

**Preventing and Mitigating Generic Drug Shortages:
Policy Options Under Federal Health Programs**

Senate Committee on Finance

January 25, 2024

Introduction

Shortages in the available supply of critical prescription drugs present a persistent and growing challenge in the United States, resulting in a range of suboptimal outcomes and costs for patients and the health care system. According to the American Society of Health-System Pharmacists (ASHP), active drug shortages rose to 301 at the end of the first quarter of 2023, up from 271 at the close of Q1 2021.^{1,2} Ongoing and active shortages have risen to their highest levels since 2014.³ New medication shortages increased by close to 30 percent between 2021 and 2022.⁴ While some shortages conclude fairly quickly, others persist for years, with shortages for certain drugs lasting well over a decade.⁵

Generic drugs comprise the majority of medications in shortage at any given time.⁶ One recent analysis found that generics typically make up two-thirds of drug shortages,⁷ while other studies have produced estimates as high as 84 percent.⁸ The least expensive (i.e., lowest-cost) generic drugs appear to have the highest shortage risk. For example, a recent analysis found that 56 percent of drugs in shortage in 2023 cost less than \$1 per unit.⁹ Shortages span a range of therapeutic classes, with oncology drug and antimicrobial access gaps attracting substantial media attention in recent months.^{10,11,12} Certain types of medications, like generic sterile injectables (GSIs) which include cancer drugs and saline solution used to flush IV lines provided in hospitals and physician offices, have proven particularly vulnerable, representing an estimated 67 percent of shortages overall.¹³

Shortages can delay or deny necessary care for patients or force prescribers to turn to second-line alternatives, which sometimes prove less effective or pose additional risks compared to the drug

¹ “Drug Shortages Statistics.” ASHP. <https://www.ashp.org/drug-shortages/shortage-resources/drug-shortages-statistics>

² Note: FDA also maintains a list of drug shortages, although the agency’s criteria differ. “FDA Drug Shortages.” U.S. Food and Drug Administration. <https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>

³ “Drug Shortages Statistics.” ASHP. <https://www.ashp.org/drug-shortages/shortage-resources/drug-shortages-statistics>

⁴ Senate Homeland Security and Governmental Affairs. “Short Supply: The Health and National Security Risks of Drug Shortages.” U.S. Senate. March 2023. <https://www.hsgac.senate.gov/wp-content/uploads/2023-06-06-HSGAC-Majority-Draft-Drug-Shortages-Report-FINAL-CORRECTED.pdf>

⁵ Scott Detrow and Marta Wosińska. “Drug shortages and national security.” NPR. March 26, 2023. <https://www.npr.org/2023/03/26/1166141399/drug-shortages-and-national-security>

⁶ Branded drugs have accounted for some high-profile shortages, generally in response to demand spikes, rather than the supply shocks that drive the majority of shortages.

⁷ Inmaculada Hernandez, Tina Batra Hersey, and Julie M. Donohue. “Drug Shortages in the United States: Are Some Prices Too Low?” *Journal of the American Medical Association*. March 3, 2020. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7099531/>

⁸ “Drug Shortages in the U.S. 2023.” IQVIA Institute for Human Data Science. November 15, 2023.

https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/drug-shortages-in-the-us-2023?utm_campaign=2023_Drug_Shortages_Report_INSTITUTE_IS&utm_medium=email&utm_source=Eloqua

⁹ *Ibid*

¹⁰ Marina Kopf and Catie Beck. “As cancer drug shortages grow, some doctors are forced to ration doses or delay care.” NBC News. May 26, 2023. <https://www.nbcnews.com/health/cancer/cancer-drug-shortages-14-medicines-now-short-supply-fda-says-rcna86106>

¹¹ Christina Jewett. “Drug Shortages Near an All-Time High, Leading to Rationing.” *The New York Times*. May 17, 2023. <https://www.nytimes.com/2023/05/17/health/drug-shortages-cancer.html>

¹² Emily Olson. “It’s not just Adderall: The number of drugs in short supply rose by 30% last year.” NPR. March 23, 2023. <https://www.npr.org/2023/03/23/1165361416/drug-shortages-adderall-flu-medicine-report>

