



July 1, 2024

Senator Ron Wyden, Chair
Senator Mike Crapo, Ranking Member
Committee on Finance
United States Senate
BY ELECTRONIC TRANSMISSION

Chairman Wyden and Ranking Member Crapo,

Thank you for the opportunity to comment on the [legislative draft](#) proposing a **Medicare Drug Shortage Prevention and Mitigation Program** (“Shortage Program”) and an exemption from Medicaid inflation rebates for multisource generics. We commend you for what is the first Congressional proposal to directly address the [most common driver of drug shortages](#) – a race-to-the bottom in prices that leads to production reliability problems with generic sterile injectable drugs.

The proposed legislative draft builds a strong foundation for increasing reliability of supply for generic sterile injectable drugs. We are concerned, however, that the Shortage Program’s approach of paying providers for meeting specific contracting standards will fail to ensure that providers secure reliable drug supplies because reliability is not explicitly addressed by those standards. We are also concerned that the program’s complexity will produce large compliance costs, discouraging program uptake and limiting the intended payment passthrough to manufacturers.

To appreciate the limitations of the proposed Shortage Program, we draw an analogy. Suppose we want to incentivize a salesperson to generate more sales. One approach is to compensate the salesperson in relation to the outcome: the level of sales they accomplish. Alternatively, we can base compensation on behaviors in which the salesperson engages: making cold calls, networking, making sales presentations, and other such activities. But a behavior-based performance scheme gets complicated quickly. What is the right number of cold calls? How do we make sure the salesperson selects cold call targets appropriately? How do we ensure that the cold calls are conducted effectively? How do we determine the right mix of cold calls to all the other efforts?

The more we try to replicate the mechanisms that produce new sales, the more complicated the performance metrics must be and the more burdensome the reporting and compliance oversight becomes. But performance metrics will not result in new sales if we miss important mechanism elements.

The proposed Shortage Program pursues the behavior-based approach. However, the limitations of that approach could be addressed by emphasizing outcomes. Namely, policymakers could directly encourage reliability by retrospectively assessing whether the long-term contracts under the Shortage Program result in timely delivery of drugs. By scoring program participants and then allowing resulting bonus payments to flow automatically to healthcare providers that are part of specific program provider pools, policymakers can minimize participation burden on providers.

In what follows, we describe the basis for our concerns that the proposed Shortage Program may fail to create the desired change, both in terms of program participation and promotion of supply reliability. Next, we offer a set of amendments that we believe would address these concerns. Finally, we discuss a set of complementary policy changes needed to assure that the Shortage Program's effectiveness is not compromised by existing government policies.

Review of current version of the Shortage Program

The Shortage Program seeks to drive stability in select sterile injectable generic drug markets (referred to as “applicable generics” under the Shortage Program) by rewarding adoption of long-term, fixed price, committed volume contracts.

Under the program, drug reimbursement continues to follow either the diagnosis-related group (DRG) prospective payment system where drugs are not separately billable or the Average Sales Price (ASP) system where reimbursement is based on a weighted average across all versions of a given molecule. In addition, providers signing contracts that meet Shortage Program criteria are eligible for add-on payments between 5 and 25% of the applicable drug's ASP, with the add-on level determined by the Secretary. An additional 2% add-on may apply for advanced standards related to domestic manufacturing and use of advanced manufacturing technologies. Payment to providers is assured even if there are supply disruptions and contracts are not fulfilled.

To be eligible for add-on payments under the Shortage Program, contracts must meet certain core standards related to length of contract, contracted volume share, off-contract purchases, and pricing stability. The proposed legislation sets targets for lengths of contracts and share of committed volume, increasing them at the same rate over time for all applicable generics.

Program providers need not sign these contracts directly with manufacturers, instead selecting among CMS-approved program participants. Program participants may include group purchasing organizations (GPOs), wholesalers, and other entities.¹ Participating manufacturers must share information about their good manufacturing practices (GMP) compliance in the facilities that manufacture applicable generics, along with other relevant information informing supply chain reliability assessments.

¹ The role of GPOs may seem similar to that of program participants in that both negotiate with manufacturers on behalf of hospitals. However, the contracts GPOs negotiate are not binding to hospitals, whereas the Shortage Program contracts would be binding to hospitals.

