

Calendar No. 467

115TH CONGRESS
2D SESSION

S. 2852

To reauthorize certain programs under the Pandemic and All-Hazards Preparedness Reauthorization Act.

IN THE SENATE OF THE UNITED STATES

MAY 15, 2018

Mr. BURR (for himself, Mr. CASEY, Mr. ALEXANDER, and Mrs. MURRAY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

JUNE 18, 2018

Reported by Mr. ALEXANDER, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

A BILL

To reauthorize certain programs under the Pandemic and All-Hazards Preparedness Reauthorization Act.

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 and Advancing

6 ~~Innovation Act of 2018”.~~

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

Sec. 1. Short title; table of contents.
 Sec. 2. References in Act.

TITLE I—STRENGTHENING THE NATIONAL HEALTH SECURITY
 STRATEGY

Sec. 101. National Health Security Strategy.

TITLE II—IMPROVING PREPAREDNESS AND RESPONSE

Sec. 201. Improving benchmarks and standards for preparedness and response.
 Sec. 202. Amendments to preparedness and response programs.
 Sec. 203. Regional health care emergency preparedness and response systems.
 Sec. 204. Public health and health care system situational awareness and bio-
 surveillance capabilities.
 Sec. 205. Strengthening and supporting the public health emergency rapid re-
 sponse fund.
 Sec. 206. Improving preparedness for and response to all-hazards by public
 health emergency volunteers.

TITLE III—REACHING ALL COMMUNITIES

Sec. 301. Strengthening and assessing the emergency response workforce.
 Sec. 302. Health system infrastructure to improve preparedness and response.
 Sec. 303. Considerations for at-risk individuals.
 Sec. 304. Improving emergency preparedness and response considerations for
 children.
 Sec. 305. Reauthorizing the National Advisory Committee on Children and Dis-
 asters.
 Sec. 306. Guidance for participation in exercises and drills.

TITLE IV—PRIORITIZING A THREAT-BASED APPROACH

Sec. 401. Assistant Secretary for Preparedness and Response.
 Sec. 402. Public Health Emergency Medical Countermeasures Enterprise.
 Sec. 403. Strategic National Stockpile.
 Sec. 404. Preparing for pandemic influenza, antimicrobial resistance, and other
 significant threats.
 Sec. 405. Reporting on the Federal Select Agent Program.

TITLE V—INCREASING COMMUNICATION IN MEDICAL
 COUNTERMEASURE ADVANCED RESEARCH AND DEVELOPMENT

Sec. 501. Medical countermeasure budget plan.
 Sec. 502. Material threat and medical countermeasure notifications.
 Sec. 503. Availability of regulatory management plans.
 Sec. 504. The Biomedical Advanced Research and Development Authority and
 the BioShield Special Reserve Fund.

TITLE VI—ADVANCING TECHNOLOGIES FOR MEDICAL
 COUNTERMEASURES

Sec. 601. Administration of countermeasures.
 Sec. 602. Medical countermeasure master files.

Sec. 603. Animal rule report.

TITLE VII—MISCELLANEOUS PROVISIONS

Sec. 701. Reauthorizations and extensions.

Sec. 702. Technical amendments.

1 **SEC. 2. REFERENCES IN ACT.**

2 Except as otherwise specified, amendments made by
3 this Act to a section or other provision of law are amend-
4 ments to such section or other provision of the Public
5 Health Service Act (42 U.S.C. 201 et seq.).

6 **TITLE I—STRENGTHENING THE**
7 **NATIONAL HEALTH SECURITY**
8 **STRATEGY**

9 **SEC. 101. NATIONAL HEALTH SECURITY STRATEGY.**

10 Section 2802 (42 U.S.C. 300hh-1) is amended—

11 (1) in subsection (a)—

12 (A) in paragraph (1)—

13 (i) by striking “2014” and inserting
14 “2018”; and

15 (ii) by striking the second sentence
16 and inserting the following: “Such Na-
17 tional Health Security Strategy shall de-
18 scribe potential emergency health security
19 threats and identify the process for achiev-
20 ing the preparedness goals described in
21 subsection (b) to be prepared to identify
22 and respond to such threats and shall be
23 consistent with the national preparedness

1 goal (as described in section 504(a)(19) of
2 the Homeland Security Act of 2002), the
3 National Incident Management System (as
4 defined in section 501(7) of such Act), and
5 the National Response Plan developed pur-
6 suant to section 504 of such Act, or any
7 successor plan.”;

8 (B) in paragraph (2), by inserting before
9 the period at the end of the second sentence the
10 following: “, and an analysis of any changes to
11 the evidence-based benchmarks and objective
12 standards under sections ~~319C-1~~ and ~~319C-2~~”;
13 and

14 (C) in paragraph (3)—

15 (i) by striking “2009” and inserting
16 “2022”;

17 (ii) by inserting “(including gaps in
18 the environmental health workforce); de-
19 scribing the status of such workforce”
20 after “gaps in such workforce”;

21 (iii) by striking “and identifying strat-
22 egies” and inserting “identifying strate-
23 gies”; and

24 (iv) by inserting before the period at
25 the end “, and identifying current capabili-

1 ties to meet the requirements of section
2 2803”; and

3 (2) in subsection (b)—

4 (A) in paragraph (2)—

5 (i) in subparagraph (A), by striking
6 “and investigation” and inserting “inves-
7 tigation, and related information tech-
8 nology activities”;

9 (ii) in subparagraph (B), by striking
10 “and decontamination” and inserting “de-
11 contamination, relevant health care serv-
12 ices and supplies, and transportation and
13 disposal of medical waste”; and

14 (iii) by adding at the end the fol-
15 lowing:

16 “(E) Response to environmental hazards.”;

17 (B) in paragraph (3)(F), by inserting “or
18 exposures to agents that could cause a public
19 health emergency” before the period;

20 (C) in paragraph (5), by inserting “and
21 other applicable compacts” after “Compact”;
22 and

23 (D) by adding at the end the following:

24 “(9) ZOOBOTIC DISEASE, FOOD, AND AGRIC-
25 ULTURE.—In consultation with the Secretary of

1 Agriculture, improving coordination among Federal,
 2 State, local, tribal, and territorial entities to prevent,
 3 detect, and respond to outbreaks of plant or animal
 4 disease (including zoonotic disease) that could com-
 5 promise national security resulting from a deliberate
 6 attack, a naturally occurring threat, the intentional
 7 adulteration of food, or other public health threats,
 8 taking into account interactions between animal
 9 health, human health, and animals' and humans'
 10 shared environment as directly related to public
 11 health emergency preparedness and response capa-
 12 bilities, as applicable.

13 “(10) GLOBAL HEALTH SECURITY.—Assessing
 14 current or potential health security threats from
 15 abroad to inform domestic public health prepared-
 16 ness and response capabilities.”.

17 **TITLE II—IMPROVING**
 18 **PREPAREDNESS AND RESPONSE**

19 **SEC. 201. IMPROVING BENCHMARKS AND STANDARDS FOR**
 20 **PREPAREDNESS AND RESPONSE.**

21 (a) **EVALUATING MEASURABLE EVIDENCE-BASED**
 22 **BENCHMARKS AND OBJECTIVE STANDARDS.**—Section
 23 319C–1 (42 U.S.C. 247d–3a) is amended by inserting
 24 after subsection (j) the following:

25 “(k) **EVALUATION.**—

1 “(1) IN GENERAL.—Not later than 2 years
2 after the date of enactment of the Pandemic and
3 All-Hazards Preparedness and Advancing Innovation
4 Act of 2018 and every 2 years thereafter, the Sec-
5 retary shall conduct an evaluation of the evidence-
6 based benchmarks and objective standards required
7 under subsection (g). Such evaluation shall be sub-
8 mitted to the congressional committees of jurisdic-
9 tion together with the National Health Security
10 Strategy under section 2802, at such time as such
11 strategy is submitted.

12 “(2) CONTENT.—The evaluation under this
13 paragraph shall include—

14 “(A) a review of evidence-based bench-
15 marks and objective standards, and associated
16 metrics and targets;

17 “(B) a discussion of changes to any evi-
18 dence-based benchmarks and objective stand-
19 ards, and the effect of such changes on the abil-
20 ity to track whether entities are meeting or
21 making progress toward the goals under this
22 section and, to the extent practicable, the appli-
23 cable goals of the National Health Security
24 Strategy under section 2802;

1 “(C) a description of amounts received by
 2 eligible entities, as described in subsection (b)
 3 and section 319C-2(b); and amounts received
 4 by sub-recipients and the effect of such funding
 5 on meeting evidence-based benchmarks and ob-
 6 jective standards; and

7 “(D) recommendations, as applicable and
 8 appropriate, to improve evidence-based bench-
 9 marks and objective standards to more accu-
 10 rately assess the ability of entities receiving
 11 awards under this section to better achieve the
 12 goals under this section and section 2802.”.

13 (b) **EVALUATING THE PARTNERSHIP FOR STATE AND**
 14 **REGIONAL HOSPITAL PREPAREDNESS.**—Section 319C-
 15 2(i)(1) (42 U.S.C. 247-3b(i)(1)) is amended by striking
 16 “section 319C-1(g), (i), and (j)” and inserting “section
 17 319C-1(g), (i), (j), and (k)”.

18 **SEC. 202. AMENDMENTS TO PREPAREDNESS AND RE-**
 19 **SPONSE PROGRAMS.**

20 (a) **COOPERATIVE AGREEMENT APPLICATIONS FOR**
 21 **IMPROVING STATE AND LOCAL PUBLIC HEALTH SECU-**
 22 **RITY.**—Section 319C-1 (42 U.S.C. 247d-3a) is amend-
 23 ed—

1 (1) in subsection (a), by inserting “, acting
2 through the Director of the Centers for Disease
3 Control and Prevention,” after “the Secretary”; and

4 (2) in subsection (b)(2)(A)—

5 (A) in clause (vi), by inserting “, including
6 public health agencies with specific expertise
7 that may be relevant to public health security,
8 such as environmental health agencies,” after
9 “stakeholders”;

10 (B) by redesignating clauses (vii) through
11 (ix) as clauses (viii) through (x); and

12 (C) by inserting after clause (vi) the fol-
13 lowing:

14 “(vii) a description of how, as applica-
15 ble, such entity may integrate information
16 to account for individuals with behavioral
17 health needs following a public health
18 emergency;”.

19 (b) PARTNERSHIP FOR STATE AND REGIONAL HOS-
20 PITAL PREPAREDNESS TO IMPROVE SURGE CAPACITY.—
21 Section 319C-2 (42 U.S.C. 247d-3b) is amended—

22 (1) in subsection (a)—

23 (A) by inserting “, acting through the As-
24 sistant Secretary for Preparedness and Re-
25 sponse,” after “The Secretary”; and

1 (B) by striking “preparedness for public
2 health emergencies” and inserting “prepared-
3 ness for, and response to, public health emer-
4 gencies in accordance with subsection (c)”; and
5 (2) in subsection (b)(1)(A)—

6 (A) in clause (iii), by redesignating sub-
7 clauses (I) through (III) as items (aa) through
8 (cc), respectively, and adjusting the margins ac-
9 cordingly;

10 (B) by redesignating clauses (i) through
11 (iii) as subclauses (I) through (III) respectively,
12 and adjusting the margins accordingly;

13 (C) by striking “partnership consisting
14 of—” and inserting “partnership—

15 “(i) consisting of—”; and

16 (D) by adding at the end the following:

17 “(ii) that may include one or more
18 emergency medical service organizations or
19 emergency management organizations;
20 and”.

21 (c) PUBLIC HEALTH SECURITY GRANTS AUTHORIZA-
22 TION OF APPROPRIATIONS.—Section 319C-1(h)(1)(A)
23 (42 U.S.C. 247d-3a(h)(1)(A)) is amended by striking
24 “\$641,900,000 for fiscal year 2014” and all that follows
25 through the period at the end and inserting

1 “\$685,000,000 for each of fiscal years 2019 through 2023
 2 for awards pursuant to paragraph (3) (subject to the au-
 3 thority of the Secretary to make awards pursuant to para-
 4 graphs (4) and (5)).”.

5 (d) PARTNERSHIP FOR STATE AND REGIONAL HOS-
 6 PITAL PREPAREDNESS AUTHORIZATION OF APPROPRIA-
 7 TIONS.—Section 319C-2(j) (42 U.S.C. 247d-3b(j)) is
 8 amended—

9 (1) by amending paragraph (1) to read as fol-
 10 lows:

11 “(1) IN GENERAL.—

12 “(A) AUTHORIZATION OF APPROPRIA-
 13 TIONS.—For purposes of carrying out this sec-
 14 tion and section 319C-3, in accordance with
 15 subparagraph (B), there is authorized to be ap-
 16 propriated \$385,000,000 for each of fiscal years
 17 2019 through 2023.

18 “(B) RESERVATIONS OF AMOUNTS FOR RE-
 19 GIONAL SYSTEMS.—

20 “(i) IN GENERAL.—Subject to clause
 21 (ii), of the amount appropriated under sub-
 22 paragraph (A) for a fiscal year, the Sec-
 23 retary may reserve up to 5 percent for the
 24 purpose of carrying out section 319C-3.

1 “(ii) RESERVATIONS CONTINGENT ON
 2 CONTINUED APPROPRIATIONS.—If the
 3 amount appropriated under subparagraph
 4 (A) for fiscal year 2019 or a subsequent
 5 fiscal year is less than or equal the amount
 6 so appropriated for the previous fiscal
 7 year, the amount that may be reserved
 8 under clause (i) shall be reduced such that
 9 the amount remaining for the purpose of
 10 carrying out this section is not less than
 11 the amount available for such purpose for
 12 the previous fiscal year.”;

13 (2) in paragraph (2), by striking “paragraph
 14 (1) for a fiscal year” and inserting “paragraph
 15 (1)(A) for a fiscal year and not reserved for the pur-
 16 pose described in paragraph (1)(B)(i)”; and

17 (3) in paragraph (3)(A), by striking “paragraph
 18 (1) and not reserved under paragraph (2)” and in-
 19 serting “paragraph (1)(A) and not reserved under
 20 paragraph (1)(B)(i) or (2)”.

21 **SEC. 203. REGIONAL HEALTH CARE EMERGENCY PRE-**
 22 **PAREDNESS AND RESPONSE SYSTEMS.**

23 (a) IN GENERAL.—Part B of title III (42 U.S.C. 243
 24 et seq.) is amended by inserting after section 319C–2 the
 25 following:

1 **“SEC. 319C-3. GUIDELINES FOR REGIONAL HEALTH CARE**
2 **EMERGENCY PREPAREDNESS AND RESPONSE**
3 **SYSTEMS.**

4 “(a) PURPOSE.—It is the purpose of this section to
5 identify and provide guidelines for regional systems of hos-
6 pitals, health care facilities, and other public and private
7 sector entities, with varying levels of capability to treat
8 patients and increase medical surge capacity during, and
9 in advance of, a public health emergency, including threats
10 posed by one or more chemical, biological, radiological,
11 and nuclear agents, including emerging infectious dis-
12 eases.

13 “(b) GUIDELINES.—The Assistant Secretary for Pre-
14 paredness and Response, in consultation with the Director
15 of the Centers for Disease Control and Prevention, the Ad-
16 ministrator of the Centers for Medicare & Medicaid Serv-
17 ices, the Administrator of the Health Resources and Serv-
18 ices Administration, the Commissioner of Food and
19 Drugs, the Assistant Secretary for Mental Health and
20 Substance Use, the Assistant Secretary of Labor for Occu-
21 pational Safety and Health, the Secretary of Veterans Af-
22 fairs, heads of such other Federal agencies as the Sec-
23 retary determines to be appropriate, and State, local, trib-
24 al, and territorial public health officials, shall, not later
25 than 2 years after the date of enactment of this section—

1 “(1) identify and develop a set of guidelines re-
2 relating to practices and protocols for all-hazards pub-
3 lie health emergency preparedness and response for
4 hospitals and health care facilities to provide appro-
5 priate patient care during, in advance of, or imme-
6 diately following, a public health emergency, result-
7 ing from one or more chemical, biological, radio-
8 logical, or nuclear agents, including emerging infec-
9 tious diseases (which may include existing practices,
10 such as trauma care and medical surge capacity and
11 capabilities), with respect to—

12 “(A) a regional approach to identifying
13 hospitals and health care facilities based on
14 varying capabilities and capacity to treat pa-
15 tients affected by such emergency, including—

16 “(i) the manner in which the system
17 will coordinate with and integrate the part-
18 nerships established under section 319C-
19 2(b); and

20 “(ii) informing and educating appro-
21 priate first responders and health care sup-
22 ply chain partners of the regional emer-
23 gency preparedness and response capabili-
24 ties and medical surge capacity of such

1 hospitals and health care facilities in the
2 community;

3 “(B) physical and technological infrastruc-
4 ture, laboratory capacity, staffing, blood supply,
5 and other supply chain needs, taking into ac-
6 count resiliency, geographic considerations, and
7 rural considerations;

8 “(C) protocols or best practices for the
9 safety and personal protection of workers who
10 handle human remains and health care workers
11 (including with respect to protective equipment
12 and supplies, waste management processes, and
13 decontamination), sharing of specialized experi-
14 ence among the health care workforce, behav-
15 ioral health, psychological resilience, and train-
16 ing of the workforce, as applicable;

17 “(D) in a manner that allows for disease
18 containment (within the meaning of section
19 2802(b)(2)(B)), coordinated medical triage,
20 treatment, and transportation of patients, based
21 on patient medical need (including patients in
22 rural areas), to the appropriate hospitals or
23 health care facilities within the regional system
24 or, as applicable and appropriate, between sys-
25 tems in different States or regions; and

1 ~~“(E) the needs of children and other at-~~
2 ~~risk individuals;~~

3 ~~“(2) make such guidelines available on the~~
4 ~~internet website of the Department of Health and~~
5 ~~Human Services in a manner that does not com-~~
6 ~~promise national security; and~~

7 ~~“(3) update such guidelines as appropriate, in-~~
8 ~~cluding based on input received pursuant to sub-~~
9 ~~sections (c), (e), and (f), to address new and emerg-~~
10 ~~ing public health threats.~~

11 ~~“(e) CONSIDERATIONS.—In identifying, developing,~~
12 ~~and updating guidelines under subsection (b), the Assist-~~
13 ~~ant Secretary for Preparedness and Response shall—~~

14 ~~“(1) include input from hospitals and health~~
15 ~~care facilities, including health care coalitions under~~
16 ~~section 319C-2, State, local, tribal, and territorial~~
17 ~~public health departments, and health care or sub-~~
18 ~~ject matter experts, including experts with relevant~~
19 ~~expertise in chemical, biological, radiological, or nu-~~
20 ~~clear threats, and emerging infectious disease as the~~
21 ~~Assistant Secretary determines appropriate, to meet~~
22 ~~the goals under section 2802(b)(3);~~

23 ~~“(2) consult and engage with appropriate~~
24 ~~health care providers and professionals, including~~
25 ~~physicians, nurses, first responders, health care fa-~~

1 facilities (including hospitals, primary care clinics,
2 community health centers, mental health facilities,
3 ambulatory care facilities, and dental health facili-
4 ties); pharmacies; emergency medical providers;
5 trauma care providers; environmental health agen-
6 cies; public health laboratories; poison control cen-
7 ters; blood banks; and other experts that the Assist-
8 ant Secretary determines appropriate, to meet the
9 goals under section 2802(b)(3);

10 “(3) consider feedback related to financial im-
11 plications for hospitals, health care facilities, public
12 health agencies, laboratories, and other entities en-
13 gaged in regional preparedness planning to imple-
14 ment and follow such guidelines, as applicable; and

15 “(4) consider financial requirements and poten-
16 tial incentives for entities to prepare for, and re-
17 spond to, public health emergencies as part of the
18 regional health care emergency preparedness and re-
19 sponse system.

20 “(d) TECHNICAL ASSISTANCE.—The Assistant Sec-
21 retary for Preparedness and Response, in consultation
22 with the Director of the Centers for Disease Control and
23 Prevention and the Assistant Secretary of Labor for Occu-
24 pational Safety and Health, may provide technical assist-

1 ance and consultation towards meeting the guidelines de-
2 scribed in subsection (b):

3 “(e) DEMONSTRATION PROJECT FOR REGIONAL
4 HEALTH CARE PREPAREDNESS AND RESPONSE SYS-
5 TEMS.—

6 “(1) IN GENERAL.—The Assistant Secretary for
7 Preparedness and Response may establish a dem-
8 onstration project pursuant to the development and
9 implementation of guidelines under subsection (b) to
10 improve medical surge capacity for all hazards, build
11 and integrate regional medical response capabilities,
12 improve specialty care expertise for all-hazards re-
13 sponse, and coordinate medical preparedness and re-
14 sponse across State, local, tribal, territorial, and re-
15 gional jurisdictions.

16 “(2) SUNSET.—The authority under this sub-
17 section shall expire on September 30, 2023.

18 “(f) GAO REPORT TO CONGRESS.—

19 “(1) REPORT.—Not later than 3 years after the
20 date of enactment of this section, the Comptroller
21 General of the United States (referred to in this
22 subsection as the ‘Comptroller General’) shall submit
23 to the Committee on Health, Education, Labor, and
24 Pensions and the Committee on Finance of the Sen-
25 ate and the Committee on Energy and Commerce

1 and the Committee on Ways and Means of the
2 House of Representatives, a report on the extent to
3 which hospitals and health care facilities have imple-
4 mented the recommended guidelines under sub-
5 section (b), including an analysis and evaluation of
6 any challenges hospitals or health care facilities ex-
7 perience in implementing such guidelines.

8 “(2) CONTENT.—The Comptroller General shall
9 include in the report under paragraph (1)—

10 “(A) data on the preparedness and re-
11 sponse capabilities that have been informed by
12 the guidelines under subsection (b) to improve
13 regional emergency health care preparedness
14 and response capability, including hospital and
15 health care facility capacity and medical surge
16 capabilities to prepare for, and respond to, pub-
17 lic health emergencies; and

18 “(B) recommendations to reduce gaps in
19 incentives for regional health partners, includ-
20 ing hospitals and health care facilities to im-
21 prove capacity and medical surge capabilities to
22 prepare for, and respond to, public health emer-
23 gencies, consistent with subsection (a), which
24 may include consideration of facilities partici-
25 pating in programs under section 319C-2, pro-

1 grams under the Centers for Medicare & Med-
2 icaid Services (including innovative health care
3 delivery and payment models); and input from
4 private sector financial institutions.

5 “(3) CONSULTATION.—In carrying out para-
6 graphs (1) and (2), the Comptroller General shall
7 consult with the heads of appropriate Federal agen-
8 cies, including—

9 “(A) the Assistant Secretary for Prepared-
10 ness and Response;

11 “(B) the Director of the Centers for Dis-
12 ease Control and Prevention;

13 “(C) the Administrator of the Centers for
14 Medicare & Medicaid Services;

15 “(D) the Assistant Secretary for Mental
16 Health and Substance Use;

17 “(E) the Assistant Secretary of Labor for
18 Occupational Safety and Health;

19 “(F) the Secretary of Veterans Affairs;
20 and

21 “(G) the heads of such other Federal agen-
22 cies as the Secretary determines appropriate.”.

23 (b) ANNUAL REPORTS.—Section ~~319C-2(i)(1)~~ (42
24 U.S.C. ~~247d-3b(i)(1)~~) is amended by inserting after the
25 first sentence the following “The reports submitted under

1 this paragraph shall also include progress towards the im-
 2 plementation of section ~~319C-3~~.”.

3 (c) NATIONAL HEALTH SECURITY STRATEGY INCOR-
 4 PORATION OF REGIONALIZED EMERGENCY PREPARED-
 5 NESS AND RESPONSE.—Section 2802(b)(3) (42 U.S.C.
 6 ~~300hh-1(b)(3)~~) is amended—

7 (1) in the matter preceding subparagraph (A),
 8 by striking “including mental health” and inserting
 9 “including pharmacies, mental health facilities,”;
 10 and

11 (2) by amending subparagraph (G) to read as
 12 follows:

13 “(G) Optimizing a coordinated and flexible
 14 approach to the emergency response and med-
 15 ical surge capacity of hospitals, other health
 16 care facilities, critical care, trauma care (which
 17 may include trauma centers), and emergency
 18 medical systems, which may include the imple-
 19 mentation of guidelines for regional health care
 20 emergency preparedness and response systems
 21 under section ~~319C-3~~.”.

