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July 16, 2018

Alex Azar, II
Secretary
Department of Health and Human Services
200 Independence Ave., SW
Washington, DC 20201

***RE: RIN 0991–ZA49; HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs***

Dear Mr. Azar:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinical 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) appreciates the opportunity to comment on the Department of Health and Human Services' (HHS) *Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*. High and rising drug prices are putting access to and quality of care at risk by straining providers' ability to access the drug therapies they need to care for their patients. We appreciate the administration's focus on this critical issue.

America's hospitals rely on innovative drug therapies to save lives every day. Without them, more lives would be lost to diseases like cancer and AIDS, and quality of life would deteriorate for the millions living with chronic conditions. In short, modern pharmaceuticals help individuals achieve their highest potential for health.

Yet, spending on pharmaceuticals has increased dramatically over the past several years. The burden of this increase falls on all purchasers, including patients and the providers who treat them. Hospitals frequently see patients who show up in the emergency department (ED) or return for follow up care sicker than when they left because they were unable to afford their medications. Just as many patients face the challenge of high drug prices at the pharmacy, hospitals, as major drug purchasers, face significant resource constraints and trade-offs as spending on drugs increases.

The primary driver behind this growth in drug spending is higher prices, not increased utilization. Within the health care field, "pharmaceuticals" was "the fastest growing category" in terms of pricing for every month of 2016 and for most months of 2017. **We see both higher launch prices for new drugs and increases in prices for existing drugs. Drug manufacturers have full control over the initial price for a drug and any subsequent price increases.** They are responsible for setting the price of a drug at $89,000[i], $159,000[ii], or even $850,000[iii] for a course of treatment. They also solely decide whether to increase that price by 20 percent,[iv] 948.4 percent,[v] or 1,468 percent[vi].

In the *Blueprint*, the department seeks feedback on a wide range of issues. The AHA is submitting two sets of comments. In this letter, we provide our input on issues related to competition, transparency in drug pricing, national drug spending data, value-based payment arrangements, site-neutral payments for drugs, competitive bidding for certain Part B drugs, and transitioning coverage of some or all drugs from Medicare Part B to Part D, among other issues. In a second letter, we provide comments specific to the 340B Drug Pricing Program. In addition, the AHA is a founding member of the Campaign for Sustainable Rx Pricing (CSRxP). We support the comments submitted by the CSRxP, which address additional issues raised in the *Blueprint*.

Hospitals and health systems cannot continue to bear the increased cost of drugs. We appreciate the opportunity to provide these comments and support the administration's attention to the issue of high and unsustainable drug prices. We remain deeply committed to working with Congress, the administration and other health care stakeholders to ensure that all Americans can access the drug therapies they need to lead healthy, happy and productive lives. Our specific feedback on issues and ideas raised in the *Blueprint* can be found in Attachment A.

Please contact me if you have questions or feel free to have a member of your team contact Molly Smith, vice president of policy, at (202) 626-4639 or mollysmith@aha.org.

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President

## ATTACHMENT A:
## AHA COMMENTS ON THE ADMINISTRATION'S BLUEPRINT TO LOWER DRUG PRICES AND REDUCE OUT-OF-POCKET COSTS

### HOSPITAL AND HEALTH SYSTEM EXPERIENCE WITH DRUG PRICES

Purchasers of prescription drugs have faced significant increases in spending over the past several years. The latest analysis of National Health Expenditures (NHE) data shows that retail drug spending increased by 1.3 percent in 2016. While this level of growth may appear low, it follows two consecutive years of expansive growth in retail drug spending: 12.4 percent in 2014 and 8.9 percent in 2015. In other words, the lower growth comes on top of a much higher spending base for drugs. In addition, these figures capture *retail* drug spending only; they do not reflect spending patterns for other purchasers. Detailed information on non-retail drug spending is neither systematically collected nor publicly available, something we address further in our comments.

In 2016, the AHA and the Federation of American Hospitals worked with the NORC at the University of Chicago (NORC) to document hospital and health system experience with inpatient drug spending. The resulting study found that increases in drug spending for inpatient care outpaced what the NHE reported for retail drug spending. **Specifically, the NORC found that, while retail spending on prescription drugs increased by 10.6 percent between 2013 and 2015, hospital spending on drugs in the inpatient space rose 38.7 percent per admission during the same period.**[vii] [viii]

Rising drug prices, not volume, were the primary driver of increased spending. After examining data from two group purchasing organizations (GPOs) that collectively purchase drugs for more than 1,400 hospitals, the NORC was able to track changes in price, utilization and total spending for a select group of drugs. Consistently, changes in price drove increases in spending. These price increases, from the hospitals' perspective, appeared to be random, inconsistent and unpredictable: large unit price increases occurred for both low- and high-volume drugs and for both branded and generic drugs.

Our members were not surprised to learn that their purchasing experience differs from what the NHE reports for retail drugs. In testimony to the Committee on Oversight and Government Reform of the U.S. House of Representatives, one drug manufacturer acknowledged targeting hospital-administered drugs for price increases. Howard Schiller, then-interim CEO of Valeant Pharmaceuticals, stated: "Because these drugs are hospital-administered, and not purchased by patients directly, increasing the cost of the drugs to hospitals would affect the hospital's profits on these procedures, but it should not reduce patient access."[ix]

While the NORC study supports Mr. Schiller's admission that manufacturers target hospitals for price increases, we challenge his assessment that such practices do not reduce patient access. Researchers at the Cleveland Clinic found that patient access to Valeant drugs nitroprusside and isoproterenol declined after the company increased the prices for both substantially. From 2012 to 2015, 53 percent fewer patients were treated with nitroprusside and 35 percent less were

treated with isoproterenol.[x] This is because hospitals bear a heavy burden when the cost of drugs increases, in large part due to how hospital reimbursement is structured. This has direct implications for the availability of certain drug therapies for patients.

Most payments to hospitals for inpatient care are made on a bundled basis – either per discharge (Diagnostic-Related Group or DRG) or per diem. In other words, all input costs are reimbursed under a single, predetermined reimbursement. As drug costs rise, they crowd out other input costs, an issue we describe in more detail in our comments related to site-neutral payments for drugs.

A number of factors contribute to the increase in drug spending, and those factors have evolved over time. In the past several years, hospital have faced widespread price increases for existing drugs. While drug manufacturers have increased some prices by multiple hundreds or even thousands of percent, hospitals report that the 10 to 20 percent increases on widely used generic drugs often have a just as big, if not a bigger, impact on their budgets given the high volumes of these drugs that hospitals purchase.

