

pyraflufen-ethyl, ethyl 2-[2-chloro-5-(4-chloro-5-difluoromethoxy)-1-methyl-1H-pyrazol-3-yl]-4-fluorophenoxy] acetate, and its acid metabolite, E-1, 2-chloro-5-(4-chloro-5-difluoromethoxy-1-methyl-1H-pyrazol-3-yl)-4-fluorophenoxyacetic acid, calculated as the stoichiometric equivalent of pyraflufen-ethyl in or on the following RACs: Cottonseed subgroup 20C at 0.04 ppm; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 0.01 ppm; fruit, stone, group 12-12 at 0.01 ppm; hop, dried cones at 0.02 ppm; nut, tree, group 14-12 at 0.01 ppm; tropical and subtropical, small fruit, edible peel, subgroup 23A at 0.01 ppm; and vegetable, tuberous and corm, subgroup 1C at 0.02 ppm. Available analytical methodology involves multiple-step extractions of the chemical residues from plants and using Gas Chromatograph-Mass Spectrometry (GC-MS) to measure and evaluate pyraflufen-ethyl residues. *Contact:* RD.

2. *PP 8E8689.* (EPA-HQ-OPP-2018-0560). IR-4, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201W, Princeton, NJ 08540, requests to establish tolerances in 40 CFR part 180.553 for residues of the fungicide fenhexamid (N-2,3-dichloro-4-hydroxyphenyl)-1-methyl cyclohexanecarboxamide in or on the raw agricultural commodities: Arugula at 30.0 ppm; berry, low growing, subgroup 13-07G at 3.0 ppm; bushberry subgroup 13-07B at 5.0 ppm; caneberry subgroup 13-07A at 20.0 ppm; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 4.0 ppm; fruit, stone, group 12-12, except plum, prune, fresh, postharvest at 10.0 ppm; garden cress at 30.0 ppm; kiwifruit, fuzzy at 30.0 ppm; leafy greens subgroup 4-16A, except spinach at 30.0 ppm; onion, bulb, subgroup 3-07A at 2.0 ppm; onion, green, subgroup 3-07B at 30.0 ppm; upland cress at 30.0 ppm; and vegetable, fruiting, group 8-10, except nonbell pepper at 2.0 ppm. The "Method for the Determination of KBR 2738 (TM-402) Residues in Plant Material by HPLC" is used to measure and evaluate the chemical fenhexamid. *Contact:* RD.

Authority: 21 U.S.C. 346a.

Dated: October 1, 2018.

Delores Barber,

Director, Information Technology and Resources Management Division, Office of Pesticide Programs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 403

[CMS-4187-P]

RIN 0938-AT87

Medicare and Medicaid Programs; Regulation To Require Drug Pricing Transparency

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Federal Health Insurance Programs for the Aged and Disabled by amending 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. We are proposing this regulation 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 not only their out-of-pocket costs, but also expenditures borne by Medicare and Medicaid, both of which are significant problems.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on December 17, 2018.

ADDRESSES: In commenting, please refer to file code CMS-4187-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-4187-P, P.O. Box 8013, Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-4187-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Cheri Rice, (410) 786-6499.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that website to view public comments.

I. Background

A. Purpose

The purpose of this proposed rule is to reduce the price to consumers of prescription drugs and biological products. This rule would require direct-to-consumer (DTC) television advertisements for prescription drug 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. We are proposing this regulation 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 not only their out-of-pocket costs, but also unreasonable expenditures borne by Medicare and Medicaid, both of which are significant problems.

Markets operate more efficiently when consumers have relevant information about a product, including its price, as well as alternative products and their prices, before making an informed decision whether to buy that product or, instead, a competing one. Consumers price shop when looking to purchase a new car, a new house, or even a new coffee maker. Price shopping is the mark of rational

economic behavior. To facilitate price shopping, sellers invariably provide potential buyers with the prices of their products; consumers gauge the reasonableness of these prices against alternatives. Even automobile dealerships, as result of federal law, post the retail or “sticker” price on the side window of each new car offered for sale.

That has not been the case with 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, but for consumers of prescription drugs, 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 and causes distortions, such as an absence of meaningful prices and the information and incentives that prices provide. In many cases prescription drug coverage is provided by an employer to its employees, or by the federal government to Medicare and Medicaid beneficiaries. These entities providing prescription drug coverage are known as payors.

