

109<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# S. 3678

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## AN ACT

To amend the Public Health Service Act with respect to public health security and all-hazards preparedness and response, and for other purposes.

1        *Be it enacted by the Senate and House of Representa-*  
2        *tives of the United States of America in Congress assembled,*

3        **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4        (a) SHORT TITLE.—This Act may be cited as the  
5        “Pandemic and All-Hazards Preparedness Act”.

1 (b) TABLE OF CONTENTS.—The table of contents of  
 2 this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—NATIONAL PREPAREDNESS AND RESPONSE,  
 LEADERSHIP, ORGANIZATION, AND PLANNING

Sec. 101. Public health and medical preparedness and response functions of the  
 Secretary of Health and Human Services.

Sec. 102. Assistant Secretary for Preparedness and Response.

Sec. 103. National Health Security Strategy.

TITLE II—PUBLIC HEALTH SECURITY PREPAREDNESS

Sec. 201. Improving State and local public health security.

Sec. 202. Using information technology to improve situational awareness in  
 public health emergencies.

Sec. 203. Public health workforce enhancements.

Sec. 204. Vaccine tracking and distribution.

Sec. 205. National Science Advisory Board for Biosecurity.

Sec. 206. Revitalization of Commissioned Corps.

TITLE III—ALL-HAZARDS MEDICAL SURGE CAPACITY

Sec. 301. National disaster medical system.

Sec. 302. Enhancing medical surge capacity.

Sec. 303. Encouraging health professional volunteers.

Sec. 304. Core education and training.

Sec. 305. Partnerships for State and regional hospital preparedness to improve  
 surge capacity.

Sec. 306. Enhancing the role of the Department of Veterans Affairs.

TITLE IV—PANDEMIC AND BIODEFENSE VACCINE AND DRUG  
 DEVELOPMENT

Sec. 401. Biomedical Advanced Research and Development Authority.

Sec. 402. National Biodefense Science Board.

Sec. 403. Clarification of countermeasures covered by Project BioShield.

Sec. 404. Technical assistance.

Sec. 405. Collaboration and coordination.

Sec. 406. Procurement.

1 **TITLE I—NATIONAL PREPARED-**  
2 **NESS AND RESPONSE, LEAD-**  
3 **ERSHIP, ORGANIZATION, AND**  
4 **PLANNING**

5 **SEC. 101. PUBLIC HEALTH AND MEDICAL PREPAREDNESS**  
6 **AND RESPONSE FUNCTIONS OF THE SEC-**  
7 **RETARY OF HEALTH AND HUMAN SERVICES.**

8 Title XXVIII of the Public Health Service Act (42  
9 U.S.C. 300hh–11 et seq.) is amended—

10 (1) by striking the title heading and inserting  
11 the following:

12 **“TITLE XXVIII—NATIONAL ALL-**  
13 **HAZARDS PREPAREDNESS**  
14 **FOR PUBLIC HEALTH EMER-**  
15 **GENCIES”;**

16 and

17 (2) by amending subtitle A to read as follows:

18 **“Subtitle A—National All-Hazards**  
19 **Preparedness and Response**  
20 **Planning, Coordinating, and Re-**  
21 **porting**

22 **“SEC. 2801. PUBLIC HEALTH AND MEDICAL PREPAREDNESS**  
23 **AND RESPONSE FUNCTIONS.**

24 “(a) IN GENERAL.—The Secretary of Health and  
25 Human Services shall lead all Federal public health and

1 medical response to public health emergencies and inci-  
2 dents covered by the National Response Plan developed  
3 pursuant to section 502(6) of the Homeland Security Act  
4 of 2002, or any successor plan.

5 “(b) INTERAGENCY AGREEMENT.—The Secretary, in  
6 collaboration with the Secretary of Veterans Affairs, the  
7 Secretary of Transportation, the Secretary of Defense, the  
8 Secretary of Homeland Security, and the head of any  
9 other relevant Federal agency, shall establish an inter-  
10 agency agreement, consistent with the National Response  
11 Plan or any successor plan, under which agreement the  
12 Secretary of Health and Human Services shall assume  
13 operational control of emergency public health and medical  
14 response assets, as necessary, in the event of a public  
15 health emergency, except that members of the armed  
16 forces under the authority of the Secretary of Defense  
17 shall remain under the command and control of the Sec-  
18 retary of Defense, as shall any associated assets of the  
19 Department of Defense.”.

20 **SEC. 102. ASSISTANT SECRETARY FOR PREPAREDNESS AND**  
21 **RESPONSE.**

22 (a) ASSISTANT SECRETARY FOR PREPAREDNESS AND  
23 RESPONSE.—Subtitle B of title XXVIII of the Public  
24 Health Service Act (42 U.S.C. 300hh–11 et seq.) is  
25 amended—

1 (1) in the subtitle heading, by inserting “All-  
2 Hazards” before “Emergency Preparedness”;

3 (2) by redesignating section 2811 as section  
4 2812;

5 (3) by inserting after the subtitle heading the  
6 following new section:

7 **“SEC. 2811. COORDINATION OF PREPAREDNESS FOR AND**  
8 **RESPONSE TO ALL-HAZARDS PUBLIC HEALTH**  
9 **EMERGENCIES.**

10 “(a) IN GENERAL.—There is established within the  
11 Department of Health and Human Services the position  
12 of the Assistant Secretary for Preparedness and Response.  
13 The President, with the advice and consent of the Senate,  
14 shall appoint an individual to serve in such position. Such  
15 Assistant Secretary shall report to the Secretary.

16 “(b) DUTIES.—Subject to the authority of the Sec-  
17 retary, the Assistant Secretary for Preparedness and Re-  
18 sponse shall carry out the following functions:

19 “(1) LEADERSHIP.—Serve as the principal ad-  
20 visor to the Secretary on all matters related to Fed-  
21 eral public health and medical preparedness and re-  
22 sponse for public health emergencies.

23 “(2) PERSONNEL.—Register, credential, orga-  
24 nize, train, equip, and have the authority to deploy  
25 Federal public health and medical personnel under

1 the authority of the Secretary, including the Na-  
2 tional Disaster Medical System, and coordinate such  
3 personnel with the Medical Reserve Corps and the  
4 Emergency System for Advance Registration of Vol-  
5 unteer Health Professionals.

6 “(3) COUNTERMEASURES.—Oversee advanced  
7 research, development, and procurement of qualified  
8 countermeasures (as defined in section 319F–1) and  
9 qualified pandemic or epidemic products (as defined  
10 in section 319F–3).

11 “(4) COORDINATION.—

12 “(A) FEDERAL INTEGRATION.—Coordinate  
13 with relevant Federal officials to ensure inte-  
14 gration of Federal preparedness and response  
15 activities for public health emergencies.

16 “(B) STATE, LOCAL, AND TRIBAL INTE-  
17 GRATION.—Coordinate with State, local, and  
18 tribal public health officials, the Emergency  
19 Management Assistance Compact, health care  
20 systems, and emergency medical service systems  
21 to ensure effective integration of Federal public  
22 health and medical assets during a public  
23 health emergency.

24 “(C) EMERGENCY MEDICAL SERVICES.—  
25 Promote improved emergency medical services

1           medical direction, system integration, research,  
2           and uniformity of data collection, treatment  
3           protocols, and policies with regard to public  
4           health emergencies.

5           “(5) LOGISTICS.—In coordination with the Sec-  
6           retary of Veterans Affairs, the Secretary of Home-  
7           land Security, the General Services Administration,  
8           and other public and private entities, provide  
9           logistical support for medical and public health as-  
10          pects of Federal responses to public health emer-  
11          gencies.

12          “(6) LEADERSHIP.—Provide leadership in  
13          international programs, initiatives, and policies that  
14          deal with public health and medical emergency pre-  
15          paredness and response.

16          “(c) FUNCTIONS.—The Assistant Secretary for Pre-  
17          paredness and Response shall—

18                 “(1) have authority over and responsibility  
19                 for—

20                         “(A) the National Disaster Medical System  
21                         (in accordance with section 301 of the Pan-  
22                         demic and All-Hazards Preparedness Act); and

23                         “(B) the Hospital Preparedness Coopera-  
24                         tive Agreement Program pursuant to section  
25                         319C-2;

1           “(2) exercise the responsibilities and authorities  
2 of the Secretary with respect to the coordination  
3 of—

4           “(A) the Medical Reserve Corps pursuant  
5 to section 2813;

6           “(B) the Emergency System for Advance  
7 Registration of Volunteer Health Professionals  
8 pursuant to section 319I;

9           “(C) the Strategic National Stockpile; and

10           “(D) the Cities Readiness Initiative; and

11           “(3) assume other duties as determined appro-  
12 priate by the Secretary.”; and

13           (4) by striking “Assistant Secretary for Public  
14 Health Emergency Preparedness” each place it ap-  
15 pears and inserting “Assistant Secretary for Pre-  
16 paredness and Response”.

17 (b) TRANSFER OF FUNCTIONS; REFERENCES.—

18           (1) TRANSFER OF FUNCTIONS.—There shall be  
19 transferred to the Office of the Assistant Secretary  
20 for Preparedness and Response the functions, per-  
21 sonnel, assets, and liabilities of the Assistant Sec-  
22 retary for Public Health Emergency Preparedness as  
23 in effect on the day before the date of enactment of  
24 this Act.

1           (2) REFERENCES.—Any reference in any Fed-  
2           eral law, Executive order, rule, regulation, or delega-  
3           tion of authority, or any document of or pertaining  
4           to the Assistant Secretary for Public Health Emer-  
5           gency Preparedness as in effect the day before the  
6           date of enactment of this Act, shall be deemed to be  
7           a reference to the Assistant Secretary for Prepared-  
8           ness and Response.

9           (c) STOCKPILE.—Section 319F–2(a)(1) of the Public  
10          Health Service Act (42 U.S.C. 247d–6b(a)(1)) is amended  
11          by—

12           (1) inserting “in collaboration with the Director  
13           of the Centers for Disease Control and Prevention,  
14           and” after “Secretary,”; and

15           (2) inserting at the end the following: “The  
16           Secretary shall conduct an annual review (taking  
17           into account at-risk individuals) of the contents of  
18           the stockpile, including non-pharmaceutical supplies,  
19           and make necessary additions or modifications to  
20           the contents based on such review.”.

21          (d) AT-RISK INDIVIDUALS.—Title XXVIII of the  
22          Public Health Service Act (42 U.S.C. 300hh et seq.), as  
23          amended by section 303 of this Act, is amended by insert-  
24          ing after section 2813 the following:

1 **“SEC. 2814. AT-RISK INDIVIDUALS.**

2 “The Secretary, acting through such employee of the  
3 Department of Health and Human Services as determined  
4 by the Secretary and designated publicly (which may, at  
5 the discretion of the Secretary, involve the appointment  
6 or designation of an individual as the Director of At-Risk  
7 Individuals), shall—

8 “(1) oversee the implementation of the National  
9 Preparedness goal of taking into account the public  
10 health and medical needs of at-risk individuals in the  
11 event of a public health emergency, as described in  
12 section 2802(b)(4);

13 “(2) assist other Federal agencies responsible  
14 for planning for, responding to, and recovering from  
15 public health emergencies in addressing the needs of  
16 at-risk individuals;

17 “(3) provide guidance to and ensure that recipi-  
18 ents of State and local public health grants include  
19 preparedness and response strategies and capabili-  
20 ties that take into account the medical and public  
21 health needs of at-risk individuals in the event of a  
22 public health emergency, as described in section  
23 319C–1(b)(2)(A)(iii);

24 “(4) ensure that the contents of the strategic  
25 national stockpile take into account at-risk popu-  
26 lations as described in section 2811(b)(3)(B);

1           “(5) oversee the progress of the Advisory Com-  
2           mittee on At-Risk Individuals and Public Health  
3           Emergencies established under section 319F(b)(2)  
4           and make recommendations with a focus on opportu-  
5           nities for action based on the work of the Com-  
6           mittee;

7           “(6) oversee curriculum development for the  
8           public health and medical response training program  
9           on medical management of casualties, as it concerns  
10          at-risk individuals as described in subparagraphs (A)  
11          through (C) of section 319F(a)(2);

12          “(7) disseminate novel and best practices of  
13          outreach to and care of at-risk individuals before,  
14          during, and following public health emergencies; and

15          “(8) not later than one year after the date of  
16          enactment of the Pandemic and All-Hazards Pre-  
17          paredness Act, prepare and submit to Congress a re-  
18          port describing the progress made on implementing  
19          the duties described in this section.”.

20 **SEC. 103. NATIONAL HEALTH SECURITY STRATEGY.**

21          Title XXVIII of the Public Health Service Act  
22          (300hh–11 et seq.), as amended by section 101, is amend-  
23          ed by inserting after section 2801 the following:

24 **“SEC. 2802. NATIONAL HEALTH SECURITY STRATEGY.**

25          “(a) IN GENERAL.—

1           “(1) PREPAREDNESS AND RESPONSE REGARD-  
2           ING PUBLIC HEALTH EMERGENCIES.—Beginning in  
3           2009 and every four years thereafter, the Secretary  
4           shall prepare and submit to the relevant committees  
5           of Congress a coordinated strategy (to be known as  
6           the National Health Security Strategy) and any revi-  
7           sions thereof, and an accompanying implementation  
8           plan for public health emergency preparedness and  
9           response. Such National Health Security Strategy  
10          shall identify the process for achieving the prepared-  
11          ness goals described in subsection (b) and shall be  
12          consistent with the National Preparedness Goal, the  
13          National Incident Management System, and the Na-  
14          tional Response Plan developed pursuant to section  
15          502(6) of the Homeland Security Act of 2002, or  
16          any successor plan.

17          “(2) EVALUATION OF PROGRESS.—The Na-  
18          tional Health Security Strategy shall include an  
19          evaluation of the progress made by Federal, State,  
20          local, and tribal entities, based on the evidence-based  
21          benchmarks and objective standards that measure  
22          levels of preparedness established pursuant to sec-  
23          tion 319C–1(g). Such evaluation shall include aggre-  
24          gate and State-specific breakdowns of obligated  
25          funding spent by major category (as defined by the

1 Secretary) for activities funded through awards pur-  
2 suant to sections 319C–1 and 319C–2.

3 “(3) PUBLIC HEALTH WORKFORCE.—In 2009,  
4 the National Health Security Strategy shall include  
5 a national strategy for establishing an effective and  
6 prepared public health workforce, including defining  
7 the functions, capabilities, and gaps in such work-  
8 force, and identifying strategies to recruit, retain,  
9 and protect such workforce from workplace expo-  
10 sures during public health emergencies.

11 “(b) PREPAREDNESS GOALS.—The National Health  
12 Security Strategy shall include provisions in furtherance  
13 of the following:

14 “(1) INTEGRATION.—Integrating public health  
15 and public and private medical capabilities with  
16 other first responder systems, including through—

17 “(A) the periodic evaluation of Federal,  
18 State, local, and tribal preparedness and re-  
19 sponse capabilities through drills and exercises;  
20 and

21 “(B) integrating public and private sector  
22 public health and medical donations and volun-  
23 teers.

24 “(2) PUBLIC HEALTH.—Developing and sus-  
25 taining Federal, State, local, and tribal essential

1 public health security capabilities, including the fol-  
2 lowing:

3 “(A) Disease situational awareness domes-  
4 tically and abroad, including detection, identi-  
5 fication, and investigation.

6 “(B) Disease containment including capa-  
7 bilities for isolation, quarantine, social  
8 distancing, and decontamination.

9 “(C) Risk communication and public pre-  
10 paredness.

11 “(D) Rapid distribution and administra-  
12 tion of medical countermeasures.

13 “(3) MEDICAL.—Increasing the preparedness,  
14 response capabilities, and surge capacity of hos-  
15 pitals, other health care facilities (including mental  
16 health facilities), and trauma care and emergency  
17 medical service systems, with respect to public  
18 health emergencies, which shall include developing  
19 plans for the following:

20 “(A) Strengthening public health emer-  
21 gency medical management and treatment ca-  
22 pabilities.

23 “(B) Medical evacuation and fatality man-  
24 agement.

1           “(C) Rapid distribution and administration  
2 of medical countermeasures.

3           “(D) Effective utilization of any available  
4 public and private mobile medical assets and in-  
5 tegration of other Federal assets.

6           “(E) Protecting health care workers and  
7 health care first responders from workplace ex-  
8 posures during a public health emergency.

9           “(4) AT-RISK INDIVIDUALS.—

10           “(A) Taking into account the public health  
11 and medical needs of at-risk individuals in the  
12 event of a public health emergency.

13           “(B) For purpose of this section and sec-  
14 tions 319C–1, 319F, and 319L, the term ‘at-  
15 risk individuals’ means children, pregnant  
16 women, senior citizens and other individuals  
17 who have special needs in the event of a public  
18 health emergency, as determined by the Sec-  
19 retary.

20           “(5) COORDINATION.—Minimizing duplication  
21 of, and ensuring coordination between, Federal,  
22 State, local, and tribal planning, preparedness, and  
23 response activities (including the State Emergency  
24 Management Assistance Compact). Such planning  
25 shall be consistent with the National Response Plan,

1 or any successor plan, and National Incident Man-  
 2 agement System and the National Preparedness  
 3 Goal.

4 “(6) CONTINUITY OF OPERATIONS.—Maintain-  
 5 ing vital public health and medical services to allow  
 6 for optimal Federal, State, local, and tribal oper-  
 7 ations in the event of a public health emergency.”.

8 **TITLE II—PUBLIC HEALTH**  
 9 **SECURITY PREPAREDNESS**

10 **SEC. 201. IMPROVING STATE AND LOCAL PUBLIC HEALTH**  
 11 **SECURITY.**

12 Section 319C–1 of the Public Health Service Act (42  
 13 U.S.C. 247d–3a) is amended—

14 (1) by amending the heading to read as follows:

15 **“IMPROVING STATE AND LOCAL PUBLIC**  
 16 **HEALTH SECURITY.”;**

17 (2) by striking subsections (a) through (i) and  
 18 inserting the following:

19 “(a) IN GENERAL.—To enhance the security of the  
 20 United States with respect to public health emergencies,  
 21 the Secretary shall award cooperative agreements to eligi-  
 22 ble entities to enable such entities to conduct the activities  
 23 described in subsection (d).