Increasingly, our members report that high launch prices and increased spending due to drug shortages are new challenges they face, as well as budget pressures associated with the ancillary service costs associated with highly complex and potent drugs. Launch prices are the basis for negotiations with purchasers, and examples of recent launch prices include:

- Talz (Eli Lilly), used for treating psoriasis, costs $50,000 a year.[xi]
- Keytruda (Merck), used for treating melanoma, costs $152,400 a year.[xii]
- Kymriah (Novartis), used for treating leukemia, costs $475,000 for a course of treatment.[xiii]
- Spinraza (Biogen), used to treat spinal muscular atrophy, costs $750,000 for the first year of treatment and $375,000 per year thereafter.[xiv]

Many of these new drug therapies are highly potent and come with significant side effects. A recent example is Kymriah, a new blood cancer drug using “CAR-T cell therapy” through which patients’ own genes are extracted, modified and reinjected to kill leukemia cells. The potential side effects require extensive ancillary services to monitor patients and prevent infections and other adverse events for a prolonged period of time. [xv] While these services do not directly increase the cost of the drug, they do impact the overall cost of care.

Drug shortages also are a major contributor to increases in drug spending. Medications that experience shortages are largely injectable products that are off patent and have few suppliers; shortages typically arise from quality concerns that cause a halt to production. If a product has few competitors, this disruption cannot be absorbed by other companies and demand outpaces supply. This not only results in a shortage but also causes prices to rise. For drugs with a sole manufacturer, shortages are exacerbated – since there is no alternative, clinicians must scramble to find the drug or compound the drug in cases where it is possible. They also may recommend an alternative (often less effective) therapy, if one exists. This, in turn, can result in higher spending because manufacturers often capitalize on the situation by increasing the price of the

alternative therapy. For example, a 2017 study that examined how drug prices change during supply disruptions[xvi] found that after quality-control issues forced a manufacturer of glycopyrrolate – an injectable agent commonly used before surgery to reduce secretions – to suspend production, the remaining manufacturer increased the price of its product by 855 percent. The list price remained at the new level even after production capacity was restored.

**TRANSPARENCY IN DRUG PRICING**

Drug purchasers, including providers, have little information about how drugs are priced. This gap in information challenges their ability to set budgets and manage formularies, and often results in mid-year cost increases that providers are unprepared to manage. We encourage the administration and Congress to pursue policy proposals that seek greater transparency parity between drug manufacturers and other sectors of the health care system. For example, hospitals already disclose a considerable amount of information on pricing, input costs and utilization. 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.

We applaud the initial steps already taken by the administration to improve transparency for drug spending and pricing, both by updating and expanding upon the Medicare Part B and D and Medicaid spending dashboards, as well as by updating guidance to allow for more communication between purchasers and drug manufacturers before a drug has final approval. However, we encourage the administration and Congress to go further. Specifically, we encourage the Food & Drug Administration (FDA) to require drug manufacturers 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. Drug manufacturers also should be required to provide information on the research that contributed to the development of the drug. Manufacturers should specify all entities that conducted research that contributed to the development of the drug, the amount spent on that research and the funding source. Finally, more of this information should be included in direct-to-consumer advertising, consistent with the idea floated in the *Blueprint*.

**INCREASING COMPETITION**

Competition for prescription drugs has shown to be one of the most effective ways of reducing the cost of drug therapies, particularly when multiple generic options are available.[xvii] Increased competition does not need to come at the expense of the development of innovative new therapies. We applaud the FDA for taking swift action to approve more generic drugs, and the AHA supports many of the ideas included in the *Blueprint*. In particular, we support action to stop practices that prevent generic manufacturers from obtaining sufficient samples to develop competitive products, and we again reiterate our support for the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act (S. 974).

In addition, we urge the administration and Congress to go further to prevent and take action against anti-competitive tactics, including by denying patents for evergreened products, deeming

"pay-for-delay" tactics to be presumptively illegal and increasing oversight, and limiting orphan drug incentives to true orphan drugs. More information on these issues can be found in Attachment B, as well as in comments submitted to the agency by the CSRxP, of which the AHA is a member.

**NATIONAL DRUG SPENDING DATA**

The AHA strongly supports increased access to national drug spending data and appreciates efforts already taken by the department to provide more granular cost and spending data through the Medicaid and Medicare Parts B and D dashboards. However, we remain concerned that there is no standardized collection and reporting on *total* drug spending in the United States. A significant portion of drug spending is masked due to how input costs, such as drugs, are bundled into a single provider reimbursement, such as DRGs in the Medicare program. NHE data, which reflects *retail* drug spending only, does not account for these costs and, therefore, does not reflect instances when drug manufacturers specifically target provider-administered drugs for price increases. We urge the department to develop an approach for collecting and reporting total drug spending data.

**VALUE-BASED PAYMENT ARRANGEMENTS**

Most health care providers are participating in some form of value-based payment (VBP) arrangements through which reimbursement is based in part on health outcomes, efficiency and quality. While considerable work already has been done in the development of VBP models for providers, very few models exist for pharmaceuticals. **The AHA supports the administration taking a leading role in developing demonstration programs through its Center for Medicare & Medicaid Innovation (CMMI) to design and test VBP models for drugs purchased under all parts of Medicare, and to make the specs of those models available for replication by commercial payers and states. However, we caution HHS that VBP arrangements alone are not a panacea for high drug prices.**

A number of VBP models may improve how we pay for drugs, including indications-based pricing and risk-sharing agreements based on outcomes.

- **Indications-based Pricing:** An indication-based payment methodology would vary payment for a drug based on its clinical effectiveness for the different indications for which it has been approved. The Centers for Medicare & Medicaid Services (CMS) would use evidence from published studies and reviews or evidence-based clinical practice guidelines that are competent and reliable, such as those issued by the Institute for Clinical and Economic Review (ICER). The AHA believes that indications-based pricing holds promise as a tool that can be further developed for future use in the Medicare program, with attention toward development of administrative measures to indicate feasibility.

  However, additional work is necessary before such a model could be implemented. For example, this model relies on knowing the clinical effectiveness of particular drugs for their various indications. This information in not consistently available at this time, and we strongly support the collection and use of comparative effectiveness data for this

purpose. Furthermore, we do not believe that hospital information systems are currently able to operationalize the coding that would be needed to correctly implement indications-based pricing. In order for this tool to be used, hospitals' electronic health records and claims processing systems would need to be able to easily link a particular drug to the indication for which it was prescribed. In addition, CMS and the FDA would need to provide an authoritative, verified cross walk of each drug to the various indications for which payment will vary that will need to be maintained over time. In that process, CMS and the FDA would need to determine whether the existing ICD-10 coding system sufficiently captures the indications for which payment will be varied. This is because the current claim standard only includes diagnosis codes, without separate fields for drug indication.

