

U.S Department of Health and Human Services

WHITE PAPER

Policy Considerations to Prevent Drug Shortages and Mitigate Supply Chain Vulnerabilities in the United States

Office of the Secretary (OS)

With input from:

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Food and Drug Administration (FDA)

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Key Highlights

- Drug shortages impact patients, families, caregivers, pharmacists, hospitals, nursing homes, hospices, and other individuals and entities across the health care system.
- Drug shortages are a decades-old problem arising, in part, from market forces that touch stakeholders across the drug supply chain—providers and pharmacies, manufacturers, and the middlemen in the system. Key issues include a broad lack of transparency, concentration among middlemen, and prices for generic drugs that are driven to levels so low that they create insufficient incentives for redundancy or resilience-oriented manufacturing, distribution, and purchasing. These market failures lead to pharmaceutical supply chains that are brittle, disruption-prone, and too slow to recover from shortages.
- Supply chain resilience involves fostering processes that are less likely to face disruptions, as well as establishing the ability to withstand and mitigate disruptions so their impact—when they occur—is limited. This resilience also comes from diversification of supply—both in redundancy of manufacturing capacity and a balance of domestic and diversified foreign sourcing—and the presence of reliable, efficient, and sustainable, robust manufacturing practices.
- The Department of Health and Human Services (HHS or Department) has made significant strides in shoring up the system’s ability to respond to shortages. Nevertheless, more impactful and enduring solutions require additional statutory authorities and funding to resolve underlying causes of shortages. All supply chain participants play a part in these solutions.
- This paper describes policy concepts for consideration, including collaboration with the private sector to develop and implement a Manufacturer Resiliency Assessment Program (MRAP) and a Hospital Resilient Supply Program (HRSP). As described, the combination of these programs would bring transparency into the market, link purchasing and payment decisions to supply chain resilience practices, and incentivize investments in supply chain resilience and diversification in the supply chain—including domestic manufacturing—at a scale that would drive impactful change in the market. This paper focuses on generic sterile injectable medicines used in inpatient settings, given their importance to acute inpatient care, and their relative risk of supply disruptions—though HHS recognizes that these challenges affect other products, and therefore, the solutions described here may be applicable in other markets.



Part I: History and Background of Drug Shortages

I.A. History of a long-standing problem

Shortages of life-saving medical products have been an ongoing public health concern for decades^{i,ii,iii,iv} and have negative consequences for patient care, health and safety, and services delivery across the health care system. Shortages may result in delays, cancellation of services, medical errors, decline in health status, abandonment of therapy, and increased costs for hospitals.^{v,vi,vii,viii,ix,x,xi,xii,xiii,xiv} According to estimates, hospitals can spend at least \$600 million per year managing shortages and diverting essential personnel who are needed for direct patient care to find alternative treatments for patients.^{xv,xvi,xvii,xviii,xix} At the peak of a drug shortage crisis in 2011, the number of new drug shortages tracked by the Food and Drug Administration (FDA) quadrupled, from approximately 61 shortages in 2005 to more than 250 in 2011.^{xx} Although the number of new drug shortages has declined since 2011 as a result of work by many groups, including HHS, shortages of critical drugs continue to occur.^{xxi}

Therefore, shortages continue to pose a real and persistent challenge to public health – particularly when the shortage involves a critical drug used to treat cancer, pain, infection, heart conditions, autoimmune disease, behavioral health conditions, or to address another serious medical condition for which adequate alternative treatments are not available.^{xxii} As of January 2024, there were 123 drugs in shortage,^{xxiii} and of these products, about a quarter were first reported in shortage prior to 2020, with the oldest dating back to 2012. Shortages occur across therapeutic areas and at the beginning of 2024, analgesics/anesthetics (17%), anti-infective (12%), and cardiovascular (13%) products comprised 42% of shortages. Generic drugs that form the basic layer of hospital and preventive healthcare comprise the vast majority of shortages. In particular, generic sterile injectable (GSI) products made up about 63% of all shortages compared to oral or topical preparations in 2013–2017.^{xxiv}

Finally, while the focus of this paper is on drug shortages, shortages of medical devices have also been an issue for many decades. It has been estimated that there were approximately five shortages of medical devices annually from 2010 to 2019, with that number increasing fourfold in the first half of 2020 because of demand increases and supply chain issues during the COVID-19 pandemic.^{xxv}

I.B. The importance of a resilient supply chain

A resilient supply chain is one that *prevents* disruption where possible, is *prepared* for disruption risks, and *recovers* quickly from unexpected events that could lead to shortages. Strategies to create a robust and resilient pharmaceutical supply chain include diversification of supply—both in overall redundancy of manufacturing capacity and in the balance of domestic and diversified, foreign sourcing—and investment in reliable, efficient, and sustainable manufacturing practices. Mitigation and prevention tools, such as buffer inventory and capacity, are also essential supply strategies. Moreover, proactive monitoring, assessment, and communication of risks and vulnerabilities to prevent or mitigate shortages of medical products are crucial. These resilience measures are particularly important for GSIs, which are especially vulnerable to supply chain disruptions.