22 (d) IMPROVING STATE AND LOCAL PUBLIC HEALTH
 23 SECURITY.—

24 (1) STATE AND LOCAL SECURITY.—Section
 25 ~~319C-1(e)~~ (42 U.S.C. ~~247d-3a(e)~~) is amended by

1 striking “, and local emergency plans.” and inserting
 2 “, local emergency plans, and any regional health
 3 care emergency preparedness and response system
 4 established pursuant to the applicable guidelines
 5 under section 319C-3.”.

6 (2) PARTNERSHIPS.—Section 319C-2(d)(1)(A)
 7 (42 U.S.C. 247d-3b(d)(1)(A)) is amended—

8 (A) in clause (i), by striking “, and” and
 9 inserting “;”;

10 (B) by redesignating clause (ii) as clause
 11 (iii); and

12 (C) inserting after clause (i), the following:

13 “(ii) among one or more facilities in a
 14 regional health care emergency system
 15 under section 319C-3; and”.

16 **SEC. 204. PUBLIC HEALTH AND HEALTH CARE SYSTEM SIT-**
 17 **UATIONAL AWARENESS AND BIOSURVEIL-**
 18 **LANCE CAPABILITIES.**

19 (a) FACILITIES, CAPACITIES, AND BIOSURVEILLANCE
 20 CAPABILITIES.—Section 319D (42 U.S.C. 247d-4) is
 21 amended—

22 (1) in the section heading, by striking “**REVI-**
 23 **TALIZING**” and inserting “**FACILITIES AND CA-**
 24 **PACITIES OF**”;

25 (2) in subsection (a)—

1 (A) in the subsection heading, by striking
2 “FACILITIES; CAPACITIES” and inserting “IN
3 GENERAL”;

4 (B) in paragraph (1), by striking “and im-
5 proved” and inserting “, improved, and appro-
6 priately maintained”;

7 (C) in paragraph (3), in the matter pre-
8 ceeding subparagraph (A), by striking “expand,
9 enhance, and improve” and inserting “expand,
10 improve, enhance, and appropriately maintain”;
11 and

12 (D) by adding at the end the following:

13 “(4) STUDY OF RESOURCES FOR FACILITIES
14 AND CAPACITIES.—Not later than June 1, 2022, the
15 Comptroller General of the United States shall con-
16 duct a study on Federal spending in fiscal years
17 2013 through 2018 for activities authorized under
18 this subsection. Such study shall include a review
19 and assessment of obligations and expenditures di-
20 rectly related to each activity under paragraphs (2)
21 and (3), including a specific accounting of, and de-
22 lineation between, obligations and expenditures in-
23 curred for the construction, renovation, equipping,
24 and security upgrades of facilities and associated
25 contracts under this subsection, and the obligations

1 and expenditures incurred to establish and improve
 2 the situational awareness and biosurveillance net-
 3 work under subsection (b), and shall identify the
 4 agency or agencies incurring such obligations and
 5 expenditures.”;

6 (3) in subsection (b)—

7 (A) in the subsection heading, by striking
 8 “NATIONAL” and inserting “ESTABLISHMENT
 9 OF SYSTEMS OF PUBLIC HEALTH ”;

10 (B) in paragraph (1)(B), by inserting “im-
 11 munization information systems,” after “cen-
 12 ters,”;

13 (C) in paragraph (2)—

14 (i) by inserting “develop a plan to,
 15 and” after “The Secretary shall”; and

16 (ii) by inserting “and in a form read-
 17 ily usable for analytical approaches” after
 18 “in a secure manner”; and

19 (D) by amending paragraph (3) to read as
 20 follows:

21 “(3) STANDARDS.—

22 “(A) IN GENERAL.—Not later than 1 year
 23 after the date of the enactment of the Pan-
 24 demic and All-Hazards Preparedness and Ad-
 25 vancing Innovation Act of 2018, the Secretary,

1 in cooperation with health care providers, State,
2 local, tribal, and territorial public health offi-
3 cials, and relevant Federal agencies (including
4 the Office of the National Coordinator for
5 Health Information Technology and the Na-
6 tional Institute of Standards and Technology),
7 shall, as necessary, adopt technical and report-
8 ing standards, including standards for inter-
9 operability as defined by section 3000, for net-
10 works under paragraph (1) and update such
11 standards as necessary. Such standards shall be
12 made available on the internet website of the
13 Department of Health and Human Services, in
14 a manner that does not compromise national se-
15 curity.

16 “(B) DEFERENCE TO STANDARDS DEVEL-
17 OPMENT ORGANIZATIONS.—In adopting and im-
18 plementing standards under this subsection and
19 subsection (c), the Secretary shall give def-
20 erence to standards published by standards de-
21 velopment organizations and voluntary con-
22 sensus-based standards entities.”;

23 (4) in subsection (c)—

24 (A) in paragraph (1)—

1 (i) by striking “Not later than 2 years
2 after the date of enactment of the Pan-
3 demic and All-Hazards Preparedness Re-
4 authorization Act of 2013, the Secretary”
5 and inserting “The Secretary”;

6 (ii) by inserting “, and improve as ap-
7 plicable and appropriate,” after “shall es-
8 tablish”;

9 (iii) by striking “of rapid” and insert-
10 ing “of, rapid”; and

11 (iv) by striking “such connectivity”
12 and inserting “such interoperability”;

13 (B) by amending paragraph (2) to read as
14 follows:

15 “(2) COORDINATION AND CONSULTATION.—In
16 establishing and improving the network under para-
17 graph (1) the Secretary shall—

18 “(A) facilitate coordination among agencies
19 within the Department of Health and Human
20 Services that provide or have the potential to
21 provide information and data to, and analyses
22 for, the situational awareness and biosurveil-
23 lance network under paragraph (1), including
24 coordination among relevant agencies related to
25 health care services; the facilitation of health

1 information exchange (including the Office of
 2 the National Coordinator for Health Informa-
 3 tion Technology), and public health emergency
 4 preparedness and response; and

5 “(B) consult with the Secretary of Agri-
 6 culture, the Secretary of Commerce (and the
 7 Director of the National Institute of Standards
 8 and Technology), the Secretary of Defense, the
 9 Secretary of Homeland Security, and the Sec-
 10 retary of Veterans Affairs, and the heads of
 11 other Federal agencies, as the Secretary deter-
 12 mines appropriate.”;

13 (C) in paragraph (3)—

14 (i) by redesignating subparagraphs
 15 (A) through (E) as clauses (i) through (v),
 16 respectively, and adjusting the margins ac-
 17 cordingly;

18 (ii) in clause (iv), as so redesign-
 19 ated—

20 (I) by inserting “immunization
 21 information programs,” after “poison
 22 control,”; and

23 (II) by striking “and clinical lab-
 24 oratories” and inserting “, clinical

1 laboratories, and public environmental
2 health agencies”;

3 (iii) by striking “The network” and
4 inserting the following:

5 “(A) IN GENERAL.—The network”;

6 (iv) by adding at the end the fol-
7 lowing:

8 “(B) REVIEW.—Not later than 2 years
9 after the date of the enactment of the Pan-
10 demic and All-Hazards Preparedness and Ad-
11 vancing Innovation Act of 2018 and every 6
12 years thereafter, the Secretary shall conduct a
13 review of the elements described in subpara-
14 graph (A). Such review shall include a discus-
15 sion of the addition of any elements pursuant to
16 clause (v), including elements added to advanc-
17 ing new technologies, and identify any chal-
18 lenges in the incorporation of elements under
19 subparagraph (A). The Secretary shall provide
20 such review to the congressional committees of
21 jurisdiction.”;

22 (D) in paragraph (5)—

23 (i) by redesignating subparagraphs
24 (A) through (D) as clauses (i) through

1 (iv), respectively, and adjusting the mar-
2 gins accordingly;

3 (ii) by striking “In establishing” and
4 inserting the following:

5 “(A) IN GENERAL.—In establishing”;

6 (iii) by adding at the end the fol-
7 lowing:

8 “(B) PUBLIC MEETING.—

9 “(i) IN GENERAL.—Not later than
10 180 days after the date of enactment of
11 the Pandemic and All-Hazards Prepared-
12 ness and Advancing Innovation Act of
13 2018, the Secretary shall convene a public
14 meeting for purposes of discussing and
15 providing input on the potential goals,
16 functions, and uses of the network de-
17 scribed in paragraph (1) and incorporating
18 the elements described in paragraph
19 (3)(A).

20 “(ii) EXPERTS.—The public meeting
21 shall include representatives of relevant
22 Federal agencies (including representatives
23 from the Office of the National Coordi-
24 nator for Health Information Technology
25 and the National Institute of Standards

1 and Technology); State, local, tribal, and
2 territorial public health officials; stake-
3 holders with expertise in biosurveillance
4 and situational awareness; and stake-
5 holders with expertise in capabilities rel-
6 evant to biosurveillance and situational
7 awareness, such as experts in informatics
8 and data analytics (including experts in
9 prediction and forecasting); and other rep-
10 resentatives as the Secretary determines
11 appropriate.

12 “(iii) TOPICS.—Such public meeting
13 shall include a discussion of—

14 “(I) data elements, including
15 minimal or essential data elements,
16 that are voluntarily provided for such
17 network, which may include elements
18 from public health and public and pri-
19 vate health care entities, to the extent
20 practicable;

21 “(II) standards and implementa-
22 tion specifications that may improve
23 the collection, analysis, and interpre-
24 tation of data during a public health
25 emergency;

1 “(III) strategies to encourage the
2 access, exchange, and use of informa-
3 tion;

4 “(IV) considerations for State,
5 local, tribal, and territorial capabilities
6 and infrastructure related to data ex-
7 change and interoperability;

8 “(V) privacy and security protec-
9 tions provided at the Federal, State,
10 local, tribal, and territorial levels, and
11 by nongovernmental stakeholders; and

12 “(VI) opportunities for the incor-
13 poration of innovative technologies to
14 improve the network.”; and

15 (iv) in subparagraph (A), as so des-
16 ignated by clause (ii)—

17 (I) in clause (i), as so redesign-
18 nated—

19 (aa) by striking “as deter-
20 mined” and inserting “as adopt-
21 ed”; and

22 (bb) by inserting “and the
23 National Institute of Standards
24 and Technology” after “Office of

1 the National Coordinator for
2 Health Information Technology”;

3 (II) in clause (iii), as so redesignated,
4 by striking “; and” and inserting
5 a semicolon;

6 (III) in clause (iv), as so redesignated,
7 by striking the period and inserting
8 “; and”; and

9 (IV) by adding at the end the following:
10

11 “(v) pilot test standards and implementation
12 specifications, consistent with
13 the process described in section
14 3002(b)(3)(C), which State, local, tribal,
15 and territorial public health entities may
16 utilize, on a voluntary basis, as a part of
17 the network.”;

18 (E) by redesignating paragraph (6) as
19 paragraph (7);

20 (F) by inserting after paragraph (5) the
21 following:

22 “(6) STRATEGY AND IMPLEMENTATION
23 PLAN.—

24 “(A) IN GENERAL.—Not later than 18
25 months after the date of enactment of the Pan-

1 demic and All-Hazards Preparedness and Ad-
2 vancing Innovation Act of 2018, the Secretary
3 shall submit to the appropriate committees of
4 Congress a coordinated strategy and an accom-
5 panying implementation plan that—

6 “(i) is informed by the public meeting
7 under paragraph (5)(B);

8 “(ii) includes a review and assessment
9 of existing capabilities of the network and
10 related infrastructure, including input pro-
11 vided by the public meeting under para-
12 graph (5)(B);

13 “(iii) identifies and demonstrates the
14 measurable steps the Secretary will carry
15 out to—

16 “(I) develop, implement, and
17 evaluate the network described in
18 paragraph (1), utilizing elements de-
19 scribed in paragraph (3)(A);

20 “(II) modernize and enhance bio-
21 surveillance activities, including strat-
22 egies to include innovative tech-
23 nologies and analytical approaches
24 (including prediction and forecasting

1 for pandemics and all-hazards) from
2 public and private entities;

3 “(III) improve information shar-
4 ing; coordination; and communication
5 among disparate biosurveillance sys-
6 tems supported by the Department of
7 Health and Human Services, includ-
8 ing the identification of methods to
9 improve accountability; better utilize
10 resources and workforce capabilities;
11 and incorporate innovative tech-
12 nologies within and across agencies;
13 and

14 “(IV) test and evaluate capabili-
15 ties of the interoperable network of
16 systems to improve situational aware-
17 ness and biosurveillance capabilities;

18 “(iv) includes performance measures
19 and the metrics by which performance
20 measures will be assessed with respect to
21 the measurable steps under clause (iii);
22 and

23 “(v) establishes dates by which each
24 measurable step under clause (iii) will be
25 implemented.”

1 “(B) ANNUAL BUDGET PLAN.—Not later
2 than 2 years after the date of enactment of the
3 Pandemic and All-Hazards Preparedness and
4 Advancing Innovation Act of 2018 and on an
5 annual basis thereafter, in accordance with the
6 strategy and implementation plan under this
7 paragraph, the Secretary shall, taking into ac-
8 count recommendations provided by the Na-
9 tional Biodefense Science Board, develop a
10 budget plan based on the strategy and imple-
11 mentation plan under this section. Such budget
12 plan shall include—

13 “(i) a summary of resources pre-
14 viously expended to establish, improve, and
15 utilize the nationwide public health situa-
16 tional awareness and biosurveillance net-
17 work under paragraph (1);

18 “(ii) estimates of costs and resources
19 needed to establish and improve the net-
20 work under paragraph (1) according to the
21 strategy and implementation plan under
22 subparagraph (A);

23 “(iii) the identification of gaps and in-
24 efficiencies in nationwide public health sit-
25 uational awareness and biosurveillance ca-

1 pabilities, resources, and authorities need-
2 ed to address such gaps; and

3 “(iv) a strategy to minimize and ad-
4 dress such gaps and improve inefficien-
5 cies.”;

6 (G) in paragraph (7), as so redesignated—

7 (i) in subparagraph (A), by inserting
8 “(taking into account zoonotic disease, in-
9 cluding gaps in scientific understanding of
10 the interactions between human, animal,
11 and environmental health)” after “human
12 health”;

13 (ii) in subparagraph (B)—

14 (I) by inserting “and gaps in sur-
15 veillance programs” after “surveil-
16 lance programs”; and

17 (II) by striking “; and” and in-
18 serting a semicolon;

19 (iii) in subparagraph (C)—

20 (I) by inserting “; animal health
21 organizations related to zoonotic dis-
22 ease,” after “health care entities”;
23 and

24 (II) by striking the period and
25 inserting “; and”;

1 (iv) by adding at the end the fol-
 2 lowing:

3 “(D) provide recommendations to the Sec-
 4 retary on policies and procedures to complete
 5 the steps described in this paragraph in a man-
 6 ner that is consistent with section 2802.”; and

7 (H) by adding at the end the following:

8 “(8) SITUATIONAL AWARENESS AND BIO-
 9 SURVEILLANCE AS A NATIONAL SECURITY PRI-
 10 ORITY.—The Secretary, on a periodic basis as appli-
 11 cable and appropriate, shall meet with the Director
 12 of National Intelligence to inform the development
 13 and capabilities of the nationwide public health situ-
 14 ational awareness and biosurveillance network.”;

15 (5) in subsection (d)—

16 (A) in paragraph (1)—

17 (i) by inserting “environmental health
 18 agencies,” after “public health agencies,”;

19 and

20 (ii) by inserting “immunization pro-
 21 grams,” after “poison control centers,”;

22 and

23 (B) in paragraph (2)—

24 (i) in subparagraph (B), by striking
 25 “and” at the end;

1 (ii) in subparagraph (C), by striking
2 the period and inserting “; and”; and

3 (iii) by adding after subparagraph (C)
4 the following:

5 “(D) an implementation plan that may in-
6 clude measurable steps to achieve the purposes
7 described in paragraph (1).”; and

8 (C) by striking paragraph (5) and insert-
9 ing the following:

10 “(5) TECHNICAL ASSISTANCE.—The Secretary
11 may provide technical assistance to States, localities,
12 tribes, and territories or a consortium of States, lo-
13 calities, tribes, and territories receiving an award
14 under this subsection regarding interoperability and
15 the technical standards set forth by the Secretary.”;

16 (6) by redesignating subsections (f) and (g) as
17 subsections (h) and (i), respectively; and

18 (7) by inserting after subsection (e) the fol-
19 lowing:

20 “(f) TIMELINE.—The Secretary shall accomplish the
21 purposes under subsections (b) and (e) no later than Sep-
22 tember 30, 2023, and shall provide a justification to Con-
23 gress for any missed or delayed implementation of measur-
24 able steps identified under subsection (e)(6)(A)(iii).

1 “(g) INDEPENDENT EVALUATION.—Not later than 3
 2 years after the date of enactment of the Pandemic and
 3 All-Hazards Preparedness and Advancing Innovation Act
 4 of 2018, the Comptroller General of the United States
 5 shall conduct an independent evaluation, and submit to
 6 the Secretary and the appropriate committees of Congress
 7 a report concerning the activities conducted under sub-
 8 sections (b) and (c), and provide recommendations, as ap-
 9 plicable and appropriate, on necessary improvements to
 10 the biosurveillance and situational awareness network.”.

11 (b) AUTHORIZATION OF APPROPRIATIONS.—Sub-
 12 section (h) of section 319D (42 U.S.C. 247d–4), as redes-
 13 igned by subsection (a)(6), is amended by striking
 14 “\$138,300,000 for each of fiscal years 2014 through
 15 2018” and inserting “\$161,800,000 for each of fiscal
 16 years 2019 through 2023”.

17 **SEC. 205. STRENGTHENING AND SUPPORTING THE PUBLIC**
 18 **HEALTH EMERGENCY RAPID RESPONSE**
 19 **FUND.**

20 Section 319 of the Public Health Service Act (42
 21 U.S.C. 247d) is amended—

22 (1) in subsection (b)—

23 (A) in paragraph (1)—

24 (i) in the first sentence, by inserting

25 “or if the Secretary determines there is the

1 significant potential for a public health
2 emergency, to allow the Secretary to rap-
3 idly respond to the immediate needs result-
4 ing from such public health emergency or
5 potential public health emergency” before
6 the period; and

7 (ii) by inserting “The Secretary shall
8 plan for the expedited distribution of funds
9 to appropriate agencies and entities.” after
10 the first sentence;

11 (B) by redesignating paragraph (2) as
12 paragraph (3);

13 (C) by inserting after paragraph (1) the
14 following:

15 “(2) USES.—The Secretary may use amounts
16 in the Fund established under paragraph (1), to—

17 “(A) facilitate coordination between and
18 among Federal, State, local, tribal, and terri-
19 torial entities and public and private health
20 care entities that the Secretary determines may
21 be affected by a public health emergency or po-
22 tential public health emergency (including com-
23 munication of such entities with relevant inter-
24 national entities, as applicable);

1 “(B) make grants, provide for awards,
2 enter into contracts, and conduct supportive in-
3 vestigations pertaining to a public health emer-
4 gency or potential public health emergency, in-
5 cluding further supporting programs under sec-
6 tion ~~319C-1~~ or ~~319C-2~~;

7 “(C) facilitate and accelerate, as applica-
8 ble, advanced research and development of secu-
9 rity countermeasures (as defined in section
10 ~~319F-2~~), qualified countermeasures (as defined
11 in section ~~319F-1~~), or qualified pandemic or
12 epidemic products (as defined in section ~~319F-~~
13 ~~3~~), that are applicable to the public health
14 emergency or potential public health emergency
15 under paragraph (1);

16 “(D) strengthen biosurveillance capabilities
17 and laboratory capacity to identify, collect, and
18 analyze information on such public health emer-
19 gency or potential public health emergency, in-
20 cluding the systems under section ~~319D~~;

21 “(E) support initial emergency operations
22 and assets related to preparation and deploy-
23 ment of intermittent disaster response per-
24 sonnel expenses under section ~~2812~~, and the
25 Medical Reserve Corps under section ~~2813~~; and

1 “(F) other activities, as the Secretary de-
2 termines applicable and appropriate.”; and

3 (D) by inserting after paragraph (3), as so
4 redesignated, the following:

5 “(4) REVIEW.—Not later than 2 years after the
6 date of enactment of the Pandemic and All-Hazards
7 Preparedness and Advancing Innovation Act of
8 2018, the Secretary, in coordination with the Assist-
9 ant Secretary for Preparedness and Response, shall
10 conduct a review of the Fund under this section, and
11 provide recommendations to the Committee on
12 Health, Education, Labor, and Pensions and the
13 Committee on Appropriations of the Senate and the
14 Committee on Energy and Commerce and the Com-
15 mittee on Appropriations of the House of Represent-
16 atives on policies to improve such Fund for the uses
17 described in paragraph (2).

18 “(5) GAO REPORT.—Not later than 4 years
19 after the date of enactment of the Pandemic and
20 All-Hazards Preparedness and Advancing Innovation
21 Act of 2018, the Comptroller General of the United
22 States shall conduct a review of the Fund under this
23 section, including the uses and the resources avail-
24 able in the Fund.”; and

25 (2) in subsection (c)—

1 (A) by inserting “rapidly respond to public
2 health emergencies or potential public health
3 emergencies and” after “used to”; and

4 (B) by striking “section.” and inserting
5 “Act or funds otherwise provided for emergency
6 response.”.

7 **SEC. 206. IMPROVING PREPAREDNESS FOR AND RESPONSE**
8 **TO ALL-HAZARDS BY PUBLIC HEALTH EMER-**
9 **GENCY VOLUNTEERS.**

10 Section 319I (42 U.S.C. 247d–7b) is amended:

11 (1) in subsection (a), by adding at the end the
12 following: “Such health care professionals may in-
13 clude members of the National Disaster Medical
14 System, members of the Medical Reserve Corps, and
15 individual health care professionals.”;

16 (2) in subsection (i) by adding at the end “In
17 order to inform the development of such mechanisms
18 by States, the Secretary shall make available infor-
19 mation and material provided by States that have
20 developed mechanisms to waive the application of li-
21 censing requirements to applicable health profes-
22 sionals seeking to provide medical services during a
23 public health emergency. Such information shall be
24 made publicly available in a manner that does not
25 jeopardize national security.”; and

1 (3) in subsection (k) by striking “\$2014
2 through 2018” and inserting “2019 through 2023”.

3 **TITLE III—REACHING ALL**
4 **COMMUNITIES**

5 **SEC. 301. STRENGTHENING AND ASSESSING THE EMER-**
6 **GENCY RESPONSE WORKFORCE.**

7 (a) NATIONAL DISASTER MEDICAL SYSTEM.—Clause
8 (ii) of section 2812(a)(3)(A) (42 U.S.C. 300hh-
9 11(a)(3)(A)) is amended to read as follows:

10 “(ii) be present at locations, and for
11 limited periods of time, specified by the
12 Secretary on the basis that the Secretary
13 has determined that a location is at risk of
14 a public health emergency during the time
15 specified, or there is a significant potential
16 for a public health emergency.”.

17 (b) VOLUNTEER MEDICAL RESERVE CORPS.—Sec-
18 tion 2813(a) (42 U.S.C. 42 U.S.C. 300hh-15(a)) is
19 amended by striking the second sentence and inserting
20 “The Secretary may appoint a Director to head the Corps
21 and oversee the activities of the Corps chapters that exist
22 at the State, local, and tribal levels.”

23 (c) REVIEW OF THE NATIONAL DISASTER MEDICAL
24 SYSTEM.—Section 2812(b)(2) (42 U.S.C. 300hh-
25 11(b)(2)) is amended to read as follows:

1 “(2) JOINT REVIEW AND MEDICAL SURGE CA-
2 PACITY STRATEGIC PLAN.—

3 “(A) REVIEW.—Not later than 180 days
4 after the date of enactment of the Pandemic
5 and All-Hazards Preparedness and Advancing
6 Innovation Act of 2018, the Secretary, in co-
7 ordination with the Secretary of Homeland Se-
8 curity, the Secretary of Defense, and the Sec-
9 retary of Veterans Affairs, shall conduct a joint
10 review of the National Disaster Medical System.
11 Such review shall include—

12 “(i) an evaluation of medical surge ca-
13 pacity, as described in section 2802(a);

14 “(ii) an assessment of the available
15 workforce of the intermittent disaster re-
16 sponse personnel described in subsection
17 (e);

18 “(iii) the capacity of the workforce de-
19 scribed in clause (ii) to respond to all haz-
20 ards, including capacity to simultaneously
21 respond to multiple public health emer-
22 gencies and the capacity to respond to a
23 nationwide public health emergency;

24 “(iv) the effectiveness of efforts to re-
25 cruit, retain, and train such workforce; and

1 “(v) gaps that may exist in such
2 workforce and recommendations for ad-
3 dressing such gaps.