- **Outcomes-based Risk-sharing Agreements:** This type of model would link the price of a drug with patient health outcome goals. The final price of a drug would be dependent on results achieved by specific patients rather than using a predetermined price based on historical population data. Manufacturers would agree to provide rebates, refunds or price adjustments if the product does not meet targeted outcomes. In exploring this option, the administration would need to evaluate potential technological, programmatic and operational challenges that hospitals may face, such as agreeing to common outcome metrics and tracking them via hospital information systems.

**We strongly urge HHS not to pursue reimbursement mechanisms that would simply extend payments over multiple years.** These "mortgage"-style payment models may reduce the burden of paying for a drug in any given year but will do nothing to actually reduce drug prices or spending or meet the quality and health outcome objectives of true VBP models. In addition, critical operational barriers would prevent implementation of this model, including how to address insurer responsibility when enrollees move in and out of coverage.

**SITE-NEUTRAL PAYMENT**

HHS states that it is considering expanding its site-neutral payment policies. Its intent is to reduce federal expenditures for similar services furnished in different settings, as well as to address possible affordability and access challenges for beneficiaries. First, HHS is considering a site-neutral payment policy to account for differences in reimbursement between the outpatient prospective payment system (OPPS) and the physician fee schedule (PFS) for drug administration services. Second, it discusses differences in Medicare's Part A inpatient and Part B outpatient drug payment policies and seeks input on the reasons for these differences, as well as the implications of these differences for patients in terms of beneficiary cost-sharing and patient safety.

**Site Neutrality for Drug Administration Services**

**The AHA opposes any expansion of site-neutral payment policy, including imposing a site-neutral payment policy for drug administration services under Medicare Part B.** Hospitals with newer off-campus hospital outpatient departments (HOPDs) are already subject to significant payment reductions for the "non-excepted" services they furnished in these settings, which have reduced their already record low Medicare margins. Any further expansion of the

site-neutral payment policy would threaten beneficiary access to critical hospital-based safety-net services, including hospitals' ability to continue to provide 24/7 access to emergency care and stand-by capacity for disaster response.

Further, we strongly disagree that the OPPS payment rates for drugs administration services in HOPDs are "many times higher" than the rates paid to physicians under the PFS because such a direct comparison does not take into account the many differences between these settings:

- OPPS payments, including for drug administration services, incorporate much higher levels of packaged costs than the PFS payments for comparable services.
- HOPDs provide services that are not otherwise available in the community to vulnerable patient populations, such as low-income and dual-eligible patients.
- Hospital costs include unique social goods not provided in other settings, such as 24/7 access to emergency care and stand-by capacity for disaster response.
- Payment to hospitals for outpatient care should reflect HOPD costs, not physician payments.

Packaging differences between settings. There is greater packaging of costs under the OPPS compared to the PFS. CMS acknowledged this in its calendar year (CY) 2017 OPPS interim final rule, stating, "OPPS payment rates include the costs of packaged items or services billed with the separately payable code, and therefore the comparison to rates under the MPFS will not be a one-to-one comparison." For instance, in CY 2018 under the OPPS (but not the PFS), drugs costing less than $120 have their cost packaged in the procedure with which they are billed, including drug administration procedures. Further, under the OPPS "policy-packaged" drug policies, the agency packages the costs of all anesthesia drugs; drugs, biologicals and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure, regardless of whether they meet the $120 per day threshold. Therefore, one cannot make a direct comparison of rates for similar services in HOPDs and freestanding physician office settings without first accounting for the additional packaging included in OPPS payments.

Access for vulnerable patient populations. Further reduction in outpatient Medicare revenue to hospitals would threaten access to critical hospital-based services, such as care for low-income patients and underserved populations. For example, relative to patients seen in physician offices, patients seen in HOPDs are:

- 2.5 times more likely to be Medicaid, self-pay or charity patients;
- 1.8 times more likely to be dually eligible for Medicare and Medicaid;
- 1.8 times more likely to live in high-poverty areas;
- 1.7 times more likely to live in low-income areas; and
- 1.7 times more likely to be Black or Hispanic.[xviii]

In addition, physicians refer more complex patients to HOPDs for safety reasons, as hospitals are better equipped to handle complications and emergencies. As such, compared to freestanding

physician offices, HOPDs treat Medicare patients who are suffering from more severe conditions and with higher prior utilization of hospitals and emergency departments.[xix]

Hospital costs include unique social goods. Hospitals have a higher cost structure than freestanding physician offices, due, in part, to the unique social goods only they provide, such as the costs of stand-by capability and capacity that they bear. Site-neutral payment policies, like that proposed in the *Blueprint*, would reimburse hospitals less for specific treatments while still expecting hospitals to continue to provide the same level of service to their patients and communities. Hospitals are the only health care provider that must maintain emergency stand-by capability 24 hours a day, 365 days a year. Hospitals are also subject to significantly greater licensing, accreditation, regulatory and quality requirements than other providers, none of which would be reduced under the proposed site-neutral payment policy. Moreover, hospitals provide access to critical standby services, such as burn care, and remain ready to treat patients from natural and man-made disasters. This stand-by role is built into the cost structure of full-service hospitals and supported by revenue from direct patient care – a situation that does not exist for physician offices or any other type of provider. Additional site-neutral payment reductions would endanger hospitals' ability to continue to provide 24/7 access to emergency care and stand-by capacity for disaster response. Following a year in which the nation experienced record-setting natural disasters, and with projections for an increase in the severity and frequency of extreme weather events, we must do everything we can to ensure that hospitals have the resources needed to prepare for and respond to future disasters.

Hospital payments should reflect hospital costs. Medicare payment systems for physicians and HOPDs are complex and fundamentally different. HOPD payment rates are based on audited hospital cost reports and claims data. In contrast, the PFS, and in particular the practice expense component, which is relevant for the site-neutral payment methodology, is based on voluntary responses to physician survey data. Further, hospitals already suffer negative margins treating Medicare patients in HOPDs. According to the fiscal year (FY) 2016 Medicare cost report data, Medicare margins for outpatient services were a record low of negative 14.8 percent in 2016.[xx] Overall Medicare margins were also a record low of negative 9.6 percent in 2016, with a new record low of negative 11.0 percent projected for 2018.[xxi] Of note, even "efficient" hospitals had a negative margin in 2016, for the first time ever.[xxii] The site-neutral payment policies implemented by CMS for 2017 and beyond are reducing these margins further. We are concerned that imposing additional payment reductions by implementing a site-neutral proposal for drug administration services would threaten beneficiary access to critical hospital-based "safety-net" services.

