S 1855

Pandemic and All-Hazards Preparedness Act Reauthorization of 2011

Congress: 112 (2011–2013, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Nov 10, 2011
Current Status: Held at the desk.
Latest Action: Held at the desk. (Mar 8, 2012)
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Sponsor

Name: Sen. Burr, Richard [R-NC]
Party: Republican • **State:** NC • **Chamber:** Senate

Cosponsors (11 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Alexander, Lamar [R-TN]	R · TN		Nov 10, 2011
Sen. Casey, Robert P., Jr. [D-PA]	D · PA		Nov 10, 2011
Sen. Collins, Susan M. [R-ME]	R · ME		Nov 10, 2011
Sen. Enzi, Michael B. [R-WY]	R · WY		Nov 10, 2011
Sen. Hagan, Kay R. [D-NC]	D · NC		Nov 10, 2011
Sen. Harkin, Tom [D-IA]	D · IA		Nov 10, 2011
Sen. Lieberman, Joseph I. [ID-CT]	ID · CT		Nov 10, 2011
Sen. Mikulski, Barbara A. [D-MD]	D · MD		Nov 10, 2011
Sen. Roberts, Pat [R-KS]	R · KS		Nov 10, 2011
Sen. Bennet, Michael F. [D-CO]	D · CO		Dec 5, 2011
Sen. Blumenthal, Richard [D-CT]	D · CT		Mar 13, 2012

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Reported By	Dec 16, 2011
Homeland Security Committee	House	Bills of Interest - Exchange of Letters	Apr 3, 2012

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
112 S 3715	Related bill	**Dec 31, 2012:** Held at the desk.
112 HR 2405	Related bill	**Dec 7, 2011:** Received in the Senate and Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

Summary (as of Mar 7, 2012)

Pandemic and All-Hazards Preparedness Act Reauthorization of 2011 - **Title I: Strengthening National Preparedness and Response for Public Health Emergencies** - (Sec. 101) Amends the Public Health Service Act (PHSA) to require the Secretary of Health and Human Services (HHS) to submit the National Health Security Strategy to the relevant congressional committees in 2014. Requires the Strategy to include: (1) provisions for increasing the preparedness, response capabilities, and surge capacity of dental health facilities and critical care service systems; (2) plans for optimizing a coordinated and flexible approach to the medical surge capacity of hospitals, other health care facilities, and trauma care and emergency medical systems; (3) provisions taking into account the unique needs of individuals with disabilities in a public health emergency; and (4) strategic initiatives to advance countermeasures to diagnose, mitigate, prevent, or treat harm from any biological agent or toxin or any chemical, radiological, or nuclear agent or agents, whether naturally occurring, unintentional, or deliberate.

Requires the Secretary to: (1) monitor emerging issues and concerns as they relate to medical and public health preparedness and response for at-risk individuals in the event of a public health emergency; (2) disseminate and update novel and best practices of outreach to and care of at-risk individuals before, during, and following public health emergencies in as timely a manner as is practicable, including from the time a public health threat is identified; and (3) ensure that public health and medical information distributed by HHS during a public health emergency is delivered in a manner that takes into account the range of communication needs of the intended recipients, including at-risk individuals.

(Sec. 102) Requires the Assistant Secretary for Preparedness and Response to provide integrated policy coordination and strategic direction with respect to all matters related to federal public health and medical preparedness and execution and deployment of the federal response for public health emergencies and incidents covered by the National Response Plan before, during, and following public health emergencies.

Give the Assistant Secretary direct authority over and responsibility for: (1) the Medical Reserve Corps, (2) the Emergency System for Advance Registration of Volunteer Health Professionals, and (3) administering grants and related authorities related to trauma care.

Authorizes the Assistant Secretary to exercise the responsibilities and authorities of the Secretary with respect to the coordination of the Public Health Emergency Preparedness Cooperative Agreement Program.

Requires the Assistant Secretary to: (1) align and coordinate medical and public health grants and cooperative agreements as applicable to preparedness and response activities authorized under PHSA; and (2) carry out drills and operational exercises to identify, inform, and address gaps in and policies related to all-hazards medical and public health preparedness.