¹³ “Drug Shortages in the U.S. 2023.” IQVIA Institute for Human Data Science. November 15, 2023.

https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/drug-shortages-in-the-us-2023?utm_campaign=2023_Drug_Shortages_Report_INSTITUTE_IS&utm_medium=email&utm_source=Eloqua

in shortage.¹⁴ According to a May 2023 study from the Office of the Assistant Secretary for Planning and Evaluation (ASPE), “[t]he average drug shortage affects at least a half a million consumers,” triggering both direct and indirect costs.¹⁵ Medicare-aged Americans represent roughly one-third of those impacted. ASPE also estimated that health care systems incur at least \$359 million in annual labor costs to manage or mitigate drug shortages, along with \$200 million to purchase therapeutic alternatives.¹⁶

Finance Committee Engagement

On December 5, 2023, the Finance Committee held a hearing entitled “Drug Shortages: Examining Supply Challenges, Impacts, and Policy Solutions from a Federal Health Program Perspective.” During the hearing, witnesses testified about the negative impacts of shortages on patients and taxpayers. The Committee also heard extensive testimony indicating that race-to-the-bottom pricing for generic drugs serves as the primary underlying driver of many drug shortages, a conclusion consistent with the bulk of the findings across the relevant academic literature.

Generic manufacturers face intense pressure to reduce prices and often face contract terms from purchasers that render revenue unpredictable. Many of these drug manufacturers thus strive to produce medications as inexpensively as possible, which can reduce revenue available to invest in manufacturing capacity, updating equipment, onshoring production, and ensuring quality. As a result, generic prescription drug supply chains can experience manufacturer exits, leading to low production or stoppages required by regulators, often stemming from failures in quality and reliability. Such disruptions have become more frequent and harder to manage and mitigate.

The Finance Committee is committed to working on bipartisan legislation to mitigate generic drug shortages to the fullest extent possible. This white paper represents the Committee’s preliminary areas of interest and ideas for how policymakers can address the problems contributing to shortages through reforms to the Medicare and Medicaid programs. The policy concepts outlined below are not final or exhaustive. This white paper represents an important step in our legislative process, and input from stakeholders, experts, and Committee members will be critical to assessing, enhancing, and otherwise modifying or adding to these potential reforms.

¹⁴ “Report to Congress: Drug Shortages for Calendar Year 2021.” U.S. Food and Drug Administration. 2021. <https://www.fda.gov/media/159302/download>

¹⁵ “Report to Congress: Impact of Drug Shortages on Consumer Costs.” U.S. Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation. May 2023.

<https://aspe.hhs.gov/sites/default/files/documents/87781bc7f9a7fc3e6633199dc4507d3e/aspe-rtc-costs-drug-shortages.pdf>

¹⁶ “Report to Congress: Impact of Drug Shortages on Consumer Costs.” U.S. Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation. May 2023. <https://aspe.hhs.gov/sites/default/files/documents/87781bc7f9a7fc3e6633199dc4507d3e/aspe-rtc-costs-drug-hereinshortages.pdf>

Potential Policy Solutions: Drugs Administered in Hospitals & Physician Offices

I. Medicare Payment Reforms for Generic Sterile Injectables

Generic sterile injectable (GSI) medicines are drugs that are typically administered via injection in a hospital or clinic by health care professionals (such as cancer drugs and saline solution used to flush an IV line). Because these drugs must, by definition, be sterile, the Food and Drug Administration (FDA) holds them to stringent manufacturing regulations and standards. Medicare is the country's largest payer of GSIs.¹⁷

GSIs serve as an essential component of care provided every day in emergency rooms and intensive care units, cancer treatment centers, and a variety of surgery sites and settings. However, GSIs are disproportionately prone to shortages, have high rates of manufacturer market exits, and are often more expensive to produce due in part to higher standards for FDA inspections compared to tablets and pills.^{18,19} For example, a 2019 FDA analysis found that sterile injectables, most of which were generic and had been on the market for nearly 35 years, accounted for 63 percent of drugs in shortage between 2013 and 2017. These products had a median price of \$11.05 per unit prior to going into shortage.²⁰

