CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE

July 11, 2016

S. 1101
Medical Electronic Data Technology Enhancement for Consumers' Health Act

As reported by the Senate Committee on Health, Education, Labor, and Pensions on April 4, 2016

SUMMARY

S. 1101 would amend the Federal Food, Drug, and Cosmetic Act (FFDCA) to exempt certain medical software from regulation as a medical device and, as a result, from an excise tax on such devices. Because enacting the bill would affect revenues, pay-as-you-go procedures apply. However, CBO and the Joint Committee on Taxation (JCT) estimate that those losses would be less than $500,000 over the 2017-2026 period. Enacting the legislation would not affect direct spending.

S. 1101 also would direct the Secretary of Health and Human Services (HHS) to classify and regulate accessories to medical devices separately from the device they operate. In addition, the legislation would require preparation of a report on the risks and benefits of using medical software. CBO estimates that implementing the legislation would cost the Food and Drug Administration (FDA) $60 million over the 2017-2021 period, assuming appropriation of the necessary amounts.

CBO estimates that enacting S. 1101 would not increase net direct spending or on-budget deficits in any of the four consecutive 10-year periods beginning in 2027.

S. 1101 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA).

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary effect of S. 1101 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By Fiscal Year, in Millions of Dollars					
	2017	2018	2019	2020	2021	2017-2021
CHANGES IN SPENDING SUBJECT TO APPROPRIATION [a]						
Estimated Authorization Level	7	11	16	16	16	66
Estimated Outlays	5	9	14	15	16	60

Note: Components do not sum to totals because of rounding.

a. S. 1101 would also affect revenues; however, CBO and JCT estimate the reduction in revenues would be less than $500,000 over the 2017-2026 period.

BASIS OF ESTIMATE

For this estimate, CBO assumes that S. 1101 will be enacted near the end of fiscal year 2016 and that spending will follow historical patterns for similar programs.

S. 1101 would exclude certain medical software from the definition of a device in the FFDCA. This exemption would remove those devices from FDA's regulation unless FDA determines that use of the software would be reasonably likely to have serious adverse health effects. In those cases, FDA would be required to publish a notice of any determination that software would be regulated as a device.

The Secretary of HHS also would be required to publish a report every two years on the risks and benefits to health associated with use of medical software including input from many outside experts. In order to complete a report every two years, CBO expects FDA would have to engage frequently with outside experts on such risks and benefits. Based on similar activities, CBO also expects that FDA would have to hire the equivalent of about 35 additional full-time employees when the program is fully established and to make an additional investment in information technology. CBO estimates implementing S. 1101 would cost $60 million over the 2017-2021 period, assuming appropriation of the necessary amounts.

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. Sales of medical devices, as defined in FFDCA, are subject to an excise tax under current law. By excluding certain medical software from the definition of a medical device, S. 1101 would exempt such

software from the excise tax on medical devices. CBO and JCT estimate that revenues would be reduced by less than $500,000 over the 2017-2026 period.

INCREASE IN LONG-TERM DIRECT SPENDING AND DEFICITS

CBO estimates that enacting S. 1101 would not increase net direct spending or on-budget deficits by more than $5 billion in any of the four consecutive 10-year periods beginning in 2027.

INTERGOVERNMENTAL AND PRIVATE-SECTOR IMPACT

S. 1101 contains no intergovernmental or private-sector mandates as defined in UMRA and would impose no costs on state, local, or tribal governments.

PREVIOUS CBO ESTIMATE

On June 23, 2015, CBO transmitted a cost estimate for H.R. 6, the 21st Century Cures Act, as ordered reported by the House Energy and Commerce Committee on May 21, 2015. In Subtitle N, that legislation included language that would also exempt certain medical software from regulation as a medical device; however, H.R. 6 would require FDA to implement a new framework to regulate medical software based on a specified definition. S. 1101 would not require FDA to establish a new framework and would require a report including input from many outside experts. CBO's estimate of S. 1101 reflects those differences.

On July 7, 2015, CBO transmitted an estimate for the Rules Committee print of H.R. 6, 21st Century Cures Act. That legislation included similar language in Subtitle N; however, the Rules Committee print of H.R. 6 would have created a new fund, the Cures Innovation Fund, and made those funds available for provisions in Subtitle N. CBO estimated those funds would be direct spending. In contrast, CBO estimates the costs of implementing the changes in S. 1101 would be subject to future appropriations action. Differences in the estimated budgetary effects of the two bills reflect those differences in legislative language.

ESTIMATE PREPARED BY:

Federal Costs: Ellen Werble
Impact on State, Local, and Tribal Governments: J'nell Blanco Suchy
Impact on the Private Sector: Amy Petz

ESTIMATE APPROVED BY:

Holly Harvey
Deputy Assistant Director for Budget Analysis