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December 17, 2018

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 electronically via www.regulations.gov

RE: Medicare and Medicaid Programs: Regulation to Require Drug Pricing Transparency—AHIP Comments

Dear Administrator Verma:

On behalf of America's Health Insurance Plans (AHIP), we appreciate the opportunity to offer comments on the Centers for Medicare and Medicaid Services (CMS) proposed rule that would require direct-to-consumer (DTC) prescription drug television ads to include information about the list price of the drug or biological product.

Drug prices are out of control, driving the costs of coverage and care higher for all Americans. AHIP strongly believes that setting drug prices in an open and honest way is essential to better affordability and choice for patients and consumers. We commend CMS for taking this bold step, and we strongly support this approach that requires drug makers to disclose their prices as they commercially market prescription drugs to consumers.

AHIP is the national trade association whose members provide coverage for health care and related services to millions of Americans every day. Through these offerings, we improve and protect the health and financial security of consumers, families, businesses, communities and the nation. We are committed to market-based solutions and public-private partnerships that improve affordability, value, access, and well-being for consumers.

Drug makers create life-saving treatments and breakthrough cures. But too many Americans must choose between paying their bills and paying for their medications. As branded drug prices continue to rise, they drive up the costs of coverage and out-of-pocket costs for consumers – and create a greater burden for taxpayers. Without bold action, access to affordable medications will be increasingly out-of-reach for millions of Americans—especially for patients with chronic health care conditions.

The entire pricing process is driven by the original list price of a branded drug—which is determined solely by the drug maker. That is why we believe that openly disclosing those list prices to consumers is an important step. Our comments:

- **Strongly support the disclosure of list prices for brand name drugs and biologics in direct-to-consumer drug advertisements.** This will empower patients to have more informed conversations with their doctors about the best approach to improve their health and manage their medical conditions.

- **Encourage CMS to consider making compliance with this rule a condition of payment or participation in government health programs (Medicare and Medicaid).**

- **Recommend CMS support additional legislative and regulatory actions that would encourage more open and honest price setting for prescription drugs.**

Out-of-Control Drug Prices Affect Every American

Spending on prescription drugs continues to grow at a rapid and unsustainable rate—significantly outpacing overall health care costs growth and general inflation. In 2015, U.S. health care spending on prescription drugs totaled $457 billion and represented 16.7 percent of total personal health spending.[1] According to the Centers for Medicare and Medicaid Services (CMS) data, "prescription drug growth is anticipated to accelerate from 5.7 percent in 2017 to an average of 7.0 percent from 2018-2019".[2] Moreover, according to official estimates from CMS, prescription drug spending is projected to grow an average of 6.3 percent per year from 2016 to 2025[3]—with total prescription drug spending reaching $597.1 billion by 2025.[4]

Recent projections from the CMS' Office of the Actuary finds that "faster drug price growth also contributes to a projected acceleration of prescription drug spending growth" and that such price growth is "largely influenced by trends in more costly specialty drugs, which are expected to represent a larger share of prescription drug spending over the projection period[5] [2017-2026]."

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[1] HHS-ASPE Report—Observations on Trends in Prescription Drug Spending. March 8, 2016. https://aspe.hhs.gov/pdf-report/observations-trends-prescription-drug-spending

[2] National Health Expenditure Projections, 2016-2025; Price Increases, Aging Push Sector to 20 Percent of Economy. Sean P. Keehan, et al. *Health Affairs;* March 2017. https://www.healthaffairs.org/doi/10.1377/hlthaff.2016.1627

[3] National Health Expenditures Projections 2016-2025 *Forecast Summary https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/proj2016.pdf*

[4] National Health Expenditure Projections, 2016-2025; Price Increases, Aging Push Sector to 20 Percent of Economy. Sean P. Keehan, et al. *Health Affairs;* March 2017. https://www.healthaffairs.org/doi/10.1377/hlthaff.2016.1627

[5] National Health Expenditure Projections, 2017-2026: Despite Uncertainty, Fundamentals Primarily Drive Spending Growth. https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2017.1655

In 2016, total US expenditures on pharmaceutical drugs were $480 billion. Two-thirds of this total ($323 billion) was captured by drug manufacturers in the form of net revenues.[6]

Every American feels the impact of these prices:

- About 23 cents of every dollar spent on health insurance premiums goes to pay for prescription drugs – more than any other category.[7]

- One in 10 Americans skipped medical care or prescription medicine in 2016 because of costs.[8]

- Medicare spending on prescription drugs (both Part B and Part D) totaled $174 billion in 2016. Between 2006 and 2015, Part D brand name drug prices rose by an average of 66 percent cumulatively[9]. Since 2009, Medicare Part B drug spending grew at an average rate of about 9 percent per year.[10]

- Medicaid spending on prescription drug totaled $64 billion in 2016, with spending increases of 25 percent and 13 percent the last several years.[11]

- For employer-provided coverage, prescription drug spending increases have consumed a growing share of employer insurance benefits. In 2015, prescription drug spending represented 21 percent of employer provided insurance benefits – nearly as much as employers spent on inpatient hospital care.[12] Employer spending on specialty drugs and biologics have increased at double-digit rates in recent years—increasing 17.7 percent in 2018 and projected to increase by 14.3 percent in 2019.[13]

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[6] Spending on Prescription Drugs in the United States—Where Does All the Money Go? Nancy L. Yu, Preston Atteberry, Peter B. Back. *Health Affairs;* July 31, 2018. https://www.healthaffairs.org/do/10.1377/hblog20180726.670593/full/?utm_source=newsletter&utm_medium=email&utm_campaign=newsletter_axiosvitals&stream=top-stories&

[7] AHIP—Where Does Your Health Care Dollar Go? May 22, 2018. https://www.ahip.org/health-care-dollar/

[8] Board of Governors of the Federal Reserve System—Report on the Economic Well-Being of U.S. Households in 2016. May 2017. https://www.federalreserve.gov/publications/files/2016-report-economic-well-being-us-households-201705.pdf

[9] MedPAC Report to Congress: Medicare Payment Policy. March 2018.

[10] MedPAC Report to Congress: Medicare and the Health Care Delivery System. June 2017.

[11] CMS National Health Expenditure Data, 2016.

[12] Kaiser Family Foundation: Drugs count for a bigger share of health spending than many think. December 20, 2017. https://www.healthsystemtracker.org/chart-collection/recent-forecasted-trends-prescription-drug-spending/?_sf_s=recent+trends#item-americans-favor-action-keep-drug-prices-down_2017

[13] Segal Consulting—Increases in Medical and Rx Cost Trends Projected to be Lower in 2019 https://www.segalco.com/about-us/news-events/news/increases-in-medical-and-rx-cost-trends-projected-to-be-lower-for-2019/#Multiemployer

Simply put, prescription drug prices are out of control, and this is a direct consequence of pharmaceutical companies taking advantage of a broken market. The lack of competition, transparency, and accountability in the prescription drug market has created extended, price-dictating monopolies that exist nowhere else in the U.S. economy. The result is everyone pays more—from patients, businesses and taxpayers to hospitals, doctors, and pharmacies.

More Information Empowers Consumers in Their Health Care Decisions

That is why the CMS proposal to require greater in the open disclosure of prescription drug prices to consumers is necessary. Consumers deserve to have all the relevant information they need to make informed health care decisions. Yet, consumers often do not have access to meaningful information about cost and quality to make decisions that are right for them. This proposal will finally put consumers in the driver's seat and empower them to work with their doctors to explore all care options for better health and well-being.

Openly disclosing drug prices will also bring additional public attention to drug price increases, which will discourage drug makers from raising their prices year after year – often multiple times a year – without justification. Government leaders, regulators, consumers, and insurance providers deserve to be part of a conversation about how prices are set and what causes them to go up. By understanding the market dynamics of why prices are going up, we can work together to mitigate those effects.

Disclosing list prices in direct-to-consumer advertising makes sense, because it is a tactic that drug makers use to increase demand and sales for their prescription drugs. Before the 1990s—when direct-to-consumer advertising became widespread—doctors drove conversations with patients about whether a drug was needed to treat a health condition. Direct-to-consumer advertising has reversed this dynamic.

