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# Policy Options to Manage Drug Spending

Proposals to reduce costs and ensure patient access to needed therapies



U.S. spending on pharmaceuticals exceeded \$450 billion in 2016. With patients and taxpayers shouldering a large portion of this financial burden, lawmakers have considered a range of policies to address the rising cost of pharmaceuticals.

In response, Pew's drug spending research initiative developed a series of fact sheets that examine many of these policies and focus on two areas: increasing competition and reforming Medicare Part D. Each fact sheet summarizes the policy proposal, evaluates its potential to manage drug spending, and outlines key issues for policymakers to consider.

As policymakers and health stakeholders debate federal approaches to drug spending, these analyses can inform that discussion.

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# Policy Proposal: Importation of Prescription Drugs

A series that examines policies to manage drug spending

## What problem is this policy meant to address?

Allowing prescription drugs to be purchased and imported from abroad has the potential to lower health care costs in the U.S. In the short term, patients could access some medicines at lower prices, since brand pharmaceuticals are generally more expensive in the United States than in other high-income countries, in part because some nations have taken steps to limit drug prices. In the long term, increased competition from imported drugs could put pressure on drug companies to reduce the price of their products in the U.S.

## How could this policy work?

Some proposed policies would allow pharmacies, wholesalers, and patients to purchase prescription drugs from other countries if the Food and Drug Administration has approved a version of the same drug for use in the U.S., which is currently illegal.<sup>1</sup> For example, the Affordable and Safe Prescription Drug Importation Act, introduced in 2017, would allow these entities to purchase drugs and biologics from sellers in Canada who are certified by the U.S. secretary of health and human services (HHS).<sup>2</sup> Individuals with a valid prescription from a U.S. health care provider could import up to a 90-day supply of drugs for personal use from pharmacies licensed to dispense drugs in Canada.<sup>3</sup> The legislation would also, after two years, give the secretary authority to allow importation of drugs from member countries of the Organization for Economic Cooperation and Development that meet certain regulatory standards comparable to those in the U.S. Controlled substances and compounded drugs would not be eligible.

The Congressional Budget Office (CBO) estimated that potential savings from a similar policy—the Pharmaceutical Market Access Act of 2003, which would have allowed pharmacists, wholesalers, and individuals to import drugs from 25 countries, among them Australia, Canada, Japan, and a number in Europe<sup>4</sup>—could have produced total savings of \$40 billion over 10 years in the U.S., including savings of \$2.9 billion for the federal government.<sup>5</sup> (This estimate does not take into account any savings in the Medicare Part D program, as it was signed into law in late 2003.) The CBO also estimated that savings from the policy would be minimal if imports were permitted only from Canada.<sup>6</sup>

Another proposed policy, the Pharmaceutical Supply and Value Enhancement Act, or Pharmaceutical SAVE Act, would allow the temporary importation of off-patent drugs for which a “noncompetitive market”—one in which fewer than five versions of an off-patent drug (approved at least 10 or more years ago) are available for at least two consecutive months<sup>7</sup>—exists in the U.S. The drug’s manufacturer would be required to certify an intention to seek FDA approval. There are no published estimates of potential savings attributable to this policy.

## What should policymakers consider?

Current law requires FDA to determine that each drug is safe and effective before it can be marketed in the U.S., approving not just the drug itself, but also the manufacturing location, source of active ingredients, processing methods, and many other factors that may affect the product's safety or effectiveness.<sup>8</sup> In some rare cases, in response to a drug shortage, FDA has allowed the temporary importation of certain approved drugs from unapproved sources. In these instances, the agency evaluates the foreign products to ensure that they are of adequate quality and do not pose significant risks to U.S. patients.<sup>9</sup> In addition, a 2003 federal law gave the HHS secretary the authority to permit importation of prescription drugs from Canada if the secretary certifies to Congress that they would pose no additional risk to the public's health and safety, and would result in a significant reduction in the cost of the drugs to Americans.<sup>10</sup> However, the secretary has never made such a certification.

Because the importation of drugs from foreign sources would bypass current FDA review processes by creating a separate certification process, it could increase safety risks. For example, some U.S. consumers have placed prescription orders online with pharmacies that falsely promoted themselves as Canadian,<sup>11</sup> and FDA identified a number of cases where consumers purchased counterfeit prescription drugs through websites that were operated by Canadian pharmacies.<sup>12</sup>

To reduce the potential risks associated with importing unapproved drugs, FDA would need additional resources and capacity. In a 2004 congressional hearing, FDA's then-commissioner speculated that a program to ensure the safety of imported drugs could cost hundreds of millions of dollars annually.<sup>13</sup> Funding would need to come from congressional appropriations or fees on industry, which could reduce the net savings from importation.

Also unclear is how imported drugs could comply with established measures to ensure that counterfeit and diverted drugs do not enter the pharmaceutical supply chain. The Drug Supply Chain Security Act (Title II of the Drug Quality and Security Act of 2013) requires that pharmaceutical manufacturers and repackagers put a unique product identifier on most prescription drug packages and outlines steps to build an electronic, interoperable system for identifying and tracing prescription drugs as they are distributed in the United States.<sup>14</sup>

Importing drugs into the U.S. could also affect foreign markets, and pharmaceutical manufacturers might alter their pricing strategies. To mitigate decreased U.S. revenue, manufacturers could seek to increase their prices abroad. In addition, the U.S. market's large size could strain the supply of pharmaceuticals, resulting in drug shortages in other countries if importation were to be implemented on a large scale.

## Endnotes

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- 2 Affordable and Safe Prescription Drug Importation Act, S. 469, 115th Cong. (2017), <https://www.congress.gov/bill/115th-congress/senate-bill/469/text?q=%7B%22search%22%3A%5B%22the+Affordable+and+Safe+Prescription+Drug+Importation+Act%22%5D%7D&r=1>.
- 3 Currently under the FDA's Personal Importation Policy, the agency may at times exercise enforcement discretion under certain circumstances. Food and Drug Administration, "Personal Importation Policy (PIP) Frequently Asked Questions (FAQs)," accessed March 27, 2017, <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/ImportsandExportsCompliance/UCM297909.pdf>.
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# Policy Proposal: Improving Generic and Biosimilar Developer Access to Brand Pharmaceutical Samples

A series that examines policies to manage drug spending

## What problem is this policy meant to address?

Generic and biosimilar manufacturers, or drug developers,<sup>1</sup> report that they have been unable to purchase samples of innovator drugs<sup>2</sup> for their product development.<sup>3</sup> Without access to these drugs, generic developers cannot conduct the testing required for Food and Drug Administration approval. They can sue brand companies for violating antitrust law, but this type of litigation can take years to conclude,<sup>4</sup> and it can be difficult for generic developers to demonstrate that a brand developer's actions caused harm to either them or consumers. As a result, patient access to generic drugs is delayed.

Generic developers assert that their ability to bring products to market is limited in three main ways:

1. Lack of access to drugs with FDA-mandated risk mitigation requirements that include elements to assure safe use.
2. Lack of access to drugs with company-initiated restricted distribution.
3. Inability to reach agreement on a statutorily required shared risk mitigation plan with innovator drug developers.

Risk evaluation and mitigation strategies (REMS) are FDA-required management plans to help ensure that the benefits of certain prescription drugs outweigh their risks.<sup>5</sup> As of May 2017, there are 71 different REMS in place for currently marketed medications.<sup>6</sup> Many REMS simply require the distribution of information to the patient, but 42 have elements to assure safe use (ETASU).<sup>7</sup> For example, an ETASU REMS may include a requirement that pharmacies, practitioners, or health care settings dispensing a high-risk drug be specially certified to handle the product, which limits the distribution of these drugs to qualified entities.

While ETASU REMS are intended to reduce specific serious risks listed in the labeling of the drug, generic developers may have difficulty acquiring samples of innovator drugs subject to these requirements, as the statute contains no provision to explicitly require makers of these drugs to sell product samples to generic developers. Current law prohibits drugmakers from using ETASU REMS to block or delay the approval of a generic drug application or to prevent a generic developer from participating in a shared ETASU REMS program with the innovator company.<sup>8</sup> The law also provides FDA the authority to deem a drug misbranded or levy fines on brand drug developers in violation.<sup>9</sup> However, the agency has not taken enforcement action against any manufacturer for violating these requirements.