The ultimate goal is to foster the development of a generic drug market that is less prone to supply disruptions and better able to withstand them when they occur, because of greater investment in resilience practices across the industry. In the immediate term, that means supporting actions that shore up the ability to respond to shortages as they occur. However, a lasting solution necessitates building a better system where there is greater transparency among actors across the entire supply chain (from the producers of raw materials to the intermediaries or “middlemen” who facilitate purchasing, to end-purchasers at hospitals and pharmacies) so that market participants have the information they need in order to support resilience and redundancy, and rapidly respond to threatened or actual supply chain disruptions. It also requires creating a system where all actors have adequate incentives and responsibility to respond to that information and support more resilience and diversification across the supply chain.

I.C. Factors that cause drug shortages are multi-faceted and involve many market participants

The supply chains and value chains for generic drugs are complex and involve many participants (Figure 1). Vast multinational supply chains and complex production, distribution, and purchasing paradigms underpin the journey of a drug from factory to patient. This system contains several market challenges that contribute to supply chain vulnerability—and to an increased risk of a drug entering shortage status. All participants—including manufacturers, middlemen, and health care organizations—play a role in these challenges.

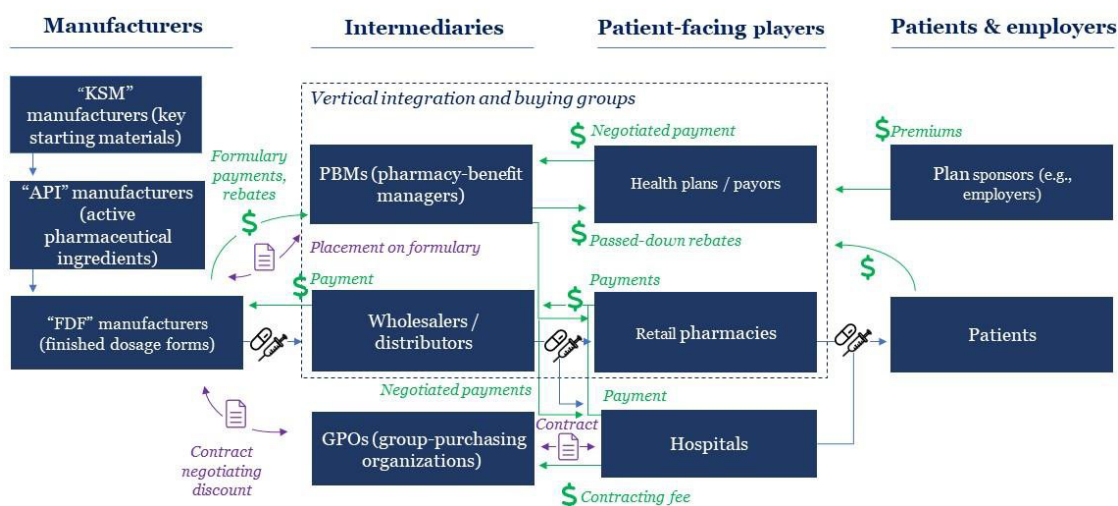
To start, manufacturers face difficult economic conditions that stem from low and/or unpredictable sales volumes, prices, and profit margins for many generic drugs. Generic drug manufacturers face intense price competition, uncertain revenue streams, and high investment requirements to maintain mature manufacturing quality systems. These conditions can incentivize reductions in manufacturing costs to potentially unsustainable levels, drive existing manufacturers out of the market, and deter potential market entrants—even when a drug is actively in shortage.^{xxvi,xxvii} Manufacturer and middle men consolidation, in turn, can lead to an over-reliance on a few suppliers or manufacturers, which can result in a lack of redundancy (geographic, product, or manufacturer types) in the supply chain.^{xxviii,xxix} Historically, most shortages often occur after quality-related breakdowns in manufacturing processes. In these situations, manufacturers must fix those problems before production can resume. If other manufacturers or facilities are not available to provide alternative supply, a shortage can occur. GSI products, which include many cancer chemotherapy treatments and other critical drugs, are particularly vulnerable to disruptions because the process of GSI manufacturing is more complex compared to that of orally administered drugs. For some shortages, particularly for low-cost generic drugs that have been off-patent for a long time, the market price has been driven too low—and the investment costs and risks are too high—for additional manufacturers to enter the market and diversify sources of supply.

Market forces have driven the manufacturing of many of these drugs and their key ingredients, such as active pharmaceutical ingredients (APIs) and key starting materials (KSMs), overseas. By some estimates, 90 to 95 percent of GSIs are used for critical acute care in the U.S. rely on KSMs and drug substances from China and India.^{xxx} This dependence means that the U.S. supply of medical products is also vulnerable to international economic, political, and public health disruptions.



