



## CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

August 8, 2016

### **S. 2503**

### **Preventing Superbugs and Protecting Patients Act**

*As reported by the Senate Committee on Health, Education, Labor, and Pensions  
on April 5, 2016*

S. 2503 would require the Secretary of Health and Human Services to publish a list of reusable medical devices for which manufacturers would be required to submit additional data in a premarket notification regarding cleaning, disinfecting, and sterilizing the device. The bill also would require the Commissioner of the Food and Drug Administration (FDA) to issue final guidance addressing when manufacturers are required to submit a notification to FDA to market a modified version of a legally marketed device.

FDA is already working on the guidance required by S. 2503 and CBO expects that other aspects of the bill would make only small changes in FDA's current activities. Based on that assessment, CBO estimates that implementing S. 2503 would cost less than \$500,000 over the 2017-2021 period; that spending would be subject to the availability of appropriated funds. Enacting S. 2503 would not affect direct spending or revenues; therefore, pay-as-you-go procedures do not apply to the bill. CBO estimates that enacting S. 2503 would not increase net direct spending or on-budget deficits in any of the four consecutive 10-year periods beginning in 2027.

The bill would impose a private-sector mandate as defined in the Unfunded Mandates Reform Act (UMRA) by requiring manufacturers of some reusable medical devices to submit additional data with their premarket applications for those devices. Manufacturers already produce the additional information and would only need to transmit it along with the premarket applications for devices designated by the Secretary. Therefore, CBO estimates that the cost to comply with the mandate would be minimal and fall well below the annual threshold established in UMRA for private-sector mandates (\$154 million in 2016, adjusted annually for inflation).

S. 2503 contains no intergovernmental mandates as defined in UMRA and would impose no costs on state, local, or tribal governments.

The CBO staff contact for this estimate is Ellen Werble. The estimate was approved by Holly Harvey, Deputy Assistant Director for Budget Analysis.