If a generic developer encounters challenges in obtaining access to a drug subject to ETASU REMS, it can be difficult for FDA to determine that a brand developer is restricting access to the product in order to block or delay

a generic application. In many cases, innovator drug developers raise patient safety concerns. In fact, FDA has stated that alleged abuses of REMS to delay or block competition would be best addressed by the Federal Trade Commission (FTC), to which it refers generic developer complaints about access to ETASU REMS products.<sup>10</sup> The FTC has filed amicus briefs in private antitrust lawsuits to express its concern about potential REMS abuses,<sup>11</sup> but it has never filed an antitrust claim against a manufacturer alleging this conduct.

Even when a REMS is not required, some manufacturers elect to limit the distribution of their products.<sup>12</sup> For example, a brand manufacturer may only offer its product through a distribution arrangement with a single wholesaler that, under its agreement with the brand manufacturer, is restricted from selling the drug to generic developers. Like ETASU REMS, this can prevent generic developer access to brand drug samples. The FTC has asserted that actions to prevent generic developer access to innovator drugs may violate antitrust laws.<sup>13</sup>

## REMS for generic products

In addition to the necessity for a generic manufacturer to obtain product samples for testing, a generic version of a drug with an ETASU REMS requirement is subject to the same safeguards as the original product. Innovator and generic developers of drugs with ETASU REMS are required to participate in a single, shared REMS protocol, unless FDA waives the requirement.<sup>14</sup> However, some generic developers have raised concerns that innovator manufacturers make it difficult for them to participate in a joint REMS protocol.<sup>15</sup> Patient access to these products can be delayed if the brand and generic manufacturers are unable to reach agreement on a shared REMS. By law, FDA may grant a waiver to the shared REMS requirement when 1) the burden of creating a single, shared system outweighs the benefits of such a system, taking into consideration the impact on health care providers, patients, the applicant for the abbreviated new drug application, and the holder of the reference drug product, or 2) when an aspect of the ETASU REMS is patent protected or is a trade secret and a generic developer is unable to obtain a license for its use.<sup>16</sup> On occasion, FDA has extended approval to a generic with a separate REMS protocol, citing its statutory authority to waive the shared REMS requirement.<sup>17</sup> One manufacturer has responded by suing FDA, arguing that the waiver granted by the agency did not meet statutory requirements,<sup>18</sup> but withdrew the complaint soon thereafter.<sup>19</sup>

Policies that improve generic developer access to brand products, streamline the development of shared REMS protocols, and speed up the resolution of disputes between innovator and generic developers have the potential to improve consumer access to generics.

## Policy options

Lawmakers have proposed two different policies that could improve the ability of generic developers to acquire innovator drugs for product development. The Fair Access for Safe and Timely Generics (FAST Generics) Act of 2017 seeks to ensure that REMS protocols and restricted distribution networks are not used to deny access to samples of innovator drugs.<sup>20</sup> Generic developers would be required to first receive authorization from FDA to obtain samples of ETASU REMS drugs. If testing of the product involves clinical trials, developers must submit a testing protocol that includes protections that will “provide an assurance of safety comparable” to that of the ETASU REMS of the innovator drug. After receiving FDA authorization, the generic developers would be entitled to purchase samples at a nondiscriminatory, commercially reasonable, market-based price from a drug wholesaler or other entity designated by the manufacturer of the REMS product. The request to purchase samples must be fulfilled within 30 days. In addition, the FAST Generics Act would improve generic developer access to samples of drugs not subject to REMS protocols by requiring brand manufacturers to sell sufficient quantities of non-REMS products to generic developers at market prices within 30 days of receiving a request.

The FAST Generics Act would also require that makers of innovator drugs with ETASU REMS not impede the development of a single, shared REMS or prevent a generic developer's entry into a previously approved REMS. In addition, it would allow FDA to waive the requirement for a single, shared REMS if a generic developer is unable to reach agreement with the innovator manufacturer on a single, shared REMS protocol within 120 days.

The FAST Generics Act would allow generic developers to sue innovator companies if they are improperly denied access to innovator product samples or if the innovator company impedes generic developer participation in a shared REMS protocol. If successful, a court could order the innovator company to sell samples of the requested drug to the generic developer; allow the generic developer to enter a single, shared ETASU REMS; and pay the generic developer damages, including amounts to deter future violations.

Another proposal, the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2017,<sup>21</sup> would expedite legal review when generic developers sue innovator companies for withholding access to product samples. Instead of having to prove that an innovator company has violated antitrust law, a generic developer would only need to demonstrate that a manufacturer has not complied with the generic developer's request to provide "sufficient quantities" of a drug for testing on "commercially reasonable, market-based terms." In the case of a product with an ETASU REMS, the generic developer may not sue unless it has received authorization from FDA to purchase product samples for testing. Authorization would be obtained after submitting a request to the agency. For product testing that involves clinical trials, the generic developer would have to submit testing protocols that provide safety protections comparable to the REMS of the innovator drug as well as meet any other requirements established by FDA.

If a generic developer brings a suit against an innovator company and is successful, the court could order the innovator company to sell samples of the requested drug to the generic developer; pay the generic developer's attorney fees and litigation costs; and pay the generic developer an additional monetary amount to deter the innovator company from refusing to sell sample product to other generic developers.

The CREATES Act would also allow a generic developer to establish its own ETASU REMS that uses "a different, comparable aspect of the elements to assure safe use," rather than participate in a single, shared REMS with the innovator drug developer. However, FDA could require manufacturers to participate in a single, shared REMS if it determines that "no different, comparable aspect of elements to assure safe use could satisfy" the REMS safety requirements.

## What should policymakers consider?

The Congressional Budget Office (CBO) estimated that the FAST Generics Act would generate \$2.35 billion in savings over 10 years for the federal government,<sup>22</sup> while the CREATES Act would generate \$3.3 billion in federal savings over the same period.<sup>23</sup> An analysis funded by the Association for Accessible Medicines, then known as the Generic Pharmaceutical Association, concluded, based on a 2014 survey of generic manufacturers to identify instances of restricted access, that there could potentially be \$5.4 billion in annual savings, including \$1.8 billion in savings for the federal government, if generic versions of REMS and non-REMS brand drugs available only through limited distribution were to immediately come to market.<sup>24</sup>

These analyses produce different estimates because they model slightly different policies. They may also diverge due to differences in underlying assumptions. A comparison of these assumptions is not possible, because the CBO analyses are not public. A critical assumption for producing any savings estimate is the amount of spending on drugs currently unavailable to generic developers due to REMS restrictions and other kinds of limited distribution. According to the survey of generic manufacturers mentioned above, 40 such

medicines were identified. However, this number has not been independently verified. In fact, no other published research has systematically and transparently documented the extent to which REMS and other kinds of limited distribution have resulted in restricted access for generic developers. This makes it difficult to estimate potential savings from new policies. Nevertheless, the spending on some brand drugs available only through limited distribution is high. For example, Medicare spent over \$2 billion in 2015 on Revlimid,<sup>25</sup> a drug used to treat multiple myeloma that was approved by FDA on the condition that the manufacturer implement an ETASU REMS protocol.

Some experts have also raised concerns that new policies intended to improve generic developer access to innovator product samples could increase risks to patients.<sup>26</sup> For example, the CREATES Act allows generic developers to obtain FDA authorization to purchase product samples for testing. To obtain authorization in cases where development and testing involve clinical trials, a generic developer would be required to show that its protocols provide safety protections that are “comparable to those” of existing brand REMS and that it meets any other requirements FDA establishes. Some experts believe that a standard that does not require the protocol to provide protections “equivalent” to the brand REMS may result in less rigorous safety protections for patients.<sup>27</sup>

While current proposals would not seek to reduce safety precautions for REMS drugs, policymakers may want to consider whether new approaches place unwarranted administrative and financial burdens on FDA. For example, requiring the agency to play a central role in mediating negotiations between manufacturers of innovator drugs and generic developers regarding the purchase of samples or the development of shared REMS protocols would likely be time-consuming and resource-intensive.

Another consideration is the trade-off between policies that would require a single, shared REMS compared with those that would allow for separate REMS protocols for brand and generic versions of a drug. In some cases, separate REMS programs may require pharmacies and prescribers to spend additional time enrolling in or training to participate in multiple REMS systems.<sup>28</sup> This approach may be less efficient than mandating a single, shared REMS system.

