percent of the wage rate. We note that, throughout, estimates are presented in 2016 dollars. We use the wages of Lawyers as a proxy for legal staff, the wages of Marketing and Sales Managers as a proxy for marketing management staff, and Office and Administrative Support Occupations as a proxy for administrative support staff. Estimated hourly rates for all relevant categories are included in Table 3 below.

Table 3. Hourly Wages

Marketing and Sales Managers	\$66.52
Lawyers	\$67.25
Office and Administrative Support Occupations	\$17.91

1. Direct Staff Costs of Implementation

⁵⁰ US Census. 2015 SUSB Annual Data Tables by Establishment Industry. <https://www.census.gov/data/tables/2015/econ/susb/2015-susb-annual.html>

We expect that the costs associated with the initial review by all companies of the policy, an ongoing review by all companies to ensure that they are in compliance with the policy, and the individual review of commercials for companies that produce DTC television advertisements.

a) Initial Review after Publication

In order to comply with the regulatory changes adopted in this rule, affected businesses would first need to review the rule. We estimate that this would require an average of two hours for affected businesses to review, divided evenly between marketing managers and lawyers, in the first year following publication of the final rule. As a result, using wage information provided in Table 2, this implies costs of \$474,884 in the first year following publication of a final rule after adjusting for overhead and benefits.⁵¹

b) Initial and Ongoing Compliance

After reviewing the rule, prescription drug or biological product manufacturers will review their marketing strategies in the context of these new requirements, and determine how to respond. For some affected entities, this may mean substantially changing their advertising paradigm or pricing strategy. For others, much more modest changes are likely needed. We estimate that this would result in affected businesses spending an average of 20 hours reviewing their policies and determining how to respond, with 5 hours spent by lawyers and 15 hours spent by marketing managers, in the first year following publication of the final rule. In subsequent years, we estimate this would result in marketing managers at affected businesses spending an average of 10 hours implementing policy changes. As a result, using wage information provided

⁵¹ $1,755 \text{ firms} \times (1 \text{ hour of legal work} \times 200\% \times \$67.25 + 1 \text{ hour of marketing work} \times 200\% \times \$66.52) = \$474,884$

in Table 2, we estimate costs of \$4.74 million in the first year⁵² and \$2.36 million in subsequent years⁵³ following publication of this final rule after adjusting for overhead and benefits.

c) Direct Advertisement Review

We estimate that 25 pharmaceutical companies will run an estimated 300 distinct pharmaceutical advertisements that appear on television each quarter and will be affected by this rule. For these advertisements, we estimate that administrative support staff and marketing managers will need to verify the prescribed language and that the correct price appears in each advertisement each quarter. We estimate that this will require 10 minutes and \$5.97 (\$35.82/hr x .167) per advertisement for administrative support staff. We also estimate five minutes and \$11.09 (\$133.04/hr x .083) per advertisement for marketing managers, for a total of 15 minutes (0.25 hours) and \$17.06 (\$5.97 + \$11.09) per advertisement per quarter or 300 hours per year across all pharmaceutical companies running affected televised advertisements ((300 ads/quarter) x (4 quarters/year) x (.25 hours/ad)). As a result, using wage information provided in Table 2, we estimate costs of \$20,472 (1200 ads x \$17.06/ad) per year in each year following publication of the final rule after adjusting for overhead and benefits.

2. Direct Costs for Changes to Advertisements

We may also want to consider the opportunity costs for the space in the advertisement that includes the list price that could have been used for other purposes. A reasonable estimate is that compliance requires 1percent of the screen space and four seconds of a 75-second commercial. That means that the opportunity cost attributable could be approximately \$2.24 million = (1% x

⁵² 1,775 firms x (5 hours of legal work x 200% x \$67.25 + 15 hours of marketing work x 200% x \$66.52) = \$4,735,878

⁵³ 1,775 firms x (10 hours of marketing work x 200% x \$66.52) = \$2,361,460

4/75 x \$4.2 billion DTC television advertising spending). We note that current DTC television advertisements currently use space to refer patients to their website for additional information, and that same space can include that website and include the list price as a reference (i.e., the advertisements could provide this information in the space that is already dedicated to referring patients to additional information).

In markets for prescription drugs and biological products, consumers often need to make decisions with incomplete information about prices. As a result, consumers are unable to make decisions that best suit their needs. This rule may improve price transparency for consumers in order to ensure that their decisions better align with their preferences and their budget, potentially improving the allocation of resources in the prescription drug market. On the other hand, consumers, intimidated and confused by high list prices, may be deterred from contacting their physicians about drugs or medical conditions. Consumers might believe they are being asked to pay the list price rather than a co-pay or co-insurance and wonder why they are paying so much when they already paid a premium for their drug plan. This could discourage patients from using beneficial medications, reduce access, and potentially increase total cost of care. We lack data to quantify these effects.

