December 17, 2018

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-4187-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Medicare and Medicaid Programs; Regulation to Require Drug Pricing Transparency, File Code CMS-4187-P

Dear Administrator Verma:

The Goldwater Institute submits the following comments on the proposed "Regulation To Require Drug Pricing Transparency," which proposes to add a new subpart L to 42 C.F.R. 403.

The Goldwater Institute is a public policy research organization based in Phoenix, Arizona, which works in courts, legislatures and communities to defend and strengthen the freedom guaranteed in the constitutions of the United States and the states. Among its other projects, the Institute focuses on market-based reforms for medical care and the importance of free speech in medicine.

Comments are warranted with regard to this proposed rule because it violates constitutional free speech protections, and because it would mandate the disclosure of inaccurate and misleading information, which would increase, rather than decrease, consumer confusion with regard to the pricing of medicine.

1. The Rule Fails to Adequately Define "Wholesale Acquisition Cost"

The proposed rule requires pharmaceutical manufacturers to state in their direct-to-consumer advertisements the "Wholesale Acquisition Cost" (WAC) for a "typical 30-day regimen or for a typical course of treatment, whichever is most appropriate." 83 Fed. Reg. 52789, 52799. It also defines WAC as "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." *Id.* § 403.1201(d).

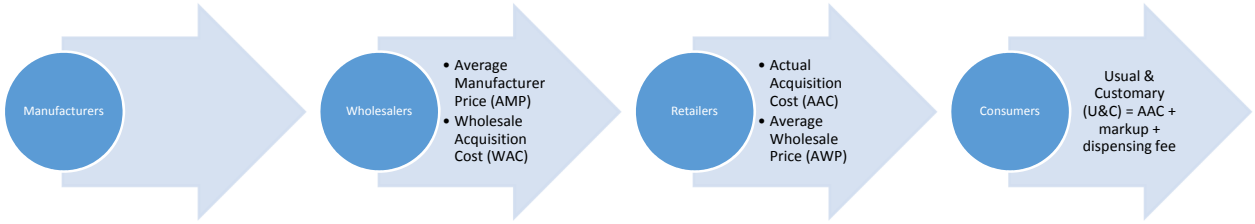
Defining WAC in this way is misleading, however, due to the unique and complicated nature of pharmaceutical sales in the United States. Unlike most products, such as coffee makers (the example used at 83 Fed. Reg. 52789), pharmaceutical products are subject to a wide array of discounts, special conditions, and other intervening circumstances so that the price consumers pay is virtually never the price at which pharmaceutical manufacturers sell their product. Indeed, there is no single, identifiable price at which a pharmaceutical manufacturer sells its products to all wholesalers.

Pharmaceutical products are priced through a multi-step process, which involves multiple discounts and rebates. A product moves from a manufacturer to a wholesaler, and then either to retailers (pharmacies), hospitals, physicians' offices, or stand-alone clinics, where the consumer purchases that product. (See Figure below.) In some instances, insurers and pharmacy benefit managers (PBM) may further negotiate the product price after that. It is only after the product moves through all of these stages that the price a consumer pays is established. It is therefore conceivable that every single buyer pays a different price once all of the applicable discounts and rebates are counted.

Wholesalers pay manufacturers an Average Manufacturing Price (AMP) or a WAC. Discounts, rebates, etc., are *not* calculated into this price, which means that each wholesaler may pay a different price for the same product. Similarly, retailers, hospitals, physicians' offices, and stand-alone clinics pay an Actual Acquisition Cost (AAC), which is typically the WAC plus 10 to 15 percent for branded drugs, or the Average Wholesale Price (AWP). And these prices still do not reflect the varying discounts and rebates that are provided to these purchasers. Finally, the consumer pays the Usual & Customary (U&C) price, which is the AAC + markup + a dispensing fee.

On top of these complicated and multi-layered pricing effects, the price a patient pays can also be affected by the kind of prescription drug insurance coverage the consumer has. In some plans, consumers pay co-pays, whereas a retailer or mail-order pharmacy based on a lower price that was negotiated by a PBM may not. That means a patient paying cash at a pharmacy will typically pay a different price than a patient who purchases a product through insurance—and, of course, patients covered by different insurance plans will typically pay different prices.

