CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE

August 3, 2018

S. 2852
Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018

As reported by the Senate Committee on Health, Education, Labor, and Pensions on June 18, 2018

SUMMARY

S. 2852 would amend the Public Health Service Act and the *United States Code* to authorize funding for certain activities to support national preparedness for public health emergencies (PHEs) and widespread medical emergencies, including acts of bioterrorism.

Using information from affected federal agencies, CBO estimates that implementing the bill would cost about $13 billion over the 2019-2023 period, assuming appropriation of the authorized amounts. The Consolidated Appropriations Act, 2018, included funding of about $3 billion in fiscal year 2018 for similar activities.

S. 2852 also would allow medical professionals in the National Disaster Medical System (NDMS) to participate in the Public Safety Officers' Benefits (PSOB) Program, resulting in an estimated increase in direct spending of about $2 million over the 2019-2028 period. Because the bill would affect direct spending, pay-as-you-go procedures apply. Enacting S. 2852 would not affect revenues.

CBO estimates that enacting S. 2852 would not increase net direct spending by more than $2.5 billion or on-budget deficits by more than $5 billion in any of the four consecutive 10-year periods beginning in 2029.

S. 2852 would impose intergovernmental and private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA). CBO estimates that the costs of those mandates would fall below the thresholds established in UMRA for intergovernmental and private-sector mandates ($80 million and $160 million in 2018, respectively, adjusted annually for inflation).

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary effect of S. 2852 is shown in the following table. The costs of the legislation fall within budget functions 550 (health), 700 (veterans benefits and services), 750 (administration of justice), and 800 (general government).

	By Fiscal Year, in Millions of Dollars						
	2018	2019	2020	2021	2022	2023	2019-2023
INCREASES IN SPENDING SUBJECT TO APPROPRIATION							
Department of Health and Human Services							
Centers for Disease Control and Prevention							
State and Local Public Health Security							
Authorization Level	0	685	685	685	685	685	3,425
Estimated Outlays	0	253	578	655	671	678	2,835
Strategic National Stockpile							
Authorization Level	0	610	610	610	610	610	3,050
Estimated Outlays	0	122	439	531	579	592	2,263
Public Health Threats							
Authorization Level	0	162	162	162	162	162	809
Estimated Outlays	0	60	137	155	159	160	671
Vaccine Tracking and Distribution							
Authorization Level	0	31	31	31	31	31	154
Estimated Outlays	0	11	26	29	30	30	126
Children's Preparedness Unit							
Estimated Authorization Level	0	*	*	*	*	*	2
Estimated Outlays	0	*	*	*	*	*	2
Food and Drug Administration							
Provisions Relating to the FDA's Regulatory Authority							
Estimated Authorization Level	0	1	1	1	1	1	4
Estimated Outlays	0	1	1	1	1	1	4
Office of the Assistant Secretary for Preparedness and Response							
BARDA and Project BioShield Special Reserve Fund							
Authorization Level	0	4,112	612	612	612	612	6,559
Estimated Outlays	0	262	958	1,167	1,246	1,272	4,906
Hospital Preparedness							
Authorization Level	0	385	385	385	385	385	1,925
Estimated Outlays	0	77	281	343	366	373	1,440

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	By Fiscal Year, in Millions of Dollars						
	2018	2019	2020	2021	2022	2023	2019-2023
INCREASES IN SPENDING SUBJECT TO APPROPRIATION							
National Disaster Medical System							
Authorization Level	0	57	57	57	57	57	287
Estimated Outlays	0	11	42	51	55	56	215
Medical Reserve Corps							
Authorization Level	0	11	11	11	11	11	56
Estimated Outlays	0	6	9	11	11	11	47
Military and Civilian Partnership for Trauma Readiness							
Authorization Level	0	7	7	7	7	7	34
Estimated Outlays	0	1	5	6	6	7	25
Emergency Volunteer Registration							
Authorization Level	0	5	5	5	5	5	25
Estimated Outlays	0	3	4	5	5	5	21
Preparing for Significant Threats							
Estimated Authorization Level	0	2	4	4	4	4	16
Estimated Outlays	0	2	4	4	4	4	16
National Advisory Committees on Disasters							
Estimated Authorization Level	0	1	1	1	1	1	4
Estimated Outlays	0	1	1	1	1	1	4
Meeting on Genomic Engineering Technologies							
Estimated Authorization Level	0	1	1	1	0	0	2
Estimated Outlays	0	1	1	1	0	0	2
Other HHS Activities							
Estimated Authorization Level	0	1	1	1	1	1	4
Estimated Outlays	0	1	1	1	1	1	4
Department of Veterans Affairs							
Veterans Health Administration							
Authorization Level	0	0	155	155	155	155	620
Estimated Outlays	0	0	136	150	152	153	591
Government Accountability Office							
Estimated Authorization Level	0	2	1	1	*	0	4
Estimated Outlays	0	2	1	1	*	0	4

