

109TH CONGRESS
2D SESSION

S. 3678

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;

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

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

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

“(C) the Strategic National Stockpile; and

“(D) the Cities Readiness Initiative; and

“(3) assume other duties as determined appropriate by the Secretary.”; and

(4) by striking “Assistant Secretary for Public Health Emergency Preparedness” each place it appears and inserting “Assistant Secretary for Preparedness and Response”.

(b) TRANSFER OF FUNCTIONS; REFERENCES.—

(1) TRANSFER OF FUNCTIONS.—There shall be transferred to the Office of the Assistant Secretary for Preparedness and Response the functions, personnel, assets, and liabilities of the Assistant Secretary for Public Health Emergency Preparedness as in effect on the day before the date of enactment of 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

“(ii) at least annually, test, exercise, and rigorously evaluate the public health and medical emergency preparedness and response capabilities of the entity, and report to the Secretary on such measured and tested capabilities and measured and tested progress toward achieving outcome goals, based on criteria established by the Secretary.

“(2) CRITERIA FOR PANDEMIC INFLUENZA PLANS.—

“(A) IN GENERAL.—Not later than 180 days after the date of enactment of the Pandemic and All-Hazards Preparedness Act, the Secretary shall develop and disseminate to the chief executive officer of each State criteria for an effective State plan for responding to pandemic influenza.

“(B) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to require the duplication of Federal efforts with respect to the development of criteria or standards, without regard to whether such efforts were carried out prior to or after the date of enactment of 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

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

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

“(6) AMOUNTS DESCRIBED.—

“(A) IN GENERAL.—The amounts described in this paragraph are the following amounts that are payable to an entity for activities described in section 319C–1 or 319C–2:

“(i) For the fiscal year immediately following a fiscal year in which an entity experienced a failure described in subparagraph (A) or (B) of paragraph (5) by the entity, an amount equal to 10 percent of the amount the entity was eligible to receive for such fiscal year.

“(ii) For the fiscal year immediately following two consecutive fiscal years in 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

health care providers and the public with regard to chemical, biological, radiological, or nuclear threats or exposures, in consultation with the appropriate State, local, and tribal public health entities; or

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

(3) by redesignating subsection (j) as subsection (i);

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

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

“(1) AUTHORIZATION OF APPROPRIATIONS.—

“(A) IN GENERAL.—For the purpose of carrying out this section, there is authorized to be appropriated \$824,000,000 for fiscal year 2007, of which \$35,000,000 shall be used to carry out subsection (h), for awards pursuant to paragraph (3) (subject to the authority of the Secretary to make awards pursuant to 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-

bility through an interoperable network of systems to share data and information to enhance early detection of rapid response to, and management of, potentially catastrophic infectious disease outbreaks and other public health emergencies that originate domestically or abroad. Such network shall be built on existing State situational awareness systems or enhanced systems that enable such connectivity.

“(2) STRATEGIC PLAN.—Not later than 180 days after the date of enactment the Pandemic and All-Hazards Preparedness Act, the Secretary shall submit to the appropriate committees of Congress, a strategic plan that demonstrates the steps the Secretary will undertake to develop, implement, and evaluate the network described in paragraph (1), utilizing the elements described in paragraph (3).

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

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

“(B) Federal health agencies;

“(C) zoonotic disease monitoring systems;

“(D) public and private sector health care 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;

“(D) identify methods for reducing legal barriers that deter health care professionals from providing telemedicine services, such as by utilizing State emergency health care professional credentialing verification systems, encouraging States to establish and implement mechanisms to improve interstate medical licensure cooperation, facilitating the exchange of information among States regarding investigations and adverse actions, and encouraging States to waive the application of licensing requirements during a public health emergency;

“(E) evaluate ways to integrate the practice of telemedicine within the National Disaster Medical System; and

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

“(2) REPORT.—Not later than 12 months after the date of enactment of the Pandemic and All-Hazards Preparedness Act, the Secretary shall prepare and submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the 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 254l) 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 propriate 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 disrup-
 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 serting “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 serting “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—

(A) in paragraph (3), by striking subparagraph (B) and inserting the following:

“(B) the direction or relocation of an individual to receive medical screening in an alternative location—

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

“(ii) in the case of a public health emergency described in subsection (g)(1)(B) that involves a pandemic infectious disease, pursuant to a State pandemic preparedness plan or a plan referred to in clause (i), whichever is applicable in the State;”;

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

(C) by adding at the end the following: “If a public health emergency described in subsection (g)(1)(B) involves a pandemic infectious disease (such as pandemic influenza), the duration of a waiver or modification under paragraph (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(c).

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 serting 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 (c) 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(c);

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 serting “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 fectionous 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;

“(ii) research on and development of research tools and other devices and technologies; and

“(iii) research to promote strategic initiatives, such as rapid diagnostics, broad spectrum antimicrobials, and vaccine manufacturing technologies.

“(5) TRANSACTION AUTHORITIES.—

“(A) OTHER TRANSACTIONS.—

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

“(ii) LIMITATIONS ON AUTHORITY.—

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

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

“(i) diagnose, mitigate, prevent, or treat harm from any biological agent (including organisms that cause an infectious disease) or toxin, chemical, radiological, or nuclear agent that may cause a public health emergency affecting national security; or

“(ii) diagnose, mitigate, prevent, or treat harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device that is used as described in this subparagraph.

“(B) INFECTIOUS DISEASE.—The term ‘infectious disease’ means a disease potentially caused by a pathogenic organism (including a bacteria, virus, fungus, or parasite) that is acquired by a person and that reproduces in that person.”.

(b) SECURITY COUNTERMEASURE.—Section 319F–2(c)(1)(B) is amended by striking “treat, identify, or prevent” each place it appears and inserting “diagnose, mitigate, 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

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

(vi) Except as otherwise provided in this subsection, entering into any agreement or engaging in any other conduct to restrict or require participation by any person participating in such covered activities, in any unilateral or joint activity that is not reasonably necessary to carry out such covered activities.

(vii) Entering into any agreement or engaging in any other conduct restricting or setting the price at which a countermeasure or product is offered for sale, whether by bid or otherwise.

SEC. 406. PROCUREMENT.

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

(1) in the section heading, by inserting “**AND SECURITY COUNTERMEASURE PROCUREMENTS**” before the period; and

(2) in subsection (c)—

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

(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

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

(ii) by striking clause (ii);
(F) in paragraph (7)(C)(ii)—

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

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

109TH CONGRESS
2D SESSION

S. 3678

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.