24 “(b) ELIGIBLE ENTITIES.—To be eligible to receive  
 25 an award under subsection (a), an entity shall—

1           “(1)(A) be a State;

2           “(B) be a political subdivision determined by  
3 the Secretary to be eligible for an award under this  
4 section (based on criteria described in subsection  
5 (i)(4)); or

6           “(C) be a consortium of entities described in  
7 subparagraph (A); and

8           “(2) prepare and submit to the Secretary an  
9 application at such time, and in such manner, and  
10 containing such information as the Secretary may  
11 require, including—

12               “(A) an All-Hazards Public Health Emer-  
13 gency Preparedness and Response Plan which  
14 shall include—

15                   “(i) a description of the activities such  
16 entity will carry out under the agreement  
17 to meet the goals identified under section  
18 2802;

19                   “(ii) a pandemic influenza plan con-  
20 sistent with the requirements of para-  
21 graphs (2) and (5) of subsection (g);

22                   “(iii) preparedness and response strat-  
23 egies and capabilities that take into ac-  
24 count the medical and public health needs

1 of at-risk individuals in the event of a pub-  
2 lic health emergency;

3 “(iv) a description of the mechanism  
4 the entity will implement to utilize the  
5 Emergency Management Assistance Com-  
6 pact or other mutual aid agreements for  
7 medical and public health mutual aid; and

8 “(v) a description of how the entity  
9 will include the State Unit on Aging in  
10 public health emergency preparedness;

11 “(B) an assurance that the entity will re-  
12 port to the Secretary on an annual basis (or  
13 more frequently as determined by the Sec-  
14 retary) on the evidence-based benchmarks and  
15 objective standards established by the Secretary  
16 to evaluate the preparedness and response capa-  
17 bilities of such entity under subsection (g);

18 “(C) an assurance that the entity will con-  
19 duct, on at least an annual basis, an exercise or  
20 drill that meets any criteria established by the  
21 Secretary to test the preparedness and response  
22 capabilities of such entity, and that the entity  
23 will report back to the Secretary within the ap-  
24 plication of the following year on the strengths  
25 and weaknesses identified through such exercise

1 or drill, and corrective actions taken to address  
2 material weaknesses;

3 “(D) an assurance that the entity will pro-  
4 vide to the Secretary the data described under  
5 section 319D(d)(3) as determined feasible by  
6 the Secretary;

7 “(E) an assurance that the entity will con-  
8 duct activities to inform and educate the hos-  
9 pitals within the jurisdiction of such entity on  
10 the role of such hospitals in the plan required  
11 under subparagraph (A);

12 “(F) an assurance that the entity, with re-  
13 spect to the plan described under subparagraph  
14 (A), has developed and will implement an ac-  
15 countability system to ensure that such entity  
16 make satisfactory annual improvement and de-  
17 scribe such system in the plan under subpara-  
18 graph (A);

19 “(G) a description of the means by which  
20 to obtain public comment and input on the plan  
21 described in subparagraph (A) and on the im-  
22 plementation of such plan, that shall include an  
23 advisory committee or other similar mechanism  
24 for obtaining comment from the public and

1 from other State, local, and tribal stakeholders;  
2 and

3 “(H) as relevant, a description of the proc-  
4 ess used by the entity to consult with local de-  
5 partments of public health to reach consensus,  
6 approval, or concurrence on the relative dis-  
7 tribution of amounts received under this sec-  
8 tion.

9 “(c) LIMITATION.—Beginning in fiscal year 2009,  
10 the Secretary may not award a cooperative agreement to  
11 a State unless such State is a participant in the Emer-  
12 gency System for Advance Registration of Volunteer  
13 Health Professionals described in section 319I.

14 “(d) USE OF FUNDS.—

15 “(1) IN GENERAL.—An award under subsection  
16 (a) shall be expended for activities to achieve the  
17 preparedness goals described under paragraphs (1),  
18 (2), (4), (5), and (6) of section 2802(b).

19 “(2) EFFECT OF SECTION.—Nothing in this  
20 subsection may be construed as establishing new  
21 regulatory authority or as modifying any existing  
22 regulatory authority.

23 “(e) COORDINATION WITH LOCAL RESPONSE CAPA-  
24 BILITIES.—An entity shall, to the extent practicable, en-  
25 sure that activities carried out under an award under sub-

1 section (a) are coordinated with activities of relevant Met-  
2 ropolitan Medical Response Systems, local public health  
3 departments, the Cities Readiness Initiative, and local  
4 emergency plans.

5 “(f) CONSULTATION WITH HOMELAND SECURITY.—  
6 In making awards under subsection (a), the Secretary  
7 shall consult with the Secretary of Homeland Security  
8 to—

9 “(1) ensure maximum coordination of public  
10 health and medical preparedness and response ac-  
11 tivities with the Metropolitan Medical Response Sys-  
12 tem, and other relevant activities;

13 “(2) minimize duplicative funding of programs  
14 and activities;

15 “(3) analyze activities, including exercises and  
16 drills, conducted under this section to develop rec-  
17 ommendations and guidance on best practices for  
18 such activities; and

19 “(4) disseminate such recommendations and  
20 guidance, including through expanding existing les-  
21 sons learned information systems to create a single  
22 Internet-based point of access for sharing and dis-  
23 tributing medical and public health best practices  
24 and lessons learned from drills, exercises, disasters,  
25 and other emergencies.

1       “(g) ACHIEVEMENT OF MEASURABLE EVIDENCE-  
2 BASED BENCHMARKS AND OBJECTIVE STANDARDS.—

3           “(1) IN GENERAL.—Not later than 180 days  
4 after the date of enactment of the Pandemic and  
5 All-Hazards Preparedness Act, the Secretary shall  
6 develop or where appropriate adopt, and require the  
7 application of, measurable evidence-based bench-  
8 marks and objective standards that measure levels of  
9 preparedness with respect to the activities described  
10 in this section and with respect to activities de-  
11 scribed in section 319C–2. In developing such bench-  
12 marks and standards, the Secretary shall consult  
13 with and seek comments from State, local, and tribal  
14 officials and private entities, as appropriate. Where  
15 appropriate, the Secretary shall incorporate existing  
16 objective standards. Such benchmarks and standards  
17 shall—

18           “(A) include outcome goals representing  
19 operational achievement of the National Pre-  
20 paredness Goals developed under section  
21 2802(b); and

22           “(B) at a minimum, require entities to—

23           “(i) measure progress toward achiev-  
24 ing the outcome goals; and

1           “(ii) at least annually, test, exercise,  
2           and rigorously evaluate the public health  
3           and medical emergency preparedness and  
4           response capabilities of the entity, and re-  
5           port to the Secretary on such measured  
6           and tested capabilities and measured and  
7           tested progress toward achieving outcome  
8           goals, based on criteria established by the  
9           Secretary.

10           “(2) CRITERIA FOR PANDEMIC INFLUENZA  
11           PLANS.—

12           “(A) IN GENERAL.—Not later than 180  
13           days after the date of enactment of the Pan-  
14           demic and All-Hazards Preparedness Act, the  
15           Secretary shall develop and disseminate to the  
16           chief executive officer of each State criteria for  
17           an effective State plan for responding to pan-  
18           demic influenza.

19           “(B) RULE OF CONSTRUCTION.—Nothing  
20           in this section shall be construed to require the  
21           duplication of Federal efforts with respect to  
22           the development of criteria or standards, with-  
23           out regard to whether such efforts were carried  
24           out prior to or after the date of enactment of  
25           this section.

1           “(3) TECHNICAL ASSISTANCE.—The Secretary  
2 shall, as determined appropriate by the Secretary,  
3 provide to a State, upon request, technical assistance  
4 in meeting the requirements of this section, includ-  
5 ing the provision of advice by experts in the develop-  
6 ment of high-quality assessments, the setting of  
7 State objectives and assessment methods, the devel-  
8 opment of measures of satisfactory annual improve-  
9 ment that are valid and reliable, and other relevant  
10 areas.

11           “(4) NOTIFICATION OF FAILURES.—The Sec-  
12 retary shall develop and implement a process to no-  
13 tify entities that are determined by the Secretary to  
14 have failed to meet the requirements of paragraph  
15 (1) or (2). Such process shall provide such entities  
16 with the opportunity to correct such noncompliance.  
17 An entity that fails to correct such noncompliance  
18 shall be subject to paragraph (5).

19           “(5) WITHHOLDING OF AMOUNTS FROM ENTI-  
20 TIES THAT FAIL TO ACHIEVE BENCHMARKS OR SUB-  
21 MIT INFLUENZA PLAN.—Beginning with fiscal year  
22 2009, and in each succeeding fiscal year, the Sec-  
23 retary shall—

24                   “(A) withhold from each entity that has  
25 failed substantially to meet the benchmarks and

1 performance measures described in paragraph  
2 (1) for the immediately preceding fiscal year  
3 (beginning with fiscal year 2008), pursuant to  
4 the process developed under paragraph (4), the  
5 amount described in paragraph (6); and

6 “(B) withhold from each entity that has  
7 failed to submit to the Secretary a plan for re-  
8 sponding to pandemic influenza that meets the  
9 criteria developed under paragraph (2), the  
10 amount described in paragraph (6).

11 “(6) AMOUNTS DESCRIBED.—

12 “(A) IN GENERAL.—The amounts de-  
13 scribed in this paragraph are the following  
14 amounts that are payable to an entity for ac-  
15 tivities described in section 319C–1 or 319C–2:

16 “(i) For the fiscal year immediately  
17 following a fiscal year in which an entity  
18 experienced a failure described in subpara-  
19 graph (A) or (B) of paragraph (5) by the  
20 entity, an amount equal to 10 percent of  
21 the amount the entity was eligible to re-  
22 ceive for such fiscal year.

23 “(ii) For the fiscal year immediately  
24 following two consecutive fiscal years in  
25 which an entity experienced such a failure,

1 an amount equal to 15 percent of the  
2 amount the entity was eligible to receive  
3 for such fiscal year, taking into account  
4 the withholding of funds for the imme-  
5 diately preceding fiscal year under clause  
6 (i).

7 “(iii) For the fiscal year immediately  
8 following three consecutive fiscal years in  
9 which an entity experienced such a failure,  
10 an amount equal to 20 percent of the  
11 amount the entity was eligible to receive  
12 for such fiscal year, taking into account  
13 the withholding of funds for the imme-  
14 diately preceding fiscal years under clauses  
15 (i) and (ii).

16 “(iv) For the fiscal year immediately  
17 following four consecutive fiscal years in  
18 which an entity experienced such a failure,  
19 an amount equal to 25 percent of the  
20 amount the entity was eligible to receive  
21 for such a fiscal year, taking into account  
22 the withholding of funds for the imme-  
23 diately preceding fiscal years under clauses  
24 (i), (ii), and (iii).

1           “(B) SEPARATE ACCOUNTING.—Each fail-  
2           ure described in subparagraph (A) or (B) of  
3           paragraph (5) shall be treated as a separate  
4           failure for purposes of calculating amounts  
5           withheld under subparagraph (A).

6           “(7) REALLOCATION OF AMOUNTS WITH-  
7           HELD.—

8           “(A) IN GENERAL.—The Secretary shall  
9           make amounts withheld under paragraph (6)  
10          available for making awards under section  
11          319C–2 to entities described in subsection  
12          (b)(1) of such section.

13          “(B) PREFERENCE IN REALLOCATION.—In  
14          making awards under section 319C–2 with  
15          amounts described in subparagraph (A), the  
16          Secretary shall give preference to eligible enti-  
17          ties (as described in section 319C–2(b)(1)) that  
18          are located in whole or in part in States from  
19          which amounts have been withheld under para-  
20          graph (6).

21          “(8) WAIVE OR REDUCE WITHHOLDING.—The  
22          Secretary may waive or reduce the withholding de-  
23          scribed in paragraph (6), for a single entity or for  
24          all entities in a fiscal year, if the Secretary deter-

1 mines that mitigating conditions exist that justify  
2 the waiver or reduction.

3 “(h) GRANTS FOR REAL-TIME DISEASE DETECTION  
4 IMPROVEMENT.—

5 “(1) IN GENERAL.—The Secretary may award  
6 grants to eligible entities to carry out projects de-  
7 scribed under paragraph (4).

8 “(2) ELIGIBLE ENTITY.—For purposes of this  
9 section, the term ‘eligible entity’ means an entity  
10 that is—

11 “(A)(i) a hospital, clinical laboratory, uni-  
12 versity; or

13 “(ii) a poison control center or professional  
14 organization in the field of poison control; and

15 “(B) a participant in the network estab-  
16 lished under subsection 319D(d).

17 “(3) APPLICATION.—Each eligible entity desir-  
18 ing a grant under this subsection shall submit to the  
19 Secretary an application at such time, in such man-  
20 ner, and containing such information as the Sec-  
21 retary may require.

22 “(4) USE OF FUNDS.—

23 “(A) IN GENERAL.—An eligible entity de-  
24 scribed in paragraph (2)(A)(i) that receives a  
25 grant under this subsection shall use the funds

1 awarded pursuant to such grant to carry out a  
2 pilot demonstration project to purchase and im-  
3 plement the use of advanced diagnostic medical  
4 equipment to analyze real-time clinical speci-  
5 mens for pathogens of public health or bioter-  
6 rorism significance and report any results from  
7 such project to State, local, and tribal public  
8 health entities and the network established  
9 under section 319D(d).

10 “(B) OTHER ENTITIES.—An eligible entity  
11 described in paragraph (2)(A)(ii) that receives a  
12 grant under this section shall use the funds  
13 awarded pursuant to such grant to—

14 “(i) improve the early detection, sur-  
15 veillance, and investigative capabilities of  
16 poison control centers for chemical, biologi-  
17 cal, radiological, and nuclear events by  
18 training poison information personnel to  
19 improve the accuracy of surveillance data,  
20 improving the definitions used by the poi-  
21 son control centers for surveillance, and  
22 enhancing timely and efficient investigation  
23 of data anomalies;

24 “(ii) improve the capabilities of poison  
25 control centers to provide information to

1 health care providers and the public with  
2 regard to chemical, biological, radiological,  
3 or nuclear threats or exposures, in con-  
4 sultation with the appropriate State, local,  
5 and tribal public health entities; or

6 “(iii) provide surge capacity in the  
7 event of a chemical, biological, radiological,  
8 or nuclear event through the establishment  
9 of alternative poison control center work-  
10 sites and the training of nontraditional  
11 personnel.”;

12 (3) by redesignating subsection (j) as sub-  
13 section (i);

14 (4) in subsection (i), as so redesignated—

15 (A) by striking paragraphs (1) through  
16 (3)(A) and inserting the following:

17 “(1) AUTHORIZATION OF APPROPRIATIONS.—

18 “(A) IN GENERAL.—For the purpose of  
19 carrying out this section, there is authorized to  
20 be appropriated \$824,000,000 for fiscal year  
21 2007, of which \$35,000,000 shall be used to  
22 carry out subsection (h), for awards pursuant  
23 to paragraph (3) (subject to the authority of  
24 the Secretary to make awards pursuant to  
25 paragraphs (4) and (5)), and such sums as may

1           be necessary for each of fiscal years 2008  
2           through 2011.

3           “(B) COORDINATION.—There are author-  
4           ized to be appropriated, \$10,000,000 for fiscal  
5           year 2007 to carry out subsection (f)(4) of this  
6           section and section 2814.

7           “(C) REQUIREMENT FOR STATE MATCHING  
8           FUNDS.—Beginning in fiscal year 2009, in the  
9           case of any State or consortium of two or more  
10          States, the Secretary may not award a coopera-  
11          tive agreement under this section unless the  
12          State or consortium of States agree that, with  
13          respect to the amount of the cooperative agree-  
14          ment awarded by the Secretary, the State or  
15          consortium of States will make available (di-  
16          rectly or through donations from public or pri-  
17          vate entities) non-Federal contributions in an  
18          amount equal to—

19                 “(i) for the first fiscal year of the co-  
20                 operative agreement, not less than 5 per-  
21                 cent of such costs (\$1 for each \$20 of Fed-  
22                 eral funds provided in the cooperative  
23                 agreement); and

24                 “(ii) for any second fiscal year of the  
25                 cooperative agreement, and for any subse-

1           quent fiscal year of such cooperative agree-  
2           ment, not less than 10 percent of such  
3           costs (\$1 for each \$10 of Federal funds  
4           provided in the cooperative agreement).

5           “(D) DETERMINATION OF AMOUNT OF  
6           NON-FEDERAL CONTRIBUTIONS.—As deter-  
7           mined by the Secretary, non-Federal contribu-  
8           tions required in subparagraph (C) may be pro-  
9           vided directly or through donations from public  
10          or private entities and may be in cash or in  
11          kind, fairly evaluated, including plant, equip-  
12          ment or services. Amounts provided by the Fed-  
13          eral government, or services assisted or sub-  
14          sidized to any significant extent by the Federal  
15          government, may not be included in deter-  
16          mining the amount of such non-Federal con-  
17          tributions.

18          “(2) MAINTAINING STATE FUNDING.—

19                 “(A) IN GENERAL.—An entity that re-  
20                 ceives an award under this section shall main-  
21                 tain expenditures for public health security at a  
22                 level that is not less than the average level of  
23                 such expenditures maintained by the entity for  
24                 the preceding 2 year period.

1           “(B) RULE OF CONSTRUCTION.—Nothing  
2           in this section shall be construed to prohibit the  
3           use of awards under this section to pay salary  
4           and related expenses of public health and other  
5           professionals employed by State, local, or tribal  
6           public health agencies who are carrying out ac-  
7           tivities supported by such awards (regardless of  
8           whether the primary assignment of such per-  
9           sonnel is to carry out such activities).

10          “(3) DETERMINATION OF AMOUNT.—

11           “(A) IN GENERAL.—The Secretary shall  
12           award cooperative agreements under subsection  
13           (a) to each State or consortium of 2 or more  
14           States that submits to the Secretary an applica-  
15           tion that meets the criteria of the Secretary for  
16           the receipt of such an award and that meets  
17           other implementation conditions established by  
18           the Secretary for such awards.”;

19           (B) in paragraph (4)(A)—

20                 (i) by striking “2003” and inserting  
21                 “2007”; and

22                 (ii) by striking “(A)(i)(I)”;

23           (C) in paragraph (4)(D), by striking  
24           “2002” and inserting “2006”;

25           (D) in paragraph (5)—

1 (i) by striking “2003” and inserting  
2 “2007”; and

3 (ii) by striking “(A)(i)(I)”; and  
4 (E) by striking paragraph (6) and insert-  
5 ing the following:

6 “(6) FUNDING OF LOCAL ENTITIES.—The Sec-  
7 retary shall, in making awards under this section,  
8 ensure that with respect to the cooperative agree-  
9 ment awarded, the entity make available appropriate  
10 portions of such award to political subdivisions and  
11 local departments of public health through a process  
12 involving the consensus, approval or concurrence  
13 with such local entities.”; and

14 (5) by adding at the end the following:

15 “(j) ADMINISTRATIVE AND FISCAL RESPONSI-  
16 BILITY.—

17 “(1) ANNUAL REPORTING REQUIREMENTS.—  
18 Each entity shall prepare and submit to the Sec-  
19 retary annual reports on its activities under this sec-  
20 tion and section 319C–2. Each such report shall be  
21 prepared by, or in consultation with, the health de-  
22 partment. In order to properly evaluate and compare  
23 the performance of different entities assisted under  
24 this section and section 319C–2 and to assure the  
25 proper expenditure of funds under this section and

1 section 319C–2, such reports shall be in such stand-  
2 ardized form and contain such information as the  
3 Secretary determines and describes within 180 days  
4 of the date of enactment of the Pandemic and All-  
5 Hazards Preparedness Act (after consultation with  
6 the States) to be necessary to—

7 “(A) secure an accurate description of  
8 those activities;

9 “(B) secure a complete record of the pur-  
10 poses for which funds were spent, and of the re-  
11 cipients of such funds;

12 “(C) describe the extent to which the enti-  
13 ty has met the goals and objectives it set forth  
14 under this section or section 319C–2;

15 “(D) determine the extent to which funds  
16 were expended consistent with the entity’s ap-  
17 plication transmitted under this section or sec-  
18 tion 319C–2; and

19 “(E) publish such information on a Fed-  
20 eral Internet website consistent with subsection  
21 (k).