4 “(B) UPDATES.—As part of the National
5 Health Security Strategy under section 2802,
6 the Secretary shall update the findings from the
7 review under subparagraph (A) and provide rec-
8 ommendations to modify the policies of the Na-
9 tional Disaster Medical System as necessary.”.

10 (d) NOTIFICATION OF NDMS SHORTAGE.—Section
11 2812(e) (42 U.S.C. 300hh–11(e)) is amended by adding
12 at the end the following:

13 “(3) SERVICE BENEFIT.—Individuals appointed
14 to serve under this subsection shall be considered
15 public safety officers under part L of title I of the
16 Omnibus Crime Control and Safe Streets Act of
17 1968. The Secretary shall provide notification to eli-
18 gible individuals of any effect such designation may
19 have on other benefits for which such individuals are
20 eligible, including benefits from private entities.

21 “(4) NOTIFICATION.—Not later than 30 days
22 after the date on which the Secretary determines the
23 number of intermittent disaster response personnel
24 of such System is insufficient to address a public
25 health emergency or potential public health emer-

1 gency, the Secretary shall submit to the congres-
2 sional committees of jurisdiction a notification de-
3 tailing the impact such shortage could have on meet-
4 ing public health needs and emergency medical per-
5 sonnel needs during a public health emergency, and
6 any identified measures to address such shortage.

7 “(5) CERTAIN APPOINTMENTS.—

8 “(A) IN GENERAL.—If the Secretary deter-
9 mines that the number of intermittent disaster
10 response personnel within the National Disaster
11 Medical System under this section is insuffi-
12 cient to address a public health emergency or
13 potential public health emergency, the Secretary
14 may appoint candidates directly to personnel
15 positions for intermittent disaster response
16 within such system. The Secretary shall provide
17 updates on the number of vacant or unfilled po-
18 sitions within such system to the congressional
19 committees of jurisdiction each quarter for
20 which this authority is in effect.

21 “(B) SUNSET.—The authority under this
22 paragraph shall expire on September 30,
23 2021.”.

1 (e) PUBLIC SAFETY OFFICER BENEFITS.—Section
2 1204(9) of title I of the Omnibus Crime Control and Safe
3 Streets Act of 1968 (34 U.S.C. 10284(9)) is amended—

4 (1) in subparagraph (C)(ii), by striking “or” at
5 the end;

6 (2) in subparagraph (D), by striking the period
7 and inserting “; or”; and

8 (3) by inserting after subparagraph (D) the fol-
9 lowing:

10 “(E) an individual appointed to the Na-
11 tional Disaster Medical System under section
12 2812 of the Public Health Service Act (42
13 U.S.C. 300hh-11) who is performing official
14 duties of the Department of Health and Human
15 Services, if those official duties are related to
16 responding to a public health emergency or po-
17 tential public health emergency, or other activi-
18 ties for which the Secretary of Health and
19 Human Services has activated such National
20 Disaster Medical System.”.

21 (f) NATIONAL DISASTER MEDICAL SYSTEM AUTHOR-
22 IZATION OF APPROPRIATIONS.—Section 2812(g) (42
23 U.S.C. 300hh-11(g)) is amended by striking
24 “\$52,700,000 for each of fiscal years 2014 through 2018”

1 and inserting “\$57,400,000 for each of fiscal years 2019
2 through 2023”.

3 (g) ~~MEDICAL RESERVE CORPS AUTHORIZATION OF~~
4 ~~APPROPRIATIONS.—~~Section 2813(i) (42 U.S.C. 300hh-
5 15(i)) is amended by striking “2014 through 2018” and
6 inserting “2019 through 2023”.

7 **SEC. 302. HEALTH SYSTEM INFRASTRUCTURE TO IMPROVE**
8 **PREPAREDNESS AND RESPONSE.**

9 (a) ~~COORDINATION OF PREPAREDNESS.—~~Section
10 ~~2811(b)(5) (42 U.S.C. 300hh-10(b)(5))~~ is amended by
11 adding at the end the following: “Such logistical support
12 shall include working with other relevant Federal, State,
13 local, tribal, and territorial public health officials and pri-
14 vate sector partners to identify the critical infrastructure
15 assets, systems, and networks needed for the proper func-
16 tioning of the health care and public health sectors that
17 need to be maintained through any emergency or disaster,
18 including entities capable of assisting with, responding to,
19 and mitigating the effect of a public health emergency,
20 including an emergency under section 319, an emergency
21 or major disaster under the Robert T. Stafford Disaster
22 Relief and Emergency Assistance Act, or the National
23 Emergencies Act, including by establishing methods to ex-
24 change critical information and deliver products consumed

1 or used to preserve, protect, or sustain life, health, or safe-
2 ty, and sharing of specialized expertise.”.

3 (b) MANUFACTURING CAPACITY.—Section
4 2811(d)(2)(C) (~~42 U.S.C. 300hh-10(d)(2)(C)~~) is amended
5 by inserting “, and ancillary medical supplies to assist
6 with the utilization of such products,” after “products”.

7 **SEC. 303. CONSIDERATIONS FOR AT-RISK INDIVIDUALS.**

8 (a) AT-RISK INDIVIDUALS IN THE NATIONAL
9 HEALTH SECURITY STRATEGY.—Section 2802(b)(4)(B)
10 (~~42 U.S.C. 300hh-1(b)(4)(B)~~) is amended—

11 (1) by striking “this section and sections 319C-
12 1, 319F, and 319L,” and inserting “this Act”; and

13 (2) by striking “special” and inserting “access
14 or functional”.

15 (b) COUNTERMEASURE CONSIDERATIONS.—Section
16 319L(c)(6) (~~42 U.S.C. 247d-7c(e)(6)~~) is amended—

17 (1) by striking “elderly” and inserting “senior
18 citizens”; and

19 (2) by inserting “with relevant characteristics
20 that warrant consideration during the process of re-
21 searching and developing such countermeasures and
22 products” before the period.

1 **SEC. 304. IMPROVING EMERGENCY PREPAREDNESS AND**
2 **RESPONSE CONSIDERATIONS FOR CHIL-**
3 **DREN.**

4 Part B of title III (42 U.S.C. 243 et seq.) is amended
5 by inserting after section 319D the following:

6 **“SEC. 319D-1. CHILDREN’S PREPAREDNESS UNIT.**

7 **“(a) ENHANCING EMERGENCY PREPAREDNESS FOR**
8 **CHILDREN.**—The Secretary, acting through the Director
9 of the Centers for Disease Control and Prevention (re-
10 ferred to in this subsection as the ‘Director’), shall main-
11 tain an internal team of experts, to be known as the Chil-
12 dren’s Preparedness Unit (referred to in this subsection
13 as the ‘Unit’), to work collaboratively to provide guidance
14 on the considerations for, and the specific needs of, chil-
15 dren before, during, and after public health emergencies.
16 The Unit shall inform the Director regarding emergency
17 preparedness and response efforts pertaining to children
18 at the Centers for Disease Control and Prevention.

19 **“(b) EXPERTISE.**—The team described in subsection
20 (a) shall include one or more pediatricians, which may be
21 a developmental-behavior pediatrician, and may also in-
22 clude behavioral scientists, child psychologists, epidemiolo-
23 gists, biostatisticians, health communications staff, and
24 individuals with other areas of expertise, as the Secretary
25 determines appropriate.

1 “(c) DUTIES.—The team described in subsection (a)
2 may—

3 “(1) assist State, local, tribal, and territorial
4 emergency planning and response activities related
5 to children, which may include developing, identi-
6 fying, and sharing best practices;

7 “(2) provide technical assistance, training, and
8 consultation to Federal, State, local, tribal, and ter-
9 ritorial public health officials to improve prepared-
10 ness and response capabilities with respect to the
11 needs of children, including providing such technical
12 assistance, training, and consultation to eligible enti-
13 ties in order to support the achievement of measur-
14 able evidence-based benchmarks and objective stand-
15 ards applicable to sections 319C-1 and 319C-2;

16 “(3) improve the utilization of methods to in-
17 corporate the needs of children in planning for and
18 responding to a public health emergency, including
19 public awareness of such methods;

20 “(4) coordinate with, and improve, public-pri-
21 vate partnerships, such as health care coalitions pur-
22 suant to sections 319C-2 and 319C-3, to address
23 gaps and inefficiencies in emergency preparedness
24 and response efforts for children;

1 “(5) provide expertise and input during the de-
2 velopment of guidance and clinical recommendations
3 to address the needs of children when preparing for,
4 and responding to, public health emergencies; and

5 “(6) carry out other duties related to prepared-
6 ness and response activities for children, as the Sec-
7 retary determines appropriate.”.

8 **SEC. 305. REAUTHORIZING THE NATIONAL ADVISORY COM-**
9 **MITTEE ON CHILDREN AND DISASTERS.**

10 Section 2811A (42 U.S.C. 300hh-10a) is amended—

11 (1) in subsection (b)(2), by inserting “, mental
12 and behavioral,” after “medical”;

13 (2) in subsection (d)—

14 (A) in paragraph (1), by striking “15” and
15 inserting “25”; and

16 (B) by striking paragraph (2) and insert-
17 ing the following:

18 “(2) ~~REQUIRED NON-FEDERAL MEMBERS.~~—The
19 Secretary, in consultation with such other heads of
20 Federal agencies as may be appropriate, shall ap-
21 point to the Advisory Committee under paragraph
22 (1) at least 13 individuals to perform the duties de-
23 scribed in subsections (b) and (c), including—

1 “(A) at least 2 non-Federal professionals
2 with expertise in pediatric medical disaster
3 planning; preparedness; response; or recovery;

4 “(B) at least 2 representatives from State,
5 local, tribal, or territorial agencies with exper-
6 tise in pediatric disaster planning; prepared-
7 ness; response; or recovery;

8 “(C) at least 4 members representing
9 health care professionals, which may include
10 members with expertise in pediatric emergency
11 medicine; pediatric trauma; critical care; or sur-
12 gery; the treatment of pediatric patients af-
13 fected by chemical, biological, radiological, or
14 nuclear agents and emerging infectious dis-
15 eases; pediatric mental or behavioral health re-
16 lated to children affected by a public health
17 emergency; or pediatric primary care; and

18 “(D) other members as the Secretary de-
19 termines appropriate, of whom—

20 “(i) at least one such member shall
21 represent a children’s hospital;

22 “(ii) at least one such member shall
23 be an individual with expertise in schools
24 or child care settings;

1 “(iii) at least one such member shall
2 be an individual with expertise in children
3 and youth with special health care needs;
4 and

5 “(iv) at least one such member shall
6 be an individual with expertise in the needs
7 of parents or family caregivers, including
8 the parents or caregivers of children with
9 disabilities.”.

10 ~~“(3) FEDERAL MEMBERS.—~~The Advisory Com-
11 mittee under paragraph (1) shall include the fol-
12 lowing Federal members or their designees:

13 ~~“(A) The Assistant Secretary for Pre-~~
14 paredness and Response.

15 ~~“(B) The Director of the Biomedical Ad-~~
16 vanced Research and Development Authority.

17 ~~“(C) The Director of the Centers for Dis-~~
18 ease Control and Prevention.

19 ~~“(D) The Commissioner of Food and~~
20 Drugs.

21 ~~“(E) The Director of the National Insti-~~
22 tutes of Health.

23 ~~“(F) The Assistant Secretary of the Ad-~~
24 ministration for Children and Families.

1 “(G) The Administrator of the Health Re-
2 sources and Services Administration.

3 “(H) The Administrator of the Federal
4 Emergency Management Agency.

5 “(I) The Administrator of the Administra-
6 tion for Community Living.

7 “(J) The Secretary of Education.

8 “(K) Representatives from such Federal
9 agencies (such as the Substance Abuse and
10 Mental Health Services Administration and the
11 Department of Homeland Security) as the Sec-
12 retary determines appropriate to fulfill the du-
13 ties of the Advisory Committee under sub-
14 sections (b) and (c).”.

15 “(4) TERM OF APPOINTMENT.—Each member
16 of the Advisory Committee appointed under para-
17 graph (2) shall serve for a term of 3 years, except
18 that the Secretary may adjust the terms of the Advi-
19 sory Committee appointees serving on the date of
20 enactment of the Pandemic and All-Hazards Pre-
21 paredness and Advancing Innovation Act of 2018, or
22 appointees who are initially appointed after such
23 date of enactment, in order to provide for a stag-
24 gered term of appointment for all members.

1 ~~“(5) CONSECUTIVE APPOINTMENTS; MAXIMUM~~
 2 ~~TERMS.—A member appointed under paragraph (2)~~
 3 ~~may serve not more than 3 terms on the Advisory~~
 4 ~~Committee, and not more than 2 of which may be~~
 5 ~~served consecutively.”;~~

6 ~~(3) in subsection (e), by adding at the end “At~~
 7 ~~least one meeting per year shall be an in-person~~
 8 ~~meeting.”; and~~

9 ~~(4) in subsection (f) by striking “2018” and in-~~
 10 ~~serting “2023”.~~

11 **SEC. 306. GUIDANCE FOR PARTICIPATION IN EXERCISES**
 12 **AND DRILLS.**

13 Not later than 2 years after the date of enactment
 14 of this Act, the Secretary of Health and Human Services
 15 shall issue final guidance regarding the participation of
 16 State, local, tribal, and territorial public health depart-
 17 ment or agency personnel funded in whole or in part
 18 through programs authorized under this Act in drills and
 19 operational exercises in order to identify, inform, and ad-
 20 dress the gaps in and policies related to all-hazards med-
 21 ical and public health preparedness and response, which
 22 may include drills and operational exercises that incor-
 23 porate medical surge capacity planning, medical counter-
 24 measure distribution and administration, and preparing
 25 for and responding to identified threats for that region.

1 The Secretary shall consult with the Department of
 2 Homeland Security, the Department of Defense, the De-
 3 partment of Veterans Affairs, and other applicable Fed-
 4 eral departments and agencies as necessary and appro-
 5 priate in the development of such guidance. The Secretary
 6 shall make the guidance available on the internet website
 7 of the Department of Health and Human Services.

8 **TITLE IV—PRIORITIZING A**
 9 **THREAT-BASED APPROACH**

10 **SEC. 401. ASSISTANT SECRETARY FOR PREPAREDNESS AND**
 11 **RESPONSE.**

12 Section 2811(b) (42 U.S.C. 300hh-10(b)) is amend-
 13 ed—

14 (1) in the matter preceding paragraph (1) by
 15 inserting “utilize experience related to public health
 16 emergency preparedness and response, biodefense,
 17 medical countermeasures, and other relevant topics
 18 to” after “shall”; and

19 (2) in paragraph (4) by adding at the end the
 20 following:

21 “(I) **THREAT AWARENESS.**—Coordinate
 22 with the Director of the Centers for Disease
 23 Control and Prevention, the Director of Na-
 24 tional Intelligence, the Secretary of Homeland
 25 Security, the Assistant to the President for Na-

1 tional Security Affairs, the Secretary of De-
 2 fense, and other relevant Federal officials, to
 3 maintain a current assessment of national secu-
 4 rity threats and inform preparedness and re-
 5 sponse capabilities based on the range of the
 6 threats that have the potential to result in a
 7 public health emergency.”.

8 **SEC. 402. PUBLIC HEALTH EMERGENCY MEDICAL COUN-**
 9 **TERMEASURES ENTERPRISE.**

10 (a) **IN GENERAL.**—Title XXVIII is amended by in-
 11 serting after section 2811 (42 U.S.C. 300hh–10) the fol-
 12 lowing:

13 **“SEC. 2811–1. PUBLIC HEALTH EMERGENCY MEDICAL**
 14 **COUNTERMEASURES ENTERPRISE.**

15 “(a) **IN GENERAL.**—The Secretary shall establish the
 16 Public Health Emergency Medical Countermeasures En-
 17 terprise (referred to in this section as the ‘PHEMCE’).
 18 The Assistant Secretary for Preparedness and Response
 19 shall serve as chair of the PHEMCE.

20 “(b) **MEMBERS.**—The PHEMCE shall include each
 21 of the following members, or the designee of such mem-
 22 bers:

23 “(1) The Assistant Secretary for Preparedness
 24 and Response.

1 ~~“(2) The Director of the Centers for Disease~~
2 ~~Control and Prevention.~~

3 ~~“(3) The Director of the National Institutes of~~
4 ~~Health.~~

5 ~~“(4) The Commissioner of Food and Drugs.~~

6 ~~“(5) The Secretary of Defense.~~

7 ~~“(6) The Secretary of Homeland Security.~~

8 ~~“(7) The Secretary of Agriculture.~~

9 ~~“(8) The Secretary of Veterans Affairs.~~

10 ~~“(9) Representatives of any other Federal agen-~~
11 ~~cy, which may include the Director of the Bio-~~
12 ~~medical Advanced Research and Development Au-~~
13 ~~thority, and the Director of the Strategic National~~
14 ~~Stockpile, as the Secretary determines appropriate.~~

15 ~~“(e) FUNCTIONS.—~~

16 ~~“(1) IN GENERAL.—The functions of the~~
17 ~~PHEMCE shall include the following:~~

18 ~~“(A) Establish a process pursuant to sec-~~
19 ~~tion 2811(d)(2)(B) to make recommendations~~
20 ~~to the Secretary regarding the prioritization of~~
21 ~~research, development, and procurement of~~
22 ~~countermeasures, as defined in section 319F-~~
23 ~~2(e), based on the health security needs of the~~
24 ~~United States. Such recommendations shall be~~
25 ~~informed by the National Health Security~~

1 Strategy pursuant to section 2802, the Stra-
2 tegic National Stockpile review required under
3 section ~~319F-2(a)(2)~~, the countermeasures
4 budget plan pursuant to section 2811(b)(7),
5 and an assessment of current national security
6 threats, including chemical, biological, radio-
7 logical and nuclear threats, including emerging
8 infectious diseases. In the event that members
9 of the PHEMCE do not agree upon a rec-
10 ommendation, the Secretary shall provide a de-
11 termination regarding such recommendation.

12 “(B) Identify national health security
13 needs, including gaps in public health prepared-
14 ness and response related to countermeasures
15 and challenges to addressing such needs (in-
16 cluding any regulatory challenges), and provide
17 for alignment of countermeasure procurement
18 with recommendations under subparagraph (A).

19 “(C) Develop strategies related to logistics,
20 deployment, distribution, dispensing, and use of
21 countermeasures that may be applicable to the
22 activities of the strategic national stockpile
23 under section ~~319F-2(a)~~.

1 “(D) Provide consultation for the develop-
2 ment of the strategy and implementation plan
3 under section 2811(d).

4 “(2) INPUT.—In carrying out subparagraphs
5 (B) and (C) of paragraph (1), the PHEMCE shall
6 solicit and consider input from State, local, tribal,
7 and territorial public health departments, as appro-
8 priate.”.

9 (b) PUBLIC HEALTH EMERGENCY MEDICAL COUN-
10 TERMEASURES ENTERPRISE STRATEGY AND IMPLEMEN-
11 TATION PLAN.—Section 2811(d)(1) (42 U.S.C. 300hh-
12 10(d)(1)) is amended—

13 (1) by striking “Not later than 180 days after
14 the date of enactment of this subsection, and every
15 year thereafter” and inserting “Not later than
16 March 15, 2020, and biennially thereafter”; and

17 (2) by striking “Director of Biomedical” and all
18 that follows through “Food and Drugs” and insert-
19 ing “Public Health Emergency Medical Counter-
20 measures Enterprise established under section
21 2811-1”.

22 **SEC. 403. STRATEGIC NATIONAL STOCKPILE.**

23 (a) Section 319F-2(a) (42 U.S.C. 247d-6b(a)) is
24 amended—

1 (1) by redesignating paragraphs (2) and (3) as
2 paragraphs (3) and (4), respectively; and

3 (2) in paragraph (1)—

4 (A) by inserting “and optimize” after
5 “provide for”;

6 (B) by inserting “and, as informed by ex-
7 isting recommendations of, or consultations
8 with, the Public Health Emergency Medical
9 Countermeasure Enterprise established under
10 section 2811-1, make necessary additions or
11 modifications to the contents of such stockpile
12 or stockpiles based on the review conducted
13 under paragraph (2)” before the period of the
14 first sentence; and

15 (C) by striking the second sentence;

16 (3) by inserting after paragraph (1) the fol-
17 lowing:

18 “~~(2) THREAT-BASED REVIEW.—~~

19 “~~(A) IN GENERAL.—~~The Secretary shall
20 conduct a biennial threat-based review (taking
21 into account at-risk individuals) of the contents
22 of the stockpile under paragraph (1), including
23 non-pharmaceutical supplies, and, in consulta-
24 tion with the Public Health Emergency Medical
25 Countermeasures Enterprise established under

1 section ~~2811-1~~, review contents within the
2 stockpile and assess whether such contents are
3 consistent with the recommendations made pur-
4 suant to section ~~2811-1(e)(1)(A)~~. Such review
5 shall be submitted biennially, beginning on
6 March ~~15, 2019~~, to the Committee on Health,
7 Education, Labor, and Pensions and the Com-
8 mittee on Appropriations of the Senate and the
9 Committee on Energy and Commerce and the
10 Committee on Appropriations of the House of
11 Representatives, in a manner that does not
12 compromise national security.

