

FAQs: Patient Access to Drugs in Shortage Act

Q. What is the problem?

A. There are national shortages of chemotherapy and ancillary drugs used to treat cancer care. The majority of drugs in short supply are low-cost, generic, sterile-injectable drugs.

Q. What is a sterile injectable drug?

A. An injectable compounded medication is a sterile drug to be administered into the body using a needle and syringe or an I.V. administration set and needle device. There are several routes of administration including:

- Intravenous (I.V.)
- Intramuscular (I.M.)
- Subcutaneous (S.C. or S.Q.)

Q. How does this effect patient cost?

A. Shortages are costing Medicare and patients more money. In some cases, there are therapeutic alternatives to generic cancer drugs but these alternatives cost Medicare and cancer patients significantly more. One example — leucovorin is a cancer drug in short supply that costs Medicare \$420 and patients \$108 for 12 cycles of the treatment. The alternative is levoleucovorin but it costs Medicare over \$24,000 and the patient \$6,000 for 12 cycles of treatment.

Q. When did this problem start?

A. The shortages started increasing since 2005 but have significantly expanded in number and scope over the past few years. According to the U.S. Food and Drug Administration, the number of times drugs were in short supply almost tripled from 61 in 2005 to 178 in 2010. The figure reached more than 250 in 2011.

Q. What changed in 2005?

A. ASP (Average Sales Price) was implemented by MMA in 2005 to calculate Medicare reimbursement rates for drugs. ASP replaced the average wholesale price (AWP) in an effort to better reflect real costs of the drugs. However, while ASP reimbursement works well in the brand market because it establishes a price ceiling, in the generic market, it causes a rapid drop in price once a drug goes off patent. The Office of the Inspector General found that on average, the ASP is about 50% of the AWP for the same drug. It is therefore not surprising that the increase in drug shortages has correlated with an increased reliance on the ASP by both Medicare and private insurers. Manufacturers who once had a strong financial incentive to produce highly complex generic injectables were suddenly faced with miniscule profits on these products.

Q. How would the Patient Access to Drugs in Shortage Act alleviate this problem?

A. This legislation puts incentives for manufacturers back into the generic injectable market to ensure the continued supply of lifesaving drugs.

Q. How will the legislation stabilize the market?

A. The legislation provides market incentives for generic sterile injectable drugs with three or fewer active manufacturers. For a single source drug, Medicare reimbursement would be based on wholesale acquisition cost (WAC) rather than ASP. The legislation would also provide manufacturers with an exemption from discount and rebate agreements.

Q. Why three or fewer manufacturers, when does this kick in?

A. Shortages are often caused when a single manufacturer ceases production of a product. This can happen due to a manufacturing glitch or requirements to update facilities. For a generic drug with only a few manufacturers, a single company stepping out of the market can upset the balance of supply and demand, leading to shortages. In these situations, incentives must be in place for the remaining active manufacturers to continue production and meet market demand.

Q. Why a weighted wholesale acquisition cost (WAC)?

A. WAC would provide stable market-based pricing. WAC is the manufacturer's list price that is the invoice price paid by the wholesaler. WAC is now used by CMS to reimburse for new drugs when launched that have no ASP. WAC is a real price established in commercial transactions between manufacturer and wholesaler. WAC is not an artificial, made-up price like AWP, so it is not prone to gaming of the system like AWP. Nor will WAC prevent manufacturers to adjust their prices to meet supply and demand (the problem with ASP+6%).

Q. How do Medicaid Rebates and 340b discounts affect the market?

A. Generic manufacturer net sales average only about 70% of ASP because the manufacturers are required to provide Medicaid rebates and 340B discounts that exert additional downward pressure on already extremely low pricing. For example, some generic injectable cancer drugs cost only \$1-3 per vial. Generic manufacturers cannot sustain production of these price-depressed products as well as upgrade production facilities or deal with manufacturing glitches. For drugs with three or fewer manufacturers, this legislation suspends Medicaid rebates and excludes these drugs from the 340b program.

Q. Why does this involve brand drugs?

A. Currently, there is little or no incentive for brand companies to continue production of drugs once they go off patent and enter the generic market. This legislation offers a financial incentive to brand companies to enter the market and help address a drug shortage.

Q. Has the administration acknowledged the connection between shortages and reimbursement?

A. Yes, the administration suspended CMS' ability to decrease reimbursement for drugs in short supply in the 2013 Medicare Physician Fee Schedule.

*Q. Did the **Food and Drug Administration Safety and Innovation Act** address this problem?*

A. This legislation focused on notification requirements when a shortage takes place, expedites reviews and inspections for drugs in a shortage, and creates a list of drugs in shortage. Although the package did not address the economic factors behind shortages, it did require the GAO to report on the cause of drug shortages including market factors.