

# 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 follow-up to a 2016 survey, the NORC at the University of Chicago recently found that hospitals and health systems continue to face unsustainable increases in drug spending. Between 2015 and 2017, total hospital and health system spending on drugs increased on average by 18.5 percent per admission, including a jump of 28.7 percent per outpatient adjusted admission.<sup>1</sup> These increases follow record growth in prescription drug spending of 38.7 percent in the inpatient setting from 2013 to 2015, as documented in our previous survey.<sup>2</sup> In 2015, 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. The cost of hydralazine jumped 723 percent, while the cost of neostigmine methylsulfate rose by 421 percent.<sup>3</sup> While 2015 was a peak year for drug price hikes by manufacturers, increases continue to present significant challenges for hospitals and health systems. In 2017 increases continued for drugs like mitomycin, which is used to treat cancer, and hydromorphone, an injectable opioid. Mytomycin nearly doubled, increasing by 99 percent, and hydromorphone increased by 107 percent. The overwhelming majority of hospitals that responded to the survey cited undertaking numerous measures, including downsizing staff, delaying capital investments, and employing alternative therapies, to cope with the high cost of drugs.

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.

The AHA continues to work with its members to document the challenges hospitals and health systems face with high drug prices and develop policy solutions to protect access to critical therapies while encouraging and supporting much-needed innovation. 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 and Innovation

Competition for prescription drugs generally results in increased options for lower cost therapies, particularly through the introduction of one or more generic competitors. 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.** Despite making progress, FDA still 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.<sup>4</sup> 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 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.
- **Provide additional guidance on the biosimilar interchangeability approval process.** While biosimilar drugs continue to receive FDA biosimilar approval, none have been granted interchangeability status. Like generic drugs, biosimilars increase competition for biological products, ultimately driving down the overall cost of these types of drugs. In order to increase biological product competition, FDA should provide additional guidance on the interchangeability approval process for biosimilar drugs and work to incentivize biosimilar products to strive for interchangeability.
- **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. 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. For example, Humira (adalimumab), Procrit (epoetin alfa) and Prolia (denosumab) all are approved for orphan drug status; however, since receiving the designation, the drugs also have been marketed for a number of other, non-rare indications. Further, each of these drugs were among the top 10 highest-spend drugs for hospitals and health systems, and each had substantial price increases of at least 15 percent from 2015-2017.<sup>5</sup>

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.** CMS began publicly reporting on the costs associated with drugs covered by Medicare Part B or Part D, as well as Medicaid.<sup>6</sup> While this is an important first step, we encourage the agency to do more to translate this information into easy-to-use resources to help providers and consumers take the cost of a medication into account when making care choices.



## 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;<sup>7</sup> and Eli Lilly and Anthem are working together to develop outcomes-based contracts for drugs.<sup>8</sup>

Under this proposal, CMS would take a leading role in developing demonstration programs through its Center for Medicare and 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 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.<sup>9</sup> 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 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.<sup>10</sup> 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.<sup>11</sup>

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 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.

In addition, in November 2018, CMS issued a notice of proposed rulemaking (NPRM) to modernize the

way in which Part D plan sponsors can negotiate drug prices and set their formularies. Specifically, the NPRM proposed flexibility for the six protected classes of drugs that are required to be covered by Part D plans. If finalized, the rule would provide three exceptions to the current rules allowing Part D plans to exclude certain drugs from their formularies with the objective of negotiating lower drug prices, benefitting both beneficiaries and taxpayers.

## 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. Drug manufacturers spend billions of dollars each year on DTC advertising, ultimately contributing to the higher price tag 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. In October of 2018, CMS issued a NPRM to require certain disclosures from drug manufacturers in DTC advertising. Specifically, if finalized, this rule would require drug manufacturers to provide the current list price of the marketed drug. While we applaud this move, additional steps are necessary to fully address this issue. For example, CMS and FDA should require additional critical information – such as 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. Additionally, in order to foster increased competition, drive down the price of prescription drugs and increase biosimilar utilization when appropriate, the clinical decision support tools could include relevant information and educational materials focused on familiarizing prescribers with biosimilar products and their clinical equivalence and applicability. 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.<sup>12</sup> 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 a Medicare Payment Advisory Commission 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.

## Sources

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