Figure: Examples of the Prescription Pricing Pipeline



Rather than simplify this process, the proposed rule actually worsens the confusion because it defines WAC as the "list price." But a WAC is typically understood to be *not* the list price, but the price at which a product is *actually sold*—the money-out-of-pocket by the consumer at the time of purchase, including all discounts. In *Mass. v. Mylan Laboratories*, 608 F.Supp. 2d 127, 143 (D. Mass. 2008), the district court noted that WAC is a contentious term, not clearly defined, and then concluded that it "*does not mean a list price*; it means the amount that goods actually cost." And it found that "[i]f …WAC were understood to mean merely a list price, a price set by manufacturers and listed at the top of invoices but rarely paid by wholesalers"—as the regulation attempts to do—then "WAC could *not* be used to accurately estimate what pharmacies actually pay for drugs without significant additional information." *Id.* at 143–44 (emphasis added).

The proposed rule commits just this error, by defining WAC as "the manufacturer's list price … not including … discounts." 83 Fed. Reg. at 52799 § 403.1201. Thus it disregards the facts that *Mylan Laboratories* found critical: that the WAC is a misleading term if it is employed "without significant additional information" about the discounts, rebates, and other reductions that affect the price that consumers ultimately pay. 608 F. Supp. 2d at 143–44. *See also* Lee H. Rosebush & Lindsay P. Holmes, *Select Issues in Negotiating Drug Pricing and Reimbursement Contracts*, 10 J. HEALTH & LIFE SCI. L. 59, 66 (2016) ("The accuracy of the WAC is subject to any unknown price reductions, rebates, or discounts that a manufacturer may have offered to a wholesaler or direct purchaser.").

Worse still, the proposed regulation does not impose any requirement that manufacturers list their *actual* price as their WAC. Instead, it defines WAC as the "list price," defined as the price "reported in wholesale price guides or other publications." § 403.1201(d). But manufacturers create those price guides and other publications, so the proposed regulation fails to ensure that the "list price" will reflect any *actual* value or cost of the product. As Charles Silver and David Hyman note in their book *Overcharged: Why Americans Pay Too Much for Health Care* 79 (2018), drug companies have in the past printed "phony" prices in their publications, enabling them to charge Medicare and Medicaid an inflated "list price." The proposed regulation does nothing to address this concern, but instead repeats the mistake made in the 1997 Balanced Budget Act and the 2003 Medicare Prescription Drug Improvement and Modernization Act, both of which set Medicare payments based on similar price statements—statements not vetted for cost-containment in *any* way. *Id.* at 84–85. The result then was higher prices and greater confusion.

The result of this failure to properly define WAC in a workable manner means that the proposal, if implemented, will fail to accomplish its laudable goals of rationalizing the price information for pharmaceutical products—but, in fact, will accomplish the opposite.

2. Requiring Disclosure of the WAC Without Other Information Will Significantly Confuse Consumers and Fail to Ensure Proper Incentives to Manufacturers

The reason advanced for the proposed rule is twofold: to ensure that consumers have better information and to create an incentive for pharmaceutical manufacturers to lower their

prices. 83 Fed. Reg. at 52789-90, 52792-93. But this goal will only be served if the information provided is accurate and not misleading. The proposed rule's definition of WAC, however, is so flawed that the proposal will fail to accomplish this.

There is no dispute that economic efficiency is best served by better information, which allows consumers to make better choices. Nor is there any dispute that those choices create incentives that encourage producers to improve products and services and reduce cost. But these beneficial consequences will *not* result if the information provided is false or misleading. And the proposed regulation will require only the disclosure of false or profoundly misleading information.

First, as described above, consumers do not pay the WAC. The WAC is a price charged by manufacturers to insurers who obtain medicines at different rates, depending on the negotiations conducted by PBMs. Depending on insurer and depending on the negotiations, the prices for a different group of medicines can be wholly different. (Nor should uniformity be mandated here, because that would reduce efficiency by barring the negotiating process that enables insurers to tailor their services to the needs of patients.) The 340B Discount Drug Pricing Program also essentially requires that pharmaceutical makers sell their products to hospitals and pharmacies at substantial discounts. Patients who obtain their medicines through that program will therefore pay still a different price for a medicine—one that bears little relationship to the WAC contemplated by the regulation.

