BREAKING DOWN FEDERAL POLICIES TO ADDRESS DRUG SHORTAGES

McDermott+ Consulting

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Background

Medication shortages threaten patient care and the safe and effective delivery of services across the US healthcare system. Such shortages can lead to delays in treatment, rationing, potential substitution of medication and increased risk of medication errors. Shortages of critical drugs, which is a persistent issue for patients and providers as monitored by the US Food & Drug Administration (FDA), span therapeutic areas, with generic drugs comprising the majority of shortages.

Following the broad supply chain disruptions of the COVID-19 pandemic, federal policymakers are expressing renewed interest in policies to bolster the resiliency of the pharmaceutical supply chain. The Biden administration and members of Congress have recently put forward policy proposals designed to influence the market forces that contribute to drug shortages. These proposals go beyond the FDA's traditional role in regulating drug manufacturing and tracking shortages to address upstream levers in the supply chain – the provider purchasers of the drugs.

The administration, acting through the Centers for Medicare & Medicaid Services (CMS), has proposed policies that would encourage certain hospitals to maintain buffer stocks of essential medications. Acting through the Department of Health & Human Services (HHS), the administration also issued a white paper outlining a broader vision for assessing drug manufacturer resiliency and applying incentives or penalties to hospitals tied to their drug purchasing practices.

In Congress, the chair of the House Energy and Commerce Committee and ranking member of the Senate Finance Committee jointly issued a request for information on drug shortages. The Energy and Commerce Committee chair also released draft legislation, including various reforms to Medicare, Medicaid and FDA authorities. Finally, the chair and ranking member of the Senate Finance Committee issued a white paper presenting policy options to address shortages of generic sterile injectable (GSI) medicines and draft legislation that would link financial incentives for hospitals to certain process and outcome measures for preventing and mitigating GSI shortages.

Below, we analyze the federal government's recent efforts to address drug shortages and offer an outlook on possible future federal policies.

ADMINISTRATION

CY 2024 Outpatient Prospective Payment System Rulemaking

In the Calendar Year (CY) 2024 Outpatient Prospective Payment System (OPPS) proposed rule, CMS included a request for comments on potential payments under the Inpatient Prospective Payment System (IPPS) and OPPS for establishing and maintaining access to essential medicines.

CMS defined "essential medicines" as the 86 medicines identified in the Assistant Secretary for Preparedness and Response (ASPR) report, Essential Medicines Supply Chain and Manufacturing Resilience Assessment. These medicines were deemed critical for minimum patient care in acute settings or important for acute care of respiratory illnesses/conditions, with no comparable alternative available.

Under the theory that additional payments to hospitals will foster a more reliable, resilient supply of essential medicines, CMS outlined a proposal to consider making separate payments under the IPPS for establishing and maintaining access to a "buffer stock" (*i.e.,* a three-month supply) of these medicines. These extra payments would help account for the additional resource costs associated with establishing and maintaining access to a buffer stock of essential medicines, including through contractual arrangements. At least initially, the payments would be based on the IPPS shares of the additional reasonable costs a hospital incurred to establish and maintain that buffer stock. The payments would be provided biweekly as interim lump-sum amounts and reconciled at cost report settlement. CMS stated that the payments under the IPPS would not be budget neutral and that it would also consider an adjustment under the OPPS.

In response to comments, CMS did not adopt any drug shortage mitigation policies in the CY 2024 OPPS final rule. Most commenters did not support the proposal, expressing concerns that payments to hospitals to maintain a buffer stock of essential medicines could exacerbate existing shortages or cause demand-driven shortages. Commenters also raised concerns about the impact of the policy on small, rural providers and safety-net hospitals that may not be able to afford the upfront costs of establishing a buffer stock of one or more essential medicines, noting that if only large, urban hospitals could benefit from the policy, the existing supply of essential medicines could become fragmented and result in reduced access for small, rural hospitals.

As next steps, CMS stated it would continue to consider feedback and made clear its intention to propose new Conditions of Participation (CoPs) in forthcoming rulemaking addressing hospital processes for pharmaceutical supply.

FY 2025 Inpatient Prospective Payment System Proposed Rule

In the recently issued Fiscal Year (FY) 2025 IPPS proposed rule, CMS included a more limited version of the policy it sought comments on in previous rulemaking. In the rule, CMS proposed a separate payment for small, independent hospitals to establish and maintain a six-month buffer stock of one or more of 86 essential medicines.