Concentration in pharmaceutical purchasing and distribution plays a role in these trends. This concentration gives most, if not all, the negotiating power to intermediaries (e.g., Group Purchasing Organizations (GPOs), Pharmacy Benefit Managers (PBMs), wholesalers), which some argue have applied strong downward price pressures to generic drugs through harmful contracting practices, including low-price clauses that allow middlemen to unilaterally walk away from a contract if they find a lower price from another manufacturer.^{xxxix} The concentrated wholesaler industry influences the purchase and distribution of prescription drugs in setting generic drug prices, leveraging list price increases, and competing in specialty drug distribution.^{xxxix} Researchers and others have expressed concerns that concentration among GPOs^{xxxix} and PBMs^{xxxix} may be undermining price competition and limiting hospital access to medical products.^{xxxix,xxxix} It has also been noted that the erosion of failure-to-supply clauses^{xxxix} in GPO contracts may be associated with drug shortages.^{xxxix} Overall, these intermediaries create a complex and opaque layer between the health care organizations that must deliver these low-cost generic drugs to patients and the manufacturers that produce them.

Hospitals and other health care organizations also play a role in these trends. They, too, face economic pressures, which can lead to pursuit of lowest-cost sources for generic drugs, without adequate consideration for whether the hospital is then reliant on a single source producer and whether the producer(s) have the resources and commitment to invest in resilient manufacturing processes. Together, these pressures can further push manufacturing costs to potentially unsustainable levels, and lead to supplier consolidation that is more vulnerable to disruptions.



Note: This diagram represents a notional, simplified view. Actual value chains vary by program, drug, and more.

Figure 1. Diagram of the U.S. Generics Supply and Value Chains



Ultimately, these market forces have created a generic drug supply chain that is shortage-prone and too slow to respond to shortages that do occur. Under the current market and regulatory environment, incentives are not generally aligned across these participants to ensure the necessary level of investment in resilient practices and supplier redundancy. These market failures lead to an insecure production base and a brittle supply of prescription drugs. Market participants throughout the supply chain lack appropriate incentives to adopt practices that foster diversification, redundancy, and investment in newer technology and mature quality systems that would reduce the impact of supply disruptions. Production practices that do not prioritize preventing manufacturing interruptions due to quality issues increase the risk and impacts of supply chain interruptions. Mismatched incentives are also associated with inadequate inventory management practices that limit safety stocks and excess capacity that would enable a swift response to increased demand or decreased supply from other market participants. The result is a lack of availability of supply of drugs when they are needed, i.e., shortages, and an inability for the market to recover from shortages when they occur.

Failure to invest in supply chain resilience – in particular, when there is little to no flexible manufacturing capacity or limited supplier diversification- can increase the frequency of breakdowns, increase the duration of a shortage, hamper mitigation efforts, and exacerbate the impacts on patients, hospitals, pharmacies, and providers. Incentives throughout the supply chain must be reimaged to ensure the resilience and supplier redundancy required to prevent drug shortages from occurring, and to quickly end ones that do occur.

Part II: Administrative Actions Taken or in Progress to Address Shortages

HHS has already taken steps toward building a better system to respond to drug shortages by proactively monitoring and assessing the risks and vulnerabilities to the supply chain to help protect patients and mitigate the impact of shortages.

II.A. Implementing immediate term solutions to improve HHS' ability to respond

HHS has established a new Supply Chain Resilience and Shortage Coordinator (Coordinator) role to strengthen HHS' coordination and implementation of strategies to enhance supply chain resilience for medical products, including pharmaceuticals. The Coordinator will facilitate ongoing work across HHS by documenting strategies, policies, and workflows, to maximize the available resources and levers. Foundational to that activity are efforts HHS has recently undertaken across operational divisions to develop complementary strategies for responding to acute supply disruptions for critical products that involve multiple HHS components. These efforts have included developing an overview of HHS responses to common types of disruptions; delineating roles and responsibilities across HHS when shortages emerge; and providing a set of case studies of past responses, a general guide of available data, authorities, and other resources that may be considered when responding to a disruption. HHS is also working to develop a plan to better understand the supply chain data available across the



Department and ways to leverage the data in a manner that enhances information sharing, aggregation, and analytical capability across HHS, while protecting confidential commercial information.

FDA's shortage response focuses on intake of information from various sources to determine if a shortage exists or is expected, for example, receiving and analyzing the potential impact of manufacturer notifications of a discontinuance or interruption in manufacturing of finished products or active pharmaceutical ingredients. FDA can then plan and execute strategies to help mitigate or prevent the impact of shortages. FDA utilizes available tools to foster access to alternate sources of a drug in shortage including prioritizing review of manufacturing supplements or abbreviated new drug applications (ANDAs) for drugs in shortage or for which there is only one approved application; working with manufacturers to increase supply; or exercising temporary regulatory discretion to increase supply. FDA also assesses manufacturers' compliance with reporting requirements enacted and effected through various laws and regulations.

