



CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

December 6, 2018

H.R. 6378 **Pandemic and All-Hazards Preparedness and Advancing Innovation** **Act of 2018**

As passed by the House of Representatives on September 25, 2018

SUMMARY

H.R. 6378 would 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 act would cost about \$11.9 billion over the 2019-2023 period, assuming appropriation of the authorized amounts. The Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019 (Public Law 115-245), included funding of \$3.1 billion in fiscal year 2019 for similar activities.

H.R. 6378 also would allow medical professionals in the National Disaster Medical System (NDMS) to participate in the Public Safety Officers' Benefits (PSOB) Program. CBO estimates that provision would increase direct spending by less than \$500,000 over the 2019-2028 period. Because the act would affect direct spending, pay-as-you-go procedures apply. Enacting H.R. 6378 would not affect revenues.

CBO estimates that enacting H.R. 6378 would not significantly increase net direct spending or on-budget deficits in any of the four consecutive 10-year periods beginning in 2029.

H.R. 6378 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 H.R. 6378 is shown in the following table. The costs of the legislation fall within budget functions 550 (health), 600 (income security), 750 (administration of justice), and 800 (general government).

	By Fiscal Year, in Millions of Dollars					2019- 2023
	2019 ^a	2020	2021	2022	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	10	685	685	685	685	2,750
Estimated Outlays	4	258	579	655	671	2,167
Strategic National Stockpile						
Authorization Level	0	610	610	610	610	2,440
Estimated Outlays	0	122	439	531	579	1,671
Mosquito Abatement						
Authorization Level	140	140	140	140	140	700
Estimated Outlays	52	118	134	137	139	580
Public Health Threats						
Authorization Level	0	162	162	162	162	647
Estimated Outlays	0	60	137	155	159	511
Vaccine Tracking and Distribution						
Authorization Level	31	31	31	31	31	154
Estimated Outlays	11	26	29	30	30	128
Combatting Antibiotic Resistance						
Estimated Authorization Level	0	1	1	1	1	5
Estimated Outlays	0	1	1	1	1	5
Loan Repayment Program						
Authorization Level	1	1	1	1	1	5
Estimated Outlays	*	1	1	1	1	4
Children's Preparedness Unit						
Estimated Authorization Level	*	*	*	*	*	2
Estimated Outlays	*	*	*	*	*	2

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	By Fiscal Year, in Millions of Dollars					2019- 2023
	2019 ^a	2020	2021	2022	2023	
INCREASES IN SPENDING SUBJECT TO APPROPRIATION						
Food and Drug Administration						
Provisions Relating to the FDA's Regulatory Authority						
Estimated Authorization Level	*	*	*	0	0	1
Estimated Outlays	*	*	*	0	0	1
Office of the Assistant Secretary for Preparedness and Response						
BARDA and Project BioShield Special Reserve Fund						
Authorization Level	6,415	612	612	612	612	8,862
Estimated Outlays	10	290	971	1,177	1,254	3,702
Hospital Preparedness						
Authorization Level	121	385	385	385	385	1,661
Estimated Outlays	24	141	300	350	368	1,183
Protection of National Security from Threats						
Authorization Level	0	250	250	250	250	1,000
Estimated Outlays	0	50	183	223	238	693
Preparing for Significant Threats						
Authorization Level	250	250	250	250	250	1,250
Estimated Outlays	50	183	223	238	243	935
National Disaster Medical System						
Authorization Level	0	57	57	57	57	230
Estimated Outlays	0	11	42	51	55	159
Military and Civilian Partnership for Trauma Readiness						
Authorization Level	15	15	15	15	15	75
Estimated Outlays	3	11	13	14	15	56
Medical Reserve Corps						
Authorization Level	5	11	11	11	11	50
Estimated Outlays	3	7	10	11	11	41
Emergency Volunteer Registration						
Authorization Level	5	5	5	5	5	25
Estimated Outlays	3	4	5	5	5	21

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	By Fiscal Year, in Millions of Dollars					2019-
	2019 ^a	2020	2021	2022	2023	2023
INCREASES IN SPENDING SUBJECT TO APPROPRIATION						
National Advisory Committees on Disasters						
Estimated Authorization Level	1	1	1	1	1	5
Estimated Outlays	1	1	1	1	1	5
Meeting on Genomic Engineering Technologies						
Estimated Authorization Level	1	1	1	*	0	2
Estimated Outlays	1	1	1	*	0	2
Other HHS Activities						
Estimated Authorization Level	2	2	1	1	1	7
Estimated Outlays	2	2	1	1	1	7
Government Accountability Office						
Estimated Authorization Level	2	1	1	*	0	5
Estimated Outlays	2	1	1	*	0	5
Department of Justice						
Estimated Authorization Level	*	*	*	0	0	*
Estimated Outlays	*	*	*	0	0	*
Total Changes						
Estimated Authorization Level	6,999	3,220	3,220	3,218	3,218	19,875
Estimated Outlays	166	1,289	3,071	3,581	3,771	11,878

INCREASES IN DIRECT SPENDING

Department of Justice						
Estimated Budget Authority	*	*	*	0	0	*
Estimated Outlays	*	*	*	0	0	*

Components may not sum to totals because of rounding.