As of last year, at least 77 GSIs had been in shortage. Medications in shortage included widely used products such as saline, morphine, solutions used to dilute other drugs, medically necessary cancer drugs, crash cart drugs, anesthesia drugs, and hormones.²¹

The Finance Committee believes reforms to Medicare payments for GSIs could help alleviate persistent shortages. Specifically, the Committee aims to explore policy options that would advance some or all of the following reforms under Medicare Parts A and B:

- A new payment benchmark for GSIs that promotes competition among drugs while reflecting a sustainable level of payment that can be pulled through the supply chain;
- Financial incentives such as lump-sum payments or other mechanisms, based on the aforementioned benchmark, for relevant providers that engage in specified shortage prevention and mitigation activities;
- An additional bonus payment pool for providers based on relative performance on outcomes measures related to drug shortages; and
- Separate payment for relevant GSIs in Medicare Part B (based on a new payment benchmark) and modifications to such payments based on the extent to which providers engage in specified shortage prevention and mitigation activities.

¹⁷ Marta Wosińska and Richard G. Frank. "Federal policies to address persistent generic drug shortages." The Brookings Institution. June 21, 2023. <https://www.brookings.edu/articles/federal-policies-to-address-persistent-generic-drug-shortages/>

¹⁸ Marta Wosińska and Richard G. Frank. "Federal policies to address persistent generic drug shortages." The Brookings Institution. June 21, 2023. <https://www.brookings.edu/articles/federal-policies-to-address-persistent-generic-drug-shortages/>

¹⁹ Richard G. Frank, Thomas G. McGuire, and Ian Nason. "The Evolution of Supply and Demand in Markets for Generic Drugs." *The Milbank Quarterly*. June 1, 2021. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8452364/#milq12517-bib-0018>

²⁰ "Drug Shortages: Root Causes and Potential Solutions." U.S. Food and Drug Administration. 2019. <https://www.fda.gov/media/131130/download>

²¹ Marta Wosińska and Richard G. Frank. "Federal policies to address persistent generic drug shortages." The Brookings Institution. June 21, 2023. <https://www.brookings.edu/articles/federal-policies-to-address-persistent-generic-drug-shortages/>

A. Background on GSI Payment under Medicare

Medicare Part A Inpatient Prospective Payment System (IPPS)

Medicare Part A covers inpatient stays in hospitals and other settings. In the hospital setting, providers typically receive reimbursement for generic drugs as part of the Inpatient Prospective Payment System (IPPS). The IPPS pays prospectively determined rates, per inpatient stay, for the hospital's operating and capital costs. Medicare then adjusts the hospital's operating and capital base rates to reflect the patients overall clinical condition and potential treatment strategies. To determine this stay-level adjustment, Medicare assigns each patient admission a diagnosis-related group (DRG). Each DRG has a payment weight attached to it that reflects the hospital resources typically needed to treat a patient assigned to the DRG.²²

GSIs used in hospital settings are typically reimbursed by Medicare through this bundled payment methodology, which may lead to hospital purchasing methods that contribute to race-to-the-bottom pricing on these products. Bundling payments can, in some contexts, help to contain Medicare costs and mitigate unnecessary utilization. By design, bundling payments exerts downward pressure on pricing for goods and services hospitals use, particularly as providers seek to minimize costs for certain goods and services with greater pricing elasticity.^{23,24} These cost constraints on providers ripple through the prescription drug supply chain, including through contractual pricing arrangements between group purchasing organizations (GPOs) and manufacturers with respect to generic drugs.

Medicare Part B Outpatient Prospective Payment System (OPPS)

Medicare Part B covers outpatient care received in hospital outpatient departments, physician offices, clinics, and other relevant provider settings. Under the OPPS, for medications whose costs exceed a given threshold, providers generally receive reimbursement for “separately payable” drugs based on a drug's Average Sales Price (ASP) plus a percentage-based add-on payment, rather than through a bundled payment. In other words, separately payable drugs have an unbundled, distinct payment stream.

However, under the OPPS, Part B reimburses providers for inexpensive medications, including most generic drugs, on a “packaged” basis. Specifically, if a drug's daily cost is less than \$135, OPPS bundles the payment for said product together with other associated services and supplies.²⁵ As noted above, bundling pricing in this manner may exacerbate purchasing tactics that lead to race-to-the-bottom pricing dynamics with respect to GSIs.