Requires the Secretary, acting through the Assistant Secretary, to: (1) conduct periodic meetings with the Assistant to the President for National Security Affairs to provide an update on, and to discuss, medical and public health preparedness and response activities; (2) develop a coordinated strategy and accompanying implementation plan for medical countermeasures to address chemical, biological, radiological, and nuclear threats. Requires the Government Accountability Office (GAO) to conduct an independent evaluation on the strategy and implementation plan.

Requires the Secretary to: (1) develop and annually update a five-year budget plan based on medical countermeasures and priorities; (2) report to the relevant congressional committees regarding coordination with the Department of Defense (DOD) regarding countermeasure activities to address chemical, biological, radiological, and nuclear threats; and (3)

ensure that information and items that could compromise national security are not disclosed.

(Sec. 103) Requires the Secretary to establish the National Advisory Committee on Children and Disasters. Terminates the Committee after five years.

(Sec. 104) Revises and reauthorizes through FY2016 the National Disaster Medical System. Requires the Secretary to take steps to ensure that a range of public health and medical capabilities are represented in the System, which take into account the needs of at-risk individuals, in the event of a public health emergency. Authorizes the Secretary to determine and pay claims for reimbursement for services provided through the System directly or through contracts that provide for payment in advance or by way of reimbursement.

(Sec. 105) Reauthorizes through FY2016 a program for public health emergency readiness of the Department of Veterans Affairs (VA) medical centers.

Title II: Optimizing State and Local All-Hazards Preparedness and Response - (Sec. 201)
Revises and reauthorizes for FY2012-FY2016 a program of cooperative agreements to improve state and local public health security. Revises requirements for the All-Hazards Public Health Emergency Preparedness and Response Plan.

Requires the Secretary to: (1) periodically update criteria for an effective state plan for responding to pandemic influenza, and (2) require the integration of such criteria into the benchmarks and standards that measure levels of preparedness.

Provides that amounts provided to an eligible entity under a cooperative agreement to achieve preparedness goals for a fiscal year that are unobligated at the end of such year shall remain available to such entity for the next fiscal year. Makes continued availability of such funds contingent upon achieving benchmarks and submitting a pandemic influenza plan. Eliminates provisions limiting the amount of an award that an entity may carry over to the succeeding fiscal year.

Reauthorizes appropriations for FY2012-FY2016 for the influenza vaccine tracking and distribution program in an influenza pandemic.

Requires GAO to conduct an evaluation of federal programs at HHS that support medical and public health preparedness and response programs at the state and local levels.

(Sec. 202) Includes dental entities among entities that may carry out education and training activities to improve responses to public health emergencies.

Reauthorizes the Emergency System for Advance Registration of Health Professions Volunteers (ESAR-VHP) for FY2012-FY2016, which provides a single national interoperable network of systems to verify the credentials and licenses of health care professionals who volunteer to provide health services during a public health emergency.

Reauthorizes through FY2016 the Medical Reserve Corps to provide for an adequate supply of volunteers in the case of a public health emergency. Revises such provisions to require the training exercises to incorporate the needs of at-risk individuals in the event of a public health emergency.

Revises and reauthorizes appropriations for FY2012-FY2016 for a program of grants and cooperative agreements to improve surge capacity and enhance community and hospital preparedness. Makes community health centers eligible for such a program. Provides that amounts provided to an eligible entity under such program for a fiscal year that are unobligated at the end of such year shall remain available to such entity for the next fiscal year for the purposes for which such funds were provided. Makes continued availability of such funds contingent upon achieving benchmarks and

submitting a pandemic influenza plan.

(Sec. 203) Reauthorizes appropriations for FY2012-FY2016 for a program to improve public health alert communications and surveillance and public health situational awareness capability. Includes poison control centers in the integrated system of public health alert communications and surveillance networks.

Requires the Secretary to submit to the appropriate congressional committees a coordinated strategy and an accompanying implementation plan that identifies and demonstrates the measurable steps the Secretary will carry out to: (1) develop, implement, and evaluate the public health situation awareness systems; and (2) modernize and enhance biosurveillance activities. Requires the network to include data from community health centers and health centers.