In addition, FDA remains committed to using all available tools to oversee the safety, effectiveness, and quality of FDA-regulated products. As drug manufacturing has globalized over the years, FDA has modernized its programs to help ensure that companies – regardless of where they are located – continue to meet the FDA's strict standards for producing medicines for U.S. patients that are high quality, safe, and effective. FDA has resumed normal inspection operations and continues to prioritize inspections that were delayed due to COVID-19 while maintaining its high standards and responsibility for the public health. In Fiscal Year (FY) 2022, FDA conducted 863 human drug inspections, of which close to 70% were domestic firms. In FY 2023, a total of 1,205 human drug good manufacturing practice (GMP) inspections were conducted (nearly a 30% increase over FY 2022), with close to 60% including foreign facilities.

Identifying critical life-saving and life-sustaining treatments is an important first step in securing the supply chain of these products. To this end, ASPR led the development of an essential medicines supply chains and manufacturing resilience assessment, which included a critical drugs list, that was published in 2022.^{xxxix} This ASPR assessment report and resulting list can and has been used to focus strategies to increase supply chain resilience, especially for drug products deemed critical for acute care of patients. For instance, the list was used to invite comment on separate payments to hospitals for establishing and maintaining access to a buffer stock of essential medicines to foster a more reliable, resilient supply of these medicines.^{xl} On December 27, 2023 the President [issued](#) a Memorandum Regarding the Presidential Determination and Waiver Pursuant to Section 303 of the Defense Production Act (DPA) of 1950, as amended, on Essential Medicines, Medical Countermeasures, and Critical Inputs (Memorandum). The Memorandum will allow HHS to utilize DPA Title III to: (1) expand public health supply chain manufacturing capacity and flexibility; (2) strengthen partnerships between the U.S. Government and the medical countermeasure industry; and (3) promote innovative and adaptable medical countermeasure development. ASPR will manage HHS's DPA Title III authorities and is exploring how it can utilize these authorities to promote the domestic production of essential medicines, medical countermeasures, and their critical ingredients. In addition, the Strategic National Stockpile (SNS), managed within ASPR, stockpiles certain medical countermeasures and devices for use in specific public



health emergencies. The SNS focuses on medical countermeasures that do not have a commercial market for chemical, biological (including emerging infectious diseases), radiological, and nuclear threats. ASPR is also exploring the creation and expansion of a virtual national strategic stockpile of API and other critical materials for use in public health emergencies should additional funding be provided.^{xli} In addition, during the COVID-19 pandemic, the Administration for Strategic Preparedness and Response (ASPR) shared supply and demand data for the selected medications that were part of the HHS Supply Chain Control Tower.

Finally, the Centers for Medicare & Medicaid Services (CMS) recently sought public comment on a separate Medicare payment to hospitals for establishing and maintaining access to a buffer stock of one or more of the 86 medicines from the ASPR critical list to foster a more reliable, resilient supply of these medicines. There was a broad consensus among commenters regarding the need to curtail pharmaceutical shortages of essential medicines and promote resilience. CMS is actively using this public input to inform the development of future potential policies, including in future Medicare payment rules and through Conditions of Participation.

II.B. More transparency so the market can reward resilience

HHS is working on facilitating greater transparency so the market can use information about mature quality management practices to reward resilience. FDA is developing a framework that would evaluate Quality Management Maturity (QMM) at drug manufacturing establishments. The QMM assessment would help gauge adoption of management practices that support a more reliable drug supply chain by reducing the occurrence of quality-related failures and improving the ability of drug manufacturers to maintain performance during supply chain disruptions, whether expected or unexpected.^{xlii} This framework may be used to develop metrics about the adoption of manufacturing practices that enhance supply chain resilience and which purchasers, providers, and consumers could then use to inform their purchasing decisions.

To further promote transparency, FDA has created a webpage that compiles various FDA inspections related data, including detailed information about FDA's inspection, compliance, recall and import actions; FDA warning letters; and select Form FDA 483 inspection findings and other correspondence to FDA-regulated companies. This [webpage](#) provides the public an overview of FDA inspections and compliance review of inspectional findings, including where to find inspection classification information and actions so users may better understand FDA processes for quality surveillance.^{xliii}

In addition, on February 5, 2024, FDA issued final guidance^{xliv} for reporting the annual amount of listed drugs produced for commercial distribution. These reports enhance FDA's visibility into the volume of drugs produced by FDA-registered drug manufacturers, and where these products are produced to further aid ongoing surveillance efforts and to identify more proactively issues that could contribute to a drug shortage.