However, a single, shared REMS protocol may be difficult to implement, especially if elements of the innovator product REMS are patent-protected. In such cases, policymakers could require brand developers to license underlying patents to the generic manufacturer.

It is important that generic developers comply with REMS standards, but the existence of a REMS program is not intended to impede generic development. Policies to remove unnecessary barriers would be beneficial. Negotiations on a shared REMS are complex and require agreement on several topics, including the design of the shared REMS, coordination of reporting, creation of standards for data collection, protocol for shared decision-making, and resolution of legal issues involving intellectual property and product liability. Furthermore, negotiations often involve multiple generic developers seeking to join a single, shared REMS with an innovator drug developer. Policies that impose specific conditions, such as the price at which a product sample must be sold, may constrain the ability of manufacturers to negotiate a mutually beneficial agreement, resulting in further delays in settlement and generic approvals.

## Endnotes

- 1 Generic and biosimilar manufacturers are referred to as “generic developers” throughout the rest of this fact sheet for brevity.
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# Policy Proposal: Banning or Limiting Reverse Payment Agreements

A series that examines policies to manage drug spending

## What problem is this policy meant to address?

Reverse payment agreements, also known as “pay-for-delay” deals, are settlements that involve a brand pharmaceutical manufacturer paying<sup>1</sup> one or more potential generic competitors to resolve patent infringement lawsuits and agree upon a date by which the generic product can come to market. In fiscal year 2014 there were 21 such settlements involving 20 different branded drugs.<sup>2</sup>

Reverse payment agreements originate with the requirement that, before the first generic version of a drug can be sold, its manufacturer must certify that it will not market the product until after all relevant patents have expired. Alternatively, the generic drugmaker may certify that the underlying brand patents are invalid or not infringed by the generic product, referred to as a Paragraph IV challenge.<sup>3</sup> Brand manufacturers often respond to Paragraph IV challenges by filing a patent infringement lawsuit against the generic developer. Critics argue that resolution of such lawsuits through reverse payment agreements delays market entry for generic drugs, inhibiting competition.

The Federal Trade Commission (FTC) and private purchasers have taken legal action against brand and generic drugmakers for entering into allegedly anticompetitive reverse payment agreements, some of which have resulted in manufacturers agreeing to compensate drug purchasers.<sup>4</sup> While the Supreme Court found in 2013 that reverse payment deals are subject to antitrust scrutiny, even when a settlement allows a generic to enter the market before the expiration of the patent, in the same ruling it also concluded that reverse payment deals are not presumptively illegal.<sup>5</sup> Beyond this, the court did not provide clear guidance for how lower courts should review reverse payment agreements. The FTC has observed that the number of these agreements appears to have declined since the 2013 ruling.<sup>6</sup>

Research suggests that reverse payment settlements are associated with delayed access to generics and higher prices, compared with cases that go to court.<sup>7</sup> Proponents of eliminating these settlements argue that such an approach could make generics available sooner, thereby lowering drug costs.

## How could this policy work?

Some policymakers have proposed a ban on reverse payment agreements. For example, the Protecting Consumer Access to Generic Drugs Act of 2013 would have prohibited manufacturers from entering into these deals.<sup>8</sup> It also would have allowed the FTC to develop a policy to exempt agreements that are “procompetitive” and thus benefit consumers. To implement this approach, the agency would need to publish its criteria for evaluating the impact of these deals on consumers. Factors that FTC could consider include the strength of underlying patents, manufacturers’ litigation costs and desire to avoid the uncertainty of patent dispute litigation, and the fact that brand manufacturers often have information on their products that is unavailable to others.

Another approach could discourage reverse payment agreements by shifting the burden of proof regarding potential harm to the manufacturers. Current law requires the FTC (or another plaintiff) to prove in court that reverse payment deals are harmful to consumers, but the Preserve Access to Affordable Generics Act would make reverse payment agreements presumptively unlawful.<sup>9</sup> As a result, manufacturers sued by the FTC or private purchasers for entering into a reverse payment deal would have the burden of demonstrating to a court that the benefits of a proposed agreement outweigh the anticompetitive effects. Brand and generic drug manufacturers in violation could be subject to a fine, and generic developers could potentially lose the 180-day exclusivity period normally awarded to the first generic on the market. The legislation would not prohibit reverse payment deals in which the brand manufacturer's payment to the generic company is limited to reasonable litigation expenses not to exceed \$7.5 million and/or an agreement not to sue the generic manufacturer for patent infringement.

In 2009, the FTC estimated that these agreements cost consumers and taxpayers \$3.5 billion annually,<sup>10</sup> but this estimate preceded the Supreme Court ruling and the subsequent decline in potentially unlawful reverse payment agreements. In addition, this analysis relied on data collected on settlements through fiscal year 2008 and estimated savings for drugs with potential settlements, according to information the FTC downloaded from the Food and Drug Administration's website in May 2009.<sup>11</sup> The Congressional Budget Office has estimated that the Preserve Access to Affordable Generics Act would reduce federal spending by \$2.4 billion over 10 years.<sup>12</sup> While the complete methodology underpinning the CBO analysis is not publicly available, the estimate was released in 2015.

## What should policymakers consider?

Brand and generic manufacturers oppose policies that would limit their ability to enter into these deals, arguing that a ban or limits could delay consumer access to generics.<sup>13</sup> One consideration is whether a ban on all reverse payment deals could prevent procompetitive settlements, delaying some generic drugs from coming to market. A reverse payment deal may be procompetitive if it results in a generic drug coming to market before the expected conclusion of litigation. Or, in cases where the brand patent is strong and likely to be upheld in court, a reverse payment deal that allows a generic to come to market prior to patent expiration may have procompetitive effects. In either of these cases, the settlement may benefit consumers by accelerating access to a lower-cost drug.<sup>14</sup> However, the competitive effects of these settlements are complex and require that each deal be evaluated separately. A wide range of factors must be considered, including the strength of the patent and litigation costs. While the Supreme Court did not provide a clear framework for how to evaluate reverse payment settlements, the FTC could develop guidance on how to assess their competitive effects.

Currently, the FTC challenges only a small number of reverse payment settlements, though the agency reported that 21 such settlements occurred in fiscal 2014.<sup>15</sup> While reducing the number of these agreements could generate savings, this policy might only deter anticompetitive agreements that the FTC and purchasers can already successfully challenge under current law. Alternatively, the policy may enable the agency and purchasers to pursue more cases against manufacturers, which could result in faster generic approvals and lower drug spending.

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# Policy Proposal: Expedited Review of Generic Drug Applications

A series that examines policies to manage drug spending

## What problem is this policy meant to address?

Competition from generic drugs can significantly reduce spending on pharmaceuticals. The number of competitors in a market can also affect drug prices. A Food and Drug Administration analysis of national sales data found that the first generic version of a drug is typically priced only slightly lower than the brand product but that the availability of a second generic version is associated with an average price of about half that of the brand drug.<sup>1</sup> Competition from additional generic competitors can drive prices down even further, reaching, on average, prices that are 80 to 85 percent lower than their brand equivalents.<sup>2</sup> Under its new agreement with manufacturers (the reauthorization of the Generic Drug User Fee Amendments), FDA will typically act on a generic drug application within 10 months of submission.<sup>3</sup> Despite a recent increase in the approvals of generic drug applications, as well as an FDA policy that prioritizes the review of an application when a single manufacturer produces the drug or when fewer than three generic versions of a drug are approved,<sup>4</sup> some eligible drugs still face limited or no generic competition. According to FDA, as of March 2017 more than 180 off-patent brand drugs were on the market without any generic competitors.<sup>5</sup> In many cases, there may be only one or two manufacturers approved to market a particular drug,<sup>6</sup> which allows these companies to charge higher prices than if there were more competitors. Incentivizing generic developers to submit applications for drugs that face limited competition and expediting FDA review of those applications may drive down costs.

## How could this policy work?

Members of Congress have proposed policies to encourage the development of generic drugs when limited competition exists by (1) reducing the statutory FDA review time frame for any such product and (2) providing an additional incentive by awarding the sponsor of such an application a voucher that could be used to obtain priority review for a second generic drug application (or sold to another company at fair-market value for that purpose).