Specifically, for cost reporting periods beginning on or after October 1, 2024, CMS proposed to establish a separate payment under the IPPS to small, independent hospitals for the estimated additional resource costs of voluntarily establishing and maintaining access to six-month buffer stocks of essential medicines. CMS proposed to define a small hospital as one with 100 or fewer beds and to define an independent hospital as one that is not part of a chain organization. (CMS defines a chain organization as "a group of two or more health care facilities which are owned, leased, or through any other device, controlled by one organization.")

The proposed separate payment could be provided biweekly or as a lump sum at cost report settlement. CMS also proposed to limit payments only to hospitals that had already established and maintained a buffer stock of an essential medicine prior to a shortage. CMS proposed that hospitals would remain eligible for separate buffer stock payment for essential medicines for the duration of the shortage. The hospital would remain eligible even if the supply of the medicine in the buffer stock dropped to less than six months' worth as the hospital drew down that buffer stock.

Department of Health and Human Services White Paper

In April 2024, the Department of Health and Human Services (HHS) issued a white paper, Policy Considerations to Prevent Drug Shortages and Mitigate Supply Chain Vulnerabilities in the United States. In this paper, HHS proposed that Congress establish new authorities and funding for two programs: a Manufacturer Resiliency Assessment Program (MRAP) and a Hospital Resilient Supply Program (HRSP). HHS estimates the 10-year budget impact of these programs at between $3.26 billion and $5.11 billion.

Under the MRAP, a private entity under a public-private partnership would develop manufacturing resilience metrics and assign generic medication manufacturers scores based on their performance. Metrics could reflect manufacturers' quality management maturity, manufacturing redundancy, and materials sourcing diversity. Assessments of manufacturers would be conducted by a nongovernmental national accreditation body based on MRAP-developed metrics and reported to HHS. Manufacturers would bear the costs of these assessments and would be incentivized to participate based on the expectation that hospitals would use the information gained from the assessments in their purchasing decisions.

Under the HRSP, hospitals would receive incentive payments (years one through five only) or be assessed penalties (all years) based on metrics of supply chain resilience in their purchasing and other practices, which HHS states would spur incentive change and cover the costs and benefits of engaging in practices that promote supply chain resilience.

The HRSP would involve a hospital scorecard with a combination of attestations and ratings reflecting hospitals' achievements and progress in adopting certain practices, such as inventory management and contracting. With respect to contracting, HHS names failure to supply clauses, minimum purchasing volume requirements, and long-term contracts as elements that promote supply chain resilience. The scorecard could be informed by MRAP information about the reliability of manufacturers that hospitals purchase from. HHS says attention would be given in the design of the HRSP to smaller hospitals that lack the purchasing power of their larger peers. HHS envisions that the HRSP would initially be for a certain set of medications and then expand to other products, including medical devices, and could be expanded to the outpatient setting.

CONGRESS

House Energy and Commerce Committee and Senate Finance Committee Request for Information

In June 2023, the chair of the House Energy and Commerce Committee and the ranking member of the Senate Finance Committee jointly issued a request for information (RFI) on drug shortages. In the RFI, they asked stakeholders for feedback on the scope and impact of the problem; the market, economic and supply chain drivers of shortages; the regulatory challenges that may be contributing to shortages; and the regulatory opportunities that exist to address the issue.

House Energy and Commerce Committee Discussion Draft

In July 2023, Energy and Commerce Committee chair McMorris Rodgers issued draft legislation presenting policy proposals to address drug shortages. The draft encompassed changes to Medicare and Medicaid, including to the 340B drug discount program, and includes the FDA's new requirements to address drug shortages. More details follow:

Changes to the Medicaid Drug Rebate Program

With respect to Medicaid, the draft legislation would suspend inflationary rebates for multi-source GSIs with at least one indication for a serious disease or condition, and for all generic drugs in shortage or at risk of shortage. It would also prohibit total rebates (statutory rebate plus inflationary rebate) on drugs in shortage or at risk of shortage from exceeding 100% of the drug's average sales price (ASP).

340B

The draft legislation connected the issue of drug shortages with discounts available under the 340B program. Specifically, it would except multi-source GSIs with at least one indication for a serious disease or condition from being required to provide 340B rebates. It would further task the Government Accountability Office with conducting a study on generic drugs that have experienced shortages

that are subject to 340B penny pricing and other price-setting policies. The legislation would also task the Health Resources Services Administration with issuing guidance to covered entities on permissible ways to share drugs during shortages.

