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Advancing Health in America

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Statement of the
American Hospital Association
to the
Finance Committee
of the
United States Senate

"Prescription Drug Price Inflation: An Urgent Need to Lower Drug Prices in Medicare"

March 16, 2022

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) writes to express support for addressing the high cost of drugs in Medicare.

The AHA is deeply committed to the availability of high-quality, efficient health care for all Americans. Hospitals and health systems, and the clinicians who work in them, rely on lifesaving drug therapies to care for their patients. In addition, researchers in U.S. academic medical centers generate much of the evidence used to develop new drugs. However, an unaffordable drug is not a lifesaving drug.

The AHA continues to work with its members to document the challenges hospitals and health systems face with high drug prices and develop policy solutions to protect access to critical therapies while encouraging and supporting much-needed innovation. We encourage Congress to consider policy recommendations in the following areas.

INCREASE COMPETITION AND INNOVATION

Competition for prescription drugs generally results in increased options for lower cost therapies, particularly through the introduction of one or more generic competitors. We encourage Congress to implement policies that would increase the introduction of generic alternatives and discourage anti-competitive tactics while maintaining incentives for the development of innovative new therapies.

- **Deny patents for "evergreened" products.** Some drug manufacturers attempt to minimize or eliminate competition through product "evergreening." A manufacturer attempts to "evergreen" a product when it applies for patent and market exclusivity protections for a "new" product that is essentially the same as the original product, such as extended release formulations or combination therapies that simply combine two existing drugs into one pill. What generally happens is that, while the older version of the drug is no longer patent-protected and, therefore, generic alternatives may be offered, drug manufacturers promote the newer version as the "latest and greatest." Without important information on the comparative value of the newer drug, many providers and consumers switch to the brand-only "evergreened" product after intense marketing by the manufacturer that suggests that the newer version is superior. Patents and market exclusivity rights for products that are simply modifications of existing products should be denied unless the new product offers significant improvements in clinical effectiveness, cost savings, access or safety.

- **Limit orphan drug incentives to true orphan drugs**. Drug manufacturers receive a number of incentives to develop drugs for rare diseases. These incentives, which include waived FDA fees, tax credits and longer market exclusivity periods, are intended to spur innovation of therapies for which the manufacturer may otherwise not recoup their investment due to low volume. These incentives have contributed to the development of innovative, life-saving drugs where no therapies previously existed. However, in some instances, manufacturers have received orphan drug status for drugs that they subsequently marketed for other, non-rare indications. In these instances, manufacturers are receiving the incentives for drugs that are broadly used. For example, Humira (adalimumab), Procrit (epoetin alfa) and Prolia (denosumab) all are approved for orphan drug status; however, since receiving the designation, the drugs also have been marketed for a number of other, non-rare indications. Further, each of these drugs were among the top 10 highest-spend drugs for hospitals and health systems, and each had substantial price increases of at least 15% from 2015-2017.[1]

  Congress should require FDA to collect information on other intended indications for a drug when evaluating eligibility for orphan drug status. FDA also should be required to do a post-market review at regular intervals throughout the market exclusivity period to determine whether the drug should retain its status as an orphan drug. In instances where the manufacturer is promoting the drug for other indications that do not meet the orphan drug status requirements, FDA should levy penalties, such as requiring that the manufacturer pay the government the value of the tax breaks and waived fees and potentially reducing the market exclusivity period.

INCREASE DRUG PRICING TRANSPARENCY

Payers, providers and the public have little information about how drugs are priced. This gap in information challenges payers' abilities to make decisions regarding coverage and pricing of

[1] AHA/FAH Drug Survey 2019.

drugs, and often results in mid-year cost increases that providers are unprepared to manage. Policies should be implemented to provide greater parity between drug manufacturers and other sectors of the health care system, including hospitals, which already disclose a considerable amount of information on pricing, input costs and utilization.

Increased disclosure requirements related to drug pricing, research and development should be included at the time of application for drug approval. There is very little evidence of what it actually costs to develop a new drug and how those costs factor into the pricing of a drug. Other components of the health care system are held to a much higher transparency standard. For example, hospitals provide detailed data to the Centers for Medicare & Medicaid Services (CMS) via the annual Medicare cost report, which includes information on facility characteristics, utilization, costs and charges, and financial data. Given the significant taxpayer investment in drugs – both through funded research and purchasing through public programs like Medicare and Medicaid – there should be greater transparency parity between drug manufacturers and other health care providers.

Drug manufacturers should be required to submit as part of the drug approval process information on anticipated product pricing for both a single unit and a course of treatment; anticipated public spending on the product (e.g., from government purchasers including Medicare, Medicaid and TRICARE, among others); and information on how the product was priced, including anticipated portion of the product price that will contribute to current or future marketing and research and development costs. In addition, drug manufacturers should be required to provide information on the research that contributed to the development of the drug and specify all entities that conducted research that contributed to the development of the drug, the amount spent on that research and the funding source.

Increased transparency into drug pricing could be used to hold drug manufacturers accountable for fairly pricing products, help calculate the value of a drug, and support future policymaking.