22 “(2) AUDITS; IMPLEMENTATION.—

23 “(A) IN GENERAL.—Each entity receiving  
24 funds under this section or section 319C–2  
25 shall, not less often than once every 2 years,

1       audit its expenditures from amounts received  
2       under this section or section 319C-2. Such au-  
3       dits shall be conducted by an entity independent  
4       of the agency administering a program funded  
5       under this section or section 319C-2 in accord-  
6       ance with the Comptroller General's standards  
7       for auditing governmental organizations, pro-  
8       grams, activities, and functions and generally  
9       accepted auditing standards. Within 30 days  
10      following the completion of each audit report,  
11      the entity shall submit a copy of that audit re-  
12      port to the Secretary.

13           “(B) REPAYMENT.—Each entity shall  
14      repay to the United States amounts found by  
15      the Secretary, after notice and opportunity for  
16      a hearing to the entity, not to have been ex-  
17      pended in accordance with this section or sec-  
18      tion 319C-2 and, if such repayment is not  
19      made, the Secretary may offset such amounts  
20      against the amount of any allotment to which  
21      the entity is or may become entitled under this  
22      section or section 319C-2 or may otherwise re-  
23      cover such amounts.

24           “(C) WITHHOLDING OF PAYMENT.—The  
25      Secretary may, after notice and opportunity for

1 a hearing, withhold payment of funds to any  
2 entity which is not using its allotment under  
3 this section or section 319C-2 in accordance  
4 with such section. The Secretary may withhold  
5 such funds until the Secretary finds that the  
6 reason for the withholding has been removed  
7 and there is reasonable assurance that it will  
8 not recur.

9 “(3) MAXIMUM CARRYOVER AMOUNT.—

10 “(A) IN GENERAL.—For each fiscal year,  
11 the Secretary, in consultation with the States  
12 and political subdivisions, shall determine the  
13 maximum percentage amount of an award  
14 under this section that an entity may carryover  
15 to the succeeding fiscal year.

16 “(B) AMOUNT EXCEEDED.—For each fis-  
17 cal year, if the percentage amount of an award  
18 under this section unexpended by an entity ex-  
19 ceeds the maximum percentage permitted by  
20 the Secretary under subparagraph (A), the enti-  
21 ty shall return to the Secretary the portion of  
22 the unexpended amount that exceeds the max-  
23 imum amount permitted to be carried over by  
24 the Secretary.

1           “(C) ACTION BY SECRETARY.—The Sec-  
2           retary shall make amounts returned to the Sec-  
3           retary under subparagraph (B) available for  
4           awards under section 319C–2(b)(1). In making  
5           awards under section 319C–2(b)(1) with  
6           amounts collected under this paragraph the  
7           Secretary shall give preference to entities that  
8           are located in whole or in part in States from  
9           which amounts have been returned under sub-  
10          paragraph (B).

11          “(D) WAIVER.—An entity may apply to  
12          the Secretary for a waiver of the maximum per-  
13          centage amount under subparagraph (A). Such  
14          an application for a waiver shall include an ex-  
15          planation why such requirement should not  
16          apply to the entity and the steps taken by such  
17          entity to ensure that all funds under an award  
18          under this section will be expended appro-  
19          priately.

20          “(E) WAIVE OR REDUCE WITHHOLDING.—  
21          The Secretary may waive the application of  
22          subparagraph (B), or reduce the amount deter-  
23          mined under such subparagraph, for a single  
24          entity pursuant to subparagraph (D) or for all  
25          entities in a fiscal year, if the Secretary deter-

1           mines that mitigating conditions exist that jus-  
2           tify the waiver or reduction.

3           “(k) COMPILATION AND AVAILABILITY OF DATA.—  
4 The Secretary shall compile the data submitted under this  
5 section and make such data available in a timely manner  
6 on an appropriate Internet website in a format that is use-  
7 ful to the public and to other entities and that provides  
8 information on what activities are best contributing to the  
9 achievement of the outcome goals described in subsection  
10 (g).”.

11 **SEC. 202. USING INFORMATION TECHNOLOGY TO IMPROVE**  
12                           **SITUATIONAL AWARENESS IN PUBLIC**  
13                           **HEALTH EMERGENCIES.**

14           Section 319D of the Public Health Service Act (42  
15 U.S.C. 247d-4) is amended—

16           (1) in subsection (a)(1), by inserting “domesti-  
17 cally and abroad” after “public health threats”; and

18           (2) by adding at the end the following:

19           “(d) PUBLIC HEALTH SITUATIONAL AWARENESS.—

20           “(1) IN GENERAL.—Not later than 2 years  
21 after the date of enactment of the Pandemic and  
22 All-Hazards Preparedness Act, the Secretary, in col-  
23 laboration with State, local, and tribal public health  
24 officials, shall establish a near real-time electronic  
25 nationwide public health situational awareness capa-

1 bility through an interoperable network of systems  
2 to share data and information to enhance early de-  
3 tection of rapid response to, and management of, po-  
4 tentially catastrophic infectious disease outbreaks  
5 and other public health emergencies that originate  
6 domestically or abroad. Such network shall be built  
7 on existing State situational awareness systems or  
8 enhanced systems that enable such connectivity.

9 “(2) STRATEGIC PLAN.—Not later than 180  
10 days after the date of enactment the Pandemic and  
11 All-Hazards Preparedness Act, the Secretary shall  
12 submit to the appropriate committees of Congress, a  
13 strategic plan that demonstrates the steps the Sec-  
14 retary will undertake to develop, implement, and  
15 evaluate the network described in paragraph (1), uti-  
16 lizing the elements described in paragraph (3).

17 “(3) ELEMENTS.—The network described in  
18 paragraph (1) shall include data and information  
19 transmitted in a standardized format from—

20 “(A) State, local, and tribal public health  
21 entities, including public health laboratories;

22 “(B) Federal health agencies;

23 “(C) zoonotic disease monitoring systems;

24 “(D) public and private sector health care  
25 entities, hospitals, pharmacies, poison control

1 centers or professional organizations in the field  
2 of poison control, and clinical laboratories, to  
3 the extent practicable and provided that such  
4 data are voluntarily provided simultaneously to  
5 the Secretary and appropriate State, local, and  
6 tribal public health agencies; and

7 “(E) such other sources as the Secretary  
8 may deem appropriate.

9 “(4) RULE OF CONSTRUCTION.—Paragraph (3)  
10 shall not be construed as requiring separate report-  
11 ing of data and information from each source listed.

12 “(5) REQUIRED ACTIVITIES.—In establishing  
13 and operating the network described in paragraph  
14 (1), the Secretary shall—

15 “(A) utilize applicable interoperability  
16 standards as determined by the Secretary  
17 through a joint public and private sector proc-  
18 ess;

19 “(B) define minimal data elements for  
20 such network;

21 “(C) in collaboration with State, local, and  
22 tribal public health officials, integrate and build  
23 upon existing State, local, and tribal capabili-  
24 ties, ensuring simultaneous sharing of data, in-  
25 formation, and analyses from the network de-

1           scribed in paragraph (1) with State, local, and  
2           tribal public health agencies; and

3           “(D) in collaboration with State, local, and  
4           tribal public health officials, develop procedures  
5           and standards for the collection, analysis, and  
6           interpretation of data that States, regions, or  
7           other entities collect and report to the network  
8           described in paragraph (1).

9           “(e) STATE AND REGIONAL SYSTEMS TO ENHANCE  
10          SITUATIONAL AWARENESS IN PUBLIC HEALTH EMER-  
11          GENCIES.—

12           “(1) IN GENERAL.—To implement the network  
13          described in subsection (d), the Secretary may award  
14          grants to States or consortia of States to enhance  
15          the ability of such States or consortia of States to  
16          establish or operate a coordinated public health situ-  
17          ational awareness system for regional or Statewide  
18          early detection of, rapid response to, and manage-  
19          ment of potentially catastrophic infectious disease  
20          outbreaks and public health emergencies, in collabo-  
21          ration with appropriate public health agencies, sen-  
22          tinel hospitals, clinical laboratories, pharmacies, poi-  
23          son control centers, other health care organizations,  
24          and animal health organizations within such States.

1           “(2) ELIGIBILITY.—To be eligible to receive a  
2 grant under paragraph (1), the State or consortium  
3 of States shall submit to the Secretary an applica-  
4 tion at such time, in such manner, and containing  
5 such information as the Secretary may require, in-  
6 cluding an assurance that the State or consortium of  
7 States will submit to the Secretary—

8                   “(A) reports of such data, information,  
9 and metrics as the Secretary may require;

10                   “(B) a report on the effectiveness of the  
11 systems funded under the grant; and

12                   “(C) a description of the manner in which  
13 grant funds will be used to enhance the  
14 timelines and comprehensiveness of efforts to  
15 detect, respond to, and manage potentially cata-  
16 strophic infectious disease outbreaks and public  
17 health emergencies.

18           “(3) USE OF FUNDS.—A State or consortium of  
19 States that receives an award under this  
20 subsection—

21                   “(A) shall establish, enhance, or operate a  
22 coordinated public health situational awareness  
23 system for regional or Statewide early detection  
24 of, rapid response to, and management of po-

1 tentially catastrophic infectious disease out-  
2 breaks and public health emergencies;

3 “(B) may award grants or contracts to en-  
4 tities described in paragraph (1) within or serv-  
5 ing such State to assist such entities in improv-  
6 ing the operation of information technology sys-  
7 tems, facilitating the secure exchange of data  
8 and information, and training personnel to en-  
9 hance the operation of the system described in  
10 subparagraph (A); and

11 “(C) may conduct a pilot program for the  
12 development of multi-State telehealth network  
13 test beds that build on, enhance, and securely  
14 link existing State and local telehealth pro-  
15 grams to prepare for, monitor, respond to, and  
16 manage the events of public health emergencies,  
17 facilitate coordination and communication  
18 among medical, public health, and emergency  
19 response agencies, and provide medical services  
20 through telehealth initiatives within the States  
21 that are involved in such a multi-State tele-  
22 health network test bed.

23 “(4) LIMITATION.—Information technology sys-  
24 tems acquired or implemented using grants awarded  
25 under this section must be compliant with—

1           “(A) interoperability and other techno-  
2           logical standards, as determined by the Sec-  
3           retary; and

4           “(B) data collection and reporting require-  
5           ments for the network described in subsection  
6           (d).

7           “(5) INDEPENDENT EVALUATION.—Not later  
8           than 4 years after the date of enactment of the Pan-  
9           demic and All-Hazards Preparedness Act, the Gov-  
10          ernment Accountability Office shall conduct an inde-  
11          pendent evaluation, and submit to the Secretary and  
12          the appropriate committees of Congress a report  
13          concerning the activities conducted under this sub-  
14          section and subsection (d).

15          “(f) TELEHEALTH ENHANCEMENTS FOR EMER-  
16          GENCY RESPONSE.—

17                 “(1) EVALUATION.—The Secretary, in consulta-  
18                 tion with the Federal Communications Commission  
19                 and other relevant Federal agencies, shall—

20                         “(A) conduct an inventory of telehealth ini-  
21                         tiatives in existence on the date of enactment of  
22                         the Pandemic and All-Hazards Preparedness  
23                         Act, including—

24                                 “(i) the specific location of network  
25                                 components;

1           “(ii) the medical, technological, and  
2           communications capabilities of such com-  
3           ponents;

4           “(iii) the functionality of such compo-  
5           nents; and

6           “(iv) the capacity and ability of such  
7           components to handle increased volume  
8           during the response to a public health  
9           emergency;

10          “(B) identify methods to expand and inter-  
11          connect the regional health information net-  
12          works funded by the Secretary, the State and  
13          regional broadband networks funded through  
14          the rural health care support mechanism pilot  
15          program funded by the Federal Communica-  
16          tions Commission, and other telehealth net-  
17          works;

18          “(C) evaluate ways to prepare for, monitor,  
19          respond rapidly to, or manage the events of, a  
20          public health emergency through the enhanced  
21          use of telehealth technologies, including mecha-  
22          nisms for payment or reimbursement for use of  
23          such technologies and personnel during public  
24          health emergencies;

1           “(D) identify methods for reducing legal  
2           barriers that deter health care professionals  
3           from providing telemedicine services, such as by  
4           utilizing State emergency health care profes-  
5           sional credentialing verification systems, en-  
6           couraging States to establish and implement  
7           mechanisms to improve interstate medical licen-  
8           sure cooperation, facilitating the exchange of in-  
9           formation among States regarding investiga-  
10          tions and adverse actions, and encouraging  
11          States to waive the application of licensing re-  
12          quirements during a public health emergency;

13           “(E) evaluate ways to integrate the prac-  
14          tice of telemedicine within the National Dis-  
15          aster Medical System; and

16           “(F) promote greater coordination among  
17          existing Federal interagency telemedicine and  
18          health information technology initiatives.

19          “(2) REPORT.—Not later than 12 months after  
20          the date of enactment of the Pandemic and All-Haz-  
21          ards Preparedness Act, the Secretary shall prepare  
22          and submit a report to the Committee on Health,  
23          Education, Labor, and Pensions of the Senate and  
24          the Committee on Energy and Commerce of the  
25          House of Representatives regarding the findings and

1 recommendations pursuant to subparagraphs (A)  
2 through (F) of paragraph (1).

3 “(g) AUTHORIZATION OF APPROPRIATIONS.—There  
4 are authorized to be appropriated to carry out this section,  
5 such sums as may be necessary in each of fiscal years  
6 2007 through 2011.”.

7 **SEC. 203. PUBLIC HEALTH WORKFORCE ENHANCEMENTS.**

8 (a) DEMONSTRATION PROJECT.—Subpart III of part  
9 D of title III of the Public Health Service Act (42 U.S.C.  
10 2541) is amended by adding at the end the following:

11 **“SEC. 338M. PUBLIC HEALTH DEPARTMENTS.**

12 “(a) IN GENERAL.—To the extent that funds are ap-  
13 propriated under subsection (e), the Secretary shall estab-  
14 lish a demonstration project to provide for the participa-  
15 tion of individuals who are eligible for the Loan Repay-  
16 ment Program described in section 338B and who agree  
17 to complete their service obligation in a State health de-  
18 partment that provides a significant amount of service to  
19 health professional shortage areas or areas at risk of a  
20 public health emergency, as determined by the Secretary,  
21 or in a local or tribal health department that serves a  
22 health professional shortage area or an area at risk of a  
23 public health emergency.

1       “(b) PROCEDURE.—To be eligible to receive assist-  
2       ance under subsection (a), with respect to the program  
3       described in section 338B, an individual shall—

4               “(1) comply with all rules and requirements de-  
5       scribed in such section (other than section  
6       338B(f)(1)(B)(iv)); and

7               “(2) agree to serve for a time period equal to  
8       2 years, or such longer period as the individual may  
9       agree to, in a State, local, or tribal health depart-  
10      ment, described in subsection (a).

11      “(c) DESIGNATIONS.—The demonstration project de-  
12      scribed in subsection (a), and any healthcare providers  
13      who are selected to participate in such project, shall not  
14      be considered by the Secretary in the designation of health  
15      professional shortage areas under section 332 during fis-  
16      cal years 2007 through 2010.

17      “(d) REPORT.—Not later than 3 years after the date  
18      of enactment of this section, the Secretary shall submit  
19      a report to the relevant committees of Congress that eval-  
20      uates the participation of individuals in the demonstration  
21      project under subsection (a), the impact of such participa-  
22      tion on State, local, and tribal health departments, and  
23      the benefit and feasibility of permanently allowing such  
24      placements in the Loan Repayment Program.

1       “(e) AUTHORIZATION OF APPROPRIATIONS.—There  
2 are authorized to be appropriated to carry out this section,  
3 such sums as may be necessary for each of fiscal years  
4 2007 through 2010.”.

5       (b) GRANTS FOR LOAN REPAYMENT PROGRAM.—  
6 Section 338I of the Public Health Service Act (42 U.S.C.  
7 254q-1) is amended by adding at the end the following:

8       “(j) PUBLIC HEALTH LOAN REPAYMENT.—

9               “(1) IN GENERAL.—The Secretary may award  
10 grants to States for the purpose of assisting such  
11 States in operating loan repayment programs under  
12 which such States enter into contracts to repay all  
13 or part of the eligible loans borrowed by, or on be-  
14 half of, individuals who agree to serve in State, local,  
15 or tribal health departments that serve health pro-  
16 fessional shortage areas or other areas at risk of a  
17 public health emergency, as designated by the Sec-  
18 retary.

19               “(2) LOANS ELIGIBLE FOR REPAYMENT.—To  
20 be eligible for repayment under this subsection, a  
21 loan shall be a loan made, insured, or guaranteed by  
22 the Federal Government that is borrowed by, or on  
23 behalf of, an individual to pay the cost of attendance  
24 for a program of education leading to a degree ap-  
25 appropriate for serving in a State, local, or tribal

1 health department as determined by the Secretary  
2 and the chief executive officer of the State in which  
3 the grant is administered, at an institution of higher  
4 education (as defined in section 102 of the Higher  
5 Education Act of 1965), including principal, inter-  
6 est, and related expenses on such loan.

7 “(3) APPLICABILITY OF EXISTING REQUIRE-  
8 MENTS.—With respect to awards made under para-  
9 graph (1)—

10 “(A) the requirements of subsections (b),  
11 (f), and (g) shall apply to such awards; and

12 “(B) the requirements of subsection (c)  
13 shall apply to such awards except that with re-  
14 spect to paragraph (1) of such subsection, the  
15 State involved may assign an individual only to  
16 public and nonprofit private entities that serve  
17 health professional shortage areas or areas at  
18 risk of a public health emergency, as deter-  
19 mined by the Secretary.

20 “(4) AUTHORIZATION OF APPROPRIATIONS.—

21 There are authorized to be appropriated to carry out  
22 this subsection, such sums as may be necessary for  
23 each of fiscal years 2007 through 2010.”

1 **SEC. 204. VACCINE TRACKING AND DISTRIBUTION.**

2 (a) IN GENERAL.—Section 319A of the Public  
3 Health Service Act (42 U.S.C. 247d–1) is amended to  
4 read as follows:

5 **“SEC. 319A. VACCINE TRACKING AND DISTRIBUTION.**

6 “(a) TRACKING.—The Secretary, together with rel-  
7 evant manufacturers, wholesalers, and distributors as may  
8 agree to cooperate, may track the initial distribution of  
9 federally purchased influenza vaccine in an influenza pan-  
10 demic. Such tracking information shall be used to inform  
11 Federal, State, local, and tribal decision makers during  
12 an influenza pandemic.

