

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

February 21, 2013

H.R. 307

Pandemic and All-Hazards Preparedness Reauthorization Act of 2013

As reported by the Senate Committee on Health, Education, Labor, and Pensions on February 14, 2013

SUMMARY

H.R. 307 would amend the Public Health Service Act and the United States Code to authorize funding for certain activities carried out by the Departments of Health and Human Services (HHS) and Veterans Affairs (VA) that would support the readiness of the public health system to address public health and medical emergencies.

Based on information provided by HHS and VA, CBO estimates that implementing the act would cost about \$11 billion over the 2014-2018 period, assuming the appropriation of the authorized amounts. The Consolidated Appropriations Act, 2012, included funding totaling about \$2 billion in fiscal year 2012 for activities similar to those that would be authorized by H.R. 307. CBO assumes that amounts appropriated through the Continuing Appropriations Resolution, 2013, for those activities are similar to 2012 levels.

H.R. 307 also would change the terms for Project Bioshield contracts, which would result in a change in direct spending. Assuming H.R. 307 is enacted this spring, it would decrease direct spending by \$58 million over the 2013-2018 period, but would result in no net change in direct spending over the 2013-2023 period. Because the legislation would affect direct spending, pay-as-you-go procedures apply. Enacting H.R. 307 would not affect revenues.

H.R. 307 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 impact of H.R. 307 is shown in the following table. The costs of this legislation fall within budget functions 550 (health) and 700 (veterans benefits and services).

| | By Fiscal Year, in Millions of Dollars | | | | | | | | | |
|---|--|-----------|--------------|-------------|---------|-------|--|--|--|--|
| | | Dy Fisca | ıı i ear, in | IVIIIIONS O | Dollars | 2014- | | | | |
| | 2014 | 2015 | 2016 | 2017 | 2018 | 2014- | | | | |
| CHANGES IN SPENDING | SUBJECT | TO APPR | ROPRIAT | ION | | | | | | |
| Department of He | ealth and H | uman Serv | vices | | | | | | | |
| Centers for Disease Control and Prevention | | | | | | | | | | |
| State and Local Public Health Security | | | | | | | | | | |
| Authorization Level | 642 | 642 | 642 | 642 | 642 | 3,210 | | | | |
| Estimated Outlays | 128 | 449 | 546 | 610 | 623 | 2,356 | | | | |
| Strategic National Stockpile | | | | | | | | | | |
| Authorization Level | 534 | 534 | 534 | 534 | 534 | 2,670 | | | | |
| Estimated Outlays | 107 | 384 | 464 | 507 | 518 | 1,980 | | | | |
| Public Health Threats | | | | | | | | | | |
| Authorization Level | 138 | 138 | 138 | 138 | 138 | 690 | | | | |
| Estimated Outlays | 48 | 104 | 125 | 131 | 134 | 542 | | | | |
| Vaccine Tracking and Distribution | | | | | | | | | | |
| Authorization Level | 31 | 31 | 31 | 31 | 31 | 155 | | | | |
| Estimated Outlays | 15 | 25 | 29 | 30 | 31 | 130 | | | | |
| Food and Drug Administration | | | | | | | | | | |
| Countermeasure Development and Review | | | | | | | | | | |
| Estimated Authorization Level | 20 | 30 | 30 | 30 | 30 | 140 | | | | |
| Estimated Outlays | 15 | 25 | 25 | 30 | 30 | 125 | | | | |
| Office of the Assistant Secretary for Health | | | | | | | | | | |
| Medical Reserve Corps | | | | | | | | | | |
| Authorization Level | 11 | 11 | 11 | 11 | 11 | 55 | | | | |
| Estimated Outlays | 5 | 10 | 10 | 10 | 10 | 45 | | | | |
| Office of the Assistant Secretary for | | | | | | | | | | |
| Preparedness and Response | | | | | | | | | | |
| Procurement of Countermeasures | | | | | | | | | | |
| Authorization Level | 2,800 | 0 | 0 | 0 | 0 | 2,800 | | | | |
| Estimated Outlays | 420 | 924 | 364 | 224 | 168 | 2,100 | | | | |

