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April 24, 2017

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Room 445-G
Washington, DC 20201

RE: Medicare Advantage and Part D Programs Request for Information

Dear Ms. Verma:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations and 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) appreciates the opportunity to comment on ways to improve the Medicare Advantage (MA) and Part D programs. The MA program is an important source of coverage for approximately a third of Medicare beneficiaries. More than 60 AHA members sponsor MA plans, and nearly all of our members contract with such plans to provide services to enrolled Medicare beneficiaries.

The MA and Part D programs are a success when measured on metrics such as marketplace competition, consumer satisfaction and quality of care. However, there are a number of areas where the program can be improved as part of continuous efforts to advance health care quality, health outcomes and health system efficiency. Below we offer recommendations for your consideration, several of which would require action by both the agency and Congress.

CMS ENGAGEMENT WITH PROVIDERS CONTRACTING WITH MA PLANS

In general, providers and plans work closely together to ensure that beneficiaries receive the high-quality care they need. There are times, however, when disputes arise. In some cases, these disputes are contractual in nature, and we appreciate that the Centers for Medicare & Medicaid Services (CMS) cannot be involved in such issues, as it is not a party to the contract. However, in other instances, these disputes arise out of lack of clarity regarding federal policy. In those cases, it is in all parties' interests – providers, plans and CMS – for the agency to provide a definitive reading of federal law and regulation and an interpretation of appropriate implementation of such policies by plans. In the past, providers have found it challenging to

engage CMS on these issues, and we ask that the agency commit to reviewing and responding to provider questions in a timely manner and, as necessary, issue clarifying guidance to plans and providers alike.

PAYING QUALITY BONUS PAYMENTS IRRESPECTIVE OF BENCHMARK CAP

CMS continues to include quality bonus payments when calculating whether a plan has met or exceeded the maximum payment threshold (benchmark cap). As a result, some high-performing MA plans are not receiving their full bonus payment. CMS has acknowledged that this "diminishes incentives for MA plans to continuously improve the care provided to Medicare beneficiaries," but argued that it does not have legal authority to pay the full bonus amount irrespective of the benchmark cap.[1] We disagree and believe that CMS's interpretation impedes access to vital resources that high-quality plans may use to further improve the quality of care and expand access to services. Specifically, we believe that the law directs the agency to only *consider* the bonus payment amount when calculating rates for purposes of applying the cap and, therefore, is not required to include such amounts. **We urge CMS to reconsider its interpretation of the statute, which is unquestionably inconsistent with its well-documented policy goals of incentivizing the highest quality care and coverage.**

INCREASING QUALITY OF CARE AND CONVENIENCE FOR MA ENROLLEES THROUGH TELEHEALTH

Innovation in technology has the potential to increase Medicare beneficiaries' timely access to services, which may increase the quality of care, improve patient satisfaction and reduce costs for the health care system. **CMS and Congress should pursue all avenues to expand access to services via telehealth, including removing barriers caused by the geographic location and practice setting "originating site" requirements and restrictions on covered services and technologies. MA plans also should be permitted to submit costs associated with telehealth as part of their bid amounts.**

At the same time, the MA program requires that plans meet certain network adequacy standards, such as the maximum travel distance and travel time for enrollees to reach providers, as well as a minimum number of providers serving MA enrollees in that plan. While telehealth holds the promise of improving access to certain health care professional for MA enrollees, it should not be used to substitute for meeting the MA plan network adequacy requirements.

ADAPTING BENEFITS TO MEET THE NEEDS OF MA ENROLLEES

In most instances, insurers must provide all plan enrollees with the same set and scope of benefits. We recognize that such a policy is intended to prevent discrimination and ensure access to care for all enrollees. However, this requirement has the negative consequence of preventing

[1] Centers for Medicare & Medicaid Services, "Advance Notice of Methodological Changes for Calendar Year (CY) 2018 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2018 Call Letter," February 1, 2017.

plans from addressing the unique needs of some enrollees. In some cases, a small subset of enrollees would benefit from a certain specialized service, but plans are unable to offer it due to the resources required to make such a service available to all enrollees. **We encourage CMS and Congress to give plans the flexibility to tailor their products to better meet the needs of subsets of enrollees, such as by expanding the concept of value-based insurance design nationally.** Consistent with existing oversight mechanisms, CMS could continue to monitor that all beneficiaries are receiving the care that they need and that such policies are not unintentionally resulting in adverse outcomes.

PERMITTING FOR HOLISTIC CARE THROUGH COVERAGE OF CERTAIN SOCIAL SERVICES

Many social, economic and demographic factors contribute to an individual's health, such as secure and safe housing, transportation, assistance with activities of daily living, and adequate nutrition and physical exercise. These factors often cannot be addressed by medical services alone, yet can have a negative impact on health outcomes, patient experience of care and total cost of care. MA plans currently have limited options for providing non-medical social services to help address these underlying social determinants of health. **We encourage CMS to allow plans to offer non-medical social services and include the costs associated with these services in their bid amounts.**

In addition, we strongly encourage CMS to allow plans to provide other supplemental services that will facilitate keeping individuals in their homes. Patients typically prefer this, and the home can be the most efficient site of care. Two examples of such services include personal care services for beneficiaries who do not have a need for skilled care and remote patient monitoring.

