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Congress and FDA Seek Drug Shortage Solutions

- Amid ongoing drug shortages for generic medications used to treat cancer, ADHD, and diabetes, Congress is [considering](#) different solutions in legislation. Proposals include a requirement for manufacturers to notify the FDA when they experience a surge in demand and [expansion](#) of the FDA's regulatory authority in bills that may be added as amendments in the reauthorization of the [Pandemic and All-Hazards Preparedness Act](#) (PAHPA). Lawmakers have also proposed certain exceptions to Medicaid rebates and 340B discounts for drugs with serious indications, stricter reporting requirements related to active ingredients, and streamlined FDA inspections for domestic manufacturing facilities. Industry experts fear that these changes may not be enough. The generic drug market incentivizes low-cost drugs rather than investment in facility upgrades and quality control. The competition between manufacturers of low-cost drugs has resulted in thin operating margins for generics in contrast to the market for new blockbuster drugs that require intensive research and development. FDA Commissioner Robert Califf has urged Congress to give the agency more authority to respond to drug shortages as the generic drug industry faces cost pressures that affect manufacturers' ability to maintain adequate distribution and quality standards. Congress recently returned from summer recess and is now debating the federal budget and other high-priority bills such as PAHPA.

HHS Announces Drugs Selected for Medicare Negotiation

- On August 29, HHS [released](#) the list of Medicare Part D drugs that will be subject to price negotiation by CMS, with pricing going into effect in 2026. The 10 drugs on the list accounted for \$3.4 billion in patient out-of-pocket costs in 2022 alone and are used to treat conditions which include diabetes, heart failure, autoimmune disorders, and blood cancer. They represent more than \$50 billion in total Medicare costs and 20% of total Part D spending over a one-year period. Legislation directs CMS to select 15 more drugs for negotiation in each subsequent year, and 20 additional drugs for each subsequent year and is scheduled to include a total of 60 drugs by 2030. These changes are part of the Inflation Reduction Act which also established Medicare rebates for drugs that rise faster than inflation and capped Medicare patients' monthly costs for insulin. The trade industry group PhRMA has decried the process as government price setting that will reduce investment in new drug product innovation, while 6 manufacturers have already sued the federal government to stop negotiation in different court systems. Companies that do not enter negotiations will be forced to either pay a large excise tax or remove their products from Medicare and Medicaid coverage.

GoodRx Builds New PBM Partnerships

- On September 13, GoodRx, a digital health company that offers discounts on generic drugs, [announced](#) a partnership with PBM MedImpact to automatically compare prescription drug prices for customers at checkout. Similar to early-stage programs recently established with CVS Caremark and Express Scripts, eligible members will receive the lowest out-of-pocket cost when comparing the price with their insurance coverage at the point of sale. MedImpact receives fees through their contracts with PBMs on either a percentage or fixed amount basis for every prescription filled at its discount price with incentives for higher volumes. PBMs then receive a fee from GoodRx, who functions as a distributor. Exact financial details on each agreement are still limited but the cash price of a drug can often be lower than the price negotiated by insurance companies. These industry changes are happening as Congress continues to consider PBM transparency and pricing reforms.

CVS Announces Corporate Layoffs

- In August, CVS [disclosed](#) they were laying off about 5,000 employees to cut expenses after 2 multi-billion-dollar mergers earlier this year. The reduction in staff equates to about 2% of their total workforce. This includes employees both in Rhode Island where the business is headquartered and employees that work for the subsidiary health plan Aetna, headquartered in Connecticut. While CVS Caremark operates one of the largest PBMs in the country with over 9,000 locations, customer-facing jobs in clinics and stores will not be affected. The company is restructuring its business as part of its growth strategy and ceased investing in clinical trial research in 2023. In an effort to increase their vertical integration of healthcare services, CVS acquired value-based primary practice business Oak Street Health for \$10.6 billion and home health provider Signify for \$8 billion earlier this year. [According](#) to their earnings report, other market pressures include manufacturers limiting 340B discounts, fewer COVID-19-related subsidies, and higher demand for Medicare Advantage outpatient services,

CMS Releases Cost-Savings Data for the MSSP

- On August 24, CMS [announced](#) monetary savings for the Medicare Shared Savings Program (MSSP) of \$1.8 billion in 2022. The program has been successful in demonstrating savings over the last 6 years and helps coordinate care for Medicare patients through Accountable Care Organizations (ACOs) responsible reducing the total cost of care. The MSSP is one of the largest

value-based purchasing programs in the US and includes 573,000 clinicians treating nearly 11 million beneficiaries. CMS reported that about 63% of ACOs earned performance-based payments in 2022, generally from smaller ACOs in rural areas. The 2024 Physician Fee Schedule proposed rule includes assigning more beneficiaries to receive care from nurses practitioners and physician assistants, and adjusting the benchmark methodology to encourage ACOs with medically complex and high-cost patients to participate. Last year, ACOs improved their quality scores on diabetes, blood pressure control, tobacco screening and smoking cessation, and screening for breast cancer, colon cancer, and depression. The success of the MSSP helps CMS realize their goal of bringing all Medicare beneficiaries under the care of ACOs by 2030 and supports the Biden Administration's goals on improving behavioral healthcare and cancer prevention through the Cancer Moonshot initiative. Data from past years [compiled](#) by the National Association of ACOs shows that both gross and net savings have greatly increased in recent years.

Other Policy News:

- Oregon [seeks](#) federal approval for basic health plan that covers those ineligible for Medicaid
- FDA approves COVID-19 booster formulations, CDC panel [recommends](#) vaccination for adults and children
- White House [reaches](#) agreement on pricing for COVID-19 monoclonal antibodies
- Senators [reintroduce](#) bill to enact stricter penalties for violence against hospital staff
- More pharmaceutical manufacturers [move](#) to limit 340B discounts
- CMS [provides](#) guidance on its policy for billing behavioral health integration services using specific CPT codes under the Psychiatric Collaborative Care Model
- Texas judge [vacates](#) more aspects of guidance related to surprise billing disputes and qualified payment calculations; CMS again suspends arbitration