13 ~~“(B) ADDITIONS, MODIFICATIONS, AND~~
14 ~~REPLENISHMENTS.—~~Each biennial threat-based
15 review under subparagraph ~~(A)~~ shall, for each
16 new or modified countermeasure procurement
17 or replenishment, provide—

18 ~~“(i) information regarding—~~

19 ~~“(I) the quantities of the addi-~~
20 ~~tional or modified countermeasure~~
21 ~~procured for, or contracted to be pro-~~
22 ~~cured for, the stockpile;~~

23 ~~“(II) planning considerations for~~
24 ~~appropriate manufacturing capacity~~
25 ~~and capability to meet the goals of~~

1 such additions or modifications (with-
2 out disclosing proprietary informa-
3 tion); including consideration of the
4 effect such additions or modifications
5 may have on the availability of such
6 products and ancillary medical sup-
7 plies in the health care system;

8 “(III) the presence or lack of a
9 commercial market for the counter-
10 measure at the time of procurement;

11 “(IV) the emergency health secu-
12 rity threat or threats such counter-
13 measure procurement is intended to
14 address; including whether such pro-
15 curement is consistent with meeting
16 emergency health security needs asso-
17 ciated with such threat or threats;

18 “(V) an assessment of whether
19 the emergency health security threat
20 or threats described in subelause (IV)
21 could be addressed in a manner that
22 better utilizes the resources of the
23 stockpile and permits the greatest
24 possible increase in the level of emer-

1 agency preparedness to address such
2 threats;

3 “(VI) whether such counter-
4 measure is replenishing an expired
5 countermeasure, is a different coun-
6 termeasure with the same indication
7 that is replacing an expired counter-
8 measure, or is a new addition to the
9 stockpile;

10 “(VII) a description of how such
11 additions or modifications align with
12 the countermeasures budget plan as
13 required under section 2811(b)(7), in-
14 cluding expected life-cycle costs, ex-
15 penditures related to countermeasure
16 procurement to address the threat or
17 threats described in subclause (IV),
18 replenishment dates (including the
19 ability to extend the maximum shelf
20 life of a countermeasure), and the
21 manufacturing capacity required to
22 replenish such countermeasure; and

23 “(VIII) appropriate protocols and
24 processes for the deployment, distribu-
25 tion, or dispensing of the counter-

1 measure at the State and local level,
2 including plans for relevant capabilities
3 of State and local entities to dis-
4 pense, distribute, and administer the
5 countermeasure; and

6 “(ii) an assurance that for each coun-
7 termeasure produced or replenished under
8 this subsection, the Secretary completed a
9 review addressing each item listed under
10 this subsection in advance of such procure-
11 ment or replenishment, which need not be
12 provided in advance of procurement.”;

13 (4) in paragraph (3), as so redesignated—

14 (A) in subparagraph (A), by inserting
15 “and the Public Health Emergency Medical
16 Countermeasures Enterprise established under
17 section 2811–1” before the semicolon;

18 (B) in subparagraph (C), by inserting “,
19 and the availability, deployment, dispensing,
20 and administration of countermeasures” before
21 the semicolon; and

22 (C) by amending subparagraph (E) to read
23 as follows:

24 “(E) devise plans for effective and timely
25 supply-chain management of the stockpile, in

1 consultation with the Director of the Centers
2 for Disease Control and Prevention, the Assist-
3 ant Secretary for Preparedness and Response,
4 the Secretary of Transportation, the Secretary
5 of Homeland Security, the Secretary of Vet-
6 erans Affairs, and the heads of other appro-
7 priate Federal agencies, State, local, tribal, and
8 territorial agencies, and the public and private
9 health care infrastructure, as applicable, taking
10 into account the manufacturing capacity and
11 other available sources of products and appro-
12 priate alternatives to supplies in the stockpile”;
13 and

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

15 “(5) GAO REPORT.—

16 “(A) IN GENERAL.—Not later than 3 years
17 after the date of enactment of the Pandemic
18 and All-Hazards Preparedness and Advancing
19 Innovation Act of 2018, and every 5 years
20 thereafter, the Comptroller General of the
21 United States shall conduct a review of any
22 changes to the contents or management of the
23 stockpile since January 1, 2015. Such review
24 shall include—

1 “(i) an assessment of the comprehen-
2 siveness and completeness of each biennial
3 threat-based review under paragraph (2),
4 including whether all newly procured or re-
5 plenished countermeasures within the
6 stockpile were described in each annual re-
7 view, and whether, consistent with para-
8 graph (2)(B), the Secretary conducted the
9 necessary internal review in advance of
10 such procurement or replenishment;

11 “(ii) an assessment of whether the
12 Secretary established health security and
13 science-based justifications, and a descrip-
14 tion of such justifications for procurement
15 decisions related to health security needs
16 with respect to the identified threat, for
17 additions or modifications to the stockpile
18 based on the information provided in such
19 reviews under paragraph (2)(B), including
20 whether such review was conducted prior
21 to procurement, modification, or replenish-
22 ment;

23 “(iii) an assessment of the plans de-
24 veloped by the Secretary for the deploy-
25 ment, distribution, and dispensing of coun-

1 countermeasures procured, modified, or replen-
2 ished under paragraph (1), including
3 whether such plans were developed prior to
4 procurement, modification, or replenish-
5 ment;

6 “(iv) an accounting of counter-
7 measures procured, modified, or replen-
8 ished under paragraph (1) that received
9 advanced research and development fund-
10 ing from the Biomedical Advanced Re-
11 search and Development Authority;

12 “(v) an analysis of how such procure-
13 ment decisions made progress towards
14 meeting emergency health security needs
15 related to the identified threats for coun-
16 termeasures added, modified, or replen-
17 ished under paragraph (1);

18 “(vi) a description of the resources ex-
19 pended related to the procurement of coun-
20 termeasures (including additions, modifica-
21 tions, and replenishments) in the stockpile,
22 and how such expenditures relate to the
23 emergency health security needs of the
24 stockpile;

1 “(vii) an assessment of the extent to
2 which additions, modifications, and replen-
3 ishments reviewed under paragraph (2)
4 align with previous relevant reports or re-
5 views by the Secretary or the Comptroller
6 General; and

7 “(viii) with respect to any change in
8 the Federal organizational management of
9 the stockpile; an assessment and compari-
10 son of the processes affected by such
11 change, including planning for potential
12 countermeasure deployment, distribution,
13 or dispensing capabilities and processes re-
14 lated to procurement decisions; use of
15 stockpiled countermeasures; and use of re-
16 sources for such activities.

17 “(B) SUBMISSION.—Not later than 6
18 months after completing a classified version of
19 the review under subparagraph (A), the Comp-
20 troller General shall submit an unclassified
21 version of the review to the appropriate commit-
22 tees of Congress.”.

23 (b) AUTHORIZATION OF APPROPRIATIONS, STRA-
24 TEGIC NATIONAL STOCKPILE.—Section 319F-2(f)(1) (42
25 U.S.C. 247d-6b(f)(1)) is amended by striking

1 “\$533,800,000 for each of fiscal years 2014 through
2 2018” and inserting “\$610,000,000 for each of fiscal
3 years 2019 through 2023”.

4 **SEC. 404. PREPARING FOR PANDEMIC INFLUENZA, ANTI-**
5 **MICROBIAL RESISTANCE, AND OTHER SIG-**
6 **NIFICANT THREATS.**

7 Section 319L(c)(4) (~~247d-7e(c)(4)~~) is amended by
8 adding at the end the following:

9 “(F) STRATEGIC INITIATIVES.—The Sec-
10 retary, acting through the Director of BARDA,
11 may implement strategic initiatives, including
12 by building on existing programs, supporting
13 innovative candidate products in preclinical and
14 clinical development, to address priority, natu-
15 rally occurring and man-made threats that, as
16 determined by the Secretary, pose a significant
17 level of risk to national security based on the
18 characteristics of a chemical, biological, radio-
19 logical or nuclear threat, or existing capabilities
20 to respond to such a threat (including medical
21 response and treatment capabilities and manu-
22 facturing infrastructure). Such initiatives shall
23 accelerate and support the advanced research,
24 development, and procurement of, counter-

1 measures and products, as applicable, to ad-
2 dress areas including—

3 “(i) chemical, biological, radiological,
4 or nuclear threats, including emerging in-
5 fectionous diseases, for which insufficient ap-
6 proved, licensed, or authorized counter-
7 measures exist, or for which such threat,
8 or the result of an exposure to such threat,
9 may become resistant to countermeasures
10 or existing countermeasures may be ren-
11 dered ineffective;

12 “(ii) threats that consistently exist or
13 continually circulate and have significant
14 potential to become a pandemic, such as
15 pandemic influenza, which may include the
16 advanced research and development, manu-
17 facturing, and appropriate stockpiling of
18 qualified pandemic or epidemic products,
19 and products, technologies, or processes to
20 support the advanced research and devel-
21 opment of such countermeasures (including
22 multiuse platform technologies for
23 diagnostics, vaccines, and therapeutics;
24 virus seeds; clinical trial lots; novel virus

1 strains; and antigen and adjuvant mate-
2 rial); and

3 “(iii) threats that may result pri-
4 marily or secondarily from a chemical, bio-
5 logical, radiological, or nuclear agent, or
6 emerging infectious disease, and which
7 may present increased treatment complica-
8 tions such as the occurrence of resistance
9 to available countermeasures or potential
10 countermeasures, including antimicrobial
11 resistant pathogens.”.

12 **SEC. 405. REPORTING ON THE FEDERAL SELECT AGENT**
13 **PROGRAM.**

14 Section 351A(k) (42 U.S.C. 262a) is amended—

15 (1) by striking “The Secretary” and inserting
16 the following:

17 “(1) IN GENERAL.—The Secretary”; and

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

19 “(2) IMPLEMENTATION OF RECOMMENDATIONS
20 OF THE FEDERAL EXPERTS SECURITY ADVISORY
21 PANEL AND THE FAST TRACK ACTION COMMITTEE
22 ON SELECT AGENT REGULATIONS.—

23 “(A) IN GENERAL.—Not later than 1 year
24 after the date of the enactment of the Pan-
25 demic and All-Hazards Preparedness and Ad-

1 vancing Innovation Act of 2018, the Secretary
 2 shall provide an update to the appropriate com-
 3 mittees of Congress on the implementation of
 4 recommendations of the Federal Experts Secu-
 5 rity Advisory Panel concerning the select agent
 6 program.

7 “(B) CONTINUED UPDATES.—The Sec-
 8 retary shall provide status updates at 6-month
 9 intervals following the submission of the update
 10 under subparagraph (A) until the recommenda-
 11 tions described in such subparagraph are fully
 12 implemented, or a justification is provided for
 13 the delay in, or lack of, implementation.”.

14 **TITLE V—INCREASING COMMU-**
 15 **NICATION IN MEDICAL COUN-**
 16 **TERMEASURE ADVANCED RE-**
 17 **SEARCH AND DEVELOPMENT**

18 **SEC. 501. MEDICAL COUNTERMEASURE BUDGET PLAN.**

19 Section 2811(b)(7) (42 U.S.C. 300hh-10(b)(7)) is
 20 amended—

21 (1) in the matter preceding subparagraph (A),
 22 by striking “March 1 of each year” and inserting
 23 “March 15, 2020 and every 2 years thereafter”;

24 (2) by striking subparagraph (A) and inserting
 25 the following:

1 “(A) include consideration of the entire
2 medical countermeasures enterprise, includ-
3 ing—

4 “(i) basic research and advanced re-
5 search and development;

6 “(ii) approval, clearance, licensure,
7 and authorized uses of products;

8 “(iii) procurement, stockpiling, main-
9 tenance, and potential replenishment (in-
10 cluding manufacturing capabilities) of all
11 products in the Strategic National Stock-
12 pile; and

13 “(iv) the availability of technologies
14 that may assist in the advanced research
15 and development of countermeasures and
16 opportunities to use such technologies to
17 accelerate and navigate challenges unique
18 to countermeasure research and develop-
19 ment.”.

20 (3) by redesignating subparagraphs (D) and
21 (E) as subparagraphs (E) and (F), respectively;

22 (4) by inserting after subparagraph (C), the fol-
23 lowing:

24 “(D) identify the full range of anticipated
25 medical countermeasure needs related to re-

1 search and development, procurement, and
2 stockpiling, including the potential need for in-
3 dications, dosing, and administration tech-
4 nologies, and other countermeasure needs as
5 applicable and appropriate;” and

6 (5) in subparagraph (E), as so redesignated, by
7 striking “March 15 of each year” and inserting
8 “March 15, 2020, and every 2 years thereafter”.

9 **SEC. 502. MATERIAL THREAT AND MEDICAL COUNTER-**
10 **MEASURE NOTIFICATIONS.**

11 (a) CONGRESSIONAL NOTIFICATION OF MATERIAL
12 THREAT DETERMINATION.—Section ~~319F-2(c)(2)(C)~~ (42
13 U.S.C. ~~247d-6b(c)(2)(C)~~) is amended by striking “The
14 Secretary and the Homeland Security Secretary shall
15 promptly notify the appropriate committees of Congress”
16 and inserting “The Secretary and the Secretary of Home-
17 land Security shall send to Congress, on an annual basis,
18 all current material threat determinations and shall
19 promptly notify the Committee on Health, Education,
20 Labor, and Pensions and the Committee on Homeland Se-
21 curity and Government Affairs of the Senate and the Com-
22 mittee on Energy and Commerce and the Committee on
23 Homeland Security of the House of Representatives”.

24 (b) CONTRACTING COMMUNICATIONS.—

1 (1) **CONTRACT DURATION.**—Section 319F-
 2 2(e)(7)(B)(ii)(III) (42 U.S.C. 247d-
 3 6b(e)(7)(B)(ii)(III)) is amended by adding at the
 4 end the following: “The Secretary shall notify the
 5 vendor within 90 days of a determination by the
 6 Secretary to renew such contract.”.

7 (2) **EXPEDITED AUTHORITIES.**—Section
 8 319L(e)(5)(B)(i) (42 U.S.C. 247d-7e(e)(5)(B)(i)) is
 9 amended by adding at the end the following: “Upon
 10 award, extension, or termination of any such con-
 11 tract, grant, cooperative agreement, and other trans-
 12 action, the Secretary shall provide a written notifica-
 13 tion to the receiving entity that includes a justifica-
 14 tion for such award, extension, or termination.”.

15 **SEC. 503. AVAILABILITY OF REGULATORY MANAGEMENT**
 16 **PLANS.**

17 Section 565(f) of the Federal Food, Drug, and Cos-
 18 metic Act (21 U.S.C. 360bbb-4(f)) is amended—

19 (1) by redesignating paragraphs (3) through
 20 (6) as paragraphs (4) through (7), respectively;

21 (2) by inserting after paragraph (2) the fol-
 22 lowing:

23 “(3) **PUBLICATION.**—The Secretary shall make
 24 available on the internet website of the Food and

1 Drug Administration information regarding regu-
2 latory management plans, including—

3 “(A) the process by which an applicant
4 may submit a request for a regulatory manage-
5 ment plan;

6 “(B) the timeframe by which the Secretary
7 is required to respond to such request;

8 “(C) the information required for the sub-
9 mission of such request;

10 “(D) a description of the types of develop-
11 ment milestones and performance targets that
12 could be discussed and included in such plans;
13 and

14 “(E) contact information for beginning the
15 regulatory management plan process.”;

16 (3) in paragraph (6), as so redesignated, in the
17 matter preceding subparagraph (A)—

18 (A) by striking “paragraph (4)(A)” and in-
19 serting “paragraph (5)(A)”; and

20 (B) by striking “paragraph (4)(B)” and
21 inserting “paragraph (5)(B)”; and

22 (4) in paragraph (7)(A), as so redesignated, by
23 striking “paragraph (3)(A)” and inserting “para-
24 graph (4)(A)”.

1 **SEC. 504. THE BIOMEDICAL ADVANCED RESEARCH AND DE-**
 2 **VELOPMENT AUTHORITY AND THE BIO-**
 3 **SHIELD SPECIAL RESERVE FUND.**

4 (a) BIOSHIELD SPECIAL RESERVE FUND.—Section
 5 ~~319F-2(g)(1)~~ (42 U.S.C. ~~247d-6b(g)(1)~~) is amended—

6 (1) by striking “\$2,800,000,000 for the period
 7 of fiscal years 2014 through 2018” and inserting
 8 “\$3,500,000,000 for the period of fiscal years 2019
 9 through 2023, to remain available until expended”;
 10 and

11 (2) by striking the second sentence.

12 (b) THE BIOMEDICAL ADVANCED RESEARCH AND
 13 DEVELOPMENT AUTHORITY.—Section ~~319L(d)(2)~~ (42
 14 U.S.C. ~~247d-7e(d)(2)~~) is amended by striking
 15 “\$415,000,000 for each of fiscal years 2014 through
 16 2018” and inserting “\$611,700,000 for each of fiscal
 17 years 2019 through 2023”.

18 **TITLE VI—ADVANCING TECH-**
 19 **NOLOGIES FOR MEDICAL**
 20 **COUNTERMEASURES**

21 **SEC. 601. ADMINISTRATION OF COUNTERMEASURES.**

22 Section ~~319L(e)(4)(D)(iii)~~ (42 U.S.C. ~~247d-~~
 23 ~~7e(e)(4)(D)(iii)~~) is amended by striking “and platform
 24 technologies” inserting “platform technologies, tech-
 25 nologies to administer countermeasures, technologies to
 26 improve storage, and transportation of countermeasures”.

1 **SEC. 602. MEDICAL COUNTERMEASURE MASTER FILES.**

2 (a) IN GENERAL.—Chapter V of the Federal Food,
3 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-
4 ed by inserting after section 565A the following:

5 **“SEC. 565B. MEDICAL COUNTERMEASURE MASTER FILES.**

6 “(a) PURPOSE.—The purpose of this section is to
7 support and accelerate the development or manufacture
8 of security countermeasures, qualified countermeasures,
9 and qualified pandemic or epidemic products by facili-
10 tating and encouraging submission of data and informa-
11 tion to support such products to master files, and through
12 clarifying the authority to cross-reference to data and in-
13 formation previously submitted to the Secretary.

14 “(b) APPLICABILITY OF REFERENCE.—

15 “(1) IN GENERAL.—A person may submit data
16 and information to the Secretary with the intent to
17 reference, or to authorize, in writing, another person
18 to reference, such data or information, in accordance
19 with subsections (d) and (e) of section 314.420 of
20 title 21, Code of Federal Regulations (or any suc-
21 cessor regulations), to support a medical counter-
22 measure submission (including a supplement or
23 amendment to any such submission), without requir-
24 ing the master file holder to disclose the data and
25 information to any such persons authorized to ref-
26 erence the master file.

1 “(2) MASTER FILE HOLDER.—In this section,
2 the term ‘master file holder’ means a person who
3 submits data and information to the Secretary with
4 the intent to reference or authorize to reference such
5 data or information to support a medical counter-
6 measure submission, as described in paragraph (1).

7 “(e) MEDICAL COUNTERMEASURE MASTER FILE
8 CONTENT.—

9 “(1) IN GENERAL.—A master file under this
10 section may include information to support and ac-
11 celerate—

12 “(A) the development of medical counter-
13 measure submissions to support the approval,
14 licensure, classification, clearance, conditional
15 approval, or authorization of one or more secu-
16 rity countermeasures, qualified counter-
17 measures, or qualified pandemic or epidemic
18 products; and

19 “(B) the manufacture of security counter-
20 measures, qualified countermeasures, or quali-
21 fied pandemic or epidemic products.

22 “(2) REQUIRED UPDATES.—The Secretary may
23 require, as appropriate, that the master file holder
24 ensure that the contents of such master file are up-

1 dated during the time such master file is referenced
2 for a medical countermeasure submission.

3 “(d) SPONSOR REFERENCE.—

4 “(1) IN GENERAL.—Each incorporation of in-
5 formation or data contained in a master file by ref-
6 erence shall describe the incorporated material in a
7 manner in which the Secretary determines appro-
8 priate and that permits the review of such informa-
9 tion without necessitating resubmission of such in-
10 formation or data. Master files shall be submitted in
11 an electronic format in accordance with section
12 745A and as specified in applicable guidance.

13 “(2) REFERENCE BY A MASTER FILE HOLD-
14 ER.—A master file holder that is the sponsor of a
15 medical countermeasure submission shall notify the
16 Secretary in writing of the intent to reference the
17 medical countermeasure master file as a part of the
18 submission.

19 “(3) REFERENCE BY AN AUTHORIZED PER-
20 SON.—A sponsor of a medical countermeasure sub-
21 mission may, where the Secretary determines appro-
22 priate, incorporate by reference all or part of the
23 contents of a medical countermeasure master file, if
24 the master file holder authorizes the incorporation in
25 writing.

1 “(e) ACKNOWLEDGEMENT OF MASTER FILE BY THE
2 SECRETARY.—The Secretary shall provide the master file
3 holder with a written notification indicating that the Sec-
4 retary has reviewed and relied upon specified information
5 or data within a master file and the purposes for which
6 such information or data was incorporated by reference
7 if the Secretary has reviewed and relied upon such speci-
8 fied information or data to support the approval, classi-
9 fication, conditional approval, clearance, licensure, or au-
10 thorization of a security countermeasure, qualified coun-
11 termeasure, or qualified pandemic or epidemic product.
12 The Secretary may rely upon the data and information
13 within the medical countermeasure master file for which
14 such written notification was provided in additional appli-
15 cations, as applicable and appropriate and upon the re-
16 quest of the master file holder so notified in writing or
17 by an authorized person of such holder.

18 “(f) RULES OF CONSTRUCTION.—Nothing in this
19 section shall be construed to—

20 “(1) alter the authority of the Secretary to ap-
21 prove, license, classify, clear, conditionally approve,
22 or authorize drugs, biological products, or devices
23 pursuant to this Act or section 351 of the Public
24 Health Service Act (as authorized prior to the date
25 of enactment of the Pandemic and All-Hazards Pre-

1 paredness and Advancing Innovation Act of 2018),
2 including the standards of evidence, and applicable
3 conditions, for approval under the applicable Act; or

4 “(2) alter the authority of the Secretary under
5 this Act or the Public Health Service Act to deter-
6 mine the types of information or data previously
7 submitted by a sponsor or any other person that
8 may be incorporated by reference in an application,
9 request, or notification for a drug, biological prod-
10 uct, or device submitted under sections 505(i),
11 505(b), 505(j), 512(b)(1), 512(b)(2), 564, 571,
12 520(g), 515(e), 513(f)(2), or 510(k) of this Act, or
13 subsection (a) or (k) of section 351 of the Public
14 Health Service Act, including a supplement or
15 amendment to any such submission, and the require-
16 ments associated with such reference.

17 “(g) DEFINITIONS.—In this section:

18 “(1) The term ‘medical countermeasure submis-
19 sion’ means an investigational new drug application
20 under section 505(i), a new drug application under
21 section 505(b), or an abbreviated new drug applica-
22 tion under section 505(j) of this Act, a biological
23 product license application under section 351(a) of
24 the Public Health Service Act or a biosimilar biologi-
25 cal product license application under section 351(k)

1 of the Public Health Service Act, a new animal drug
2 application under section 512(b)(1) or abbreviated
3 new animal drug application under section
4 512(b)(2), an application for conditional approval of
5 a new animal drug under 571, an investigational de-
6 vice application under section 520(g), an application
7 with respect to a device under section 515(e), a re-
8 quest for classification of a device under section
9 513(f)(2), a notification with respect to a device
10 under section 510(k), or request for an emergency
11 use authorization under section 564 to support—

12 “(A) the approval, licensure, classification,
13 clearance, conditional approval, or authorization
14 of a security countermeasure, qualified counter-
15 measure, or qualified pandemic or epidemic
16 product; or

17 “(B) a new indication to an approved secu-
18 rity countermeasure, qualified countermeasure,
19 or qualified pandemic or epidemic product.

20 “(2) The terms ‘qualified countermeasure’, ‘se-
21 curity countermeasure’, and ‘qualified pandemic or
22 epidemic product’ have the meanings given such
23 terms in sections 319F-1, 319F-2, and 319F-3, re-
24 spectively, of the Public Health Service Act.”.

1 (b) **STAKEHOLDER INPUT.**—Not later than 18
2 months after the date of enactment of this Act, the Sec-
3 retary of Health and Human Services (referred to in this
4 section as the “Secretary”), acting through the Commis-
5 sioner of Food and Drugs and in consultation with the
6 Assistant Secretary for Preparedness and Response, shall
7 solicit input from stakeholders, including stakeholders de-
8 veloping security countermeasures, qualified counter-
9 measures, or qualified pandemic or epidemic products, and
10 stakeholders developing technologies to assist in the devel-
11 opment of such countermeasures with respect to how the
12 Food and Drug Administration can advance the use of
13 tools and technologies to support and accelerate the devel-
14 opment or manufacture of security countermeasures,
15 qualified countermeasures, and qualified pandemic or epi-
16 demic products, including through the reliance on cross-
17 referenced data and information contained within master
18 files and submissions previously submitted to the Sec-
19 retary as set forth in section 565B of the Federal Food,
20 Drug, and Cosmetic Act, as added by subsection (a).

21 (c) **GUIDANCE.**—Not later than 2 years after the
22 after the date of enactment of this Act, the Secretary, act-
23 ing through the Commissioner of Food and Drugs, shall
24 publish draft guidance about how reliance on cross-ref-
25 erenced data and information contained within master

1 files under section 565B of the Federal Food, Drug, and
2 Cosmetic Act, as added by subsection (a) or submissions
3 otherwise submitted to the Secretary may be used for spe-
4 cific tools or technologies (including platform technologies)
5 that have the potential to support and accelerate the devel-
6 opment or manufacture of security countermeasures,
7 qualified countermeasures, qualified pandemic or epidemic
8 products. The Secretary, acting through the Commissioner
9 of Food and Drugs, shall publish the final guidance not
10 later than 3 years after the enactment of this Act.

11 **SEC. 603. ANIMAL RULE REPORT.**

12 (a) STUDY.—The Comptroller General of the United
13 States shall conduct a study on the application of the re-
14 quirements under section 565(d) of the of the Federal
15 Food, Drug, and Cosmetic Act (~~21 U.S.C. 360bbb-4(d)~~)
16 (referred to in this section as the “animal rule”) as a com-
17 ponent of medical countermeasure advanced development
18 under the Biomedical Advanced Research and Develop-
19 ment Authority and regulatory review by the Food and
20 Drug Administration. In conducting such study, the
21 Comptroller General shall examine the following:

22 (1) The extent to which advanced development
23 and review of a medical countermeasure are coordi-
24 nated between the Biomedical Advanced Research
25 and Development Authority and the Food and Drug

1 Administration, including activities facilitate appro-
2 priate and efficient design of studies to support ap-
3 proval, licensure, and authorization under the ani-
4 mal rule, consistent with the recommendations in the
5 animal rule guidance, issued pursuant to section
6 565(e) of the Federal Food, Drug, and Cosmetic Act
7 (21 U.S.C. 360bbb-4(e)) and entitled “Product De-
8 velopment Under the Animal Rule Guidance for In-
9 dustry” (issued in October 2015), to resolve discrep-
10 ancies in the design of adequate and well-controlled
11 efficacy studies conducted in animal models related
12 to the provision of substantial evidence of effective-
13 ness for the product approved, licensed, or author-
14 ized under the animal rule.