IMPROVE ACCESS THROUGH INFLATION-BASED REBATES FOR MEDICARE DRUGS

The Medicaid program consistently achieves better pricing on drugs than the Medicare program. The primary driver behind the lower net unit costs are mandated, additional rebates that kick in when the average manufacturer price (AMP) for a drug increases faster than inflation. A similar inflation cap should be implemented on the price of drugs under the Medicare program. Under Medicare Part B, such a cap could be operationalized through a manufacturer rebate to Medicare when the average sales price (ASP) for a drug increases faster than a specified inflation benchmark. A similar cap could be placed on increases in the prices of Part D drugs.

This policy would protect the program and beneficiaries from dramatic increases in the Medicare payment rate for drugs, notable past increases included examples like 533% (Miacalcin, used for treating bone disease), 638% (Neostigmine, used in anesthesia) and 1,261% (Vasopressin, used to treat diabetes and bleeding in a critical care environment). This policy also could potentially generate savings for drugs with price growth above the inflation

benchmark. According to a 2019 report, the Congressional Budget Office estimated that an inflationary rebate requirement would reduce direct spending by about $35 billion over 10 years.[2]

Better Align Incentives by Testing Changes to the Federally-Funded Part D Reinsurance Program

Under the Part D prescription drug program, the federal government covers 80% of the costs for enrollees who cross the out-of-pocket threshold. Insurers and beneficiaries share the responsibility for the remaining 20%, at 15% and 5%, respectively. These reinsurance payments are substantial: in 2013, the federal government's portion totaled nearly $20 billion for approximately 2 million Medicare beneficiaries.[3] This program shields Part D plan sponsors from high costs and may create disincentives for plan sponsors to aggressively negotiate drug prices with manufacturers and manage enrollees' care.

Congress should require CMS to design a pilot project to test a new Part D payment model that either reduces or eliminates reinsurance payments while making appropriate adjustments to the direct subsidy rate. While CMMI has recently taken action in an attempt to modernize the Part D program through rewards and incentives, medication management programs and changes to the Low-Income Subsidy, congressional action would require CMS to test whether shifting more of the financial risk to insurers leads to appropriate reductions in program spending due to stronger negotiations with drug manufacturers or improved care management. This alternative is consistent with a Medicare Payment Advisory Commission recommendation on improvements to the Part D program.

Protect the 340B Drug Pricing Program

The 340B program is a critical program that helps eligible providers to care for the patients and communities they serve. The program requires pharmaceutical companies participating in Medicaid to sell certain outpatient drugs at discounted prices to health care organizations that care for high numbers of uninsured and low-income patients or care for specific populations, such as children or patients with cancer or AIDS. 340B hospitals use the savings they receive on the discounted drugs to stretch scarce federal resources and provide more affordable and effective care, just as Congress intended. In fact, 340B hospitals reinvest their 340B savings in programs that are critical for the communities and patients they serve, which can include enhancing patient services and access to care, as well as providing free or reduced priced prescription drugs to vulnerable patient populations. In 2018 alone, 340B hospitals provided $68 billion in community benefits. Despite the 340B program's proven track record for 30 years, pharmaceutical manufacturers have repeatedly attempted to scale back or significantly reduce its benefits to hospitals and the patients they serve.

Since July 2020, several of the largest drug manufacturers have engaged in unprecedented and unlawful actions to limit the scope of the 340B program by denying 340B pricing through

[2] https://www.cbo.gov/system/files/2019-12/hr3_complete.pdf
[3] MedPAC, "Chapter 6: Sharing risk in Medicare Part D," June 2015.

contract pharmacies and demanding superfluous, detailed reporting of 340B drug claims distributed through hospitals' contract pharmacies. These drug companies have knowingly violated the statute and ignored calls by both the Biden and Trump Administrations to end these harmful actions.

The Health Resources and Services Administration (HRSA) has long authorized 340B covered entities to contract with community pharmacies to dispense drugs to eligible patients in order to expand the reach of the program and ensure access to prescribed medications for their patients. The use of outside pharmacies is especially important for hospitals that are located in and/or serve rural communities, as many of these hospitals do not operate in-house pharmacies, so they must rely on contracting with outside pharmacies to ensure their patients have access to their medications. More than 80% of rural 340B hospitals use contract pharmacies to ensure their patients receive outpatient drugs, as well as other essential services. These contract pharmacy arrangements have also proven especially important during the COVID-19 pandemic when patients have relied more heavily on alternative pharmacy channels such as mail order, online and small localized retail pharmacies. Hospitals have increasingly contracted with such pharmacies to ensure that their patients are able to access their prescribed medications and are not lost to follow-up. For these reasons, it is imperative that these pernicious actions by pharmaceutical companies be stopped immediately and restore access to 340B pricing for hospitals with contract pharmacy arrangements.

The 340B program is now more crucial than ever as 340B hospitals continue to be on the front lines of the COVID-19 public health emergency, despite incurring historic financial and operational challenges. Among these challenges is the high cost of pharmaceuticals. As of January 2022, hospital drug expenses are 22% higher on an absolute basis and 65% higher on a per patient basis compared to pre-pandemic levels in January 2020.

The fact remains that pharmaceutical companies continue to raise the prices of their products and enjoy double-digit profit margins, while 340B hospitals continue to care for the nation's most vulnerable patients and communities and operate on razor-thin margins. It is imperative for Congress to continue its bipartisan support of the program and ensure that eligible hospitals and their patients can continue to benefit from the 340B program.

CONCLUSION

Thank you for your attention to the ever increasing cost of prescription drugs and consideration of our comments on behalf of hospitals and health systems. We look forward to working with Congress to lower the cost of drugs to protect access to critical therapies.