Medicare Reforms

Similar to its Medicaid reforms, the McMorris Rodgers draft included Medicare provisions to phase out rebate reductions or waivers for both Medicare Part B and Part D drugs exiting a shortage. The legislation would prohibit HHS from conditioning waivers or reductions of the rebate penalties for the duration of a supply chain disruption or shortage. The legislation would also require an Innovation Center test of market-based pricing reimbursement policies for GSI, and it would require HHS to study and make recommendations on reimbursement and coding policies for GSIs and other Part B drugs in shortage.

Transparency Requirements

The draft legislation included new transparency requirements for hospitals and group purchasing organizations (GPOs). For hospitals, the legislation would require reporting on remuneration from GPOs. For GPOs, it would require annual reporting to the HHS secretary and Office of Inspector General on the GPO's written agreements and disclosures.

FDA Reforms

The FDA section of the McMorris Rodgers draft legislation proposed flexibilities for drug manufacturers that engage in practices to ease drug shortages. Specifically, the legislation would incentivize manufacturers to complete shelf-life extension studies by allowing for the award of an additional month of patent exclusivity, and by allowing compounding facilities to compound and dispense a drug within certain timeframes of the drug appearing on the FDA's drug shortage list. The legislation would also establish a pilot program under which the FDA would conduct preapproval inspections for new domestic pharmaceutical manufacturing facilities to expedite the licensure and distribution of domestically manufactured generics.

Senate Finance Committee White Paper

In January 2024, Senate Finance Committee chair Wyden (D-OR) and Ranking Member Crapo (R-ID) issued a bipartisan white paper, Preventing and Mitigating Generic Drug Shortages: Policy Options Under Federal Health Programs, in which it presented policy options to address shortages of GSI medicines.

The paper presented three potential Medicare reforms to mitigate GSI shortages. First, it proposed a payment benchmark for GSIs that would promote competition and reflect a sustainable level of payment for these medicines. The document suggested that provider reimbursement based on the benchmark could be coupled with policies that create incentives for providers, GPOs and wholesalers to contract with GSI manufacturers at sustainable prices.

Second, the white paper proposed linking financial incentives for hospitals to certain process and outcome measures for preventing and mitigating GSI shortages. For example, payments could be linked to the hospital's business practices, maintenance of a buffer stock of GSI, features of the hospital's contracts with GPOs and manufacturers, and quality and transparency standards. The chair and ranking member outlined two tiers of process measures with different lump-sum payments: a basic set of process measures and an advanced set. Under this tiered model, quarterly lump-sum payments could be awarded to hospitals by multiplying the GSI benchmark for a given medication by the hospital's utilization of that medication and then adjusted for the hospital's performance on process measures. Separately, the paper contemplated a pool of bonus payments based on hospital performance on outcome measures, such as retrospective assessment of hospitals' success at preventing and mitigating shortages of GPIs. Bonus payments would be determined by comparing hospitals' relative performance on outcome measures, with the top-performing hospitals receiving the highest bonus payments. Payments would be made annually and would apply on an all-GSI

basis (rather than drug by drug). Payments from the outcome measures bonus pool could be limited to hospitals that satisfy all basic process measures.

Third, the white paper sought to align its approach to addressing GSI shortages across Medicare fee-for-service through corresponding policies under the hospital OPPS and the physician fee schedule (PFS). Under the OPPS, they proposed separate, rather than packaged, payment for GSIs based on the payment benchmark. Under the PFS, physicians would be paid for GSIs based on the benchmark rather than the medication's ASP. In both cases, payments could be modified quarterly based on the provider's performance on process measures. Notably, the white paper contemplates both upward and downward adjustments for these payment settings.

Senate Finance Committee Discussion Draft

Drawing from the proposals in its white paper, in May 2024, the Senate Finance Committee chair and ranking member issued bipartisan draft legislation to address drug shortages. The draft legislation included reforms to both Medicare and Medicaid. Comments on the proposal are due on June 6, 2024. More details follow:

Medicare Drug Shortage Prevention and Mitigation Program

With respect to Medicare, the Senate Finance Committee draft legislation would establish a new Medicare Drug Shortage Prevention and Mitigation Program. This voluntary program would make payment incentives available to hospitals, physician practices, and other Medicare providers of services or suppliers (Payment-Eligible Providers) that utilize – through wholesalers, GPOs, nonprofits, other entities (Program Participants) or directly – certain contacting and purchasing practices to acquire applicable generics (*i.e.*, multi-source drugs furnished under Medicare Parts A or B that are injectable or infused, excluding self-administered drugs and vaccines), with the potential for expansion to additional multiple-source drugs over time.

