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How Medicare Price Controls Have Contributed to Drug Shortages

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Recent drug shortages have received national attention as patients are forced to wait for vital treatments or substitute an alternative. As Congress searches for policy solutions, it is crucial that lawmakers understand the role that government price controls, specifically in Medicare, have played in the crisis.

A Growing Problem. According to the Food and Drug Administration (FDA), there were 178 drug shortages reported in 2010, 132 of which were sterile injectable drugs, which are administered by health care providers.[1] Shortages increased in 2011 and will continue to grow. Oncology has the largest share of shortages, affecting more than half a million cancer patients.[2]

Reasons behind the drug shortages are complex and vary from drug to drug, but one of the biggest problems is that Medicare drug reimbursement under Part B keeps prices low. At the same time, drug manufacturers face increasing production costs but cannot easily adjust prices, leading many to halt production.

Medicare's Disastrous Drug Pricing. Medicare price fixing for outpatient drugs covered under Part B is one of the major reasons for shortages. The program pays based on the average sales price (ASP) posted for more than six months. This scheme was enacted in response to the consequences of price controls that preceded it. Before passage of the Medicare Modernization Act of 2003, Medicare payments were based on drugs' average wholesale price (AWP), a suggested retail price set by manufacturers completely independent of what providers actually paid to acquire the drugs.

Not surprisingly, the dynamics of flawed government price setting created huge incentives for drug manufacturers to mark up the AWP, especially for older generic drugs. It did not help that Medicare underpaid the physicians, mostly oncologists and related specialists, administering the drugs. In this environment, drug manufacturers could get ahead of competitors by either inflating the AWP or discounting provider prices. As MedPAC reported in 2003:

> A manufacturer may raise the AWP for its product without changing the price charged to purchasers. Although the manufacturer's profit per dose will not increase with the rise in the listed price, the bigger difference between providers' acquisition costs and Medicare payment leads to higher profits for providers when they choose the manufacturer's product over its competitor.[3]

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In one case, a company sold a chemotherapy drug with an AWP of $740 to physicians for just $7.50. Taxpayers and beneficiaries made up the difference. Total Part B spending on outpatient drugs rose from $700 million in 1992 to $4 billion in 1999 (a 570 percent increase).[4] From 1997 on, Medicare reduced its payments to 95 percent of AWP, but without changing the incentives set in place by the system itself, this did little to resolve the problem.

Another Flawed Approach. The current "cost-plus" Medicare drug pricing scheme has controlled costs, but due to the system's conflicting incentives, many manufacturers have stopped making low-cost, generic injectable drugs rather than increase their prices.

Medicare sets reimbursement based on the ASP for all drugs within a general category of drugs, rather than individually, so manufacturers benefit more if they offer the lowest price. American Enterprise Institute Resident Fellow Scott Gottlieb describes this as a "race to the bottom."[5] This sort of behavior is beneficial to consumers as long as prices can increase again, which is necessary to keep drugs on the market if demand or production costs increase. But as Gottlieb explains, "even if a single manufacturer raises its price, this price increase will be diluted once it gets averaged into the prices charged by competitors."[6]

Also keeping prices from increasing to reflect actual manufacturing costs is the fact that rates paid by Medicare are based on drug prices that have been in existence for at least six months. If a manufacturer increased its price for a drug, Medicare reimbursement to providers would not immediately reflect the change, putting providers who administer the drugs at risk of losing money in the meantime.

As the cost of production and demand for certain drugs rise, manufacturers must either raise prices to keep their products available to patients, or stop making them to avoid growing losses. Unfortunately, Medicare's payment policy is one of the main reasons the latter has taken root.

Consequences for Patients. Drug shortages have an obvious, negative impact on patient care. Critical treatments are delayed as patients are put on waiting lists, and physicians must pursue alternative treatment options with which they are less familiar, increasing the risk of mistakes. Health care spending increases when doctors have to substitute more expensive drugs or patients' illnesses worsen due to delayed care.