The Lower Drug Costs Through Competition Act (H.R. 749), introduced in 2017, would require FDA to prioritize the review of generic applications for drugs in shortage (i.e., where currently approved manufacturers are unable to meet market demand) and for drugs (1) that have been recently introduced to market by a single manufacturer in the last three months and (2) for which two or fewer generic applications have been tentatively approved.<sup>7</sup> FDA would be required to review these generic drug applications within 180 days of submission. In addition, a transferable generic drug priority review voucher<sup>8</sup> would be awarded to the sponsor of an approved generic drug application if the drug establishes “a sustained market presence.” Senate legislation introduced in 2017, the Increasing Competition in Pharmaceuticals Act (S. 297), is similar but would require FDA review of priority and voucher applications within 150 days and would waive user fees for priority applications, except those that include a patent challenge to the innovator product.<sup>9</sup>

Another approach is included in the Generic Drug User Fee Amendments' reauthorization agreement (GDUFA-II), as part of the FDA Reauthorization Act (FDARA), which Congress passed in August 2017.<sup>10</sup> This requires FDA to review within eight months applications for drugs that have three or fewer competitors, if certain requirements are met.<sup>11</sup> And it codifies recent FDA policy updates to expand priority review to more applications for generic drugs with limited competition<sup>12</sup> as well as FDA's agreement with industry<sup>13</sup> to review 90 percent of priority applications within eight months. The reauthorization act also requires FDA to publicly report information related to generic application review, including the volume and status of priority applications, approval times, and the number of review cycles prior to approval. Additionally, FDA is required to publish both a semiannual list of drugs with limited competition and monthly information on drugs withdrawn from the market.

The act also creates a program that extends priority review and pre-application support to generic applications for drugs with a single manufacturer. In some cases, a qualifying generic may also be eligible for six months of exclusivity, barring additional competitors from entering the market.<sup>14</sup>

## What should policymakers consider?

A range of factors can influence a generic drug developer's decision to bring a product to market. These may include a drug's market size; manufacturer production costs; costs associated with the development of the drug, including conducting tests that are required for FDA approval; anticipated revenue; and time and resources needed to obtain FDA approval, including user fees paid to FDA to review marketing applications. How manufacturers weigh these considerations may vary significantly from product to product and company to company. Policies to expedite review of generic drug applications target only the last of these factors, and it is not clear whether they would increase the amount of competition from generic drugs.

While FDA currently prioritizes the review of applications for the first generic version of a drug and applications for drugs with only a single manufacturer, and an eight-month review timeline was included in FDARA, some of the proposals would create a statutory time frame for FDA action that is shorter than eight months. Whether this requirement would improve current approval times is unknown. According to FDA officials, it may be difficult to review a generic drug application in less than eight months, due in part to the time necessary to inspect manufacturing facilities, many of which are overseas.<sup>15</sup> FDA has also stated that eight months allows the agency to effectively communicate with generic developers on any deficiencies in their applications, which enables developers to quickly make necessary changes to a submission so that it may be approved in the first review cycle, rather than waiting to receive a formal response from FDA in the form of a Complete Response Letter before making any necessary revisions to the application.<sup>16</sup> Any additional requirements for a faster review that have not been agreed to by FDA and industry as part of GDUFA-II may not accelerate generic approvals. If the agency is required to act on some applications in less than eight months, FDA may not have adequate time to conduct any necessary facility inspections and communicate with sponsors to request clarifications or changes to the application. This could increase the share of applications requiring multiple review cycles, which would lengthen the overall time to approval and delay access to generics.

Not enough information exists to determine whether a priority review voucher program would provide sufficient incentive to overcome the underlying reasons that generic developers have declined to enter markets with limited competition. However, the FDA experience with other voucher programs should be considered. FDA has had a Tropical Disease Priority Review Voucher program since 2007, but as of January 2017 the program had awarded only three vouchers.<sup>17</sup> The Pediatric Voucher Program, an FDA initiative that rewards development of innovator drugs for rare pediatric diseases, has resulted in six vouchers. Four of them have been sold to other manufacturers for prices ranging from \$67.5 million to \$350 million.<sup>18</sup> A 2016 Government Accountability Office

report found that FDA officials did not see any evidence that the Pediatric Voucher Program had been effective in incentivizing drug development for rare pediatric diseases.<sup>19</sup> Officials also expressed concern that the program had strained agency resources and affected the agency's ability to set its public health priorities.

The market for innovator drugs differs significantly from the generic market, as innovators are granted patent protections and exclusivity periods that shield them from generic competition. These protections allow innovator products to command higher prices than generics. Therefore, the market value of generic priority review vouchers is likely to be lower than that of innovator products. In addition, it is not clear in what situations a generic developer would find a priority review voucher to be of high utility. Under FDARA, first, second, and third generics could all be granted priority review status without a voucher. Therefore, an application for which a sponsor could use a priority review voucher would be limited to cases where (1) multiple manufacturers sell the drug on the market, or (2) FDA is already considering multiple applications for the same drug on a priority review timeline. A voucher would not allow an application to move ahead of other applications with priority review status. Additional study may be needed to determine whether a voucher program, as structured in current proposals, would be sufficient incentive for generic developers to bring products to market in cases of limited competition.

Policies to expand priority review and create a voucher program are likely to increase FDA's workload, but it is not clear what additional resources, beyond those negotiated in the user fee agreements, the agency would need. Absent additional resources, it is not known what effect these policies would have on FDA's ability to review other generic applications on the timelines outlined in GDUFA-II. Proposals that waive user fees for priority applications may be especially challenging, because they pair faster FDA review with a reduction in resources.

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# Policy Proposal: Reducing the Exclusivity Period for Biological Products

A series that examines policies to manage drug spending

## What problem is this policy meant to address?

Biological products, or biologics, are drugs made up of proteins or other materials derived from living cells through a complex manufacturing process. They are used to treat a wide range of health conditions, including cancer, rheumatoid arthritis, and multiple sclerosis, and are some of the most expensive drugs on the market, measured by both unit price and net contribution to spending. In 2015, eight of the 10 highest-expenditure drugs in Medicare Part B were biological products,<sup>1</sup> and growth in the spending on biologics has exceeded 10 percent for each of the past five years.<sup>2</sup>

Biologics approved by the U.S. Food and Drug Administration are granted 12 years of exclusivity<sup>3</sup>—substantially longer than the five years typically granted to traditional, small-molecule pharmaceuticals.<sup>4</sup> Other high-income countries grant biologics fewer years of exclusivity than the U.S.,<sup>5</sup> and many provide small-molecule drugs and biologics the same period of exclusivity.<sup>6</sup>

During the exclusivity period, these medicines do not face competition from biosimilars, which are follow-on, highly similar products to FDA-approved biologics. After the expiration of all patents and 12 years of FDA-granted exclusivity, drug developers can obtain FDA approval to market a biosimilar through an abbreviated licensure pathway for biological products.<sup>7</sup> Instead of having to reproduce evidence that demonstrates safety and effectiveness, developers must only demonstrate that a biosimilar is “highly similar” or “interchangeable” with the previously approved reference biologic.<sup>8</sup>

However, analysis has shown that costs to develop biological and traditional, small-molecule drugs are similar,<sup>9</sup> which has prompted some to argue that 12 years of protection from biosimilar competition is excessive.<sup>10</sup> Policies that reduce this period would allow lower-cost biosimilars to enter the market sooner and could increase competition among biological products. Increased competition has the potential to reduce drug spending in the U.S.<sup>11</sup>

## How could this policy work?

Policymakers have proposed reducing the length of exclusivity for biologic drugs, which would allow biosimilars to come to market more quickly. The Obama administration proposed reducing biologic exclusivity to seven years in its budget for fiscal year 2017.<sup>12</sup> This proposal also included a prohibition on “additional periods of exclusivity for brand biologics due to minor changes in product formulations.”<sup>13</sup> According to the Office of Management and Budget, these proposals together would have generated federal savings of \$6.96 billion over 10 years.<sup>14</sup>

The Price Relief, Innovation, and Competition for Essential Drugs (PRICED) Act, introduced in 2016, would reduce exclusivity for biological drugs from 12 to seven years.<sup>15</sup> The Congressional Budget Office has not publicly released an estimate of the impact this policy would have on federal government spending.