ASPR has just commissioned a survey and assessment of the domestic API supply chain with the Department of Commerce's Bureau of Industry and Security (BIS) focusing on drugs for use in public health emergencies. This study will focus on examining domestic API manufacturing and supply chain vulnerabilities and map the relationships and network of critical drug product inputs that are produced domestically, in addition to how they are utilized by domestic manufacturers to produce finished dosage form drug products.

Finally, on February 14, 2024, HHS alongside the Federal Trade Commission (FTC) requested information from the public about the role GPOs and wholesalers play in supply chain disruptions and drug shortages.^{xlv} The agencies [jointly released](#) a Request for Information (RFI) seeking input on GPO and wholesaler market concentration as well as contracting practices and negotiations.

II.C. Aligned incentives to make sure the market rewards resilience

HHS is utilizing its tools to align certain incentives to bolster supply chain resilience and further promote adoption of supply chain resilient practices. As discussed, in the Calendar Year (CY) 2024 Outpatient Prospective Payment System (OPPS) final rule, CMS solicited public comment on providing separate payment under the Medicare Inpatient Prospective Payment System (IPPS), and potentially the OPPS, for establishing and maintaining access to a buffer stock of essential medicines to foster a more reliable, resilient supply (88 FR 82127-30).^{xlvi} Although CMS did not adopt a policy regarding separate payment under the IPPS or OPPS for establishing and maintaining access to a buffer stock of essential medicines, CMS continues to seek feedback from interested parties on ways to address the additional costs hospitals face to address pharmaceutical shortages and prepare for future emergencies. CMS also noted in the CY 2024 OPPS final rule that as part of the agency's initial efforts, CMS intends to propose new Conditions of Participation in forthcoming notice and comment rulemaking addressing hospital processes for pharmaceutical supply (88 FR 82130). CMS continues to review the comments received to consider ways the Medicare program can promote hospital resilience practices and help mitigate the impact of drug shortages on patients.

HHS also recognizes the importance of domestic manufacturing in market resilience and supplier diversification, and remains committed to exploring ways to support and reward domestic manufacturing capabilities for essential medicines and other critical medical products. This includes investment to support domestic manufacturing of key ingredients and drugs. HHS also recognizes the importance of strengthening linkages with partner and allied nations that can produce products made using quality manufacturing practices that support supply chain resilience. Given the likely continued cost differentials between domestic and foreign products, innovation in manufacturing is likely to be a key component of the strategy to diversify manufacturing and increase domestic supply. To date, ASPR has invested \$17 billion in domestic manufacturing for the medical supply chain, including \$500 million to support API manufacturing. ASPR is also assessing domestic manufacturing capabilities and capacities for essential medical products to identify critical crosscutting raw materials and inputs that would benefit from, and meet the requirements of, Title III investments. Further, HHS is working with the Office of Management and Budget (OMB) on efforts to improve federal demand signals for domestically manufactured critical medical products. These efforts include: 1) development of a white paper



compiling the projected government demand for specific personal protective equipment (PPE) over the next 2 years with input from HHS, the U.S. Department of Veterans Affairs (VA), and Department of Homeland Security (DHS); 2) sharing industry insights with OMB's Made in America Office; and 3) working with procurement category managers to align and leverage Defense Logistics Agency (DLA) acquisition vehicles, to both aggregate demand and promote domestic sourcing in Federal procurement pursuant to Executive Order 14005 (Ensuring the Future Is Made in All of America by All of America's Workers). HHS will also coordinate with the Made in America Office and the Manufacturing Extension Partnership to connect stakeholders with domestic manufacturing support programs.

Part III: Additional Solutions

HHS has made significant strides with available resources, but meaningful solutions require additional authorities and funding in order to more holistically address the underlying causes of shortages. Specifically, programs that link inpatient hospital purchasing and payment decisions to supply chain resilience practices would better incentivize investments in mature manufacturing practices, increase transparency, and foster a more diversified supply chain.^{xlvii} One way in which this goal could be accomplished is through work with Congress to create new authorities and provide additional funding to develop and implement a Manufacturer Resiliency Assessment Program (MRAP) and a new Hospital Resilient Supply Program (HRSP). Through a public-private partnership (PPP), the MRAP would measure manufacturer resilience practices and assign manufacturers scores based on their performance (i.e., develop a reliable manufacturer metric). The HRSP would establish financial incentives and/or penalties to hospitals based on a combination of meeting certain requirements and performance on a hospital scorecard. The hospital scorecard would be developed by HRSP and could include reliant manufacturer metrics developed by MRAP and hospital pro-resilience purchasing behavior metrics developed by HRSP using attestations or other information reported to CMS by hospitals.