13 “(b) DISTRIBUTION.—The Secretary shall promote  
14 communication between State, local, and tribal public  
15 health officials and such manufacturers, wholesalers, and  
16 distributors as agree to participate, regarding the effective  
17 distribution of seasonal influenza vaccine. Such commu-  
18 nication shall include estimates of high priority popu-  
19 lations, as determined by the Secretary, in State, local,  
20 and tribal jurisdictions in order to inform Federal, State,  
21 local, and tribal decision makers during vaccine shortages  
22 and supply disruptions.

23 “(c) CONFIDENTIALITY.—The information submitted  
24 to the Secretary or its contractors, if any, under this sec-  
25 tion or under any other section of this Act related to vac-  
26 cine distribution information shall remain confidential in

1 accordance with the exception from the public disclosure  
2 of trade secrets, commercial or financial information, and  
3 information obtained from an individual that is privileged  
4 and confidential, as provided for in section 552(b)(4) of  
5 title 5, United States Code, and subject to the penalties  
6 and exceptions under sections 1832 and 1833 of title 18,  
7 United States Code, relating to the protection and theft  
8 of trade secrets, and subject to privacy protections that  
9 are consistent with the regulations promulgated under sec-  
10 tion 264(c) of the Health Insurance Portability and Ac-  
11 countability Act of 1996. None of such information pro-  
12 vided by a manufacturer, wholesaler, or distributor shall  
13 be disclosed without its consent to another manufacturer,  
14 wholesaler, or distributor, or shall be used in any manner  
15 to give a manufacturer, wholesaler, or distributor a propri-  
16 etary advantage.

17       “(d) GUIDELINES.—The Secretary, in order to main-  
18 tain the confidentiality of relevant information and ensure  
19 that none of the information contained in the systems in-  
20 volved may be used to provide proprietary advantage with-  
21 in the vaccine market, while allowing State, local, and trib-  
22 al health officials access to such information to maximize  
23 the delivery and availability of vaccines to high priority  
24 populations, during times of influenza pandemics, vaccine  
25 shortages, and supply disruptions, in consultation with

1 manufacturers, distributors, wholesalers and State, local,  
 2 and tribal health departments, shall develop guidelines for  
 3 subsections (a) and (b).

4 “(e) AUTHORIZATION OF APPROPRIATIONS.—There  
 5 are authorized to be appropriated to carry out this section,  
 6 such sums for each of fiscal years 2007 through 2011.

7 “(f) REPORT TO CONGRESS.—As part of the National  
 8 Health Security Strategy described in section 2802, the  
 9 Secretary shall provide an update on the implementation  
 10 of subsections (a) through (d).”.

11 (b) CONFORMING AMENDMENTS.—

12 (1) IN GENERAL.—Title III of the Public  
 13 Health Service Act (42 U.S.C. 241 et seq.) is  
 14 amended by striking sections 319B and 319C.

15 (2) TECHNICAL AMENDMENT.—Section  
 16 319D(a)(3) of the Public Health Service Act (42  
 17 U.S.C. 247d–4(a)(3)) is amended by striking “, tak-  
 18 ing into account evaluations under section  
 19 319B(a).”.

20 **SEC. 205. NATIONAL SCIENCE ADVISORY BOARD FOR BIO-**  
 21 **SECURITY.**

22 The National Science Advisory Board for Biosecurity  
 23 shall, when requested by the Secretary of Health and  
 24 Human Services, provide to relevant Federal departments

1 and agencies, advice, guidance, or recommendations  
2 concerning—

3           (1) a core curriculum and training requirements  
4           for workers in maximum containment biological lab-  
5           oratories; and

6           (2) periodic evaluations of maximum contain-  
7           ment biological laboratory capacity nationwide and  
8           assessments of the future need for increased labora-  
9           tory capacity.

10 **SEC. 206. REVITALIZATION OF COMMISSIONED CORPS.**

11           (a) **PURPOSE.**—It is the purpose of this section to  
12 improve the force management and readiness of the Com-  
13 missioned Corps to accomplish the following objectives:

14           (1) To ensure the Corps is ready to respond  
15 rapidly to urgent or emergency public health care  
16 needs and challenges.

17           (2) To ensure the availability of the Corps for  
18 assignments that address clinical and public health  
19 needs in isolated, hardship, and hazardous duty po-  
20 sitions, and, when required, to address needs related  
21 to the well-being, security, and defense of the United  
22 States.

23           (3) To establish the Corps as a resource avail-  
24 able to Federal and State Government agencies for

1 assistance in meeting public health leadership and  
2 service roles.

3 (b) COMMISSIONED CORPS READINESS.—Title II of  
4 the Public Health Service Act (42 U.S.C. 202 et seq.) is  
5 amended by inserting after section 203 the following:

6 **“SEC. 203A. DEPLOYMENT READINESS.**

7 “(a) READINESS REQUIREMENTS FOR COMMIS-  
8 SIONED CORPS OFFICERS.—

9 “(1) IN GENERAL.—The Secretary, with respect  
10 to members of the following Corps components, shall  
11 establish requirements, including training and med-  
12 ical examinations, to ensure the readiness of such  
13 components to respond to urgent or emergency pub-  
14 lic health care needs that cannot otherwise be met  
15 at the Federal, State, and local levels:

16 “(A) Active duty Regular Corps.

17 “(B) Active Reserves.

18 “(2) ANNUAL ASSESSMENT OF MEMBERS.—The  
19 Secretary shall annually determine whether each  
20 member of the Corps meets the applicable readiness  
21 requirements established under paragraph (1).

22 “(3) FAILURE TO MEET REQUIREMENTS.—A  
23 member of the Corps who fails to meet or maintain  
24 the readiness requirements established under para-  
25 graph (1) or who fails to comply with orders to re-

1       spond to an urgent or emergency public health care  
2       need shall, except as provided in paragraph (4), in  
3       accordance with procedures established by the Sec-  
4       retary, be subject to disciplinary action as prescribed  
5       by the Secretary.

6               “(4) WAIVER OF REQUIREMENTS.—

7                       “(A) IN GENERAL.—The Secretary may  
8       waive one or more of the requirements estab-  
9       lished under paragraph (1) for an individual  
10      who is not able to meet such requirements be-  
11      cause of—

12                      “(i) a disability;

13                      “(ii) a temporary medical condition;

14                      or

15                      “(iii) any other extraordinary limita-  
16      tion as determined by the Secretary.

17                      “(B) REGULATIONS.—The Secretary shall  
18      promulgate regulations under which a waiver  
19      described in subparagraph (A) may be granted.

20               “(5) URGENT OR EMERGENCY PUBLIC HEALTH  
21      CARE NEED.—For purposes of this section and sec-  
22      tion 214, the term ‘urgent or emergency public  
23      health care need’ means a health care need, as de-  
24      termined by the Secretary, arising as the result of—

1           “(A) a national emergency declared by the  
2           President under the National Emergencies Act  
3           (50 U.S.C. 1601 et seq.);

4           “(B) an emergency or major disaster de-  
5           clared by the President under the Robert T.  
6           Stafford Disaster Relief and Emergency Assist-  
7           ance Act (42 U.S.C. 5121 et seq.);

8           “(C) a public health emergency declared by  
9           the Secretary under section 319 of this Act; or

10          “(D) any emergency that, in the judgment  
11          of the Secretary, is appropriate for the deploy-  
12          ment of members of the Corps.

13          “(b) CORPS MANAGEMENT FOR DEPLOYMENT.—The  
14          Secretary shall—

15               “(1) organize members of the Corps into units  
16               for rapid deployment by the Secretary to respond to  
17               urgent or emergency public health care needs;

18               “(2) establish appropriate procedures for the  
19               command and control of units or individual members  
20               of the Corps that are deployed at the direction of the  
21               President or the Secretary in response to an urgent  
22               or emergency public health care need of national,  
23               State or local significance;

24               “(3) ensure that members of the Corps are  
25               trained, equipped and otherwise prepared to fulfill

1 their public health and emergency response roles;  
2 and

3 “(4) ensure that deployment planning takes  
4 into account—

5 “(A) any deployment exemptions that may  
6 be granted by the Secretary based on the  
7 unique requirements of an agency and an indi-  
8 vidual’s functional role in such agency; and

9 “(B) the nature of the urgent or emer-  
10 gency public health care need.

11 “(c) DEPLOYMENT OF DETAILED OR ASSIGNED OF-  
12 FICERS.—For purposes of pay, allowances, and benefits  
13 of a Commissioned Corps officer who is detailed or as-  
14 signed to a Federal entity, the deployment of such officer  
15 by the Secretary in response to an urgent or emergency  
16 public health care need shall be deemed to be an author-  
17 ized activity of the Federal entity to which the officer is  
18 detailed or assigned.”.

19 (c) PERSONNEL DEPLOYMENT AUTHORITY.—

20 (1) PERSONNEL DETAILED.—Section 214 of  
21 the Public Health Service Act (42 U.S.C. 215) is  
22 amended by adding at the end the following:

23 “(e) Except with respect to the United States Coast  
24 Guard and the Department of Defense, and except as pro-  
25 vided in agreements negotiated with officials at agencies

1 where officers of the Commissioned Corps may be as-  
2 signed, the Secretary shall have the sole authority to de-  
3 ploy any Commissioned Corps officer assigned under this  
4 section to an entity outside of the Department of Health  
5 and Human Services for service under the Secretary’s di-  
6 rection in response to an urgent or emergency public  
7 health care need (as defined in section 203A(a)(5)).”.

8           (2) NATIONAL HEALTH SERVICE CORPS.—Sec-  
9 tion 331(f) of the Public Health Service Act (42  
10 U.S.C. 254d(f)(1)) is amended by inserting before  
11 the period the following: “, except when such mem-  
12 bers are Commissioned Corps officers who entered  
13 into a contract with Secretary under section 338A or  
14 338B after December 31, 2006 and when the Sec-  
15 retary determines that exercising the authority pro-  
16 vided under section 214 or 216 with respect to any  
17 such officer to would not cause unreasonable interrup-  
18 tion to health care services provided in the commu-  
19 nity in which such officer is providing health care  
20 services”.

## 21           **TITLE III—ALL-HAZARDS** 22           **MEDICAL SURGE CAPACITY**

### 23           **SEC. 301. NATIONAL DISASTER MEDICAL SYSTEM.**

24           (a) NATIONAL DISASTER MEDICAL SYSTEM.—Sec-  
25 tion 2812 of subtitle B of title XXVIII of the Public

1 Health Service Act (42 U.S.C. 300hh–11 et seq.), as re-  
2 designated by section 102, is amended—

3 (1) by striking the section heading and insert-  
4 ing “**NATIONAL DISASTER MEDICAL SYSTEM**”;

5 (2) by striking subsection (a);

6 (3) by redesignating subsections (b) through (h)  
7 as subsections (a) through (g);

8 (4) in subsection (a), as so redesignated—

9 (A) in paragraph (2)(B), by striking “Fed-  
10 eral Emergency Management Agency” and in-  
11 sserting “Department of Homeland Security”;  
12 and

13 (B) in paragraph (3)(C), by striking “Pub-  
14 lic Health Security and Bioterrorism Prepared-  
15 ness and Response Act of 2002” and inserting  
16 “Pandemic and All-Hazards Preparedness Act”;

17 (5) in subsection (b), as so redesignated, by—

18 (A) striking the subsection heading and in-  
19 sserting “MODIFICATIONS”;

20 (B) redesignating paragraph (2) as para-  
21 graph (3); and

22 (C) striking paragraph (1) and inserting  
23 the following:

24 “(1) IN GENERAL.—Taking into account the  
25 findings from the joint review described under para-

1 graph (2), the Secretary shall modify the policies of  
2 the National Disaster Medical System as necessary.

3 “(2) JOINT REVIEW AND MEDICAL SURGE CA-  
4 PACITY STRATEGIC PLAN.—Not later than 180 days  
5 after the date of enactment of the Pandemic and  
6 All-Hazards Preparedness Act, the Secretary, in co-  
7 ordination with the Secretary of Homeland Security,  
8 the Secretary of Defense, and the Secretary of Vet-  
9 erans Affairs, shall conduct a joint review of the Na-  
10 tional Disaster Medical System. Such review shall  
11 include an evaluation of medical surge capacity, as  
12 described by section 2803(a). As part of the Na-  
13 tional Health Security Strategy under section 2802,  
14 the Secretary shall update the findings from such re-  
15 view and further modify the policies of the National  
16 Disaster Medical System as necessary.”;

17 (6) by striking “subsection (b)” each place it  
18 appears and inserting “subsection (a)”;

19 (7) by striking “subsection (d)” each place it  
20 appears and inserting “subsection (c)”;

21 (8) in subsection (g), as so redesignated, by  
22 striking “2002 through 2006” and inserting “2007  
23 through 2011”.

24 (b) TRANSFER OF NATIONAL DISASTER MEDICAL  
25 SYSTEM TO THE DEPARTMENT OF HEALTH AND HUMAN

1 SERVICES.—There shall be transferred to the Secretary  
2 of Health and Human Services the functions, personnel,  
3 assets, and liabilities of the National Disaster Medical  
4 System of the Department of Homeland Security, includ-  
5 ing the functions of the Secretary of Homeland Security  
6 and the Under Secretary for Emergency Preparedness and  
7 Response relating thereto.

8 (c) CONFORMING AMENDMENTS TO THE HOMELAND  
9 SECURITY ACT OF 2002.—The Homeland Security Act of  
10 2002 (6 U.S.C. 312(3)(B), 313(5)) is amended—

11 (1) in section 502(3)(B), by striking “, the Na-  
12 tional Disaster Medical System,”; and

13 (2) in section 503(5), by striking “, the Na-  
14 tional Disaster Medical System”.

15 (d) UPDATE OF CERTAIN PROVISION.—Section  
16 319F(b)(2) of the Public Health Service Act (42 U.S.C.  
17 247d–6(b)(2)) is amended—

18 (1) in the paragraph heading, by striking  
19 “CHILDREN AND TERRORISM” and inserting “AT-  
20 RISK INDIVIDUALS AND PUBLIC HEALTH EMER-  
21 GENCIES”;

22 (2) in subparagraph (A), by striking “Children  
23 and Terrorism” and inserting “At-Risk Individuals  
24 and Public Health Emergencies”;

25 (3) in subparagraph (B)—

1 (A) in clause (i), by striking “bioterrorism  
2 as it relates to children” and inserting “public  
3 health emergencies as they relate to at-risk in-  
4 dividuals”;

5 (B) in clause (ii), by striking “children”  
6 and inserting “at-risk individuals”; and

7 (C) in clause (iii), by striking “children”  
8 and inserting “at-risk individuals”;

9 (4) in subparagraph (C), by striking “children”  
10 and all that follows through the period and inserting  
11 “at-risk populations.”; and

12 (5) in subparagraph (D), by striking “one  
13 year” and inserting “six years”.

14 (e) CONFORMING AMENDMENT.—Section  
15 319F(b)(3)(B) of the Public Health Service Act (42  
16 U.S.C. 247d–6(b)(3)(B)) is amended by striking “and the  
17 working group under subsection (a)”.

18 (f) EFFECTIVE DATE.—The amendments made by  
19 subsections (b) and (c) shall take effect on January 1,  
20 2007.

21 **SEC. 302. ENHANCING MEDICAL SURGE CAPACITY.**

22 (a) IN GENERAL.—Title XXVIII of the Public Health  
23 Service Act (300hh–11 et seq.), as amended by section  
24 103, is amended by inserting after section 2802 the fol-  
25 lowing:

1 **“SEC. 2803. ENHANCING MEDICAL SURGE CAPACITY.**

2       “(a) STUDY OF ENHANCING MEDICAL SURGE CA-  
3 PACITY.—As part of the joint review described in section  
4 2812(b), the Secretary shall evaluate the benefits and fea-  
5 sibility of improving the capacity of the Department of  
6 Health and Human Services to provide additional medical  
7 surge capacity to local communities in the event of a pub-  
8 lic health emergency. Such study shall include an assess-  
9 ment of the need for and feasibility of improving surge  
10 capacity through—

11           “(1) acquisition and operation of mobile med-  
12 ical assets by the Secretary to be deployed, on a con-  
13 tingency basis, to a community in the event of a  
14 public health emergency;

15           “(2) integrating the practice of telemedicine  
16 within the National Disaster Medical System; and

17           “(3) other strategies to improve such capacity  
18 as determined appropriate by the Secretary.

19       “(b) AUTHORITY TO ACQUIRE AND OPERATE MO-  
20 BILE MEDICAL ASSETS.—In addition to any other author-  
21 ity to acquire, deploy, and operate mobile medical assets,  
22 the Secretary may acquire, deploy, and operate mobile  
23 medical assets if, taking into consideration the evaluation  
24 conducted under subsection (a), such acquisition, deploy-  
25 ment, and operation is determined to be beneficial and fea-  
26 sible in improving the capacity of the Department of

1 Health and Human Services to provide additional medical  
2 surge capacity to local communities in the event of a pub-  
3 lic health emergency.

4 “(c) USING FEDERAL FACILITIES TO ENHANCE  
5 MEDICAL SURGE CAPACITY.—

6 “(1) ANALYSIS.—The Secretary shall conduct  
7 an analysis of whether there are Federal facilities  
8 which, in the event of a public health emergency,  
9 could practicably be used as facilities in which to  
10 provide health care.

11 “(2) MEMORANDA OF UNDERSTANDING.—If,  
12 based on the analysis conducted under paragraph  
13 (1), the Secretary determines that there are Federal  
14 facilities which, in the event of a public health emer-  
15 gency, could be used as facilities in which to provide  
16 health care, the Secretary shall, with respect to each  
17 such facility, seek to conclude a memorandum of un-  
18 derstanding with the head of the Department or  
19 agency that operates such facility that permits the  
20 use of such facility to provide health care in the  
21 event of a public health emergency.”.

22 (b) EMTALA.—

23 (1) IN GENERAL.—Section 1135(b) of the So-  
24 cial Security Act (42 U.S.C. 1320b–5(b)) is  
25 amended—

1 (A) in paragraph (3), by striking subpara-  
2 graph (B) and inserting the following:

3 “(B) the direction or relocation of an indi-  
4 vidual to receive medical screening in an alter-  
5 native location—

6 “(i) pursuant to an appropriate State  
7 emergency preparedness plan; or

8 “(ii) in the case of a public health  
9 emergency described in subsection  
10 (g)(1)(B) that involves a pandemic infec-  
11 tious disease, pursuant to a State pan-  
12 demic preparedness plan or a plan referred  
13 to in clause (i), whichever is applicable in  
14 the State;”;

15 (B) in the third sentence, by striking “and  
16 shall be limited to” and inserting “and, except  
17 in the case of a waiver or modification to which  
18 the fifth sentence of this subsection applies,  
19 shall be limited to”; and

20 (C) by adding at the end the following: “If  
21 a public health emergency described in sub-  
22 section (g)(1)(B) involves a pandemic infectious  
23 disease (such as pandemic influenza), the dura-  
24 tion of a waiver or modification under para-  
25 graph (3) shall be determined in accordance

1 with subsection (e) as such subsection applies  
2 to public health emergencies.”.