²² “Hospital Acute Inpatient Services Payment System.” MedPAC. October 2022. https://www.medpac.gov/wp-content/uploads/2021/11/MedPAC_Payment_Basics_22_hospital_FINAL_SEC.pdf

²³ Inmaculada Hernandez, Tina Batra Hershey, and Julie M. Donohue. “Drug Shortages in the United States: Are Some Prices Too Low?” *Journal of the American Medical Association*. March 3, 2020. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7099531/>

²⁴ Marta Wosińska and Richard G. Frank. “Federal policies to address persistent generic drug shortages.” The Brookings Institution. June 21, 2023. https://www.brookings.edu/wp-content/uploads/2023/06/20230621_ES_THP_GSI_Report_Final.pdf

²⁵ “Part B Drugs Payment Systems.” MedPAC. November 2021. https://www.medpac.gov/wp-content/uploads/2021/11/medpac_payment_basics_21_partb_final_sec.pdf

Medicare Part B Physician Fee Schedule (PFS)

Under the PFS, providers generally receive reimbursement for GSIs based on the ASP+6% formula. The ASP reflects the average price for which a manufacturer sells a drug, inclusive of commercial prices, discounts and rebates. For purposes of calculating the ASP, all versions of a particular generic product are included under the same Healthcare Common Procedure Coding System (HCPCS) code. Thus, race-to-the-bottom pricing across all markets can drive down the ASP and can create disincentives for Medicare providers to select products from more reliable manufacturers that may have higher prices. The two-quarter lag in ASP data also makes it difficult for manufacturers to take necessary price increases during a shortage because provider reimbursement would still be based on lower pricing from six months ago (this dynamic is known as “sticky pricing”).^{26,27}

Subsections B through D outline potential Medicare reforms to mitigate GSI shortages.

B. New Payment Benchmark for GSIs

The Finance Committee is interested in exploring policy options that would tie payment for GSIs to new payment benchmarks under the Medicare fee-for-service program. This new benchmark methodology would aim to promote competition among drugs while also ensuring that reimbursement reflects a sustainable level of payment that generally does not fall below the average cost of goods sold for the GSI. The Committee is contemplating how to design such a benchmark, as well as types of information manufacturers would need to report to inform benchmark development in this context. The Committee is also considering which care settings and payment methodologies are most appropriate for this approach.

Provider reimbursement based on the new payment benchmark could also be coupled with policies that create incentives for providers and their business partners (e.g., GPOs, wholesalers) to contract with GSI manufacturers at sustainable prices. Policies in this context can be designed to reward manufacturers that prioritize reliability, resiliency, quality, and shortage mitigation. With these goals in mind, the Committee is exploring adjusting payment or bonus payments, as applicable, upward or downward based on whether a provider meets specified process and/or outcome measures (see subsection C below).

Questions under Consideration

1. What design features of a new payment benchmark for GSIs would avoid exacerbating race-to-the-bottom pricing while still promoting competition between drugs?

²⁶ Gottlieb, Scott. Testimony before the U.S. Senate Finance Committee entitled “Drug Shortages: Why They Happen and Why They Mean.” December 7, 2011. <https://www.finance.senate.gov/imo/media/doc/Gottlieb%20Testimony1.pdf>

²⁷ Westin, Jason. Testimony before the U.S. Senate Finance Committee entitled “Drug Shortages: Examining Supply Challenges, Impacts, and Policy Solutions from a Federal Health Program Perspective.” December 5, 2023. https://www.finance.senate.gov/imo/media/doc/1205_westin_testimony.pdf

2. What design features of a new payment benchmark for GSIs would avoid misaligned incentives and other issues sometimes associated with Medicare Part B’s ASP-based model?
3. What types of cost and pricing information would be helpful for manufacturers to report to inform a new benchmark that reflects sustainable pricing for GSIs?