Requires the National Biodefense Science Board to provide expert advice and guidance regarding the measurable steps the Secretary should take to modernize and enhance biosurveillance activities pursuant to the efforts of HHS to ensure comprehensive, real-time all-hazards biosurveillance capabilities.

Title III: Enhancing Medical Countermeasure Review - (Sec. 301) Amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to revise provisions governing special protocol assessments to include agreements on the design and size of animal and any associated clinical trials which, in combination, are intended to form the primary basis of an effectiveness claim for a countermeasure or epidemic or pandemic product when human efficacy studies are not ethical or feasible.

(Sec. 302) Revises provisions permitting the Secretary to authorize the use of unapproved medical products or the unapproved use of an approved product, including to: (1) allow the Secretary to base the determination on a threat (rather than a specific threat as under current law); (2) allow the Secretary to base the determination on a significant potential for a public health emergency; (3) allow the Secretary to base the determination on the identification of a material threat sufficient to affect national security or the health and security of U.S. citizens abroad; (4) eliminate the one-year expiration date; and (5) allow a person to revise the label to reflect the new expiration date.

Authorizes the Secretary to extend the expiration date of eligible medical countermeasures if the Secretary determines: (1) that the extension will help protect public health; (2) the extension is supported by scientific evaluation that is conducted or accepted by the Secretary; (3) what changes to the product labeling, if any, are required or permitted; and (4) that any other conditions that the Secretary deems appropriate have been met.

Authorizes the Secretary to permit deviations from good manufacturing practice requirements when the circumstances of a domestic, military, or public health emergency or material threat so warrant.

Authorizes the Secretary to waive requirements for a risk evaluation and mitigation strategy for domestic, military, and public health emergencies (currently, such waiver authority applies only to public health emergencies) and for the identification of a material threat sufficient to affect national security or the health and security of U.S. citizens abroad.

Permits a government entity to introduce into interstate commerce a product intended for emergency use if that product is intended to be held and not used, and is held and not used, unless and until it is: (1) approved, cleared, or licensed; (2) authorized for investigational use; or (3) authorized for emergency use.

Requires the Secretary to: (1) ensure the appropriate involvement of FDA personnel in interagency activities related to countermeasure advanced research and development, (2) ensure the appropriate involvement and consultation of FDA personnel in flexible manufacturing activities, (3) promote countermeasure expertise within the FDA, and (4) maintain teams composed of FDA personnel with expertise on countermeasures.

Requires the Secretary to establish a procedure by which a sponsor or applicant that is developing a countermeasure for which human efficacy studies are not ethical or practicable, and that has an approved investigational new drug application or investigation device exemption, may request and receive: (1) a meeting to discuss proposed animal model development activities, and (2) a meeting prior to initiating pivotal animal studies. Requires such meetings to include discussion of animal models for pediatric populations, as appropriate.

Requires the Secretary to take into account the material threat posed by the chemical, biological, radiological, or nuclear agent for which the countermeasure under review is intended when evaluating a countermeasure for approval, licensure, or clearance.

Directs that, when practicable and appropriate, teams of FDA personnel reviewing applications or submissions shall include a reviewer with sufficient training or experience with countermeasures pursuant to established protocols.

Requires the Secretary to establish a formal process for obtaining scientific feedback and interactions regarding the development and regulatory review of eligible countermeasures by facilitating the development of written regulatory management plans. Allows prioritization of countermeasures to receive regulatory management plans if the Commissioner of Food and Drugs determines that resources are not available to establish regulatory management plans for all eligible countermeasures.

Directs the Secretary to submit to the specified congressional committees a report detailing the countermeasure development and review activities of the FDA.

Requires the Secretary to solicit input from the Assistant Secretary for Preparedness and Response and the Director of the Biomedical Advanced Research and Development Authority (BARDA) regarding pediatric studies for medical countermeasures.

Requires the Secretary to notify the Assistant Secretary and the Director of BARDA of all pediatric studies in the written request for a pediatric study issued by the Commissioner of Food and Drugs.