**Site Neutrality between Inpatient and Outpatient Settings**

**The AHA opposes any site-neutral payment policy for prescription drugs between inpatient and outpatient settings.** Costs associated with prescription drugs vary across care settings as a result of differences in payment structure as well as patient needs, outlined below.

Medicare reimbursement differs for inpatient and outpatient drugs. As noted earlier, while most Part B drugs are reimbursed at the average sales price (ASP) plus 6 percent (or ASP minus 22.5 percent for Part B drugs purchased through the 340B Drug Pricing Program), payments to

hospitals for drugs administered as part of inpatient care are generally made on a bundled basis. In the inpatient prospective payment system (IPPS), all costs for the patient – including drug costs – are reimbursed under a single, predetermined reimbursement based on DRG.

Hospitals are responsible for managing input costs within the fixed payment amount, but reimbursement does not necessarily increase as input costs, such as those for drugs, increase. Specifically, despite Medicare being one of the largest payers for hospitals in general, the program is not able to keep pace with new and sometimes volatile drug prices. For example, in calculating its annual payment updates, the Medicare program relies on drug pricing data collected and reported by the Bureau of Labor Statistics, which completes a full drug price data update only every five to seven years. This data lag means that hospital reimbursement does not necessarily increase proportionally to drug price increases. Moreover, new pharmaceutical or biologics coming to the market, such as expensive immunotherapies, are not immediately accounted for in the DRG system, leading hospitals to take on enormous financial burden in order to provide life-saving care. As a result, hospitals must divert other resources to cover higher drug costs, forcing difficult choices between providing adequate compensation to employees, many of whom are highly skilled in professions facing shortages; upgrading and modernizing facilities; purchasing new technologies to improve care; or paying for drugs.

The level of patient need is higher in the inpatient setting. A patient is considered to be "inpatient" when a doctor admits the patient to the hospital for inpatient care. A patient is admitted when in the exercise of the physician's medical judgment, considering such factors as the patient's history and comorbidities, the severity of the patient's signs and symptoms, the risk of an adverse event, and risks to the patient if he or she is not admitted, the patient needs inpatient care. As a result, patients in the inpatient setting are considered by a medical expert to be in need of a higher level of care than those patients treated in the outpatient setting. In light of this greater patient complexity, more resources are directed to inpatient care, including medication management and administration. With more than two-thirds of individuals 65 years or older taking three or more prescription drugs,[1] substantial expertise is needed to balance pharmaceutical products (e.g., side effects, contraindications, risks) along with inpatient care services.

The inpatient setting may be more appropriate to address drug risks. Although some drugs may be safely administered in both inpatient and outpatient settings, risks and side effects may be better managed on an inpatient basis depending on severity and patient characteristics. For example, CAR T-cell therapies described earlier may lead to severe side effects such as cytokine release syndrome or serious neurological events, both of which require intensive care unit services. Moreover, given that patients receiving CAR T are already immunosuppressed, they can experience increased risk of infection and therefore require prolonged monitoring and care. Correspondingly, many of our members have affirmed that the inpatient setting is more clinically appropriate than an outpatient setting for such drugs. Identifying – and being able to address – severe side effects quickly also may contain overall patient care costs. Thus, although safe administration of a drug or biologic may be feasible in either location, inpatient and outpatient settings are not simply interchangeable.

**COMPETITIVE BIDDING FOR PART B DRUGS**

HHS is considering reactivating the Competitive Acquisition Program (CAP) for certain Part B drugs that operated approximately 10 years ago. The intent is to create an alternative to the ASP payment system that leverages a third-party entity negotiating with manufacturers to obtain lower prices. This option may be worth further exploration as a voluntary option for free-standing physician practices. However, while it was unclear whether HHS is interested in extending the program beyond physicians, hospitals and health systems are unlikely to benefit from such a program. Most hospitals already have access to reduced drug prices through their membership in GPOs, and many of the tools that CAP vendors could use to encourage savings, such as step-therapy and formularies, are already widely used within hospitals and health systems. **Therefore, we encourage the administration to evaluate such a model in the physician fee schedule context only.**

**TRANSITION OF COVERAGE FROM MEDICARE PART B TO PART D**

The AHA agrees that negotiation is an important tool for lowering prices. For that reason, hospitals and health systems rely on GPOs to assist them in getting the best prices from drug manufacturers, including for drugs eligible for reimbursement under Part B. Therefore, we question whether introducing Part D insurers into this process will yield substantial savings.

The *Blueprint* did not provide sufficient detail to fully understand how such a transition would be operationalized. Therefore, in lieu of specific feedback, we pose a number of questions about how this proposal would work in practice. **We urge the department not to move forward with this concept without providing stakeholders with the opportunity to evaluate detailed specifications of any model to move coverage of some or all drugs from Part B to Part D.**

- How would beneficiaries without Part D coverage access drug therapies currently covered under Part B? HHS recognized that a significant limitation of this policy is how to cover physician-administer drugs for the 27 percent of Part B beneficiaries without Part D coverage. We do not believe it is HHS's intent to force individuals to purchase supplementary drug coverage so that they can receive their full Part B benefits. Therefore, it appears that the Part B program would need to remain in place for those beneficiaries. We question whether the administrative burden of operating both programs would be worth any benefits.

- Would beneficiaries be subject to Part D cost-sharing instead of Part B cost-sharing for drugs delivered during a service otherwise covered through Part B? If so, would the beneficiary face two different co-payments – one for the drug and one for the service? Will protections be put in place to ensure that the proposal does not increase beneficiary out-of-pocket costs overall?

- How would drug supply management work? Would beneficiaries be responsible for collecting the drug from the pharmacy and bringing it to the physician's office or outpatient department for administration? If so, how would HHS ensure that appropriate safeguards were in place to prevent the diversion of drugs and ensure that the beneficiary

stores the drug in the right conditions? Given these risks, we do not believe that HHS intended for beneficiaries to collect and deliver the drug.