Another consequence of drug shortages is the emergence of a gray market, defined as "a supply channel that is unofficial, unauthorized, or unintended by the original manufacturer."[7] When providers cannot purchase a scarce drug from standard

1. Food and Drug Administration, Frequently Asked Questions About Drug Shortages, at *http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050796.htm#q1* (December 19, 2011).
2. IMS Institute for Healthcare Informatics, "Drug Shortages: A Closer Look at Products, Suppliers, and Volume Volatility," November 2011, pp. 6–7.
3. Medicare Payment Advisory Commission, "Report to the Congress: Variation and Innovation in Medicare," June 2003, Chapter 9 ("Medicare Payments for Outpatient Drugs Under Part B"), at *http://www.medpac.gov/publications%5Ccongressional_reports%5CJune03_Ch9.pdf* (December 19, 2011).
4. *Ibid.*
5. *Ibid.*
6. Scott Gottlieb, "Drug Shortages: Why They Happen and What They Mean," testimony before the Finance Committee, U.S. Senate, December 7, 2011, at *http://finance.senate.gov/imo/media/doc/Gottlieb%20Testimony1.pdf* (December 19, 2011).
7. Coleen Cherici, Patrick McGinnis, and Wayne Russell, "Buyer Beware: Drug Shortages and the Gray Market," Premier Healthcare Alliance, August 2011, at *http://www.premierinc.com/about/news/11-aug/Gray-Market/Gray-Market-Analysis-08152011.pdf* (December 19, 2011).

suppliers, they look elsewhere. According to the Department of Health and Human Services (HHS), the problem occurs when secondary distributors purchase drugs from end users and then re-sell them to other end users.[8]

Drugs supplied on the gray market may be stolen or counterfeit, and their cost is exorbitantly higher. The Premier Healthcare Alliance, which includes more than 2,500 hospitals, reported an average markup of 650 percent, but the most significant markups were as high as 4,533 percent. The disruption to the normal distribution process has increased concerns that patients will receive drugs that have been improperly stored and handled. This can cause treatments to lose their efficacy, threatening patient safety in addition to raising costs.

Addressing the Problem. Experts and policymakers on both sides of the aisle acknowledge the severity of the drug shortage. Representatives Diana DeGette (D–CO) and Thomas Rooney (R–FL) put forth legislation to require drug manufacturers to alert the FDA when they anticipate a shortage, and President Obama has issued executive orders to achieve some of the bill's goals.[9] But these initiatives target the symptoms, not the root causes, of drug shortages. Without addressing flawed government payment policies, they will not work and risk making matters even worse. As National Center for Policy Analysis Senior Fellow Devon Herrick writes, "Expanding the number and type of companies required to provide advance notice of impending shortages would exacerbate shortages by encouraging hospitals to hoard drugs."[10]

Instead, Congress should apply the market forces that have successfully contained costs and maintained access to prescription drugs in Medicare Part D to the rest of Medicare. When it comes to drug coverage, combining Part B and Part D would go a long way to restoring access and appropriate pricing for drugs currently covered under Part B.[11] Short of the necessary structural reform, Congress should change Part B drug payments to reflect the actual acquisition costs for individual drugs.

Ultimately, drug shortages are just one of the consequences of decades of government price controls in programs like Medicare.[12] A rethinking of health care entitlements is necessary to restore robust and well-functioning markets for health care goods and services.

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8. Department of Health and Human Services, "Economic Analysis of the Causes of Drug Shortages," *ASPE* [Assistant Secretary for Planning and Evaluation] Issue Brief, October 2011, at *http://aspe.hhs.gov/sp/reports/2011/DrugShortages/ib.pdf* (December 19, 2011).
9. The White House, Office of the Press Secretary, "Executive Order—Reducing Prescription Drug Shortages," October 31, 2011, at *http://www.whitehouse.gov/the-press-office/2011/10/31/executive-order-reducing-prescription-drug-shortages* (December 19, 2011).
10. Devon Herrick, "What to Do about Drug Shortages," National Center for Policy Analysis *Issue Brief* No. 104, December 13, 2011, at *http://www.ncpa.org/pub/ib104* (December 19, 2011).
11. James C. Capretta, "The Case for Competition in Medicare," Heritage Foundation *Backgrounder* No. 2605, September 12, 2011, at *http://www.heritage.org/Research/Reports/2011/09/The-Case-for-Competition-in-Medicare*.
12. See Kathryn Nix, "Government Price Controls for Health Care: A Deficit-Reduction Strategy to Avoid," Heritage Foundation *Backgrounder* No. 2627, November 30, 2011, at *http://www.heritage.org/research/reports/2011/11/government-price-controls-for-health-care*.