Title IV: Accelerating Medical Countermeasure Advanced Research and Development - (Sec. 401) Reauthorizes appropriations for FY2014-FY2018 for the Special Reserve Fund. Requires the Secretary to report to the appropriate congressional committees if the amount in such Fund falls below a specified threshold.

Extends from eight years to ten years: (1) the time during which a security countermeasure should qualify for approval or licensing for inclusion in Project Bioshield, and (2) the duration of a procurement contract for a security countermeasure. Requires a contract to procure security countermeasures to include a clear statement of defined government purpose limited to uses related to a security countermeasure.

Authorizes the Secretary to enter into contracts and other agreements that are in the best interest of the government in meeting identified security countermeasure needs, including reimbursement of the cost of advanced research and development as a reasonable, allowable, and allocable direct cost of the contract involved.

Revises provisions governing BARDA. Expands the program authorizing the Secretary to support innovation to include promotion of dose sparing technologies, efficacy increasing technologies, and platform technologies.

Authorizes the Secretary, acting through the Director of BARDA, to enter into an agreement with an independent non-profit entity to support innovation related to medical countermeasures. Terminates such authority on October 1, 2016.

Requires the Secretary to provide a clear statement of defined government purpose related to BARDA activities for the awarding of contracts, grants, and cooperative agreements for a qualified countermeasure or qualified pandemic or epidemic product.

Revises and reauthorizes for FY2012-FY2016 the Biodefense Medical Countermeasure Development Fund used to support BARDA to accelerate countermeasure and product advanced research and development.

Extends the Freedom of Information Act (FOIA) exemption for specific technical data or scientific information that is created or obtained during countermeasure and product advanced research and development carried out under PHSA that reveals significant and not otherwise known vulnerabilities of existing medical or public health defenses against biological, chemical, nuclear, or radiological threats.

Extends the antitrust exemption to permit meetings and consultations to discuss the development of security countermeasures, qualified countermeasures, or qualified pandemic or epidemic products.

Requires GAO to report on activities carried out to facilitate flexible manufacturing capacity.

Includes within the definition of a qualified countermeasure and a qualified pandemic or epidemic product a product or technology intended to enhance the use or effect of a drug, biological product, or device that is a medical countermeasure.

(Sec. 403) Reauthorizes the Strategic National Stockpile through FY2016. Requires the Secretary to submit to Congress the annual review of the contents of the Stockpile and to identify and address the potential depletion of, and ensure appropriate replenishment of, medical countermeasures.

Directs the Secretary to submit to the appropriate congressional committees a report on the stockpiling of potassium iodide.

(Sec. 404) Revises membership requirements for the National Biodefense Science Board. Requires the Board to provide any recommendation, finding, or report provided to the Secretary to the appropriate congressional committees.

Actions Timeline

- **Mar 8, 2012:** Message on Senate action sent to the House.
- **Mar 8, 2012:** Received in the House.
- **Mar 8, 2012:** Held at the desk.
- **Mar 7, 2012:** Measure laid before Senate by unanimous consent. (consideration: CR S1476-1493)
- **Mar 7, 2012:** The committee substitute as amended agreed to by Unanimous Consent. (text: CR S1476-1484)
- **Mar 7, 2012:** Passed/agreed to in Senate: Passed Senate with an amendment by Unanimous Consent.(text: CR S1484-1493)
- **Mar 7, 2012:** Passed Senate with an amendment by Unanimous Consent. (text: CR S1484-1493)
- **Dec 16, 2011:** Committee on Health, Education, Labor, and Pensions. Reported by Senator Harkin with an amendment in the nature of a substitute. Without written report.
- **Dec 16, 2011:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 263.
- **Dec 14, 2011:** Committee on Health, Education, Labor, and Pensions. Ordered to be reported with an amendment in the nature of a substitute favorably.
- **Nov 10, 2011:** Introduced in Senate
- **Nov 10, 2011:** Sponsor introductory remarks on measure. (CR S7382-7384)
- **Nov 10, 2011:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.