



December 17, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-4187-P, P.O. Box 8013, Baltimore, MD 21244-8013

Submitted via www.regulations.gov

RE: Regulation to require drug pricing transparency – CMS-4187-P

Dear Administrator Verma,

The Alliance of Community Health Plans (ACHP) applauds the administration's continued efforts to address the high cost of prescription drugs. It is clear through the steps being taken across the Department of Health and Human Services (HHS or the Department) that the administration is fully committed to remedying this long-standing problem.

We appreciate the opportunity to comment on the Center for Medicare and Medicaid Services' (CMS or the agency) proposed rule regarding drug pricing transparency in Direct-to-Consumer (DTC) advertisements. Transparency on pharmaceutical prices will help consumers make more informed choices about their healthcare, the same way they make decisions about almost every other product or service they purchase.

Specifically, ACHP offers the following comments on the proposal, which are explained in greater detail throughout this document.

- ACHP supports use of the Wholesale Acquisition Cost (WAC) as the list price, however, we urge CMS to consider methods to ensure manufacturers cannot game how this list price is reported.
- We understand addressing televised advertisements are a priority, but believe all DTC ads should be subject to the proposed regulation.
- ACHP does not believe there should be any exemption for products with a price of less than \$35.00. We view the requirement to disclose a low-list price as a strategic marketing advantage, not a burden.

- We are concerned about the enforcement mechanism proposed under the regulation. We strongly encourage the agency to examine other ways to ensure compliance, including utilization of authorities under the Department’s Inspector General.
- The requirements laid out in the proposed regulation should be viewed as a regulatory floor and not a ceiling that may preclude efforts at the state level to improve transparency in the pharmaceutical market.

Greater regulation of Direct-to-Consumer Advertisements needed

The United States and New Zealand are the only countries that allow DTC advertisements that include product claims.¹ Most other countries don’t allow DTC ads at all; however, Canada does allow advertisements that mention either the product or the indication, but not both.²

As a result, healthcare consumers in the United States may be subjected to as many as nine drug advertisements per day and approximately 16 hours per year.³

As the proposed regulation indicates, such extensive exposure to DTC advertisements may distort the pharmaceutical market by increasing consumer demand, inappropriate prescribing, and higher pharmaceutical spending.

Furthermore, DTC advertisements may not be fully compliant with existing regulations. A recent study that examined 97 unique DTC ads found that few broadcast DTC ads complied with all of the Food and Drug Administration’s (FDA) guidelines.⁴ For these reasons, ACHP supports enhanced efforts to regulate DTC advertisements to ensure consumers have access to accurate and helpful information that can inform the choices they make about their healthcare.

We expect the availability of list prices for drugs advertised to consumers could help mitigate some of the upward pressure DTC advertising has had on physicians’ prescribing practices. Increasing manufacturers’ accountability for costs could help to reduce launch prices for new products, which are often set solely based on what a non-competitive market could bear. We expect that the availability of price information will draw increasing light to price escalation – with the possibility that improved accountability and transparency could temper such outrageous growth.

Disclosure of a drug’s list price

ACHP supports CMS’ proposal to require pharmaceutical and biological manufacturers to provide the Wholesale Acquisition Cost for a product in a DTC advertisement. The WAC, which is the list price paid for a pharmaceutical or biological product by wholesalers or direct purchasers, is an important cost marker for consumers and purchasers.

The list price is especially important and relevant to the large and growing number of individuals who are subject to high deductibles or who have no insurance coverage. For consumers who share the cost of pharmaceutical products with their insurers, the list price can be used to increase their understanding of the price upon which their coinsurance will be based.

¹ Direct-to-Consumer Pharmaceutical Advertising: Therapeutic or Toxic?. *P T*. 2011;36(10):669-84.

² Ibid.

³ Parekh, N. & Shrank, W.H. *J GEN INTERN MED* (2018) 33: 586. <https://doi.org/10.1007/s11606-018-4342-9>

⁴ Klara, K., Kim, J. & Ross, J.S. *J GEN INTERN MED* (2018) 33: 651. <https://doi.org/10.1007/s11606-017-4274-9>

We believe it is the best alternative to support transparency for consumers, providers, and suppliers across the prescription drug supply chain. To simplify its administration and make it harder for companies to game, CMS may consider requiring display of the WAC price over a certain lookback period (e.g., the previous year) instead of its proposal to require the *current list price* determined on the first day of the quarter during which the advertisement is being aired.

Additionally, ACHP believes the list price should simply reflect a 30-day supply. We believe including the price for a “normal course of treatment” could allow companies to game the price that is disclosed to consumers. If a normal course of treatment is less than 30 days, it effectively would be included in the list price required to be disclosed under the proposal. For example, if a dosing regimen includes 7 day’s worth of medications, then a 30-day supply would reflect the list price for that 7-day supply.

ACHP encourages CMS to remove the provision allowing drug advertisements to include the closest competitor’s list price. We are concerned that this provision could be easily manipulated by bad actors and potentially add to consumer confusion about the price of pharmaceuticals.