List price plays a role in negotiations between payors, Pharmacy Benefit Managers (PBMs), and manufacturers, which all impact beneficiary cost sharing. Payors hire third party providers such as PBMs to manage the payor’s prescription drug benefit for the payor’s employees and negotiate improved drug pricing for medications based on the level of utilization management a payor is willing to apply to the benefit. Prescription drug benefit designs are typically based on the manufacturer’s list price, however, in many cases the PBM can negotiate a lower price than a manufacturer’s list price if there is high deductible plans, copay or coinsurance, formulary either tiered or closed, utilization management including step therapy and prior authorizations. The willingness of a payor to apply varying degrees of utilization control impacts savings for each individual payor and beneficiary. A PBM could have ten different clients with ten different benefit designs and it would be possible that an employee from each client could get the exact same product and all ten could pay a different price.

A number of factors make list price relevant across a variety of drug benefit

designs, even though the PBM may have negotiated a lower price for the product dispensed to the beneficiary. First, in the commercial market, over 40% of beneficiaries are in high deductible plans. Under such plans, beneficiaries pay the full list price of the product until they meet their deductible, which can be thousands of dollars. Second, benefit designs are built off of list price, because the negotiated rebate rate is not paid until months after the product was dispensed. Third, co-insurance has become a standard payor mechanism applicable to high cost drugs, requiring the patient to pay a percentage of the list price. All of the top 10 PDPs use coinsurance rather than fixed dollar copayments for medications on nonpreferred drug tiers, charging 30 percent to 50 percent of each prescription’s full price in 2017.¹ Finally, very few drugs have coverage on all the formularies in the country. If a plan does not cover a particular drug requested by a patient, then the patient may have to pay the full list price to access the medication.

Due at least in part to the market-distorting effects of third-party payors, pharmaceutical manufacturers tend not to compete based on list price, and hence there is little to no market pressure voluntarily to disclose a product’s list price. Not only does transparency promote a more competitive environment, but data indicate that it will likely motivate manufacturers to be less willing to raise prices, which have dramatically increased over the past decade. *See, e.g.,* John F. Cady, “An Estimate of the Price Effects of Restrictions on Drug Advertising,” 44 *Economic Inquiry*, 493–510 (Dec. 1976) (finding that prescription drug prices were 4.3% higher on average in states restricting advertising of prices than in states allowing such advertising.). While study results vary depending on the design, the population studied, and product at issue, according to the Congressional Research Service

[m]ost research suggests that when better price information is available prices for goods sold to consumers fall. The largest and most straightforward body of evidence relates to the effect of advertising, where nearly all research indicates advertising prices is associated with lower prices. This reduction in prices suggests that advertising’s increased information on prices and increases in competition outweigh any tendency to increase prices through increasing demand and brand identification.²

¹ MEDPAC Report to the Congress: Medicare Payment Policy. March 2017. 383.

² D. Andrew Austin and Jane G. Gravelle, “Does Price Transparency Improve Market Efficiency?

This proposed rule seeks to fill this informational gap by adding a new subpart L to part 403 to title 42 that would require that for prescription drug and biological products that can be reimbursed directly or indirectly through or under Medicare or Medicaid, DTC ads on television (including broadcast, cable, streaming, and satellite communication) for such products must include the product’s current list price, defined as the Wholesale Acquisition Cost.³ CMS is proposing this rule in the context of broadcast advertisements, an area in which the Supreme Court historically has recognized that the government may take special steps to help ensure that viewers receive appropriate information. *See Red Lion Broad. Co. v. FCC*, 395 U.S. 367, 390, 394 (1969) (“It is the right of the viewers and listeners, not the right of the broadcasters, which is paramount.”).

B. Legal Authority

HHS recognizes that “an administrative agency’s power to regulate . . . must always be grounded in a valid grant of authority from Congress.” *Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 161 (2000). Thus, in proposing new regulations HHS must pay close attention to the text and structure of the legislation granting an agency authority. “Agencies are . . . bound, not only by the ultimate purposes Congress has selected, but by the means it has deemed appropriate, and prescribed, for the pursuit of those purposes.” *Colorado River Indian Tribes v. Nat’l Indian Gaming Comm’n*, 466 F.3d 134, 139–40 (D.C. Cir. 2006) (quoting *MCI Telecomms. Corp. v. AT&T*, 512 U.S. 218, 231 n.4, (1994)). This proposed rule is issued pursuant to sections 1102 and 1871 of the Social Security Act. Section 1102(a) of the Social Security Act authorizes the Secretary to issue “such rules and regulations, not inconsistent with this Act, as may be necessary to the efficient administration of the functions . . . under this Act[.]” The Secretary has “broad rule-making authority” under section 1102, for both Medicare and Medicaid. *See, e.g., Thorpe v. Housing Authority of City of Durham*, 393 U.S. 268, 277 n.28 (1969). Under Section 1871(a), which instructs “[t]he Secretary [to] prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this title [XVIII],” the

Implications of Empirical Evidence in Other Markets for the Health Sector, CRS Report 46 (July 24, 2007).

