# CONGRESSIONAL BUDGET OFFICE
# COST ESTIMATE

July 15, 2013

# S. 959
## Pharmaceutical Quality, Security, and Accountability Act

*As reported by the Senate Committee on Health, Education, Labor, and Pensions on June 19, 2013*

## SUMMARY

S. 959 would broaden the regulatory authority of the Food and Drug Administration (FDA) over prescription drugs. Title I would expand FDA's oversight role relating to compounded drugs. Traditionally, compounded drugs are those products that contain ingredients that have been combined, mixed, or altered by a pharmacist to create medications that are tailored to a specific patient's needs. The bill would authorize FDA to collect and spend fees to cover the costs of registering and inspecting certain facilities that compound drugs for human use.

Title II would require FDA to establish national standards for monitoring the movement of prescription drugs through the "drug distribution system." That drug distribution system encompasses the network of companies that produce, handle, distribute, and dispense drug products. The legislation would impose new regulatory requirements on such companies relating to handling drug products and maintaining records of transactions, and would create notification rules concerning drugs that are potentially unsuitable for distribution. The legislation also would authorize FDA to collect and spend fees to cover the costs of licensing programs for drug wholesalers and certain third parties that provide logistics services for pharmaceutical manufacturers, wholesalers, and dispensers.

CBO estimates that implementing S. 959 would have a net discretionary cost of $31 million over the 2014–2018 period, assuming appropriation actions consistent with the bill. In addition, S. 959 could increase revenues and direct spending from criminal and civil penalties; therefore, pay-as-you-go procedures apply. However, any such collections are estimated to be insignificant in each year.

S. 959 would impose mandates, as defined in the Unfunded Mandates Reform Act (UMRA), on both public and private-sector entities by requiring them to comply with standards for compounding prescription drugs and for monitoring the movement of prescription drugs through the distribution system. Because few public entities manufacture, distribute, or dispense prescription drugs, CBO estimates that the intergovernmental costs of the mandates would be small and below the threshold established in UMRA ($75 million in 2013, adjusted annually for inflation). CBO estimates that the costs to private entities would exceed the threshold established in UMRA ($150 million in 2013, adjusted annually for inflation).

## ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary impact of S. 959 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

## BASIS OF ESTIMATE

For this estimate, CBO assumes that the legislation will be enacted near the end of fiscal year 2013, and that the Congress will take appropriation actions consistent with the bill for the funding of FDA activities. We also assume that outlays will follow historical patterns for similar activities.

### Spending Subject to Appropriation

S. 959 would clarify and expand regulatory requirements relating to compounded drugs, create national standards for monitoring the distribution of drugs from manufacturers to dispensers, and authorize funding for related FDA activities. CBO estimates that implementing the bill would cost $31 million over the 2014-2018 period, assuming appropriation actions consistent with the bill.

| | By Fiscal Year, in Millions of Dollars | | | | | |
|---|---|---|---|---|---|---|
| | 2014 | 2015 | 2016 | 2017 | 2018 | 2014-2018 |
| **CHANGES IN SPENDING SUBJECT TO APPROPRIATION[a]** | | | | | | |
| **Title I: Human Drug Compounding** | | | | | | |
| Collection of Fees | | | | | | |
| Estimated Authorization Level | 0 | -19 | -19 | -21 | -20 | -79 |
| Estimated Outlays | 0 | -19 | -19 | -21 | -20 | -79 |
| Spending of Fees | | | | | | |
| Estimated Authorization Level | 0 | 19 | 19 | 21 | 20 | 79 |
| Estimated Outlays | 0 | 15 | 18 | 21 | 20 | 74 |
| Subtotal, Estimated Authorization Level | 0 | 0 | 0 | 0 | 0 | 0 |
| Subtotal, Estimated Outlays | 0 | -4 | -1 | * | * | -5 |
| **Title II: Drug Supply Chain Security** | | | | | | |
| Collection of Licensing Fees | | | | | | |
| Estimated Authorization Level | 0 | 0 | -11 | -12 | -12 | -35 |
| Estimated Outlays | 0 | 0 | -11 | -12 | -12 | -35 |
| Spending of Licensing Fees | | | | | | |
| Estimated Authorization Level | 0 | 0 | 11 | 12 | 12 | 35 |
| Estimated Outlays | 0 | 0 | 9 | 11 | 12 | 32 |
| Subtotal, Estimated Authorization Level | 0 | 0 | 0 | 0 | 0 | 0 |
| Subtotal, Estimated Outlays | 0 | 0 | -2 | -1 | * | -3 |
| **Other Activities Not Related to Fees[b]** | | | | | | |
| Estimated Authorization Level | 20 | 12 | 10 | 6 | 6 | 54 |
| Estimated Outlays | 16 | 10 | 7 | 3 | 3 | 39 |
| **Total Changes in Discretionary Spending** | | | | | | |
| Estimated Authorization Level | 20 | 12 | 10 | 6 | 6 | 54 |
| Estimated Outlays | 16 | 6 | 4 | 2 | 3 | 31 |