C. New Financial Incentives for Providers that use GSIs

The Committee is considering developing new financial incentives for hospitals to purchase GSIs based on quality and reliability. For instance, providers that meet certain basic and advanced “process measures” by engaging in specified shortage prevention and mitigation activities could qualify for periodically distributed lump-sum payments, tied to the aforementioned GSI benchmark methodology. Separately, a pay-for-performance policy could award bonus payments to providers that perform well, relative to their similarly situated peers, on “outcome measures.”

Financial Incentives Based on Process Measures

The Committee is interested in exploring mechanisms to award hospitals with periodically distributed (such as quarterly) lump-sum payments linked to the new GSI payment benchmark methodology when said providers meet specified process measures related to preventing and mitigating GSI shortages. These process measures would assess whether a hospital has engaged in a specified activity, rather than the outcome ultimately achieved by engaging in such an activity.

For example, the Committee may consider developing process measures that touch on the following areas (this list is illustrative and not intended to be exhaustive):

- Provider business practices, processes, and strategies related to shortage mitigation, prevention, and management;
- Whether the hospital maintains a buffer inventory of the GSI that meets certain criteria;
- Contract features between hospitals and/or GPOs and GSI manufacturers; and
- Whether GSI manufacturers that hospitals do business with meet certain quality and transparency standards.

The Committee is considering creating two tiers of process measures, each associated with different lump-sum payments. For instance, the Committee may develop a “basic” set of process measures that represent essential shortage prevention and mitigation activities that we hope a broad range of facilities could and would adopt. Ideally, adoption of the basic process measures alone would go a long way toward course-correcting perverse market dynamics. The Committee is also considering whether to develop an “advanced” set of process measures, which could represent more resource-intensive and high-impact shortage prevention and mitigation activities that go above and beyond the basic process measures.

CMS could, under such a tiered model, award quarterly lump-sum payments to providers by multiplying the relevant GSI benchmark for a particular product by a facility’s utilization of said

GSI, and then adjusting the resulting amount based on the extent to which the hospital has met the aforementioned basic and advanced process measures. The Committee will work to ensure new payments are implemented in a manner that does not result in duplicate payments for GSIs.

Questions under Consideration

1. What basic process measures should be considered? What features would best categorize these measures as basic?
2. What advanced process measures should be considered? What features would best categorize these measures as advanced?
3. What unique impact might these payment reforms have on rural and safety net hospitals? What, if any, adjustments to the process measure-based payment should be made based on hospital characteristics (e.g., size, geographic location, hospital type/scope of services, population served)?
4. What types of plans, protocols, staffing, and other business practices should providers have in place to help prevent, mitigate, and manage shortages?
5. What minimum criteria should buffer inventories maintained by hospitals meet in order to satisfy a process measure (e.g., six-month supply, warehousing product domestically)?
6. What contract features should be considered as potential process measures (e.g., contract duration, volume guarantees, sustainability of pricing, inclusion or exclusion of certain terms)?
7. What existing resources would help assess GSI manufacturer reliability and resiliency? What additional types of information from GSI manufacturers would be helpful to providers and their business partners in assessing manufacturer reliability and resiliency?

Financial Incentives Based on Outcome Measures

The Finance Committee is interested in policy options that would create bonus payments based on hospital performance on outcome measures. Outcome measures could, for example, retrospectively assess the extent to which providers have successfully prevented and mitigated shortages in a given year, such as by evaluating relevant inventory of affected products at the time a shortage occurred or by assessing steps taken in response to a shortage.²⁸

The Committee envisions assessing outcome measures in a comparative manner, based on the relative performance of similarly situated peer hospitals. In other words, the top-performing hospitals in a particular peer group would receive the highest bonus payments. The Committee is

²⁸ Marta Wosińska and Richard G. Frank. “Federal policies to address persistent generic drug shortages.” The Brookings Institution. June 21, 2023. https://www.brookings.edu/wp-content/uploads/2023/06/20230621_ES_THP_GSI_Report_Final.pdf

also considering limiting eligibility for bonus pool payments to hospitals that satisfy all of the aforementioned basic process measures so as to ensure alignment across proposals.

Because it may take time to evaluate outcomes, we envision such payments occurring annually and coming from a separate bonus pool fund, as opposed to relying on outcome measure performance to modify the quarterly lump-sum payments described in previous sections. To facilitate efficient administration of this outcome-based policy, we would likely apply these separate bonus payments on an all-GSI, as opposed to drug-by-drug, basis.