Spending by drug manufacturers on direct-to-consumer ads has increased by 62 percent since 2012 and exceeded $6 billion in 2017.[14] Pharmaceuticals ads directed at the general public, which were largely not present 30 years ago, now represent one of the largest categories of advertising on television. This has resulted in a significant increase in utilization of brand name drugs, including both new initiations of treatment and improved adherence.[15]

While these ads can make patients aware of new treatment options, the lack of pricing information means patients are missing critical information that is necessary for making informed choices about their treatment options. Increasing access to pricing information can help patients minimize their out-of-pocket costs, enabling them to compare different treatment options

[14] USA Today/Kaiser Health News—Prescription Drug Costs are Up; So are TV Ads Promoting Them. March 16, 2017. https://www.usatoday.com/story/money/2017/03/16/prescription-drug-costs-up-tv-ads/99203878/

[15] Cause and Effect—Do Prescription Drug Ads Really Work? Wharton/University of Pennsylvania, January 4, 2017. http://knowledge.wharton.upenn.edu/article/prescription-drug-ads/

and help them identify lower cost, but equally effective treatment options, such as generic drugs or biosimilars.

CMS' proposal would require manufacturers to disclose list prices in most DTC drug ads—using a drug's wholesale acquisition cost (WAC) for a 30-day regimen or a typical course of treatment. We believe disclosure of a drug's list price or WAC—as proposed by CMS—is appropriate given the role that list price plays in negotiations between payers and manufacturers and can serve as a reference or benchmark for consumers in making cost comparisons for different drugs and treatment options. The cost threshold for required drug price disclosure—$35 for a 30-day regimen—is reasonable and would apply to the most brand name drugs that are currently advertised to consumers.

While we agree that the use of WAC is an appropriate benchmark for prescription drug pricing disclosure in DTC ads, the price an individual consumer pays will vary based on a number of factors such as the specific of insurance coverage and plan design. As such, we recommend CMS make appropriate explanations that an individual's out-of-pocket cost may be different from the list price—as contemplated in the proposed rule.

Finally, we also request that CMS clarify which National Drug Code (NDC) would need to be used in determining the WAC or "list price" in a DTC ad. As many medications have multiple NDCs and WAC list prices may not always correspond directly with NDC codes, we recommend that CMS examine and address this issue as price transparency regulations are finalized.

In addition to supporting drug price transparency in DTC television ads, we also recommend CMS broaden and strengthen the regulation to apply such transparency requirements to all drug companies' DTC ads—including those in newspapers, print publications and on the web. CMS should also consider extending drug pricing transparency—including disclosure of a drug's list price—to include any drug manufacturers' marketing or detailing materials distributed to physicians and other prescribers.

Separate from the CMS proposed rule on prescription drug price transparency, we also support efforts by the FDA—including new draft guidance—to ensure that direct-to-consumer (DTC) promotional materials containing quantitative efficacy or risk information are accurate and understandable. The new FDA guidance—which provides policy recommendations on how manufacturers and others present information in DTC promotional materials—can help ensure that consumes receive balanced and accurate information about a drug's efficacy and risks.

CMS Should Consider Whether Compliance With the Rule Should be a Condition of Payment

The proposed regulation is being promulgated under CMS' broad authority to operate and administer the Medicare and Medicaid programs in an efficient manner and CMS has concluded that "promoting pricing transparency, and thus efficient markets, for drugs funded through those programs falls within the scope of that mandate."

For enforcement purposes, the proposed rule contemplates that the Secretary of Health and Human Services (HHS) would maintain a public list that would include the drugs and biologics identified to be in violation of the regulation. The list would be published and updated on an annually, but no other HHS-specific enforcement mechanism is proposed in the regulation. Rather, CMS anticipates that the primary enforcement mechanism will be threat of private actions under the Latham Act.

CMS is also seeking comment "as to whether compliance with this rule should be a condition of payment, directly or indirectly" from the Medicare and Medicaid programs. AHIP strongly encourages CMS to explore this type of enforcement authority in implementing the drug pricing transparency regulation.

CMS develops Conditions of Participation (CoPs) and Conditions for Coverage (CfCs) that health care organizations must meet in order to begin and continue participating in the Medicare and Medicaid programs. These health and safety standards are the foundation for improving quality and protecting the health and safety of beneficiaries and area widely used tool in promulgating regulations under federal health care programs. In the area of prescription drugs, CMS has promulgated implementing regulations that rely on a similar enforcement mechanism.