15 (2) The consistency of the application of the
16 animal rule among and between review divisions
17 within the Food and Drug Administration.

18 (3) The flexibilities pursuant to the animal rule
19 to address variations in countermeasure development
20 and review processes, including the extent to which
21 qualified animal models are adopted and used within
22 the Food and Drug Administration in regulatory de-
23 cisionmaking with respect to medical counter-
24 measures.

1 (4) The extent to which the guidance issued
2 under section 565(e) of the Federal Food, Drug, and
3 Cosmetic Act (21 U.S.C. 360bbb-4(e)), entitled,
4 “Product Development Under the Animal Rule
5 Guidance for Industry”² (issued in October 2015),
6 has assisted in achieving the purposes described in
7 paragraphs (1), (2), and (3).

8 (b) CONSULTATIONS.—In conducting the study under
9 subsection (a), the Comptroller General of the United
10 States shall consult with—

11 (1) the Federal agencies responsible for advancing,
12 reviewing, and procuring medical counter-
13 measures, including the Office of the Assistant Secretary
14 for Preparedness and Response, the Biomedical Advanced
15 Research and Development Authority, the Food and Drug Administration,
16 and the Department of Defense;

17 (2) manufacturers involved in the research and
18 development of medical countermeasures to address
19 biological, chemical, radiological, and nuclear
20 threats; and
21 threats; and

22 (3) other biodefense stakeholders, as applicable.

23 (c) REPORT.—Not later than 3 years after the date
24 of enactment of this Act, the Comptroller General of the
25 United States shall submit to the Committee on Health,

1 Education, Labor, and Pensions of the Senate and the
 2 Committee on Energy and Commerce of the House of
 3 Representatives a report containing the results of the
 4 study conducted under subsection (a) and recommenda-
 5 tions to improve the application and consistency of the re-
 6 quirements under subsections (c) and (d) of section 565
 7 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 8 360bbb-4) to support and expedite the research and devel-
 9 opment of medical countermeasures, as applicable.

10 (d) PROTECTION OF NATIONAL SECURITY.—The
 11 Comptroller General of the United States shall conduct
 12 the study and issue the assessment and report under this
 13 section in a manner that does not compromise national
 14 security.

15 **TITLE VII—MISCELLANEOUS** 16 **PROVISIONS**

17 **SEC. 701. REAUTHORIZATIONS AND EXTENSIONS.**

18 (a) VETERANS AFFAIRS.—Section 8117(g) of title
 19 38, United States Code, is amended by striking “2014
 20 through 2018” and inserting “2019 through 2023”.

21 (b) VACCINE TRACKING AND DISTRIBUTION.—Sec-
 22 tion 319A(e) (42 U.S.C. 247d-1(e)) is amended by strik-
 23 ing “2014 through 2018” and inserting “2019 through
 24 2023”.

1 (e) TEMPORARY REASSIGNMENT.—Section 319(e)(8)
2 (42 U.S.C. 247d(e)(8)) is amended by striking “2018”
3 and inserting “2023”.

4 (d) STRATEGIC INNOVATION PARTNER.—Section
5 319L(e)(4)(E)(ix) (42 U.S.C. 247d–7e(e)(4)(E)(ix)) is
6 amended by striking “2022” and inserting “2023”.

7 (e) PUBLIC DISCLOSURE EXEMPTION.—Section
8 319L(e)(1)(C) (42 U.S.C. 247d–7e(e)(1)(C)) is amended
9 by striking “12” and inserting “17”.

10 (f) LIMITED ANTITRUST EXEMPTION.—

11 (1) IN GENERAL.—Section 405 of the Pandemic
12 and All-Hazards Preparedness Act (42 U.S.C.
13 247d–6a note) is amended—

14 (A) by redesignating such section as sec-
15 tion 319L–1;

16 (B) transferring such section to the Public
17 Health Service Act (42 U.S.C. 201 et seq.); to
18 appear after section 319L of such Act (42
19 U.S.C. 247d–7e);

20 (C) in subsection (a)(1)—

21 (i) by striking “Secretary of Health
22 and Human Services (referred to in this
23 subsection as the ‘Secretary’)” and insert-
24 ing “Secretary”;

1 (ii) by striking “of the Public Health
2 Service Act (42 U.S.C. 247d–6b)) (as
3 amended by this Act”;

4 (iii) by striking “of the Public Health
5 Service Act (42 U.S.C. 247d–6a)) (as
6 amended by this Act”; and

7 (iv) by striking “of the Public Health
8 Service Act (42 U.S.C. 247d–6d)”;

9 (D) in subsection (b), by striking “12-
10 year” and inserting “17-year”.

11 (2) EFFECTIVE DATE.—The amendment made
12 by paragraph (1)(D) shall take effect as if enacted
13 on December 17, 2012.

14 (3) CONFORMING AMENDMENT.—The table of
15 contents in section 1(b) of the Pandemic and All-
16 Hazards Preparedness Act (Public Law 109–417) is
17 amended by striking the item related to section 405.

18 **SEC. 702. TECHNICAL AMENDMENTS.**

19 (a) PUBLIC HEALTH SERVICE ACT.—Title III (42
20 U.S.C. 241 et seq.) is amended—

21 (1) in paragraphs (1) and (5) of section 319F–
22 1(a) (42 U.S.C. 247d–6a(a)), by striking “section
23 319F(h)” each place such term appears and insert-
24 ing “section 319F(e)”; and

1 (2) in section 319K(a) (42 U.S.C. 247d-7d(a)),
 2 by striking “section 319F(h)(4)” and inserting “sec-
 3 tion 319F(e)(4)”.

4 (b) PUBLIC HEALTH SECURITY GRANTS.—Section
 5 319C-1(b)(2) (42 U.S.C. 247d-3a(b)(2)) is amended—

6 (1) in subparagraph (C), by striking “individ-
 7 uals,” and inserting “individuals,”; and

8 (2) in subparagraph (F), by striking “make sat-
 9 isfactory annual improvement and describe” and in-
 10 serting “makes satisfactory annual improvement and
 11 describes”.

12 (c) FEDERAL FOOD, DRUG, AND COSMETIC ACT.—
 13 The Federal Food, Drug, and Cosmetic Act is amended—

14 (1) in section 564A(e)(2)(A) (21 U.S.C.
 15 360bbb-3a(e)(2)(A)), by striking “subsection
 16 (a)(1)(C)(i)” and inserting “subsection (a)(1)(C)”;
 17 and

18 (2) in section 564B(2)(C) (21 U.S.C. 360bbb-
 19 3b(2)(C)), by inserting “or section 564A”.

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

21 (a) *SHORT TITLE.*—*This Act may be cited as the*
 22 *“Pandemic and All-Hazards Preparedness and Advancing*
 23 *Innovation Act of 2018”.*

24 (b) *TABLE OF CONTENTS.*—*The table of contents for*
 25 *this Act is as follows:*

Sec. 1. Short title; table of contents.

Sec. 2. References in Act.

TITLE I—STRENGTHENING THE NATIONAL HEALTH SECURITY STRATEGY

Sec. 101. National Health Security Strategy.

TITLE II—IMPROVING PREPAREDNESS AND RESPONSE

- Sec. 201. Improving benchmarks and standards for preparedness and response.*
Sec. 202. Amendments to preparedness and response programs.
Sec. 203. Regional health care emergency preparedness and response systems.
Sec. 204. Military and civilian partnership for trauma readiness.
Sec. 205. Public health and health care system situational awareness and bio-surveillance capabilities.
Sec. 206. Strengthening and supporting the public health emergency rapid response fund.
Sec. 207. Improving preparedness for and response to all-hazards by public health emergency volunteers.
Sec. 208. Clarifying State liability law for volunteer health care professionals.

TITLE III—REACHING ALL COMMUNITIES

- Sec. 301. Strengthening and assessing the emergency response workforce.*
Sec. 302. Health system infrastructure to improve preparedness and response.
Sec. 303. Considerations for at-risk individuals.
Sec. 304. Improving emergency preparedness and response considerations for children.
Sec. 305. Reauthorizing the National Advisory Committee on Children and Disasters.
Sec. 306. Authorizing the National Advisory Committee on Seniors and Disasters.
Sec. 307. Guidance for participation in exercises and drills.

TITLE IV—PRIORITIZING A THREAT-BASED APPROACH

- Sec. 401. Assistant Secretary for Preparedness and Response.*
Sec. 402. Public Health Emergency Medical Countermeasures Enterprise.
Sec. 403. Strategic National Stockpile.
Sec. 404. Preparing for pandemic influenza, antimicrobial resistance, and other significant threats.
Sec. 405. Reporting on the Federal Select Agent Program.

TITLE V—INCREASING COMMUNICATION IN MEDICAL COUNTERMEASURE ADVANCED RESEARCH AND DEVELOPMENT

- Sec. 501. Medical countermeasure budget plan.*
Sec. 502. Material threat and medical countermeasure notifications.
Sec. 503. Availability of regulatory management plans.
Sec. 504. The Biomedical Advanced Research and Development Authority and the BioShield Special Reserve Fund.

TITLE VI—ADVANCING TECHNOLOGIES FOR MEDICAL COUNTERMEASURES

- Sec. 601. Administration of countermeasures.*
Sec. 602. Medical countermeasure master files.
Sec. 603. Priority zoonotic animal drugs.
Sec. 604. Animal rule report.

Sec. 605. Review of the benefits of genomic engineering technologies and their potential role in national security.

TITLE VII—MISCELLANEOUS PROVISIONS

Sec. 701. Reauthorizations and extensions.

Sec. 702. Technical amendments.

1 SEC. 2. REFERENCES IN ACT.

2 *Except as otherwise specified, amendments made by*
 3 *this Act to a section or other provision of law are amend-*
 4 *ments to such section or other provision of the Public Health*
 5 *Service Act (42 U.S.C. 201 et seq.).*

6 **TITLE I—STRENGTHENING THE**
 7 **NATIONAL HEALTH SECURITY**
 8 **STRATEGY**

9 **SEC. 101. NATIONAL HEALTH SECURITY STRATEGY.**

10 *Section 2802 (42 U.S.C. 300hh–1) is amended—*

11 *(1) in subsection (a)—*

12 *(A) in paragraph (1)—*

13 *(i) by striking “2014” and inserting*
 14 *“2018”; and*

15 *(ii) by striking the second sentence and*
 16 *inserting the following: “Such National*
 17 *Health Security Strategy shall describe po-*
 18 *tential emergency health security threats*
 19 *and identify the process for achieving the*
 20 *preparedness goals described in subsection*
 21 *(b) to be prepared to identify and respond*
 22 *to such threats and shall be consistent with*

1 *the national preparedness goal (as described*
2 *in section 504(a)(19) of the Homeland Se-*
3 *curity Act of 2002), the National Incident*
4 *Management System (as defined in section*
5 *501(7) of such Act), and the National Re-*
6 *sponse Plan developed pursuant to section*
7 *504 of such Act, or any successor plan.”;*

8 *(B) in paragraph (2), by inserting before*
9 *the period at the end of the second sentence the*
10 *following: “, and an analysis of any changes to*
11 *the evidence-based benchmarks and objective*
12 *standards under sections 319C–1 and 319C–2”;*
13 *and*

14 *(C) in paragraph (3)—*

15 *(i) by striking “2009” and inserting*
16 *“2022”;*

17 *(ii) by inserting “(including gaps in*
18 *the environmental health and animal health*
19 *workforces, as applicable), describing the*
20 *status of such workforce” after “gaps in*
21 *such workforce”;*

22 *(iii) by striking “and identifying*
23 *strategies” and inserting “identifying strat-*
24 *egies”; and*

1 (iv) by inserting before the period at
2 the end “, and identifying current capabili-
3 ties to meet the requirements of section
4 2803”; and

5 (2) in subsection (b)—

6 (A) in paragraph (2)—

7 (i) in subparagraph (A), by striking
8 “and investigation” and inserting “inves-
9 tigation, and related information technology
10 activities”;

11 (ii) in subparagraph (B), by striking
12 “and decontamination” and inserting “de-
13 contamination, relevant health care services
14 and supplies, and transportation and dis-
15 posal of medical waste”; and

16 (iii) by adding at the end the fol-
17 lowing:

18 “(E) Response to environmental hazards.”;

19 (B) in paragraph (3)(F), by inserting “or
20 exposures to agents that could cause a public
21 health emergency” before the period;

22 (C) in paragraph (5), by inserting “and
23 other applicable compacts” after “Compact”; and

24 (D) by adding at the end the following:

1 “(9) *ZOONOTIC DISEASE, FOOD, AND AGRICULTURE.—Improving coordination among Federal,*
 2 *State, local, tribal, and territorial entities (including*
 3 *through consultation with the Secretary of Agriculture)* to prevent, detect, and respond to outbreaks
 4 *of plant or animal disease (including zoonotic disease)* that could compromise national security result-
 5 *ing from a deliberate attack, a naturally occurring*
 6 *threat, the intentional adulteration of food, or other*
 7 *public health threats, taking into account interactions*
 8 *between animal health, human health, and animals’*
 9 *and humans’ shared environment as directly related*
 10 *to public health emergency preparedness and response*
 11 *capabilities, as applicable.*

15 “(10) *GLOBAL HEALTH SECURITY.—Assessing*
 16 *current or potential health security threats from*
 17 *abroad to inform domestic public health preparedness*
 18 *and response capabilities.”.*

19 **TITLE II—IMPROVING**
 20 **PREPAREDNESS AND RESPONSE**

21 **SEC. 201. IMPROVING BENCHMARKS AND STANDARDS FOR**
 22 **PREPAREDNESS AND RESPONSE.**

23 (a) *EVALUATING MEASURABLE EVIDENCE-BASED*
 24 *BENCHMARKS AND OBJECTIVE STANDARDS.—Section*

1 *319C-1 (42 U.S.C. 247d-3a) is amended by inserting after*
2 *subsection (j) the following:*

3 “(k) *EVALUATION.*—

4 “(1) *IN GENERAL.*—*Not later than 2 years after*
5 *the date of enactment of the Pandemic and All-Haz-*
6 *ards Preparedness and Advancing Innovation Act of*
7 *2018 and every 2 years thereafter, the Secretary shall*
8 *conduct an evaluation of the evidence-based bench-*
9 *marks and objective standards required under sub-*
10 *section (g). Such evaluation shall be submitted to the*
11 *congressional committees of jurisdiction together with*
12 *the National Health Security Strategy under section*
13 *2802, at such time as such strategy is submitted.*

14 “(2) *CONTENT.*—*The evaluation under this para-*
15 *graph shall include—*

16 “(A) *a review of evidence-based benchmarks*
17 *and objective standards, and associated metrics*
18 *and targets;*

19 “(B) *a discussion of changes to any evi-*
20 *dence-based benchmarks and objective standards,*
21 *and the effect of such changes on the ability to*
22 *track whether entities are meeting or making*
23 *progress toward the goals under this section and,*
24 *to the extent practicable, the applicable goals of*

1 *the National Health Security Strategy under sec-*
 2 *tion 2802;*

3 “(C) *a description of amounts received by*
 4 *eligible entities, as described in subsection (b)*
 5 *and section 319C–2(b), and amounts received by*
 6 *subrecipients and the effect of such funding on*
 7 *meeting evidence-based benchmarks and objective*
 8 *standards; and*

9 “(D) *recommendations, as applicable and*
 10 *appropriate, to improve evidence-based bench-*
 11 *marks and objective standards to more accu-*
 12 *rately assess the ability of entities receiving*
 13 *awards under this section to better achieve the*
 14 *goals under this section and section 2802.”.*

15 **(b) EVALUATING THE PARTNERSHIP FOR STATE AND**
 16 **REGIONAL HOSPITAL PREPAREDNESS.—***Section 319C–*
 17 *2(i)(1) (42 U.S.C. 247–3b(i)(1)) is amended by striking*
 18 *“section 319C–1(g), (i), and (j)” and inserting “section*
 19 *319C–1(g), (i), (j), and (k)”.*

20 **SEC. 202. AMENDMENTS TO PREPAREDNESS AND RE-**
 21 **SPONSE PROGRAMS.**

22 **(a) COOPERATIVE AGREEMENT APPLICATIONS FOR IM-**
 23 **PROVING STATE AND LOCAL PUBLIC HEALTH SECURITY.—**
 24 *Section 319C–1 (42 U.S.C. 247d–3a) is amended—*

1 (1) *in subsection (a), by inserting “, acting*
 2 *through the Director of the Centers for Disease Con-*
 3 *trol and Prevention,” after “the Secretary”; and*

4 (2) *in subsection (b)(2)(A)—*

5 (A) *in clause (vi), by inserting “, including*
 6 *public health agencies with specific expertise that*
 7 *may be relevant to public health security, such*
 8 *as environmental health agencies,” after “stake-*
 9 *holders”;*

10 (B) *by redesignating clauses (vii) through*
 11 *(ix) as clauses (viii) through (x); and*

12 (C) *by inserting after clause (vi) the fol-*
 13 *lowing:*

14 *“(vii) a description of how, as applica-*
 15 *ble, such entity may integrate information*
 16 *to account for individuals with behavioral*
 17 *health needs following a public health emer-*
 18 *gency;”.*

19 (b) *PARTNERSHIP FOR STATE AND REGIONAL HOS-*
 20 *PITAL PREPAREDNESS TO IMPROVE SURGE CAPACITY.—*
 21 *Section 319C–2 (42 U.S.C. 247d–3b) is amended—*

22 (1) *in subsection (a)—*

23 (A) *by inserting “, acting through the As-*
 24 *stant Secretary for Preparedness and Re-*
 25 *sponse,” after “The Secretary”; and*

1 (B) by striking “preparedness for public
2 health emergencies” and inserting “preparedness
3 for, and response to, public health emergencies in
4 accordance with subsection (c)”; and

5 (2) in subsection (b)(1)(A)—

6 (A) in clause (iii), by redesignating sub-
7 clauses (I) through (III) as items (aa) through
8 (cc), respectively, and adjusting the margins ac-
9 cordingly;

10 (B) by redesignating clauses (i) through
11 (iii) as subclauses (I) through (III) respectively,
12 and adjusting the margins accordingly;

13 (C) by striking “partnership consisting of—
14 ” and inserting “partnership—

15 “(i) consisting of—”; and

16 (D) by adding at the end the following:

17 “(ii) that may include one or more
18 emergency medical service organizations or
19 emergency management organizations;
20 and”.

21 (c) *PUBLIC HEALTH SECURITY GRANTS AUTHORIZA-*
22 *TION OF APPROPRIATIONS.—Section 319C–1(h)(1)(A) (42*
23 *U.S.C. 247d–3a(h)(1)(A)) is amended by striking*
24 *“\$641,900,000 for fiscal year 2014” and all that follows*
25 *through the period at the end and inserting “\$685,000,000*

1 *for each of fiscal years 2019 through 2023 for awards pur-*
 2 *suant to paragraph (3) (subject to the authority of the Sec-*
 3 *retary to make awards pursuant to paragraphs (4) and*
 4 *(5)).”.*

5 *(d) PARTNERSHIP FOR STATE AND REGIONAL HOS-*
 6 *PITAL PREPAREDNESS AUTHORIZATION OF APPROPRIA-*
 7 *TIONS.—Section 319C–2(j) (42 U.S.C. 247d–3b(j)) is*
 8 *amended—*

9 *(1) by amending paragraph (1) to read as fol-*
 10 *lows:*

11 *“(1) IN GENERAL.—*

12 *“(A) AUTHORIZATION OF APPROPRIA-*
 13 *TIONS.—For purposes of carrying out this sec-*
 14 *tion and section 319C–3, in accordance with*
 15 *subparagraph (B), there is authorized to be ap-*
 16 *propriated \$385,000,000 for each of fiscal years*
 17 *2019 through 2023.*

18 *“(B) RESERVATIONS OF AMOUNTS FOR RE-*
 19 *GIONAL SYSTEMS.—*

20 *“(i) IN GENERAL.—Subject to clause*
 21 *(ii), of the amount appropriated under sub-*
 22 *paragraph (A) for a fiscal year, the Sec-*
 23 *retary may reserve up to 5 percent for the*
 24 *purpose of carrying out section 319C–3.*

1 “(i) *RESERVATIONS CONTINGENT ON*
2 *CONTINUED APPROPRIATIONS FOR THIS*
3 *SECTION.—If for fiscal year 2019 or a sub-*
4 *sequent fiscal year, the amount appro-*
5 *priated under subparagraph (A) is such*
6 *that, after application of clause (i), the*
7 *amount remaining for the purpose of car-*
8 *rying out this section would be less than the*
9 *amount available for such purpose for the*
10 *previous fiscal year, the amount that may*
11 *be reserved under clause (i) shall be reduced*
12 *such that the amount remaining for the*
13 *purpose of carrying out this section is not*
14 *less than the amount available for such pur-*
15 *pose for the previous fiscal year.*

16 “(iii) *SUNSET.—The authority to re-*
17 *serve amounts under clause (i) shall expire*
18 *on September 30, 2023.”;*

19 (2) *in paragraph (2), by striking “paragraph (1)*
20 *for a fiscal year” and inserting “paragraph (1)(A)*
21 *for a fiscal year and not reserved for the purpose de-*
22 *scribed in paragraph (1)(B)(i)”;* and

23 (3) *in paragraph (3)(A), by striking “paragraph*
24 *(1) and not reserved under paragraph (2)” and in-*

1 serting “paragraph (1)(A) and not reserved under
2 paragraph (1)(B)(i) or (2)”.