Questions under Consideration

1. What outcome measures should be considered? What data would CMS need to evaluate against such measures?
2. What factors should be used in defining hospital peer groups for outcome measure evaluation (e.g., size, hospital type/scope of services, population served, geographic location)?

D. Modifications to Medicare Part B Payments for Providers that Purchase GSIs

The Committee is also interested in developing a consistent approach to GSI reimbursement under Medicare Part B, under both the hospital OPPS and PFS. Such an approach may help address persistent GSI shortages in these settings, including for critical oncology medications. Under the OPPS, the Committee is exploring policy options to require separate—rather than packaged—payment for GSIs, based on the new benchmark described above. Under the PFS, physicians would receive reimbursement for GSIs based on the new payment benchmark, rather than the ASP.

In both contexts, payment amounts could be modified based on the provider’s performance against process measures such as those described in the sections above. Specifically, a percentage-based modifier could adjust the benchmark payment for a given GSI upward or downward, depending on provider performance relative to basic and advanced process measures for a given quarter.

Questions under Consideration

1. Are there distinguishing factors between how hospitals and physician practices contract for and purchase GSIs?
2. What basic process measures should be considered in the context of the OPPS and PFS? Why should these measures be categorized as basic?
3. What advanced process measures should be considered in the context of the OPPS and PFS? Why should these measures be categorized as advanced?

4. What, if any, adjustments to the process measure-based payment process should be made based on provider characteristics (e.g., size, geographic location)?

II. Hospital Shortage Prevention & Mitigation Plans

The Committee is interested in options for ensuring that hospitals develop and share drug shortage prevention and mitigation plans across the range of drugs they use in providing care to patients. One option could, for instance, require hospitals to update and submit such plans to the Secretary at a regular cadence (e.g., at least once every several years). The Committee is considering requiring that such plans be reviewed and approved by an accountable executive. The goal of this policy would be to create another layer of transparency and accountability for addressing drug shortages, as a complement to the payment reforms described above.

This Committee is considering identifying specific elements that should be included in hospital shortage prevention and mitigation plans. Such elements might include, for example, explanations about how a hospital plans to identify critical drugs at risk of shortage, how and whether the hospital plans to maintain a buffer inventory of such drugs, and how the hospital leverages contracting procedures to try to ensure a sufficient supply of such products.

Questions under Consideration

1. What elements should be considered in hospital shortage prevention and mitigation plans?
2. Would it be appropriate to extend similar requirements or incentives to develop such plans to other supply chain stakeholders?

Potential Policy Solutions: Drugs Dispensed in Retail Settings

I. Medicaid Drug Rebate Program

Medicaid payment for prescription drugs varies from state to state. Certain federal Medicaid policies, such as elements of the Medicaid Drug Rebate Program (MDRP), are designed to put downward pressure on drug manufacturer prices. They also put downward pricing pressure on generic medicines, including those that are prone to shortages. The extent to which reforms to the MDRP can potentially help relieve generic drug shortages has attracted considerable debate.^{29,30}

The MDRP requires manufacturers to pay rebates to states and Medicaid managed care organizations (MCOs) on covered outpatient drugs in exchange for coverage and reimbursement under Medicaid. Under MDRP, manufacturers report pricing information to CMS, which officials use to calculate a drug's "unit rebate amount" (URA). The URA with respect to a given drug comprises the sum of the drug's "basic rebate" and an inflation-based rebate calculated based the medication's price increases in excess of inflation.³¹ Until 2015, MDRP's inflation rebate requirements exempted generic medications.

