

November 30, 2018

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington DC, 20201

RE: CMS-4187-P

Dear Ms. Verma:

The Medicare Payment Advisory Commission (MedPAC) welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) notice of proposed rulemaking entitled “Medicare and Medicaid programs: Regulation to require drug pricing transparency,” published in the *Federal Register*, vol. 83, no. 202, pages 52789 to 52799. We appreciate your staff’s work on the notice, particularly considering the competing demands on the agency.

This proposed rule would require direct-to-consumer (DTC) television advertisements for prescription drugs and biological products for which reimbursement is available through Medicare or Medicaid to include the wholesale acquisition cost (WAC) of that drug or biological. Drugs with a WAC of \$35 or less for a 30-day supply would be exempt.

The Commission supports several of CMS’s broad objectives laid out in the proposed rule. One of CMS’s objectives is to encourage more efficient use of resources within the Medicare (and Medicaid) program(s). Obtaining good value for Medicare’s program expenditures is a central tenet of the Commission’s work on Medicare payment policy. We also share CMS’s goal of making available information that can help beneficiaries evaluate options for medical care. For this reason, in 2009, the Commission recommended that the Congress require manufacturers and distributors of drugs, biological products, medical devices, and supplies to report financial relationships with prescribers and other organizations to the Secretary, and for the Secretary to make that information available on a public website.¹ The Congress subsequently adopted part of this recommendation, which led to CMS’s Open Payments disclosure program.²

The Commission further supports CMS’s objective of constraining growth in prices and spending for prescription drugs. As the proposed rule points out, the cost of drugs and biological products

¹ Medicare Payment Advisory Commission. 2009. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

² <https://www.cms.gov/openpayments>.

has grown dramatically over the past decade, and growth in spending on drugs is projected to continue to outpace growth in overall health spending.³ Over the past several years, the Commission has recommended major changes to payment systems for provider-administered drugs within Medicare Part B (2017) and for outpatient drugs delivered by private plans in Part D (2016).⁴ We believe both sets of recommendations would improve Medicare payment incentives while using market competition to constrain growth in drug prices.

Although the Commission has not deliberated on the specific policy outlined in the proposed rule, we support the principle of raising beneficiary awareness of the full price of their treatment options. Insurance coverage, such as through Medicare Part B and Part D, often masks the full cost of prescription drugs.⁵ But list prices are relevant to many patients for understanding how much cost sharing they will face. In Part D, some enrollees pay the full list price of medicines during a deductible phase or a percentage coinsurance for specialty-tier drugs or those on nonpreferred-drug tiers. In Part B, beneficiaries who have no supplemental insurance must pay 20 percent of the average sales price (ASP)-based payment for the drugs. Including WAC prices in advertisements thus could help patients make more informed decisions about treatment. Given the growing importance of DTC advertisements in other media forms (such as internet platforms, social media, podcasts, radio, and print), the agency may want to consider applying a price disclosure requirement more broadly. Arguably, greater transparency about drugs' list prices could lead manufacturers to exhibit more restraint in setting and increasing prices or to reduce their purchases of DTC advertisements, including television advertisement.⁶

³ G. Cuckler, A. Sisko, J. Poisal, et al. 2018. National health expenditure projections, 2017–26: Despite uncertainty, fundamentals primarily drive spending growth. *Health Affairs* 37, no. 3 (March): 482–492.

⁴ Medicare Payment Advisory Commission. 2017. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC. Medicare Payment Advisory Commission. 2016. *Report to the Congress: Medicare and the health care delivery system Medicare*. Washington, DC: MedPAC.

⁵ The same point typically holds true for other types of health care such as physician services and hospital stays.