In addition to the add-on payment tied to contract features, the Shortage Program has additional payment incentives that start two years after the Shortage Program begins. Starting in 2029, providers are eligible for specified payments for holding three months of buffer inventory, with large providers eligible for an additional three months. Also, providers are eligible for a yet-to-be-determined payment for establishing appropriate buffers and for purchasing product from what, in retrospect, turn out to be reliable manufacturers. Such outcome payments would be available to the top 30% of top performers among providers.

In our review, we focus our analysis of the Shortage Program on two areas: incentive alignment and compliance burden.

Incentives continue to be misaligned

The Shortage Program creates explicit incentives to sign up for long-term contracts. However, the incentive to select more reliable manufacturers and pay them a premium is muted. Because hospitals continue to be reimbursed on DRG or molecule-specific ASP, the proposed payment structure incentivizes hospitals to select the lowest-cost generic option that meets the program criteria, which do not include direct measures of reliability in the set of core measures. The advanced measures are at best [weakly correlated](#) with reliability. Providers continue receiving Shortage Program payments when the contracted product is not delivered, subverting incentives to pay more for reliability.

Instead of relying on direct measures of reliability, the Shortage Program addresses reliability indirectly by requiring manufacturers to disclose supply chain and good manufacturing practices (GMP) information under Manufacturing Reliability Agreements they would sign with program providers. The key incentive for program participants to act on this supply chain reliability information is through program oversight, with CMS decertifying participants after attempts to mitigate program compliance fail. This is a weak incentive.

The buffer inventory strategy design can also be substantially strengthened. Our concern is based on the way in which different types of [hospitals respond](#) to information on emerging shortages. Well-resourced hospitals can quickly place large orders through multiple accounts, building buffer stock at the earliest sign of potential shortage. Smaller hospitals and providers find themselves with little product to go around, especially as large hospital systems shift to direct purchases from manufacturers that lower product available through wholesalers. Yet the Shortage Program plans to buffer large hospital systems more than the providers that need it most.

Setting aside the differential need for buffering, inventory allocated to end users is neither effective nor cost effective [relative to](#) keeping buffer inventory upstream (e.g., wholesalers or manufacturers).

Shortage Program creates compliance burdens that will likely adversely affect participation

Because the Shortage Program relies on adherence to contractual features, it has many measures for establishing compliance. The Shortage Program has separate payment mechanisms for meeting core standards, advanced standards, buffer inventories, and outcome measures. It specifies the length of contracts, the share of committed volume, the level of buffer inventory

that must be held, and markups for private labels. It also requires a web of contracts with the Secretary, presumably to enable oversight. Providers must periodically submit drug-level data on drug volume contracted and inventories held. They are also subject to CMS audits.

The complexity of this approach would likely adversely affect provider willingness to participate in the program. In general, willingness to participate in a program depends on the benefits and costs of program participation. The benefits of participation in the Shortage Program would include higher CMS payments and greater supply chain reliability (for which providers have generally not shown willingness to pay, as uptake of various buffering programs [show](#)). The costs would include not only the added spending on drugs at the time of purchase but also participation costs in the program. The latter includes the cost of signing up for the program with CMS and program participants, collecting data required for payment, and then submitting data to CMS.

The higher the participation costs, the less room there is for passthrough to manufacturers and, separately, the lower the likely provider uptake of the Shortage Program. We should expect lower uptake for lower volume purchases, not only across providers but also across products for a given provider if enrollment or reporting must be done product by product.

Of note is that 340B providers should have a higher incentive than other providers to sign up for the Shortage Program if Medicaid inflation rebates and, with it, part of the 340B discounts for applicable generics are eliminated.² Because of [GPO prohibition](#), 340B providers cannot use GPOs in the outpatient setting, but the Shortage Program would enable them to use program participants for applicable generics. Because program participants will likely obtain discounts closer to existing GPO rates than the mandatory 13% Medicaid rebate, 340B providers will have an incentive to enroll.

Recommendations for improving the Shortage Program

The proposed long-term contract nature of the Shortage Program is well suited for using retrospective outcome measures directly tied to reliability, with it improving incentive alignment. Using outcome measures would also reduce complexity and participation costs. To further lower participation costs, we recommend the Committee consider structuring the Shortage Program around program participants, not providers.

We recommend the Committee considers revising the Shortage Program as follows:

1. CMS would authorize program participants to sign contracts with manufacturers and, separately, with healthcare providers.
2. At the end of the year, CMS would retrospectively assess program participants on whether the contracts they signed with manufacturers delivered applicable generics as contracted in that year, no matter contract length. This assessment would be quantitatively summarized through a **program participant performance index (PPPI)** that adjusts for shortage risk and other measures we discuss in the Technical Appendix.