Second, the regulation requires the publication of the WAC for a "typical 30-day regimen or for a typical course of treatment, whichever is most appropriate." § 403.1202. But for many medications, there is no such "typical" number. For example, Humira® has dosing instructions[1] that depend on the illness being treated (indication), whether the patient is an adult or adolescent, the patient's weight, etc. To further complicate matters, the treatment timing may differ between patients—it may be recommended as weekly or bi-weekly, for example. And what qualifies as "appropriate"—or who decides what qualifies—is left undefined in the proposed regulation. This means either that the *agency* will determine what is appropriate through some unspecified process—thereby intruding on the professional judgment of practitioners and, in effect, regulating the practice of medicine—or that manufacturers will define for themselves what is appropriate, which will result in the same problem noted above: manufacturers would be free to set the relevant WAC amount however they please, thereby obliterating any possible efficiency gains from the proposed regulation.

To put it simply, consumers are not served by a rule that forces manufacturers to disclose what is essentially an arbitrary number—a number which is only intended as a starting point for a lengthy process of negotiations, and which, even after the close of negotiations, will be whittled down still further by various discounts and offsets before the customer is asked to pay. That would be akin to requiring automobile manufacturers to state in their advertisements the "invoice cost" charged to dealers—which is itself *not* the actual cost dealers pay, and which is then subject to such factors as the "dealer holdback," factory to dealer incentives, discounts,

[1] https://www.rxabbvie.com/pdf/humira.pdf

factory rebates, and government subsidies, before the bottom line sticker price for a car becomes available. Unlike automobiles, there is no "manufacturer suggested retail price" in the pharmaceutical market, and the proposed regulation does not establish one.

While the effort to increase efficiency and transparency is laudable, requiring disclosure of an arbitrary, poorly defined figure such as the regulation does will not serve that need and will mislead consumers rather than informing their decisions. It will also create a perverse incentive that will not encourage companies to lower their prices, but rather to announce prices in ways that serve their interests.

3. The Proposed Rule Violates the First Amendment

As the proposed rule notes, the applicable legal precedent that allows the government to require businesses to disclose information to consumers is *Zauderer v. Office of Disciplinary Counsel of Sup. Ct. of Ohio*, 471 U.S. 626 (1985). But *Zauderer* only allows the government to compel the disclosure of "information" that is "purely factual and uncontroversial." *Id.* at 651. It does not allow the government to compel disclosure of information unless it is "both indisputably accurate and not subject to misinterpretation by consumers." *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1216 (D.C. Cir. 2012). And it does not allow the government to compel disclosure of information that is "so … incomplete that [it] would not qualify as 'factual and uncontroversial,'" *Am. Meat Inst. v. U.S. Dep't of Agric*., 760 F.3d 18, 27 (D.C. Cir. 2014) (citation omitted).

Nor does it allow the government to compel disclosure of information that is "literally true but misleading," because that would "create[] the possibility of consumer deception," and "[a] disclosure that may deceive consumers does not further the free flow of accurate information or add to the 'value to consumers of the information [commercial] speech provides.'" *Am. Beverage Ass'n v. City & Cnty. of S.F.*, 871 F.3d 884, 893 (9th Cir. 2017) (citation omitted).[2]

As noted above, the WAC information is so misleading and incomplete that it does not qualify as factual or uncontroversial. The WAC is *not* the price consumers pay. Nor is it even consistently related to the price consumers pay. A customer hearing an advertisement that says "Drug X costs $1,500 per month for a normal course of treatment" could not calculate to herself the drug's actual price by deducting or dividing some figure in her mind. On the contrary, the actual price she pays for Drug X bears so unpredictable a relationship to the WAC—assuming WAC can even be coherently defined—that the $1,500 figure is meaningless. Worse than meaningless, in fact, as it is likely to mislead the patient into thinking she cannot afford Drug X when she can, or that she can afford it when she cannot.

