HR 2405

Pandemic and All-Hazards Preparedness Reauthorization Act of 2011

Congress: 112 (2011–2013, Ended)
Chamber: House
Policy Area: Health
Introduced: Jun 28, 2011
Current Status: Received in the Senate and Read twice and referred to the Committee on Health, Education, Labor, and
Latest Action: Received in the Senate and Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (Dec 7, 2011)
Official Text: https://www.congress.gov/bill/112th-congress/house-bill/2405

Sponsor

Name: Rep. Rogers, Mike J. [R-MI-8]
Party: Republican • **State:** MI • **Chamber:** House

Cosponsors (4 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Green, Gene [D-TX-29]	D · TX		Jun 28, 2011
Rep. Myrick, Sue Wilkins [R-NC-9]	R · NC		Jun 28, 2011
Rep. Burgess, Michael C. [R-TX-26]	R · TX		Jul 6, 2011
Rep. Eshoo, Anna G. [D-CA-14]	D · CA		Sep 7, 2011

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Jul 6, 2011
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Dec 7, 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 1855	Related bill	**Mar 8, 2012:** Held at the desk.
112 S 1814	Related bill	**Nov 7, 2011:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

Summary (as of Dec 6, 2011)

Pandemic and All-Hazards Preparedness Reauthorization Act of 2011 - (Sec. 2) Amends the Public Health Service Act (PHSA) to reauthorize appropriations for FY2012-FY2016 for the influenza vaccine tracking and distribution program in an influenza pandemic.

Revises and reauthorizes appropriations for FY2012-FY2016 for a program of cooperative agreements to improve state and local public health security. Requires eligible entities to include in their application to the Secretary of Health and Human Services (HHS) a description of any activities that such entity will use to analyze real-time clinical specimens for pathogens of public health or bioterrorism significance, including any utilization of poison control centers.

Eliminates the authority for pilot demonstration projects to purchase and implement the use of advanced diagnostic medical equipment to analyze real-time clinical specimens for pathogens of public health or bioterrorism significance.

Revises and reauthorizes appropriations for FY2012-FY2016 for a grant program to improve hospital surge capacity and enhance community and hospital preparedness for public health emergencies. Expands the purpose of the program to address the needs of pediatric and other at-risk populations. Requires the Secretary to implement metrics to ensure the entities receiving awards under the program are meeting, to the extent practicable, the goals of the National Health Security Strategy.

Reauthorizes appropriations for FY2012-FY2016 for a program to improve public health alert communications and surveillance and public health situational awareness capability.

Includes dental entities among entities that may carry out education and training activities to improve responses to public health emergencies. Authorize the inclusion of dental health facilities in the National Health Security Strategy for purposes of preparedness during public health emergencies.

Reauthorizes appropriations to the special reserve fund (Biodefense Countermeasures' appropriations account) for FY2014-FY2018 for procurement of security countermeasures and for countermeasure advanced research and development under the Biomedical Advanced Research and Development Authority (BARDA). Prohibits amounts in the special reserve fund from being used to pay: (1) costs other than payments made by the Secretary to a vendor for advanced development or for procurement of a security countermeasure, or (2) any administrative expenses.

Requires a contract to procure security countermeasures to include a clear statement of defined government purpose limited to uses related to a security countermeasure.

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.

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.

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.

Extends the 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 the PHSA that reveals significant and not otherwise known vulnerabilities of existing medical or public health defenses against biological, chemical, nuclear, or radiological threats.

Reauthorizes the National Disaster Medical System for FY2012-FY2016. Authorizes the Secretary to determine and pay claims for reimbursement for services directly or by contract providing for payment in advance or by way of reimbursement.

Requires the Secretary to submit the National Health Security Strategy to the relevant congressional committees in 2014.

Revises National Health Security Strategy preparedness goals, including by: (1) ensuring that the periodic evaluations of federal, state, local and tribal preparedness and response capabilities include drills and exercises to ensure medical surge capacity for events without notice; and (2) requiring medical preparedness goals to include the preparedness, response capabilities, and surge capacity of ambulatory care facilities.

Reauthorizes through FY2016 the Medical Reserve Corps to provide for an adequate supply of volunteers in the case of a public health emergency.

Extends until September 30, 2016, the antitrust exemption to permit meetings and consultations to discuss the development of security countermeasures, qualified countermeasures, or qualified pandemic or epidemic products.

(Sec. 3) Authorizes the Secretary to temporarily redeploy non-federal personnel (funded in whole or in part through PHSA or HHS) to immediately address a public health emergency upon request from a state, locality, territory, tribe, or Freely Associated State.