For example, if the advertisers were to choose to provide only a higher-priced competitor’s price point while excluding any price points for lower-priced competitors’ products then this policy could introduce incomplete and biased information that could ultimately raise healthcare costs and cause further market distortion.

Finally, the WAC does not reflect the price that any particular insured consumer would be expected to pay for advertised products. This is because, as CMS points out in the preamble to the proposed rule, the list price of a drug doesn’t reflect manufacturer rebates and other discounts negotiated by PBMs and plans. Those discounts and rebates can obscure the price of a product and sometimes result in shifting costs to consumers. For those reasons, ACHP believes the use of rebates is in need of systemic reform to improve transparency and negotiations between health plans and manufacturers, including the possibility of reducing the utilization of rebates or eliminating their use altogether.

Media format and content requirements

The proposed regulation seeks comment on whether it should be applied to other media formats. ACHP believes all DTC advertisements should include a disclosure about price, regardless of technology or medium.

ACHP agrees with CMS that focusing on televised advertisements is an important first step in ensuring consumers have access to important pricing information. Research conducted on multimedia advertising indicates 771,368 televised ads for pharmaceuticals were shown in 2016 an increase of almost 65 percent over 2012.⁵ Television’s share of the DTC ad pie has grown 12% since that time, while magazine and other print media’s share has shrunk by 6%.⁶

Digital platforms are increasingly utilized by the pharmaceutical industry as a means to communicate with consumers. Expenditures for digital marketing grew in 2016. Advertisers spent

⁵ <https://www.nytimes.com/2017/12/24/business/media/prescription-drugs-advertising-tv.html>

⁶ The US Healthcare and Pharma Industry H2 2016 Update: Digital Ad Spending Forecast and Trends. By Patricia Orsini. Published December 2016 by eMarketer.

\$2.02 billion on healthcare and pharma digital promotions in 2016, a 20% gain over 2015, accounting for 2.8% of the total digital ad spend among all U.S. industries.⁷

Drug manufacturers are already subject to FDA oversight with respect to advertisements regardless of whether they are televised, appear in print form, as well as internet and social media platforms. Accordingly, the pharmaceutical industry is well accustomed to providing appropriate disclosures on the risk and benefits of their products across different types of media.

The same standard should apply with respect to pricing information. Otherwise, pharmaceutical companies could use other mediums, such as dedicated websites, to share information with consumers that does not include a drug's list price. ACHP urges CMS to ensure drug manufacturers include the list price disclosure throughout an advertisement, especially for websites that display ads, which may have multiple pages of content.

Regarding content requirements, ACHP is concerned that drug manufacturers could minimize the list price in a way that consumers may easily overlook. Accordingly, we encourage the agency to include requirements that would prevent such gaming to occur. For instance, the regulation could require DTC ads to include the list price in a size and format that is equivalent to the largest size and format used to display the drug's name included in the advertisement.

Additionally, there is existing evidence suggesting that both information content and the format in which it is presented will impact comprehension among healthcare consumers. We encourage CMS to utilize evidence already collected or being generated by the FDA and other federal agencies with respect to consumer comprehension.

For instance, research with the format of over-the-counter (OTC) drug labels, the nutrition facts label, and other information formats demonstrates that information presented with section headings, graphics (such as bullets), and other design elements is more easily read than information presented in paragraph format.^{8 9 10}

These existing insights may help the agency in finalizing a format that will result in readability and comprehension amongst audiences exposed to DTC ads, particularly older consumers who are a primary target of such ads.

No exemption for drugs less than \$35

The proposed regulation fails to adequately explain the rationale for including such an exemption, other than the dollar amount approximates the average copayment for a preferred brand drug. We understand other thresholds were considered, which the agency is seeking comment on.

⁷ Ibid.

⁸ Levy, A.S., Fein, S.B. & Schucker, R.E. (1992). More effective nutrition label formats are not necessarily more preferred. *Journal of the American Dietetic Association*, 92(10), 1230-1234

⁹ Aikin, K.J. (1998). Consumer Comprehension and Preference for Variations in the Proposed Over-The-Counter Drug Labeling Format, Final Report; Vigilante, W.J. & Wogalter, M.S. (1997). The preferred order of over-the-counter (OTC) pharmaceutical label components. *Drug Information Journal*, 31, 973-988.

¹⁰ Lorch, R. & Lorch, E. (1995). Effects of organizational signals on text-processing strategies. *Journal of Educational Psychology*, 87(4), 537-544; Lorch, R. & Lorch, E. (1996). Effects of organizational signals on free recall of expository text. *Journal of Educational Psychology*, 88(1), 38- 48; Lorch, R., Lorch, E. & Inman, W. (1993). Effects of signaling topic structure on text recall. *Journal of Educational Psychology*, 85(2), 281-290.

ACHP does not believe any exemption from the proposed regulation is warranted based on list price alone. However, we do agree with the exemption for over-the-counter drugs covered under Medicaid.

