

(Millions of dollars, by fiscal year) 2018- 2018-
2022 2027

CHANGES IN DIRECT SPENDING ^a												
Section	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2022	2027
601. Reauthorization of Provision Relating to Exclusivity of Certain Drugs Containing Single Enantiomers												
Estimated Budget Authority	0	0	0	0	0	1	3	5	4	1	0	13
Estimated Outlays	0	0	0	0	0	1	3	5	4	1	0	13
608. Pediatric Information Added to Labeling												
Estimated Budget Authority	0	0	-1	-1	-2	-2	-2	-3	-3	-3	-4	-17
Estimated Outlays	0	0	-1	-1	-2	-2	-2	-3	-3	-3	-4	-17
808. Incentivizing Competitive Generic Drug Development												
Estimated Budget Authority	0	0	-1	-2	-4	-6	-7	-10	-12	-14	-7	-56
Estimated Outlays	0	0	-1	-2	-4	-6	-7	-10	-12	-14	-7	-56
Total Changes in Direct Spending												
Estimated Budget Authority	0	0	-2	-3	-6	-7	-6	-8	-11	-16	-11	-60
Estimated Outlays	0	0	-2	-3	-6	-7	-6	-8	-11	-16	-11	-60

CHANGES IN REVENUES ^{a,b,c}												
Section	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2022	2027
601. Reauthorization of Provision Relating to Exclusivity of Certain Drugs Containing Single Enantiomers												
Estimated Revenues	0	0	0	0	0	*	-1	-1	-1	*	0	-2
On-Budget	0	0	0	0	0	*	*	-1	-1	*	0	-2
Off-Budget	0	0	0	0	0	0	*	*	*	*	0	-1
608. Pediatric Information Added to Labeling												
Estimated Revenues	0	0	*	*	*	*	1	1	1	1	1	4
On-Budget	0	0	*	*	*	*	*	*	*	1	1	3
Off-Budget	0	0	0	*	*	*	*	*	*	*	*	1
808. Incentivizing Competitive Generic Drug Development												
Estimated Revenues	0	0	*	1	1	1	1	2	3	3	2	11
On-Budget	0	0	*	*	1	1	1	1	2	2	1	8
Off-Budget	0	0	*	*	*	*	*	1	1	1	*	3
Total Changes in Estimated Revenues												
On-Budget	0	0	*	1	1	1	1	1	2	2	2	9
Off-Budget	0	0	*	*	*	*	*	*	1	1	1	3

NET DECREASE (-) IN THE DEFICIT ^c												
Impact on the Deficit	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2022	2027
Impact on the Deficit	0	0	-2	-4	-7	-9	-8	-10	-14	-19	-13	-72
On-Budget	0	0	-2	-4	-7	-8	-7	-9	-13	-18	-13	-69
Off-Budget	0	0	*	*	*	*	*	*	-1	-1	-1	-3

Sources: Congressional Budget Office; staff of the Joint Committee on Taxation (JCT).

Notes: Components may not sum to totals because of rounding; * = an increase or decrease of less than \$500,000.

H.R. 2430 would impose intergovernmental and private-sector mandates, as defined in the Unfunded Mandates Reform Act (UMRA), on public and private manufacturers of prescription drugs and medical devices. In addition, the bill would preempt state and local laws that interfere with the distribution of over-the-counter hearing aids. CBO estimates that the cost of the mandates on public entities would be small and fall well below the annual threshold established in UMRA for intergovernmental mandates (\$78 million in 2017, adjusted annually for inflation). However, in aggregate, CBO estimates that the cost of the mandates on private entities would well exceed the annual threshold established in UMRA for private-sector mandates (\$156 million in 2017, adjusted annually for inflation) in each of the first five years the mandates are in effect, primarily because of the requirement to pay fees.

- a. Policies affect both direct spending and revenues.
- b. Positive numbers indicate an increase in revenues; negative numbers indicate a decrease in revenues.
- c. All off-budget revenue effects would come from changes in Social Security revenues (the payroll taxes for Social Security are classified as "off-budget").