(Sec. 4) Requires the Assistant Secretary for Preparedness to: (1) identify gaps, duplication, and other inefficiencies in public health preparedness activities and the actions necessary to overcome these obstacles; (2) lead the development of a coordinated Countermeasure Implementation Plan; (3) oversee the development of a five-year budget analysis; and (4) coordinate HHS grant programs relating to medical and public health preparedness capabilities and the activities of local communities to respond to public health emergencies.

Gives the Assistant Secretary for Preparedness: (1) lead responsibility within HHS for emergency preparedness and response policy and coordination, and (2) authority over and responsibility for BARDA.

Requires the Secretary to submit to the relevant congressional committees: (1) a Countermeasure Implementation Plan that includes a description of the chemical, biological, radiological and nuclear threats facing the nation and the efforts to develop countermeasures or pandemic or epidemic products for such threats; and (2) a plan to improve information sharing, coordination, and communications among disparate biosurveillance systems supported by HHS.

(Sec. 5) Repeals provisions of the Project Bioshield Act of 2004 that required reports on the exercise of authority related to preparedness.

(Sec. 6) Amends the Federal Food, Drug, and Cosmetic Act to revise 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 make a determination of a threat (rather than of a specific threat as under current law); (2) apply such provisions to threats to U.S. citizens aborad; (3) eliminate the one-year expiration date; (4) allow a person to revise the label to reflect the new expiration date.

Authorizes the Secretary to modify an authorization under this section or the conditions of such an authorization

(Sec. 7) Authorizes the Secretary to extend the expiration date of eligible medical countermeasure if: (1) the countermeasure is intended to be held for use for a domestic, military or public health emergency; (2) the expiration date extension is intended to support the U.S.'s ability to protect the public health or military preparedness and effectiveness; and (3) the expiration date extension is supported by an appropriate scientific evaluation that is conducted or accepted by the Secretary. Authorizes the Secretary to authorize deviations from good manufacturing practice requirements with respect to such countermeasure.

Permits medical countermeasures to be dispensed without a prescription during an actual emergency in accordance with state law or an order issued by the Secretary.

Authorizes the Secretary to create and issue emergency use instructions to inform health care providers or individuals to whom a medical countermeasure is to be administered concerning such product's approved, licensed, or cleared conditions of use. Sets forth emergency use provisions.

Authorizes the Secretary to waive requirements for a risk evaluation and mitigation strategy for a medical countermeasure as required to mitigate the effects of, or reduce the severity of: (1) an actual or potential domestic emergency or military emergency involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent, or (2) an actual or potential public health emergency affecting national security or the health and security of U.S. citizens abroad.

(Sec. 8) Permits a government entity to introduce into interstate commerce a product intended for emergency use if that product is held and not used, unless and until the product: (1) is approved, cleared, or licensed; (2) is authorized for investigational use; or (3) is authorized for emergency use.

(Sec. 9) Requires the Secretary to expand the involvement of Food and Drug Administration (FDA) personnel in interagency activities with the Assistant Secretary for Preparedness and Response, the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and the Department of Defense (DOD) for the purpose of accelerating the development, stockpiling, approval, clearance, and licensure of countermeasures and pandemic or epidemic products.

Directs the Secretary to establish a process for frequent scientific feedback and interactions between the FDA and security countermeasure sponsors to facilitate the approval, clearance, and licensing of security countermeasures. Requires such process to allow for the development of a written regulatory management plan for a security countermeasure.

Requires the Secretary to provide final guidance to industry within one year after enactment of this Act regarding the development of animal models to support approval, clearance, or licensure of countermeasures and epidemic and pandemic products when human efficacy studies are not ethical or feasible.

Revises provisions governing special protocol assessments to include agreements on the design and size of animal efficacy trials and any associated clinical trials that, 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.

Actions Timeline

- **Dec 7, 2011:** Received in the Senate and Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
- **Dec 6, 2011:** Mr. Pitts moved to suspend the rules and pass the bill, as amended.
- **Dec 6, 2011:** Considered under suspension of the rules. (consideration: CR H8153-8159)
- **Dec 6, 2011:** DEBATE - The House proceeded with forty minutes of debate on H.R. 2405.
- **Dec 6, 2011:** Passed/agreed to in House: On motion to suspend the rules and pass the bill, as amended Agreed to by voice vote.(text: CR H8153-8157)
- **Dec 6, 2011:** On motion to suspend the rules and pass the bill, as amended Agreed to by voice vote. (text: CR H8153-8157)
- **Dec 6, 2011:** Motion to reconsider laid on the table Agreed to without objection.
- **Nov 16, 2011:** Reported (Amended) by the Committee on Energy and Commerce. H. Rept. 112-286.
- **Nov 16, 2011:** Placed on the Union Calendar, Calendar No. 189.
- **Jul 6, 2011:** Referred to the Subcommittee on Health.
- **Jun 28, 2011:** Introduced in House
- **Jun 28, 2011:** Referred to the House Committee on Energy and Commerce.

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