Wholesalers, GPOs, nonprofits, and other eligible entities, including providers themselves, would apply with the HHS secretary to become Program Participants. To do so, they would specify the scope of applicable genetics they supply and the "core" and "advanced" contract standards with respect to which they plan to participate in for a given year. Core standards include provisions on duration, off-contract purchases, pricing stability, upward price adjustments, on-time delivery, and truthfulness. Advanced contract standards include using advanced manufacturing technologies and domestic manufacturing thresholds.

Generic manufacturers, in turn, would become eligible suppliers, for program purposes, by entering into Manufacturer Reliability Agreements with Program Participants. These agreements would 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.

Payment-Eligible Providers that enter into agreements with Program Participants that meet the core and advanced standards would be eligible for additional payments. Specifically, during a quarter in which a Payment-Eligible Provider, with respect to an applicable generic, acquires that medication through a contract that meets all of the core standards, that provider would receive a lump-sum incentive payment of between 5% and 25% of the medication's ASP. If the advanced standards are met, the provider would receive an additional 2% add-on payment.

Payment-Eligible Providers would also be eligible for additional payments for maintaining a six-month buffer inventory of an applicable generic and for performance on outcome measures. The buffer inventory bonus payment would be equal to 150% of the bonus for meeting the core standards multiplied by ASP. The outcome measures bonus payment would be available for the top 30% of providers based on performance relative to their peers on outcome measures that would be designed by the HHS secretary to evaluate

practices, such as the extent to which a provider maintains a sufficient inventory of an applicable generic, doesn't experience a shortage, or purchases inventory from a primary or secondary supplier.

The draft legislation would require Payment-Eligible Providers to submit annual pricing stability certifications to the secretary under which they 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.

Changes to the Medicaid Drug Rebate Program (MDRP)

With respect to Medicaid, the Senate Finance Committee draft legislation would limit the application of drug inflation rebates under the MDRP to sole-source generics. However, certain sole-source generics would be exempt from this treatment to preserve generic market entry and competition, as would any generic that has an average annual total cost of less than $100.

Additionally, the HHS secretary would have the authority to reduce or waive inflation rebates for non-exempt generics when 1) the generic is on the FDA's shortage list or 2) the HHS secretary determines there is a severe supply chain disruption, or that without such reduction or waiver, the drug is likely to be on the FDA's shortage list in a subsequent quarter.

POLICY OUTLOOK

Despite CMS's comment solicitation and the policies proposed in the HHS white paper, the administration's actions to address drug shortages remain limited, and the policy proposal included in the FY 2025 IPPS rule seems to be only a small step toward achieving HHS's broader vision, as outlined in its white paper. That is likely because, as also outlined in its white paper, HHS believes it needs additional authority to implement the scale of policy changes necessary to move the needle on drug shortages. For further discussion on the need for additional authority, see our *Regs & Eggs* post here.

Despite that request for more authority, we believe there is a remaining – and to this point, unutilized – authority HHS could employ, and that would be to include requirements on drug shortage preparedness in Medicare provider and supplier CoPs. The administration's upcoming Healthcare System Resiliency and Modernization rule, listed in the fall 2023 Unified Agenda, could be the administration's regulatory vehicle to propose such requirements. The administration has hinted at using this rule to address overarching issues impacting Medicare providers and suppliers, such as cybersecurity. Drug shortages could be treated similarly.

However, CoPs are a blunt instrument: either a provider is complying with them, or it's not, and a provider not in compliance with the CoPs can be terminated from the Medicare and Medicaid programs. As evidenced by the proposals included in the HHS white paper, the administration seems to believe that, when it comes to drug shortages, a more nuanced policy approach is called for.

As far as the prospect for legislation, both the Energy and Commerce Committee chair and bipartisan Senate Finance Committee leaders have taken important steps forward in identifying policy solutions to address drug shortages. In some instances – for example, with respect to Medicaid rebates – the committees appear to agree on policy actions they could take. However, enacting legislation that reimagines the market forces impacting the generic drug supply chain will be no small feat, particularly when Congress's healthcare to-do list is long, with many policy priorities competing for attention, and it is a presidential election year. Thus far, the House and Senate have shown neither interest in, nor bandwidth for, harmonizing their proposals toward comprehensive drug shortage legislation.

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