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Summary

Title X of the Food and Drug Safety and Innovation Act of 2012

Title X of the Food and Drug Safety and Innovation Act of 2012 (P.L. 112-144) is devoted to drug shortages and includes a provision championed by ASHP—an early notification requirement. The following provisions are included in the new law.

EARLY NOTIFICATION

Manufacturers of drugs that are life-supporting, life-sustaining, prevent or treat a debilitating disease or condition, or are used in emergency medical care or during surgery, would have to report to the agency when it experiences a production interruption or discontinues a product.

In the case of a production interruption the notification would be as soon as possible. For a product discontinuation notification must be six (6) months in advance. If the product is a controlled substance, the Food and Drug Administration (FDA) will notify the Drug Enforcement Administration (DEA) within 30 days and coordinate with DEA to adjust production quotas if necessary.

If a manufacturer fails to comply with this section, FDA will issue a letter asking the reason for non-compliance. The manufacturer has 30 days to respond to the agency.

EXPEDITED REVIEW

The section also enables the FDA to expedite review of a new or abbreviated drug application to mitigate a potential drug shortage.

REGULATIONS

Within 18 months of enactment, FDA will have to promulgate and adopt regulations implementing section 1001. The regulations will allow FDA to include biologic products, plasma products derived from human protein and their recombinant analogs, as well as vaccines.

FDA ANNUAL REPORT

FDA must also provide an annual report to Congress on drug shortages. The report must include:

- The number of manufacturers who submitted notification;
- A description of the communication between field offices of FDA and the Drug Shortages Program;
- A list of the actions taken by the agency to mitigate drug shortages;
- A description of the coordination between the FDA and the DEA;
- The number and description of the instances where FDA has used regulatory flexibility to prevent or alleviate a shortage; and
- Names of the manufacturers that failed to comply with early notification requirements

FDA TASK FORCE

The FDA must establish a task force to develop and implement a strategic plan for enhancing the agency's ability to prevent and mitigate drug shortages. The strategic plan will include strategies for:

- Enhanced interagency and intra-agency communication;
- Considering drug shortages prior to a regulatory action that could cause or worsen a drug shortage;
- Effective communication with external stakeholders; and
- Consideration of the impact of drug shortages on clinical trials.

The strategic plan will also examine whether a qualified manufacturing partner program is needed.

DRUG SHORTAGES LIST

The FDA is required to maintain an up to date list of drugs in short supply. The list will be publicly available and must include:

- The name of the drug in short supply;
- The manufacturer of the drug;
- The reason for the shortage; and
- The estimated duration of the shortage.

QUOTAS

The Attorney General must examine the potential impact that manufacturing quotas have upon drug shortages and adjust if necessary.

ATTORNEY GENERAL REPORT

Each year the Attorney General must submit a report to Congress that:

- Identifies the number of requests for adjustments to manufacturing quotas, the average review time for such requests, the number of requests granted and denied under such section, and, for each of the requests denied under such section, the basis for such denial;
- Describes the coordination between the Drug Enforcement Administration and Food and Drug Administration on efforts to prevent or alleviate drug shortages; and
- Identifies drugs in shortage that contain a controlled substance.

HOSPITAL REPACKAGING

With the exception of controlled drugs, hospitals may repackage medications in short supply into smaller volume doses for use within the health system. Health system is defined as a collection of hospitals that are owned and operated by the same entity and share access to databases with drug order information. The repackaged drug must be for intra system use only, and must comply with applicable state laws governing prescription drugs.

GOVERNMENT ACCOUNTABILITY OFFICE STUDY

The Comptroller General shall conduct a study on drug shortages looking at causes and making recommendations on how to prevent or mitigate shortages. The study will take into account pricing (including federal reimbursement), number of manufacturers, impact of regulations on shortages, impact of hoarding, and explore incentives to prevent shortages.