- Will physicians be required to contract with a patient's Part D insurer in order to receive reimbursement for Part B services? Given that it is unlikely that patients would directly handle the drugs as discussed above, we expect there must be some relationship between the insurer and the physician to order and manage the supply of drugs. Would beneficiaries be restricted to receiving Part B services only from physicians contracted with their Part D plan? If so, we strongly oppose this move as it would violate the fundamental structure of the Medicare fee-for-service program. Beneficiaries interested in such a managed model can opt for Medicare Advantage.

**LEVERAGING TECHNOLOGY TO INFORM PATIENTS ABOUT COST-SHARING AND LOWER-COST ALTERNATIVES**

Hospitals and health systems have made great strides in implementing electronic health records (EHRs) and other health information technology tools. Increasingly, these systems are used to share health information with individuals and across provider settings to better coordinate care. For example, 93 percent of hospitals now allow individuals to access their health information, including prescriptions, online. In addition, 50 percent of hospitals allow individuals to request refills for prescriptions online. However, this information generally only includes what has been prescribed. As noted in the *Blueprint*, clinicians could do even more to help patients make informed choices about drugs if they had real-time information on the total and out-of-pocket costs of alternative drug therapies at the time of prescription. In addition, having access to information about whether a prescription has been filled would provide clinicians with valuable information about whether individuals are having challenges complying with a treatment plan or need to consider alternatives. To derive these benefits, of course, the information about alternatives must be accurate, presented in a comparable way across drugs, and be easily available within the workflow of the clinician.

We recommend continued efforts across drug companies, health plans, pharmacies and health care providers to leverage technology and make pricing and pharmacy fill data available to clinicians at the point of care. It is important that these efforts to result in real-world implementations that ease clinician burdens, rather than regulatory mandates that add to them. The experience from the Medicare and Medicaid EHR Incentive Programs demonstrates that widespread adoption of technology functionality based on a regulatory mandate is hindered by several factors. Different technology vendors will have various levels of readiness to accommodate demand for the new technology, and each health care setting must determine if updates to existing systems are necessary in order to accommodate the demands of the new technology. And, for the EHR incentive program, the timeline for technology changes has been too compressed to support successful change management.

**MEDICAID REBATES**

HHS expressed interest in examining several aspects of the Medicaid rebate program regarding inflationary rebate limits and the determination of the Average Manufacturer Price (AMP) and Best Price. The Medicaid and CHIP Payment and Access Commission (MACPAC), in their June

2018 Report to Congress, made two recommendations to improve the Medicaid rebate program that the AHA believes HHS should carefully consider. Under current law, Medicaid rebates are calculated based on the AMP with brand and generic drugs having different rebate formulas. Drug manufacturers are required to classifying which of their products are brand and which are generic. They are then required to average the price of its authorized generic with the brand drug in calculating the brand drug AMP. MACPAC's recommendations address two areas where drug manufacturers maybe manipulating the AMP using generic drugs to lower their rebate obligations. The first recommendation calls on Congress to close a loophole in which a manufacturer could sell its authorized generic to a corporate subsidiary to lower the brand AMP, thus lowering its rebate obligation. The second recommendation addresses drug manufacturers' classification of whether a drug is brand or generic and recommends that Congress grant the Secretary more enforcement authority when drug manufacturers deliberately misclassify a drug as generic to lower rebate obligations. Both recommendations are intended to help ensure Medicaid programs are receiving the proper drug rebates, thus helping tight state Medicaid budgets address expenditure growth in prescription drugs.

[i] Triblle, SJ., "Duchenne Drug Delayed After Outrage Over Price," National Public Radio, Feb. 14, 2017 https://www.npr.org/sections/health-shots/2017/02/14/515046376/duchenne-drug-delayed-after-outrage-over-price
[ii] Szabo, L., "As Drug Costs Soar, People Delay Or Skip Cancer Treatments," National Public Radio, Mar. 15, 2017, https://www.npr.org/sections/health-shots/2017/03/15/520110742/as-drug-costs-soar-people-delay-or-skip-cancer-treatments
[iii] Fox, M. "Luxturna gene therapy for blindness to cost $850,000," NBC News, Jan. 3, 2018. https://www.nbcnews.com/health/health-news/luxturna-gene-therapy-blindness-cost-850-000-n834261
[iv] Herman, B. "Drug prices are still going through the roof," Axios, Mar. 21, 2018. https://www.axios.com/drug-prices-exploding-2017-1521564090-aa025591-9e50-491d-b3e2-c981e85adb60.html
[v] Tirrell, M. "Martin Shkreli's legacy: Putting a 'fine point' on the drug pricing debate," CNBC, Mar. 9, 2018 https://www.cnbc.com/2018/03/09/martin-shkrelis-legacy-shaping-the-drug-pricing-debate.html
[vi] Herman, B. "Drug prices are still going through the roof," Axios, Mar. 21, 2018. https://www.axios.com/drug-prices-exploding-2017-1521564090-aa025591-9e50-491d-b3e2-c981e85adb60.html
[vii] National Health Expenditure Data for 2013 - 2015
[viii] "Trends in Hospital Inpatient Drug Costs: Issues and Challenges," American Hospital Association and the Federation of American Hospitals, October 11, 2016. http://www.aha.org/content/16/aha-fah-rx-report.pdf
[ix] Statement of Howard B. Schiller, Interim Chief Executive Officer and Director, Valeant Pharmaceuticals International, Inc. before the Committee on Oversight and Government Reform of the U.S. House of Representatives, February 4, 2016. https://oversight.house.gov/wp-content/uploads/2016/02/Statement-of-Howard-Schiller-2016-02-04.pdf
[x] Khot UN, et al. Nitroprusside and Isoproterenol Use after Major Price Increases, New England Journal of Medicine, August 10, 2017. http://dx.doi.org/10.1056/NEJMc1700244
[xi] Waxman, H. et.al, "Getting to the Root of High Prescription Drug Prices: Drivers and potential solutions," Commonwealth Fund, Jul 2017. http://www.commonwealthfund.org/~/media/files/publications/fund-report/2017/jul/waxman_high_drug_prices_drivers_solutions_report.pdf?la=en
[xii] Szabo, L., "As Drug Costs Soar, People Delay Or Skip Cancer Treatments," National Public Radio, Mar. 15, 2017, https://www.npr.org/sections/health-shots/2017/03/15/520110742/as-drug-costs-soar-people-delay-or-skip-cancer-treatments
[xiii] Sagonowsky, E. "At $475,000, is Novartis' Kymriah a bargain—or another example of skyrocketing prices?" FiercePharma, August 31, 2017, https://www.fiercepharma.com/pharma/at-475-000-per-treatment-novartis-kymriah-a-bargain-or-just-another-example-skyrocketing
[xiv] Picci, A., "The cost of Biogen's new drug: $750,000 per patient," CBS News, December 16, 2016. https://www.cbsnews.com/news/the-cost-of-biogens-new-drug-spinraza-750000-per-patient/
[xv] Food & Drug Administration, "FDA approval brings first gene therapy to the United States," August 30, 2017. https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm574058.htm
[xvi] *Davies, B., Hwang, T., and Kesselheim, A.*, "Ensuring Access to Injectable Generic Drugs — The Case of Intravesical BCG for Bladder Cancer," New England Journal of Medicine, April 13, 2017.
[xvii] Hoadley, J., "Drug Pricing, Repricing, Rebates, and Patient Access," Delivered at the Bipartisan Policy Center, Apr. 13, 2016. https://bipartisanpolicy.org/wp-content/uploads/2016/03/Hoadley-BPC.pdf
[xviii] Source: KNG Health Consulting analysis of 2013-2014 Medicare claims data, 2008-2011 National Ambulatory Medical Care Survey and 2008-2011 National Hospital Ambulatory Medical Care Survey data.
[xix] Source: KNG Health Consulting analysis of 2013-2014 Medicare claims data, 2008-2011 National Ambulatory Medical Care Survey and 2008-2011 National Hospital Ambulatory Medical Care Survey data.
[xx] Source: AHA analysis of FY 2016 Medicare cost reports.
[xxi] Source: MedPAC's March 2018 Report to the Congress: Medicare Payment Policy.
[xxii] Source: MedPAC's March 2018 Report to the Congress: Medicare Payment Policy.
[1] https://www.cdc.gov/nchs/data/hus/hus16.pdf#079.

