Section-by Section:
Senate Finance Committee Prescription Drug Shortage Discussion Draft

Given the breadth of stakeholder interest in addressing drug shortages, the Finance Committee has created a dedicated inbox to receive feedback. Please submit any comments on the proposal to DrugShortages@finance.senate.gov no later than June 6, 2024.

I. Medicare Drug Shortage Prevention and Mitigation Program

Overview

This section would create a new Medicare Drug Shortage Prevention and Mitigation Program within Medicare Part E. The program aims to leverage targeted, tailored payment incentives to shift certain practices and incentives among stakeholders across the supply chain for generic sterile injectable drugs, along with other generics at heightened shortage risk, in order to prevent and mitigate the market failures driving many critical shortages. To participate in the voluntary program and receive corresponding incentive payments, key supply chain entities (e.g. group purchasing organizations (GPOs), wholesalers, providers) would be required to adopt responsible, resiliency-driven reforms to contracting and purchasing practices, promoting a market that improves outcomes and better meets patient, clinician, and health care system needs.

Subsection (a): Establishment

Subsection (a) requires the Secretary to establish the Medicare Drug Shortage Prevention and Mitigation Program no later than [January 1, 2027].

Subsection (b): Program Participation & Design

Paragraph (1): Application Process for Program Participants

These provisions specify requirements for the application process for eligible entities (such as wholesalers, GPOs, and nonprofits, along with avenues for direct health care provider participation) to become program participants, including by specifying the scope of applicable generics, core standards, and (if applicable) advanced standards with respect to which an applicant plans to participate for a given program year.

These provisions also ensure an assessment of applicants' capacity to perform key program functions, and provide for an abridged application process for later program years with respect to applicants that have participated previously.

Paragraph (2): Program Participants

These provisions describe the role of program participants, which facilitate health care provider participation in the program and serve as key hubs for the various agreements and administrative functions necessitated by said program. Specifically, the draft describes a **"program participant"** as an entity or consortium of entities that: (a) receives approval to participate through the processes specified under paragraph (1); (b) enters into a Program Participation Agreement with the Secretary of Health and Human Services (HHS); and (c) complies with all requirements of such agreement.

Applicants approved by the Secretary will become program participants for the upcoming program year. In order to become program participants, such applicants will have [15 days] following application approval to enter into **Program Participation Agreements** with the Secretary. Under Program Participation Agreements, participants must agree to provide timely updates and information related to the program to the Secretary, submit to audits, and comply with processes for modifying or termination agreements under this subsection.

By January 1 of each year prior to the upcoming program year, the Secretary will publish a list of program participants. This list will give providers an opportunity to shop between different program participants, facilitating a competitive market.

Paragraph (3): Payment-Eligible Providers

Payment-eligible providers include hospitals, physician practices, and other providers that are eligible for payment incentives under the program. Specifically, the draft defines a **"payment-eligible provider"** as a provider of services or supplier that: (1) furnishes items and services, including applicable generics, to Medicare beneficiaries; (2) enters into a Program Provider Agreement with a program participant (or a Direct Program Participation Agreement with the Secretary, if opting to participate directly); (3) complies with specified reporting requirements, certifications, and attestations; and (4) complies with the terms of all such agreements.

Payment-eligible providers may enter into **Program Provider Agreements** with program participants by October 1 of each year. Under Program Provider Agreements, providers shall agree to provide timely updates and information related to the program to the program participant, maintain records and report information related to inventory and purchases, submit to audits, and comply with processes for modifying or termination agreements under this subsection. Program participants will also have to agree to provide timely notification and information to providers related to the program and may not include terms in these agreements that prohibit or effect of prohibiting providers from entering into arrangements with other program participants.

Payment-eligible providers may apply to become **"direct program participants"** through a similar application process as the one outlined for program participants. These providers will participate in the program, with respect to all or some applicable generics, without using a program participant as an intermediary.

Payment-eligible providers must report information related to their purchasing and inventory of applicable generics to the program participant and the Secretary.

Payment-eligible providers must submit annual pricing stability certifications to the Secretary under which the provider will agree not to seek or accept additional rebates, discounts, or other price concessions from applicable manufacturers on applicable generics subject to the program, including 340B discounts. These provisions help ensure that manufacturers have a true fixed price in contracts under the program.

Payment-eligible providers shall also submit attestations to the Secretary that such provider is compliant with any standard under subsection (d) for which such provider intends to receive incentive payments for an applicable generic.