³ Over-the-counter drugs covered by Medicaid, to the extent that they cost more than \$35 per month, are not within the scope of this rule.

Secretary similarly possesses broad rulemaking authority with respect to the Medicare program. *See, e.g., Cottage Health Sys. v. Sebelius*, 631 F. Supp. 2d 80, 92 (D.D.C. 2009). Rules issued under such broad rulemaking authorities must be “sustained so long as [they are] ‘reasonably related to the purposes of the enabling legislation.’” and do not contradict or undermine that legislation. *Mourning v. Family Publ’ns Servs., Inc.*, 411 U.S. 356, 369 (1973) (quoting *Thorpe*, 393 U.S. at 280–81).

HHS has concluded that the proposed 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. *See, e.g.*, Sections 1842(b)(8) and (9), 1860D–4(c)(3), 1860D–4(c)(5)(H), 1866(j)(2)(A), 1893(g), 1902(a)(64), 1902(a)(65), 1936(b)(2). In addition, Congress recognized the value of disclosures about drug prices. In section 1927(b)(3)(A) of the Act, manufacturers with Part B rebate agreements must disclose pricing information to the government, including the average manufacturer price, the manufacturer’s average sales price, and at times the manufacturer’s wholesale acquisition cost as well as the manufacturer’s best price for certain drugs. And in the Part D program, section 1860(k)(1) compels certain sponsors offering prescription drug plans to disclose the difference between the price of a dispensed drug and the price of the lowest priced generic available that is therapeutically equivalent and bioequivalent. This 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.

In addition, although Congress has not explicitly provided HHS with authority to compel the disclosure of list prices to the public, Congress has explicitly directed HHS to operate Medicare and Medicaid programs efficiently. Promoting pricing transparency, and thus efficient markets, for drugs funded through those programs falls within the scope of that mandate. Drugs and biological products are covered under the Medicare Part B benefit (authorized by various provisions including sections 1832, 1861(s)(2) of the Social Security Act (the Act)), the Medicare Part D benefit (authorized by section 1860D–1 *et seq.* of the Act), and as part of hospital inpatient admissions under Medicare

Part A’s prospective payment system (authorized by Sections 1814, 1886 of the Act). The Medicaid drug benefit is authorized by sections 1902(a)(54) and 1905(a)(12).

The Secretary has determined that the proposed regulation is necessary to the efficient administration of the Medicare and Medicaid programs. The Secretary has an obligation to ensure the wise expenditure of federal trust fund dollars, and may promulgate regulations to advance these goals. *See, e.g., Sid Peterson Mem’l Hosp. v. Thompson*, 274 F.3d 301, 313 (5th Cir. 2001); *see also* 42 U.S.C. 1395i (Medicare Part A trust fund); 42 U.S.C. 1395t (Medicare Parts B and D trust fund). Efficient administration of both Medicare and Medicaid encompasses federal efforts to achieve good value for funds spent in the Medicare and Medicaid programs. Toward that end, the agency has issued regulations that promote the responsible use of federal funds. *See, e.g.*, 42 CFR part 413, subpart C (limitations on reasonable cost reimbursement), § 421.122 (oversight of contractors), § 424.5 (conditions for payment), § 438.4 *et seq.* (actuarial soundness of capitation rates). Nonetheless, the cost to the federal government, Medicare beneficiaries, and State Medicaid programs of prescription drugs and biological products has been increasing at an alarming rate due both to increasing prices and increasing utilization. *See, e.g., https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/*. As discussed further below, DTC advertising without price transparency has a direct nexus to these trends of increasing price and utilization. This proposed regulation combats these trends by ensuring that beneficiaries are provided with relevant information about the costs of prescription drugs and biological products, so they can make informed decisions. Based on a combination of all of these reasons, the Act authorizes HHS to issue this proposed rule.

C. The Cost of Prescription Pharmaceuticals to Medicare and Medicaid and Their Beneficiaries Has Been Rising Annually

The cost of drugs and biological products over the past decade has increased dramatically, and 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.⁴

Manufacturers of prescription drugs in competitive classes often offer price concessions in the form of rebates that are paid after the prescription is filled. Manufacturer rebates have grown approximately 10% of gross Part D drug costs in 2008 to 20% of gross Part D drug costs in 2016. The CMS Office of the Actuary projects rebates will exceed 28% of gross Part D drug costs over the next ten years.⁵

Because the list price of a drug does not reflect manufacturer rebates paid to a PBM, insurer, health plan, or government program, obscuring these discounts can shift costs to consumers in commercial health plans and Medicare beneficiaries. Many incentives in the current system reward higher list prices, all participants in the chain of distribution, *e.g.*, manufacturers, wholesalers, pharmacy benefit managers, and even private insurers, gain as the list price of any given drug increases. These financial gains come at the expense of increased costs to patients and public payors, such as Medicare and Medicaid, which ultimately fall on the backs of American taxpayers.