3 (2) EFFECTIVE DATE.—The amendments made  
4 by paragraph (1) shall take effect on the date of the  
5 enactment of this Act and shall apply to public  
6 health emergencies declared pursuant to section 319  
7 of the Public Health Service Act (42 U.S.C. 247d)  
8 on or after such date.

9 **SEC. 303. ENCOURAGING HEALTH PROFESSIONAL VOLUN-**  
10 **TEERS.**

11 (a) VOLUNTEER MEDICAL RESERVE CORPS.—Title  
12 XXVIII of the Public Health Service Act (42 U.S.C.  
13 300hh–11 et seq.), as amended by this Act, is amended  
14 by inserting after section 2812 the following:

15 **“SEC. 2813. VOLUNTEER MEDICAL RESERVE CORPS.**

16 “(a) IN GENERAL.—Not later than 180 days after  
17 the date of enactment of the Pandemic and All-Hazards  
18 Preparedness Act, the Secretary, in collaboration with  
19 State, local, and tribal officials, shall build on State, local,  
20 and tribal programs in existence on the date of enactment  
21 of such Act to establish and maintain a Medical Reserve  
22 Corps (referred to in this section as the ‘Corps’) to provide  
23 for an adequate supply of volunteers in the case of a Fed-  
24 eral, State, local, or tribal public health emergency. The  
25 Corps shall be headed by a Director who shall be ap-

1 pointed by the Secretary and shall oversee the activities  
2 of the Corps chapters that exist at the State, local, and  
3 tribal levels.

4 “(b) STATE, LOCAL, AND TRIBAL COORDINATION.—  
5 The Corps shall be established using existing State, local,  
6 and tribal teams and shall not alter such teams.

7 “(c) COMPOSITION.—The Corps shall be composed of  
8 individuals who—

9 “(1)(A) are health professionals who have ap-  
10 propriate professional training and expertise as de-  
11 termined appropriate by the Director of the Corps;  
12 or

13 “(B) are non-health professionals who have an  
14 interest in serving in an auxiliary or support capac-  
15 ity to facilitate access to health care services in a  
16 public health emergency;

17 “(2) are certified in accordance with the certifi-  
18 cation program developed under subsection (d);

19 “(3) are geographically diverse in residence;

20 “(4) have registered and carry out training ex-  
21 ercises with a local chapter of the Medical Reserve  
22 Corps; and

23 “(5) indicate whether they are willing to be de-  
24 ployed outside the area in which they reside in the  
25 event of a public health emergency.

1 “(d) CERTIFICATION; DRILLS.—

2 “(1) CERTIFICATION.—The Director, in collabo-  
3 ration with State, local, and tribal officials, shall es-  
4 tablish a process for the periodic certification of in-  
5 dividuals who volunteer for the Corps, as determined  
6 by the Secretary, which shall include the completion  
7 by each individual of the core training programs de-  
8 veloped under section 319F, as required by the Di-  
9 rector. Such certification shall not supercede State  
10 licensing or credentialing requirements.

11 “(2) DRILLS.—In conjunction with the core  
12 training programs referred to in paragraph (1), and  
13 in order to facilitate the integration of trained volun-  
14 teers into the health care system at the local level,  
15 Corps members shall engage in periodic training ex-  
16 ercises to be carried out at the local level.

17 “(e) DEPLOYMENT.—During a public health emer-  
18 gency, the Secretary shall have the authority to activate  
19 and deploy willing members of the Corps to areas of need,  
20 taking into consideration the public health and medical ex-  
21 pertise required, with the concurrence of the State, local,  
22 or tribal officials from the area where the members reside.

23 “(f) EXPENSES AND TRANSPORTATION.—While en-  
24 gaged in performing duties as a member of the Corps pur-  
25 suant to an assignment by the Secretary (including peri-

1 ods of travel to facilitate such assignment), members of  
2 the Corps who are not otherwise employed by the Federal  
3 Government shall be allowed travel or transportation ex-  
4 penses, including per diem in lieu of subsistence.

5 “(g) IDENTIFICATION.—The Secretary, in coopera-  
6 tion and consultation with the States, shall develop a Med-  
7 ical Reserve Corps Identification Card that describes the  
8 licensure and certification information of Corps members,  
9 as well as other identifying information determined nec-  
10 essary by the Secretary.

11 “(h) INTERMITTENT DISASTER-RESPONSE PER-  
12 SONNEL.—

13 “(1) IN GENERAL.—For the purpose of assist-  
14 ing the Corps in carrying out duties under this sec-  
15 tion, during a public health emergency, the Sec-  
16 retary may appoint selected individuals to serve as  
17 intermittent personnel of such Corps in accordance  
18 with applicable civil service laws and regulations. In  
19 all other cases, members of the Corps are subject to  
20 the laws of the State in which the activities of the  
21 Corps are undertaken.

22 “(2) APPLICABLE PROTECTIONS.—Subsections  
23 (c)(2), (d), and (e) of section 2812 shall apply to an  
24 individual appointed under paragraph (1) in the

1 same manner as such subsections apply to an indi-  
2 vidual appointed under section 2812(e).

3 “(3) LIMITATION.—State, local, and tribal offi-  
4 cials shall have no authority to designate a member  
5 of the Corps as Federal intermittent disaster-re-  
6 sponse personnel, but may request the services of  
7 such members.

8 “(i) AUTHORIZATION OF APPROPRIATIONS.—There is  
9 authorized to be appropriated to carry out this section,  
10 \$22,000,000 for fiscal year 2007, and such sums as may  
11 be necessary for each of fiscal years 2008 through 2011.”.

12 (b) ENCOURAGING HEALTH PROFESSIONS VOLUN-  
13 TEERS.—Section 319I of the Public Health Service Act  
14 (42 U.S.C. 247d–7b) is amended—

15 (1) by redesignating subsections (e) and (f) as  
16 subsections (j) and (k), respectively;

17 (2) by striking subsections (a) and (b) and in-  
18 sserting the following:

19 “(a) IN GENERAL.—Not later than 12 months after  
20 the date of enactment of the Pandemic and All-Hazards  
21 Preparedness Act, the Secretary shall link existing State  
22 verification systems to maintain a single national inter-  
23 operable network of systems, each system being main-  
24 tained by a State or group of States, for the purpose of  
25 verifying the credentials and licenses of health care profes-

1 sionals who volunteer to provide health services during a  
2 public health emergency.

3 “(b) REQUIREMENTS.—The interoperable network of  
4 systems established under subsection (a) (referred to in  
5 this section as the ‘verification network’) shall include—

6 “(1) with respect to each volunteer health pro-  
7 fessional included in the verification network—

8 “(A) information necessary for the rapid  
9 identification of, and communication with, such  
10 professionals; and

11 “(B) the credentials, certifications, li-  
12 censes, and relevant training of such individ-  
13 uals; and

14 “(2) the name of each member of the Medical  
15 Reserve Corps, the National Disaster Medical Sys-  
16 tem, and any other relevant federally-sponsored or  
17 administered programs determined necessary by the  
18 Secretary.”;

19 (3) in subsection (c), strike “system” and insert  
20 “network”; and

21 (4) by striking subsection (d) and inserting the  
22 following:

23 “(d) ACCESSIBILITY.—The Secretary shall ensure  
24 that the verification network is electronically accessible by

1 State, local, and tribal health departments and can be  
2 linked with the identification cards under section 2813.

3 “(e) CONFIDENTIALITY.—The Secretary shall estab-  
4 lish and require the application of and compliance with  
5 measures to ensure the effective security of, integrity of,  
6 and access to the data included in the verification network.

7 “(f) COORDINATION.—The Secretary shall coordinate  
8 with the Secretary of Veterans Affairs and the Secretary  
9 of Homeland Security to assess the feasibility of inte-  
10 grating the verification network under this section with  
11 the VetPro system of the Department of Veterans Affairs  
12 and the National Emergency Responder Credentialing  
13 System of the Department of Homeland Security. The  
14 Secretary shall, if feasible, integrate the verification net-  
15 work under this section with such VetPro system and the  
16 National Emergency Responder Credentialing System.

17 “(g) UPDATING OF INFORMATION.—The States that  
18 are participants in the verification network shall, on at  
19 least a quarterly basis, work with the Director to provide  
20 for the updating of the information contained in the  
21 verification network.

22 “(h) CLARIFICATION.—Inclusion of a health profes-  
23 sional in the verification network shall not constitute ap-  
24 pointment of such individual as a Federal employee for  
25 any purpose, either under section 2812(c) or otherwise.

1 Such appointment may only be made under section 2812  
2 or 2813.

3 “(i) HEALTH CARE PROVIDER LICENSES.—The Sec-  
4 retary shall encourage States to establish and implement  
5 mechanisms to waive the application of licensing require-  
6 ments applicable to health professionals, who are seeking  
7 to provide medical services (within their scope of practice),  
8 during a national, State, local, or tribal public health  
9 emergency upon verification that such health professionals  
10 are licensed and in good standing in another State and  
11 have not been disciplined by any State health licensing or  
12 disciplinary board.”; and

13 (5) in subsection (k) (as so redesignated), by  
14 striking “2006” and inserting “2011”.

15 **SEC. 304. CORE EDUCATION AND TRAINING.**

16 Section 319F of the Public Health Service Act (42  
17 U.S.C. 247d–6) is amended—

18 (1) by striking subsection (a) and inserting the  
19 following;

20 “(a) ALL-HAZARDS PUBLIC HEALTH AND MEDICAL  
21 RESPONSE CURRICULA AND TRAINING.—

22 “(1) IN GENERAL.—The Secretary, in collabo-  
23 ration with the Secretary of Defense, and in con-  
24 sultation with relevant public and private entities,  
25 shall develop core health and medical response cur-

1       ricula and trainings by adapting applicable existing  
2       curricula and training programs to improve re-  
3       sponses to public health emergencies.

4           “(2) CURRICULUM.—The public health and  
5       medical response training program may include  
6       course work related to—

7           “(A) medical management of casualties,  
8       taking into account the needs of at-risk individ-  
9       uals;

10          “(B) public health aspects of public health  
11       emergencies;

12          “(C) mental health aspects of public health  
13       emergencies;

14          “(D) national incident management, in-  
15       cluding coordination among Federal, State,  
16       local, tribal, international agencies, and other  
17       entities; and

18          “(E) protecting health care workers and  
19       health care first responders from workplace ex-  
20       posures during a public health emergency.

21          “(3) PEER REVIEW.—On a periodic basis, prod-  
22       ucts prepared as part of the program shall be rigor-  
23       ously tested and peer-reviewed by experts in the rel-  
24       evant fields.

1           “(4) CREDIT.—The Secretary and the Sec-  
2           retary of Defense shall—

3                   “(A) take into account continuing profes-  
4                   sional education requirements of public health  
5                   and healthcare professions; and

6                   “(B) cooperate with State, local, and tribal  
7                   accrediting agencies and with professional asso-  
8                   ciations in arranging for students enrolled in  
9                   the program to obtain continuing professional  
10                  education credit for program courses.

11           “(5) DISSEMINATION AND TRAINING.—

12                   “(A) IN GENERAL.—The Secretary may  
13                   provide for the dissemination and teaching of  
14                   the materials described in paragraphs (1) and  
15                   (2) by appropriate means, as determined by the  
16                   Secretary.

17                   “(B) CERTAIN ENTITIES.—The education  
18                   and training activities described in subpara-  
19                   graph (A) may be carried out by Federal public  
20                   health or medical entities, appropriate edu-  
21                   cational entities, professional organizations and  
22                   societies, private accrediting organizations, and  
23                   other nonprofit institutions or entities meeting  
24                   criteria established by the Secretary.

1           “(C) GRANTS AND CONTRACTS.—In car-  
2           rying out this subsection, the Secretary may  
3           carry out activities directly or through the  
4           award of grants and contracts, and may enter  
5           into interagency agreements with other Federal  
6           agencies.”.

7           (2) by striking subsections (e) through (g) and  
8           inserting the following:

9           “(c) EXPANSION OF EPIDEMIC INTELLIGENCE SERV-  
10          ICE PROGRAM.—The Secretary may establish 20 officer  
11          positions in the Epidemic Intelligence Service Program, in  
12          addition to the number of the officer positions offered  
13          under such Program in 2006, for individuals who agree  
14          to participate, for a period of not less than 2 years, in  
15          the Career Epidemiology Field Officer program in a State,  
16          local, or tribal health department that serves a health pro-  
17          fessional shortage area (as defined under section 332(a)),  
18          a medically underserved population (as defined under sec-  
19          tion 330(b)(3)), or a medically underserved area or area  
20          at high risk of a public health emergency as designated  
21          by the Secretary.

22          “(d) CENTERS FOR PUBLIC HEALTH PREPARED-  
23          NESS; CORE CURRICULA AND TRAINING.—

24                 “(1) IN GENERAL.—The Secretary may estab-  
25          lish at accredited schools of public health, Centers

1 for Public Health Preparedness (hereafter referred  
2 to in this section as the ‘Centers’).

3 “(2) ELIGIBILITY.—To be eligible to receive an  
4 award under this subsection to establish a Center,  
5 an accredited school of public health shall agree to  
6 conduct activities consistent with the requirements  
7 of this subsection.

8 “(3) CORE CURRICULA.—The Secretary, in col-  
9 laboration with the Centers and other public or pri-  
10 vate entities shall establish core curricula based on  
11 established competencies leading to a 4-year bach-  
12 elor’s degree, a graduate degree, a combined bach-  
13 elor and master’s degree, or a certificate program,  
14 for use by each Center. The Secretary shall dissemi-  
15 nate such curricula to other accredited schools of  
16 public health and other health professions schools  
17 determined appropriate by the Secretary, for vol-  
18 untary use by such schools.

19 “(4) CORE COMPETENCY-BASED TRAINING PRO-  
20 GRAM.—The Secretary, in collaboration with the  
21 Centers and other public or private entities shall fa-  
22 cilitate the development of a competency-based train-  
23 ing program to train public health practitioners. The  
24 Centers shall use such training program to train  
25 public health practitioners. The Secretary shall dis-

1 seminate such training program to other accredited  
2 schools of public health, health professions schools,  
3 and other public or private entities as determined by  
4 the Secretary, for voluntary use by such entities.

5 “(5) CONTENT OF CORE CURRICULA AND  
6 TRAINING PROGRAM.—The Secretary shall ensure  
7 that the core curricula and training program estab-  
8 lished pursuant to this subsection respond to the  
9 needs of State, local, and tribal public health au-  
10 thorities and integrate and emphasize essential pub-  
11 lic health security capabilities consistent with section  
12 2802(b)(2).

13 “(6) ACADEMIC-WORKFORCE COMMUNICA-  
14 TION.—As a condition of receiving funding from the  
15 Secretary under this subsection, a Center shall col-  
16 laborate with a State, local, or tribal public health  
17 department to—

18 “(A) define the public health preparedness  
19 and response needs of the community involved;

20 “(B) assess the extent to which such needs  
21 are fulfilled by existing preparedness and re-  
22 sponse activities of such school or health de-  
23 partment, and how such activities may be im-  
24 proved;

1           “(C) prior to developing new materials or  
2           trainings, evaluate and utilize relevant materials  
3           and trainings developed by others Centers; and

4           “(D) evaluate community impact and the  
5           effectiveness of any newly developed materials  
6           or trainings.

7           “(7) PUBLIC HEALTH SYSTEMS RESEARCH.—In  
8           consultation with relevant public and private enti-  
9           ties, the Secretary shall define the existing knowl-  
10          edge base for public health preparedness and re-  
11          sponse systems, and establish a research agenda  
12          based on Federal, State, local, and tribal public  
13          health preparedness priorities. As a condition of re-  
14          ceiving funding from the Secretary under this sub-  
15          section, a Center shall conduct public health systems  
16          research that is consistent with the agenda described  
17          under this paragraph.”;

18          (3) by redesignating subsection (h) as sub-  
19          section (e);

20          (4) by inserting after subsection (e) (as so re-  
21          designated), the following:

22          “(f) AUTHORIZATION OF APPROPRIATIONS.—

23          “(1) FISCAL YEAR 2007.—There are authorized  
24          to be appropriated to carry out this section for fiscal  
25          year 2007—

1 “(A) to carry out subsection (a)—

2 “(i) \$5,000,000 to carry out para-  
3 graphs (1) through (4); and

4 “(ii) \$7,000,000 to carry out para-  
5 graph (5);

6 “(B) to carry out subsection (c),  
7 \$3,000,000; and

8 “(C) to carry out subsection (d),  
9 \$31,000,000, of which \$5,000,000 shall be used  
10 to carry out paragraphs (3) through (5) of such  
11 subsection.

12 “(2) SUBSEQUENT FISCAL YEARS.—There are  
13 authorized to be appropriated such sums as may be  
14 necessary to carry out this section for fiscal year  
15 2008 and each subsequent fiscal year.”; and

16 (5) by striking subsections (i) and (j).

17 **SEC. 305. PARTNERSHIPS FOR STATE AND REGIONAL HOS-**  
18 **PITAL PREPAREDNESS TO IMPROVE SURGE**  
19 **CAPACITY.**

20 Section 319C–2 of the Public Health Service Act (42  
21 U.S.C. 247d–3b) is amended to read as follows:

1 **“SEC. 319C-2. PARTNERSHIPS FOR STATE AND REGIONAL**  
2 **HOSPITAL PREPAREDNESS TO IMPROVE**  
3 **SURGE CAPACITY.**

4 “(a) IN GENERAL.—The Secretary shall award com-  
5 petitive grants or cooperative agreements to eligible enti-  
6 ties to enable such entities to improve surge capacity and  
7 enhance community and hospital preparedness for public  
8 health emergencies.

9 “(b) ELIGIBILITY.—To be eligible for an award under  
10 subsection (a), an entity shall—

11 “(1)(A) be a partnership consisting of—

12 “(i) one or more hospitals, at least one of  
13 which shall be a designated trauma center, con-  
14 sistent with section 1213(e);

15 “(ii) one or more other local health care  
16 facilities, including clinics, health centers, pri-  
17 mary care facilities, mental health centers, mo-  
18 bile medical assets, or nursing homes; and

19 “(iii)(I) one or more political subdivisions;

20 “(II) one or more States; or

21 “(III) one or more States and one or more  
22 political subdivisions; and

23 “(B) prepare, in consultation with the Chief  
24 Executive Officer and the lead health officials of the  
25 State, District, or territory in which the hospital and  
26 health care facilities described in subparagraph (A)

1 are located, and submit to the Secretary, an applica-  
2 tion at such time, in such manner, and containing  
3 such information as the Secretary may require; or

4 “(2)(A) be an entity described in section 319C-  
5 1(b)(1); and

6 “(B) submit an application at such time, in  
7 such manner, and containing such information as  
8 the Secretary may require, including the information  
9 or assurances required under section 319C-1(b)(2)  
10 and an assurance that the State will adhere to any  
11 applicable guidelines established by the Secretary.