Notes: * = less than $500,000.

Components may not add to totals because of rounding.

a. Enacting the legislation would also increase revenues and direct spending by less than $500,000 per year, with insignificant net effects for each year.

b. Other activities include costs for the Government Accountability Office to conduct a study on the safety of compounding drugs for animal use and the availability of safe and effective drugs for animals. CBO estimates that completing the study would cost less than $500,000, assuming the availability of appropriated funds.

**Title I: Human Drug Compounding.** S. 959 would expand FDA's oversight role relating to compounded drugs. Traditionally, compounded drugs are those products that contain ingredients that have been combined, mixed, or altered by a pharmacist to create medications that are tailored to a specific patient's needs. Under current law, compounding of drugs for human use is primarily performed in pharmacies, which are regulated by state boards of pharmacies. Certain pharmacies compound sterile drugs before receiving a prescription order for an identified patient and distribute such drugs in interstate commerce. S. 959 would classify such facilities as "compounding manufacturers" under the Federal Food, Drug, and Cosmetic Act. Facilities that repackage or combine certain sterile drugs also would be considered compounding manufacturers. Key provisions of the title include:

- Creating national standards that govern the compounding of human drugs,
- Mandating compliance with current Good Manufacturing Practices,
- Requiring the reporting of adverse drug events and the types of drugs compounded, and
- Establishing a fee program to cover the costs of such oversight activities.

Title I would authorize FDA to assess and spend fees from manufacturers of compounded drugs for use in humans to help defray FDA's costs to regulate such drugs. Two categories of fees would be authorized by the legislation: (1) compounding manufacturer establishment fees, and (2) reinspection fees. The legislation would authorize specific amounts per facility for both the establishment and reinspection fees. The fees would be adjusted each year by an inflation factor to reflect changes in FDA's operating costs.

The fee programs would be authorized for fiscal year 2015 and for each subsequent fiscal year. Such fees could be collected and made available for obligation only to the extent and in the amounts provided in advance in appropriation acts.

CBO estimates collections from those fees would total $79 million over the 2015-2018 period. Because FDA would have the authority to spend the collections, the estimated budget authority for both collections and spending would offset each other exactly for each fiscal year. The outlays associated with those collections would initially lag behind the collections, thus generating net discretionary savings over the 2015-2018 period.

**Title II: Drug Supply Chain Security.** Title II would authorize FDA to expand its oversight of the drug distribution system in the United States. The legislation aims to improve the safety of the U.S. drug supply by requiring enhanced monitoring of the chain of transactions from the manufacturer of a drug to the party that ultimately dispenses the drug to the consumer.

Key provisions of title II include new requirements on entities in the drug distribution system relating to:

- Storage and handling of prescription drug products,
- Maintenance of records of the transaction history,
- Mandatory use of uniform identification numbers (UIDs) on packages and cases,
- Verification of the UIDs and transaction history of drug products, and
- Identification and notification rules concerning products that are potentially counterfeit, diverted, or stolen, or otherwise appear unfit for distribution.

The legislation would require FDA to license certain drug wholesalers and third parties that provide logistics services for a pharmaceutical manufacturer, wholesaler, or distributor. Such logistics services include warehousing and transporting drug products without taking ownership or responsibility for the sale or disposition of the products. The bill would require all such facilities to be licensed by a state or FDA. The bill would authorize the collection and spending of fees by FDA to cover the costs of activities related to issuing those licenses such as periodic inspections.

CBO expects that FDA would begin licensing facilities in fiscal year 2016 and that fee collections would start in that year. Such fees could be collected and made available for obligation only to the extent and in the amounts provided in advance in appropriation acts.