III.A. Manufacturer Resiliency Assessment Program (MRAP)

A Manufacturing Resiliency Assessment Program (MRAP) could measure resilience of manufacturers and bring transparency to the prescription drug supplier base. Actors throughout the supply chain could use this information to better inform drug development, purchasing, production, and other activities. Through a PPP, a private entity administering the MRAP would assign resilience scores to manufacturers of generic drugs, based on an assessment of manufacturer practices and past performance. The MRAP could develop new manufacturing resilience metrics (e.g., manufacturer and/or product ratings) and a process to assess manufacturers' practices to address market information failures and promote improvements in manufacturing performance. While specific metrics have not yet been developed, and would be developed in collaboration with external organizations, MRAP metrics could reflect manufacturers' quality management maturity, manufacturing redundancy, and API/KSM sourcing diversity, among other resilience-related metrics. These metrics would be intended to enhance transparency about manufacturer management practices. MRAP would provide oversight of a non-governmental national accreditation body and conduct core activities including establishing accreditation standards, collecting data, conducting analyses, developing and submitting reporting



requirements and consulting with a new or established group of experts. The national accreditation body would be established by external nonprofit organizations that meet HHS standards and requirements for accreditation; these include, but are not limited to, annual audits, personnel qualifications, recordkeeping and reporting. The national accreditation body would conduct manufacturer assessments based on criteria developed by the MRAP and report the ratings to HHS. (HHS would then use these ratings in its HRSP Program, described in greater detail below.) Manufacturer assessments would be paid by manufacturers.^{xlviii} Manufacturers would be incentivized to participate based on the expectations that hospitals would use this information in their purchasing decisions and would be willing to pay higher prices for drugs from more resilient manufacturers and supply chain systems. The expected term of a nonprofit organization is to be determined; it would need to be long enough to ensure efficiency and continuity, as well as accountability to HHS. After expiration of the term, the nonprofit organization(s) must seek renewal and approval to operate as part of the accreditation body. This governance model enables accountability of a non-government body to HHS and leverages capability and expertise in HHS and industry. It also fosters transparency and participation from industry.

III.B. Hospital Resilient Supply Program (HRSP)

Resilience must also be a priority of prescription drug *demand*. A Hospital Resilient Supply Program (HRSP) could establish demand incentives and/or penalties, facilitating hospital purchasing that prioritizes supply chain resilience, rather than the current structure which generally prioritizes cost alone. To start, hospitals that provide inpatient services would need to consider quality management maturity and the reliability of drug supply in their purchasing practices. At its core, the HRSP would draw on the same principles behind existing CMS programs, such as the Promoting Interoperability program (formerly the Medicare and Medicaid Electronic Health Record Incentive Program).^{xlix} More specifically, the HRSP could optimize new and existing authorities to link Medicare payments and/or penalties to hospitals based on a hospital scorecard that would be a combination of attestations and ratings reflecting the hospitals' achievement and progress in adopting practices that promote supply chain resilience or prevent shortages. Hospital attestations or other hospital resilience-oriented activities that could be considered include hospital inventory management practices (stockpiling or buffer stocks) and hospital contracting practices with middlemen (e.g., inclusion of effective failure-to-supply clauses, minimum purchasing volume requirements, long-term contracts) that promote supply chain resilience. Attestation measures could also consider whether the hospital purchases from diverse sources, including domestic ones, thus supporting redundancy in the market. The attestation measures could be based on information that facilities already have available, which would enhance transparency about existing practices. In addition, MRAP could provide HRSP with information about the reliability of manufacturers that hospitals purchase from, thus expanding the hospital scorecard to base purchasing decisions on manufacturer resilience as well as price. As a whole, the scorecard developed by the HRSP could include lagging and leading indicators of practices that promote supply chain resilience among hospitals, middlemen, and manufacturers. HRSP could develop the scorecard for payments and/or incentives for an initial set of drugs that are considered eligible and eventually expand to other products



prioritized by MRAP or CMS. The scorecard could be scaled based on various factors, including but not limited to hospital size, hospital attestations, and hospitals' performance on the hospital scorecard.

Incentives and/or penalties could be phased-in initially for reporting the attestation measures or other hospital information, and then could be expanded to include manufacturer resilience ratings. Similarly, the incentives and/or penalties could be based on the scorecard, or could be based on achieving a certain rating or improvements in scorecard ratings or other factors such as size or volume of the hospital, with attention to smaller hospitals that lack the purchasing power of larger hospitals or health systems. HRSP payment and/or penalty amounts would have to be large enough to incentivize change and cover the cost and benefits of engaging in practices that promote supply chain resilience, while being fiscally responsible to the program. If successful, the HRSP could be expanded to the outpatient setting or to include medical devices. Ultimately, this would promote investment in resiliency at the manufacturer level, and facilitate market participation or support market entry for multiple or more diversified producers.