12 “(c) USE OF FUNDS.—An award under subsection  
13 (a) shall be expended for activities to achieve the prepared-  
14 ness goals described under paragraphs (1), (3), (4), (5),  
15 and (6) of section 2802(b).

16 “(d) PREFERENCES.—

17 “(1) REGIONAL COORDINATION.—In making  
18 awards under subsection (a), the Secretary shall give  
19 preference to eligible entities that submit applica-  
20 tions that, in the determination of the Secretary—

21 “(A) will enhance coordination—

22 “(i) among the entities described in  
23 subsection (b)(1)(A)(i); and

1                   “(ii) between such entities and the en-  
2                   tities described in subsection (b)(1)(A)(ii);  
3                   and

4                   “(B) include, in the partnership described  
5                   in subsection (b)(1)(A), a significant percentage  
6                   of the hospitals and health care facilities within  
7                   the geographic area served by such partnership.

8                   “(2) OTHER PREFERENCES.—In making  
9                   awards under subsection (a), the Secretary shall give  
10                  preference to eligible entities that, in the determina-  
11                  tion of the Secretary—

12                  “(A) include one or more hospitals that are  
13                  participants in the National Disaster Medical  
14                  System;

15                  “(B) are located in a geographic area that  
16                  faces a high degree of risk, as determined by  
17                  the Secretary in consultation with the Secretary  
18                  of Homeland Security; or

19                  “(C) have a significant need for funds to  
20                  achieve the medical preparedness goals de-  
21                  scribed in section 2802(b)(3).

22                  “(e) CONSISTENCY OF PLANNED ACTIVITIES.—The  
23                  Secretary may not award a cooperative agreement to an  
24                  eligible entity described in subsection (b)(1) unless the ap-  
25                  plication submitted by the entity is coordinated and con-

1 sistent with an applicable State All-Hazards Public Health  
2 Emergency Preparedness and Response Plan and relevant  
3 local plans, as determined by the Secretary in consultation  
4 with relevant State health officials..

5 “(f) LIMITATION ON AWARDS.—A political subdivi-  
6 sion shall not participate in more than one partnership  
7 described in subsection (b)(1).

8 “(g) COORDINATION WITH LOCAL RESPONSE CAPA-  
9 BILITIES.—An eligible entity shall, to the extent prac-  
10 ticable, ensure that activities carried out under an award  
11 under subsection (a) are coordinated with activities of rel-  
12 evant local Metropolitan Medical Response Systems, local  
13 Medical Reserve Corps, the Cities Readiness Initiative,  
14 and local emergency plans.

15 “(h) MAINTENANCE OF FUNDING.—

16 “(1) IN GENERAL.—An entity that receives an  
17 award under this section shall maintain expenditures  
18 for health care preparedness at a level that is not  
19 less than the average level of such expenditures  
20 maintained by the entity for the preceding 2 year  
21 period.

22 “(2) RULE OF CONSTRUCTION.—Nothing in  
23 this section shall be construed to prohibit the use of  
24 awards under this section to pay salary and related  
25 expenses of public health and other professionals

1 employed by State, local, or tribal agencies who are  
2 carrying out activities supported by such awards (re-  
3 gardless of whether the primary assignment of such  
4 personnel is to carry out such activities).

5 “(i) PERFORMANCE AND ACCOUNTABILITY.—The re-  
6 quirements of section 319C–1(g), (j), and (k) shall apply  
7 to entities receiving awards under this section (regardless  
8 of whether such entities are described under subsection  
9 (b)(1)(A) or (b)(2)(A)) in the same manner as such re-  
10 quirements apply to entities under section 319C–1. An en-  
11 tity described in subsection (b)(1)(A) shall make such re-  
12 ports available to the lead health official of the State in  
13 which such partnership is located.

14 “(j) AUTHORIZATION OF APPROPRIATIONS.—

15 “(1) IN GENERAL.—For the purpose of car-  
16 rying out this section, there is authorized to be ap-  
17 propriated \$474,000,000 for fiscal year 2007, and  
18 such sums as may be necessary for each of fiscal  
19 years 2008 through 2011.

20 “(2) RESERVATION OF AMOUNTS FOR PART-  
21 NERSHIPS.—Prior to making awards described in  
22 paragraph (3), the Secretary may reserve from the  
23 amount appropriated under paragraph (1) for a fis-  
24 cal year, an amount determined appropriate by the

1 Secretary for making awards to entities described in  
2 subsection (b)(1)(A).

3 “(3) AWARDS TO STATES AND POLITICAL SUB-  
4 DIVISIONS.—

5 “(A) IN GENERAL.—From amounts appro-  
6 priated for a fiscal year under paragraph (1)  
7 and not reserved under paragraph (2), the Sec-  
8 retary shall make awards to entities described  
9 in subsection (b)(2)(A) that have completed an  
10 application as described in subsection (b)(2)(B).

11 “(B) AMOUNT.—The Secretary shall deter-  
12 mine the amount of an award to each entity de-  
13 scribed in subparagraph (A) in the same man-  
14 ner as such amounts are determined under sec-  
15 tion 319C–1(h).”.

16 **SEC. 306. ENHANCING THE ROLE OF THE DEPARTMENT OF**  
17 **VETERANS AFFAIRS.**

18 (a) IN GENERAL.—Section 8117 of title 38, United  
19 States Code, is amended—

20 (1) in subsection (a)—

21 (A) in paragraph (1), by—

22 (i) striking “chemical or biological at-  
23 tack” and inserting “a public health emer-  
24 gency (as defined in section 2801 of the  
25 Public Health Service Act)”;

1 (ii) striking “an attack” and inserting  
2 “such an emergency”; and

3 (iii) striking “public health emer-  
4 gencies” and inserting “such emergencies”;  
5 and

6 (B) in paragraph (2)—

7 (i) in subparagraph (A), by striking “;  
8 and” and inserting a semicolon;

9 (ii) in subparagraph (B), by striking  
10 the period and inserting a semicolon; and

11 (iii) by adding at the end the fol-  
12 lowing:

13 “(C) organizing, training, and equipping  
14 the staff of such centers to support the activi-  
15 ties carried out by the Secretary of Health and  
16 Human Services under section 2801 of the  
17 Public Health Service Act in the event of a pub-  
18 lic health emergency and incidents covered by  
19 the National Response Plan developed pursuant  
20 to section 502(6) of the Homeland Security Act  
21 of 2002, or any successor plan; and

22 “(D) providing medical logistical support  
23 to the National Disaster Medical System and  
24 the Secretary of Health and Human Services as  
25 necessary, on a reimbursable basis, and in co-

1            ordination with other designated Federal agen-  
2            cies.”;

3            (2) in subsection (c), by striking “a chemical or  
4            biological attack or other terrorist attack.” and in-  
5            sserting “a public health emergency. The Secretary  
6            shall, through existing medical procurement con-  
7            tracts, and on a reimbursable basis, make available  
8            as necessary, medical supplies, equipment, and phar-  
9            maceuticals in response to a public health emergency  
10          in support of the Secretary of Health and Human  
11          Services.”;

12          (3) in subsection (d), by—

13            (A) striking “develop and”;

14            (B) striking “biological, chemical, or radio-  
15          logical attacks” and inserting “public health  
16          emergencies”; and

17            (C) by inserting “consistent with section  
18          319F(a) of the Public Health Service Act” be-  
19          fore the period; and

20          (4) in subsection (e)—

21            (A) in paragraph (1), by striking  
22          “2811(b)” and inserting “2812”; and

23            (B) in paragraph (2)—

24            (i) by striking “bioterrorism and  
25          other”; and

1 (ii) by striking “319F(a)” and insert-  
2 ing “319F”.

3 (b) AUTHORIZATION OF APPROPRIATIONS.—Section  
4 8117 of title 38, United States Code, is amended by add-  
5 ing at the end the following:

6 “(g) AUTHORIZATION OF APPROPRIATIONS.—There  
7 are authorized to be appropriated, such sums as may be  
8 necessary to carry out this section for each of fiscal years  
9 2007 through 2011.”.

10 **TITLE IV—PANDEMIC AND BIO-**  
11 **DEFENSE VACCINE AND**  
12 **DRUG DEVELOPMENT**

13 **SEC. 401. BIOMEDICAL ADVANCED RESEARCH AND DEVEL-**  
14 **OPMENT AUTHORITY.**

15 Title III of the Public Health Service Act (42 U.S.C.  
16 241 et seq.) is amended by inserting after section 319K  
17 the following:

18 **“SEC. 319L. BIOMEDICAL ADVANCED RESEARCH AND DE-**  
19 **VELOPMENT AUTHORITY.**

20 “(a) DEFINITIONS.—In this section:

21 “(1) BARDA.—The term ‘BARDA’ means the  
22 Biomedical Advanced Research and Development  
23 Authority.

1           “(2) FUND.—The term ‘Fund’ means the Bio-  
2 defense Medical Countermeasure Development Fund  
3 established under subsection (d).

4           “(3) OTHER TRANSACTIONS.—The term ‘other  
5 transactions’ means transactions, other than pro-  
6 curement contracts, grants, and cooperative agree-  
7 ments, such as the Secretary of Defense may enter  
8 into under section 2371 of title 10, United States  
9 Code.

10           “(4) QUALIFIED COUNTERMEASURE.—The term  
11 ‘qualified countermeasure’ has the meaning given  
12 such term in section 319F–1.

13           “(5) QUALIFIED PANDEMIC OR EPIDEMIC PROD-  
14 UCT.—The term ‘qualified pandemic or epidemic  
15 product’ has the meaning given the term in section  
16 319F–3.

17           “(6) ADVANCED RESEARCH AND DEVELOP-  
18 MENT.—

19           “(A) IN GENERAL.—The term ‘advanced  
20 research and development’ means, with respect  
21 to a product that is or may become a qualified  
22 countermeasure or a qualified pandemic or epi-  
23 demic product, activities that predominantly—

1           “(i) are conducted after basic research  
2           and preclinical development of the product;  
3           and

4           “(ii) are related to manufacturing the  
5           product on a commercial scale and in a  
6           form that satisfies the regulatory require-  
7           ments under the Federal Food, Drug, and  
8           Cosmetic Act or under section 351 of this  
9           Act.

10           “(B) ACTIVITIES INCLUDED.—The term  
11           under subparagraph (A) includes—

12           “(i) testing of the product to deter-  
13           mine whether the product may be ap-  
14           proved, cleared, or licensed under the Fed-  
15           eral Food, Drug, and Cosmetic Act or  
16           under section 351 of this Act for a use  
17           that is or may be the basis for such prod-  
18           uct becoming a qualified countermeasure  
19           or qualified pandemic or epidemic product,  
20           or to help obtain such approval, clearance,  
21           or license;

22           “(ii) design and development of tests  
23           or models, including animal models, for  
24           such testing;

1           “(iii) activities to facilitate manufac-  
2           ture of the product on a commercial scale  
3           with consistently high quality, as well as to  
4           improve and make available new tech-  
5           nologies to increase manufacturing surge  
6           capacity;

7           “(iv) activities to improve the shelf-life  
8           of the product or technologies for admin-  
9           istering the product; and

10           “(v) such other activities as are part  
11           of the advanced stages of testing, refine-  
12           ment, improvement, or preparation of the  
13           product for such use and as are specified  
14           by the Secretary.

15           “(7) SECURITY COUNTERMEASURE.—The term  
16           ‘security countermeasure’ has the meaning given  
17           such term in section 319F-2.

18           “(8) RESEARCH TOOL.—The term ‘research  
19           tool’ means a device, technology, biological material  
20           (including a cell line or an antibody), reagent, ani-  
21           mal model, computer system, computer software, or  
22           analytical technique that is developed to assist in the  
23           discovery, development, or manufacture of qualified  
24           countermeasures or qualified pandemic or epidemic  
25           products.

1           “(9) PROGRAM MANAGER.—The term ‘program  
2           manager’ means an individual appointed to carry out  
3           functions under this section and authorized to pro-  
4           vide project oversight and management of strategic  
5           initiatives.

6           “(10) PERSON.—The term ‘person’ includes an  
7           individual, partnership, corporation, association, en-  
8           tity, or public or private corporation, and a Federal,  
9           State, or local government agency or department.

10          “(b) STRATEGIC PLAN FOR COUNTERMEASURE RE-  
11          SEARCH, DEVELOPMENT, AND PROCUREMENT.—

12                 “(1) IN GENERAL.—Not later than 6 months  
13                 after the date of enactment of the Pandemic and  
14                 All-Hazards Preparedness Act, the Secretary shall  
15                 develop and make public a strategic plan to inte-  
16                 grate biodefense and emerging infectious disease re-  
17                 quirements with the advanced research and develop-  
18                 ment, strategic initiatives for innovation, and the  
19                 procurement of qualified countermeasures and quali-  
20                 fied pandemic or epidemic products. The Secretary  
21                 shall carry out such activities as may be practicable  
22                 to disseminate the information contained in such  
23                 plan to persons who may have the capacity to sub-  
24                 stantially contribute to the activities described in  
25                 such strategic plan. The Secretary shall update and

1 incorporate such plan as part of the National Health  
2 Security Strategy described in section 2802.

3 “(2) CONTENT.—The strategic plan under  
4 paragraph (1) shall guide—

5 “(A) research and development, conducted  
6 or supported by the Department of Health and  
7 Human Services, of qualified countermeasures  
8 and qualified pandemic or epidemic products  
9 against possible biological, chemical, radio-  
10 logical, and nuclear agents and to emerging in-  
11 fectious diseases;

12 “(B) innovation in technologies that may  
13 assist advanced research and development of  
14 qualified countermeasures and qualified pan-  
15 demic or epidemic products (such research and  
16 development referred to in this section as ‘coun-  
17 termeasure and product advanced research and  
18 development’); and

19 “(C) procurement of such qualified coun-  
20 termeasures and qualified pandemic or epidemic  
21 products by such Department.

22 “(c) BIOMEDICAL ADVANCED RESEARCH AND DE-  
23 VELOPMENT AUTHORITY.—

24 “(1) ESTABLISHMENT.—There is established  
25 within the Department of Health and Human Serv-

1 ices the Biomedical Advanced Research and Develop-  
2 ment Authority.

3 “(2) IN GENERAL.—Based upon the strategic  
4 plan described in subsection (b), the Secretary shall  
5 coordinate the acceleration of countermeasure and  
6 product advanced research and development by—

7 “(A) facilitating collaboration between the  
8 Department of Health and Human Services and  
9 other Federal agencies, relevant industries, aca-  
10 demia, and other persons, with respect to such  
11 advanced research and development;

12 “(B) promoting countermeasure and prod-  
13 uct advanced research and development;

14 “(C) facilitating contacts between inter-  
15 ested persons and the offices or employees au-  
16 thorized by the Secretary to advise such persons  
17 regarding requirements under the Federal  
18 Food, Drug, and Cosmetic Act and under sec-  
19 tion 351 of this Act; and

20 “(D) promoting innovation to reduce the  
21 time and cost of countermeasure and product  
22 advanced research and development.

23 “(3) DIRECTOR.—The BARDA shall be headed  
24 by a Director (referred to in this section as the ‘Di-  
25 rector’) who shall be appointed by the Secretary and

1 to whom the Secretary shall delegate such functions  
2 and authorities as necessary to implement this sec-  
3 tion.

4 “(4) DUTIES.—

5 “(A) COLLABORATION.—To carry out the  
6 purpose described in paragraph (2)(A), the Sec-  
7 retary shall—

8 “(i) facilitate and increase the expedi-  
9 tious and direct communication between  
10 the Department of Health and Human  
11 Services and relevant persons with respect  
12 to countermeasure and product advanced  
13 research and development, including by—

14 “(I) facilitating such communica-  
15 tion regarding the processes for pro-  
16 curing such advanced research and  
17 development with respect to qualified  
18 countermeasures and qualified pan-  
19 demic or epidemic products of inter-  
20 est; and

21 “(II) soliciting information about  
22 and data from research on potential  
23 qualified countermeasures and quali-  
24 fied pandemic or epidemic products  
25 and related technologies;

1 “(ii) at least annually—

2 “(I) convene meetings with rep-  
3 resentatives from relevant industries,  
4 academia, other Federal agencies,  
5 international agencies as appropriate,  
6 and other interested persons;

7 “(II) sponsor opportunities to  
8 demonstrate the operation and effec-  
9 tiveness of relevant biodefense coun-  
10 termeasure technologies; and

11 “(III) convene such working  
12 groups on countermeasure and prod-  
13 uct advanced research and develop-  
14 ment as the Secretary may determine  
15 are necessary to carry out this sec-  
16 tion; and

17 “(iii) carry out the activities described  
18 in section 405 of the Pandemic and All-  
19 Hazards Preparedness Act.

20 “(B) SUPPORT ADVANCED RESEARCH AND  
21 DEVELOPMENT.—To carry out the purpose de-  
22 scribed in paragraph (2)(B), the Secretary  
23 shall—

24 “(i) conduct ongoing searches for, and  
25 support calls for, potential qualified coun-

1           termeasures and qualified pandemic or epi-  
2           demic products;

3           “(ii) direct and coordinate the coun-  
4           termeasure and product advanced research  
5           and development activities of the Depart-  
6           ment of Health and Human Services;

7           “(iii) establish strategic initiatives to  
8           accelerate countermeasure and product ad-  
9           vanced research and development and in-  
10          novation in such areas as the Secretary  
11          may identify as priority unmet need areas;  
12          and

13          “(iv) award contracts, grants, cooper-  
14          ative agreements, and enter into other  
15          transactions, for countermeasure and prod-  
16          uct advanced research and development.

17          “(C) FACILITATING ADVICE.—To carry out  
18          the purpose described in paragraph (2)(C) the  
19          Secretary shall—

20                 “(i) connect interested persons with  
21                 the offices or employees authorized by the  
22                 Secretary to advise such persons regarding  
23                 the regulatory requirements under the  
24                 Federal Food, Drug, and Cosmetic Act  
25                 and under section 351 of this Act related

1 to the approval, clearance, or licensure of  
2 qualified countermeasures or qualified pan-  
3 demic or epidemic products; and

4 “(ii) with respect to persons per-  
5 forming countermeasure and product ad-  
6 vanced research and development funded  
7 under this section, enable such offices or  
8 employees to provide to the extent prac-  
9 ticable such advice in a manner that is on-  
10 going and that is otherwise designed to fa-  
11 cilitate expeditious development of quali-  
12 fied countermeasures and qualified pan-  
13 demic or epidemic products that may  
14 achieve such approval, clearance, or licen-  
15 sure.