Furthermore, consumers who have not met their deductible or are subject to coinsurance, pay based on the pharmacy list price, which is not reduced by the substantial drug manufacturer rebates paid to PBMs and health plans. As a result, the growth in list prices, and the widening gap between list and net prices, markedly increases consumer out-of-pocket spending, particularly for high-cost drugs not subject to negotiation.

The Centers for Medicare & Medicaid Services (CMS) is the single largest drug

⁴ ASPE Issue Brief. Observations on Trends in Prescription Drug Spending. March 8, 2016.

⁵ 2018 ANNUAL REPORT OF THE BOARDS OF TRUSTEES OF THE FEDERAL HOSPITAL INSURANCE AND FEDERAL SUPPLEMENTARY MEDICAL INSURANCE TRUST FUNDS.

payor in the nation. In 2016, CMS and its beneficiaries spent \$174 billion on drugs covered under Parts B and D, and \$64 billion on drugs covered under Medicaid. 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.

For Part D, according to the 2018 Trustees' Report, CMS's costs have grown,

[o]ver 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, there has been a substantial increase in the proportion of prescriptions filled with low-cost generic drugs that has helped constrain cost growth, while there has also been a significant increase in the cost of specialty drugs that has increased cost growth.⁶

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.⁷

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.⁸ Since 2009, Medicare Part B drug spending grew at an average rate of about 9% per year. About half of the growth in Part B drug spending

between 2009 and 2013 was accounted for by price growth, which reflects increased prices for existing products and shifts in the mix of drugs, including the adoption of new drugs.⁹ Medicaid drug spending grew 25% in 2015 and 13% in 2015.¹⁰

Price transparency will help improve the efficiency of Medicare and Medicaid programs by reducing wasteful and abusive increases in drug and biological list prices—spiraling drug costs that are then passed on to federal healthcare program beneficiaries and American taxpayers more broadly. 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. As discussed further below, consumers make a series of critical health care decisions related to their treatment with prescription drugs, and the list price of those drugs may be informative to those decisions. Even where the consumer may be insured, and therefore will be paying substantially less than the list price, the coinsurance borne by some consumers will necessarily increase as the prices negotiated by PBMs increase.

D. Direct-to-Consumer Advertising and Its Role, in Part, in Fueling the Demand for Higher Cost Drugs

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 drugs; whether to fill a prescription; whether to take the drug; and whether to continue taking it in adherence to the prescribed regimen. Drug manufacturers, therefore, spend billions of dollars annually promoting their prescription drugs 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 Studies show how consumers exposed to drug advertisements can exert sufficient pressure on their physicians to prescribe the advertised product.¹³ In one recent survey, one in eight adults (12%) said they were prescribed a specific drug after asking a doctor about it as a result of seeing or hearing an advertisement.¹⁴ When manufacturers direct their DTC advertising to consumers, such messaging can help facilitate more informed discussions between consumers and their health care providers in making decisions about treatment. But it can also result in increased utilization through patients demanding costly drugs and biological products based on advertising messaging, with a resulting increase in government spending—a problem if less costly alternatives are available, or would be available through market pressures resulting from greater price transparency.

To have the necessary information in making critical decisions related to prescription drugs, consumers need some idea of the magnitude of the cost of the advertised drug. More informed consumer decision making will impact not only each individual beneficiary's own finances, but also positively affect the shared taxpayer responsibility to fund the Medicare and Medicaid drug benefit programs.

E. Transparency in Drug Pricing Promotes Lower Prices and More Informed Purchasing by Beneficiaries

Both Titles XVIII and XIX of the 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), 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

¹² Dhaval Dave & Henry Saffer, Impact of Direct-to-Consumer Advertising on Pharmaceutical Prices and Demand, 79 Southern Economic Journal 97–126 (2012); Balaji Datti & Mary W. Carter, The Effect of Direct-to-Consumer Advertising on Prescription Drug Use by Older Adults, 23 Drugs Aging 71–81 (2006).

¹³ Barbara Mintzes et al., Influence of direct to consumer pharmaceutical advertising and patients' requests on prescribing decisions: Two site cross sectional survey, 324 The BMJ 278–79 (2002).

¹⁴ Kaiser Health Tracking Poll (October 2015) <https://www.kff.org/health-costs/poll-finding/kaiser-health-tracking-poll-october-2015/>.

⁶ 2018 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds at 106, available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2018.pdf>.