3 **SEC. 203. REGIONAL HEALTH CARE EMERGENCY PRE-**
4 **PAREDNESS AND RESPONSE SYSTEMS.**

5 (a) *IN GENERAL.*—Part B of title III (42 U.S.C. 243
6 *et seq.*) is amended by inserting after section 319C–2 the
7 following:

8 **“SEC. 319C–3. GUIDELINES FOR REGIONAL HEALTH CARE**
9 **EMERGENCY PREPAREDNESS AND RESPONSE**
10 **SYSTEMS.**

11 “(a) *PURPOSE.*—It is the purpose of this section to
12 *identify and provide guidelines for regional systems of hos-*
13 *pitals, health care facilities, and other public and private*
14 *sector entities, with varying levels of capability to treat pa-*
15 *tients and increase medical surge capacity during, in ad-*
16 *vance of, and immediately following a public health emer-*
17 *gency, including threats posed by one or more chemical, bio-*
18 *logical, radiological, and nuclear agents, including emerg-*
19 *ing infectious diseases.*

20 “(b) *GUIDELINES.*—The Assistant Secretary for Pre-
21 *paredness and Response, in consultation with the Director*
22 *of the Centers for Disease Control and Prevention, the Ad-*
23 *ministrator of the Centers for Medicare & Medicaid Serv-*
24 *ices, the Administrator of the Health Resources and Services*
25 *Administration, the Commissioner of Food and Drugs, the*

1 *Assistant Secretary for Mental Health and Substance Use,*
2 *the Assistant Secretary of Labor for Occupational Safety*
3 *and Health, the Secretary of Veterans Affairs, the heads of*
4 *such other Federal agencies as the Secretary determines to*
5 *be appropriate, and State, local, tribal, and territorial pub-*
6 *lic health officials, shall, not later than 2 years after the*
7 *date of enactment of this section—*

8 “(1) *identify and develop a set of guidelines re-*
9 *lating to practices and protocols for all-hazards pub-*
10 *lic health emergency preparedness and response for*
11 *hospitals and health care facilities to provide appro-*
12 *priate patient care during, in advance of, or imme-*
13 *diately following, a public health emergency, resulting*
14 *from one or more chemical, biological, radiological, or*
15 *nuclear agents, including emerging infectious diseases*
16 *(which may include existing practices, such as trau-*
17 *ma care and medical surge capacity and capabili-*
18 *ties), with respect to—*

19 “(A) *a regional approach to identifying*
20 *hospitals and health care facilities based on*
21 *varying capabilities and capacity to treat pa-*
22 *tients affected by such emergency, including—*

23 “(i) *the manner in which the system*
24 *will coordinate with and integrate the part-*

1 *nerships and health care coalitions estab-*
2 *lished under section 319C–2(b); and*

3 *“(ii) informing and educating appro-*
4 *priate first responders and health care sup-*
5 *ply chain partners of the regional emer-*
6 *gency preparedness and response capabili-*
7 *ties and medical surge capacity of such hos-*
8 *pitals and health care facilities in the com-*
9 *munity;*

10 *“(B) physical and technological infrastruc-*
11 *ture, laboratory capacity, staffing, blood supply,*
12 *and other supply chain needs, taking into ac-*
13 *count resiliency, geographic considerations, and*
14 *rural considerations;*

15 *“(C) protocols or best practices for the safe-*
16 *ty and personal protection of workers who handle*
17 *human remains and health care workers (includ-*
18 *ing with respect to protective equipment and*
19 *supplies, waste management processes, and de-*
20 *contamination), sharing of specialized experience*
21 *among the health care workforce, behavioral*
22 *health, psychological resilience, and training of*
23 *the workforce, as applicable;*

24 *“(D) in a manner that allows for disease*
25 *containment (within the meaning of section*

1 2802(b)(2)(B)), *coordinated medical triage,*
2 *treatment, and transportation of patients, based*
3 *on patient medical need (including patients in*
4 *rural areas), to the appropriate hospitals or*
5 *health care facilities within the regional system*
6 *or, as applicable and appropriate, between sys-*
7 *tems in different States or regions; and*

8 *“(E) the needs of children and other at-risk*
9 *individuals;*

10 *“(2) make such guidelines available on the inter-*
11 *net website of the Department of Health and Human*
12 *Services in a manner that does not compromise na-*
13 *tional security; and*

14 *“(3) update such guidelines as appropriate, in-*
15 *cluding based on input received pursuant to sub-*
16 *sections (c), (e), and (f), to address new and emerging*
17 *public health threats.*

18 *“(c) CONSIDERATIONS.—In identifying, developing,*
19 *and updating guidelines under subsection (b), the Assistant*
20 *Secretary for Preparedness and Response shall—*

21 *“(1) include input from hospitals and health*
22 *care facilities (including health care coalitions under*
23 *section 319C–2), State, local, tribal, and territorial*
24 *public health departments, and health care or subject*
25 *matter experts (including experts with relevant exper-*

1 *tise in chemical, biological, radiological, or nuclear*
2 *threats, and emerging infectious disease), as the As-*
3 *stant Secretary determines appropriate, to meet the*
4 *goals under section 2802(b)(3);*

5 *“(2) consult and engage with appropriate health*
6 *care providers and professionals, including physi-*
7 *cians, nurses, first responders, health care facilities*
8 *(including hospitals, primary care clinics, commu-*
9 *nity health centers, mental health facilities, ambula-*
10 *tory care facilities, and dental health facilities), phar-*
11 *macies, emergency medical providers, trauma care*
12 *providers, environmental health agencies, public*
13 *health laboratories, poison control centers, blood*
14 *banks, and other experts that the Assistant Secretary*
15 *determines appropriate, to meet the goals under sec-*
16 *tion 2802(b)(3);*

17 *“(3) consider feedback related to financial impli-*
18 *cations for hospitals, health care facilities, public*
19 *health agencies, laboratories, and other entities en-*
20 *gaged in regional preparedness planning to imple-*
21 *ment and follow such guidelines, as applicable; and*

22 *“(4) consider financial requirements and poten-*
23 *tial incentives for entities to prepare for, and respond*
24 *to, public health emergencies as part of the regional*

1 *health care emergency preparedness and response sys-*
2 *tem.*

3 “(d) *TECHNICAL ASSISTANCE.—The Assistant Sec-*
4 *retary for Preparedness and Response, in consultation with*
5 *the Director of the Centers for Disease Control and Preven-*
6 *tion and the Assistant Secretary of Labor for Occupational*
7 *Safety and Health, may provide technical assistance and*
8 *consultation towards meeting the guidelines described in*
9 *subsection (b).*

10 “(e) *DEMONSTRATION PROJECT FOR REGIONAL*
11 *HEALTH CARE PREPAREDNESS AND RESPONSE SYS-*
12 *TEMS.—*

13 “(1) *IN GENERAL.—The Assistant Secretary for*
14 *Preparedness and Response may establish a dem-*
15 *onstration project pursuant to the development and*
16 *implementation of guidelines under subsection (b) to*
17 *award grants to improve medical surge capacity for*
18 *all hazards, build and integrate regional medical re-*
19 *sponse capabilities, improve specialty care expertise*
20 *for all-hazards response, and coordinate medical pre-*
21 *paredness and response across State, local, tribal, ter-*
22 *ritorial, and regional jurisdictions.*

23 “(2) *SUNSET.—The authority under this sub-*
24 *section shall expire on September 30, 2023.*

25 “(f) *GAO REPORT TO CONGRESS.—*

1 “(1) *REPORT.*—Not later than 3 years after the
2 date of enactment of this section, the Comptroller
3 General of the United States (referred to in this sub-
4 section as the ‘Comptroller General’) shall submit to
5 the Committee on Health, Education, Labor, and
6 Pensions and the Committee on Finance of the Senate
7 and the Committee on Energy and Commerce and the
8 Committee on Ways and Means of the House of Rep-
9 resentatives, a report on the extent to which hospitals
10 and health care facilities have implemented the rec-
11 ommended guidelines under subsection (b), including
12 an analysis and evaluation of any challenges hos-
13 pitals or health care facilities experienced in imple-
14 menting such guidelines.

15 “(2) *CONTENT.*—The Comptroller General shall
16 include in the report under paragraph (1)—

17 “(A) data on the preparedness and response
18 capabilities that have been informed by the
19 guidelines under subsection (b) to improve re-
20 gional emergency health care preparedness and
21 response capability, including hospital and
22 health care facility capacity and medical surge
23 capabilities to prepare for, and respond to, pub-
24 lic health emergencies; and

1 “(B) recommendations to reduce gaps in in-
2 centives for regional health partners, including
3 hospitals and health care facilities, to improve
4 capacity and medical surge capabilities to pre-
5 pare for, and respond to, public health emer-
6 gencies, consistent with subsection (a), which
7 may include consideration of facilities partici-
8 pating in programs under section 319C–2, pro-
9 grams under the Centers for Medicare & Med-
10 icaid Services (including innovative health care
11 delivery and payment models), and input from
12 private sector financial institutions.

13 “(3) CONSULTATION.—In carrying out para-
14 graphs (1) and (2), the Comptroller General shall
15 consult with the heads of appropriate Federal agen-
16 cies, including—

17 “(A) the Assistant Secretary for Prepared-
18 ness and Response;

19 “(B) the Director of the Centers for Disease
20 Control and Prevention;

21 “(C) the Administrator of the Centers for
22 Medicare & Medicaid Services;

23 “(D) the Assistant Secretary for Mental
24 Health and Substance Use;

1 “(E) the Assistant Secretary of Labor for
2 Occupational Safety and Health;

3 “(F) the Secretary of Veterans Affairs; and

4 “(G) the heads of such other Federal agen-
5 cies as the Secretary determines appropriate.”.

6 (b) ANNUAL REPORTS.—Section 319C-2(i)(1) (42
7 U.S.C. 247d-3b(i)(1)) is amended by inserting after the
8 first sentence the following “The reports submitted under
9 this paragraph shall also include progress towards the im-
10 plementation of section 319C-3.”.

11 (c) NATIONAL HEALTH SECURITY STRATEGY INCOR-
12 PORATION OF REGIONALIZED EMERGENCY PREPAREDNESS
13 AND RESPONSE.—Section 2802(b)(3) (42 U.S.C. 300hh-
14 1(b)(3)) is amended—

15 (1) in the matter preceding subparagraph (A),
16 by striking “including mental health” and inserting
17 “including pharmacies, mental health facilities,”; and

18 (2) by amending subparagraph (G) to read as
19 follows:

20 “(G) Optimizing a coordinated and flexible
21 approach to the emergency response and medical
22 surge capacity of hospitals, other health care fa-
23 cilities, critical care, trauma care (which may
24 include trauma centers), and emergency medical
25 systems, which may include the implementation

1 *of guidelines for regional health care emergency*
2 *preparedness and response systems under section*
3 *319C-3.”.*

4 *(d) IMPROVING STATE AND LOCAL PUBLIC HEALTH*
5 *SECURITY.—*

6 (1) *STATE AND LOCAL SECURITY.—Section*
7 *319C-1(e) (42 U.S.C. 247d-3a(e)) is amended by*
8 *striking “, and local emergency plans.” and inserting*
9 *“, local emergency plans, and any regional health*
10 *care emergency preparedness and response system es-*
11 *tablished pursuant to the applicable guidelines under*
12 *section 319C-3.”.*

13 (2) *PARTNERSHIPS.—Section 319C-2(d)(1)(A)*
14 *(42 U.S.C. 247d-3b(d)(1)(A)) is amended—*

15 (A) *in clause (i), by striking “; and” and*
16 *inserting “;”*

17 (B) *by redesignating clause (ii) as clause*
18 *(iii); and*

19 (C) *inserting after clause (i), the following:*

20 *“(ii) among one or more facilities in a*
21 *regional health care emergency system*
22 *under section 319C-3; and”.*

1 **SEC. 204. MILITARY AND CIVILIAN PARTNERSHIP FOR**
 2 **TRAUMA READINESS.**

3 *Title XII (42 U.S.C. 300d et seq.) is amended by add-*
 4 *ing at the end the following new part:*

5 **“PART I—MILITARY AND CIVILIAN PARTNERSHIP**
 6 **FOR TRAUMA READINESS GRANT PROGRAM**

7 **“SEC. 1291. MILITARY AND CIVILIAN PARTNERSHIP FOR**
 8 **TRAUMA READINESS GRANT PROGRAM.**

9 *“(a) MILITARY TRAUMA TEAM PLACEMENT PRO-*
 10 *GRAM.—*

11 *“(1) IN GENERAL.—The Secretary, acting*
 12 *through the Assistant Secretary for Preparedness and*
 13 *Response and in consultation with the Secretary of*
 14 *Defense, shall award grants to not more than 20 eligi-*
 15 *ble high acuity trauma centers to enable military*
 16 *trauma teams to provide, on a full-time basis, trauma*
 17 *care and related acute care at such trauma centers.*

18 *“(2) LIMITATIONS.—In the case of a grant*
 19 *awarded under paragraph (1) to an eligible high acu-*
 20 *ity trauma center, such grant—*

21 *“(A) shall be for a period of not fewer than*
 22 *3 fiscal years and not more than 5 fiscal years*
 23 *(and may be renewed at the end of such period);*
 24 *and*

25 *“(B) shall be in an amount that does not*
 26 *exceed \$1,000,000 per fiscal year.*

1 “(b) *MILITARY TRAUMA CARE PROVIDER PLACEMENT*
2 *PROGRAM.*—

3 “(1) *IN GENERAL.*—*The Secretary, acting*
4 *through the Assistant Secretary for Preparedness and*
5 *Response and in consultation with the Secretary of*
6 *Defense, shall award grants to eligible trauma centers*
7 *to enable military trauma care providers to provide*
8 *trauma care and related acute care at such trauma*
9 *centers.*

10 “(2) *LIMITATIONS.*—*In the case of a grant*
11 *awarded under paragraph (1) to an eligible trauma*
12 *center, such grant—*

13 “(A) *shall be for a period of at least 1 fiscal*
14 *year and not more than 3 fiscal years (and may*
15 *be renewed at the end of such period); and*

16 “(B) *shall be in an amount that does not*
17 *exceed, in a fiscal year—*

18 “(i) *\$100,000 for each military trauma*
19 *care provider that is a physician at such el-*
20 *igible trauma center; and*

21 “(ii) *\$50,000 for each other military*
22 *trauma care provider at such eligible trau-*
23 *ma center.*

24 “(c) *GRANT REQUIREMENTS.*—

1 “(1) *DEPLOYMENT AND PUBLIC HEALTH EMER-*
2 *GENCIES.—As a condition of receipt of a grant under*
3 *this section, a grant recipient shall agree to allow*
4 *military trauma care providers providing care pursu-*
5 *ant to such grant to—*

6 “(A) *be deployed by the Secretary of Defense*
7 *for military operations, for training, or for re-*
8 *sponse to a mass casualty incident; and*

9 “(B) *be deployed by the Secretary of Health*
10 *and Human Services for response to a public*
11 *health emergency pursuant to section 319.*

12 “(2) *USE OF FUNDS.—Grants awarded under*
13 *this section to an eligible trauma center may be used*
14 *to train and incorporate military trauma care pro-*
15 *viders into such trauma center, including incorpora-*
16 *tion into operational exercises and training drills re-*
17 *lated to public health emergencies, expenditures for*
18 *malpractice insurance, office space, information tech-*
19 *nology, specialty education and supervision, trauma*
20 *programs, and State license fees for such military*
21 *trauma care providers.*

22 “(d) *RULE OF CONSTRUCTION.—Nothing in this sec-*
23 *tion shall be construed to affect any other provision of law*
24 *that preempts State licensing requirements for health care*

1 *professionals with respect to military trauma care pro-*
2 *viders.*

3 “(e) *REPORTING REQUIREMENTS.*—

4 “(1) *REPORT TO THE SECRETARY AND THE SEC-*
5 *RETARY OF DEFENSE.*—*Each eligible trauma center*
6 *or eligible high acuity trauma center awarded a grant*
7 *under subsection (a) or (b) for a fiscal year shall sub-*
8 *mit to the Secretary and the Secretary of Defense a*
9 *report for such fiscal year that includes information*
10 *on—*

11 “(A) *the number and types of trauma cases*
12 *managed by military trauma teams or military*
13 *trauma care providers pursuant to such grant*
14 *during such fiscal year;*

15 “(B) *the ability to maintain the integration*
16 *of the military trauma providers or teams of*
17 *providers as part of the trauma center, including*
18 *the financial effect of such grant on the trauma*
19 *center;*

20 “(C) *the educational effect on resident*
21 *trainees in centers where military trauma teams*
22 *are assigned;*

23 “(D) *any research conducted during such*
24 *fiscal year supported by such grant; and*

1 “(E) any other information required by the
2 Secretaries for the purpose of evaluating the ef-
3 fect of such grant.

4 “(2) REPORT TO CONGRESS.—Not less than once
5 every 2 fiscal years, the Secretary, in consultation
6 with the Secretary of Defense, shall submit a report
7 to the congressional committees of jurisdiction that
8 includes information on the effect of placing military
9 trauma care providers in trauma centers awarded
10 grants under this section on—

11 “(A) maintaining military trauma care
12 providers’ readiness and ability to respond to
13 and treat battlefield injuries;

14 “(B) providing health care to civilian trau-
15 ma patients in urban and rural settings;

16 “(C) the capability of trauma centers and
17 military trauma care providers to increase med-
18 ical surge capacity, including as a result of a
19 large scale event;

20 “(D) the ability of grant recipients to main-
21 tain the integration of the military trauma pro-
22 viders or teams of providers as part of the trau-
23 ma center;

24 “(E) efforts to incorporate military trauma
25 care providers into operational exercises and

1 *training and drills for public health emergencies;*
2 *and*

3 “(F) *the capability of military trauma care*
4 *providers to participate as part of a medical re-*
5 *sponse during or in advance of a declared public*
6 *health emergency.*

7 “(f) *DEFINITIONS.—For purposes of this part:*

8 “(1) *ELIGIBLE TRAUMA CENTER.—The term ‘eli-*
9 *gible trauma center’ means a Level I, II, or III trau-*
10 *ma center that satisfies each of the following:*

11 “(A) *Such trauma center has an agreement*
12 *with the Secretary of Defense to enable military*
13 *trauma care providers to provide trauma care*
14 *and related acute care at such trauma center.*

15 “(B) *Such trauma center utilizes a risk-ad-*
16 *justed benchmarking system and metrics to*
17 *measure performance, quality, and patient out-*
18 *comes.*

19 “(C) *Such trauma center demonstrates a*
20 *need for integrated military trauma care pro-*
21 *viders to maintain or improve the trauma clin-*
22 *ical capability of such trauma center.*

23 “(2) *ELIGIBLE HIGH ACUITY TRAUMA CENTER.—*
24 *The term ‘eligible high acuity trauma center’ means*

1 *a Level I trauma center that satisfies each of the fol-*
2 *lowing:*

3 “(A) *Such trauma center has an agreement*
4 *with the Secretary of Defense to enable military*
5 *trauma teams to provide trauma care and re-*
6 *lated acute care at such trauma center.*

7 “(B) *At least 20 percent of patients treated*
8 *at such trauma center in the most recent 3-*
9 *month period for which data is available are*
10 *treated for a major trauma at such trauma cen-*
11 *ter.*

12 “(C) *Such trauma center utilizes a risk-ad-*
13 *justed benchmarking system and metrics to*
14 *measure performance, quality, and patient out-*
15 *comes.*

16 “(D) *Such trauma center is an academic*
17 *training center—*

18 “(i) *affiliated with a medical school;*

19 “(ii) *that maintains residency pro-*
20 *grams and fellowships in critical trauma*
21 *specialties and subspecialties, and provides*
22 *education and supervision of military trau-*
23 *ma team members according to those spe-*
24 *cialties and subspecialties; and*

1 “(iii) that undertakes research in the
2 prevention and treatment of traumatic in-
3 jury.

4 “(E) Such trauma center serves as a med-
5 ical and public health preparedness and response
6 leader for its community, such as by partici-
7 pating in a partnership for State and regional
8 hospital preparedness established under section
9 319C-2 or 319C-3.

10 “(3) MAJOR TRAUMA.—The term ‘major trauma’
11 means an injury that is greater than or equal to 15
12 on the injury severity score.

13 “(4) MILITARY TRAUMA TEAM.—The term ‘mili-
14 tary trauma team’ means a complete military trau-
15 ma team consisting of military trauma care providers
16 specializing in providing trauma care.

17 “(5) MILITARY TRAUMA CARE PROVIDER.—The
18 term ‘military trauma care provider’ means a mem-
19 ber of the Armed Forces who furnishes emergency,
20 critical care, and other trauma acute care services,
21 including a physician, surgeon or military surgeon,
22 physician assistant, nurse, nurse practitioner, res-
23 piratory therapist, flight paramedic, combat medic,
24 or enlisted medical technician, or other military trau-

1 *improve, enhance, and appropriately maintain*”;
2 *and*

3 *(D) by adding at the end the following:*

4 “(4) *STUDY OF RESOURCES FOR FACILITIES AND*
5 *CAPACITIES.—Not later than June 1, 2022, the Comp-*
6 *troller General of the United States shall conduct a*
7 *study on Federal spending in fiscal years 2013*
8 *through 2018 for activities authorized under this sub-*
9 *section. Such study shall include a review and assess-*
10 *ment of obligations and expenditures directly related*
11 *to each activity under paragraphs (2) and (3), in-*
12 *cluding a specific accounting of, and delineation be-*
13 *tween, obligations and expenditures incurred for the*
14 *construction, renovation, equipping, and security up-*
15 *grades of facilities and associated contracts under this*
16 *subsection, and the obligations and expenditures in-*
17 *curring to establish and improve the situational*
18 *awareness and biosurveillance network under sub-*
19 *section (b), and shall identify the agency or agencies*
20 *incurring such obligations and expenditures.”;*

21 *(3) in subsection (b)—*

22 *(A) in the subsection heading, by striking*
23 *“NATIONAL” and inserting “ESTABLISHMENT OF*
24 *SYSTEMS OF PUBLIC HEALTH ”;*

1 (B) in paragraph (1)(B), by inserting “im-
2 munization information systems,” after “cen-
3 ters,”; and

4 (C) in paragraph (2)—

5 (i) by inserting “develop a plan to,
6 and” after “The Secretary shall”; and

7 (ii) by inserting “and in a form read-
8 ily usable for analytical approaches” after
9 “in a secure manner”; and

10 (D) by amending paragraph (3) to read as
11 follows:

12 “(3) STANDARDS.—

13 “(A) IN GENERAL.—Not later than 1 year
14 after the date of the enactment of the Pandemic
15 and All-Hazards Preparedness and Advancing
16 Innovation Act of 2018, the Secretary, in co-
17 operation with health care providers, State,
18 local, tribal, and territorial public health offi-
19 cials, and relevant Federal agencies (including
20 the Office of the National Coordinator for Health
21 Information Technology and the National Insti-
22 tute of Standards and Technology), shall, as nec-
23 essary, adopt technical and reporting standards,
24 including standards for interoperability as de-
25 fined by section 3000, for networks under para-

1 *graph (1) and update such standards as nec-*
2 *essary. Such standards shall be made available*
3 *on the internet website of the Department of*
4 *Health and Human Services, in a manner that*
5 *does not compromise national security.*

6 “(B) *DEFERENCE TO STANDARDS DEVELOP-*
7 *MENT ORGANIZATIONS.—In adopting and imple-*
8 *menting standards under this subsection and*
9 *subsection (c), the Secretary shall give deference*
10 *to standards published by standards development*
11 *organizations and voluntary consensus-based*
12 *standards entities.”;*

13 *(4) in subsection (c)—*

14 *(A) in paragraph (1)—*

15 *(i) by striking “Not later than 2 years*
16 *after the date of enactment of the Pandemic*
17 *and All-Hazards Preparedness Reauthoriza-*
18 *tion Act of 2013, the Secretary” and insert-*
19 *ing “The Secretary”;*

20 *(ii) by inserting “, and improve as ap-*
21 *plicable and appropriate,” after “shall es-*
22 *tablish”;*

23 *(iii) by striking “of rapid” and insert-*
24 *ing “of, rapid”; and*

1 *(iv) by striking “such connectivity”*
2 *and inserting “such interoperability”;*

3 *(B) by amending paragraph (2) to read as*
4 *follows:*

5 “*(2) COORDINATION AND CONSULTATION.—In es-*
6 *tablishing and improving the network under para-*
7 *graph (1) the Secretary shall—*

8 “*(A) facilitate coordination among agencies*
9 *within the Department of Health and Human*
10 *Services that provide, or have the potential to*
11 *provide, information and data to, and analyses*
12 *for, the situational awareness and biosurveil-*
13 *lance network under paragraph (1), including*
14 *coordination among relevant agencies related to*
15 *health care services, the facilitation of health in-*
16 *formation exchange (including the Office of the*
17 *National Coordinator for Health Information*
18 *Technology), and public health emergency pre-*
19 *paredness and response; and*

20 “*(B) consult with the Secretary of Agri-*
21 *culture, the Secretary of Commerce (and the Di-*
22 *rector of the National Institute of Standards and*
23 *Technology), the Secretary of Defense, the Sec-*
24 *retary of Homeland Security, and the Secretary*
25 *of Veterans Affairs, and the heads of other Fed-*

1 *eral agencies, as the Secretary determines appro-*
2 *priate.”;*

3 *(C) in paragraph (3)—*

4 *(i) by redesignating subparagraphs (A)*
5 *through (E) as clauses (i) through (v), re-*
6 *spectively, and adjusting the margins ac-*
7 *cordingly;*

8 *(ii) in clause (iv), as so redesignated—*

9 *(I) by inserting “immunization*
10 *information systems,” after “poison*
11 *control,”; and*

12 *(II) by striking “ and clinical*
13 *laboratories” and inserting “, clinical*
14 *laboratories, and public environmental*
15 *health agencies”;*

16 *(iii) by striking “The network” and*
17 *inserting the following:*

18 *“(A) IN GENERAL.—The network”;* and

19 *(iv) by adding at the end the following:*

20 *“(B) REVIEW.—Not later than 2 years after*
21 *the date of the enactment of the Pandemic and*
22 *All-Hazards Preparedness and Advancing Inno-*
23 *vation Act of 2018 and every 6 years thereafter,*
24 *the Secretary shall conduct a review of the ele-*
25 *ments described in subparagraph (A). Such re-*

1 view shall include a discussion of the addition of
2 any elements pursuant to clause (v), including
3 elements added to advancing new technologies,
4 and identify any challenges in the incorporation
5 of elements under subparagraph (A). The Sec-
6 retary shall provide such review to the congres-
7 sional committees of jurisdiction.”;

8 (D) in paragraph (5)—

9 (i) by redesignating subparagraphs (A)
10 through (D) as clauses (i) through (iv), re-
11 spectively, and adjusting the margins ac-
12 cordingly;

13 (ii) by striking “In establishing” and
14 inserting the following:

15 “(A) *IN GENERAL.*—In establishing”;

16 (iii) by adding at the end the fol-
17 lowing:

18 “(B) *PUBLIC MEETING.*—

19 “(i) *IN GENERAL.*—Not later than 180
20 days after the date of enactment of the Pan-
21 demic and All-Hazards Preparedness and
22 Advancing Innovation Act of 2018, the Sec-
23 retary shall convene a public meeting for
24 purposes of discussing and providing input
25 on the potential goals, functions, and uses of