In addition, we believe that this rule may provide a moderating force to counteract prescription drug or biological product price increases. This rule will provide direct evidence of prescription drug or biological product prices to the general public, potentially improving awareness and allowing the general public to signal in some cases that prescription drug or biological product prices have risen beyond their willingness to pay. We believe that this, in turn, may further improve the rule's effect on the efficient utilization of prescription drugs or biological products. We lack data to quantify these effects.

We believe that this rule may also have impacts along other dimensions. In particular, it may affect the number of televised DTC advertisements, the rate at which televised DTC advertisements are updated, prices for prescription drugs or biological products, the set of pharmaceutical products available for sale, and utilization of various prescription drugs or biological products. A possibility not reflected in the quantitative estimates above is that drug companies would find the cost of revising their advertisements to be prohibitively expensive (for example, if they change their WACs so frequently that there is extensive monitoring and revision necessary to ensure that advertisements airing on a particular day match the WAC for that day). In this case, DTC television advertising would be reduced. However, we think this is unlikely as prices are usually changed on a twice-a-year cycle, and manufacturers may already frequently revise their advertisements to align with quarterly marketing plans. We requested comment, but did not get any comments, on the following questions:

- What is the frequency with which WACs are changed?
- What would be the effect of this potential advertising reduction on patient behavior, including as regards the information they seek out from their medical providers?
- How might patient outcomes vary depending on advertising choices among competitor drug companies? For example, if only some producers of drugs that treat a particular condition cease advertising on television, are patients likely to switch between drug brands—from the no-longer-advertised to the advertised? If all producers of drugs for a condition cease advertising on television, to what extent are patients likely to switch to other forms of treatment—such as surgery—or to forgo treatment?
- To what extent will drug companies, in order to increase the feasibility of continuing to advertise on television, reduce the frequency of changing their WACs? What would be

the consequences for drug supply chains and the prices experienced by patients and other payors?

Furthermore, the Department recognizes that some studies indicate DTC advertising increases disease awareness, and that if this rule decreases disease awareness such that untreated illness occurs, there may be other impacts. We lack data to quantify the effects of this rule along these dimensions.

Comment: One commenter suggested that the RIA overlooks the costs to pharmaceutical industry due to potential lost sales.

Response: We disagree with this comment because there is no clear evidence that posting the list price will adversely affect sales. As discussed in Section II.C., including a disclaimer that the drug could be available at a lower price, such as the wording we include in this rule, mitigate patient concerns about price. This rule makes the patient a more informed consumer. At the same time, the information is not expected to cause patients to forgo treatment. Instead, patients may select the lowest cost alternative, so the revenue is still going into the industry as a whole. It may be a transfer from high cost drugs to their marginally lower cost alternatives. Additionally, as discussed above, it is difficult to predict exactly how the industry will respond, but one potential is that their list prices are lowered closer to their net price, so while the list price would go down, it would not necessarily affect the revenue going into the industry.

Comment: One commenter suggested that we overlooked potential costs to consumers based on their behavior changes, such as choosing to forgo treatment.

Response: We disagree with this comment for the same reason we disagree with the above comment. The 2019 JAMA Study showed that including a stipulation that the medication

could be available at a lower price mitigates potential adverse, unintended consequences,⁵⁴ so we do not expect patients to choose to forego treatment. Instead, we expect them to become informed consumers that engage in shared-decision making with their providers, which may allow them to select the lowest cost alternative based on their specific situation. This can reduce the cost to the patient while increasing revenue to some manufacturers in reducing the revenue to others.

D. Alternatives Considered

We carefully considered the alternative of maintaining the status quo and not pursuing regulatory action. However, we believe that the price transparency is fundamental to ensuring that prescription drug and biological product markets function properly. This rule may improve price transparency in order for consumers to make better decisions. As a result, we have determined that the benefits of the rule justify the costs imposed on industry, and as a result we chose to pursue this regulatory action.

We also carefully considered requiring the disclosure of alternative or additional prices, which better reflect the actual costs paid by patients and payors. If an alternative definition were used for list price, the burden imposed by the rule would likely be higher. For example, manufacturers set the Wholesale Acquisition Cost, also known as list price, for their products. The Department recognizes that other prices may be paid by distributors, pharmacies, patients, and others in the supply chain. Because these other prices vary by contracts established by payors or others, only the WAC is certain to be known by the manufacturer when creating DTC advertisements. As such, it would be harder for manufacturers to report prices other than

⁵⁴ Garrett JB, Tayler WB, Bai G, et. al. Consumer Responses to Price Disclosure in Direct-to-Consumer Pharmaceutical Advertising. *JAMA Intern Med.* 2019;179(3):435-437. (“JAMA 2019 Study”)

Wholesale Acquisition Cost. We believe that requiring the disclosure of WAC minimizes administrative burden among feasible alternatives and balances the need to provide information to the general public.