⁷ https://data.bls.gov/pdq/SurveyOutputServlet?request_action=wh&graph_name=CU_cpibrief.

⁸ MEDPAC. Report to the Congress: Medicare Payment Policy. March 2018. 415.

⁹ MEDPAC. Report to the Congress: Medicare and the Health Care Delivery System. June 2017. 37.

¹⁰ CMS National Health Expenditure Data. 2016.

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

consumers have cost sharing obligations that may be significant.

As discussed above, DTC advertisements that do not provide pricing information may contribute to rising drug prices and rising premiums. 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 on-line 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, and the patient may not even know exactly which drug is prescribed. Second, meaningful price shopping is further hindered because the average consumer has no anchor price, such as an MSRP for automobiles, to gauge the reasonableness of the various price quotes.

Arming a beneficiary with basic price information will provide him or her with an anchor price, in other words, a reference comparison to be used when making decisions about therapeutic options. Triggering conversations about a particular drug or biological and its substitutes may lead to conversations not only about price, but also efficacy and side effects, which in turn may cause both the consumer and 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. We seek comment on how providing consumers with the list price of a medication may influence interactions with prescribers, the selection of drug products, and the perceived efficacy of the prescribed drug. We also seek comment about how benefit design influences these choices.

Requiring DTC television ads to disclose pricing information to consumers, as proposed in this rule, is

consistent with First Amendment jurisprudence. Rules, such as this one, that require certain factual commercial disclosures pass muster under the First Amendment where the disclosure advances a government interest and does not unduly burden speech.

When the government requires accurate disclosures in the marketing of regulated products under appropriate circumstances, it does not infringe on protected First Amendment interests. As the United States Supreme Court recognized in *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985) and recently confirmed in *Nat'l Inst. of Family and Life Advocates v. Becerra*, 138 S. Ct. 2361, 2372, 2376 (2018) (“*NIFLA*”), required disclosures of factual, noncontroversial information in commercial speech may be subject to more deferential First Amendment scrutiny. Under the approach articulated in *Zauderer*, courts have upheld required disclosures of factual information in the realm of commercial speech where the disclosure requirement reasonably relates to a government interest and is not unjustified or unduly burdensome such that it would chill protected speech. See *Zauderer*, 471 U.S. at 651; *Milavetz v. United States*, 559 U.S. 229, 250, 252–53 (2010); *NIFLA*, 138 S. Ct. at 2376 (“[W]e do not question the legality of . . . purely factual and uncontroversial disclosures about commercial products.”). In addition, the United States Supreme Court has long recognized that broadcast viewers and listeners have a significant First Amendment interest in receiving information about matters of public concern. See *Red Lion Broad. Co. v. FCC*, 395 U.S. 367, 390, 394 (1969).

In this proposed rule, the required disclosure consists of purely factual and uncontroversial information about a firm's own product, namely the list price of the drug or biological product. The required disclosure here advances the government's substantial interest in the efficient administration of both Medicare and Medicaid programs by minimizing unreasonable expenditures. Increased price transparency will help reduce unreasonable expenditures associated with soaring drug costs by providing manufacturers with an incentive to reduce their list prices by exposing overly costly drugs compared to alternatives to public scrutiny, and providing consumers with price information to facilitate more informed health care decisions. See *generally Pharm. Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294, 310 (1st Cir. 2005) (recognizing that the government interest in cost-effective health care

justified disclosure of financial interests of pharmacy benefit managers); *N.Y. State Rest. Ass'n v. N.Y. City Bd. of Health*, 556 F.3d 114, 134 (2d Cir. 2009) (recognizing that the government interest in “promot[ing] informed consumer decision-making” justified posting of calories on menus in chain restaurants). Indeed, the United States Supreme Court has long recognized a strong societal interest in the free flow of information about prescription drug prices:

Those whom the suppression of prescription drug price information hits the hardest are the poor, the sick, and particularly the aged. A disproportionate amount of their income tends to be spent on prescription drugs; yet they are the least able to learn, by shopping from pharmacist to pharmacist, where their scarce dollars are best spent. When drug prices vary as strikingly as they do, information as to who is charging what becomes more than a convenience. It could mean the alleviation of physical pain or the enjoyment of basic necessities.

Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, 425 U.S. 748, 763–64 (1976).