⁶ We do not comment here on whether fewer DTC ads would be better or worse for beneficiaries. However, a number of studies have found a positive relationship between DTC advertising and spending for prescription drugs. For example, a 2013 study found that the implementation of Part D led to a 14 percent to 19 percent increase in pharmaceutical advertising expenditures, particularly in the least competitive drug classes, and that the advertising significantly boosted drug spending among both the elderly and non-elderly. See Lakdawalla, D., N. Sood, and Q. Gu. 2013. Pharmaceutical advertising and Medicare Part D. *Journal of Health Economics* 32, no. 6 (December): 1356–1367. Another study found that, around the start of Medicare Part D, use of prescription drugs was highly responsive to DTC exposure, with 70 percent of the higher use stemming from expanded take up and 30 percent from increased adherence among existing patients. See Alpert, A., D. Lakdawalla, and N. Sood. 2015. *Prescription drug advertising and drug utilization: The role of Medicare Part D*. National Bureau of Economic Research working paper #21714. Cambridge, MA: NBER. <http://www.nber.org/papers/w21714>. The aim of increased medication adherence is to improve health outcomes, so higher adherence may be beneficial. However, adherence was lower among people who initiated treatment compared with those already using the medications. According to the lead author, “This is a concern if advertising is capturing people for whom treatment is marginally less appropriate or for people who are simply less attached to treatment. This is because initiating a treatment without complying with it will lead to increased drug spending without very many gains to health.” See Alpert, A. 2017. Cause and effect: Do prescription drug ads really work? *Knowledge@Wharton*, January 4. <http://knowledge.wharton.upenn.edu/article/prescription-drug-ads/>.

The remainder of our comments offer a few ideas for CMS to consider if the agency moves forward with this proposal. We focus on the following provisions:

- Use of WAC as an amount that best reflects “list price” for purposes of transparency
- Thirty-day supply and typical course of treatment as appropriate metrics for gauging costs
- Requiring drug pricing transparency as a condition of payment in Medicare and Medicaid
- Alternative approaches for supporting price transparency and informed decision making

Use of WAC as an amount that best reflects “list price” for purposes of transparency

The proposed rule would require manufacturers to disclose in DTC advertising the WAC, or “list price,” of a prescription drug or biological product. The agency seeks comment on whether WAC is the amount that best reflects the list price for the purposes of providing greater price transparency and encouraging informed decision making by consumers.

Comment

The WAC is a benchmark price set by a manufacturer, representing its list price to wholesalers or direct purchasers. Although the WAC does not include prompt pay or other discounts, rebates, or price concessions, there are reasons to believe that it would be a reasonable choice as a list price for reporting in DTC advertising. First, the WAC is a metric that is available across all types of products, sold across different supply channels. Second, it provides a general sense of the order of magnitude of the price for all brand-name drugs and biological products.

For single-source drugs (i.e., brand-name drugs still under patent protection), the WAC often approximates the prices that retail pharmacies pay to wholesalers.⁷ Further, studies show that payments to pharmacies for brand-name drugs generally align closely with the WAC.⁸ Because DTC advertising is primarily, if not exclusively, used to market single-source drugs, the WAC could contribute to greater price transparency and provide price information for brand-name drugs supplied through the retail pharmacies that is relevant to consumers. For example, the WAC would be relevant for estimating consumers’ financial liability at pharmacies for brand-name drugs that are subject to a percentage coinsurance, or when consumers must pay the full retail price.

Thirty-day supply and typical course of treatment as appropriate metrics for gauging cost

The rule proposes that DTC advertisements include the current list price for a typical 30-day regimen or for a typical course of treatment, whichever is most appropriate. CMS seeks comment

⁷ Fein, A. 2017. *The 2017 economic report on U.S. pharmacies and pharmacy benefit managers*. Philadelphia, PA: Pembroke Consulting and Drug Channels Institute. Congressional Budget Office. 2007. *Prescription drug pricing in the private sector*. Washington, DC: CBO.

⁸ Bruen, B. and K. Young. 2014. *Paying for prescribed drugs in Medicaid: Current policy and upcoming changes*. Issue brief. Washington, DC: Kaiser Family Foundation. <https://www.medicare.gov/medicaid/prescription-drugs/downloads/retail-price-survey/nadac-equiv-metrics.pdf>.

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

Comment

If list prices are required in advertisements, it would be important that the list price be conveyed using metrics that are meaningful to consumers and that are as consistent as possible across advertisements for competing products. The metrics that the proposed rule specifies—30-day supply or typical course of treatment—seem reasonable for most products. To promote consistent reporting across products, CMS should provide additional guidance about products that do not fit well in these metrics.

For maintenance drugs used to treat chronic conditions that are taken or administered each month, the metric of list price for a 30-day supply (or one-month period) would be meaningful to consumers. However, with respect to maintenance drugs for chronic conditions that are taken or administered with longer intervals between doses (e.g., every 8 or 12 weeks), CMS should provide additional guidance for how price reporting should be handled. For example, CMS could consider requiring that manufacturers report both the list price per dose and typical number of doses each year for these drugs with longer intervals between doses. Although this approach might mean that some manufacturers report their list prices using different metrics than others, each advertisement would include sufficient information to permit the consumer to calculate the list price per year of treatment.