A second, related issue may also place the proposed rule outside of the *Zauderer* category. Courts are currently in disagreement over whether *Zauderer* allows the government to compel disclosure of information for reasons *other than* preventing possible deception. In *Zauderer* itself, the Supreme Court appeared to apply such mandates solely to cases in which the

[2] The Ninth Circuit granted rehearing en banc in this case, and that decision is still pending.

consumer might be deceived in the absence of a disclosure. 471 U.S. at 651; *see also Video Software Dealers Ass'n v. Schwarzenegger*, 556 F.3d 950, 966–67 (9th Cir. 2009). Other courts have expanded that rule to allow compulsory disclosure to accomplish other purposes, even where there is no concern that consumers might be deceived. *See, e.g., CTIA-The Wireless Ass'n v. City of Berkeley*, 854 F.3d 1105, 1115 (9th Cir. 2017).[3] The proposed rule does not aim at remedying consumer deception, but at other purposes, and therefore is built on contentious legal ground. While the proposed rule cites *Pharm. Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294 (1st Cir. 2005) and *N.Y. State Rest. Ass'n v. N.Y. City Bd. of Health*, 556 F.3d 114 (2d Cir. 2009), for the proposition that compelled commercial speech may be upheld if it serves interests unrelated to preventing deception, it remains unclear whether the Supreme Court will ultimately affirm that position.

Be that as it may, the proposed rule fails the *Zauderer* test because the WAC is, at best, "literally true but nonetheless misleading," *CTIA*, 854 F.3d at 1119, and, at worst, wholly false information which can only mislead consumers, obstruct market incentives, and ultimately worsen the provision of health care in the United States.

4. A Preferable Alternative

Consumers benefit from accurate information regarding drug prices and the incentive information provides for reducing drug prices. But the information must be accurate and useful. Nor can efficiency gains warrant an intrusion on the First Amendment. The Goldwater Institute would therefore recommend rejecting the proposal, in light of a voluntary set of guiding principles adopted by the biopharmaceutical industry. These principles aim to use DTC advertising to direct patients to an online platform that more fully educates patients about illnesses, treatment options, and treatment costs.

Originally adopted in 2006, and revised in October 2018, a new principle has been added to the PhRMA Guiding Principles on Direct to Consumer Advertisements about Prescription Medicines which states, "All DTC television advertising that identifies a prescription medicine by name should include direction as to where patients can find information about the cost of the medicine, such as a company-developed website, including the list price and average, estimated, or typical patient out-of-pocket costs, or other context about the potential cost of the medicine."[4]

Given the freedom of speech concerns raised by the proposed rule, it is appropriate to take this alternative into account. As the Supreme Court has often stressed, restrictions on free speech should be adopted only where there is no other option: "If a less restrictive alternative would serve the Government's purpose, the legislature must use that alternative." *United States v. Playboy Entm't Grp.*, 529 U.S. 803, 813 (2000). As part of this "less restrictive means" determination, it is appropriate to consider the availability of "market-based solutions" that

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[3] The U.S. Supreme Court vacated and reversed this decision for reconsideration, 138 S. Ct. 2708 (2018), in light of *Nat'l Inst. of Family & Life Advocates v. Beccara*, 138 S. Ct. 2361 (2018).
[4] Available at http://phrma-docs.phrma.org/files/dmfile/PhRMA_Guiding_Principles_2018.pdf, pg. 6.

involve no government mandate or compulsion. *Id.* at 821. If such an alternative is available, and it is here, then the government may not disregard it and restrict free speech on the theory that consumers may not choose to take advantage of that alternative. "A court should not assume a plausible, less restrictive alternative would be ineffective; and a court should not presume [patients], given full information, will fail to act." *Id*. at 824. Because such an alternative does exist here, and given the flaws in the proposed regulation, there is no constitutional basis for employing the *Zauderer* rule.

Conclusion

The desire to encourage transparency and facilitate efficient free markets in medicine is a laudable one. Unfortunately, the proposed rule falls short of that mark while the adopted voluntary approach is far more likely to achieve the stated goals of the proposed rule.

Sincerely,

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