## What should policymakers consider?

Exclusivity for new drugs allows manufacturers to set higher prices, because no biosimilars can be approved during this time. This is a powerful incentive for drugmakers to bring new products to market, especially given the high costs involved with developing novel therapies. Experts estimated in 2016 that an average of \$2.6 billion is spent to bring a drug to market, which includes the opportunity cost of not using these funds for other purposes, as well as expenses companies incur developing products that fail to reach the market.<sup>16</sup>

Shorter biologic exclusivity could allow biosimilar developers to bring products to market more quickly, which has the potential to reduce drug spending at a cost of reduced revenue for the reference product developer.

Reducing the period of FDA-granted exclusivity would have limited effect when patent protections exceed the exclusivity period. For example, Humira—a biologic used to treat inflammatory conditions such as rheumatoid arthritis and Crohn’s disease—was initially FDA-approved in 2002,<sup>17</sup> yet some experts believe it may be shielded from biosimilar competition until 2022.<sup>18</sup> While biosimilar developers can challenge existing patents, the time and costs associated with these disputes can discourage manufacturers from such attempts.

Savings from biologic competition may be less marked than those achieved with traditional generic drugs. Compared with generic drugs, follow-on biologics will probably take longer to develop (three to five years versus eight to 10 years, respectively), and their development costs are likely to be higher (\$1 million to \$5 million versus \$100 million to \$200 million, respectively).<sup>19</sup> Additionally, under current federal law, biosimilars that have been deemed interchangeable by FDA may be automatically substituted for a reference biologic by a pharmacist without provider intervention.<sup>20</sup> However, states may place limits on when these products can be substituted. Biosimilar uptake will probably be limited by the fact that not all biosimilars will be approved with the interchangeable designation.<sup>21</sup> In the traditional drug market, savings have been driven in large part by laws that typically allow pharmacists to automatically substitute generics for brand drugs that are therapeutically equivalent.

Because of the factors outlined above, most experts believe that biosimilar uptake rates will be lower than those of generic drugs and that savings from biosimilars will be restrained by more modest price decreases.<sup>22</sup> As a result, innovator biological product developers are likely to experience a smaller reduction in revenue from the expiration of exclusivity and patents than currently experienced by brand drug developers. This suggests that though reducing the length of biological exclusivity may increase competition, biological product developers may still be able to maintain significant revenue after biosimilars have entered the market.

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# Policy Proposal: Require Rebates on Drugs for Low-Income Medicare Beneficiaries

A series that examines policies to manage drug spending

## What problem is this policy meant to address?

Of the 41 million Medicare Part D beneficiaries in 2016 (approximately 7.5 million of whom were also eligible for Medicaid),<sup>1</sup> 12 million received a low-income subsidy (LIS, also known as Extra Help). The LIS helps beneficiaries with limited incomes to pay their Part D premiums and any cost-sharing on drugs, including deductibles and co-payments. This assistance comes from subsidies the federal government pays to the Part D commercial drug plan in which the beneficiary enrolls.<sup>2</sup> The Medicare Payment Advisory Commission estimates that in 2014, nearly 70 percent of Medicare spending on the Part D benefit was for the 30 percent of enrollees receiving the LIS.<sup>3</sup>

Before 2006, low-income seniors and disabled individuals eligible for both Medicare and Medicaid received outpatient prescription drug benefits through Medicaid.<sup>4</sup> In 2006, when Medicare Part D was implemented, such “dually eligible” beneficiaries began receiving prescription drug coverage through Medicare Part D instead,<sup>5</sup> as required by the Medicare Modernization Act (MMA).<sup>6</sup> Today, state Medicaid programs do not directly pay the entire cost of prescription drugs used by dually eligible beneficiaries, but states continue to pay a large share of beneficiaries’ Part D coverage through monthly payments intended to offset some Medicare spending for these individuals.<sup>7</sup> In 2016, states contributed approximately 9 percent of the revenue used to operate the Part D program.<sup>8</sup>

States receive mandatory rebates from drug manufacturers on prescription drugs provided through Medicaid in agreements established between manufacturers and the federal Department of Health and Human Services. The rebates are paid quarterly to states, and the savings are shared with the federal government.<sup>9</sup> Medicaid rebates apply to both brand and generic drugs and include an additional payment when a drug’s price increases faster than inflation.<sup>10</sup>

However, Medicaid rebates are not available for dually eligible beneficiaries because they receive prescription drug benefits through Medicare Part D. Although private Part D plans are able to negotiate rebates and discounts directly with drug manufacturers, the savings are typically smaller than with mandatory Medicaid rebates.<sup>11</sup> Implementing mandatory rebates to the federal government for beneficiaries receiving the Medicare low-income subsidy, including dually eligible beneficiaries, could lower the cost of drugs for these beneficiaries and generate substantial federal savings.

## How could this policy work?

Congress could update the MMA to create a mandatory rebate program for LIS beneficiaries in Medicare Part D that is similar to the Medicaid mandatory rebate program. Manufacturers could be required to pay a

rebate equal to 23.1 percent of a brand drug's average manufacturer price (AMP) (13 percent for generics) or the difference between AMP and the Medicaid Best Price,<sup>12</sup> plus an additional rebate for price increases that exceed the rate of inflation since the drug's introduction to market. The program would also include a requirement that manufacturers participate in the rebate program in order for their drugs to be covered under Medicaid and Medicare.

Private Part D plans already negotiate rebates on brand drugs, which reduce beneficiary premiums and some government costs.<sup>13</sup> Mandatory federal rebates would need to account for these price concessions. Manufacturers would be required to pay the difference between the total rebates secured by Part D plans for LIS beneficiaries and the mandatory rebate level. The rebate amounts could be calculated using data already reported by Part D plans, which are required to report the rebates and other discounts they received in the previous year to Medicare on a per-drug basis.<sup>14</sup> Medicare could use these reports to determine the difference between the rebates paid to the Part D plans and the mandatory rebate level for LIS beneficiaries, with the drug manufacturer required to pay this amount to the federal government. In cases in which negotiated Part D plan rebates exceed mandatory rebate levels, no additional payments would be required.

In 2014, the Congressional Budget Office (CBO) estimated that requiring mandatory rebates for LIS Part D beneficiaries would save the federal government \$103 billion over 10 years.<sup>15</sup> While this estimate includes rebates of 23.1 percent for brand drugs, it does not include rebates for generic products. President Barack Obama's budget for fiscal year 2017 included a proposal to apply Medicaid-level rebates on brand and generic drugs to the Medicare LIS population<sup>16</sup> that was projected to generate \$121 billion in savings to the federal government through 2026. No information is available on the assumptions used to inform these estimates.

## What should policymakers consider?

This policy would generate federal savings. Medicaid rebates are typically larger than those negotiated by Part D plans.<sup>17</sup> The CBO wrote in 2014 that it expects Medicaid's average net price for drugs to remain at least 20 percent to 30 percent lower than Part D's average price after controlling for differences in health conditions.<sup>18</sup> Additional savings generated by mandatory rebates in Part D could be used to defray costs to fund and administer the program. In 2016, the federal government incurred more than \$82 billion in expenses in the Part D program.<sup>19</sup> However, absent additional changes to the program, this policy would not directly reduce costs for Medicare LIS enrollees.

Some have argued that mandating minimum rebates on Part D drugs for LIS beneficiaries would create incentives for drug companies to raise prices or reduce voluntary rebates to Medicare Part D plans or outside Medicare Part D in order to compensate for revenue lost through increased rebates.<sup>20</sup> Similarly, manufacturers might launch new drugs at higher prices. The CBO also warns that some savings could erode over time because drug manufacturers may choose to raise prices for new brand drugs.<sup>21</sup>

These arguments assume that manufacturers do not already launch drugs at the highest, profit-maximizing price and that they currently offer larger-than-necessary rebates to some payers, including Part D plans. There is limited evidence on pharmaceutical cost shifting, though one study examining the effect of new mandatory rebates and the Best Price rule adopted by Medicaid in the 1990s found that the price of branded products facing generic competition increased an average of 4 percent and that brands protected by patents did not cost significantly more.<sup>22</sup> This analysis has limited applicability to the present day because of changes in drug pricing and reimbursement but suggests that additional rebates may not lead to higher prices for brand name drugs except in cases where generic alternatives are available. It is estimated that generic drugs account for 89.5 percent of dispensed prescriptions.<sup>23</sup>

However, given the complexity of pharmaceutical markets and the lack of empirical evidence on mandatory rebates in Medicare Part D, consideration should be given to other potential impacts if drug manufacturers were to respond to this policy by reducing voluntary rebates to Part D plans (or commercial payers). Rebates to Part D plans serve to lower overall Part D program costs, so this could result in higher premiums for enrollees as well as increased costs to the federal government to support the program. This may partially offset any savings from the mandatory rebates.