- a. The Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019 included amounts for several of the provisions in this bill. Authorized amounts above those provided for 2019 in those acts are shown in this table.

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

BASIS OF ESTIMATE

For this estimate, CBO assumes that H.R. 6378 will be enacted early in 2019 and that the Congress will appropriate the authorized amounts. Estimated authorization levels for 2019 are for the authorized amounts in excess of the levels provided by Public Law 115-245. 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 H.R. 6378 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).

Centers for Disease Control and Prevention. H.R. 6378 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. The legislation 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 descriptions of partnerships with nursing homes, hospitals, and utility companies as part of their all-hazards PHE preparedness and response plans. H.R. 6378 would authorize the annual appropriation of \$685 million for the 2019-2023 period for CDC to administer those agreements; in fiscal year 2019, \$675 million has already been allocated for such activities. Over the 2019-2023 period, CBO estimates, implementing the provision would cost about \$2.2 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. H.R. 6378 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 act would authorize the continuation of the Strategic National Stockpile and an annual appropriation of about \$610 million over the 2019-2023 period; in fiscal year 2019, \$610 million has already been allocated for such activities. CBO estimates that implementing the provision would cost about \$1.7 billion over the 2019-2023 period.

Mosquito Abatement. H.R. 6378 would authorize funding for CDC to provide grants to state health departments to develop, implement, and improve laboratory and surveillance programs that address infectious diseases, including mosquito-borne diseases. The act

would authorize the appropriation of \$140 million annually over the 2019-2023 period for those activities. CBO estimates that implementing this provision would cost \$580 million over the 2019-2023 period.

Public Health Threats. H.R. 6378 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. H.R. 6378 also would authorize funding to maintain surveillance programs and networks to respond to infectious-disease outbreaks. The act would authorize the appropriation of \$162 million annually over the 2019-2023 period for those activities; in fiscal year 2019, \$172 million has already been allocated for such activities. CBO estimates that implementing this provision would cost \$511 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. H.R. 6378 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 implementing that provision would cost \$128 million over the 2019-2023 period.

Combating Antibiotic Resistance. Under current law, the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria and its activities were established by an Executive Order which expires on September 30, 2019. The Advisory Council is tasked to provide recommendations on effective use of antibiotics and combating antibiotic-resistant bacterial infections. H.R. 6378 would permanently authorize the Council and its activities. Based on information from HHS, operating expenses for 2017 were about \$1 million. Subject to the availability of funds, CBO estimates that permanently authorizing the Council would cost \$5 million over the 2020-2023 period.

Loan Repayment Program for Prevention Activities. H.R. 6378 would allow CDC to repay certain educational loan amounts for qualified health professionals who agree to conduct prevention activities. H.R. 6378 would authorize the appropriation of \$1 million annually over the 2019-2023 period for those activities. CBO estimates that implementing the provision would cost about \$4 million over the 2019-2023 period.

Children's Preparedness Unit. H.R. 6378 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. H.R. 6378 would change the way the FDA interacts with manufacturers of certain medical products for countering infectious-disease outbreaks or chemical, biological, radiological, or nuclear attacks. The act would require the FDA to:

- 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 about two additional employees would be needed to review and update guidance. Using information from the FDA, CBO estimates that those provisions would cost \$1 million over the 2019-2023 period.

Office of the Assistant Secretary for Preparedness and Response. H.R. 6378 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 act would authorize funding for advanced research, development, and procurement of certain biomedical products (funded by Project BioShield). In total, the act would authorize about \$7.7 billion for such activities in fiscal year 2019, of which about \$1.3 billion has already been allocated in fiscal year 2019. On net, the bill authorizes \$6.4 billion in excess of amounts already allocated in 2019. That amount includes:

- About \$612 million annually over the 2019-2023 period for The Biomedical Advanced Research and Development Authority office (funded by the Biodefense Medical Countermeasure Development Fund), which supports the advanced development of medical countermeasures to respond to bioterrorism and other PHEs. In fiscal year 2019, \$561.7 million has already been allocated for such activities.
- \$7.1 billion over the 2019-2028 period for the BioShield Special Reserve Fund. The reserve fund is used to procure medical countermeasures for the strategic national stockpile. In fiscal year 2019, \$735 million has already been appropriated for such activities. (CBO displays the net amount authorized for the 2019-2028 period, about \$6.4 billion, in fiscal year 2019.)