1 *the network described in paragraph (1) and*
2 *incorporating the elements described in*
3 *paragraph (3)(A).*

4 “(ii) *EXPERTS.*—*The public meeting*
5 *shall include representatives of relevant*
6 *Federal agencies (including representatives*
7 *from the Office of the National Coordinator*
8 *for Health Information Technology and the*
9 *National Institute of Standards and Tech-*
10 *nology); State, local, tribal, and territorial*
11 *public health officials; stakeholders with ex-*
12 *pertise in biosurveillance and situational*
13 *awareness; stakeholders with expertise in ca-*
14 *pabilities relevant to biosurveillance and*
15 *situational awareness, such as experts in*
16 *informatics and data analytics (including*
17 *experts in prediction, modeling, or fore-*
18 *casting); and other representatives as the*
19 *Secretary determines appropriate.*

20 “(iii) *TOPICS.*—*Such public meeting*
21 *shall include a discussion of—*

22 “(I) *data elements, including*
23 *minimal or essential data elements,*
24 *that are voluntarily provided for such*
25 *network, which may include elements*

1 *from public health and public and pri-*
2 *vate health care entities, to the extent*
3 *practicable;*

4 “(II) *standards and implementa-*
5 *tion specifications that may improve*
6 *the collection, analysis, and interpreta-*
7 *tion of data during a public health*
8 *emergency;*

9 “(III) *strategies to encourage the*
10 *access, exchange, and use of informa-*
11 *tion;*

12 “(IV) *considerations for State,*
13 *local, tribal, and territorial capabili-*
14 *ties and infrastructure related to data*
15 *exchange and interoperability;*

16 “(V) *privacy and security protec-*
17 *tions provided at the Federal, State,*
18 *local, tribal, and territorial levels, and*
19 *by nongovernmental stakeholders; and*

20 “(VI) *opportunities for the incor-*
21 *poration of innovative technologies to*
22 *improve the network.”; and*

23 *(iv) in subparagraph (A), as so des-*
24 *ignated by clause (ii)—*

1 (I) in clause (i), as so redesign-
2 nated—

3 (aa) by striking “as deter-
4 mined” and inserting “as adopt-
5 ed”; and

6 (bb) by inserting “and the
7 National Institute of Standards
8 and Technology” after “Office of
9 the National Coordinator for
10 Health Information Technology”;

11 (II) in clause (iii), as so redesign-
12 nated, by striking “; and” and insert-
13 ing a semicolon;

14 (III) in clause (iv), as so redesign-
15 nated, by striking the period and in-
16 serting “; and”; and

17 (IV) by adding at the end the fol-
18 lowing:

19 “(v) pilot test standards and imple-
20 mentation specifications, consistent with the
21 process described in section 3002(b)(3)(C),
22 which State, local, tribal, and territorial
23 public health entities may utilize, on a vol-
24 untary basis, as a part of the network.”;

1 (E) by redesignating paragraph (6) as
2 paragraph (7);

3 (F) by inserting after paragraph (5) the fol-
4 lowing:

5 “(6) *STRATEGY AND IMPLEMENTATION PLAN.*—

6 “(A) *IN GENERAL.*—Not later than 18
7 months after the date of enactment of the Pan-
8 demic and All-Hazards Preparedness and Ad-
9 vancing Innovation Act of 2018, the Secretary
10 shall submit to the congressional committees of
11 jurisdiction a coordinated strategy and an ac-
12 companying implementation plan that—

13 “(i) is informed by the public meeting
14 under paragraph (5)(B);

15 “(ii) includes a review and assessment
16 of existing capabilities of the network and
17 related infrastructure, including input pro-
18 vided by the public meeting under para-
19 graph (5)(B);

20 “(iii) identifies and demonstrates the
21 measurable steps the Secretary will carry
22 out to—

23 “(I) develop, implement, and
24 evaluate the network described in para-

1 *graph (1), utilizing elements described*
2 *in paragraph (3)(A);*

3 *“(II) modernize and enhance bio-*
4 *surveillance activities, including strat-*
5 *egies to include innovative technologies*
6 *and analytical approaches (including*
7 *prediction and forecasting for*
8 *pandemics and all-hazards) from pub-*
9 *lic and private entities;*

10 *“(III) improve information shar-*
11 *ing, coordination, and communication*
12 *among disparate biosurveillance sys-*
13 *tems supported by the Department of*
14 *Health and Human Services, including*
15 *the identification of methods to im-*
16 *prove accountability, better utilize re-*
17 *sources and workforce capabilities, and*
18 *incorporate innovative technologies*
19 *within and across agencies; and*

20 *“(IV) test and evaluate capabili-*
21 *ties of the interoperable network of sys-*
22 *tems to improve situational awareness*
23 *and biosurveillance capabilities;*

24 *“(iv) includes performance measures*
25 *and the metrics by which performance*

1 *measures will be assessed with respect to the*
2 *measurable steps under clause (iii); and*

3 *“(v) establishes dates by which each*
4 *measurable step under clause (iii) will be*
5 *implemented.”.*

6 *“(B) ANNUAL BUDGET PLAN.—Not later*
7 *than 2 years after the date of enactment of the*
8 *Pandemic and All-Hazards Preparedness and*
9 *Advancing Innovation Act of 2018 and on an*
10 *annual basis thereafter, in accordance with the*
11 *strategy and implementation plan under this*
12 *paragraph, the Secretary shall, taking into ac-*
13 *count recommendations provided by the National*
14 *Biodefense Science Board, develop a budget plan*
15 *based on the strategy and implementation plan*
16 *under this section. Such budget plan shall in-*
17 *clude—*

18 *“(i) a summary of resources previously*
19 *expended to establish, improve, and utilize*
20 *the nationwide public health situational*
21 *awareness and biosurveillance network*
22 *under paragraph (1);*

23 *“(ii) estimates of costs and resources*
24 *needed to establish and improve the network*
25 *under paragraph (1) according to the strat-*

1 *egy and implementation plan under sub-*
2 *paragraph (A);*

3 *“(iii) the identification of gaps and in-*
4 *efficiencies in nationwide public health situ-*
5 *ational awareness and biosurveillance capa-*
6 *bilities, resources, and authorities needed to*
7 *address such gaps; and*

8 *“(iv) a strategy to minimize and ad-*
9 *dress such gaps and improve inefficien-*
10 *cies.”;*

11 *(G) in paragraph (7), as so redesignated—*

12 *(i) in subparagraph (A), by inserting*
13 *“(taking into account zoonotic disease, in-*
14 *cluding gaps in scientific understanding of*
15 *the interactions between human, animal,*
16 *and environmental health)” after “human*
17 *health”;*

18 *(ii) in subparagraph (B)—*

19 *(I) by inserting “and gaps in sur-*
20 *veillance programs” after “surveillance*
21 *programs”; and*

22 *(II) by striking “; and” and in-*
23 *serting a semicolon;*

24 *(iii) in subparagraph (C)—*

1 (I) by inserting “, animal health
2 organizations related to zoonotic dis-
3 ease,” after “health care entities”; and

4 (II) by striking the period and in-
5 serting “; and”; and

6 (iv) by adding at the end the following:

7 “(D) provide recommendations to the Sec-
8 retary on policies and procedures to complete the
9 steps described in this paragraph in a manner
10 that is consistent with section 2802.”; and

11 (H) by adding at the end the following:

12 “(8) *SITUATIONAL AWARENESS AND BIOSURVEIL-*
13 *LANCE AS A NATIONAL SECURITY PRIORITY.—The Sec-*
14 *retary, on a periodic basis as applicable and appro-*
15 *priate, shall meet with the Director of National Intel-*
16 *ligence to inform the development and capabilities of*
17 *the nationwide public health situational awareness*
18 *and biosurveillance network.”;*

19 (5) in subsection (d)—

20 (A) in paragraph (1)—

21 (i) by inserting “environmental health
22 agencies,” after “public health agencies,”;
23 and

24 (ii) by inserting “immunization pro-
25 grams,” after “poison control centers,”; and

- 1 (B) in paragraph (2)—
- 2 (i) in subparagraph (B), by striking
- 3 “and” at the end;
- 4 (ii) in subparagraph (C), by striking
- 5 the period and inserting “; and”; and
- 6 (iii) by adding after subparagraph (C)
- 7 the following:
- 8 “(D) an implementation plan that may in-
- 9 clude measurable steps to achieve the purposes
- 10 described in paragraph (1).”; and
- 11 (C) by striking paragraph (5) and inserting
- 12 the following:
- 13 “(5) *TECHNICAL ASSISTANCE.*—The Secretary
- 14 may provide technical assistance to States, localities,
- 15 tribes, and territories or a consortium of States, local-
- 16 ities, tribes, and territories receiving an award under
- 17 this subsection regarding interoperability and the
- 18 technical standards set forth by the Secretary.”;
- 19 (6) by redesignating subsections (f) and (g) as
- 20 subsections (i) and (j), respectively; and
- 21 (7) by inserting after subsection (e) the following:
- 22 “(f) *PERSONNEL AUTHORITIES.*—
- 23 “(1) *SPECIALLY QUALIFIED PERSONNEL.*—In ad-
- 24 dition to any other personnel authorities, to carry out

1 subsection (b) and subsection (c), the Secretary
2 may—

3 “(A) appoint highly qualified individuals to
4 scientific or professional positions at the Centers
5 for Disease Control and Prevention, not to exceed
6 30 such employees at any time (specific to posi-
7 tions authorized by this subsection), with exper-
8 tise in capabilities relevant to biosurveillance
9 and situational awareness, such as experts in
10 informatics and data analytics (including ex-
11 perts in prediction, modeling, or forecasting),
12 and other related scientific or technical fields;
13 and

14 “(B) compensate individuals appointed
15 under subparagraph (A) in the same manner
16 and subject to the same terms and conditions in
17 which individuals appointed under 9903 of title
18 5, United States Code, are compensated, without
19 regard to the provisions of chapter 51 and sub-
20 chapter III of chapter 53 of that title relating to
21 classification and General Schedule pay rates.

22 “(2) LIMITATIONS.—The Secretary shall exercise
23 the authority under paragraph (1) in a manner that
24 is consistent with the limitations described in section
25 319F-1(e)(2).

1 “(g) *TIMELINE.*—*The Secretary shall accomplish the*
2 *purposes under subsections (b) and (c) no later than Sep-*
3 *tember 30, 2023, and shall provide a justification to the*
4 *congressional committees of jurisdiction for any missed or*
5 *delayed implementation of measurable steps identified*
6 *under subsection (c)(6)(A)(iii).*

7 “(h) *INDEPENDENT EVALUATION.*—*Not later than 3*
8 *years after the date of enactment of the Pandemic and All-*
9 *Hazards Preparedness and Advancing Innovation Act of*
10 *2018, the Comptroller General of the United States shall*
11 *conduct an independent evaluation, and submit to the Sec-*
12 *retary and the congressional committees of jurisdiction a*
13 *report concerning the activities conducted under subsections*
14 *(b) and (c), and provide recommendations, as applicable*
15 *and appropriate, on necessary improvements to the bio-*
16 *surveillance and situational awareness network.”.*

17 “(b) *AUTHORIZATION OF APPROPRIATIONS.*—*Sub-*
18 *section (i) of section 319D (42 U.S.C. 247d–4), as redesi-*
19 *gnated by subsection (a)(6), is amended by striking*
20 *“\$138,300,000 for each of fiscal years 2014 through 2018”*
21 *and inserting “\$161,800,000 for each of fiscal years 2019*
22 *through 2023”.*

1 **SEC. 206. STRENGTHENING AND SUPPORTING THE PUBLIC**
2 **HEALTH EMERGENCY RAPID RESPONSE**
3 **FUND.**

4 *Section 319 (42 U.S.C. 247d) is amended—*

5 *(1) in subsection (b)—*

6 *(A) in paragraph (1)—*

7 *(i) in the first sentence, by inserting*
8 *“or if the Secretary determines there is the*
9 *significant potential for a public health*
10 *emergency, to allow the Secretary to rapidly*
11 *respond to the immediate needs resulting*
12 *from such public health emergency or poten-*
13 *tial public health emergency” before the pe-*
14 *riod; and*

15 *(ii) by inserting “The Secretary shall*
16 *plan for the expedited distribution of funds*
17 *to appropriate agencies and entities.” after*
18 *the first sentence;*

19 *(B) by redesignating paragraph (2) as*
20 *paragraph (3);*

21 *(C) by inserting after paragraph (1) the fol-*
22 *lowing:*

23 *“(2) USES.—The Secretary may use amounts in*
24 *the Fund established under paragraph (1), to—*

25 *“(A) facilitate coordination between and*
26 *among Federal, State, local, tribal, and terri-*

1 *torial entities and public and private health care*
2 *entities that the Secretary determines may be af-*
3 *ected by a public health emergency or potential*
4 *public health emergency (including communica-*
5 *tion of such entities with relevant international*
6 *entities, as applicable);*

7 *“(B) make grants, provide for awards, enter*
8 *into contracts, and conduct supportive investiga-*
9 *tions pertaining to a public health emergency or*
10 *potential public health emergency, including fur-*
11 *ther supporting programs under section 319C–1,*
12 *319C–2, or 319C–3;*

13 *“(C) facilitate and accelerate, as applicable,*
14 *advanced research and development of security*
15 *countermeasures (as defined in section 319F–2),*
16 *qualified countermeasures (as defined in section*
17 *319F–1), or qualified pandemic or epidemic*
18 *products (as defined in section 319F–3), that are*
19 *applicable to the public health emergency or po-*
20 *tential public health emergency under paragraph*
21 *(1);*

22 *“(D) strengthen biosurveillance capabilities*
23 *and laboratory capacity to identify, collect, and*
24 *analyze information regarding such public*
25 *health emergency or potential public health*

1 *emergency, including the systems under section*
2 *319D;*

3 *“(E) support initial emergency operations*
4 *and assets related to preparation and deploy-*
5 *ment of intermittent disaster response personnel*
6 *expenses under section 2812, and the Medical Re-*
7 *serve Corps under section 2813; and*

8 *“(F) other activities, as the Secretary deter-*
9 *mines applicable and appropriate.”; and*

10 *(D) by inserting after paragraph (3), as so*
11 *redesignated, the following:*

12 *“(4) REVIEW.—Not later than 2 years after the*
13 *date of enactment of the Pandemic and All-Hazards*
14 *Preparedness and Advancing Innovation Act of 2018,*
15 *the Secretary, in coordination with the Assistant Sec-*
16 *retary for Preparedness and Response, shall conduct*
17 *a review of the Fund under this section, and provide*
18 *recommendations to the Committee on Health, Edu-*
19 *cation, Labor, and Pensions and the Committee on*
20 *Appropriations of the Senate and the Committee on*
21 *Energy and Commerce and the Committee on Appro-*
22 *propriations of the House of Representatives on policies*
23 *to improve such Fund for the uses described in para-*
24 *graph (2).*

1 “(5) *GAO REPORT.*—Not later than 4 years after
 2 the date of enactment of the *Pandemic and All-Haz-*
 3 *ards Preparedness and Advancing Innovation Act of*
 4 2018, the Comptroller General of the United States
 5 shall conduct a review of the Fund under this section,
 6 including the uses and the resources available in the
 7 Fund.”; and

8 (2) in subsection (c)—

9 (A) by inserting “rapidly respond to public
 10 health emergencies or potential public health
 11 emergencies and” after “used to”; and

12 (B) by striking “section.” and inserting
 13 “Act or funds otherwise provided for emergency
 14 response.”.

15 **SEC. 207. IMPROVING PREPAREDNESS FOR AND RESPONSE**
 16 **TO ALL-HAZARDS BY PUBLIC HEALTH EMER-**
 17 **GENCY VOLUNTEERS.**

18 Section 319I (42 U.S.C. 247d–7b) is amended:

19 (1) in subsection (a), by adding at the end the
 20 following: “Such health care professionals may in-
 21 clude members of the National Disaster Medical Sys-
 22 tem, members of the Medical Reserve Corps, and indi-
 23 vidual health care professionals.”;

24 (2) in subsection (i) by adding at the end “In
 25 order to inform the development of such mechanisms

1 *by States, the Secretary shall make available informa-*
 2 *tion and material provided by States that have devel-*
 3 *oped mechanisms to waive the application of licens-*
 4 *ing requirements to applicable health professionals*
 5 *seeking to provide medical services during a public*
 6 *health emergency. Such information shall be made*
 7 *publicly available in a manner that does not com-*
 8 *promise national security.”; and*

9 *(3) in subsection (k) by striking “2014 through*
 10 *2018” and inserting “2019 through 2023”.*

11 **SEC. 208. CLARIFYING STATE LIABILITY LAW FOR VOLUN-**
 12 **TEER HEALTH CARE PROFESSIONALS.**

13 *(a) IN GENERAL.—Part B of title III (42 U.S.C. 243*
 14 *et seq.) is amended by inserting after section 319I the fol-*
 15 *lowing:*

16 **“SEC. 319I-1. HEALTH CARE PROFESSIONALS ASSISTING**
 17 **DURING A PUBLIC HEALTH EMERGENCY.**

18 *“(a) LIMITATION ON LIABILITY.—Notwithstanding*
 19 *any other provision of law, a health care professional who*
 20 *is a member of the Medical Reserve Corps under section*
 21 *2813 or who is included in the verification network under*
 22 *section 319I and who—*

23 *“(1) is responding to a public health emergency*
 24 *declared under section 319(a) during the initial 90-*
 25 *day period of the public health emergency determina-*

1 *tion (excluding any period covered by a renewal of*
2 *such determination);*

3 *“(2) is alleged to be liable for an act or omis-*
4 *sion—*

5 *“(A) during the 90-day period of the public*
6 *health emergency described in paragraph (1) and*
7 *related to the treatment of individuals in need of*
8 *health care services due to such public health*
9 *emergency;*

10 *“(B) in the State or States in which the*
11 *public health emergency is declared;*

12 *“(C) in the health care professional’s capac-*
13 *ity as a member of the Medical Reserve Corps or*
14 *a professional included in the verification net-*
15 *work under section 319I; and*

16 *“(D) in the course of providing services that*
17 *are within the scope of the license, registration,*
18 *or certification of the professional, as defined by*
19 *the State of licensure, registration, or certifi-*
20 *cation; and*

21 *“(3) prior to the rendering of such act or omis-*
22 *sion, was authorized by the State’s authorization of a*
23 *deploying State’s Emergency System for Advance*
24 *Registration of Volunteer Health Professionals de-*
25 *scribed in section 319I or the Medical Reserve Corps*

1 *established under section 2813, to provide health care*
2 *services,*
3 *shall be subject only to the State liability laws of the State*
4 *in which such act or omission occurred, in the same manner*
5 *and to the same extent as a similar health care professional*
6 *who is a resident of such State would be subject to such*
7 *State laws, except with respect to the licensure, registration,*
8 *and certification of such individual.*

9 *“(b) VOLUNTEER PROTECTION ACT.—Nothing in this*
10 *section shall be construed to affect an individual’s right to*
11 *protections under the Volunteer Protection Act of 1997.*

12 *“(c) PREEMPTION.—This section shall supercede the*
13 *laws of any State that would subject a health care profes-*
14 *sional described in subsection (a) to the liability laws of*
15 *any State other than the State liability laws to which such*
16 *individual is subject pursuant to such subsection.*

17 *“(d) DEFINITIONS.—In this section:*

18 *“(1) The term ‘health care professional’ means*
19 *an individual licensed, registered, or certified under*
20 *Federal or State laws or regulations to provide health*
21 *care services.*

22 *“(2) The term ‘health care services’ means any*
23 *services provided by a health care professional, or by*
24 *any individual working under the supervision of a*
25 *health care professional, that relate to—*

1 “(A) the diagnosis, prevention, or treatment
2 of any human disease or impairment; or

3 “(B) the assessment or care of the health of
4 human beings.”.

5 (b) *EFFECTIVE DATE.*—

6 (1) *IN GENERAL.*—Section 319I–1 of the Public
7 Health Service Act, as added by subsection (a), shall
8 take effect 90 days after the date of the enactment of
9 this Act.

10 (2) *APPLICATION.*—Section 319I–1 of the Public
11 Health Service Act, as added by subsection (a), ap-
12 plies to a claim for harm only if the act or omission
13 that caused such harm occurred on or after the effec-
14 tive date described in paragraph (1).

15 (c) *GAO STUDY.*—Not later than one year after the
16 date of enactment of this Act, the Comptroller General of
17 the United States shall conduct a review of—

18 (1) the number of health care providers who reg-
19 ister under the verification network pursuant to sec-
20 tion 319I of the Public Health Service Act (42 U.S.C.
21 247d–7b) in advance to provide services during a
22 public health emergency;

23 (2) the number of health care providers who are
24 credentialed to provide services during the period of
25 a public health emergency declaration, including

1 *those who are credentialed through programs estab-*
 2 *lished in the verification network pursuant to such*
 3 *section 319I and those credentialed by authorities*
 4 *within the State in which the emergency occurred;*

5 *(3) the average time to verify the credentials of*
 6 *a health care provider during the period of a public*
 7 *health emergency declaration, including the average*
 8 *time pursuant to the verification network under such*
 9 *section 319I and for an individual's credentials to be*
 10 *verified by an authority within the State; and*

11 *(4) the States' Emergency System for Advance*
 12 *Registration of Volunteer Health Professionals volun-*
 13 *teer program, including whether physician or medical*
 14 *groups, associations, or other relevant provider orga-*
 15 *nizations utilize such program for purposes of volun-*
 16 *teering during public health emergencies.*

17 **TITLE III—REACHING ALL**
 18 **COMMUNITIES**

19 **SEC. 301. STRENGTHENING AND ASSESSING THE EMER-**
 20 **GENCY RESPONSE WORKFORCE.**

21 *(a) NATIONAL DISASTER MEDICAL SYSTEM.—Clause*
 22 *(ii) of section 2812(a)(3)(A) (42 U.S.C. 300hh–11(a)(3)(A))*
 23 *is amended to read as follows:*

24 *“(ii) be present at locations, and for*
 25 *limited periods of time, specified by the Sec-*

1 *retary on the basis that the Secretary has*
2 *determined that a location is at risk of a*
3 *public health emergency during the time*
4 *specified, or there is a significant potential*
5 *for a public health emergency.”.*

6 *(b) VOLUNTEER MEDICAL RESERVE CORPS.—Section*
7 *2813(a) (42 U.S.C. 42 U.S.C. 300hh–15(a)) is amended by*
8 *striking the second sentence and inserting “The Secretary*
9 *may appoint a Director to head the Corps and oversee the*
10 *activities of the Corps chapters that exist at the State, local,*
11 *tribal, and territorial levels.”*

12 *(c) REVIEW OF THE NATIONAL DISASTER MEDICAL*
13 *SYSTEM.—Section 2812(b)(2) (42 U.S.C. 300hh–11(b)(2))*
14 *is amended to read as follows:*

15 *“(2) JOINT REVIEW AND MEDICAL SURGE CAPAC-*
16 *ITY STRATEGIC PLAN.—*

17 *“(A) REVIEW.—Not later than 180 days*
18 *after the date of enactment of the Pandemic and*
19 *All-Hazards Preparedness and Advancing Inno-*
20 *vation Act of 2018, the Secretary, in coordina-*
21 *tion with the Secretary of Homeland Security,*
22 *the Secretary of Defense, and the Secretary of*
23 *Veterans Affairs, shall conduct a joint review of*
24 *the National Disaster Medical System. Such re-*
25 *view shall include—*

1 “(i) an evaluation of medical surge ca-
2 pacity, as described in section 2803(a);

3 “(ii) an assessment of the available
4 workforce of the intermittent disaster re-
5 sponse personnel described in subsection (c);

6 “(iii) the capacity of the workforce de-
7 scribed in clause (ii) to respond to all haz-
8 ards, including capacity to simultaneously
9 respond to multiple public health emer-
10 gencies and the capacity to respond to a na-
11 tionwide public health emergency;

12 “(iv) the effectiveness of efforts to re-
13 cruit, retain, and train such workforce; and

14 “(v) gaps that may exist in such work-
15 force and recommendations for addressing
16 such gaps.