# ATTACHMENT B:
# AHA DRUG PRICE PROPOSALS

The U.S. health care system is facing a prescription drug spending crisis fueled by staggering increases in the price of drugs. While the need and potential for the development of innovative drug therapies is large, the dramatic increases in the price of both new and existing drugs threatens to make them inaccessible to patients and the providers who care for them. In a recent survey conducted by the American Hospital Association (AHA) and the Federation of American Hospitals (FAH) and analyzed by NORC at the University of Chicago, hospitals reported that spending on inpatient drugs increased by 24 percent per admission in 2014 and 12 percent per admission in 2015.[1] These increases were due to drugs like hydralazine, a drug used in hospital settings to manage blood pressure, and neostigmine methylsulfate, a neuromuscular blocking agent used after surgery. In 2015, the cost of hydralazine jumped 723 percent, while the cost of neostigmine methylsulfate rose by 421 percent.[2] As a result, more than 90 percent of hospital administrators report moderate to severe challenges in managing hospital budgets within the fixed reimbursement inpatient payment model.

The AHA is deeply committed to the availability of high-quality, efficient health care for all Americans. Hospitals, and the clinicians who work in them, know firsthand the lifesaving potential of drug therapies. Indeed, 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.

Over the past 12 months, the AHA has worked with its members to document the challenges hospitals and health systems face with drug prices and develop policy solutions to protect access to critical therapies while encouraging and supporting much-needed innovation. The following policy recommendations, approved by the AHA Board of Trustees, were surfaced by the AHA's work with the Campaign for Sustainable Rx Pricing. The recommendations, detailed below, support the following overarching goals with respect to drug pricing:

1) Increased competition and innovation
2) Increased transparency
3) Payment for value
4) Improved access
5) Alignment of incentives

## INCREASE COMPETITION & INNOVATION

Competition for prescription drugs generally results in increased options for lower cost therapies, particularly through the introduction of one or more generic competitors. These proposals seek to increase the introduction of generic alternatives and discourage anti-competitive tactics while maintaining incentives for the development of innovative new therapies.

[1] AHA/FAH Drug Survey 2016
[2] AHA/FAH Drug Survey 2016

- **Fully resource Food and Drug Administration (FDA) review and approval offices.** FDA has a significant backlog of both generic and branded drug applications. While a number of fast-track programs exist, FDA does not have the resources available to process applications in a timely manner. Under this proposal, Congress would appropriate additional resources to FDA specifically for purposes of hiring personnel to process applications.

- **Fast-track generic applications when no or limited generic competition exists.** Generic competition is critical to a functioning drug marketplace. Research suggests that optimal pricing is achieved when there are five or more generic manufacturers competing on the same drug.[3] In order to encourage additional generic entrants to the market, this proposal would require FDA to prioritize review of applications where there is no generic option available or in instances of a drug shortage. While FDA voluntarily decided earlier this year to prioritize generic applications for drugs without generic competition, this policy proposal would codify this approach in federal law with statutory deadlines for review.

- **Incentivize generic manufacturers with fast-track voucher rewards.** In order to further promote the introduction of generic drugs, this policy would reward generic manufacturers that have a drug approved under the above process with a voucher to fast-track any other generic application.

- **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 assuming that the newer version is superior. This policy proposal would deny patents for products that are simply modifications of existing products unless the new product offers significant improvements in clinical effectiveness, cost savings, access or safety.

- **Deem "pay-for-delay" tactics to be presumptively illegal and increase oversight.** Some brand drug manufacturers pay generic manufacturers to delay entry into the market. In 2013, the U.S. Supreme Court ruled that such deals could be a violation of antitrust law, but declined to declare them presumptively illegal. Subsequently, the

[3] MedPAC, based on FDA analysis of retail sales data from IMS Health, IMS National Sales Perspective, 1999-2004, as analyzed by Jack Hoadley, Ph.D., Health Policy Institute, Georgetown University, for the Bipartisan Policy Center, April 13, 2016. Accessible at: http://cdn.bipartisanpolicy.org/wp-content/uploads/2016/03/Hoadley-BPC.pdf

Federal Trade Commission (FTC) has reported a significant decrease in pay-for-delay deals but an increase in other "settlements" between brand and generic manufacturers. This policy proposal would clarify in federal law that such practices are presumptively illegal and increase FTC resources to investigate these and other settlements.

- **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. This proposal would direct FDA to collect information on other intended indications for the drug when evaluating eligibility for orphan drug status. It also would direct FDA 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 could levy penalties, such as requiring that the manufacturer pay the government back the value of the tax breaks and waived fees and potentially reducing the market exclusivity period.