In total, CBO estimates that implementing section 504 would cost \$3.7 billion over the 2019-2023 period.

Hospital Preparedness. H.R. 6378 would authorize a grant program for states, localities, or health care facilities to enhance hospital capacity in the event of a PHE. The act would authorize the annual appropriation of \$385 million over the 2019-2023 period for ASPR to administer those cooperative agreements and grants; in fiscal year 2019, about \$265 million has already been allocated for such activities. Over the 2019-2023 period, CBO estimates implementing the provision would cost about \$1.2 billion.

Protection of National Security from Threats. The act would direct the Assistant Secretary for Preparedness and Response to implement strategic initiatives to address threats, including pandemic influenza, that pose a significant risk to public health and national security. The act would authorize the annual appropriation of \$250 million over the 2019-2023 period to implement those initiatives. In fiscal year 2019, \$260 million has already been allocated for activities to prepare for or respond to an influenza pandemic. Based on spending patterns for similar initiatives, CBO estimates that implementing the provision would cost \$693 million over the 2019-2023 period.

Preparing for Significant Threats. H.R. 6378 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. The act also would direct BARDA to establish and implement a program that supports research and development for products to address emerging infectious diseases. The act would authorize the annual appropriation of \$250 million over the 2019-2023 period to implement this provision. Based on spending patterns for similar initiatives, CBO estimates that implementing the provision would cost \$935 million over the 2019-2023 period.

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. H.R. 6378 would authorize annual funding of \$57 million over the 2019-2023 period—the same amount that has been allocated in 2019. Based on historical spending patterns, CBO estimates that implementing the provision would cost \$159 million over the 2019-2023 period, assuming appropriation of the authorized amounts.

Military and Civilian Partnership for Trauma Readiness. H.R. 6378 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 act would authorize an annual appropriation of \$15 million over the 2019-2023 period. CBO estimates that implementing the provision would cost about \$56 million over the 2019-2023 period.

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. H.R. 6378 would authorize annual funding of about \$11 million over the 2019-2023 period; in fiscal year 2019, \$6 million has already been allocated for that purpose. CBO estimates that implementing the provision would cost \$41 million over the 2019-2023 period.

H.R. 6378 also would clarify the applicability of liability laws for MRC volunteers. Under the act, 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.

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 act 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.

National Advisory Committees on Disasters. H.R. 6378 would establish the National Advisory Committee on Seniors and Disasters, and the National Advisory Committee on Individuals With Disabilities and Disasters. The act also would 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 members drawn from federal agencies, state and local governments, and medical professions, and members with expertise in disaster planning. Using information from HHS, CBO expects that implementation would require about six FTE employees annually at an average annual rate of \$180,000 per FTE employee. CBO estimates that implementing the provision would cost about \$5 million over the 2019-2023 period.

Meeting on Genomic Engineering Technologies. Within one year of the act's enactment, H.R. 6378 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 act 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 guidances and reports on public health

emergency preparedness, response, and other issues. Based on information from HHS, CBO estimates that those activities would cost about \$7 million over the 2019-2023 period.

Spending Subject to Appropriation for the Government Accountability Office

H.R. 6378 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 \$5 million over the 2019-2023 period.

Spending Subject to Appropriation for the Department of Justice

H.R. 6378 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. The act would sunset those provisions at the end of fiscal year 2021.

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 H.R. 6378, which would allow surviving beneficiaries of NDMS medical professionals to collect death benefits under the PSOB Program, would total less than \$500,000 in any year and over the 2019-2028 period. The act would sunset those benefits at the end of fiscal year 2021. 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 would not be significant, CBO estimates.

INCREASE IN LONG-TERM DIRECT SPENDING AND DEFICITS

CBO estimates that enacting H.R. 6378 would not significantly increase net direct spending or on-budget deficits in any of the four consecutive 10-year periods beginning in 2029.

MANDATES

H.R. 6378 would impose intergovernmental and private-sector mandates as defined in UMRA. The act 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 act 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).

PREVIOUS CBO ESTIMATE

On August 3, 2018, CBO transmitted a cost estimate for S. 2852, The 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. Differences in our estimate of direct spending reflect modifications to section 301, which would provide death benefits to beneficiaries of NDMS medical professionals. Specifically, H.R. 6378 would sunset the provision at the end of fiscal year 2021. Differences in our estimates of spending subject to appropriation reflect appropriation actions for 2019, new sections, and different specified amounts in the language.

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