Policymakers should consider the potential savings to the federal government from rebates in the LIS subset of Medicare Part D beneficiaries in the context of the potential for some distortions in private-market drug prices.

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# Policy Proposal: Allow Medicare to Negotiate Drug Prices in Part D

## What problem is this policy meant to address?

Spending in Medicare Part D reached \$100 billion in 2016, more than double the program's expenditures in 2006.<sup>1</sup> Within five to six years, program costs are expected to reach \$150 billion annually.<sup>2</sup> Over three-quarters of Part D costs are borne by the federal government, with the remaining portion paid by beneficiaries and state governments.<sup>3</sup>

Under the Part D program, private prescription drug plans (PDPs) provide drug coverage to Medicare enrollees. PDPs negotiate drug rebates and other discounts with pharmaceutical manufacturers, which reduce program costs and allow plans to compete for beneficiaries based on lowering premiums and patient out-of-pocket costs. However, the federal government is prohibited from negotiating drug prices in the Part D program as part of the Social Security Act's noninterference clause. The clause states that the Department of Health and Human Services "may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors, and may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs."<sup>4</sup> Proponents of government negotiation believe that the HHS could secure lower drug prices than individual PDPs. Ninety-two percent of Americans favor allowing the government to negotiate with drug companies to lower drug prices for people on Medicare.<sup>5</sup>

## How could this policy work?

Current law could be updated to permit the HHS to negotiate drug prices on behalf of the approximately 43 million Part D beneficiaries.<sup>6</sup> The department has significantly larger purchasing power than individual PDPs but would likely need additional authority to achieve discounts beyond those negotiated by PDPs.

In 2007, the Congressional Budget Office (CBO) estimated that allowing the HHS to negotiate Part D drug prices would have a "negligible effect" on spending unless the agency were also given additional authorities, such as the ability to manage a federal formulary.<sup>7</sup> To date, there is no CBO estimate on the effect that allowing the HHS to negotiate both drug prices and formulary placement could have.

The primary tool that payers use to negotiate discounts, often in the form of rebates, is through preferred formulary status, where plans reduce patient cost-sharing requirements or ease the use of utilization management tools such as prior authorization or step therapy. Preferred formulary status increases the sale of a drug and provides an incentive for manufacturers to offer discounts. This approach is most effective when multiple therapies are available to treat the same condition. In addition to granting the HHS the authority to negotiate drug prices, lawmakers could permit it to establish a formulary for Part D. Alternatively, policymakers could provide the HHS with the ability to set prices administratively if manufacturers do not offer price concessions.

The Improving Access to Affordable Prescription Drugs Act of 2017 would strike the noninterference clause from the law and instead grant the HHS the authority to negotiate Part D drug prices.<sup>8</sup> The proposal would also give

the HHS the authority to use negotiating techniques involving “formularies, reference pricing, discounts, rebates, other price concessions, and coverage determinations” to lower prices paid to PDPs. The CBO has not released an estimate of the impact such an approach could have on Medicare drug spending.

## What should policymakers consider?

In order for negotiations to have an impact on Part D drug prices, the government would need the ability to pressure drug companies to lower their prices through the use of a formulary, utilization management tools, or administrative price setting. Policymakers would also need to consider the potential impact of these policies on patient access to medicines. Opponents argue that allowing the government to negotiate prices would inhibit innovation and limit patient access. For instance, the Veterans Health Administration has been able to purchase drugs at prices that are 40 percent below those paid in Medicare Part D.<sup>9</sup> However, there is also evidence that the VA National Formulary covers 16 percent fewer top prescription drugs than do Medicare Part D plans.<sup>10</sup>

Potential approaches would require policymakers to define the scope of government negotiations, including:<sup>11</sup>

- Which drugs would the HHS have the authority to negotiate?
- Could the HHS negotiate both the price of drugs and formulary design?
- Would the negotiated terms apply to all Part D plans?

A recent proposal would grant the government the ability to negotiate the price on products that face little competition, are subject to the Part D reinsurance benefit,<sup>12</sup> and have a significant impact on Part D spending.<sup>13</sup> This proposal would target a significant driver of Part D spending—high-cost medicines.<sup>14</sup>

Under this proposal, the minimum payment amount for a drug could be based on the costs of development. An additional bonus payment based on the value of the product—as measured by quality-adjusted life years<sup>15</sup>—could increase the final price above the minimum payment amount. As leverage, the government could require higher cost sharing for drugs with higher prices or even exclude drugs from coverage. Though the federal government would negotiate the price of these select products for all PDPs, the PDPs themselves would continue to pay claims.

Given the large number of Part D beneficiaries, HHS negotiation has the potential to reduce program costs. However, proposals must be explicit about the scope of the government’s authority and the specific circumstances under which the HHS could negotiate drug prices. Elements to be clarified include what is being negotiated (e.g., prices and/or formulary placement) and what to do if the negotiating parties are unable to reach an agreement.

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# Policy Proposal: Revising Medicare's Protected Classes Policy

A series that examines policies to manage drug spending

## What problem is this policy meant to address?

Medicare Part D plans (PDPs) are required to cover at least two drugs in each therapeutic class, defined as a group of drugs used to treat the same disease or condition. However, for six therapeutic classes PDPs are required to cover “all or substantially all” drugs.<sup>1</sup> These are known as the protected classes, and include antiretrovirals (used to treat HIV), immunosuppressants (when used to prevent organ rejection), antidepressants, antipsychotics, anticonvulsant agents (used to treat epilepsy), and antineoplastics (used to treat cancer). While this requirement is intended to ensure a beneficiary's broad access to all drugs in these protected classes, it may reduce the PDP's ability to negotiate discounts for these drugs, leading to higher costs for Medicare and its beneficiaries.

Rescinding the protected class designation for certain therapeutic classes could improve a PDP's ability to secure larger rebates from drug manufacturers, as it would allow a PDP to exclude a drug from its formulary. Medicare has previously projected savings from reducing coverage requirements in certain classes, as discussed below. However, given the current high rates of generic use within the protected classes, there may be limited potential for savings from changes to this policy. Moreover, because PDPs already have some ability to restrict coverage within protected classes, and because other Medicare requirements may prevent PDPs from generally excluding a drug,<sup>2</sup> the magnitude of any savings from changing the protected classes requirement remains unclear.

While the protected classes are currently established in statute, they were originally developed under Medicare's general authority to require adequate formularies in PDPs. In 2005, prior to the first year of the Part D program, Medicare released the Medicare Prescription Drug Benefit Manual,<sup>3</sup> which provided instructions to PDPs on developing their formularies, created the protected classes policy, and identified the six classes for the first time. Medicare created the protected classes policy to ensure that beneficiaries with certain chronic conditions who were transitioning from Medicaid coverage to the Part D program would have uninterrupted access to their current drugs.<sup>4</sup>

In 2008, Congress revised the Part D statute to require Medicare to identify protected classes through the regulatory process;<sup>5</sup> the 2005 identification was subregulatory guidance, not binding regulation. In 2009, Medicare issued initial regulations outlining a process to subsequently identify classes through binding regulation, but did not actually define any through that process.<sup>6</sup> In 2010, Congress again revised the statute, requiring Medicare to recognize the six existing classes until Medicare finalized rule-making to identify protected classes.<sup>7</sup>

In 2014, Medicare issued a proposed rule to identify these classes. The agency would recognize a class as protected when:<sup>8</sup>