² The 340B program allows qualifying hospitals to obtain outpatient drugs at a discount. The discounts [reflect prices](#) paid by the Medicaid program.

3. For each program participant, CMS would assign bonus payments based on PPPI assessment and the size of the program participant's provider pool.
4. Bonus payments would automatically flow to participating providers, with each provider getting a share proportional to its participation in the program participant's provider pool.
5. CMS would publish current and past program participant performance scores, helping providers to select program participants that persistently generate higher performance scores and therefore higher payments to providers. This would create competition among program participants.
6. CMS would further promote provider participation by incorporating Shortage Program participation in the provider's [Medicare star ratings](#).

By realigning incentives through outcome measures, our proposal is significantly less complex. For example, the Shortage Program would not need to spell out who can keep what share of the CMS payment because the incentive is self-regulating: reliability will not result if there is not enough passthrough to manufacturers and uptake will be limited if program participants charge providers too high an administrative fee. The Program would not need to spell out the level of buffer inventory across products, letting program participants decide what level is appropriate given risk of disruption and how to efficiently administer such buffers (likely without committing it in advance to specific providers).

The proposed changes to the Shortage Program would also increase provider willingness to participate. For one, there would be no reporting requirements for providers, with payments automatically flowing to providers based on the performance of program participants they selected. Incorporating program participation into Medicare star ratings would provide an additional incentive because those [ratings have monetary value](#) through increased outpatient visits from Medicare participants.

Recommendations for complementary policies

The Shortage Program rests on a premise that if hospitals are incentivized to select more reliable manufacturers, they will be willing to pay a premium for their drugs. This, in turn, will change incentives for manufacturers to invest more in manufacturing quality systems. However, without passthrough to manufacturers, the Shortage Program will not achieve its goals.

Government policies can stand in the way of passthrough. Here we discuss two such policies: Medicaid inflation rebates and Drug Enforcement Administration (DEA) manufacturer quota.

We commend the Committee for addressing **Medicaid inflation rebates**, and with it the **340B discounts** that follow the Medicaid formula. Under the Shortage Program, such rebates and discounts would directly penalize manufacturers that enter into agreements with hospitals willing to pay a premium for reliability, partially blunting the incentives that the Shortage Program aims to create. Similarly, they would partially unwind the Program features that explicitly allow for within-contract price adjustment for input cost increases. Blocking passthrough would particularly disadvantage generic cancer drugs, which not only have a high share in 340B but also are produced on dedicated lines, limiting spillover investment from other applicable generics. Blocking passthrough for some products but not others would also raise the manufacturer incentive to repurpose such lines for products with higher passthrough.

Ideally, the Committee would eliminate Medicaid inflation rebates for generics without reallocating those inflation rebates to base rebates that are currently set to 13%. If reallocation is necessary, we would recommend narrowing the Medicaid inflation rebate exemption to generics that are part of the Shortage Program, with the value of those inflation rebates spread over all generic products, the majority of which are oral dose products without a high risk for shortage. Such an adjustment would enable passthrough where it is needed most, while spreading the cost of the passthrough over a much larger base of drugs.

We do, however, recommend expanding the scope of the Medicaid inflation rebate exemption to so-called [505b2 generics](#), many of which have been affected by shortages. These products are pharmaceutically equivalent copies of branded products, but for various reasons, manufacturers [chose](#) the 505b2 abbreviated approval pathway over the standard Abbreviated New Drug Application (ANDA) pathway. The 505b2 pathway [does not](#) automatically come with a therapeutic equivalence (TE) rating, which was not an issue until the 2022 [CMS determination](#) that 505b2 generics without a TE rating are considered single-source drugs. Manufacturers can request a TE rating from FDA, but a lag may exist between CMS assessment of rebates and FDA's action. We propose the Committee allow 505b2 generics to obtain a temporary waiver from Medicaid inflation rebates while FDA considers the TE request, repayable if FDA denies that request.

We also recommend that the Committee revisit [how Medicaid inflation rebates are assessed](#) for all generics, including those that would be exempt but whose rebate would be reallocated. There are three aspects of the **inflation rebate calculation** that require further scrutiny. First, the Consumer Price Index (CPI) may not be the appropriate inflation index for drugs manufactured through chemical synthesis. Second, Average Manufacturer Price (AMP) is structured in a way that it can trigger a penalty when no underlying prices increase. Third, the treatment is unequal across manufacturers of the same drug – generic versions that enter after April 2013 can influence the benchmark against which inflation is calculated [whereas](#) older generic versions cannot.