E. Accounting Statement

Table 3. Accounting Table of Benefits and Costs of All Proposed Changes

	Present Value over 2020-2024 by Discount Rate		Annualized Value over 2020- 2024 by Discount Rate	
	(Millions of 2016 Dollars)		(Millions of 2016 Dollars)	
BENEFITS	3 Percent	7 Percent	3 Percent	7 Percent
Quantified Benefits	0	0	0	0
Non-quantified Benefits Improved transparency for prescription drug and biological product prices				
COSTS	3 Percent	7 Percent	3 Percent	7 Percent
Quantified Costs	25.6	23.1	6.1	6.8
Non-quantified Costs Due to Lack of Data Costs based on resulting changes in drug prices Costs based on potential changes in manufacturer behavior based on perceived value of DTC advertising Costs based potential changes in patient and provide behavior				

List of Subjects in 42 CFR Part 403

Grant programs-health, Health insurance, Hospitals, Intergovernmental relations, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 403 -- SPECIAL PROGRAMS AND PROJECTS

1. The authority citation for part 403 is revised to read as follows:

Authority: 42 U.S.C. 1302, and 1395hh.

2. Subpart L is added to read as follows:

Subpart L – Requirements for Direct-to-Consumer Television Advertisements of Drugs and Biological Products to Include the List Price of that Advertised Product

Sec.

- 403.1200 Scope.
- 403.1201 Definitions.
- 403.1202 Pricing information.
- 403.1203 Specific presentation requirements.
- 403.1204 Compliance.

Subpart L – Requirements for Direct-to-Consumer Television Advertisements of Drugs and Biological Products to Include the List Price of that Advertised Product

§ 403.1200 Scope.

- (a) Covered pharmaceuticals. Except as specified in paragraph (b) of this section, this subpart applies to advertisements for a prescription drug or biological product distributed in the United States for which payment is available, directly or indirectly, under titles XVIII or XIX of the Social Security Act.
- (b) Excepted pharmaceuticals. An advertisement for any prescription drug or biological product that has a list price, as defined in §403.1201, less than \$35 per month for a 30-day supply or typical course of treatment shall be exempt from the requirements of this subpart.

§ 403.1201 Definitions.

For the purposes of this subpart, the following definitions apply:

- (a) Biological product. Biological product means any biological product, as that term is defined

in Public Health Service Act (“PHS Act”) section 351(i), that is licensed by the Food and Drug Administration pursuant to section 351 and is subject to the requirements of Federal Food, Drug, and Cosmetic Act (FDCA) section 503(b)(1).

- (b) Prescription drug. Prescription drug means any drug, as defined in the FDCA section 201(g), that has been approved by the Food and Drug Administration pursuant to FDCA section 505 and is subject to the requirements of FDCA section 503(b)(1).
- (c) List price. List price means the wholesale acquisition cost, as defined in paragraph (d) of this section.
- (d) Wholesale acquisition cost. Wholesale acquisition cost means, with respect to a prescription drug or biological product, the manufacturer’s list price for the prescription drug or biological product to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological product pricing data.

§ 403.1202 Pricing information.

Any advertisement for any prescription drug or biological product on television (including broadcast, cable, streaming, or satellite) must contain a textual statement indicating the current list price for a typical 30-day regimen or for a typical course of treatment, whichever is most appropriate, as determined on the first day of the quarter during which the advertisement is being aired or otherwise broadcast, as follows: “The list price for a [30-day supply of] [typical course of treatment with] [name of prescription drug or biological product] is [insert list price]. If you have health insurance that covers drugs, your cost may be different.” Where the price is related to the typical course of treatment and that typical course of treatment varies depending on the

indication for which a prescription drug or biological product is prescribed, the list price to be used is the one for the typical course of treatment associated with the primary indication addressed in the advertisement.

§ 403.1203 Specific presentation requirements.

The textual statement described in §403.1202 shall be presented at the end of an advertisement in a legible manner, meaning that it is placed appropriately and is presented against a contrasting background for sufficient duration and in a size and style of font that allows the information to be read easily.

§ 403.1204 Compliance.

- (a) Identification of non-compliant products. The Secretary will maintain a public list that will include the prescription drugs and biological products identified by the Secretary to be advertised in violation of this subpart.
- (b) State or local requirements. No State or political subdivision of any State may establish or continue in effect any requirement concerning the disclosure in a television advertisement of the pricing of a prescription drug or biological product which is different from, or in addition to, any requirement imposed by this subpart.

Dated: April 25, 2019.

Seema Verma,

Administrator,

Centers for Medicare & Medicaid Services.

Dated: April 26, 2019.

Alex M. Azar II,

Secretary,

Department of Health and Human Services.