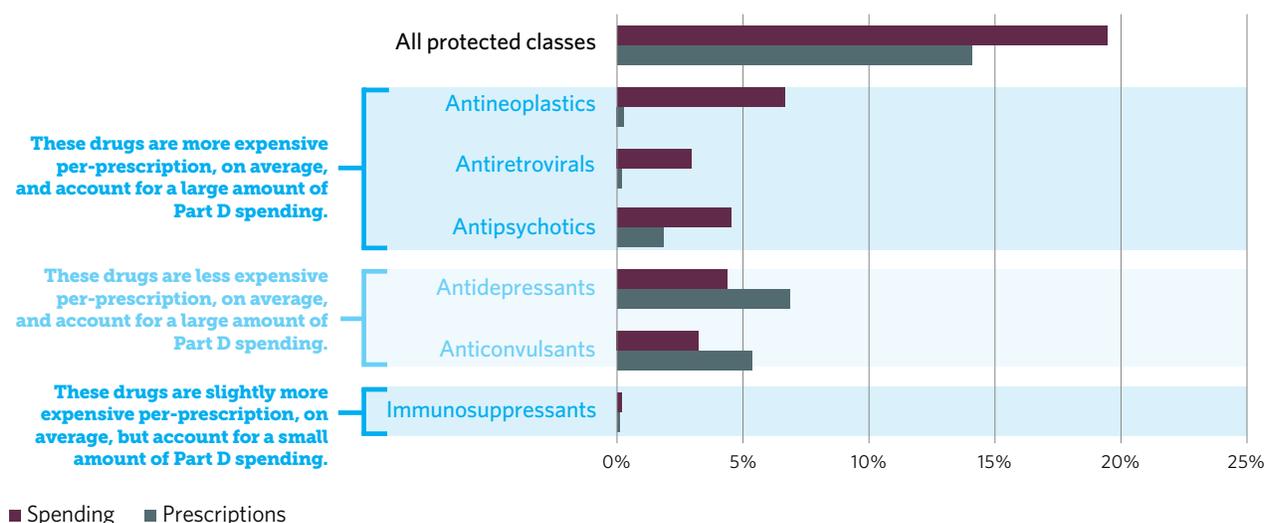
- 1) A typical beneficiary, who is initiating therapy, must administer a drug within the category or class in less than seven days or failure to do so will lead to hospitalization, incapacity, disability, or death; and
- 2) Other CMS [Centers for Medicare & Medicaid Services] formulary requirements are not sufficient to ensure access to an appropriate range of therapies, either due to the diversity of disease or condition manifestations or the associated specificity or variability of drug therapies necessary to treat such manifestations.

CMS proposed that this definition would remove the protected status from the antidepressants, antipsychotics, and immunosuppressants classes and projected a savings of \$720 million over five years, including \$420 million in 2019. These potential savings represent less than 0.4 percent of the \$116 billion in projected Medicare Part D spending in 2019.<sup>9</sup> Following opposition from many parties,<sup>10</sup> Medicare did not finalize this proposed change, and the protected classes previously defined in statute remained in force.

### Spending and generics use in protected classes

The protected classes policy has been a focus for potential cost savings because of concerns that its coverage requirements would limit payer strategies to manage utilization of specific drugs or to negotiate pricing. As a group, protected class drugs cost more per prescription than other drugs—in 2015 they accounted for 20 percent of Part D spending, but only 14 percent of prescriptions.<sup>11</sup> Antineoplastics and antiretrovirals have per-prescription costs that are significantly higher than drugs in other protected classes. However, not all of the protected class drugs have higher average per-prescription costs. Antidepressants and anticonvulsants have lower average per-prescription costs than other Part D drugs, which could reduce any potential cost savings from changing their status.<sup>12</sup>

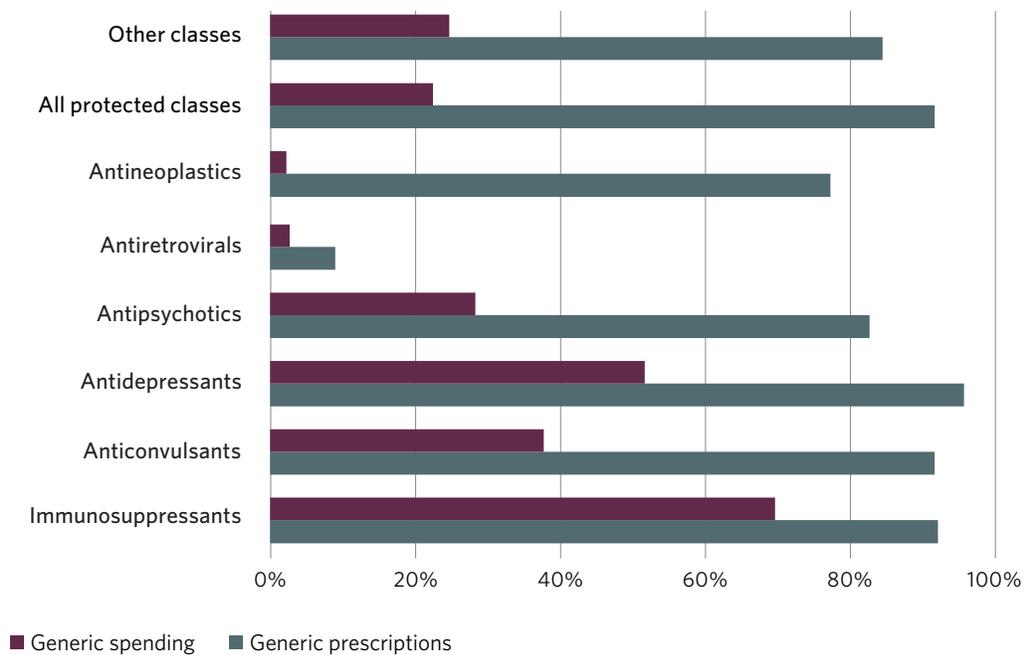
Figure 1  
**Percentages of Total Part D Spending and Prescriptions by Drug Class, 2015**



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Protected classes currently have a higher overall rate of generic utilization than other drug classes (92 percent and 84 percent of prescriptions, respectively).<sup>13</sup> Generic uptake has affected prices for these therapies. According to the Medicare Payment Advisory Commission (MedPAC), prices for protected-class drugs have increased at the same rate as all Part D drugs, and cumulative prices actually decreased by 16 percent between 2006 and 2013 due to generic substitution.<sup>14</sup> MedPAC has concluded that “protected status does not appear to affect plan sponsors’ ability to encourage the use of generics.”<sup>15</sup> Antiretrovirals are a notable outlier among protected classes. Ninety-one percent of these prescriptions are for branded drugs, accounting for 97 percent of spending in that class. While some generic antiretrovirals are available, federal clinical guidelines recommend the use of newer brand drugs based on effectiveness.<sup>16</sup>

Figure 2  
**Generic Spending and Generic Prescription Rates as a Share of Each Part D Drug Class, 2015**



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## Rebates for protected classes drugs compared to other drugs

The drug spending estimates above consider only PDPs' payments to pharmacies; after these payments, PDPs receive rebates to offset drug costs (typically limited to brand-name drugs). These rebates, in turn, reduce Part D premiums, though they generally do not reduce beneficiary out-of-pocket costs. Medicare provides limited information on the magnitude of rebates received. In 2014, plans received on average a 17.5 percent rebate on all Part D brand-name drugs.<sup>17</sup> Among 40 drugs identified by Medicare as having high total spending, high per-user spending, or large price increases in 2014,<sup>18</sup> the average rebate was 17.8 percent. Of these 40 drugs, about a third (13) were in protected classes and accounted for roughly one-third (30 percent) of the spending on those 40 drugs. As the rebates on these 40 drugs were consistent with rebates across all Part D brand-name drugs, this may suggest that rebates on protected-class drugs are consistent with other brand-name drugs. However, it does not preclude the possibility that plans could obtain higher-than-average rebates for these products if they had a greater ability to exclude them from coverage.

## Insurer restrictions on drugs in protected classes

PDPs are generally required to cover brand-name drugs in a protected class when no generic equivalent is available, but they may exclude brand-name drugs from coverage when a generic equivalent is available.<sup>19</sup> PDPs may also exclude extended-release formulations if an immediate-release formulation is available, and multiple formulations with the same route of administration are not required (e.g., both tablets and capsules of the same dosage are not required, but tablets and transdermal patches with the same dosage are). PDPs also have tools to manage drug use, such as prior authorization or requiring a patient to try another drug first (called "step therapy"). They can also subject drugs in protected classes to higher patient cost-sharing, which is usually achieved by placing the drug on a "specialty tier" in the PDP's formulary. The ability to implement utilization management requirements and to place these drugs on specialty tiers may allow plans to negotiate discounts on them for more favorable access.