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Continued

| National Committee on Children and Disasters Estimated Authorization Level 1 | 5 415 5 382 5 375 2 318 3 53 | 415 407 375 356 | 2018 415 415 375 363 53 | 2014- 2018 2,075 1,602 1,875 1,374 |
|--|--|--------------------------|--|---|
| Countermeasures Authorization Level 415 415 Estimated Outlays 83 315 Hospital Preparedness Authorization Level 375 375 Estimated Outlays 75 265 National Disaster Medical System Authorization Level 53 55 Estimated Outlays 11 46 Emergency Volunteer Registration Authorization Level 5 5 5 Estimated Outlays 3 4 National Committee on Children and Disasters Estimated Authorization Level 1 | 5 382 5 375 2 318 3 53 | 407 375 356 53 | 375 363 53 | 1,602 1,875 1,374 |
| Authorization Level 415 415 Estimated Outlays 83 315 Hospital Preparedness Authorization Level 375 375 Estimated Outlays 75 262 National Disaster Medical System Authorization Level 53 53 Estimated Outlays 11 46 Emergency Volunteer Registration Authorization Level 5 5 5 Estimated Outlays 3 4 National Committee on Children and Disasters Estimated Authorization Level 1 | 5 382 5 375 2 318 3 53 | 407 375 356 53 | 375 363 53 | 1,602 1,875 1,374 |
| Estimated Outlays Hospital Preparedness Authorization Level Estimated Outlays National Disaster Medical System Authorization Level Estimated Outlays Emergency Volunteer Registration Authorization Level Estimated Outlays National Committee on Children and Disasters Estimated Authorization Level 1 | 5 382 5 375 2 318 3 53 | 407 375 356 53 | 375 363 53 | 1,602 1,875 1,374 |
| Hospital Preparedness Authorization Level 375 375 Estimated Outlays 75 262 National Disaster Medical System Authorization Level 53 55 Estimated Outlays 11 40 Emergency Volunteer Registration Authorization Level 5 5 5 Estimated Outlays 3 4 National Committee on Children and Disasters Estimated Authorization Level 1 | 5 375 2 318 3 53 | 375 356 53 | 375 363 53 | 1,875 1,374 |
| Authorization Level 375 375 Estimated Outlays 75 262 National Disaster Medical System Authorization Level 53 55 Estimated Outlays 11 40 Emergency Volunteer Registration Authorization Level 5 3 45 Estimated Outlays 3 4 National Committee on Children and Disasters Estimated Authorization Level 1 | 3183 53 | 356 53 | 363 53 | 1,374 |
| Authorization Level 375 375 Estimated Outlays 75 262 National Disaster Medical System Authorization Level 53 55 Estimated Outlays 11 40 Emergency Volunteer Registration Authorization Level 5 3 45 Estimated Outlays 3 4 National Committee on Children and Disasters Estimated Authorization Level 1 | 3183 53 | 356 53 | 363 53 | 1,374 |
| National Disaster Medical System Authorization Level 53 53 Estimated Outlays 11 40 Emergency Volunteer Registration Authorization Level 5 3 Estimated Outlays 3 4 National Committee on Children and Disasters Estimated Authorization Level 1 | 3 53 | 53 | 53 | 1,374 |
| Authorization Level 53 53 Estimated Outlays 11 40 Emergency Volunteer Registration Authorization Level 5 5 Estimated Outlays 3 4 National Committee on Children and Disasters Estimated Authorization Level 1 | | | | 265 |
| Authorization Level 53 53 Estimated Outlays 11 40 Emergency Volunteer Registration Authorization Level 5 5 Estimated Outlays 3 4 National Committee on Children and Disasters Estimated Authorization Level 1 | | | | 265 |
| Estimated Outlays Emergency Volunteer Registration Authorization Level Estimated Outlays National Committee on Children and Disasters Estimated Authorization Level 1 | | | | _00 |
| Authorization Level 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 | | | 55 | 204 |
| Authorization Level 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 | | | | |
| Estimated Outlays 3 National Committee on Children and Disasters Estimated Authorization Level 1 | 5 5 | 5 | 5 | 25 |
| Estimated Authorization Level 1 | 1 5 | 5 | 5 | 22 |
| Estimated Authorization Level 1 | | | | |
| | 1 | 1 | 1 | 5 |
| | 1 | 1 | 1 | 5 |
| Department of Veterans Affai | irs | | | |
| Veterans Affairs Medical Centers | | | | |
| Authorization Level 155 155 | 5 155 | 155 | 155 | 775 |
| Estimated Outlays 140 140 | 154 | 154 | 155 | 743 |
| Total Changes in Spending Subject to A | ppropriatio | n | | |
| Estimated Authorization Level 5,180 2,390 | 2,390 | 2,390 | 2,390 | 14,740 |
| Estimated Outlays 1,051 2,683 | | 2,517 | 2,506 | 11,228 |
| CHANGES IN DIRECT SPEND | ING ^a | | | |
| Project Bioshield | | | | |
| Estimated Budget Authority 0 -19 | 1.2 | -13 | -13 | -58 |
| Estimated Outlays 0 -19 | -13 | -13 | -13 | -58 |