For drugs that are part of a time-limited treatment regimen, the list price for the typical course of treatment would be meaningful to consumers. It is possible that some time-limited drugs may not fit well in this approach, and CMS could consider permitting manufacturers to report the list price in different terms, subject to CMS approval.⁹

As the proposed rule notes, the typical course of treatment may vary across indications for a drug. The rule's proposal to have manufacturers provide the list price for the typical course of treatment associated with the primary indication addressed in the advertisement seems reasonable. Even for a single indication, dosage amounts may vary by patient (e.g., some medication dosages are based on the patient's weight; some medications have a dosing range rather than a specific dose amount), so CMS may need to provide further guidance on how to handle such situations to promote consistency.

Requiring drug transparency as a condition of payment in Medicare and Medicaid

CMS proposes that the Secretary maintain a public list of drug and biological products that are in violation of the rule (i.e., whose manufacturers have not included WAC prices in their DTC advertisements). The agency expects that this list would be posted on the CMS web site and updated no less than annually, and the list would be the only HHS-specific mechanism for

⁹ For example, with supportive drugs that are provided as an adjunct to chemotherapy, the drugs may be provided as part of a variety of different chemotherapy regimens that have different numbers of cycles and lengths of therapy. In such situations, CMS could consider permitting the manufacturer to report the list price of the drug per cycle of chemotherapy, for example.

enforcing the proposed rule. The agency believes that the primary means of enforcement would come from self-policing among manufacturers. Under provisions related to unfair competition in the Lanham Act, biopharmaceutical manufacturers would sue competitors for false or misleading advertising that did not disclose WAC prices. Because Lanham Act cases typically involve “sophisticated parties doing business in the same sector,” CMS believes that “the likelihood of meritless lawsuits is acceptably low.” At the same time, CMS proposes that the rule would preempt any state-law-based claim that depended in whole or in part on any pricing statement required under the rule. The agency seeks comment on this enforcement approach and asks about other approaches to enforcing compliance, such as making reporting drug prices pursuant to the proposed rule a condition of payment, directly or indirectly, from Medicare and Medicaid.

Comment

It is unclear whether manufacturers would comply with the rule under enforcement mechanisms that are proposed. Risk of being listed on CMS’s web site would not, alone, appear to be sufficient. Self-policing among biopharmaceutical manufacturers might not occur. Under the Lanham Act, only competing manufacturers or other entities that could demonstrate competitive harm from the defendant’s advertising would have standing to challenge a manufacturer that omitted its drug’s WAC price in DTC advertisements. Consumers would not have legal standing to do so.¹⁰ Commercial harm may also be difficult to prove.¹¹ One legal analysis notes that, “omissions (e.g., omission of list price) can be actionable under the Lanham Act only to the extent the advertising contains affirmative statements that, while literally true, may be misleading to an appreciable percentage of the audience in the absence of the information that has been omitted.”¹²

CMS asks for comment on an alternative enforcement approach: making disclosure of the WAC in DTC advertisements a condition of payment. This approach would be an indirect one, since the Medicare program does not pay biopharmaceutical manufacturers directly. In both Part B and Part D, Medicare pays providers (such as physicians, hospital outpatient departments, and private plans) that, in turn, purchase drugs through a distribution chain (e.g., through group purchasing organizations, wholesalers, or pharmacies). Making compliance with the proposed rule a condition of payment would thus presumably mean that providers could not be paid for a drug they purchased if the manufacturer of the drug did not disclose the WAC in its DTC advertisements. This enforcement approach would thus put the provider in the position of having to ensure that, before purchasing a drug, the manufacturer was in compliance. Another enforcement approach would be to make compliance with the proposed rule a condition of Medicare and Medicaid coverage. This approach would likely be less burdensome for providers. A requirement for either condition of coverage or condition of indirect payment would be a much stronger enforcement mechanism than self-policing among manufacturers. Pursuing either of those stronger approaches would require a change in law. Notable precedents used in other programs include the Medicaid

¹⁰ Ropes & Gray. 2018. CMS issues proposed rule to require disclosure of list price in direct-to-consumer advertising for prescription drugs and biological products. October 23. www.ropesgray.com/en/newsroom/alerts/2018/10/CMS-Issues-Proposed-Rule-to-Require-Disclosure-of-List-Price?utm_source=Mondaq&utm_medium=syndication&utm_campaign=View-Original.