CBO expects that FDA would set fees to cover $35 million in estimated gross costs for the licensing programs over the 2016-2018 period. Because FDA would have the authority to spend the collections, the estimated budget authority for both collections and spending would offset each other exactly for each fiscal year. The outlays associated with those collections would initially lag behind the collections, thus generating net discretionary savings over the 2016-2018 period.

**Other Activities not Related to Fees**. Administrative costs for certain activities required by S. 959 would not be covered by fees. For example, the fees established under title I would not cover all of the inspection and other regulatory activities required by the legislation. In addition, title II would require FDA to establish a number of standards to enhance the safety and security of prescription drugs through the drug distribution system. In developing those standards, FDA would be required to host at least three public meetings, implement at least one pilot project, and promulgate regulations. The legislation also would require the Government Accountability Office to conduct a study

on the safety of compounding drugs for animal use and the availability of safe and effective drugs for animals. Taken together, CBO estimates the costs of implementing those provisions would be $39 million over the 2014-2018 period, subject to appropriation of the necessary amounts.

### Revenues and Direct Spending

Enacting S. 959 could increase federal revenues and direct spending as a result of additional criminal and civil penalties assessed for violations of various requirements under the bill. Collections of civil and criminal penalties are recorded in the budget as revenues. Criminal penalties are deposited in the Crime Victims Fund and later spent. CBO expects that the net budgetary effects of those transactions would be insignificant for each year because of the small number of cases likely to be affected.

## PAY-AS-YOU-GO CONSIDERATIONS

The Statutory Pay-As-You-Go Act of 2010 establishes budget-reporting and enforcement procedures for legislation affecting direct spending or revenues. The net changes in outlays and revenues that are subject to those pay-as-you-go procedures are shown in the following table.

**CBO Estimate of Pay-As-You-Go Effects for S. 959, as reported by the Senate Committee on Health, Education, Labor, and Pensions on June 19, 2013**

| | By Fiscal Year, in Millions of Dollars | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 | 2021 | 2022 | 2023 | 2013-2018 | 2013-2023 |
| **NET INCREASE OR DECREASE (-) IN THE DEFICIT** | | | | | | | | | | | | | |
| Statutory Pay-As-You-Go Impact | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

## INTERGOVERNMENTAL AND PRIVATE-SECTOR IMPACT

S. 959 would impose both intergovernmental and private-sector mandates as defined in UMRA by requiring public and private-sector entities to comply with standards for compounding prescription drugs and for monitoring the movement of prescription drugs through the distribution system.

**Effects on the Private Sector**

In total, CBO estimates that costs incurred by private-sector entities to comply with S. 959 would exceed the threshold established in UMRA ($150 million in 2013, adjusted annually for inflation) in at least one of the first five years in which the mandates would be in effect.

Title I of the bill would impose several mandates on pharmacies that compound prescription drugs. Compounding manufacturers would be required to:

- Register with FDA as a compounding manufacturer and pay applicable registration and inspection fees,
- Provide reports to FDA about adverse drug events and the types of drugs sold,
- Ensure that their operations would be directly supervised by pharmacists licensed in the state in which the compounding manufacturer is located,
- Label products with certain information, including a statement identifying the product as a compounded drug,
- Comply with current Good Manufacturing Practices, and
- Not participate in the wholesale market.

The cost of compliance with those mandates would vary across pharmacies and would depend on the extent to which those pharmacies would need to modify their facilities. CBO estimates that roughly 1,000 pharmacies would be classified as compounding manufacturers under the proposed legislation. The compounding manufacturer establishment fees and reinspection fees discussed earlier in this estimate would cost them roughly $20 million a year starting in fiscal year 2015. In addition, the requirement to comply with current Good Manufacturing Practices may be costly to implement, as some pharmacies may need to build or renovate existing facilities or purchase new equipment in order to comply with the new requirements. CBO does not have sufficient information to estimate those costs.

In addition to the mandates on pharmacies designated as compounding manufacturers, the bill would establish mandates on pharmacies that compound drugs but do not fall under FDA's definition of compounding manufacturer. All pharmacies would not be allowed to compound certain drugs, including marketed drugs, biological products, and drugs subject to special regulatory procedures called Risk Evaluation and Mitigation Strategies. A pharmacy also would be required to notify the Secretary if it is compounding a drug on

the drug shortage list maintained by the FDA. CBO estimates that pharmacies would, in aggregate, incur annual costs in the tens of millions of dollars to comply with the requirements in title I.