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

a. CBO estimates that there would be no net change in direct spending under H.R. 307 over the 2014-2023 period.

BASIS OF ESTIMATE

For this estimate, CBO assumes that H.R. 307 will be enacted in the spring of 2013, that Congress will appropriate the authorized amounts, and that spending will follow historical patterns for existing and similar programs.

H.R. 307 contains provisions that would authorize funding for activities administered by HHS and the VA to improve the coordination of preparedness activities and to increase medical system capacity in the event of a public health emergency.

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

The majority of HHS activities would be carried out by the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the Office of the Assistant Secretary of Health, and the Office of the Assistant Secretary for Preparedness and Response.

Centers for Disease Control and Prevention. H.R. 307 would authorize funding over the 2014-2018 period for activities related to preparing for a public health emergency at levels similar to the appropriations for recent years.

State and Local Public Health Security. H.R. 307 would allow CDC to continue to administer cooperative agreements with state and local governments to help prepare for public health emergencies. H.R. 307 would require entities receiving funding through those cooperative agreements to include planning for pandemic influenza as part of their all-hazards public health emergency preparedness and response plan. The act would authorize the appropriation of \$642 million for each of fiscal years 2014 through 2018 for CDC to administer those cooperative agreements. CBO estimates about \$660 million was allocated to those activities for fiscal year 2012. Over the 2014-2018 period, CBO estimates that implementing this provision would cost about \$2.4 billion, assuming appropriation of the authorized amounts.

Strategic National Stockpile. The Strategic National Stockpile is a national repository of pharmaceuticals, medical supplies, and other equipment for the rapid delivery of medical countermeasures in response to a catastrophic health event. H.R. 307 would authorize the continuation of the Strategic National Stockpile and would authorize the appropriation of about \$534 million a year for fiscal years 2014 through 2018. The Consolidated Appropriations Act, 2012, provided \$509 million for the Strategic National Stockpile for 2012. Based on historical spending patterns, CBO estimates that implementing the provision would cost about \$2.0 billion over the 2014-2018 period, assuming appropriation of the authorized amounts.

Public Health Threats. H.R. 307 would authorize funding for the Secretary to continue to expand, enhance, and improve the capacity for CDC to respond effectively to bioterrorism and other public health emergencies. H.R. 307 would also authorize funding to establish and maintain surveillance programs and networks that enhance coordinated efforts in response to outbreaks of infectious diseases and public health emergencies. The act would authorize the appropriation of \$138 million a year for fiscal years 2014 through 2018. CBO estimates that about \$135 million was authorized for such activities for fiscal year 2012. Based on historical spending patterns, CBO estimates that implementing this provision would cost about \$540 million over the 2014-2018 period, assuming appropriation of the authorized amounts.