Paragraph (4): Applicable Generic Manufacturers

An **"applicable generic manufacturer"** is a manufacturer that: (1) makes at least one applicable generic; (2) is in a Manufacturer Reliability Agreement; and (3) adheres to the terms of such agreements; and (4) reports an Average Sales Price (ASP) on all applicable generics subject to the program (including with respect to applicable generics with no ASP reporting requirements under current law, such as drugs that never receive separate payment under Medicare).

For the first three years of the program, **"applicable generics,"** for program purposes, comprise multiple-source drugs furnished under Part A or Part B (or, in the absence of A or B utilization, are furnished under a State Medicaid program and approved for at least one pediatric indication) that are injectable or infused, excluding self-administered drugs and vaccines. [For program years after 2030, applicable generics may also include drugs determined by the Secretary (in consultation with FDA and stakeholders) to be at heightened risk of supply disruption or shortage, including certain non-injectable or infusible multiple-source products.]

Private-label drugs that otherwise meet the definition above may qualify as applicable generics only insofar as the entity marketing or distributing such a drug discloses its initial acquisition cost for the product (to relevant program participants and program-eligible providers). Such an entity would also need to limit any markup charged to program-eligible providers (above such acquisition cost) to no more than [10 percent], and contracts between initial sellers and such marketing/distribution entities would need to meet the program's relevant core standards.

Applicable generic manufacturers that participate in the program must enter into Manufacturer Reliability Agreements with program participants. The terms and conditions of **Manufacturer Reliability Agreements** include a description with supporting evidence of why the manufacturer has capabilities to meet program requirements, relevant supply chain reliability and quality information, an attestation of compliance with FDA rules related to quality and shortages, and an agreement to provide timely information to program participants and submit to audits.

With respect to supply chain, compliance, and quality information provided under Manufacturer Reliability Agreements, the Secretary shall consult with FDA and stakeholders to develop standards for what specific information must be submitted. Submissions may include appropriate redactions and revisions related to proprietary information. The information shall include the following:

- Information related to compliance, inspection, enforcement action, and pre-/non-enforcement action history;
- Geographic information of the establishments that are utilized by the manufacturer with respect to the applicable generics and a list of entities that contract with manufacturers for relevant functions related to the applicable generic;
- Any redundancy risk management plan submitted to FDA;
- A list of discontinuance or interruption notifications submitted to the FDA;
- A list of all instances where the applicable generic has been placed on FDA's drug shortage list; and
- Any other information the Secretary determines appropriate.

Paragraph (5): Clarifications, Standards, and Processes for Agreements

All agreements under the program carry the force of a binding contract. The Secretary shall establish processes to allow participating parties under this subsection to enter into such agreements for multi-year terms, subject to requirements to update such agreements, as appropriate.

The Secretary shall establish processes for modifications, suspensions, and terminations of all the agreements under this subsection. The Secretary shall also establish a process for holding payment-eligible providers harmless for no longer than [6 months] with respect to incentive payments in the event of a mandatory termination or suspension of an agreement that was not caused by such provider. The Secretary may grant temporary waivers or modifications of the terms of the agreements under this subsection on a case-by-case basis in the event of significant hardship interfering with the ability of the relevant entity to comply, such as a natural disaster, public health emergency, bankruptcy, or other unique or unexpected catastrophe.

Paragraph (6): Outreach & Technical Assistance

The Secretary shall provide education, outreach and technical assistance to relevant entities for purposes of facilitating program participation and compliance with the program.

Subsection (c): Prevention & Mitigation Incentive Payments

Paragraph (1): In General

The Secretary shall calculate and make: (1) quarterly lump-sum payments for meeting core standards and advanced standards; (2) additional annual lump-sum payments related to buffer inventory standards; and (3) additional bonus payments related to outcome measures.

Paragraph (2): Payments Related to Core Standards & Advanced Standards

When a payment-eligible provider meets all of the core standards with respect to an applicable generic, the provider will receive a quarterly lump-sum incentive payment, in addition to (and separate from) any payment made to said provider for the generic and/or associated services under the relevant Medicare payment system. The provider will receive an additional payment that will typically range between [five and 25 percent] of the applicable generic's ASP (subsequently indexed, for program purposes, to changes in the Producer Price Index, Pharmaceuticals) on each unit of the drug that is part of the provider's "total committed inventory"[1] under contracts under subsection (d) with applicable generic manufacturers that are primary and secondary suppliers. Additional two-percent add-on payments will be made when the provider meets an advanced standard related to advanced manufacturing or domestic manufacturing for an applicable generic.

Specifically, under the discussion draft, during a quarter where a provider meets all core standards with respect to an applicable generic, the Secretary shall calculate a payment for that quarter equal to the total committed volume for the quarter or such generic multiplied by the payment factor for such generic.