Furthermore, these price disclosures would neither “drown [] out the [speaker's] own message” or “effectively rule [] out” a mode of communication. *NIFLA*, 138 S. Ct. at 2378. Indeed, 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. v. United States Dep't of Transp.*, 687 F.3d 403, 414 (D.C. Cir. 2012) (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). Indeed, there are many regulatory schemes that require the disclosure of price information to consumers. See 12 CFR 1026.33(b)(2) (2018) (mortgage lenders must disclose to consumers total annual loan cost rates for reverse mortgages); 12 CFR 226.18 (2018) (creditors must disclose to borrowers multiple terms including the annual percentage rate); 12 CFR 1030.4(a) and (b) (2018) (depository institutions must provide to a consumer, before an account is opened or service provided, account information including fixed or variable interest rates); Mass. Ann. Laws ch. 94 Section 295C (2018) (retail

dealers of motor fuel must publicly display and maintain on each pump a sign on which the price per gallon per grade is clearly visible); Minn. Stat. Section 239.751 (2017) (retail dealers of petroleum must clearly display the price of per gallon and the price cannot be obscured in any way).¹⁵

II. Provisions of Proposed Regulation (§§ 403.1200, 403.1201, 403.1202, 403.1203, and 403.1204)

As discussed at length above, we are proposing this regulation 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 not only their out-of-pocket costs, but also unreasonable Medicare and Medicaid expenditures, both of which are significant problems.

Keeping these principles in mind, we are proposing to amend subchapter A, part 403 by adding a new subpart L. Proposed § 403.1202 sets forth the requirement that advertisements for certain prescription drug or biological products on television (including broadcast, cable, streaming, and satellite), must 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, 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.” 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 Wholesale Acquisition Cost is certain to be known by the manufacturer when creating DTC ads.

The price stated in the advertisement must be current as of the date of publication or broadcast. This provision would specify that where the price is related to the “typical course of treatment,” and the course of treatment varies depending on the indication for which the drug is prescribed, the list price used should be the one for the “course of treatment” associated with the primary indication addressed in the advertisement. To the extent permissible under current laws, manufacturers would be permitted to include an up-to-date competitor product’s list price, so long as they do so in a truthful, non-misleading way. In § 403.1200(b) we are proposing an exception to the requirement at proposed § 403.1202(a) to provide that an advertisement for any prescription drug or biological product and that has a list price, as defined herein, of less than \$35 per month for a 30-day supply or typical course of treatment will be exempt from these transparency requirements.

We are also proposing that § 403.1200 set forth the scope of applicability to specify that this requirement will apply 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.

We are further proposing in § 403.1203 that the required price disclosure set forth in proposed § 403.1202 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. We seek 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.

We are proposing in § 403.1204(a) that the Secretary shall 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 is proposed in this rule. However, we anticipate that the primary enforcement mechanism

will be the threat of private actions under the Lanham Act Section 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 seek 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 including any HHS-specific enforcement mechanism in this proposal, we are proposing at § 403.1204(b) that this rule preempt any state-law-based claim which depends in whole or in part on any pricing statement required by this rule.

In publishing this proposed rule, we are seeking comment on the specifics of the proposal. In particular, we seek comment on whether Wholesale Acquisition Cost is the amount that best reflects the “list price” for the stated purposes of price transparency and comparison shopping under this proposed regulation. We also seek comment on whether 30-day supply and typical course of treatment are

¹⁵ In addition, regulated entities are required to report price information to the government in a variety of settings. *See, e.g.,* 7 CFR 59.301(a) and (b) (2018) (packer processing plants must daily report to the Secretary of Agriculture the sale price for lambs which the Secretary of Agriculture then makes public); 7 CFR 59.104(a)(1) (2018) (packer processing plants must report to the Secretary of Agriculture twice a day the sale price of each lot of “boxed beef” which the Secretary of Agriculture then makes public); 17 CFR 229.1204(b)(1) (2018) (oil and gas producers must report to the SEC the average sale price per unit of oil, gas, or other product by geographic area for three preceding fiscal years).

appropriate metrics for a consumer to gauge the cost of the drug. We further seek comment on how to treat an advertised drug that must be used in combination with another non-advertised drug or device.

We also seek 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. This threshold was selected because it approximates the average copayment for a preferred brand drug. Given that the public is already accustomed to pay roughly this amount for drugs—and thus, in the absence of new information, may presume that patients will pay this amount for a drug—the public's interest in being informed of prices that are equal to or less than this amount is less strong than for prices in excess of this amount. 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. These prices are also well below the lowest list price of advertised drugs. We seek 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.

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

We considered whether this regulation should apply to advertisements that are in other media forums such as radio, magazines, newspapers, internet websites and other forms of social media, but concluded that the purpose of this regulation is best served by limiting the requirements to only those identified herein. We seek comment as to whether we should apply this regulation to other media formats and, if so, what the presentation requirements should be.

We further seek comment as to whether compliance with this rule

should be a condition of payment, directly or indirectly, from these federal health programs.

