



The Evolving Landscape of Drug Pricing Transparency

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Moderated by **James Davidson**, Shareholder, Polsinelli PC



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The Evolving Landscape of Drug Pricing Transparency:
Advertising and Promotion for Medical Products Conference

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A Brief Recap

- In its “Blueprint,” in May 2018, the Trump Administration proposed to direct the U.S. Food and Drug Administration (“FDA”) to evaluate requiring drug list prices in direct-to-consumer (“DTC”) advertisements.

"We believe it's an important part of fair balance that if you're telling a patient, activating a patient to have a discussion with their doctor about a drug, telling them all the good things that drug can do for them, it's material and relevant to know if it's a \$50,000-drug or a \$100-drug, because often that patient is going to have to bear a lot of that cost."

-Alex Azar (May 11, 2018)

- Following this announcement, the U.S. Department of Health and Human Services published a similar policy statement and request for information.

October 15, 2018, CMS proposed rule

- TV advertisements (including broadcast, cable, streaming, or satellite) to include a “textual statement” indicating current list price for “typical 30-day regimen or for a typical course of treatment, whichever is most appropriate”
 - Prescription drugs or biological products for which payment is available, directly or indirectly, through or under Medicare or Medicaid
 - Exception for drugs with list price less than \$35
- Relies on two generalized rulemaking provisions in the Social Security Act
 - Section 1102
 - Section 1871

PhRMA Comments on Proposed Rule

Statutory Concerns

- Social Security Act does not grant CMS the sweeping power to regulate DTC advertising of a major industry
- Lack of CMS authority bolstered by fact Congress specifically authorized a separate agency (FDA) to regulate drug advertising

Constitutional Concerns

- Unconstitutional compelled speech

Policy Concerns

- Full list price does not typically relate to what the beneficiaries actually pay out of pocket and could confuse beneficiaries
- No evidence that proposed rule would help beneficiaries

Why not FDA?

Some Possible Reasons

- First Amendment
 - Commercial speech/scientific exchange
 - November 2016: Part 15 hearing
 - June 2018: Final Payor and Consistent with Labeling Guidance
 - Compelled speech
- Prior FDA statements that the Agency does not have the authority to compel price disclosure in advertisements:

“The decision to engage in public disclosure of prescription prices is not for the Food and Drug Administration to make.” 40 Fed. Reg. 58794 (Dec. 18, 1975).
- “Fair Balance” cannot be read to require price information:

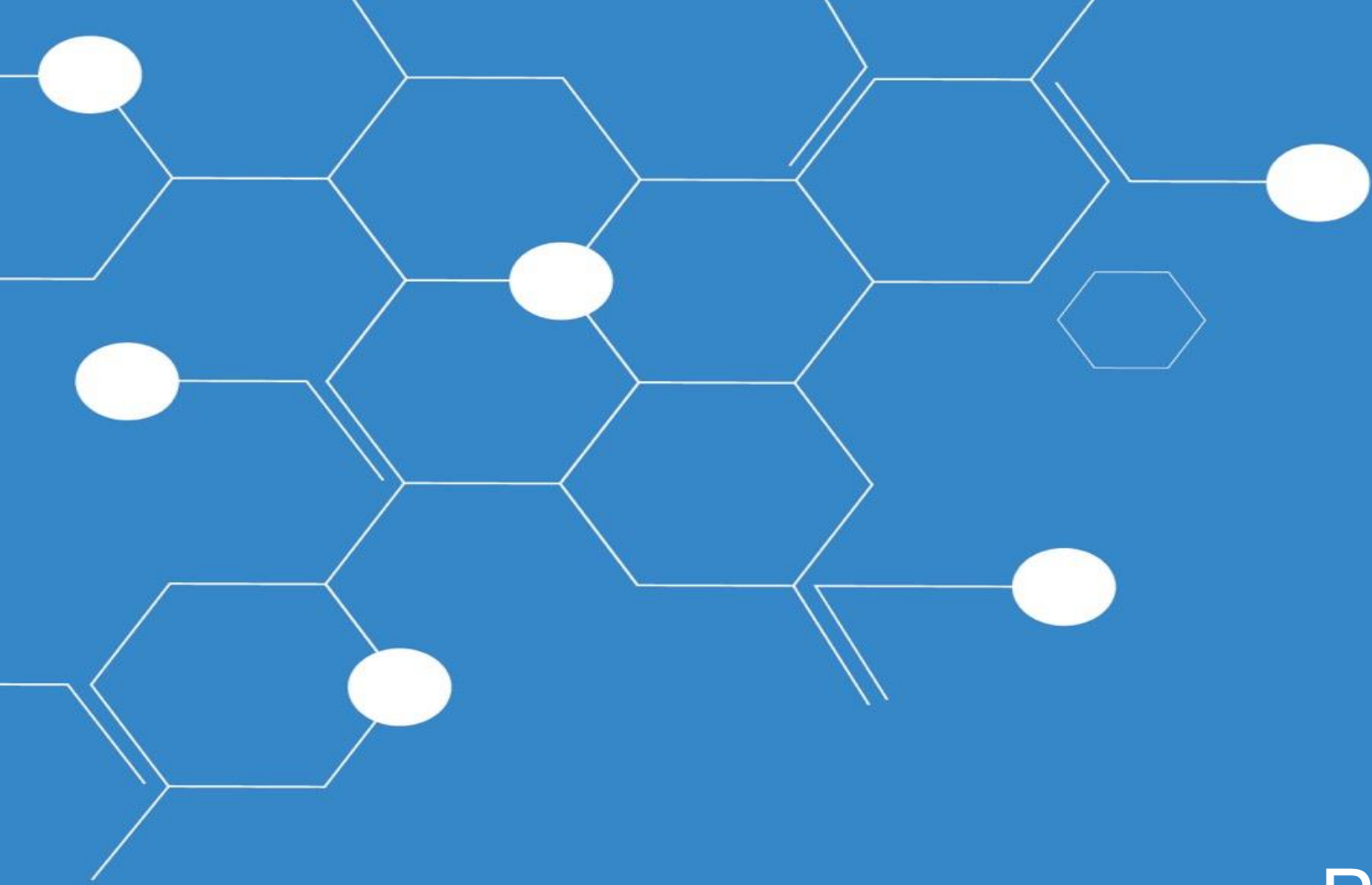
An advertisement "does not satisfy the requirement that the advertisement present a 'true statement' of information in brief summary relating to side effects, contraindications and effectiveness" if “it does not present a *fair balance* between information relating to side effects and contraindications and information relating to effectiveness...” 21 CFR 202.1(e)(5)(ii)

Inexact Price Disclosure = Product Claim?

- FDA regulations exempt certain “price reminder” advertisements from requirements of fair balance requirements of 21 CFR 202.1
 - Like other “reminders,” price reminder advertisement must not contain any representation or suggestion concerning the drug’s safety, effectiveness, or indications for use
 - Unlike other reminders, price reminders permitted for products with boxed warnings
 - Must include the actual price charged for a prescription for a specific quantity of the drug product, and must include all charges to the consumer
- Failure to include exact price takes advertisement outside exemption, and therefore subject to 202.1 requirements, including fair balance

Additional FDA Issues Implicated by CMS Rule

- HHS stated in preamble that “[t]o 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.”
 - FDA has historically regulated price comparisons as product claims.
 - 1993 FDA Warning Letter: “[D]rug acquisition cost comparisons, such as daily medication costs, are acceptable in prescription drug promotion provided the manufacturer acknowledges in such promotion that lower acquisition cost alone does not necessarily reflect a cost advantage.”
- Price disclosed must be the current list price “for a typical 30-day regimen or for a typical course of treatment, whichever is most appropriate.”
 - What is a “typical 30-day regimen” or “typical course of treatment”?
 - How to square with FDA-approved labeling?



PhRMA's Approach



PhRMA DTC Principles

- In Oct. 2018, PhRMA published revised voluntary “Guiding Principles on Direct to Consumer Advertisements about Prescription Medicines”
- Key addition of new **Principle 19** and associated Q&A:
 - “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.”
- Provides meaningful, contextualized information about the price of the drug for patients
- Became effective on April 15, 2019

PhRMA DTC Principles

- PhRMA DTC Principles Q&A provide examples of how companies can “include direction” consistent with Principle 19:
 - “[I]f the Company is providing information on a company-developed website, the Company could choose within its television advertisements to provide a textual link or URL to the web page where such information is available and clearly identify that cost information can be obtained at that web page. As another example, a company could choose to include a voiceover mentioning a website and clearly identifying that cost information can be obtained there.”
- Each company to “determine on an individual basis what is necessary to provide patients with useful information” consistent with Principle 19.