In at least one protected class, PDPs actually have more restrictive formularies than commercial health insurance plans, despite the protected class and other formulary protections.<sup>20</sup> In 2013, commercial plans covered 80 percent of unique formulations in the anticonvulsant class (including both brand and generic formulations), while PDPs covered only 62 percent. While both insurer types covered nearly all generic formulations, commercial plans covered 76 percent of branded drugs, compared with only 46 percent coverage by PDPs, demonstrating that PDPs frequently use their ability to exclude branded drugs when a generic is available. PDPs also place anticonvulsants on higher tiers than do commercial plans. These findings suggest that the protected classes policy does not prevent PDPs from managing formularies consistent with commercial insurance plans.

## How could this policy work?

Removing coverage requirements for some or all protected classes may provide PDPs with a greater ability to negotiate rebates when designing a drug benefit compared to their current abilities through utilization management and formulary placement. However, Medicare's other formulary protections may limit PDPs' ability to exclude a drug, even absent a protected class designation.

Either Congress or Medicare has the ability to change the protected classes. Congress could amend the statute to change the baseline protected classes now in place, or Medicare (under its current authority or at the direction of Congress) could finalize a regulation defining the protected classes in a way that results in fewer of them.

Outside of the protected classes, PDPs are required to cover at least two drugs per therapeutic class.<sup>21</sup> PDPs are required to have a Pharmacy and Therapeutics Committee that issues binding recommendations on which drugs are included on the formulary, using a “clinical appropriateness” standard. Formularies are also reviewed by CMS to determine whether they are consistent with those in “widespread use.” These clinical appropriateness and widespread-use criteria limit PDPs’ ability to exclude drugs from the formulary regardless of protected class status.

## What should policymakers consider?

If a protected class designation were removed, plans would gain additional negotiating power only for brand-name drugs that could credibly be excluded from formularies under Medicare’s clinical appropriateness criteria. Within certain protected classes, many patients use brand-name drugs that do not have a generic alternative, indicating widespread clinical use that may inhibit PDPs’ ability to exclude these drugs from formularies. In 2015, 90 percent of Part D antiretroviral prescriptions and 22 percent of antineoplastic prescriptions were for brand-name drugs with no generic alternatives. If clinical appropriateness criteria allow PDPs to exclude any of these drugs, PDPs may be able to negotiate additional rebates in these two classes.

However, other protected classes had low utilization of brand-name drugs without generic equivalents, limiting the potential savings from removing those drugs from formularies. For example, only 8 percent of antipsychotic and 7 percent of anticonvulsant prescriptions were for branded drugs with no generic alternatives, and these drugs comprised only 2 percent of the antidepressants used and less than 0.05 percent of the immunosuppressants used. Given this high level of generic use, savings from Medicare’s proposed elimination of protected class status for antidepressants, antipsychotics, and immunosuppressants may be minimal within the context of total program spending. However, if new brand-name drugs are introduced in one of these classes, the contribution to overall spending—and the potential savings—could increase.

When evaluating updates to protected class designations, policymakers should weigh the potential savings against the adequacy of other requirements designed to ensure appropriate access to medication. Lack of adequate access to medications can in some circumstances increase costs to other Medicare programs through increased hospitalizations from complications or increased physician visits to manage medications.<sup>22</sup>

## Endnotes

- 1 Centers for Medicare & Medicaid Services, “Medicare Prescription Drug Benefit Manual Chapter 6—Part D Drugs and Formulary Requirements” (2016), <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf>.
- 2 Centers for Medicare & Medicaid Services, “Medicare Prescription Drug Benefit Manual Chapter 6,” Sec. 30.2.5.
- 3 Ibid.
- 4 For a discussion of concerns in transitioning Medicaid clients with HIV, mental illness, and other cognitive disorders, see Centers for Medicare & Medicaid Services, “CMS-4068-F: Medicare Prescription Drug Benefit,” 70 Fed. Reg. 4264 (Jan. 28, 2005), <https://www.gpo.gov/fdsys/pkg/FR-2005-01-28/pdf/05-1321.pdf>.
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- 9 Centers for Medicare & Medicaid Services, “2017 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds” (2017), <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2017.pdf>.
- 10 Elise Viebeck, “Drug Rule Is Ditched by Obama,” *The Hill*, March 10, 2014, <http://thehill.com/policy/healthcare/200338-obama-drops-medicare-changes>.
- 11 Centers for Medicare & Medicaid Services, “2015 Medicare Drug Spending Data” (2015), last modified Dec. 7, 2016, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/2015MedicareData.html>. Drugs in the protected classes were identified by comparing to the United States Pharmacopeia (USP) Medicare Model Guidelines v. 6.0, a model classification for Part D drugs required by the Medicare statute. In prior analyses, the Medicare Payment Advisory Commission (MedPAC) has used the First Databank Enhanced Therapeutic Classification System 1.0 drug classification, which is often used by commercial insurers and pharmacies, rather than the USP. See Medicare Payment Advisory Commission, “A Data Book: Health Care Spending and the Medicare Program” (2017), [http://www.medpac.gov/docs/default-source/data-book/jun17\\_databookentirereport\\_sec.pdf](http://www.medpac.gov/docs/default-source/data-book/jun17_databookentirereport_sec.pdf). Many central nervous system drugs can be used as either antipsychotics, antidepressants, or anticonvulsants, depending on the individual patient; the USP and First Databank differ on how they organize many of these drugs between the three categories, leading to some differences between Pew’s analysis and MedPAC’s. For example, many drugs categorized by the USP primarily as anticonvulsants are primarily antipsychotics in the First Databank classification.
- 12 Two drugs, Abilify (aripiprazole) and Seroquel (quetiapine fumarate) are classified as both antidepressants and antipsychotics in the USP. These drugs are included in both individual protected class analyses but are included only once in analyses of all protected class drugs and all drugs. These drugs account for 2 percent of total Part D spending and over half of both the antidepressant and antipsychotic spending (56 and 54 percent, respectively); they account for only 11 percent of antidepressant prescriptions but 41 percent of antipsychotic prescriptions.
- 13 Centers for Medicare & Medicaid Services, “2015 Medicare Drug Spending Data.”
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- 15 Medicare Payment Advisory Commission, “Status Report on the Medicare Prescription Drug Program (Part D)” (2017): 412, [http://www.medpac.gov/docs/default-source/reports/mar17\\_medpac\\_ch14.pdf](http://www.medpac.gov/docs/default-source/reports/mar17_medpac_ch14.pdf).
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- 18 Centers for Medicare & Medicaid Services, “2014 Medicare Drug Spending Dashboard,” last modified Dec. 7, 2016, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/2014Medicare.html>.
- 19 Centers for Medicare & Medicaid Services, “Medicare Prescription Drug Benefit Manual Chapter 6,” Sec. 30.2.5.

- 20 Kelly Brantley, Jacqueline Wingfield, and Bonnie Washington, "An Analysis of Access to Anticonvulsants in Medicare Part D and Commercial Health Insurance Plans," Avalere Health (2013), [http://avalere.com/research/docs/Anticonvulsants\\_in\\_Part\\_D\\_and\\_Commercial\\_Health\\_Insurance.pdf](http://avalere.com/research/docs/Anticonvulsants_in_Part_D_and_Commercial_Health_Insurance.pdf).
- 21 Centers for Medicare & Medicaid Services, "Medicare Prescription Drug Benefit Manual Chapter 6," Sec. 30.2.5.
- 22 For example, one study found that patients with schizophrenia who relapse may have five times greater annual costs than patients who do not relapse; the same study also found that medication non-adherence was a significant factor in predicting relapse. Haya Ascher-Svanum et al., "The Cost of Relapse and the Predictors of Relapse in the Treatment of Schizophrenia," *BMC Psychiatry* 10, no. 2 (2010), <https://doi.org/10.1186/1471-244X-10-2>.

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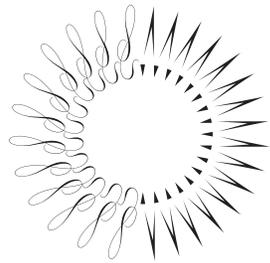
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