Vaccine Tracking and Distribution. CDC collaborates with officials in state, local, and tribal governments as well as private entities, such as vaccine manufacturers, wholesalers, and distributors, to track the distribution of vaccines for pandemic flu and to promote effective distribution of vaccines for the seasonal flu. H.R. 307 would authorize the Secretary to continue those activities and would authorize the appropriation of \$31 million for each fiscal year over the 2014-2018 period. CBO estimates that \$31 million was allocated to such activities in 2012. Assuming appropriation of authorized amounts, CBO estimates that implementing that provision would cost about \$130 million over the 2014-2018 period, based on historical spending patterns.

Food and Drug Administration. H.R. 307 would expand the role of FDA personnel in supporting the development, stockpiling, approval, and licensure of medical countermeasures (such as diagnostic tests, drugs, vaccines, and other treatments for response to chemical, biological, radiological, and nuclear threats) as well as medical responses to pandemics and epidemics. The act would require FDA to provide technical assistance and feedback to manufacturers of those products. H.R. 307 also would amend the Best Pharmaceuticals for Children Act (Public Law 107-109) by expanding the duties of the Pediatric Advisory Committee to advise the FDA Commissioner on the development of countermeasures for pediatric populations. Under current law, FDA engages in certain activities relating to medical countermeasures. The act would authorize and expand on such activities. CBO estimates such activities would require funding of \$140 million over the 2014-2018 period. Assuming the appropriation of those amounts, CBO estimates those provisions would cost \$125 million over that period.

Office of the Assistant Secretary of Health. The Medical Reserve Corps (MRC) is a community-based program that coordinates medical and public health volunteers to support public health activities, including emergency preparedness and response efforts. H.R. 307 would authorize funding for the MRC, which is operated by the HHS Office of the Surgeon General. The act would authorize the appropriation of \$11 million a year for fiscal years 2014 through 2018. CBO estimates that about \$11 million was allocated to the MRC for fiscal year 2012. Based on historical spending patterns for similar programs,

CBO estimates that implementing that provision would cost \$45 million over the 2014-2018 period, assuming appropriation of authorized amounts.

Office of the Assistant Secretary for Preparedness and Response. H.R. 307 would authorize funding for the following activities related to medical system capacity and countermeasure development and procurement.

Procurement of Countermeasures. Project Bioshield, established for the procurement of biodefense countermeasures, was funded by an appropriation of almost \$5.6 billion for fiscal years 2004 through 2013. H.R. 307 would authorize an additional appropriation to the fund of \$2.8 billion for the 2014-2018 period for continuing those activities. H.R. 307 would allow up to 50 percent of the \$2.8 billion to be used for advance research and development of countermeasures. Based on historical spending patterns, CBO estimates that implementing the provision would cost \$2.1 billion over the 2014-2018 period, assuming appropriation of the authorized amount, with additional outlays occurring after 2018.

Advanced Research and Development of Countermeasures. The Biomedical Advance Research and Development Authority (BARDA) office supports the advance development of medical countermeasures to respond to bioterrorism and other public health emergencies. BARDA is funded by the Biodefense Medical Countermeasure Development Fund. H.R. 307 would authorize the appropriation of \$415 million for the fund in each of fiscal years 2014 through 2018. The Consolidated Appropriations Act, 2012, appropriated about \$415 million to the fund for fiscal year 2012. Based on historical spending patterns, CBO estimates that implementing this provision would cost \$1.6 billion over the 2014-2018 period, assuming appropriation of the authorized amounts for the next five years.

Hospital Preparedness. H.R. 307 would authorize a grant program that provides funding to entities such as states, localities, or health care facilities to enhance hospital capacity to handle a surge of patients in the event of a public health emergency. The act would authorize the appropriation of \$375 million annually for fiscal years 2014 through 2018. CBO estimates that about \$375 million was allocated to such activities for fiscal year 2012. Assuming appropriation of authorized amounts, CBO estimates that implementing that provision would cost \$1.4 billion over the 2014-2018 period, based on historical spending patterns.