In addition to Medicaid inflation rebate reforms, the Committee should consider that the **DEA's quota system** can serve as a barrier to the Shortage Program's success because the DEA in effect controls what market share a [manufacturer can obtain](#). Because provider-administered controlled substances are [commonly in shortage](#), we recommend the Committee add coordination language between CMS and DEA. We also recommend that the Judiciary Committee consider legislation requiring DEA to align with the Shortage Program by creating assurance that Shortage Program long-term contracts in stable utilization markets are given the necessary quota expeditiously. We also recommend that the Judiciary Committee direct the DEA to set terms under which program participants could contract for higher buffer inventory than now allowed under DEA regulations.

Conclusion

We thank you and your staff for your commitment to solving drug shortages through your proposal.

Despite our concerns about the effectiveness of the current version of the Shortage Program, we are confident the general framework of long-term contracts can be adjusted in ways to address such concerns. By leveraging the Shortage Program's long-term contract structure and focusing

on outcomes, policymakers can avoid much of the complexity that currently exists while creating stronger incentives to achieve the ultimate aim – delivering quality product as contracted. By scoring program participants and then allowing the bonus payments to flow automatically to participating providers, policymakers can minimize participation burden on those providers, with it encouraging Shortage Program uptake.

There are aspects of our proposal that require further development. One area is addressing that our proposed framework does not incentivize delivery of substandard products. In the Appendix, we describe potential avenues. Another area is identifying the appropriate level of spending needed to create sufficient incentives to the market. A potential starting point is the existing legislative proposal, however, there are reasons to frontload spending when startup costs for participants are higher. Similarly, initial years of the Shortage Program would benefit from greater bonus payment clarity, perhaps by structuring initial bonus payments as program participation payments while CMS collects program participant performance data.

We are committed to providing objective analysis to support policymakers in their efforts and look forward to working with your staff as this legislative proposal develops.

Sincerely,

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Technical Appendix: Program participant performance index (PPPI)

Under our proposal, the primary outcome measure is whether the long-term contract was fulfilled in terms of delivering products as contracted. CMS could collect such data by requiring program providers to report, at the beginning of applicable year, the characteristics of long-term contracts for applicable generics. The data would include which drugs, which manufacturers, and which providers are involved, and how much committed volume is covered. CMS would either define on-time delivery in regulation (e.g., monthly or quarterly targets) or let program participants define it. At year's end, each program participant would report to CMS on-time performance, which CMS can verify using data that wholesalers submit to [ASPR Control Tower](#).

The contract performance measure would require further refinement because grading solely on “did the manufacturer deliver” can create an adverse incentive to program providers for cherry picking easiest-to-fulfill contracts. To attenuate such behavior, CMS should either adjust payments for shortage risk or require that each program participant has contracts for each applicable drug. CMS should determine shortage risk weights in collaboration with FDA, the [HHS Supply Chain Coordinator](#), and input from an external advisory panel of experts.

It is also important to address the potential incentive that payment on product delivery can create for all Shortage Program parties, namely delivering and accepting product that may not be made to specification. For this reason, we recommend the PPPI be adjusted for contracted products that faced GMP issues and other measures Secretary determines appropriate.

One concept to explore in this context is the previously [proposed drug quality Sentinel program](#) where Academic Medical Centers (AMCs) would use qualified technologies such as [water proton NMR](#) or [near-infrared spectrometry](#) to identify products out of specification and report them to FDA for follow up, with it generating much data about product quality. This Committee could create financial incentives to AMCs to participate in such testing and reporting, with the possibility that the Shortage Program could later use information from such a Sentinel program to assess whether delivered products meet specification.

The PPPI can also be used to get away from one-size-fits all in baseline Shortage Program requirements. That would serve to address concerns that too high a threshold set in legislation could result, in some markets, in forcing program participants into contracts with unreliable manufacturers. PPPI could create room for setting lower certain contract thresholds, allowing the market to figure out the most appropriate contract share for the state of a particular drug market.

The PPPI can also be used to advance other objectives, such as addressing the uneven nature of which providers are most affected by shortages. PPPI could reward allocation mechanisms that maximize patient access in case of product shortfall. This voluntary bonus could be based on data from program participants showing the extent to which participating providers had declines in typical drug use (as shown by EHR data) at a rate that is greater than normalized product shortfall.