The generic medicines industry has expressed concern that application of the inflation penalty to generics presents challenges for manufacturers in addressing shortages, given that market stabilization, sustainability, and entry in the event of a shortage might carry higher input costs, and under certain circumstances, price increases.³² Other experts, however, have expressed skepticism regarding this perspective. They contend that manufacturers have sufficient room to increase pricing under the inflation rebate threshold in the event of a shortage and that the application of inflation rebates to generic medicines are an important tool in protecting Medicaid from price increases.³³

The Committee is interested in exploring the extent to which reforms of certain aspects of the MDRP can relieve generic drug shortages. Specifically, we would like to better understand the potential impact of the MDRP's inflation rebates on manufacturer business decisions related to generic drugs in shortage or at risk of shortage. Any policies the Committee would consider in this area must be directly relevant to drug shortages and apply exclusively to generic medicines. Should the Committee pursue policy options in this area, it will be important to keep the Medicaid program whole for any lost rebates. The Committee plans to explore policy options to achieve this goal.

²⁹ "Medicaid Generics Penalty." Association for Accessible Medicines. <https://accessiblemeds.org/advocacy/medicaid-generics-penalty>

³⁰ Edwin Park. "Medicaid Provision of Draft House Drug Shortages Bill Raises Concerns." Georgetown University McCourt School of Public Policy Center for Children and Families. August 23, 2023. <https://ccf.georgetown.edu/2023/08/23/medicaid-provision-of-draft-house-drug-shortages-bill-raises-concerns/>

³¹ 42 U.S.C. 1396r-8. https://www.ssa.gov/OP_Home/ssact/title19/1927.htm

³² Richard Manning and Fred Selck. "Penalizing Generic Drugs with the CPI Rebate will Reduce Competition and Increase the Likelihood of Drug Shortages." Bates White Economic Consulting. September 12, 2017. <https://www.accessiblemeds.org/sites/default/files/2017-09/Bates-White-White-Paper-Report-CPI-Penalty-09-12-2017.pdf>

³³ Edwin Park. "Medicaid Provision of Draft House Drug Shortages Bill Raises Concerns." Georgetown University McCourt School of Public Policy Center for Children and Families. August 23, 2023. <https://ccf.georgetown.edu/2023/08/23/medicaid-provision-of-draft-house-drug-shortages-bill-raises-concerns/>

Questions under Consideration

1. What data can stakeholders and experts share related to the impact of the MDRP on generic drug shortages and manufacturer business decisions related to drugs in or at risk of shortage?
2. What policies, if any, should be considered to address any potential impact the MDRP has on drug shortages? How can the Medicaid program be kept whole in response to any changes that would reduce rebates paid by generic manufacturers?
3. What impact, if any, does the MDRP have on GSIs?

II. Medicare Part D Prescription Drug Benefit

During our December hearing, the Committee heard testimony from expert witnesses that there may also be a need to create stronger economic incentives for drug purchasers in the retail prescription drug supply chain to focus more on manufacturer quality and reliability in their generic drug purchasing decisions.³⁴ The Committee is therefore interested in exploring whether financial incentives could be created under the Medicare Part D program to help address prescription drug shortages of generic medicines that are commonly dispensed in retail settings.

Specifically, we are interested in whether similar approaches to the payment reforms we outlined for GSIs under Medicare Parts A and B could potentially be extended to Part D to influence pharmacy and wholesaler purchasing incentives. We imagine such a policy would apply, at least initially, to a narrow subset of drugs that have historically experienced significant shortages. For example, the Committee could potentially create financial incentives for Part D plans and their pharmacy benefit manager (PBM) business partners to pay bonuses to pharmacies for meeting basic process measures similar to those described above for providers. The Committee would be open to testing potential approaches through a pilot or demonstration program that is large enough in scale to have a material impact on shortages for the particular drug(s) subject to the program.

Questions under Consideration

1. What strategies and business practices do stakeholders in the retail prescription drug supply chain (e.g., pharmacies, wholesalers, plans, PBMs, manufacturers) currently use to help prevent, mitigate, and manage drug shortages?
2. What types of generic drugs should be targeted with respect to potential policies under Medicare Part D and why?

³⁴ Hernandez, Inmaculada. Testimony before the U.S. Senate Finance Committee entitled “Drug Shortages: Examining Supply Challenges, Impacts, and Policy Solutions from a Federal Health Program Perspective.” December 5, 2023. https://www.finance.senate.gov/imo/media/doc/1205_hernandez_testimony.pdf.

3. What policy options would create incentives for pharmacies and wholesalers to purchase from generic manufacturers that invest in quality and reliability?