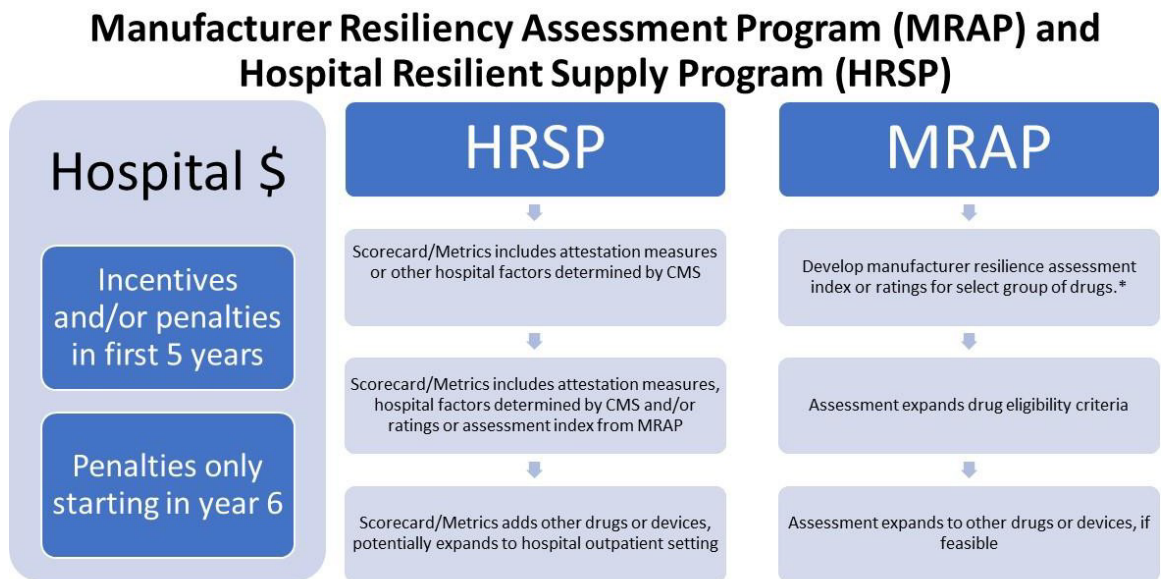
III.C. Overall timeline to implement MRAP and HRSP

The MRAP and HRSP could be implemented in stages as a long-term approach to addressing this problem. This could start with hospitals that provide inpatient services (Figure 2) for certain types of drugs. This phased-in approach is intended to optimize existing resources and expertise in a timely manner, while allowing HHS and industry to adapt to changes in a way that ensures long-term success.

MRAP implementation would begin by developing manufacturer resilience assessment metrics for an initial set of drugs, such as the drugs in ASPR's list of critical medicines,ⁱ or a slightly larger set to include other critical drugs such as chemotherapy, and establishing the standards and necessary requirements for the program, e.g., requirements for accreditation, and ratings informed in part by the QMM program. The MRAP could assess the feasibility of metrics at the drug product level,^{li,lii} or other medical products, including, medical devices.

In the first five years, HRSP could develop and apply payment incentives and/or penalties in multiple ways: 1) apply penalties and incentives simultaneously; 2) introduce penalties first and then incentives; or 3) introduce incentives first and then penalties. This would allow HHS to share in the upfront cost to invest in supply chain resilience. The Electronic Health Records Incentive Program used incentives first, then turned to penalties after three and five years of implementation when 87% and 95% of hospitals respectively were participating.





* MRAP may need 1-3 years to stand up, establish standards/requirements, develop metrics, implement initial assessments, and report data.

Figure 2. Illustrative Timeline for MRAP and HRSP

III.D. Budget

While the combined 10-year budget impact would vary depending on the particular policy choices made, our initial estimate is that such a program would cost between \$3.26 billion and \$5.11 billion. This reflects operational costs of about \$750 million for MRAP and \$2.51-\$4.36 billion for HSRP.

III.E Complementary legislative initiatives

In addition to the initiatives described in this paper, HHS has proposed a number of complementary legislative initiatives that are included in the President's FY 2025 Budget:

- Require drug manufacturers to notify FDA of an increase in demand that the manufacturer will likely be unable to meet for certain drugs, which would assist the FDA in its shortage prevention and mitigation efforts.
- Require manufacturers to provide FDA data identifying the suppliers they relied on to manufacture their drug products and the extent of such reliance, which would help FDA to identify vulnerabilities in the supply chain.
- Require labeling to include the original manufacturer of API and finished dosage form to enable FDA to identify the original manufacturer of an API and finished dosage form more quickly and to facilitate taking appropriate action related to poor quality products.
- Require Site Master Files (SMFs) for drug manufacturing facilities, which will assist FDA with risk identification for sites for surveillance and for-cause inspections. SMFs can improve FDA



understanding of quality management practices and supply chain management, which will improve overall supply chain resiliency.