We are also considering 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 out-of-pocket costs but also expenditures borne by Medicare and Medicaid. We seek 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) a new payment code for drug pricing counseling, and (3) intelligent plan selection or use of intelligent assignment. We are also interested in other approaches to price transparency and informed decision making that we have not contemplated.

CMS has released several information products that provide greater transparency on spending for drugs in the Medicare and Medicaid programs. The CMS Drug Spending Dashboards are interactive, web-based tools that provide spending information for drugs in the Medicare Part B and D programs as well as Medicaid. The Dashboards focus on average spending per dosage unit and change in average spending per dosage unit over time. The tools also include additional manufacturer-level drug spending information as well as consumer-friendly descriptions of the drug uses and clinical indications. We seek comment on whether manufacturers or others submitting additional information such as list price, typical out-of-pocket cost, therapeutic alternatives, pharmacoeconomic research, and other data could be helpful for consumers and what information would be most useful. We are also interested in feedback about the ease of which CMS dashboard data could be used by a non-government entity creating and maintaining such a price transparency resource for consumers and others. Additionally, CMS could announce updated information when a new DTC ad campaign is launched and public service announcements could be made to draw attention to the dashboard.

In an effort to incentivize provider engagement with patients on their prescription drug out-of-pocket 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 out-of-pocket costs, thus improving adherence, but also could increase provider awareness of drug pricing which may influence prescribing when appropriate cheaper options are available.

Through intelligent plan selection or use of intelligent assignment, beneficiaries could be provided with an auto-generated list of plans each year, based upon their most recent drug utilization, that would highlight opportunities for savings through competitor plans or alternative drugs (e.g., generics or biosimilars). This intelligent plan selection would help alleviate beneficiary anxiety associated with plan selection and encourage annual plan review by beneficiaries. Enrollment in suggested plans would be voluntary.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In this proposed rule, we are soliciting public comment on the issues in this document that contain information collection requirements (ICRs).

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 F1—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	\$18.24	\$36.48
Marketing Managers	11-2021	63.57	127.14

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

B. ICRs Regarding Pricing Information (§ 403.1202)

Proposed § 403.1202 would require 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 earlier in Section II of this notice of proposed rulemaking, 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 ads that appear on television each quarter and will be affected by this rule. For these ads, 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 \$24.08 (\$34.48/hr × .66) per advertisement for administrative support staff. We also estimate 5 minutes and \$41.96 (\$127.14/hr × .33) per advertisement for marketing managers, for a total of 15 minutes (0.25 hours) and \$66.04 (\$24.08 + \$41.96) per

advertisement per quarter or 300 hours per year across all pharmaceutical companies running affected televised advertisements ((300 ads/quarter) × (4 quarters/year) × (.25 hours/ad)). As a result, using wage information provided in Table 1, we estimate costs of \$19,812 (300 ads × \$66.04/ad) per quarter or \$79,248 in each year following publication of the final rule after adjusting for overhead and benefits.

C. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the rule’s information collection and recordkeeping requirements. These requirements are not effective until they have been approved by the OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections discussed above, please visit CMS’ website at website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html> or call the Reports Clearance Office at 410-786-1326.

We invite public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule and identify the rule (CMS-4187-P) and where applicable the ICR’s CFR citation, CMS ID number, and OMB control number.

See the **DATES** and **ADDRESSES** sections of this proposed rule for further information.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Analysis

A. Statement of Need

This proposed rule aims to improve the quality, accessibility and affordability of the Medicare Part C and Part D 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. This proposal will require disclosure of prescription drug prices to the general public for products advertised on television. This may improve awareness and allow the general public to respond, potentially increasing the efficiency of prescription drug utilization.

B. Overall Impact

We acknowledge that examination of the impact of this proposed 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., Pub. L. 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 businesses, 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.

In addition, section 1102(b) of the Act requires us to prepare a regulatory analysis for any rule or regulation proposed 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 \$150 million. This proposed rule is not anticipated to have an effect only on State, local, or tribal governments, in the aggregate, of \$150 million or more, adjusted for inflation. We believe that the proposed rule would impose mandates on the private sector that would result in an expenditure of \$150 million in at least one year.

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 proposed 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.

Executive Order 13771 (January 30, 2017) requires that the costs associated with significant new regulations “to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.” The Department believes that this proposed rule is a significant regulatory action as defined by Executive Order 12866

which imposes costs, and therefore is considered a regulatory action under Executive Order 13771.

C. Anticipated Effects

This proposed rule would affect the operations of prescription drug manufacturers. According to the U.S. Census, there were 1,775 pharmaceutical and medicine manufacturing firms operating in the U.S. in 2015.¹⁶ 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 proposed rule using the May 2016 National Occupational Employment and Wage Estimates provided by the U.S. 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 below.