Title I also would restrict other entities, such as physicians, who would no longer be able to repackage preservative-free sterile drugs in an office setting. Because most medical practices do not compound regularly in an office setting, CBO estimates that the cost of the mandate would be small.

Title II would impose a number of mandates, as defined in UMRA, on drug manufacturers, repackagers, wholesale distributors, dispensers (primarily pharmacies), and third parties that provide logistic services (TPLs). Such entities would be required to:

- Maintain records of the transaction history of all drug products for six years,
- Accept or transfer ownership of only those drug products with a UID and applicable transaction history,
- Verify the transaction history and UIDs of drug products,
- Identify suspect or illegitimate drug products and notify FDA and entities that may have received such products of such a discovery,
- Identify, quarantine, dispose, and maintain records of illegitimate drug products, and
- Pay fees to cover the costs of licensing.

Because existing law in California contains similar requirements and affects nearly all manufacturers, repackagers, wholesale distributors, and TPLs, CBO estimates that the cost of the mandates contained in S. 959 for those private-sector entities would be small; the affected entities already comply with most of those requirements in order to conduct business in California. However, independent pharmacies and pharmacies based in hospitals—currently unaffected by the laws in California—would face new costs to comply with the mandates. According to data from the National Community Pharmacy Association, roughly 20,000 independent pharmacies operate outside of California, most of which would incur new costs to comply with the requirements in S. 959.

Little evidence is available on the cost to independent and hospital-based pharmacies of complying with the mandates. Discussions with outside experts indicate that the cost of compliance could vary widely across pharmacies. Those costs would depend on the methods and data systems they adopted. CBO anticipates most pharmacies would take

measures to limit costs, such as entering into agreements with third parties to maintain appropriate records or requesting an exemption of the standards from FDA. Because about 20,000 pharmacies would have to comply with the new standards, CBO estimates that the costs to private-sector entities in title II would exceed the UMRA threshold —$150 million in 2013—in at least one of the first five years that the mandates are in effect.

### Effects on State, Local, and Tribal Governments

Because few pharmacies are public entities, CBO estimates that the intergovernmental costs of the mandates in title II of the bill would be small and below the threshold established in UMRA ($75 million in 2013, adjusted annually for inflation). The bill also would preempt several state laws including:

- Laws that require tracing prescription drugs through the distribution system if those laws are inconsistent or more stringent than the federal standard,

- State licensing laws that govern wholesale drug distributors or TPLs if those laws are less stringent than the standards established by the bill, and

- Laws that regulate TPLs as wholesale distributors.

Because they would limit the application of state law, those preemptions would be intergovernmental mandates as defined in UMRA; however, they would impose no duty on states that would result in additional spending.

## PREVIOUS CBO ESTIMATE

On May 31, 2013, CBO transmitted a cost estimate for H.R. 1919, the Safeguarding America's Pharmaceuticals Act of 2013, as ordered reported by the House Committee on Energy and Commerce on May 15, 2013. That legislation also would establish national standards for monitoring the safety of the drug distribution system.

Both H.R. 1919 and S. 959 would establish fee programs to cover certain regulatory costs necessary to implement the legislation, but we anticipate that differences in the authorizing language contained in each bill for such fee programs would result in different budgetary treatment of the collections. Because fees established by S. 959 would be subject to appropriation, we expect they would be classified as offsets to discretionary spending. Fees established by H.R. 1919, however, would not be subject to appropriation; thus, we expect they would be classified as federal revenues. Unlike S. 959, H.R. 1919 does not address the oversight of compounded drugs for human use. Differences in the estimates reflect that and other differences in the legislation.

**ESTIMATE PREPARED BY:**

Federal Costs and Revenues: Ellen Werble, Lisa Ramirez-Branum, and Barbara Edwards
Impact on State, Local, and Tribal Governments: Lisa Ramirez-Branum
Impact on the Private Sector: Michael Levine and Alexia Diorio

**ESTIMATE APPROVED BY:**

Holly Harvey
Deputy Assistant Director for Budget Analysis