PhRMA DTC Principles

- PhRMA DTC Principle 19 approach parallels thinking underlying “major statement” and “adequate provision” for DTC broadcast advertisements
 - “Major statement” (of side effects and contraindications) in the ad, supplemented by “adequate provision” for dissemination of approved labeling
 - “Serious and Actionable” risks?
 - Adequate Provision
 - *See our ad in Golf Digest*
 - *Visit www.DRUGX.com*
- Similar to this approach, the DTC Principles provide that DTC TV ads include “direction” where patients can obtain contextual information about the potential cost of the medicine.

Meet MAT

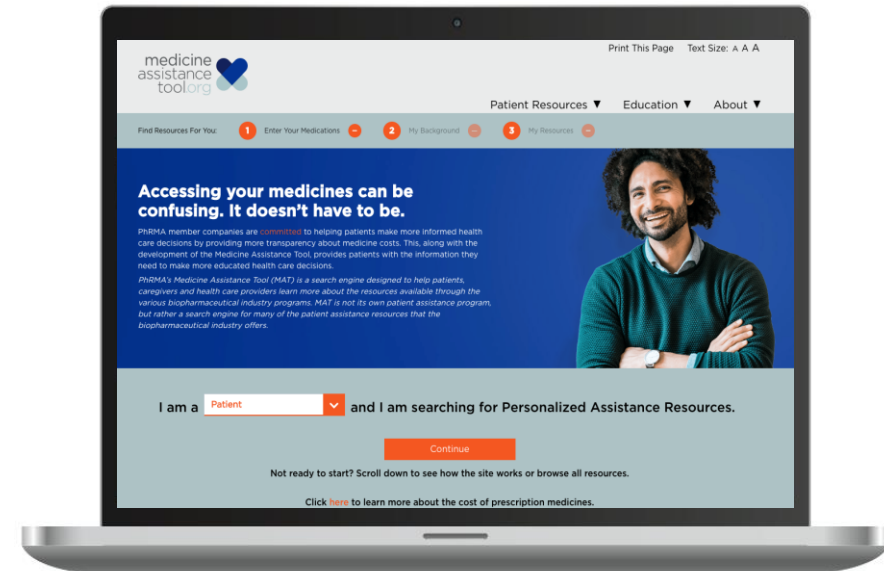
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What is MAT?

900+

Public and Private Programs made up of patient assistance programs to cost-sharing assistance programs



The Medicine Assistance Tool (MAT) is a web platform designed to help patients, caregivers and health care providers learn more about some of the resources available to assist in accessing and affording medicines.

How can MAT help patients learn more about their medicine costs?

PhRMA member companies are committed to helping patients make more informed health care decisions by providing more transparency about medicine costs. Through MAT.org, we share links to member company websites that include:

- List price of a medicine
- Average estimated or typical patient out-of-pocket costs
- Other context about potential cost of the medicine

Each member company has individually and independently determined the content of any cost information provided on their websites.





The WAC Disclosure Rule and the Pitfalls of Statutory Forum Shopping

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Basics of The WAC Disclosure Rule

- Would apply to:
 - “advertisements for a prescription drug or biological product distributed in the United States for which payment is available [under Medicare or Medicaid]” where such drug has a “list price” of >\$35/month.
- Would require any TV advertisements (“including broadcast, cable, streaming, or satellite”) to indicate in text:
 - “the current list price for a typical 30-day regimen or for a typical course of treatment, with the caveat that “If you have health insurance that covers drugs, your cost may be different.”
- “List price” = “wholesale acquisition cost” = “manufacturer's list price...to wholesalers or direct purchasers in the U.S.” excluding discounts/rebates etc.

Enforcement of The Final Rule

- No direct enforcement provision for violations, just a “Name and Shame” approach: “The Secretary will maintain a public list [of] drugs...advertised in violation of this subpart.”
- “We [HHS] anticipate that the primary enforcement mechanism will be the threat of private actions under the Lanham Act sec. 43(a), 15 U.S.C. 1125(a), for unfair competition in the form of false or misleading advertising.”
 - *But*, if failure to disclose WAC would be misleading under the Lanham Act, we would have already seen many such cases because such disclosures have never been routinely made; and, in general, the Lanham Act cannot be used as a means to privately enforce violations of federal administrative laws.

