

Legislative Summary: Preserving Access to Life-Saving Medications Act

(February 7, 2011)

Senators Amy Klobuchar (D-Minn.) and Robert Casey (D-Pa.) have introduced S. 296, the Preserving Access to Life Saving Medications Act. The legislation directs the Food and Drug Administration (FDA), to address drug shortages by requiring drug manufacturers to notify FDA about manufacturing problems or when a drug product will be discontinued, requires the agency to maintain an online list of drugs in shortage situations, and revises FDA's definition of medically necessary.

Manufacturer Reporting

The bill would require manufacturers to notify the FDA of any discontinuance, interruption or adjustment in the manufacture of a drug that may result in a shortage. If the manufacture plans on discontinuing the drug, notification must be made to FDA at least 6 months in advance. For other disruptions in manufacturing attributed to supply of raw materials, disruptions in the supply chain, output changes and other problems identified by FDA, notification will be required as soon as the manufacturer becomes aware of the problem. FDA would then be required to promulgate regulations establishing penalties for non-compliance with the reporting requirement.

Public Notification by FDA

The bill would additionally require FDA to publish information relating to manufacturing problems and drugs experiencing an actual shortage on its web site.

Develop Criteria for Drugs Vulnerable to Shortage

The bill would require FDA to implement evidence-based criteria for identifying drugs vulnerable to a shortage. This would be based upon factors such as: number of manufacturers, sources of raw material or active pharmaceutical ingredients, supply chain characteristics, and the availability of therapeutic alternatives. If FDA can determine based upon the above criteria that a drug is vulnerable to a shortage, FDA would have to publish that information on their web site. Further, for those drugs deemed vulnerable to a shortage and medically necessary, FDA would collaborate with manufacturers to establish continuity of operations plans to address drug shortages.

Revise Medically Necessary Definition

The bill would require FDA to revise the definition of medically necessary to include the prevalence of use of a drug as a factor in determining whether the drug is medically necessary.

Next Steps for ASHP

ASHP worked closely with Klobuchar's and Casey's offices as they developed the legislation and will [strongly advocate](#) along with you for its passage by soliciting cosponsors in the Senate. The Society will also continue to work to implement recommendations from the [November 2010 Drug Shortages Summit](#).