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	By Fiscal Year, in Millions of Dollars						
	2018	2019	2020	2021	2022	2023	2019-2023
INCREASES IN SPENDING SUBJECT TO APPROPRIATION							
Total Changes							
Estimated Authorization Level	0	6,072	2,728	2,728	2,726	2,726	16,980
Estimated Outlays	0	813	2,623	3,111	3,286	3,344	13,177

Components may not sum to totals because of rounding.

BARDA = Biomedical Advanced Research and Development Authority; FDA = Food and Drug Administration; HHS = Department of Health and Human Services; * = between -$500,000 and $500,000.

BASIS OF ESTIMATE

For this estimate, CBO assumes that S. 2852 will be enacted late in 2018 and that the Congress will appropriate the authorized amounts. Estimated outlays follow historical patterns for similar programs.

Spending Subject to Appropriation for the Department of Health and Human Services

Most activities of the Department of Health and Human Services (HHS) under S. 2852 would be carried out by the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the Office of the Assistant Secretary for Preparedness and Response (ASPR). Spending would be subject to the availability of appropriated funds.

Centers for Disease Control and Prevention. S. 2852 would authorize funding over the 2019-2023 period at levels similar to appropriations in recent years for activities related to preparing for PHEs.

State and Local Public Health Security. S. 2852 would allow CDC to continue to administer cooperative agreements with state and local governments. The entities that receive funding also would be required to include planning for behavioral health needs as part of their all-hazards PHE preparedness and response plans. S. 2852 would authorize the annual appropriation of $685 million for the 2019-2023 period for CDC to administer

those agreements; in 2018, $670 million was allocated for such activities. Over the 2019-2023 period, CBO estimates, implementing the provision would cost about $2.8 billion.

Strategic National Stockpile. The Strategic National Stockpile is a national repository for medical countermeasures—pharmaceuticals, medical supplies, and equipment for the rapid delivery of aid in response to a catastrophic health event. S. 2852 would require CDC to conduct an annual, threat-based review for each countermeasure added, modified, or replenished within the stockpile. The review would include information on manufacturing capacity to meet supply needs and effects on the availability of products in the health care system. The bill would authorize the continuation of the Strategic National Stockpile and an annual appropriation of about $610 million over the 2019-2023 period; in 2018, $610 million was allocated for such activities. CBO estimates that implementing the provision would cost about $2.3 billion over the 2019-2023 period.

Public Health Threats. S. 2852 would authorize funding for the Secretary of HHS to continue to expand, enhance, and improve CDC's capacity to respond to PHEs, including acts of bioterrorism. S. 2852 also would authorize funding to maintain surveillance programs and networks to respond to infectious-disease outbreaks. The bill would authorize the appropriation of $162 million annually over the 2019-2023 period for those activities; in 2018, $162 million was allocated for such activities. CBO estimates that implementing this provision would cost $671 million over the 2019-2023 period.

Vaccine Tracking and Distribution. CDC collaborates with state, local, and tribal governments and private entities—including vaccine manufacturers, wholesalers, and distributors—to track the distribution of vaccines used to prevent pandemic influenza and to promote effective distribution of seasonal-influenza vaccines. S. 2852 would authorize the Secretary of HHS to continue those activities and authorize an annual appropriation of $31 million for the 2019-2023 period; CBO estimates that $31 million was allocated to such activities in fiscal year 2018. CBO estimates that implementing that provision would cost $126 million over the 2019-2023 period.

Children's Preparedness Unit. S. 2852 would authorize CDC to assemble an internal team of experts to provide guidance on the needs of children before, during, and after PHEs. The team would assist state, local, and tribal entities with emergency planning and coordinate with public-private partnerships to address gaps in emergency response efforts for children. CBO estimates that implementing that provision would cost about $2 million over the 2019-2023 period.

Food and Drug Administration. S. 2852 would change the way the FDA reviews and interacts with manufacturers of certain medical products for countering infectious-disease outbreaks or chemical, biological, radiological, or nuclear attacks. The bill would require the FDA to:

- Expedite the review of certain animal drugs that may prevent or treat diseases in animals that could be particularly harmful if transmitted to humans,

- Update the process used by manufacturers to interact with the agency about certain medical countermeasures, and

- Meet with stakeholders and update guidance on data and information submissions for medical countermeasures.