Preemption by the Final Rule

- The Rule also contains a Preemption provision:
 - “*State or local requirements.* No State or political subdivision of any State may establish or continue in effect any requirement concerning the disclosure in a television advertisement of the pricing of a prescription drug or biological product which is different from, or in addition to, any requirement imposed by this subpart.”
- Impact on state pricing legislation?

Legal Basis of The Final Rule

- Rule was based on amending CMS's Social Security Act regulations for the Medicare and Medicaid programs, not on changing any FDA related regulations.
- HHS relied on its general authority “to make rules necessary for the efficient administration of the Medicare and Medicaid programs.”
- In the court challenge to the Rule, the District Court rejected the Rule based solely on the conclusion that the Medicare and Medicaid laws did not authorize the attempted amendments to those regulations.
- *So....Why did the administration choose the “wrong” regulations to amend?*

Why Wasn't the Rule Based on the FDCA?

- Proposed rule acknowledged that “Congress has not explicitly provided HHS with authority to compel the disclosure of list prices to the public,” and it does not claim to interpret any particular provision in the Social Security Act.
 - The SSA nowhere mentions drug advertising, and Medicare and Medicaid have been in place for over 50 years without encompassing the regulation of drug advertising.
- In contrast, the Food, Drug, and Cosmetic Act (FDCA), since 1962, has expressly granted FDA authority to regulate Rx drug advertising.
 - FDA’s authority over drug advertising includes the authority to require “Fair Balance” in most advertisements, and FDA has required additional specific informational requirements for broadcast advertisements.

Why Wasn't the Rule Based on the FDCA?

- The FDCA deems an Rx drug “misbranded” if advertisements do not include “information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in [FDA] regulations.” 21 U.S.C. § 352(n).
- Reminder Labeling and Advertising rule (1975).
 - “The decision to engage in public disclosure of prescription prices is not for the Food and Drug Administration to make.”
- Congress also empowered FDA to require submission of drug television ads for pre-review, but forbid FDA to “make or direct changes in any material submitted,” except specific disclosures “*about a serious risk listed in the labeling of the drug involved.*”

FDA Enforcement Statements on Value Claims

- In more than one warning letter, FDA warned that cost comparisons based on price alone were misleading because the stated prices “misleadingly imply that all costs associated with [the drug] have been considered....[and] the presentation does not disclose all costs involved with [the drug] compared to [the other] therapy (e.g., healthcare provider office visits, surgical procedures, ...management of adverse events, dosage adjustments, and laboratory monitoring).”
- Put more succinctly, FDA has stated that cost-effectiveness claims can be misleading because “lower acquisition cost alone does not necessarily reflect a cost advantage....”
- And, in Congressional testimony an FDA Deputy Commissioner testified that “[t]raditionally, [FDA] has not been involved in cost effectiveness or comparative effectiveness issues,” and reiterated the position that variables beyond acquisition cost can affect the relative costs of competing therapies, and thus that cost-effectiveness claims based on acquisition costs can be misleading.

The District Court's Conclusions

- “Congress deliberately and precisely legislated in the area of drug marketing under the FDCA. Such purposeful action demonstrates that Congress knows how to speak on that subject when it wants to. It is therefore telling that the SSA contains no provisions concerning drug marketing.”
- “...when it released the Blueprint in May 2018, HHS said that it may “[c]all on the FDA to evaluate the inclusion of list prices in direct-to-consumer advertising.” Yet, a mere five months later, CMS became the issuing sub-agency. It thus would seem that HHS at first believed that the FDA, presumably under the FDCA, would be the proper sub-agency through which to promulgate the WAC Disclosure Rule, as opposed to CMS under the SSA....”
- “The WAC Disclosure Rule feels like agency action in search of a statutory home.”

Where Does the Administration Go From Here?

Appeal of the District Court Decision:

- Even if HHS overcomes the statutory authority issue, the district court did not address the 1st Amendment challenge, or claims that WAC is misleading to consumers, and HHS could well lose on those.
- Publish WAC prices on its own?
 - But WAC may be a trade secret exempt from government disclosure.
- Require a different “price” to be disclosed?
 - But there is no single price applicable to all possible consumers.
- Formally adopt the PhRMA DTC Principle 19?
- Do nothing directly but encourage states to legislate similar rules?
- What would a President Warren, or a President Sanders, propose?

Thank you!

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