TABLE 1—HOURLY WAGES

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

In order to comply with the regulatory changes proposed in this proposed rule, affected businesses would first need to review the rule. We estimate that this would require an average of 2 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 1, this implies costs of \$0.47 million in the first year following publication of a final rule after adjusting for overhead and benefits.

After reviewing the rule, prescription drug 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 in Table 1, we estimate costs of \$4.74 million in the first year and \$2.36 million in subsequent years following publication of the final rule after adjusting for overhead and benefits.

We estimate that 25 pharmaceutical companies will run an estimated 300 distinct pharmaceutical ads that appear on television each quarter and will be affected by this rule. For these ads, 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 \$24.08 ($\$34.48/\text{hr} \times .66$) per advertisement for administrative support staff. We also estimate 5 minutes and \$41.96 ($\$127.14/\text{hr} \times .33$) per advertisement for marketing managers, for a total of 15 minutes (0.25 hours) and \$66.04 ($\$24.08 + \41.96) per advertisement per quarter or 300 hours per year across all pharmaceutical companies running affected televised advertisements ($(300 \text{ ads/quarter}) \times (4 \text{ quarters/year}) \times (.25 \text{ hours/ad})$). As a result, using wage information provided in Table 1, we estimate costs of \$19,812 ($300 \text{ ads} \times \$66.04/\text{ad}$) per quarter or \$79,248 in each year following publication of the final rule after adjusting for overhead and benefits.

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 market 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

¹⁶ <https://www.census.gov/data/tables/2015/econ/susb/2015-susb-annual.html>.

potentially increase total cost of care. We lack data to quantify these effects, and seek public comment on these impacts, including comment on the best methods for extrapolating, to the prescription drug market, estimates of consumer response to the inclusion of prices in advertising that may have been developed in other contexts.

In addition, we believe that this rule may provide a moderating force to counteract prescription drug increases. This rule will provide direct evidence of prescription drug prices to the general public, potentially improving awareness and allowing the general public to signal in some cases that prescription drug 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. We lack data to quantify these effects, and seek public comment on these impacts.

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, the set of pharmaceutical products available for sale, and utilization of various prescription drugs. A possibility not reflected in the quantitative estimates above is that, with this proposed rule, drug companies would find the cost of revising their ads to be prohibitively expensive (for example, if they change their WACs so frequently that there is extensive monitoring and revision necessary to ensure that ads airing on a particular day match the WAC for that day). In this case, TV drug 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 ads to align with quarterly marketing plans. We therefore request comment 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 payers?

Furthermore, the Department recognizes that some studies indicate direct-to-consumer 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, and we seek public comment on these impacts. In addition, we acknowledge that we may not have considered all areas in which the rule may have effects, and we seek public comment on impacts of the rule in areas we have not discussed here.

As discussed above, the RFA requires agencies that issue a regulation to analyze options for regulatory relief of small entities if a proposed rule has a significant impact on a substantial number of small entities. HHS considers a rule to have a significant economic impact on a substantial number of small entities if at least 5 percent of small entities experience an impact of more than 3 percent of revenue. As discussed below, we calculate the costs of the proposed changes per affected business over 2020–2024. The estimated average 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 costs of the rule are estimated to be \$5.2 million in 2020

and \$2.4 million in subsequent years. According to the U.S. Census, 1,775 pharmaceutical and medicine manufacturing firms operating in the U.S. in 2015 had annual payroll of \$23.2 billion. Since the estimated costs of this proposed rule are a tiny fraction of payroll for covered entities, the Department anticipates that the proposed rule will not have a significant economic impact on a substantial number of small entities. We seek public comment on this determination, and the rule's impact on small entities.

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. If an alternative definition were used for list price, 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 Wholesale Acquisition Cost is certain to be known by the manufacturer when creating DTC ads. As such, it would be harder for manufacturers to report prices other than 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. We seek comments on these regulatory alternatives.

E. Accounting Statement

TABLE 2—ACCOUNTING TABLE OF BENEFITS AND COSTS OF ALL PROPOSED CHANGES

Benefits:	Present value over 2020–2024 by discount rate (millions of 2016 dollars)		Annualized value over 2020– 2024 by discount rate (millions of 2016 dollars)	
	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	12.1	9.4	2.6	2.3
Non-quantified Costs: See narrative discussion.				

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 proposes to amend 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. Add subpart L 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.

(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 drug or biological, the manufacturer’s list price for the drug or biological 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 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 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 course of treatment varies depending on the indication for which a drug is prescribed, the list price to be used is the one for the “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 shall maintain a public list that will include the 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 that depends in whole or in part on any pricing statement required by this subpart.

Dated: October 11, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: October 11, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

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