- The Medicaid Drug Rebate Program[16] [17] requires drug manufacturers to enter into a national drug rebate agreement with the Secretary of HHS in exchange for Medicaid coverage of most of the manufacturers' drugs. This requirement assures that the Medicaid program benefits from lower prescription drug costs through statutorily required drug rebates that are paid by drug manufacturers to offset the cost for most outpatient prescription drugs used by beneficiaries under the Medicaid program. Drug manufacturers are also required to enter into agreement to make similar pricing discounts available to 340B entities and the VA (under the Federal Supply Schedule).

- The Medicare Coverage Gap Discount Program—which lowers Medicare Part D beneficiaries out-of-pocket costs in the coverage gap—requires drug manufacturers to enter into agreements with HHS to provide statutorily required discounts for brand drugs in the coverage gap (70 percent discounts). Manufacturers' participation in these

[16] Medicaid Drug Rebate Program. https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html

[17] 1927(a) requires a rebate agreement as a condition of coverage for a drug under Medicaid while 1927(b) details required terms for rebate agreements. CMS has broad authority to implement requirements under provisions of the Medicaid statute for the efficient administration of the program. We encourage CMS to explore interpreting these statutory provisions broadly to include adding the DTC provisions as a means of limiting Medicaid drug costs.

agreements is a condition for Medicare Part D coverage for brand name prescription drugs.[18][19]

To meet CMS goals of efficient administration of the Medicare and Medicaid programs, we recommend that CMS explore whether a condition of payment standard would improve enforcement of this regulation and further advance CMS goals of lowering drug prices and patients' out-of-pocket costs.

Additional Policy Recommendations to Promote Drug Price Transparency to Lower Costs

To further support CMS' goals of greater transparency and lower drug prices, we also offer the following additional legislative and regulatory policy options for CMS consideration:

- **Require that drug manufacturers disclose information regarding the intended launch price, use, manufacturing costs, and direct and indirect R&D costs.** Bipartisan legislation has been introduced in Congress—the Fair Accountability and Innovative Research (FAIR) Drug Pricing Act—that would require drug manufacturers to submit a transparency and justification report to HHS before they increase the price for certain drugs that cost at least $100 by more than 10 percent in one year or 25 percent over 3 years. An alterative approach could require drug manufacturers to publish list prices and relevant information about their launch prices (or price increases) as part of the FDA approval process.

- **Support state efforts that seek to promote greater transparency through enhanced reporting and disclosure requirements for drug manufacturers.** A number of states—CA, CT, ME, MD, NV, OR, and VT—have passed laws requiring drug manufacturers to report the reasons behind drug price increases—through annual reporting and disclosure requirements. Common data elements in state transparency laws include: data about brand name and generic drug prices; drug prices and percentage increases over time; production costs, including manufacturing and marketing costs; sales revenue and profits; and amount spent on patient assistance programs.

- **Support efforts to limit third-party payment schemes that raise costs.** Public policy efforts should examine and address the impact of drug coupons and copay card programs—and related charitable foundations—on overall pharmaceutical cost trends. Stricter federal oversight can ensure that existing protections prohibiting their use in

[18] Medicare Coverage Gap Discount Program Agreement https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/downloads/ManuAgreement.pdf

[19] Section 1860D-14A of the Social Security Act requires drug manufacturers to comply with "requirements imposed by the Secretary…for the purposes of Administering the program…" We encourage CMS to examine whether this provides authority for CMS to include the DTC requirement in a coverage gap discount program contract. Should CMS add this requirement and a drug manufacturer that fails to comply with DTC price disclosure rules, 1860D-43 provides that the manufacturer's drug is not eligible for coverage under Medicare Part D.

federal programs are sufficient. Moreover, the use of drug co-pay coupons for brand name drugs in the exchange marketplace should be barred if there is a less expensive, equally effective alternative—similar to prohibitions in place for Medicare, Medicaid and the VA health system. We also urge CMS to increase scrutiny and oversight over third-party payments of premiums and cost-sharing for prescriptions—given their role in increasing health care costs for the health care system.

Health insurance providers stand for lower drug prices for Americans, because every person deserves access to the medications they need at a price they can afford. By working together, and with the right solutions, we can achieve both innovation and affordability in the U.S. prescription drug market. We look forward to continuing to collaborate with CMS as implementation of this rule moves forward.

Sincerely,

Matthew Eyles

Matthew Eyles
President and CEO