- Require companies to notify FDA when there is an interruption or discontinuance in the manufacturing of critical devices which will help mitigate critical device shortages beyond public health emergency situations.
- Provide authority for acquisition, construction, or alteration of non-federally owned facilities, which would allow ASPR to support efforts to develop domestic manufacturing capacity for medical countermeasures and related products.
- Expand ASPR's Other Transaction Authority to enable ASPR to fund development and move directly into large-scale manufacturing of a product, whether for a response or for stockpiling.
- Provide authority to acquire innovative commercial products, services, processes, and/or methods, which would allow ASPR to acquire products or services such as technology investment agreements, research and development activities, and other capabilities needed, particularly in response to an outbreak in the future.
- Provide funding to advance ASPR's permanent industrial base management capabilities, since domestic manufacturing efforts to increase supply of essential medicines are critical to ensuring national health supply chain resilience.

HHS is also aware of many additional ideas that have been proposed as ways to address drug shortages and supply chain vulnerabilities in both the long and short term. A small sample of these ideas includes:

- Establishing a pay-for-performance program to reward providers for long-term contracts or quality of purchasing decisions, or for preventing or reducing shortages;
- Increasing payments for generics to stimulate supply;
- Facilitating public-private partnerships and emerging manufacturing and distribution models;
- Exploring federal stockpiling; and
- Supporting existing determinations of the use of DPA authorities such as Title I to promote a faster, more robust response, and Title III authorities to enhance supply resilience through longer-term investments in domestic capacity and sustainability.

HHS appreciates the efforts of stakeholders who have proposed policies to address the root causes of drug shortages. No one solution alone will address the complex market failures and misaligned incentives that contribute to prescription drug shortages. HHS stands ready to work with Congress to adopt bipartisan solutions to prevent the dire harms that befall patients and their families as well as health care providers who lack access to needed drugs in shortages.

Part IV: Conclusion

Drug shortages have been a decades-long public health issue that continues to impact individuals, providers, and health care workers, among others. The COVID-19 pandemic brought significant vulnerabilities in America's supply chains to the forefront and highlighted the causes and impacts of shortages. Using all the tools and resources available at its disposal, HHS is working tirelessly to



strengthen the U.S. drug supply chain to improve the situation for all. Researchers and many other organizations have recognized the steps the federal government and others have taken to mitigate the impacts of shortages but have highlighted that further actions are needed to make the U.S. drug market more reliable.^{liii,liv,lvi} This effort would require federal investment and addressing gaps to align market incentives to reward investment in supply chain resilience, increase transparency and diversification, address the underlying root causes of drug shortages, and help alleviate challenges faced by people who need certain medications to support their health and well-being.

Appendix

Legislative Proposals Included in HHS Fiscal Year 2025 President's Budget.

- Require drug manufacturers to notify FDA of an increase in demand that the manufacturer will likely be unable to meet for certain drugs, which would assist the FDA in its shortage prevention and mitigation efforts.
- Require manufacturers to provide FDA data identifying the suppliers they relied on to manufacture their drug products and the extent of such reliance, which would help FDA to identify vulnerabilities in the supply chain.
- Require labeling to include the original manufacturer of API and finished dosage form to enable FDA to identify the original manufacturer of an API and finished dosage form more quickly and to facilitate taking appropriate action related to poor quality products.
- Require Site Master Files (SMFs) for drug manufacturing facilities, which will assist FDA with risk identification for sites for surveillance and for-cause inspections. SMFs can improve FDA understanding of quality management practices and supply chain management, which will improve overall supply chain resiliency.
- Require applicants evaluate and submit data to FDA that could be used to lengthen expiration dates to help mitigate critical drug shortages.
- Require companies to notify FDA when there is an interruption or discontinuance in the manufacturing of critical devices which will help mitigate critical device shortages beyond public health emergency situations.
- Provide authority for acquisition, construction, or alteration of non-federally owned facilities, which would allow ASPR to support efforts to develop domestic manufacturing capacity for medical countermeasures and related products.
- Expand ASPR's Other Transaction Authority to enable ASPR to fund development and move directly into large-scale manufacturing of a product, whether for a response or for stockpiling.
- Provide authority to acquire innovative commercial products, services, processes, and/or methods, which would allow ASPR to acquire products or services such as technology investment agreements, research and development activities, and other capabilities needed, particularly in response to an outbreak in the future.
- Provide funding to advance ASPR's permanent industrial base management capabilities, since domestic manufacturing efforts to increase supply of essential medicines are critical to ensuring the national health supply chain resilience.



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- ⁱ FDA considers a drug to be in shortage when the total supply of all versions of a commercially available product cannot meet the current demand, and a registered alternative manufacturer will not meet the current and/or projected demands for the potentially medically necessary use(s) at the patient level. Although alternative definitions exist, this issue brief will use the FDA definition when referring to shortages.
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