First and foremost, regardless of the list price of a prescription drug and biologics, ACHP believes that healthcare consumers have a fundamental right to know what their prescription medications cost. That right should not be voided simply because a product has a low-list price.

It is also unlikely there will be DTC advertisements for prescription drugs with such a low-list price. As the proposed regulation notes itself, the cost thresholds considered by the agency are well below the lowest list price of advertised drugs.

Additionally, industry consultants have publicly acknowledged that DTC ads that once focused on treatments for nonfatal conditions have recently turned to more serious – more expensive – ailments to treat, such as cancer.¹¹

Finally, ACHP believes price transparency for all prescription drugs and biologic products can help facilitate a more competitive marketplace. The proposed regulation acknowledges this in permitting manufacturers to include an up-to-date list price for a competitor's product.

As noted previously, this provision if implemented correctly may help consumers make price comparisons and more informed choices about their treatment options. Manufacturers that have a low-list price and who choose to advertise their product may be well-positioned with consumers who are shopping for therapies that are more affordable. Accordingly, ACHP does not view the requirement as a burden for such manufacturers, as opposed to a strategic marketing advantage.

Enforcement

ACHP remains concerned about the ability of pharmaceutical manufacturers to be held accountable under the enforcement framework laid out under the proposed regulation. We urge CMS to reconsider the frequency in which it will alert the public to violations of the requirements laid out under the proposal. We also urge the agency to consider other means to disseminate information to consumers and other healthcare purchasers about manufacturers who fail to comply.

ACHP also urges the agency to examine what investigative powers might be applicable through the Department of Health and Human Service's Office of the Inspector General (OIG). A key priority of the OIG is to maximize value by improving the efficiency and effectiveness of programs operated by the Department. The OIG's work helps ensure the Department's programs do not overpay for products and services. Ensuring pharmaceutical manufacturers comply with the pricing transparency requirements may aid in those efforts by facilitating a more competitive marketplace based on price.

ACHP urges the Department to examine whether the OIG's audit and investigative authority as it relates to the price disclosure requirements in the proposed regulation may be another means to ensure compliance by pharmaceutical manufacturers.

¹¹ <https://www.nytimes.com/2017/12/24/business/media/prescription-drugs-advertising-tv.html>

State preemption

The proposed regulation notes that under principles of implied preemption, to the extent state law makes compliance with both state law and federal law impossible or would frustrate federal purposes and objectives, the state requirements would be preempted.

ACHP notes that there are a number of state laws or proposed laws to address prescription drug pricing. According to the latest information from the National Academy for State Health Policy, there are at least 27 states with legislation pending to enhance transparency on the cost of prescription drugs.¹²

Many of the transparency laws or bills pending in states are different in nature than the pricing requirements laid out in the proposed regulation. For instance, some state laws require disclosures around marketing budgets, as well as research and development expenditures by pharmaceutical manufacturers.¹³

ACHP urges CMS to include clarifying language that the intent of the regulation is not to occupy the entire field on the subject of pricing transparency or disclosure requirements for drug makers. The requirements laid out in the proposed regulation should be viewed as a regulatory floor and not a ceiling that may preclude efforts at the state level to improve transparency.

Alternative approaches

We urge CMS and the Department to continue its work towards improving price transparency for pharmaceuticals and biologicals. Specifically, ACHP urges the administration to work with Congress to help enact the [Fair Accountability and Innovative Research \(FAIR\) Drug Pricing Act](#), bipartisan legislation that would provide transparency into how prices are set. The FAIR Act would raise awareness about planned price hikes by drug manufacturers as well as advertising and research and development costs.

We also believe CMS' Drug Pricing Dashboard is a promising source of transparency. But the dashboard has a number of limitations. First, few consumers are aware of the existence of the dashboard and the information offered through the dashboards. Second, neither the dashboard nor the DTC advertising transparency proposal if finalized will make it easy for individuals to compare the cost of therapeutic alternatives.

We recommend that CMS explore ways to make the dashboard more useful and accessible to consumers. In addition, CMS should consider adding the WAC to the dashboard to better connect the disparate price information that consumers would be exposed to.

Finally, we were encouraged to see provisions contained in the proposed regulation, Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses, which would provide cost and coverage information at the point of prescribing. ACHP encourages the administration to examine additional ways to extend pricing transparency to prescribers.

¹² <https://nashp.org/state-legislative-action-on-pharmaceutical-prices/>

¹³ Ibid.

Conclusion

Thank you for consideration of ACHP's recommendations. We welcome the administration's continued engagement on this issue and look forward to working together to enact real and long-lasting change on behalf of American patients. Please contact me at cconnolly@achp.org if you have questions or require additional information.

Sincerely,

Ceci Connolly



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Alliance of Community Health Plans (ACHP) and its members improve the health of the communities we serve and actively lead the transformation of health care to promote high quality, affordable care and superior consumer experience.