- **Investigate potential abuses of the Risk Evaluation and Mitigation Strategies (REMS) program.** Some drug manufacturers inaccurately claim as part of the REMS program that certain drugs come with such significant risks that it is not safe to allow generic manufacturers access to samples for purposes of bioequivalency testing. This practice inappropriately stifles competition by preventing the generic manufacturer from obtaining sufficient quantities of the drug for testing and duplication, therefore, ensuring that the branded version of the drug remains the only option available. This proposal would require FDA to evaluate the use of REMS and issue a report on its findings, including whether manufacturers are using REMS protections to inhibit generic manufacturer access to samples and develop recommendations for increased oversight and enforcement.

- **Disallow co-pay assistance cards.** Some drug manufacturers offer co-pay assistance cards to encourage patients to request certain higher-cost drugs. While these cards may lower patients' out-of-pocket costs for certain high-priced drugs, they have a number of negative consequences that drive up overall costs for patients and the health care system. These cards often inappropriately steer patients to higher cost drugs rather than cheaper alternatives. They also disrupt insurance plan design by enabling consumers to use the value of the card to more quickly reach out-of-pocket maximums. As a result, patients appear to be shielded from the cost of the drugs. However, insurers facing substantial increases in prescription drug costs must raise consumer premiums to cover the cost of

the drug. This proposal would prohibit drug manufacturers from using co-pay cards as a patient inducement.

## INCREASE 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 drugs, and often results in mid-year cost increases that providers are unprepared to manage. These policy proposals seek 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.

- **Increase disclosure requirements related to drug pricing, research and development 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.

  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. Under this policy proposal, drug manufacturers would 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. Drug manufacturers also would be required to provide information on the research that contributed to the development of the drug. Manufacturers would need to specify all entities that conducted research that contributed to the development of the drug, the amount spent on that research and the funding source.

- **Issue consumer and provider-facing annual reports on drug pricing.** Recently, CMS began publicly reporting on the costs associated with 80 drugs covered by either Medicare Part B or Part D benefits.[4] CMS selects the drugs based on whether they are in the top 15 in total program spending, high annual cost per user or annual cost increase. While this is an important first step, the data are not presented in an easy-to-use format

[4] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Dashboard/Medicare-Drug-Spending/Drug_Spending_Dashboard.html

for patients or providers. This policy proposal would expand CMS's reporting on drug costs and spending to the Medicaid program and require the agency to issue consumer and provider-friendly reports on an annual basis. Such information will help providers and consumers make informed decisions about preferred drugs, and will help hold drug manufacturers accountable for their initial launch prices and price changes over time.

## PAY FOR VALUE

The health care system is reorienting toward value. While significant strides have been made in developing value-based payment (VBP) models for hospitals and physicians, little work has been done on drug purchasing models. These proposals would advance the development and implementation of such arrangements for drugs.

- **Develop Medicare-negotiated VBP arrangements.** Most health care providers are participating in some form of VBP through which reimbursement is based, at least in part, on health outcomes, efficiency and quality. While considerable work already has been done in the development of VBP models for providers, very few models exist for pharmaceutical drugs. There are several exceptions. For example, Harvard Pilgrim and Amgen have implemented an outcomes-based payment model for a cholesterol drug;[5] and Eli Lilly and Anthem are working together to develop outcomes-based contracts for drugs.[6]

  Under this proposal, CMS would take a leading role in developing demonstration programs through its Center for Medicare & Medicaid Innovation to test VBP models for drugs purchased under all parts of Medicare. Specifically, we recommend that CMS undertake a public, multi-stakeholder process to develop potential VBP models for drugs. This process would begin with an initial meeting between CMS and a broad group of stakeholders to discuss the scope of potential demonstration projects (e.g., limited to Parts B or D, condition-specific, etc.) and potential VBP models for consideration. Subsequently, CMS would issue a request for information for more details on specific proposals. Based on this information, CMS would follow the standard regulatory process for proposing, modifying and finalizing VBP models for testing. Drug purchasers, including hospitals, could use these CMS-developed models in negotiations with manufacturers for other populations as well.

  Examples of potential VBP models include:

  - **Indications-based pricing.** This model would vary the payment for a drug based on its clinical effectiveness for the different indications for which it has been approved. CMS would use evidence from published studies and reviews, such as those issued by the Institute for Clinical and Economic Review (ICER), or

[5] Herman, Bob, "Harvard Pilgrim cements risk-based contract for pricey cholesterol drug Repatha," Modern Healthcare, November 9, 2015.
[6] Eli Lilly and Anthem, "Promoting Value-Based Contracting Arrangements," January 2016

evidence-based clinical practice guidelines that are competent and reliable. The AHA recognizes that additional work would be needed to determine the clinical effectiveness of particular drugs for their various indications. Furthermore, CMS would need to consider the information systems requirements. For example, hospitals' electronic health records would need to be able to easily link a particular drug to the indication for which it was prescribed. However, this approach should be further explored recognizing that the additional work required will take time to complete.

- **Risk-sharing agreements based on outcomes.** This model would link the price of a drug with patient health outcome goals. The outcome-based agreements would tie the final price of a drug to results achieved by specific patients rather than using a predetermined price based on historical population data. Manufacturers would agree to provide rebates, refunds or price adjustments if the product does not meet targeted outcomes. In exploring this option, CMS would need to evaluate potential technological, programmatic and operational challenges that hospitals may face, such as agreeing to common outcome metrics and tracking them via hospital information systems.

- **Develop a comparative effectiveness evidence base.** We have little data on how different treatments perform relative to other treatments in their class. This information is critical to supporting providers in making care decisions, helping payers make coverage decisions and develop value-based purchasing models, and support policymakers in evaluating and advancing appropriate drug policy. While some of this work is being done by the government, such as through the Patient-Centered Outcomes Research Institute, and through private-sector initiatives, more must be done to collect and centralize this information. This proposal would require drug manufacturers to submit to FDA a dossier of comparative effectiveness research as part of the drug approval process, something that already is required by other countries as part of their drug review and approval processes. FDA would make this information publicly available and would serve as a starting point for assessing the value of an individual drug.

- **Align payment with the most commonly used dosage.** Many common medications are packaged in sizes that do not align with the most common dosages. Frequently, too much medication is included in the package, resulting in waste when a provider discards the now potentially tainted remaining content. One study found that packaging size alone results in $3 billion of wasted cancer drugs each year.[7] In this proposal, CMS would require drug manufacturers selling products that are used for Medicare and Medicaid beneficiaries to package drugs in the most common dosage or face reduced reimbursement. For example, if the most common dosage of a drug is 10ml but the drug is sold in 15ml vials only, the drug manufacturer would be required to provide a rebate for the portion of the drug above the common dosage amount unless the purchaser

[7] Bach, P. et al, "Overspending driven by oversized single dose vials of cancer drugs," BMJ, March 1, 2016

specifically requests a different amount. This proposal would incentivize manufacturers to align package sizes with common dosage amounts while not requiring mandatory reductions.