16 “(D) SUPPORTING INNOVATION.—To carry  
17 out the purpose described in paragraph (2)(D),  
18 the Secretary may award contracts, grants, and  
19 cooperative agreements, or enter into other  
20 transactions, such as prize payments, to  
21 promote—

22 “(i) innovation in technologies that  
23 may assist countermeasure and product  
24 advanced research and development;

1           “(ii) research on and development of  
2           research tools and other devices and tech-  
3           nologies; and

4           “(iii) research to promote strategic  
5           initiatives, such as rapid diagnostics, broad  
6           spectrum antimicrobials, and vaccine man-  
7           ufacturing technologies.

8           “(5) TRANSACTION AUTHORITIES.—

9           “(A) OTHER TRANSACTIONS.—

10           “(i) IN GENERAL.—The Secretary  
11           shall have the authority to enter into other  
12           transactions under this subsection in the  
13           same manner as the Secretary of Defense  
14           enters into such transactions under section  
15           2371 of title 10, United States Code.

16           “(ii) LIMITATIONS ON AUTHORITY.—

17           “(I) IN GENERAL.—Subsections  
18           (b), (c), and (h) of section 845 of the  
19           National Defense Authorization Act  
20           for Fiscal Year 1994 (10 U.S.C. 2371  
21           note) shall apply to other transactions  
22           under this subparagraph as if such  
23           transactions were for prototype  
24           projects described by subsection (a) of  
25           such section 845.

1                   “(II) WRITTEN DETERMINATIONS  
2                   REQUIRED.—The authority of this  
3                   subparagraph may be exercised for a  
4                   project that is expected to cost the  
5                   Department of Health and Human  
6                   Services in excess of \$20,000,000 only  
7                   upon a written determination by the  
8                   senior procurement executive for the  
9                   Department (as designated for pur-  
10                  pose of section 16(c) of the Office of  
11                  Federal Procurement Policy Act (41  
12                  U.S.C. 414(c))), that the use of such  
13                  authority is essential to promoting the  
14                  success of the project. The authority  
15                  of the senior procurement executive  
16                  under this subclause may not be dele-  
17                  gated.

18                  “(iii) GUIDELINES.—The Secretary  
19                  shall establish guidelines regarding the use  
20                  of the authority under clause (i). Such  
21                  guidelines shall include auditing require-  
22                  ments.

23                  “(B) EXPEDITED AUTHORITIES.—

24                  “(i) IN GENERAL.—In awarding con-  
25                  tracts, grants, and cooperative agreements,

1 and in entering into other transactions  
2 under subparagraph (B) or (D) of para-  
3 graph (4), the Secretary shall have the ex-  
4 pedited procurement authorities, the au-  
5 thority to expedite peer review, and the au-  
6 thority for personal services contracts, sup-  
7 plied by subsections (b), (c), and (d) of  
8 section 319F-1.

9 “(ii) APPLICATION OF PROVISIONS.—  
10 Provisions in such section 319F-1 that  
11 apply to such authorities and that require  
12 institution of internal controls, limit re-  
13 view, provide for Federal Tort Claims Act  
14 coverage of personal services contractors,  
15 and commit decisions to the discretion of  
16 the Secretary shall apply to the authorities  
17 as exercised pursuant to this paragraph.

18 “(iii) AUTHORITY TO LIMIT COMPETI-  
19 TION.—For purposes of applying section  
20 319F-1(b)(1)(D) to this paragraph, the  
21 phrase ‘BioShield Program under the  
22 Project BioShield Act of 2004’ shall be  
23 deemed to mean the countermeasure and  
24 product advanced research and develop-  
25 ment program under this section.

1           “(iv) AVAILABILITY OF DATA.—The  
2           Secretary shall require that, as a condition  
3           of being awarded a contract, grant, cooper-  
4           ative agreement, or other transaction  
5           under subparagraph (B) or (D) of para-  
6           graph (4), a person make available to the  
7           Secretary on an ongoing basis, and submit  
8           upon request to the Secretary, all data re-  
9           lated to or resulting from countermeasure  
10          and product advanced research and devel-  
11          opment carried out pursuant to this sec-  
12          tion.

13          “(C) ADVANCE PAYMENTS; ADVER-  
14          TISING.—The Secretary may waive the require-  
15          ments of section 3324(a) of title 31, United  
16          States Code, or section 3709 of the Revised  
17          Statutes of the United States (41 U.S.C. 5)  
18          upon the determination by the Secretary that  
19          such waiver is necessary to obtain counter-  
20          measures or products under this section.

21          “(D) MILESTONE-BASED PAYMENTS AL-  
22          LOWED.—In awarding contracts, grants, and  
23          cooperative agreements, and in entering into  
24          other transactions, under this section, the Sec-

1           retary may use milestone-based awards and  
2           payments.

3           “(E) FOREIGN NATIONALS ELIGIBLE.—  
4           The Secretary may under this section award  
5           contracts, grants, and cooperative agreements  
6           to, and may enter into other transactions with,  
7           highly qualified foreign national persons outside  
8           the United States, alone or in collaboration with  
9           American participants, when such transactions  
10          may inure to the benefit of the American peo-  
11          ple.

12          “(F) ESTABLISHMENT OF RESEARCH CEN-  
13          TERS.—The Secretary may assess the feasibility  
14          and appropriateness of establishing, through  
15          contract, grant, cooperative agreement, or other  
16          transaction, an arrangement with an existing  
17          research center in order to achieve the goals of  
18          this section. If such an agreement is not fea-  
19          sible and appropriate, the Secretary may estab-  
20          lish one or more federally-funded research and  
21          development centers, or university-affiliated re-  
22          search centers, in accordance with section  
23          303(c)(3) of the Federal Property and Adminis-  
24          trative Services Act of 1949 (41 U.S.C.  
25          253(c)(3)).

1           “(6) AT-RISK INDIVIDUALS.—In carrying out  
2 the functions under this section, the Secretary may  
3 give priority to the advanced research and develop-  
4 ment of qualified countermeasures and qualified  
5 pandemic or epidemic products that are likely to be  
6 safe and effective with respect to children, pregnant  
7 women, elderly, and other at-risk individuals.

8           “(7) PERSONNEL AUTHORITIES.—

9           “(A) SPECIALLY QUALIFIED SCIENTIFIC  
10 AND PROFESSIONAL PERSONNEL.—

11           “(i) IN GENERAL.—In addition to any  
12 other personnel authorities, the Secretary  
13 may—

14           “(I) without regard to those pro-  
15 visions of title 5, United States Code,  
16 governing appointments in the com-  
17 petitive service, appoint highly quali-  
18 fied individuals to scientific or profes-  
19 sional positions in BARDA, such as  
20 program managers, to carry out this  
21 section; and

22           “(II) compensate them in the  
23 same manner and subject to the same  
24 terms and conditions in which individ-  
25 uals appointed under section 9903 of

1           such title are compensated, without  
2           regard to the provisions of chapter 51  
3           and subchapter III of chapter 53 of  
4           such title relating to classification and  
5           General Schedule pay rates.

6           “(ii) MANNER OF EXERCISE OF AU-  
7           THORITY.—The authority provided for in  
8           this subparagraph shall be exercised sub-  
9           ject to the same limitations described in  
10          section 319F–1(e)(2).

11          “(iii) TERM OF APPOINTMENT.—The  
12          term limitations described in section  
13          9903(c) of title 5, United States Code,  
14          shall apply to appointments under this  
15          subparagraph, except that the references  
16          to the ‘Secretary’ and to the ‘Department  
17          of Defense’s national security missions’  
18          shall be deemed to be to the Secretary of  
19          Health and Human Services and to the  
20          mission of the Department of Health and  
21          Human Services under this section.

22          “(B) SPECIAL CONSULTANTS.—In carrying  
23          out this section, the Secretary may appoint spe-  
24          cial consultants pursuant to section 207(f).

25          “(C) LIMITATION.—

1           “(i) IN GENERAL.—The Secretary  
2           may hire up to 100 highly qualified indi-  
3           viduals, or up to 50 percent of the total  
4           number of employees, whichever is less,  
5           under the authorities provided for in sub-  
6           paragraphs (A) and (B).

7           “(ii) REPORT.—The Secretary shall  
8           report to Congress on a biennial basis on  
9           the implementation of this subparagraph.

10          “(d) FUND.—

11           “(1) ESTABLISHMENT.—There is established  
12           the Biodefense Medical Countermeasure Develop-  
13           ment Fund, which shall be available to carry out this  
14           section in addition to such amounts as are otherwise  
15           available for this purpose.

16           “(2) FUNDING.—To carry out the purposes of  
17           this section, there are authorized to be appropriated  
18           to the Fund—

19           “(A) \$1,070,000,000 for fiscal years 2006  
20           through 2008, the amounts to remain available  
21           until expended; and

22           “(B) such sums as may be necessary for  
23           subsequent fiscal years, the amounts to remain  
24           available until expended.

25          “(e) INAPPLICABILITY OF CERTAIN PROVISIONS.—

1           “(1) DISCLOSURE.—

2                   “(A) IN GENERAL.—The Secretary shall  
3 withhold from disclosure under section 552 of  
4 title 5, United States Code, specific technical  
5 data or scientific information that is created or  
6 obtained during the countermeasure and prod-  
7 uct advanced research and development carried  
8 out under subsection (c) that reveals significant  
9 and not otherwise publicly known vulnerabilities  
10 of existing medical or public health defenses  
11 against biological, chemical, nuclear, or radio-  
12 logical threats. Such information shall be  
13 deemed to be information described in section  
14 552(b)(3) of title 5, United States Code.

15                   “(B) REVIEW.—Information subject to  
16 nondisclosure under subparagraph (A) shall be  
17 reviewed by the Secretary every 5 years, or  
18 more frequently as determined necessary by the  
19 Secretary, to determine the relevance or neces-  
20 sity of continued nondisclosure.

21                   “(C) SUNSET.—This paragraph shall cease  
22 to have force or effect on the date that is 7  
23 years after the date of enactment of the Pan-  
24 demic and All-Hazards Preparedness Act.

1           “(2) REVIEW.—Notwithstanding section 14 of  
2 the Federal Advisory Committee Act, a working  
3 group of BARDA under this section and the Na-  
4 tional Biodefense Science Board under section 319M  
5 shall each terminate on the date that is 5 years after  
6 the date on which each such group or Board, as ap-  
7 plicable, was established. Such 5-year period may be  
8 extended by the Secretary for one or more additional  
9 5-year periods if the Secretary determines that any  
10 such extension is appropriate.”.

11 **SEC. 402. NATIONAL BIODEFENSE SCIENCE BOARD.**

12           Title III of the Public Health Service Act (42 U.S.C.  
13 241 et seq.), as amended by section 401, is further amend-  
14 ed by inserting after section 319L the following:

15 **“SEC. 319M. NATIONAL BIODEFENSE SCIENCE BOARD AND**  
16 **WORKING GROUPS.**

17           “(a) IN GENERAL.—

18           “(1) ESTABLISHMENT AND FUNCTION.—The  
19 Secretary shall establish the National Biodefense  
20 Science Board (referred to in this section as the  
21 ‘Board’) to provide expert advice and guidance to  
22 the Secretary on scientific, technical and other mat-  
23 ters of special interest to the Department of Health  
24 and Human Services regarding current and future  
25 chemical, biological, nuclear, and radiological agents,

1 whether naturally occurring, accidental, or delib-  
2 erate.

3 “(2) MEMBERSHIP.—The membership of the  
4 Board shall be comprised of individuals who rep-  
5 resent the Nation’s preeminent scientific, public  
6 health, and medical experts, as follows—

7 “(A) such Federal officials as the Sec-  
8 retary may determine are necessary to support  
9 the functions of the Board;

10 “(B) four individuals representing the  
11 pharmaceutical, biotechnology, and device in-  
12 dustries;

13 “(C) four individuals representing aca-  
14 demia; and

15 “(D) five other members as determined ap-  
16 propriate by the Secretary, of whom—

17 “(i) one such member shall be a prac-  
18 ticing healthcare professional; and

19 “(ii) one such member shall be an in-  
20 dividual from an organization representing  
21 healthcare consumers.

22 “(3) TERM OF APPOINTMENT.—A member of  
23 the Board described in subparagraph (B), (C), or  
24 (D) of paragraph (2) shall serve for a term of 3  
25 years, except that the Secretary may adjust the

1 terms of the initial Board appointees in order to  
2 provide for a staggered term of appointment for all  
3 members.

4 “(4) CONSECUTIVE APPOINTMENTS; MAXIMUM  
5 TERMS.—A member may be appointed to serve not  
6 more than 3 terms on the Board and may serve not  
7 more than 2 consecutive terms.

8 “(5) DUTIES.—The Board shall—

9 “(A) advise the Secretary on current and  
10 future trends, challenges, and opportunities pre-  
11 sented by advances in biological and life  
12 sciences, biotechnology, and genetic engineering  
13 with respect to threats posed by naturally oc-  
14 ccurring infectious diseases and chemical, bio-  
15 logical, radiological, and nuclear agents;

16 “(B) at the request of the Secretary, re-  
17 view and consider any information and findings  
18 received from the working groups established  
19 under subsection (b); and

20 “(C) at the request of the Secretary, pro-  
21 vide recommendations and findings for ex-  
22 panded, intensified, and coordinated biodefense  
23 research and development activities.

24 “(6) MEETINGS.—

1           “(A) INITIAL MEETING.—Not later than  
2           one year after the date of enactment of the  
3           Pandemic and All-Hazards Preparedness Act,  
4           the Secretary shall hold the first meeting of the  
5           Board.

6           “(B) SUBSEQUENT MEETINGS.—The  
7           Board shall meet at the call of the Secretary,  
8           but in no case less than twice annually.

9           “(7) VACANCIES.—Any vacancy in the Board  
10          shall not affect its powers, but shall be filled in the  
11          same manner as the original appointment.

12          “(8) CHAIRPERSON.—The Secretary shall ap-  
13          point a chairperson from among the members of the  
14          Board.

15          “(9) POWERS.—

16                 “(A) HEARINGS.—The Board may hold  
17                 such hearings, sit and act at such times and  
18                 places, take such testimony, and receive such  
19                 evidence as the Board considers advisable to  
20                 carry out this subsection.

21                 “(B) POSTAL SERVICES.—The Board may  
22                 use the United States mails in the same man-  
23                 ner and under the same conditions as other de-  
24                 partments and agencies of the Federal Govern-  
25                 ment.

1           “(10) PERSONNEL.—

2                   “(A) EMPLOYEES OF THE FEDERAL GOV-  
3           ERNMENT.—A member of the Board that is an  
4           employee of the Federal Government may not  
5           receive additional pay, allowances, or benefits  
6           by reason of the member’s service on the  
7           Board.

8                   “(B) OTHER MEMBERS.—A member of the  
9           Board that is not an employee of the Federal  
10          Government may be compensated at a rate not  
11          to exceed the daily equivalent of the annual rate  
12          of basic pay prescribed for level IV of the Exec-  
13          utive Schedule under section 5315 of title 5,  
14          United States Code, for each day (including  
15          travel time) during which the member is en-  
16          gaged in the actual performance of duties as a  
17          member of the Board.

18                  “(C) TRAVEL EXPENSES.—Each member  
19          of the Board shall receive travel expenses, in-  
20          cluding per diem in lieu of subsistence, in ac-  
21          cordance with applicable provisions under sub-  
22          chapter I of chapter 57 of title 5, United States  
23          Code.

24                  “(D) DETAIL OF GOVERNMENT EMPLOY-  
25          EES.—Any Federal Government employee may

1           be detailed to the Board with the approval for  
2           the contributing agency without reimbursement,  
3           and such detail shall be without interruption or  
4           loss of civil service status or privilege.

5           “(b) OTHER WORKING GROUPS.—The Secretary may  
6           establish a working group of experts, or may use an exist-  
7           ing working group or advisory committee, to—

8           “(1) identify innovative research with the po-  
9           tential to be developed as a qualified countermeasure  
10          or a qualified pandemic or epidemic product;

11          “(2) identify accepted animal models for par-  
12          ticular diseases and conditions associated with any  
13          biological, chemical, radiological, or nuclear agent,  
14          any toxin, or any potential pandemic infectious dis-  
15          ease, and identify strategies to accelerate animal  
16          model and research tool development and validation;  
17          and

18          “(3) obtain advice regarding supporting and fa-  
19          cilitating advanced research and development related  
20          to qualified countermeasures and qualified pandemic  
21          or epidemic products that are likely to be safe and  
22          effective with respect to children, pregnant women,  
23          and other vulnerable populations, and other issues  
24          regarding activities under this section that affect  
25          such populations.

1 “(c) DEFINITIONS.—Any term that is defined in sec-  
2 tion 319L and that is used in this section shall have the  
3 same meaning in this section as such term is given in sec-  
4 tion 319L.

5 “(d) AUTHORIZATION OF APPROPRIATIONS.—There  
6 are authorized to be appropriated \$1,000,000 to carry out  
7 this section for fiscal year 2007 and each fiscal year there-  
8 after.”.

9 **SEC. 403. CLARIFICATION OF COUNTERMEASURES COV-**  
10 **ERED BY PROJECT BIOSHIELD.**

11 (a) QUALIFIED COUNTERMEASURE.—Section 319F–  
12 1(a) of the Public Health Service Act (42 U.S.C. 247d–  
13 6a(a)) is amended by striking paragraph (2) and inserting  
14 the following:

15 “(2) DEFINITIONS.—In this section:

16 “(A) QUALIFIED COUNTERMEASURE.—The  
17 term ‘qualified countermeasure’ means a drug  
18 (as that term is defined by section 201(g)(1) of  
19 the Federal Food, Drug, and Cosmetic Act (21  
20 U.S.C. 321(g)(1))), biological product (as that  
21 term is defined by section 351(i) of this Act (42  
22 U.S.C. 262(i))), or device (as that term is de-  
23 fined by section 201(h) of the Federal Food,  
24 Drug, and Cosmetic Act (21 U.S.C. 321(h))),  
25 that the Secretary determines to be a priority

1 (consistent with sections 302(2) and 304(a) of  
2 the Homeland Security Act of 2002) to—

3 “(i) diagnose, mitigate, prevent, or  
4 treat harm from any biological agent (in-  
5 cluding organisms that cause an infectious  
6 disease) or toxin, chemical, radiological, or  
7 nuclear agent that may cause a public  
8 health emergency affecting national secu-  
9 rity; or

10 “(ii) diagnose, mitigate, prevent, or  
11 treat harm from a condition that may re-  
12 sult in adverse health consequences or  
13 death and may be caused by administering  
14 a drug, biological product, or device that is  
15 used as described in this subparagraph.

16 “(B) INFECTIOUS DISEASE.—The term ‘in-  
17 fectious disease’ means a disease potentially  
18 caused by a pathogenic organism (including a  
19 bacteria, virus, fungus, or parasite) that is ac-  
20 quired by a person and that reproduces in that  
21 person.”.

22 (b) SECURITY COUNTERMEASURE.—Section 319F-  
23 2(c)(1)(B) is amended by striking “treat, identify, or pre-  
24 vent” each place it appears and inserting “diagnose, miti-  
25 gate, prevent, or treat”.