ENSURING ACCURATE PAYMENT

The AHA strongly urges CMS to further explore refinements to the Hierarchical Condition Categories (HCC) risk-adjustment model, specifically adjusting for socioeconomic and demographic information. We applaud the agency for recent changes that better account for dual-eligible status. However, these changes do not go far enough. There is a strong and growing body of evidence that a number of patient characteristics impact health outcomes, health care utilization and cost of care. The National Academies of Medicine (NAM) recently identified five social – not medical – factors that influence access to care, health care use, health outcomes and cost:

1) socioeconomic position (SEP);
2) race, ethnicity and cultural context;
3) gender;
4) social relationships; and
5) residential and community context.[2]

[2]National Academies of Sciences, Engineering, and Medicine. 2016. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: The National Academies Press. https://doi.org/10.17226/21858

These factors are not fully accounted for in the HCC risk-adjustment model and should be considered for future adjustments. Better accounting of sociodemographic information, where appropriate, will ensure that plans are adequately reimbursed for more complex patients. Failing to account for these factors when establishing reimbursement rates can harm patients and worsen health care disparities by diverting resources away from plans serving large proportions of disadvantaged patients and their network providers.

PROVIDING MA ENROLLEES WITH HOSPICE BENEFITS

The AHA supports the integration of hospice services into the MA benefit package. Today, hospice benefits for MA enrollees are coordinated and delivered through the fee-for-service Medicare program while other covered, but "unrelated," services are managed separately by the MA plan. Integrating these two care coordination streams may enhance the quality and efficiency of care, as well as the patient and family experience.

In pursuing this change, however, adequate beneficiary safeguards must be put in place. Plan rates will need to be adjusted to incorporate costs associated with the hospice benefit. Additionally, nothing in the integration of these services or in the development of the plan rates should disrupt or dismantle the important interdisciplinary structure of hospice services, which includes social work, chaplaincy and family bereavement services in addition to the management of pain and other symptoms. Moreover, given the unique nature of this benefit, plans should be required to implement instant coverage determinations and expedited appeals processes for coverage denials.

PROVIDING CONTINUED ACCESS TO MA SPECIAL NEEDS PLANS (SNPS) FOR VULNERABLE POPULATIONS

The AHA recognizes the importance of offering tailored plans to individuals with special needs and supports making SNPs a permanent component of the MA program. Currently, the SNP program is set to expire on Dec. 31, 2018. **We encourage CMS to work with Congress to extend or make permanent the SNP program while making critical program reforms, particularly to remove the excessive regulatory burden facing plans.** For example, plans must make all services available to all enrollees, whether they are necessary and appropriate for a particular beneficiary nor not. This means that they have limited ability to tailor benefits to different enrollees within a SNP, an important shortcoming because, despite sharing many common characteristics, no two enrollees are alike. We strongly encourage CMS and Congress to reduce the administrative burdens associated with SNP plans.

REDUCING THE AMOUNT OF ENCOUNTER DATA USED TO FORMULATE RISK SCORES

We applaud CMS's recent decision to reduce the portion of the risk score that is based on encounter data. We continue, however, to have strong reservations about relying on encounter data to calculate risk scores at this time. Specifically, provider data collection efforts were not designed to support MA risk-adjustment calculations. For example, in some cases, certain

provider billing systems limit coding to only four diagnoses. In other cases, some providers choose to only code some diagnoses, not all. While the coding done by providers may be sufficient for treatment and their own billing purposes, it could lead to undercoding for purposes of MA risk adjustment, which may inadvertently reduce plan risk scores.

These challenges continue to be documented by the Government Accountability Office (GAO), which earlier this year updated its report on CMS's efforts to ensure the quality and accuracy of encounter data. The GAO found that "CMS has yet to undertake activities that fully address encounter data accuracy… Given the agency's limited progress, GAO continues to believe that CMS should implement GAO's July 2014 recommendation that CMS fully assess data quality before use."[3] **We encourage CMS to reconsider use of encounter data until the issues related to data quality and provider and plan burden are resolved.**

ADDRESSING HIGH AND RISING DRUG PRICING

CMS repeatedly has raised concerns about the impact of unanticipated and excessive increases in drug prices on the Part D prescription drug program. In Attachment A, we provide for your consideration a comprehensive set of policy recommendations to address the unsustainable increases in drug prices. We particularly point you to those that could be used within the Part D programs, including disallowing co-pay assistance cards; using Center for Medicare and Medicaid Innovation authority to develop and test Medicare-negotiated value-based purchasing arrangements that could be used by Part D sponsors; and building on CMS's existing drug pricing dashboards to issue consumer and provider-facing annual reports on drug pricing.

We thank you again for the opportunity to comment on ways to improve the MA and Part D programs. Please contact me if you have questions or feel free to have a member of your team contact Molly Smith, senior associate director of policy, at (202) 626-4639 or mollysmith@aha.org.

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President

[3] Government Accountability Office, "Limited Progress Made to Validate Encounter Data Used to Ensure Proper Payments," January 2017.

ATTACHMENT A:
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.

- **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

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

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 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.

[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

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.

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DRUG PRICE PROPOSALS

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 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

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

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 evidence-based clinical practice guidelines that are competent and reliable. The AHA recognizes that additional work would be needed to determine the clinical

[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

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 specifically requests a different amount. This proposal would incentivize manufacturers

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

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 kick in when the average manufacturer price (AMP) for a drug increases faster than

[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.

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.