## IMPROVE ACCESS

Hospitals and the patients they serve need access to more affordable drugs. Policies in this category would immediately increase hospital and patient access to less costly, safe drugs.

- **Allow providers and patients to reimport drugs.** It is illegal for individuals or providers to purchase prescription drugs in other countries and bring them back into the U.S. for use. This prohibition includes drugs that were manufactured in the U.S. and sent to other countries for sale and distribution. Reimportation is enticing given the substantial price discounts that are available to purchasers in other countries. While the federal government has opted not to enforce this law against individuals who reimport U.S.-manufactured drugs for personal use, the practice remains illegal. It also is not available to hospitals or other providers who could benefit from access to substantially lower cost drugs. The federal government could loosen restrictions around reimportation to allow individuals, hospitals and other providers to purchase drugs in other countries that were either: a) manufactured in the U.S., or b) manufactured in another country that meets or exceeds U.S. safety standards for drug manufacturing. Under this proposal, FDA would conduct an assessment of the manufacturing standards in other countries and identify those that meet U.S. standards. In addition, FDA would require that any drugs that are imported follow safe transport guidelines.

- **Require mandatory, inflation-based rebates for Medicare drugs.** The Medicaid program consistently achieves better pricing on drugs than the Medicare program. For example, in 2012, the Department of Health and Human Services Office of Inspector General (OIG) found that Medicaid programs achieved rebates worth 47 percent of Medicaid expenditures, while Medicare Part D plan sponsors achieved rebates worth only 15 percent of their expenditures. Medicaid programs also were able to negotiate net unit costs of less than half of the amount paid by Part D sponsors for 110 of the 200 drugs evaluated by OIG. Part D sponsors were only successful in negotiating lower net unit prices for five of the drugs.[8] Other evidence suggests consistent findings for other drugs purchased for Medicare beneficiaries through Part B of the program. In a 2013 report, OIG found that Medicare could have saved $2.4 billion (or 26 percent) in Part B spending in 2010 if drug manufacturers had provided Medicare with the same rebates they give to Medicaid programs for just 20 high-cost drugs.[9]

  The primary driver behind the lower net unit costs were mandated, additional rebates that

[8] HHS Office of Inspector General, "Medicaid Rebates for Brand-name Drugs Exceeded Part D Rebates by a Substantial Margin," April 2015.
[9] Office of Inspector General, "Medicare Could Collect Billions if Pharmaceutical Manufacturers Were Required to Pay Rebates for Part B Drugs," September 2013.

kick in when the average manufacturer price (AMP) for a drug increases faster than inflation. This proposal would implement a similar inflation cap 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 proposal would protect the program and beneficiaries from dramatic increases in the Medicare payment rate for drugs, such increases in the range of 533 percent (Miacalcin, used for treating bone disease), 638 percent (Neostigmine, used in anesthesia) and 1,261 percent (Vasopressin, used to treat diabetes and bleeding in a critical care environment). Such a policy also could potentially generate savings for drugs with price growth above the inflation benchmark.

**ALIGN INCENTIVES**

Incentives within the health care system do not always direct patients, payers, drug manufacturers or providers to the highest-quality, lowest-cost drug alternatives. These policy proposals would help align incentives toward high value.

- **Implement stricter requirements on direct-to-consumer (DTC) advertising disclosures.** The U.S. is only one of two countries that allows DTC advertising. Physicians routinely report that they receive pressure from patients to prescribe specific drugs based on advertisements. DTC advertising costs drug manufacturers billions of dollars each year and, thus, directly contributes to the price of a drug. Such advertising also drives up health care spending by increasing patient demand for newer, more expensive drugs, even when earlier versions or generics may work just as well.

  In 1999, rules governing how much information must be included in DTC advertising were loosened. Since then, there has been an explosion of new ads directed at consumers. While some helpful information is provided to consumers on the drug's use and potential side effects, little to no information is provided on how the drug compares clinically and from a cost perspective to other alternatives. Pricing information also is not required. This policy proposal would direct FDA to implement stricter rules around DTC advertising, specifically requiring additional critical information – such as drug list price for a common course of treatment (or annually in the case of drugs that manage ongoing, chronic conditions) and comparative effectiveness results – to consumers.

- **Remove tax incentives for drug promotion activities.** Drug manufacturers can write off billions of dollars that they spend promoting their products. This not only gives these multi-billion dollar organizations a tax break, it encourages them to promote drugs directly to consumers and prescribers. Information included in these promotions is often incomplete, fails to disclose how the product compares to other treatments in its class and the anticipated cost of a course of treatment, and is linked to increased demand for higher cost drugs. This proposal would remove the tax breaks for drug promotion activities.

- **Develop prescriber education and clinical decision support tools, including prescriber monitoring programs.** This proposal would direct CMS to work with providers to develop clinical decision support and benchmarking tools for drug prescribing practices. Clinical decision support tools could provide prescribers with evidence-based and timely information to help them select the most clinically effective drugs for their patients and promote safe prescribing. Benchmarking tools enable providers to compare their performance with their peers at the local, state and national levels. Similar tools already in use in some hospitals and health systems have been effective in changing clinicians' practice patterns to better align with evidence-based developments and best practices.

- **Test changes to the federally-funded Part D reinsurance program.** Under the Part D prescription drug program, the federal government covers 80 percent of the costs for enrollees who cross the out-of-pocket threshold. Insurers and beneficiaries share the responsibility for the remaining 20 percent, at 15 and 5 percent, respectively. These reinsurance payments are substantial: in 2013, the federal government's portion totaled nearly $20 billion for approximately 2 million Medicare beneficiaries.[10] 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. This proposal would require that CMS 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. CMS could 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 the Medicare Payment Advisory Commission's recent recommendation on improvements to the Part D program.

- **Vary patient cost-sharing for certain drugs based on value.** Cost-sharing can be a strong incentive for patients and their providers to select the most clinically and cost-effective drug regimen available ("high value" drug). Lower cost-sharing also supports greater compliance with treatment plans and, therefore, could help decrease unnecessary utilization across the health care system, such as unplanned emergency department visits and hospitalizations. This policy would decrease or eliminate cost-sharing to improve beneficiaries' access and appropriate use of high-value drugs.

[10] MedPAC, "Chapter 6: Sharing risk in Medicare Part D," June 2015.