CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE

May 9, 2016

H.R. 4978
Nurturing and Supporting Healthy Babies Act

As reported by the House Committee on Energy and Commerce on April 27, 2016

SUMMARY

H.R. 4978 would exclude formulations of prescription drugs that include abuse deterrents from Medicaid's requirement that new drug formulations pay additional rebates. The bill also would prevent the disclosure of algorithms used to detect fraud, provide additional funding to the Medicaid Improvement Fund, and require the Government Accountability Office to submit a report to the Congress on neonatal abstinence syndrome in the United States.

CBO estimates that enacting H.R. 4978 would not, on net, change direct spending over the 2017-2026 period. Some provisions of the bill would increase direct spending by $80 million over that period while other provisions would decrease direct spending by the same amount. In addition, CBO estimates that implementing H.R. 4978 would have a discretionary cost of less than $500,000; any such spending would be subject to the availability of appropriated funds. Pay-as-you-go procedures apply because enacting the legislation would affect direct spending. Enacting the legislation would not affect revenues.

CBO estimates that enacting the legislation 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.

H.R. 4978 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 H.R. 4978 is shown in the following table. The budgetary effects of this legislation fall within budget functions 550 (health) and 570 (Medicare).

	By Fiscal Year, in Millions of Dollars											
	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2017-2021	2017-2026
CHANGES IN DIRECT SPENDING												
Exclusion from Medicaid Rebate Requirements												
Estimated Budget Authority	1	3	5	8	8	9	9	10	10	11	26	75
Estimated Outlays	1	3	5	8	8	9	9	10	10	11	26	75
Disclosure of Predictive Modeling												
Estimated Budget Authority	-8	-8	-8	-8	-8	-8	-8	-8	-8	-8	-40	-80
Estimated Outlays	-8	-8	-8	-8	-8	-8	-8	-8	-8	-8	-40	-80
Medicaid Improvement Fund												
Budget Authority	0	0	0	0	5	0	0	0	0	0	5	5
Estimated Outlays	0	0	0	0	5	0	0	0	0	0	5	5
Total Changes												
Estimated Budget Authority	-7	-5	-3	0	5	1	1	2	2	3	-9	0
Estimated Outlays	-7	-5	-3	0	5	1	1	2	2	3	-9	0
CHANGES IN SPENDING SUBJECT TO APPROPRIATION												
GAO Report												
Estimated Authorization Level	*	0	0	0	0	0	0	0	0	0	*	*
Estimated Outlays	*	0	0	0	0	0	0	0	0	0	*	*

Notes: * = Less than $500,000; Components may not add to totals because of rounding.

BASIS OF ESTIMATE

For this estimate, CBO assumes that H.R. 4978 will be enacted near the end of fiscal year 2016.

Changes in Direct Spending

CBO estimates that enacting H.R. 4978 would not have a net effect on direct spending over the 2017-2026 period.

Exclusion from Medicaid Rebate Requirements. Section 3 of H.R. 4978 would reduce the Medicaid rebate amount paid by some manufacturers of brand-name drugs that contain abuse-deterrent formulations (ADFs). ADFs are designed to make it more difficult to intentionally use prescription drugs for non-therapeutic purposes. For example, some ADFs make it more difficult for an individual to crush, break, or dissolve a drug to inappropriately extract and use its active ingredient.

Under current law, pharmaceutical manufacturers are required to pay rebates to states for prescription drugs provided through Medicaid. Based on administrative data from the Centers for Medicare and Medicaid Services (CMS), manufactures paid more than $20 billion in rebates to the Medicaid program in FY 2015. The formula which determines rebate amounts in the Medicaid program has several components. Some components generate rebates that are paid to states and shared with the federal government and others generate rebates that are paid to states and subsequently transferred in their entirety to the federal government. Under the bill, the component of the rebate formula that would no longer apply to ADFs of brand-name drugs is one that is paid to states and transferred in full to the federal government. Therefore, states would not be directly affected by this section of the bill.

CBO estimates that this section would increase federal Medicaid costs by about $75 million over the 2017-2026 period by reducing rebates. CBO anticipates that an increasing number of ADFs of brand name drugs will launch over time; therefore, the component of the rebate affected by H.R. 4978 would also grow over time. This estimate is based on a review of potential classes of drugs where ADFs may be introduced over the next 10 years and on rebate calculations generated from Medicaid data obtained from the Centers for Medicare and Medicaid Services and Red Book data available from Truven Health Analytics.

Disclosure of Predictive Modeling. CMS currently uses the Fraud Prevention System (FPS) to detect questionable and fraudulent activity within the fee-for-service Medicare program. The FPS uses sophisticated computer algorithms—similar to those used by credit-card issuers—to review millions of claims to look for evidence of inappropriate utilization or problematic billing. Originally authorized by the Small Business Jobs Act of 2010, the FPS is currently used to review Medicare claims. In the future, use of the FPS may expand to Medicaid and the Children's Health Insurance Program (CHIP), which are administered by the states.

Section 4 of H.R. 4978 would prevent disclosure of the FPS algorithms through requests under the Freedom of Information Act. The bill also would forbid disclosure of that information by state agencies unless such disclosure is necessary to administer their Medicaid and CHIP programs. Permitting public access to the algorithms would facilitate fraudulent schemes to circumvent the FPS. Because H.R. 4978 prevents public access to the FPS algorithms and discourages fraud, CBO estimates that enacting Section 4 of H.R. 4978 would reduce direct spending in the Medicare, Medicaid, and CHIP programs by about $80 million over the 2017-2026 period.

Medicaid Improvement Fund. Section 5 of H.R. 4978 would provide $5 million in mandatory funding to the Medicaid Improvement Fund (MIF) in 2021, which would be available to the Secretary of Health and Human Services to improve federal management of the Medicaid program. Activities that could be funded by the MIF include oversight of

contracts and contractors, and evaluation of demonstration programs. CBO estimates that Section 5 would increase spending by $5 million over the 2017-2026 period.

Changes in Spending Subject to Appropriation

Section 2 of H.R. 4978 would require the Government Accountability Office to submit a report to the Congress on neonatal abstinence syndrome in the United States. CBO estimates that implementing section 2 would cost less than $500,000 over the 2017-2026 period; any such spending would be subject to the availability of appropriated funds.

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 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 H.R. 4978, the Nurturing and Supporting Healthy Babies Act, as ordered reported by the House Committee on Energy and Commerce on April 27, 2016

	By Fiscal Year, in Millions of Dollars												
	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2016-2021	2016-2026
NET INCREASE OR DECREASE (-) IN THE DEFICIT													
Statutory Pay-As-You-Go Impact	0	-7	-5	-3	0	5	1	1	2	2	3	-9	0

INCREASE IN LONG-TERM DIRECT SPENDING AND DEFICITS

CBO estimates that enacting the legislation 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 2026.

INTERGOVERNMENTAL AND PRIVATE-SECTOR IMPACT

H.R. 4978 contains no intergovernmental or private-sector mandate as defined in UMRA and would impose no costs on state, local, or tribal governments.

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