1 (c) LIMITATION ON USE OF FUNDS.—Section 510(a)  
2 of the Homeland Security Act of 2002 (6 U.S.C. 320(a))  
3 is amended by adding at the end the following: “None of  
4 the funds made available under this subsection shall be  
5 used to procure countermeasures to diagnose, mitigate,  
6 prevent, or treat harm resulting from any naturally occur-  
7 ring infectious disease or other public health threat that  
8 are not security countermeasures under section 319F–  
9 2(c)(1)(B).”.

10 **SEC. 404. TECHNICAL ASSISTANCE.**

11 Subchapter E of chapter V of the Federal Food,  
12 Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) is  
13 amended by adding at the end the following:

14 **“SEC. 565. TECHNICAL ASSISTANCE.**

15 “The Secretary, in consultation with the Commis-  
16 sioner of Food and Drugs, shall establish within the Food  
17 and Drug Administration a team of experts on manufac-  
18 turing and regulatory activities (including compliance with  
19 current Good Manufacturing Practice) to provide both off-  
20 site and on-site technical assistance to the manufacturers  
21 of qualified countermeasures (as defined in section 319F–  
22 1 of the Public Health Service Act), security counter-  
23 measures (as defined in section 319F–2 of such Act), or  
24 vaccines, at the request of such a manufacturer and at  
25 the discretion of the Secretary, if the Secretary determines

1 that a shortage or potential shortage may occur in the  
2 United States in the supply of such vaccines or counter-  
3 measures and that the provision of such assistance would  
4 be beneficial in helping alleviate or avert such shortage.”.

5 **SEC. 405. COLLABORATION AND COORDINATION.**

6 (a) LIMITED ANTITRUST EXEMPTION.—

7 (1) MEETINGS AND CONSULTATIONS TO DIS-  
8 CUSS SECURITY COUNTERMEASURES, QUALIFIED  
9 COUNTERMEASURES, OR QUALIFIED PANDEMIC OR  
10 EPIDEMIC PRODUCT DEVELOPMENT.—

11 (A) AUTHORITY TO CONDUCT MEETINGS  
12 AND CONSULTATIONS.—The Secretary of  
13 Health and Human Services (referred to in this  
14 subsection as the “Secretary”), in coordination  
15 with the Attorney General and the Secretary of  
16 Homeland Security, may conduct meetings and  
17 consultations with persons engaged in the devel-  
18 opment of a security countermeasure (as de-  
19 fined in section 319F–2 of the Public Health  
20 Service Act (42 U.S.C. 247d–6b)) (as amended  
21 by this Act), a qualified countermeasure (as de-  
22 fined in section 319F–1 of the Public Health  
23 Service Act (42 U.S.C. 247d–6a)) (as amended  
24 by this Act), or a qualified pandemic or epi-  
25 demic product (as defined in section 319F–3 of

1 the Public Health Service Act (42 U.S.C.  
2 247d–6d)) for the purpose of the development,  
3 manufacture, distribution, purchase, or storage  
4 of a countermeasure or product. The Secretary  
5 may convene such meeting or consultation at  
6 the request of the Secretary of Homeland Secu-  
7 rity, the Attorney General, the Chairman of the  
8 Federal Trade Commission (referred to in this  
9 section as the “Chairman”), or any interested  
10 person, or upon initiation by the Secretary. The  
11 Secretary shall give prior notice of any such  
12 meeting or consultation, and the topics to be  
13 discussed, to the Attorney General, the Chair-  
14 man, and the Secretary of Homeland Security.

15 (B) MEETING AND CONSULTATION CONDI-  
16 TIONS.—A meeting or consultation conducted  
17 under subparagraph (A) shall—

18 (i) be chaired or, in the case of a con-  
19 sultation, facilitated by the Secretary;

20 (ii) be open to persons involved in the  
21 development, manufacture, distribution,  
22 purchase, or storage of a countermeasure  
23 or product, as determined by the Sec-  
24 retary;

1 (iii) be open to the Attorney General,  
2 the Secretary of Homeland Security, and  
3 the Chairman;

4 (iv) be limited to discussions involving  
5 covered activities; and

6 (v) be conducted in such manner as to  
7 ensure that no national security, confiden-  
8 tial commercial, or proprietary information  
9 is disclosed outside the meeting or con-  
10 sultation.

11 (C) LIMITATION.—The Secretary may not  
12 require participants to disclose confidential  
13 commercial or proprietary information.

14 (D) TRANSCRIPT.—The Secretary shall  
15 maintain a complete verbatim transcript of each  
16 meeting or consultation conducted under this  
17 subsection. Such transcript (or a portion there-  
18 of) shall not be disclosed under section 552 of  
19 title 5, United States Code, to the extent that  
20 the Secretary, in consultation with the Attorney  
21 General and the Secretary of Homeland Secu-  
22 rity, determines that disclosure of such tran-  
23 script (or portion thereof) would pose a threat  
24 to national security. The transcript (or portion  
25 thereof) with respect to which the Secretary has

1           made such a determination shall be deemed to  
2           be information described in subsection (b)(3) of  
3           such section 552.

4           (E) EXEMPTION.—

5           (i) IN GENERAL.—Subject to clause  
6           (ii), it shall not be a violation of the anti-  
7           trust laws for any person to participate in  
8           a meeting or consultation conducted in ac-  
9           cordance with this paragraph.

10          (ii) LIMITATION.—Clause (i) shall not  
11          apply to any agreement or conduct that re-  
12          sults from a meeting or consultation and  
13          that is not covered by an exemption grant-  
14          ed under paragraph (4).

15          (2) SUBMISSION OF WRITTEN AGREEMENTS.—

16          The Secretary shall submit each written agreement  
17          regarding covered activities that is made pursuant to  
18          meetings or consultations conducted under para-  
19          graph (1) to the Attorney General and the Chairman  
20          for consideration. In addition to the proposed agree-  
21          ment itself, any submission shall include—

22                 (A) an explanation of the intended purpose  
23                 of the agreement;

24                 (B) a specific statement of the substance  
25                 of the agreement;

1           (C) a description of the methods that will  
2           be utilized to achieve the objectives of the  
3           agreement;

4           (D) an explanation of the necessity for a  
5           cooperative effort among the particular partici-  
6           pating persons to achieve the objectives of the  
7           agreement; and

8           (E) any other relevant information deter-  
9           mined necessary by the Attorney General, in  
10          consultation with the Chairman and the Sec-  
11          retary.

12          (3) EXEMPTION FOR CONDUCT UNDER AP-  
13          PROVED AGREEMENT.—It shall not be a violation of  
14          the antitrust laws for a person to engage in conduct  
15          in accordance with a written agreement to the extent  
16          that such agreement has been granted an exemption  
17          under paragraph (4), during the period for which  
18          the exemption is in effect.

19          (4) ACTION ON WRITTEN AGREEMENTS.—

20                (A) IN GENERAL.—The Attorney General,  
21                in consultation with the Chairman, shall grant,  
22                deny, grant in part and deny in part, or pro-  
23                pose modifications to an exemption request re-  
24                garding a written agreement submitted under  
25                paragraph (2), in a written statement to the

1 Secretary, within 15 business days of the re-  
2 ceipt of such request. An exemption granted  
3 under this paragraph shall take effect imme-  
4 diately.

5 (B) EXTENSION.—The Attorney General  
6 may extend the 15-day period referred to in  
7 subparagraph (A) for an additional period of  
8 not to exceed 10 business days.

9 (C) DETERMINATION.—An exemption shall  
10 be granted regarding a written agreement sub-  
11 mitted in accordance with paragraph (2) only to  
12 the extent that the Attorney General, in con-  
13 sultation with the Chairman and the Secretary,  
14 finds that the conduct that will be exempted  
15 will not have any substantial anticompetitive ef-  
16 fect that is not reasonably necessary for ensur-  
17 ing the availability of the countermeasure or  
18 product involved.

19 (5) LIMITATION ON AND RENEWAL OF EXEMP-  
20 TIONS.—An exemption granted under paragraph (4)  
21 shall be limited to covered activities, and such ex-  
22 emption shall be renewed (with modifications, as ap-  
23 propriate, consistent with the finding described in  
24 paragraph (4)(C)), on the date that is 3 years after  
25 the date on which the exemption is granted unless

1 the Attorney General in consultation with the Chair-  
2 man determines that the exemption should not be  
3 renewed (with modifications, as appropriate) consid-  
4 ering the factors described in paragraph (4).

5 (6) AUTHORITY TO OBTAIN INFORMATION.—  
6 Consideration by the Attorney General for granting  
7 or renewing an exemption submitted under this sec-  
8 tion shall be considered an antitrust investigation for  
9 purposes of the Antitrust Civil Process Act (15  
10 U.S.C. 1311 et seq.).

11 (7) LIMITATION ON PARTIES.—The use of any  
12 information acquired under an agreement for which  
13 an exemption has been granted under paragraph (4),  
14 for any purpose other than specified in the exemp-  
15 tion, shall be subject to the antitrust laws and any  
16 other applicable laws.

17 (8) REPORT.—Not later than one year after the  
18 date of enactment of this Act and biannually there-  
19 after, the Attorney General and the Chairman shall  
20 report to Congress on the use of the exemption from  
21 the antitrust laws provided by this subsection.

22 (b) SUNSET.—The applicability of this section shall  
23 expire at the end of the 6-year period that begins on the  
24 date of enactment of this Act.

25 (c) DEFINITIONS.—In this section:

1           (1) ANTITRUST LAWS.—The term “antitrust  
2 laws”—

3           (A) has the meaning given such term in  
4 subsection (a) of the first section of the Clayton  
5 Act (15 U.S.C. 12(a)), except that such term  
6 includes section 5 of the Federal Trade Com-  
7 mission Act (15 U.S.C. 45) to the extent such  
8 section 5 applies to unfair methods of competi-  
9 tion; and

10           (B) includes any State law similar to the  
11 laws referred to in subparagraph (A).

12           (2) COUNTERMEASURE OR PRODUCT.—The  
13 term “countermeasure or product” refers to a secu-  
14 rity countermeasure, qualified countermeasure, or  
15 qualified pandemic or epidemic product (as those  
16 terms are defined in subsection (a)(1)).

17           (3) COVERED ACTIVITIES.—

18           (A) IN GENERAL.—Except as provided in  
19 subparagraph (B), the term “covered activities”  
20 includes any activity relating to the develop-  
21 ment, manufacture, distribution, purchase, or  
22 storage of a countermeasure or product.

23           (B) EXCEPTION.—The term “covered ac-  
24 tivities” shall not include, with respect to a  
25 meeting or consultation conducted under sub-

1 section (a)(1) or an agreement for which an ex-  
2 emption has been granted under subsection  
3 (a)(4), the following activities involving 2 or  
4 more persons:

5 (i) Exchanging information among  
6 competitors relating to costs, profitability,  
7 or distribution of any product, process, or  
8 service if such information is not reason-  
9 ably necessary to carry out covered  
10 activities—

11 (I) with respect to a counter-  
12 measure or product regarding which  
13 such meeting or consultation is being  
14 conducted; or

15 (II) that are described in the  
16 agreement as exempted.

17 (ii) Entering into any agreement or  
18 engaging in any other conduct—

19 (I) to restrict or require the sale,  
20 licensing, or sharing of inventions, de-  
21 velopments, products, processes, or  
22 services not developed through, pro-  
23 duced by, or distributed or sold  
24 through such covered activities; or

1 (II) to restrict or require partici-  
2 pation, by any person participating in  
3 such covered activities, in other re-  
4 search and development activities, ex-  
5 cept as reasonably necessary to pre-  
6 vent the misappropriation of propri-  
7 etary information contributed by any  
8 person participating in such covered  
9 activities or of the results of such cov-  
10 ered activities.

11 (iii) Entering into any agreement or  
12 engaging in any other conduct allocating a  
13 market with a competitor that is not ex-  
14 pressly exempted from the antitrust laws  
15 under subsection (a)(4).

16 (iv) Exchanging information among  
17 competitors relating to production (other  
18 than production by such covered activities)  
19 of a product, process, or service if such in-  
20 formation is not reasonably necessary to  
21 carry out such covered activities.

22 (v) Entering into any agreement or  
23 engaging in any other conduct restricting,  
24 requiring, or otherwise involving the pro-  
25 duction of a product, process, or service

1 that is not expressly exempted from the  
2 antitrust laws under subsection (a)(4).

3 (vi) Except as otherwise provided in  
4 this subsection, entering into any agree-  
5 ment or engaging in any other conduct to  
6 restrict or require participation by any per-  
7 son participating in such covered activities,  
8 in any unilateral or joint activity that is  
9 not reasonably necessary to carry out such  
10 covered activities.

11 (vii) Entering into any agreement or  
12 engaging in any other conduct restricting  
13 or setting the price at which a counter-  
14 measure or product is offered for sale,  
15 whether by bid or otherwise.

16 **SEC. 406. PROCUREMENT.**

17 Section 319F–2 of the Public Health Service Act (42  
18 U.S.C. 247d–6b) is amended—

19 (1) in the section heading, by inserting “**AND**  
20 **SECURITY COUNTERMEASURE PROCURE-**  
21 **MENTS**” before the period; and

22 (2) in subsection (c)—

23 (A) in the subsection heading, by striking  
24 “BIOMEDICAL”;

25 (B) in paragraph (3)—

1 (i) by striking “COUNTER-  
2 MEASURES.—The Secretary” and inserting  
3 the following: “COUNTERMEASURES.—

4 “(A) IN GENERAL.—The Secretary”; and

5 (ii) by adding at the end the fol-  
6 lowing:

7 “(B) INFORMATION.—The Secretary shall  
8 institute a process for making publicly available  
9 the results of assessments under subparagraph  
10 (A) while withholding such information as—

11 “(i) would, in the judgment of the  
12 Secretary, tend to reveal public health  
13 vulnerabilities; or

14 “(ii) would otherwise be exempt from  
15 disclosure under section 552 of title 5,  
16 United States Code.”;

17 (C) in paragraph (4)(A), by inserting “not  
18 developed or” after “currently”;

19 (D) in paragraph (5)(B)(i), by striking “to  
20 meet the needs of the stockpile” and inserting  
21 “to meet the stockpile needs”;

22 (E) in paragraph (7)(B)—

23 (i) by striking the subparagraph head-  
24 ing and all that follows through “Home-  
25 land Security Secretary” and inserting the

1 following: “INTERAGENCY AGREEMENT;  
2 COST.—The Homeland Security Sec-  
3 retary”; and

4 (ii) by striking clause (ii);

5 (F) in paragraph (7)(C)(ii)—

6 (i) by amending subclause (I) to read  
7 as follows:

8 “(I) PAYMENT CONDITIONED ON  
9 DELIVERY.—The contract shall pro-  
10 vide that no payment may be made  
11 until delivery of a portion, acceptable  
12 to the Secretary, of the total number  
13 of units contracted for, except that,  
14 notwithstanding any other provision of  
15 law, the contract may provide that, if  
16 the Secretary determines (in the Sec-  
17 retary’s discretion) that an advance  
18 payment, partial payment for signifi-  
19 cant milestones, or payment to in-  
20 crease manufacturing capacity is nec-  
21 essary to ensure success of a project,  
22 the Secretary shall pay an amount,  
23 not to exceed 10 percent of the con-  
24 tract amount, in advance of delivery.  
25 The Secretary shall, to the extent

1 practicable, make the determination of  
2 advance payment at the same time as  
3 the issuance of a solicitation. The con-  
4 tract shall provide that such advance  
5 payment is required to be repaid if  
6 there is a failure to perform by the  
7 vendor under the contract. The con-  
8 tract may also provide for additional  
9 advance payments of 5 percent each  
10 for meeting the milestones specified in  
11 such contract, except that such pay-  
12 ments shall not exceed 50 percent of  
13 the total contract amount. If the spec-  
14 ified milestones are reached, the ad-  
15 vanced payments of 5 percent shall  
16 not be required to be repaid. Nothing  
17 in this subclause shall be construed as  
18 affecting the rights of vendors under  
19 provisions of law or regulation (in-  
20 cluding the Federal Acquisition Regu-  
21 lation) relating to the termination of  
22 contracts for the convenience of the  
23 Government.”; and  
24 (ii) by adding at the end the fol-  
25 lowing:

1           “(VII) SALES EXCLUSIVITY.—  
2           The contract may provide that the  
3           vendor is the exclusive supplier of the  
4           product to the Federal Government  
5           for a specified period of time, not to  
6           exceed the term of the contract, on  
7           the condition that the vendor is able  
8           to satisfy the needs of the Govern-  
9           ment. During the agreed period of  
10          sales exclusivity, the vendor shall not  
11          assign its rights of sales exclusivity to  
12          another entity or entities without ap-  
13          proval by the Secretary. Such a sales  
14          exclusivity provision in such a con-  
15          tract shall constitute a valid basis for  
16          a sole source procurement under sec-  
17          tion 303(c)(1) of the Federal Property  
18          and Administrative Services Act of  
19          1949 (41 U.S.C. 253(c)(1)).

20           “(VIII) WARM BASED SURGE CA-  
21          PACITY.—The contract may provide  
22          that the vendor establish domestic  
23          manufacturing capacity of the product  
24          to ensure that additional production  
25          of the product is available in the event

1 that the Secretary determines that  
2 there is a need to quickly purchase  
3 additional quantities of the product.  
4 Such contract may provide a fee to  
5 the vendor for establishing and main-  
6 taining such capacity in excess of the  
7 initial requirement for the purchase of  
8 the product. Additionally, the cost of  
9 maintaining the domestic manufac-  
10 turing capacity shall be an allowable  
11 and allocable direct cost of the con-  
12 tract.

13 “(IX) CONTRACT TERMS.—The  
14 Secretary, in any contract for procure-  
15 ment under this section, may  
16 specify—

17 “(aa) the dosing and admin-  
18 istration requirements for coun-  
19 termeasures to be developed and  
20 procured;

21 “(bb) the amount of funding  
22 that will be dedicated by the Sec-  
23 retary for development and ac-  
24 quisition of the countermeasure;  
25 and

1           “(cc) the specifications the  
2           countermeasure must meet to  
3           qualify for procurement under a  
4           contract under this section.”; and  
5           (G) in paragraph (8)(A), by adding at the  
6           end the following: “Such agreements may allow  
7           other executive agencies to order qualified and  
8           security countermeasures under procurement  
9           contracts or other agreements established by  
10          the Secretary. Such ordering process (including  
11          transfers of appropriated funds between an  
12          agency and the Department of Health and  
13          Human Services as reimbursements for such or-  
14          ders for countermeasures) may be conducted  
15          under the authority of section 1535 of title 31,  
16          United States Code, except that all such orders  
17          shall be processed under the terms established  
18          under this subsection for the procurement of  
19          countermeasures.”.

Passed the Senate December 5, 2006.

Attest:

*Secretary.*

109<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

**S. 3678**

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**AN ACT**

To amend the Public Health Service Act with respect to public health security and all-hazards preparedness and response, and for other purposes.