¹¹ Wilkerson, J. 2018. Brands might not be willing, able to enforce drug ad price disclosure. *Inside Health Politics*, October 16.

¹² Ropes & Gray, op cit.

best price program (condition of payment)¹³ and Part D's coverage-gap discount program (condition of coverage).¹⁴

Alternative approaches for supporting price transparency and informed decision making

CMS seeks comment on additional approaches to support price transparency and informed decision making by beneficiaries, either in addition to or in lieu of the price disclosure requirement for DTC advertising discussed above. Specifically, the agency mentions the following approaches: (1) an enhanced CMS drug pricing dashboard, (2) a new payment code for drug price counseling, and (3) intelligent plan selection or use of intelligent assignment.

Comment

The CMS Drug Spending Dashboards provide data on drug spending under Medicare Parts B and D and Medicaid. The agency seeks comment on whether including information such as list price, typical out-of-pocket cost, therapeutic alternatives, and pharmacoeconomic research on the dashboards could be helpful for consumers. While the dashboards provide historical trends in average spending and use as well as certain clinical information, inclusion of current pricing data, such as WAC and/or CMS's National Average Drug Acquisition Cost data, could further enhance the dashboards' usefulness to consumers, particularly for Part D drugs. Because the dashboards are based on historic Medicare data, they lack information on new drugs for a period of one to two years after launch. Since new drugs are sometimes the focus of DTC advertising, CMS should explore approaches to filling that gap. For example, CMS could consider updating the dashboard data more frequently or including additional pricing metrics that do not require historic Medicare data. Further, to improve the accessibility of information provided by the dashboards, CMS may want to consider making available pricing and other information, such as therapeutic alternatives, through an application software (app) that beneficiaries could use on their computers and mobile devices. The app could be designed to highlight specific drugs, for example, in response to the launch of a new DTC ad campaign.

CMS is also seeking comments on whether new payment codes for drug pricing counseling could support price transparency and informed decision making, either in addition to or in lieu of the measures proposed in the proposed rule. The agency does not describe how fee-for-service Medicare would either cover or pay for such a service (e.g., there is no discussion about the number of counseling sessions covered per beneficiary and the providers who would be eligible to bill for such services).

CMS should not create a new billing code to separately pay for drug pricing counseling. The current documentation guidelines for evaluation and management services are broad enough to include this activity: The 2017 CPT manual specifies that counseling, including a discussion about the risks and benefits of treatment options, is a component of evaluation and management services. Furthermore, according to recent focus groups convened by the Commission, discussions between a beneficiary and his/her clinician about the pricing of drugs (as well as other medical services)

¹³ 42 U.S.C. 1396r-8.

¹⁴ 42 U.S. Code Section 1395w-153 and 1395w-114a.

already occur. Consequently, creating a new billing code for drug pricing counseling could be viewed as unbundling packaged services and duplicating payment. With unbundling of services, there would be concern about the financial incentives for volume growth and the potential for large program expenditures.

Under intelligent plan selection (or intelligent assignment), CMS would provide information to beneficiaries about lower-cost plan options or lower-cost drugs based on their most recent drug utilization to facilitate plan selections that minimize costs to them and/or to Medicare. In 2008, the Commission considered a similar approach, beneficiary-centered assignment, as a potential alternative to the random assignment CMS currently uses for automatically assigning certain LIS beneficiaries to lower-premium plans in Part D. However, the Commission ultimately did not pursue this approach. Specifically, a number of commissioners at the time discussed the potential of such a policy to introduce adverse selection and market instability, which could increase overall program costs. Another concern was that intelligent assignment would lack clinical nuance about each specific patient's circumstances. Given these concerns, we do not support the use of intelligent plan selection. However, we support providing information to beneficiaries on lower-cost drug alternatives. Beneficiaries can already obtain this information from Medicare's plan finder tool at www.medicare.gov, but making this information more accessible, such as through an app, may allow more beneficiaries to make informed decisions about their medications.

Conclusion

The Commission values the ongoing cooperation and collaboration between CMS and our staff on technical policy issues. We look forward to continuing this productive relationship. If you have any questions, or require clarification of our comments, please feel free to contact James E. Mathews, the Commission's Executive Director, at 202-220-3700.

Sincerely,

A handwritten signature in black ink that reads "Francis J. Crosson M.D." in a cursive script.

Francis J. Crosson, M.D.
Chairman