National Disaster Medical System (NDMS). H.R. 307 would authorize funding for the NDMS, which is a partnership between HHS, VA, and the Departments of Defense and Homeland Security. It provides for medical assistance to states and localities when responding to a large-scale public health emergency. The act would authorize funding of \$53 million in each fiscal year over the 2014-2018 period. CBO estimates that the NDMS received approximately \$52 million for fiscal year 2012. Based on historical spending

patterns, CBO estimates that implementing the provision would cost \$204 million over the 2014-2018 period, assuming appropriation of the authorized amounts.

Emergency Volunteer Registration. The Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP) is a national database that links state credential verification systems in order to streamline the pre-registration of volunteer health professionals who are willing to respond in the event of a public health emergency. The act would authorize the appropriation of \$5 million for the ESAR-VHP in each fiscal year over the 2014-2018 period. CBO estimates that the ESAR-VHP received approximately \$5 million for fiscal year 2012 for such activities. Assuming appropriation of authorized amounts, CBO estimates that implementing that provision would cost about \$22 million over the 2014-2018 period.

National Advisory Committee on Children and Disasters. H.R. 307 would establish a National Advisory Committee on Children and Disasters. This committee would provide advice regarding the needs of children in relation to the preparation for and response to hazards and emergencies. The committee would comprise as many as 15 people, most drawn from federal agencies. The remainder of the committee's members would be drawn from other occupations such as state and local governments or the medical profession. Assuming appropriation of authorized amounts, CBO estimates that implementing this provision would cost about \$5 million over the 2014-2018 period.

Spending Subject to Appropriation for the Department of Veterans Affairs

H.R. 307 would authorize the appropriation of \$155 million for each year over the 2014-2018 period for emergency preparedness activities at medical centers operated by VA. The VA received \$156 million for these activities in fiscal year 2013. Assuming appropriation of authorized amounts for years after 2013, CBO estimates that implementing this provision would cost \$743 million over the 2014-2018 period.

Direct Spending

Project Bioshield, established for the procurement of biodefense countermeasures, was funded by an appropriation of approximately \$5.6 billion for fiscal years 2004 through 2013. H.R. 307 would change the contract terms for Project Bioshield procurements from a maximum of eight years to a maximum of 10 years. As the length of new contracts for biodefense countermeasures funded through the original appropriation are extended, there would be a decrease in direct spending of \$58 million for fiscal years 2013 through 2018 and no net change in direct spending over the 2013-2023 period, assuming H.R. 307 is enacted in the spring of 2013. CBO assumes the remaining funds from the original \$5.6 billion appropriation will continue to be obligated through the end of the fiscal year.

Thus, later enactment would mean that there is a decrease in the funds available for contracts under the new terms.

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. (Enacting the legislation would not affect revenues.)

CBO Estimate of Pay-As-You-Go Effects for H.R. 307, as reported by the Senate Committee on Health, Education, Labor, and Pensions on February 14, 2013

| | By Fiscal Year, in Millions of Dollars | | | | | | | | | | | | |
|-----------------------------------|--|-------|--------|-------|-------|----------|------|-------|------|------|------|---------------|---------------|
| | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 | 2021 | 2022 | 2023 | 2013- 2018 | 2013- 2023 |
| | NET | INCRI | EASE (| OR DE | CREAS | E (-) IN | THE | DEFIC | IT | | | | |
| Statutory Pay-As-You-Go Impact | 0 | 0 | -19 | -13 | -13 | -13 | 6 | 6 | 6 | 20 | 20 | -58 | 0 |

INTERGOVERNMENTAL AND PRIVATE-SECTOR IMPACT

H.R. 307 contains no intergovernmental or private-sector mandates as defined in UMRA. Programs and activities authorized in the act would benefit state, local, and tribal agencies that prepare for, and respond to, public health emergencies.

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