CBO expects that additional employees would be needed to review and update guidance and expedite reviews. Using information from the FDA, CBO estimates that those provisions would cost $4 million over the 2019-2023 period.

Office of the Assistant Secretary for Preparedness and Response. S. 2852 would authorize funding for activities related to medical system capacity and the development and procurement of countermeasures.

Biomedical Advanced Research and Development Authority and the Project BioShield Special Reserve Fund. The bill would authorize funding for advanced research, development, and procurement of certain biomedical products (funded by Project BioShield). The Biomedical Advanced Research and Development Authority office (funded by the Biodefense Medical Countermeasure Development Fund) now supports the advanced development of medical countermeasures to respond to bioterrorism and other PHEs. S. 2852 would authorize the annual appropriation of about $612 million for the fund over the 2019-2023 period; in 2018, $537 million was allocated for such activities.

In addition, the bill would authorize the appropriation of $3.5 billion over the 2019-2023 period for the BioShield Special Reserve Fund. The reserve fund is used to procure medical countermeasures for the strategic national stockpile. For the 2014-2018 period, $2.8 billion was appropriated for the fund from which $710 million was allocated to be used in 2018.

In total, CBO estimates that implementing section 504 would cost $4.9 billion over the 2019-2023 period.

Hospital Preparedness. S. 2852 would authorize a grant program for states, localities, or health care facilities to enhance hospital capacity in the event of a PHE. The bill would authorize the annual appropriation of $385 million over the 2019-2023 period for ASPR to administer those cooperative agreements and grants; in 2018, about $265 million was allocated for such activities. Over the 2019-2023 period, CBO estimates, implementing the provision would cost about $1.4 billion.

National Disaster Medical System. The NDMS provides medical assistance to states and localities to respond to large-scale PHEs. The system is a partnership of HHS and the Departments of Veterans Affairs, Defense, and Homeland Security. S. 2852 would authorize annual funding of $57 million over the 2019-2023 period—the same amount that was allocated in 2018. Based on historical spending patterns, CBO estimates that implementing the provision would cost $215 million over the 2019-2023 period, assuming appropriation of the authorized amounts.

Medical Reserve Corps (MRC). The MRC is a community-based effort to coordinate the work of medical and public health volunteers in support of public health activities, including emergency preparedness and response. S. 2852 would authorize annual funding of about $11 million over the 2019-2023 period; in 2018, $6 million was allocated for that purpose. CBO estimates that implementing the provision would cost $47 million over the 2019-2023 period.

S. 2852 also would clarify the applicability of liability laws for MRC volunteers. Under the bill, medical professionals who are MRC volunteers would be subject to the liability laws of the state in which they offer emergency services, rather than to the laws of the state in which they are licensed and usually practice. CBO estimates that the provision would not change the quantity of health care services furnished or the cost of those services; thus, the provision would have no federal budgetary effect.

Military and Civilian Partnership for Trauma Readiness. S. 2852 would require ASPR, in consultation with the Secretary of Defense, to award grants to as many as 20 trauma centers to allow military trauma teams to care for severely injured patients and to help those teams prepare for PHEs and military operations. The bill would authorize an annual appropriation of almost $7 million over the 2019-2023 period. CBO estimates that implementing the provision would cost about $25 million over the 2019-2023 period.

Emergency Volunteer Registration. The Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP) is a national database that verifies health professionals' identification credentials so they can respond quickly in the event of a PHE. The bill would authorize an annual appropriation of $5 million for the ESAR-VHP over the 2019-2023 period. CBO estimates that implementing that provision would cost about $21 million over the 2019-2023 period.

Preparing for Significant Threats. S. 2852 would give ASPR additional authority to implement strategic initiatives by expanding programs that accelerate and support advanced research, development, and procurement of countermeasures for a variety of public health threats. Using information from HHS, CBO expects that implementing the provision would require, on average, 18 full-time-equivalent (FTE) employees in each year at an average annual rate of about $180,000 per FTE employee. CBO estimates that implementing the provision would cost about $16 million over the 2019-2023 period.

National Advisory Committees on Disasters. S. 2852 would establish the National Advisory Committee on Seniors and Disasters and reauthorize the National Advisory Committee on Children and Disasters. Those committees would advise public agencies regarding the needs of their targeted populations in relation to preparation for and response to hazards and emergencies. The committees would consist of up to 15 members drawn from federal agencies, state and local governments, and the medical professions. Using information from HHS, CBO expects that implementation would require about four FTE employees annually at an average annual rate of $180,000 per FTE employee. CBO estimates that implementing the provision would cost about $4 million over the 2019-2023 period.