The **"payment factor"** is equal to the applicable incentive percentage for such generic multiplied by the applicable pricing input for such generic.

The **"applicable incentive percentage"** is equal to the sum of:

- The baseline incentive percentage for such generic where the provider meets all core standards; and
- [Two] additional percentage points for each advanced standard met by the provider.

[1] Because providers do not purchase drugs based on line of business, the total committed inventory can capture units of applicable generics that are ultimately utilized by Medicare beneficiaries or patients with other forms of coverage. In other words, the payment incentives described under this subsection extend beyond drug units ultimately utilized in Medicare.

The **"applicable pricing input"** for an applicable generic is the ASP for such generic, trended forward by the Producer Price Index for Pharmaceuticals.

In order to determine the **"base applicable incentive percentage,"** the Secretary shall assign each applicable generic to a cost band (similar, methodologically, to the cost bands used by CMS when assigning an innovative technology to an appropriate New Technology Ambulatory Payment Classification under the Part B Hospital Outpatient Prospective Payment System (OPPS)) based on such generic's applicable pricing input and publish such percentages publicly. No base applicable percentage would be lower than [five] percent or higher than [25] percent, subject to limited exceptions.

Paragraph (3): Payments Related to Buffer Inventory Standards

Beginning with program year [2029], where a payment-eligible provider meets a buffer inventory standard for a program year, the Secretary would calculate and provide an additional lump-sum payment equal to:

- The total units of buffer inventory for such generic, up to a 6-month supply; multiplied by
- [150%] of the average applicable incentive percentage for such generic (i.e. based on the achievement of core standards), multiplied by the applicable pricing input for such generic.

Paragraph (4): Payments Related to Outcome Measures

Beginning with program year [2029], payment-eligible providers would be eligible to receive additional payments (from a bonus pool, with allocations determined by the Secretary) based on performance relative to their peers on Secretary-designed outcome measures. Outcome-related payments would reward at least the [top thirty percent] of the highest-ranked providers across all outcome measures, in aggregate.

The draft currently includes placeholders for annual bonus pool funding, as the Committee works to determine what amounts would sufficiently incent provider purchasing and inventory management practices aligned with the legislation's goals.

Paragraph (5): Authority to Reconcile and Adjust Payments

The Secretary shall reconcile or adjust payments, as needed, based on data reported by providers and program participants, including to account for:

- Any reductions in total committed volume for the program year;
- Any reductions in total buffer inventory for the program year; or
- Cases where an advanced standard is met by a primary or secondary supplier, but not both.

Subsection (d): Program Standards & Measures for Determining Incentive Payment Eligibility & Amounts

Paragraph (1): In General

With respect to any applicable generic included in such an agreement, any Program Participation Agreement or Direct Program Participation Agreement shall comply with and meet the standards and measures established under this subsection in order for payment-eligible providers to receive incentive payments corresponding to such standards and measures.

Paragraph (2): Minimum Committed Volume

To become eligible for payment, a payment-eligible provider must commit and subject at least the **"minimum committed volume"** of an applicable generic to program terms and conditions for a given year. The percentage for minimum committed volume is:

- [40%] of total standard inventory for program years [2027 – 2028];
- [60%] of total standard inventory for program years [2029 – 2031]; and
- [75%] of total standard inventory for [2032] and beyond.

Providers can choose to commit amounts in excess of the minimum committed volume under the contracts described under paragraph (3). The total committed volume for primary and secondary suppliers under paragraph (3) is the amount that will be used to calculate payment incentives related to the core standards under subsection (c).

Paragraph (3): Core Standards

Beginning in program year [2027], a payment-eligible provider can become eligible for incentive payments when they enter into contracts with suppliers that meet all of the **"core standards"** with respect to their total committed volume for an applicable generic. The core standards aim to set a floor for contracting and purchasing practices under the program. Different standards apply with respect to contracts with primary and secondary suppliers.

Payment-eligible providers must purchase a majority of total committed volume of an applicable generic from a **primary supplier** that has a Manufacturer Reliability Agreement in effect with the provider (or a program participant acting on behalf of such provider). Contracts with primary suppliers must include the following terms:

- Duration: Such contracts must have a duration of at least two years for contracts entered into during program years [2027 or 2028], and at least three years for contracts entered into in program year [2029] and beyond.
- Off-Contract Purchases: Such contracts must prohibit off-contract purchases that would reduce the total committed volume, except in cases where the provider could not adequately furnish the generic without making such off-contract purchases. Providers will be required to keep records of off-contract purchases, including certifications that sufficient quantities of the generic could not be purchased from the primary or secondary supplier.
- Pricing Stability: The price agreed to in the contract may not be reduced through rebates, discounts, price concessions, fees or other forms of remuneration paid by the manufacturer to the program participant, except for: (1) bona fide service fees; and (2) reasonable fees for failure to meet on-time delivery standards when such failure is the fault of the manufacturer.
- Upward Price Adjustments: Such contract must permit upward price adjustments by the supplier for the applicable generic in the event of a natural disaster or other severe supply chain disruption that significantly affects the supply of such applicable generic (unless such disruption was caused by the manufacturer failing an inspection and/or related FDA enforcement actions).
- On-Time Deliveries: Such contract must include uniform standards established by the Secretary related to on-time deliveries for purchase orders and require the primary supplier to provide: (1) advance notice to program participants and providers with which such supplier has entered into a Manufacturer Reliability Agreement of inability or anticipated inability to meet such on-time

delivery standards; and (2) quarterly reports on the percentage of deliveries that met such standards.
- Truthfulness: The parties must attest that any information submitted pursuant to the contract is true, to the best knowledge of the party.

To the extent there is more than [one/two] manufacturer[s] that produces and markets a generic, providers must also have in place a contract for the applicable generic with a **secondary supplier** that is different from the primary supplier. These requirements are subject to a good cause exception. Contracts with secondary suppliers include many of the same terms as contracts with primary suppliers, except for the following differences:

- There is no contract duration requirement for secondary suppliers.
- The secondary supplier must certify that it has a distinct source of API from the primary supplier, unless there is only one establishment that makes such API.
- Secondary suppliers must submit contingency plans to providers that describe their capacity and how the supplier intends to meet the provider's purchasing needs in the event that the primary supplier cannot.
- The provider must commit at least [10%] of total committed volume to the secondary supplier.
- Rather than the off-contract prohibition outlined above, the provider must commit to attempt to purchase any remaining total committed volume or buffer inventory from the secondary supplier before making an off-contract purchase, in the event a primary supplier cannot adequately furnish the drug.

Paragraph (4): Advanced Standards

Beginning in program year [2029], payment-eligible providers may receive additional payments when they meet one or more advanced standards.

- Advanced Manufacturing Standard: Providers can receive additional payment where they meet the advanced manufacturing standard. The standard is met where the provider's primary or secondary supplier for an applicable generic (or both) uses an advanced manufacturing technology, as defined by FDA, for a substantial portion of the manufacture of the applicable generic. A substantial portion must be more than *de minimis*.

- Domestic Manufacturing Standard: Providers can receive additional payment where they meet the domestic manufacturing standard. To meet this standard, the provider's primary or secondary supplier (or both) must make the finished dosage form of the applicable generic in the United States, cannot make any component of the drug in a region of interest, and shall meet minimum sourcing standards from OECD countries with respect to API.

Paragraph (5): Buffer Inventory Standards

Beginning in program year [2029], providers can receive additional payment where they meet the enhanced or customary buffer inventory standard. The **enhanced buffer inventory standard** will be available to larger providers and requires the provider to purchase 6-months' worth of supply of an applicable generic (calculated based on such provider's total standard inventory) from a primary supplier. The **customary buffer inventory standard** will be available to all other providers and requires maintenance of 3-months' worth of supply of an applicable generic.

Both standards will be subject to anti-hoarding measures developed by the Secretary and standards related to third-party storage. The provider can store the buffer inventory directly or through another entity acting on the provider's behalf as long as the drug is physically stored within the United States and the third-party entity provides evidence that it can meet the provider's needs.

The Secretary may adjust the 6-month or 3-month threshold: (1) by provider peer group; (2) when the 6-month threshold could create risk of disruptions or shortages; and (3) when the expiration date for the generic limits how much volume a provider should reasonably hold in inventory.

Paragraph (6): Outcome Measures

Beginning in program year [2029], payment-eligible providers may receive additional payments when they perform well on outcomes measures relative to their peers. The Secretary [may/shall] establish the outcome measures that evaluate:

- The extent to which a provider or third party acting on behalf of such provider maintained sufficient inventory of an applicable generic for which a notification of discontinuance or interruption was submitted to FDA during the program year;
- The portion of inventory a provider purchased from a manufacturer that's a primary or secondary supplier to such provider, did not [cause/experience] a shortage during the program year, complied with attestations of compliance with various FDA rules and laws, and [meet other standards established by the Secretary through rulemaking]; and
- Any other measure that evaluates the extent to which a provider prevented or mitigated shortages during the program year based on the purchasing or inventory management practices of such provider.