Meeting on Genomic Engineering Technologies. Within one year of the bill's enactment, S. 2852 would require HHS to convene a meeting of experts and report to the Congress on the effects of genomic engineering technologies, such as gene editing, on national health security. Using information from HHS, CBO expects that implementing the provision would require the equivalent of about three FTE employees each year for three years at an average annual rate of about $180,000 per FTE employee. CBO estimates that implementing the provision would cost of about $2 million over the 2019-2023 period.

Other HHS Activities. The bill would require HHS to provide additional support to agencies to ensure coordination of the public health aspects of a federal response to PHEs. HHS also would be required to issue guidance and to report on public health emergency preparedness and response. Based on information from HHS, CBO estimates that those activities would cost about $4 million over the 2019-2023 period.

Spending Subject to Appropriation for the Department of Veterans Affairs

S. 2852 would authorize the annual appropriation of $155 million over the 2019-2023 period for emergency preparedness at medical centers operated by the Department of Veterans Affairs. Funding for such activities in 2019 was provided in advance appropriations; therefore, CBO estimates that no additional funding would be required for that year. Assuming appropriation of authorized amounts for years after 2019, CBO estimates that implementing the provision would cost $591 million over the 2020-2023 period.

Spending Subject to Appropriation for the Government Accountability Office

S. 2852 would require the Government Accountability Office to prepare seven reports related to federal preparedness and response activities. Based on the proposed scope of the reports and the cost of similar activities, CBO estimates that implementing the provision would cost $4 million over the 2019-2023 period.

Spending Subject to Appropriation for the Department of Justice

S. 2852 would add medical professionals who are part of the NDMS to the PSOB Program, which pays death benefits to designated beneficiaries when a public safety officer dies in the line of duty. The program also provides benefits to eligible officers who are permanently disabled because of a catastrophic injury sustained in the line of duty. Death benefits are paid from mandatory spending (discussed in the next section). Spending on disability benefits is subject to appropriation, and historically, spending on disability benefits has been significantly less than spending on death benefits.

CBO estimates that including the NDMS in the PSOB Program's disability benefits plan would cost less than $500,000 over the 10-year period.

Direct Spending

CBO estimates that the cost of section 301 of S. 2852, which would allow surviving beneficiaries of NDMS medical professionals to collect death benefits under the PSOB Program, would amount to about $2 million over the 2019-2028 period (less than $500,00 in any year). Using data from HHS and the Social Security Administration, CBO estimates that the probability of death in the line of duty among the 5,000 members of NDMS is less than 0.01 percent annually.

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 changes in outlays that are subject to those pay-as-you-go procedures are shown in the following table. Enacting the legislation would not affect revenues.

CBO ESTIMATE OF PAY-AS-YOU-GO EFFECTS FOR S. 2852, THE PANDEMIC AND ALL-HAZARDS PREPAREDNESS AND ADVANCING INNOVATON ACT OF 2018, AS REPORTED BY THE SENATE COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS ON JUNE 18, 2018

	By Fiscal Year, in Millions of Dollars												
	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2018-2023	2018-2028
NET CHANGE IN THE DEFICIT													
Statutory Pay-As-You-Go Effect	0	0	0	0	0	0	0	0	0	0	0	1	2

INCREASE IN LONG-TERM DIRECT SPENDING AND DEFICITS

CBO estimates that enacting S. 2852 would not increase net direct spending by more than $2.5 billion or on-budget deficits by more than $5 billion in any of the four consecutive 10-year periods beginning in 2029.

MANDATES

S. 2852 would impose intergovernmental and private-sector mandates as defined in UMRA. The bill would impose an intergovernmental mandate by preempting state laws that conflict with a new restriction on the venue in which people may pursue liability claims against certain medical personnel responding to PHEs. Although the preemption would limit the application of state laws, it would impose no duty on state, local, or tribal governments that would result in additional spending or a loss of revenues.

Similarly, the bill would impose a private-sector mandate by restricting the venue in which a liability claim may be pursued. The cost of the mandate would include the value of damages lost because of the venue restriction. Although CBO cannot predict how liability claims would be raised or adjudicated, the cost of the mandate is estimated to be small because an individual's right to pursue a claim and seek damages is not otherwise limited. Furthermore, current laws that limit liability claims against volunteers would reduce the number of applicable claims. CBO estimates that the cost of the mandate would fall below the private-sector threshold established in UMRA ($160 million in 2018, adjusted annually for inflation).

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