The Secretary shall evaluate providers against the outcome measures on an annual basis based on information and data reported by providers or program participants. To be eligible for payment related to the outcome measures, a provider must comply with all data submission and reporting requirements.

No later than program year [2027], the Secretary shall establish and publish peer groups to differentiate among different types and features of payment-eligible providers. The Secretary shall consider factors such as location, category or type of provider, size and scale, affiliation with large health systems/entities, number of beneficiaries served, and types of items and services furnished.

Subsection (e): Program Oversight, Enforcement, & Accountability

Paragraph (1): Audits

The Secretary shall conduct periodic audits of the agreements under this section, of the information submitted and records maintained in relation to such agreements, and of any other information required to be reported or maintained under this section. Any failure to comply with such an audit shall be considered a violation of the terms of such agreements. The Secretary may use a vendor to carry out such audits.

Paragraph (2): Enforcement Actions

With respect to violations by providers, the Secretary may impose intermediate sanctions and may require timely submission of a corrective action plan, as determined appropriate by the Secretary. The Secretary may impose a civil monetary penalty on a payment-eligible provider where the Secretary determines that intermediate sanctions do not result in remediation actions.

Paragraph (3): Public Reporting Related to Program

The Secretary shall publish, update, and maintain on an ongoing basis on a publicly available website consumer-friendly descriptions of information about program participants, payment-eligible providers, and applicable generic manufacturers related to agreement terminations and suspensions, audit findings, and other program compliance and enforcement information.

Paragraph (4): Non-Duplication & Streamlining Implementation

The Secretary shall establish procedures to streamline any information submission requirements under this subsection to prevent duplication with other reporting requirements under this title.

Paragraph (5): Significant Hardship

The Secretary may waive or reduce penalties for violations of this section in the event of significant hardship interfering with the ability of an entity to comply with program requirements.

Paragraph (6): Reporting of Alleged Violations

The Secretary shall make available and maintain a mechanism for providers, program participants, manufacturers, and other stakeholder to report on a confidential basis alleged violations of the requirements of this section.

Subsection (f): Definitions

This subsection includes definitions of the following terms:

- Active pharmaceutical ingredient
- Affiliate
- Bona fide service fee
- Corrective action plan
- Drug product quality initiatives
- Generic drug component
- Manufacturer
- Material modification
- Minimum committed volume
- Off-contract purchase
- Primary supplier
- Private label drug
- Remediation plan
- Secondary supplier
- Total buffer inventory
- Total committed volume
- Total standard inventory

Subsection (g): Program Reports, Studies, and Evaluations

This subsection outlines periodic GAO studies related to the impact of and participation in the program.

Subsection (h): Implementation

This subsection is currently a placeholder for implementation funding.

I. Medicaid Shortage Provisions

This section would make targeted changes to the Medicaid Drug Rebate Program's (MDRP's) generic drug inflation rebate provisions to help prevent and mitigate shortages of generic medicines sold at the retail level and dispensed at pharmacies. This section would take effect on [January 1, 2027].

Amendments to Section 1927(c)(3)(C): Generic Inflation Rebates

These provisions would limit the application of generic drug inflation rebates under the MDRP only to generic medicines that have no generic competitors ("sole-source generics"), since presumably, these generics (in many cases) would have more pricing power than multi-source generics. Certain sole-source generics would, however, also be exempt from the inflation rebate to preserve generic market entry and competition.

The discussion draft also exempts any generic that has an average annual total cost of less than $100. The $100 amount would be adjusted for inflation based on the consumer price index for all urban consumers (CPI-U).

The generic drugs exempt from inflation rebates under these provisions would remain subject to basic rebates under the MDRP, as applicable.

In addition, these provisions would allow the Secretary to reduce or waive inflation rebates for generic medicines that are not exempt from the inflation rebates when:

- The generic is on FDA's drug shortage list;
- The Secretary determines there is a severe supply chain disruption, such as a natural disaster or other unique or unexpected event; and
- The Secretary determines that, without such reduction or waiver, the drug is likely to be on FDA's drug shortage list during a subsequent quarter.

Amendments to Section 1927(c)(3)(B): Changes to the Applicable Percentage for Generics

These provisions would offset the cost of new exemptions from generic inflation rebates under the MDRP by making proportional adjustments to basic rebates paid by generic manufacturers as a predetermined percentage of the Average Manufacturer Price (AMP). The goal of this language would be to keep the Medicaid program whole for any lost rebates while still increasing pricing predictability and stability for generic manufacturers.

Specifically, these provisions would increase the "applicable percentage" of AMP used to calculate generic basic rebates. The current basic rebate for generic medicines is 13% of AMP. The draft currently includes placeholders for adjusted percentages.