17 “(B) *UPDATES.*—As part of the National
18 Health Security Strategy under section 2802, the
19 Secretary shall update the findings from the re-
20 view under subparagraph (A) and provide rec-
21 ommendations to modify the policies of the Na-
22 tional Disaster Medical System as necessary.”.

23 (d) *NOTIFICATION OF NDMS SHORTAGE.*—Section
24 2812(c) (42 U.S.C. 300hh–11(c)) is amended by adding at
25 the end the following:

1 “(3) *SERVICE BENEFIT.*—*Individuals appointed*
2 *to serve under this subsection shall be considered pub-*
3 *lic safety officers under part L of title I of the Omni-*
4 *bus Crime Control and Safe Streets Act of 1968. The*
5 *Secretary shall provide notification to eligible indi-*
6 *viduals of any effect such designation may have on*
7 *other benefits for which such individuals are eligible,*
8 *including benefits from private entities.*

9 “(4) *NOTIFICATION.*—*Not later than 30 days*
10 *after the date on which the Secretary determines the*
11 *number of intermittent disaster response personnel of*
12 *such System is insufficient to address a public health*
13 *emergency or potential public health emergency, the*
14 *Secretary shall submit to the congressional committees*
15 *of jurisdiction a notification detailing the impact*
16 *such shortage could have on meeting public health*
17 *needs and emergency medical personnel needs during*
18 *a public health emergency, and any identified meas-*
19 *ures to address such shortage.*

20 “(5) *CERTAIN APPOINTMENTS.*—

21 “(A) *IN GENERAL.*—*If the Secretary deter-*
22 *mines that the number of intermittent disaster*
23 *response personnel within the National Disaster*
24 *Medical System under this section is insufficient*
25 *to address a public health emergency or potential*

1 *public health emergency, the Secretary may ap-*
2 *point candidates directly to personnel positions*
3 *for intermittent disaster response within such*
4 *system. The Secretary shall provide updates on*
5 *the number of vacant or unfilled positions within*
6 *such system to the congressional committees of*
7 *jurisdiction each quarter for which this author-*
8 *ity is in effect.*

9 “(B) *SUNSET.*—*The authority under this*
10 *paragraph shall expire on September 30, 2021.*”.

11 *(e) PUBLIC SAFETY OFFICER BENEFITS.*—*Section*
12 *1204(9) of title I of the Omnibus Crime Control and Safe*
13 *Streets Act of 1968 (34 U.S.C. 10284(9)) is amended—*

14 (1) *in subparagraph (C)(ii), by striking “or” at*
15 *the end;*

16 (2) *in subparagraph (D), by striking the period*
17 *and inserting “; or”; and*

18 (3) *by inserting after subparagraph (D) the fol-*
19 *lowing:*

20 “(E) *an individual appointed to the Na-*
21 *tional Disaster Medical System under section*
22 *2812 of the Public Health Service Act (42 U.S.C.*
23 *300hh–11) who is performing official duties of*
24 *the Department of Health and Human Services,*
25 *if those official duties are related to responding*

1 *entities capable of assisting with, responding to, and miti-*
 2 *gating the effect of a public health emergency, including an*
 3 *emergency under section 319, an emergency or major dis-*
 4 *aster under the Robert T. Stafford Disaster Relief and*
 5 *Emergency Assistance Act, or the National Emergencies*
 6 *Act, including by establishing methods to exchange critical*
 7 *information and deliver products consumed or used to pre-*
 8 *serve, protect, or sustain life, health, or safety, and sharing*
 9 *of specialized expertise.”.*

10 (b) **MANUFACTURING CAPACITY.**—Section
 11 2811(d)(2)(C) (42 U.S.C. 300hh–10(d)(2)(C)) is amended
 12 by inserting “, and ancillary medical supplies to assist with
 13 the utilization of such products,” after “products”.

14 **SEC. 303. CONSIDERATIONS FOR AT-RISK INDIVIDUALS.**

15 (a) **AT-RISK INDIVIDUALS IN THE NATIONAL HEALTH**
 16 **SECURITY STRATEGY.**—Section 2802(b)(4)(B) (42 U.S.C.
 17 300hh–1(b)(4)(B)) is amended—

18 (1) by striking “this section and sections 319C–
 19 1, 319F, and 319L,” and inserting “this Act”; and

20 (2) by striking “special” and inserting “access or
 21 functional”.

22 (b) **COUNTERMEASURE CONSIDERATIONS.**—Section
 23 319L(c)(6) (42 U.S.C. 247d–7e(c)(6)) is amended—

24 (1) by striking “elderly” and inserting “senior
 25 citizens”; and

1 (2) by inserting “with relevant characteristics
2 that warrant consideration during the process of re-
3 searching and developing such countermeasures and
4 products” before the period.

5 **SEC. 304. IMPROVING EMERGENCY PREPAREDNESS AND RE-**
6 **SPONSE CONSIDERATIONS FOR CHILDREN.**

7 Part B of title III (42 U.S.C. 243 et seq.) is amended
8 by inserting after section 319D the following:

9 **“SEC. 319D–1. CHILDREN’S PREPAREDNESS UNIT.**

10 “(a) *ENHANCING EMERGENCY PREPAREDNESS FOR*
11 *CHILDREN.*—The Secretary, acting through the Director of
12 the Centers for Disease Control and Prevention (referred to
13 in this subsection as the ‘Director’), shall maintain an in-
14 ternal team of experts, to be known as the Children’s Pre-
15 paredness Unit (referred to in this subsection as the ‘Unit’),
16 to work collaboratively to provide guidance on the consider-
17 ations for, and the specific needs of, children before, during,
18 and after public health emergencies. The Unit shall inform
19 the Director regarding emergency preparedness and re-
20 sponse efforts pertaining to children at the Centers for Dis-
21 ease Control and Prevention.

22 “(b) *EXPERTISE.*—The team described in subsection
23 (a) shall include one or more pediatricians, which may be
24 a developmental-behavioral pediatrician, and may also in-
25 clude behavioral scientists, child psychologists, epidemiolo-

1 *gists, biostatisticians, health communications staff, and in-*
2 *dividuals with other areas of expertise, as the Secretary de-*
3 *termines appropriate.*

4 “(c) *DUTIES.—The team described in subsection (a)*
5 *may—*

6 “(1) *assist State, local, tribal, and territorial*
7 *emergency planning and response activities related to*
8 *children, which may include developing, identifying,*
9 *and sharing best practices;*

10 “(2) *provide technical assistance, training, and*
11 *consultation to Federal, State, local, tribal, and terri-*
12 *torial public health officials to improve preparedness*
13 *and response capabilities with respect to the needs of*
14 *children, including providing such technical assist-*
15 *ance, training, and consultation to eligible entities in*
16 *order to support the achievement of measurable evi-*
17 *dence-based benchmarks and objective standards ap-*
18 *plicable to sections 319C–1 and 319C–2 ;*

19 “(3) *improve the utilization of methods to incor-*
20 *porate the needs of children in planning for and re-*
21 *sponding to a public health emergency, including*
22 *public awareness of such methods;*

23 “(4) *coordinate with, and improve, public-pri-*
24 *vate partnerships, such as health care coalitions pur-*
25 *suant to sections 319C–2 and 319C–3, to address gaps*

1 *and inefficiencies in emergency preparedness and re-*
 2 *sponse efforts for children;*

3 *“(5) provide expertise and input during the de-*
 4 *velopment of guidance and clinical recommendations*
 5 *to address the needs of children when preparing for,*
 6 *and responding to, public health emergencies, includ-*
 7 *ing pursuant to section 319C–3; and*

8 *“(6) carry out other duties related to prepared-*
 9 *ness and response activities for children, as the Sec-*
 10 *retary determines appropriate.”.*

11 **SEC. 305. REAUTHORIZING THE NATIONAL ADVISORY COM-**
 12 **MITTEE ON CHILDREN AND DISASTERS.**

13 *Section 2811A (42 U.S.C. 300hh–10a) is amended—*

14 *(1) in subsection (b)(2), by inserting “, mental*
 15 *and behavioral,” after “medical”;*

16 *(2) in subsection (d)—*

17 *(A) in paragraph (1), by striking “15” and*
 18 *inserting “25”; and*

19 *(B) by striking paragraph (2) and inserting*
 20 *the following:*

21 *“(2) REQUIRED NON-FEDERAL MEMBERS.—The*
 22 *Secretary, in consultation with such other heads of*
 23 *Federal agencies as may be appropriate, shall ap-*
 24 *point to the Advisory Committee under paragraph (1)*

1 *at least 13 individuals to perform the duties described*
2 *in subsections (b) and (c), including—*

3 “(A) *at least 2 non-Federal professionals*
4 *with expertise in pediatric medical disaster*
5 *planning, preparedness, response, or recovery;*

6 “(B) *at least 2 representatives from State,*
7 *local, tribal, or territorial agencies with expertise*
8 *in pediatric disaster planning, preparedness, re-*
9 *sponse, or recovery;*

10 “(C) *at least 4 members representing health*
11 *care professionals, which may include members*
12 *with expertise in pediatric emergency medicine;*
13 *pediatric trauma, critical care, or surgery; the*
14 *treatment of pediatric patients affected by chem-*
15 *ical, biological, radiological, or nuclear agents*
16 *and emerging infectious diseases; pediatric men-*
17 *tal or behavioral health related to children af-*
18 *ected by a public health emergency; or pediatric*
19 *primary care; and*

20 “(D) *other members as the Secretary deter-*
21 *mines appropriate, of whom—*

22 “(i) *at least one such member shall*
23 *represent a children’s hospital;*

1 “(ii) at least one such member shall be
2 an individual with expertise in schools or
3 child care settings;

4 “(iii) at least one such member shall be
5 an individual with expertise in children
6 and youth with special health care needs;
7 and

8 “(iv) at least one such member shall be
9 an individual with expertise in the needs of
10 parents or family caregivers, including the
11 parents or caregivers of children with dis-
12 abilities.”.

13 “(3) *FEDERAL MEMBERS.*—*The Advisory Com-*
14 *mittee under paragraph (1) shall include the fol-*
15 *lowing Federal members or their designees:*

16 “(A) *The Assistant Secretary for Prepared-*
17 *ness and Response.*

18 “(B) *The Director of the Biomedical Ad-*
19 *vanced Research and Development Authority.*

20 “(C) *The Director of the Centers for Disease*
21 *Control and Prevention.*

22 “(D) *The Commissioner of Food and Drugs.*

23 “(E) *The Director of the National Institutes*
24 *of Health.*

1 “(F) *The Assistant Secretary of the Admin-*
2 *istration for Children and Families.*

3 “(G) *The Administrator of the Health Re-*
4 *sources and Services Administration.*

5 “(H) *The Administrator of the Federal*
6 *Emergency Management Agency.*

7 “(I) *The Administrator of the Administra-*
8 *tion for Community Living.*

9 “(J) *The Secretary of Education.*

10 “(K) *Representatives from such Federal*
11 *agencies (such as the Substance Abuse and Men-*
12 *tal Health Services Administration and the De-*
13 *partment of Homeland Security) as the Sec-*
14 *retary determines appropriate to fulfill the du-*
15 *ties of the Advisory Committee under subsections*
16 *(b) and (c).”.*

17 “(4) *TERM OF APPOINTMENT.—Each member of*
18 *the Advisory Committee appointed under paragraph*
19 *(2) shall serve for a term of 3 years, except that the*
20 *Secretary may adjust the terms of the Advisory Com-*
21 *mittee appointees serving on the date of enactment of*
22 *the Pandemic and All-Hazards Preparedness and Ad-*
23 *vancing Innovation Act of 2018, or appointees who*
24 *are initially appointed after such date of enactment,*

1 *in order to provide for a staggered term of appoint-*
 2 *ment for all members.*

3 “(5) *CONSECUTIVE APPOINTMENTS; MAXIMUM*
 4 *TERMS.—A member appointed under paragraph (2)*
 5 *may serve not more than 3 terms on the Advisory*
 6 *Committee, and not more than 2 of which may be*
 7 *served consecutively.”;*

8 (3) *in subsection (e), by adding at the end “At*
 9 *least one meeting per year shall be an in-person meet-*
 10 *ing.”;*

11 (4) *by redesignating subsection (f) as subsection*
 12 *(g);*

13 (5) *by inserting after subsection (e) the following:*

14 “(f) *COORDINATION.—The Secretary shall coordinate*
 15 *activities authorized under this section and section 2811B,*
 16 *in accordance with section 2811B(d).”;* and

17 (6) *in subsection (g), as so redesignated, by strik-*
 18 *ing “2018” and inserting “2023”.*

19 **SEC. 306. AUTHORIZING THE NATIONAL ADVISORY COM-**
 20 **MITTEE ON SENIORS AND DISASTERS.**

21 *Subtitle B of title XXVIII (42 U.S.C. 300hh et seq.)*
 22 *is amended by inserting after section 2811A the following:*

1 **“SEC. 2811B. NATIONAL ADVISORY COMMITTEE ON SENIORS**
2 **AND DISASTERS.**

3 “(a) *ESTABLISHMENT.*—*The Secretary, in consulta-*
4 *tion with the Secretary of Homeland Security and the Sec-*
5 *retary of Veterans Affairs, shall establish an advisory com-*
6 *mittee to be known as the National Advisory Committee on*
7 *Seniors and Disasters (referred to in this section as the ‘Ad-*
8 *visory Committee’).*

9 “(b) *DUTIES.*—

10 “(1) *IN GENERAL.*—*The Advisory Committee*
11 *shall—*

12 “(A) *provide advice and consultation with*
13 *respect to the activities carried out pursuant to*
14 *section 2814, as applicable and appropriate;*

15 “(B) *evaluate and provide input with re-*
16 *spect to the medical and public health needs of*
17 *seniors related to the preparation for, response*
18 *to, and recovery from all-hazards emergencies;*
19 *and*

20 “(C) *provide advice and consultation with*
21 *respect to State emergency preparedness and re-*
22 *sponse activities and seniors, including related*
23 *drills and exercises pursuant to the preparedness*
24 *goals under section 2802(b).*

25 “(2) *ADDITIONAL DUTIES.*—*The Advisory Com-*
26 *mittee may provide advice and recommendations to*

1 *the Secretary with respect to seniors and the medical*
2 *and public health grants and cooperative agreements*
3 *as applicable to preparedness and response activities*
4 *under this title and title III.*

5 “(3) *MEMBERSHIP.*—

6 “(A) *IN GENERAL.*—*The Secretary, in con-*
7 *sultation with such other heads of agencies as*
8 *appropriate, shall appoint not more than 15*
9 *members to the Advisory Committee. In appoint-*
10 *ing such members, the Secretary shall ensure*
11 *that the total membership of the Advisory Com-*
12 *mittee is an odd number.*

13 “(B) *REQUIRED MEMBERS.*—*The members*
14 *appointed under paragraph (1) shall include—*

15 “(i) *the Assistant Secretary for Pre-*
16 *paredness and Response;*

17 “(ii) *the Director of the Biomedical*
18 *Advanced Research and Development Au-*
19 *thority;*

20 “(iii) *the Director of the Centers for*
21 *Disease Control and Prevention;*

22 “(iv) *the Commissioner of Food and*
23 *Drugs;*

24 “(v) *the Director of the National Insti-*
25 *tutes of Health;*

1 “(vi) *the Administrator of the Centers*
2 *for Medicare & Medicaid Services;*

3 “(vii) *the Administrator of the Admin-*
4 *istration for Community Living;*

5 “(viii) *the Administrator of the Fed-*
6 *eral Emergency Management Agency;*

7 “(ix) *the Under Secretary for Health of*
8 *the Department of Veterans Affairs;*

9 “(x) *at least 2 non-Federal health care*
10 *professionals with expertise in medical dis-*
11 *aster planning, preparedness, response, or*
12 *recovery;*

13 “(xi) *at least 2 representatives of State,*
14 *local, territorial, or tribal agencies with ex-*
15 *pertise in disaster planning, preparedness,*
16 *response, or recovery; and*

17 “(xii) *representatives of such other*
18 *Federal agencies (such as the Department of*
19 *Energy and the Department of Homeland*
20 *Security) as the Secretary determines nec-*
21 *essary to fulfill the duties of the Advisory*
22 *Committee.*

23 “(c) *MEETINGS.—The Advisory Committee shall meet*
24 *not less frequently than biannually.*

25 “(d) *ADVISORY COMMITTEE COORDINATION.—*

1 “(1) *IN GENERAL.*—*The Secretary shall coordi-*
2 *nate activities authorized under this section and sec-*
3 *tion 2811A, and make efforts to reduce unnecessary or*
4 *duplication of meetings, recommendations, and re-*
5 *porting under such sections. Members of the advisory*
6 *committees under this section and section 2811A, or*
7 *their designees, shall meet periodically, and not less*
8 *than annually, to—*

9 “(A) *review the recommendations developed*
10 *by such committees to coordinate, as appro-*
11 *priate, the implementation of recommendations,*
12 *in order to reduce gaps, overlap, and duplication*
13 *of effort in Federal programs or by Federal*
14 *grantees; and*

15 “(B) *align preparedness and response pro-*
16 *grams or activities to address the dual or over-*
17 *lapping needs of children and seniors and any*
18 *challenges in preparing for and responding to*
19 *such needs.*

20 “(2) *NOTIFICATION.*—*The Secretary shall notify*
21 *the congressional committees of jurisdiction upon the*
22 *convening of each meeting under paragraph (1), and*
23 *provide minutes from such meeting not later than 90*
24 *days after the meeting.*

1 **TITLE IV—PRIORITIZING A**
2 **THREAT-BASED APPROACH**

3 **SEC. 401. ASSISTANT SECRETARY FOR PREPAREDNESS AND**
4 **RESPONSE.**

5 *Section 2811(b) (42 U.S.C. 300hh–10(b)) is amend-*
6 *ed—*

7 *(1) in the matter preceding paragraph (1) by in-*
8 *serting “utilize experience related to public health*
9 *emergency preparedness and response, biodefense,*
10 *medical countermeasures, and other relevant topics*
11 *to” after “shall”; and*

12 *(2) in paragraph (4) by adding at the end the*
13 *following:*

14 *“(I) THREAT AWARENESS.—Coordinate*
15 *with the Director of the Centers for Disease Con-*
16 *trol and Prevention, the Director of National In-*
17 *telligence, the Secretary of Homeland Security,*
18 *the Assistant to the President for National Secu-*
19 *rity Affairs, the Secretary of Defense, and other*
20 *relevant Federal officials, such as the Secretary*
21 *of Agriculture, to maintain a current assessment*
22 *of national security threats and inform pre-*
23 *paredness and response capabilities based on the*
24 *range of the threats that have the potential to re-*
25 *sult in a public health emergency.”.*

1 **SEC. 402. PUBLIC HEALTH EMERGENCY MEDICAL COUNTER-**
2 **MEASURES ENTERPRISE.**

3 (a) *IN GENERAL.*—*Title XXVIII is amended by insert-*
4 *ing after section 2811 (42 U.S.C. 300hh–10) the following:*

5 **“SEC. 2811–1. PUBLIC HEALTH EMERGENCY MEDICAL COUN-**
6 **TERMEASURES ENTERPRISE.**

7 “(a) *IN GENERAL.*—*The Secretary shall establish the*
8 *Public Health Emergency Medical Countermeasures Enter-*
9 *prise (referred to in this section as the ‘PHEMCE’). The*
10 *Assistant Secretary for Preparedness and Response shall*
11 *serve as chair of the PHEMCE.*

12 “(b) *MEMBERS.*—*The PHEMCE shall include each of*
13 *the following members, or the designee of such members:*

14 “(1) *The Assistant Secretary for Preparedness*
15 *and Response.*

16 “(2) *The Director of the Centers for Disease Con-*
17 *trol and Prevention.*

18 “(3) *The Director of the National Institutes of*
19 *Health.*

20 “(4) *The Commissioner of Food and Drugs.*

21 “(5) *The Secretary of Defense.*

22 “(6) *The Secretary of Homeland Security.*

23 “(7) *The Secretary of Agriculture.*

24 “(8) *The Secretary of Veterans Affairs.*

25 “(9) *Representatives of any other Federal agen-*
26 *cy, which may include the Director of the Biomedical*

1 *Advanced Research and Development Authority, the*
2 *Director of the Strategic National Stockpile, the Di-*
3 *rector of the National Institute of Allergy and Infec-*
4 *tious Diseases, and the Director of the Office of Public*
5 *Health Preparedness and Response, as the Secretary*
6 *determines appropriate.*

7 “(c) *FUNCTIONS.*—

8 “(1) *IN GENERAL.*—*The functions of the*
9 *PHEMCE shall include the following:*

10 “(A) *Establish a process pursuant to section*
11 *2811(d)(2)(B) to make recommendations to the*
12 *Secretary regarding the prioritization of re-*
13 *search, development, and procurement of counter-*
14 *measures, as defined in section 319F–2(c), based*
15 *on the health security needs of the United States.*
16 *Such recommendations shall be informed by the*
17 *National Health Security Strategy pursuant to*
18 *section 2802, the Strategic National Stockpile re-*
19 *view required under section 319F–2(a)(2), the*
20 *countermeasures budget plan pursuant to section*
21 *2811(b)(7), and an assessment of current na-*
22 *tional security threats, including chemical, bio-*
23 *logical, radiological and nuclear threats, includ-*
24 *ing emerging infectious diseases. In the event*
25 *that members of the PHEMCE do not agree*

1 upon a recommendation, the Secretary shall pro-
2 vide a determination regarding such rec-
3 ommendation.

4 “(B) Identify national health security
5 needs, including gaps in public health prepared-
6 ness and response related to countermeasures and
7 challenges to addressing such needs (including
8 any regulatory challenges), and provide for
9 alignment of countermeasure procurement with
10 recommendations under subparagraph (A).

11 “(C) Develop strategies related to logistics,
12 deployment, distribution, dispensing, and use of
13 countermeasures that may be applicable to the
14 activities of the strategic national stockpile
15 under section 319F–2(a).

16 “(D) Provide consultation for the develop-
17 ment of the strategy and implementation plan
18 under section 2811(d).

19 “(2) INPUT.—In carrying out subparagraphs (B)
20 and (C) of paragraph (1), the PHEMCE shall solicit
21 and consider input from State, local, tribal, and ter-
22 ritorial public health departments, as appropriate.”.

23 (b) PUBLIC HEALTH EMERGENCY MEDICAL COUNTER-
24 MEASURES ENTERPRISE STRATEGY AND IMPLEMENTATION

1 *PLAN.—Section 2811(d) (42 U.S.C. 300hh–10(d)) is*
2 *amended—*

3 *(1) in paragraph (1)—*

4 *(A) by striking “Not later than 180 days*
5 *after the date of enactment of this subsection,*
6 *and every year thereafter” and inserting “Not*
7 *later than March 15, 2020, and biennially there-*
8 *after”; and*

9 *(B) by striking “Director of Biomedical”*
10 *and all that follows through “Food and Drugs”*
11 *and inserting “Public Health Emergency Med-*
12 *ical Countermeasures Enterprise established*
13 *under section 2811–1”; and*

14 *(2) in paragraph (2)(J)(v), by striking “one-year*
15 *period” and inserting “2-year period”.*

16 **SEC. 403. STRATEGIC NATIONAL STOCKPILE.**

17 *(a) Section 319F–2(a) (42 U.S.C. 247d–6b(a)) is*
18 *amended—*

19 *(1) by redesignating paragraphs (2) and (3) as*
20 *paragraphs (3) and (4), respectively; and*

21 *(2) in paragraph (1)—*

22 *(A) by inserting “and optimize” after “pro-*
23 *vide for”;*

24 *(B) by inserting “and, as informed by exist-*
25 *ing recommendations of, or consultations with,*

1 *the Public Health Emergency Medical Counter-*
2 *measure Enterprise established under section*
3 *2811–1, make necessary additions or modifica-*
4 *tions to the contents of such stockpile or stock-*
5 *piles based on the review conducted under para-*
6 *graph (2)” before the period of the first sentence;*
7 *and*

8 *(C) by striking the second sentence;*

9 *(3) by inserting after paragraph (1) the fol-*
10 *lowing:*

11 *“(2) THREAT-BASED REVIEW.—*

12 *“(A) IN GENERAL.—The Secretary shall*
13 *conduct an annual threat-based review (taking*
14 *into account at-risk individuals) of the contents*
15 *of the stockpile under paragraph (1), including*
16 *non-pharmaceutical supplies, and, in consulta-*
17 *tion with the Public Health Emergency Medical*
18 *Countermeasures Enterprise established under*
19 *section 2811–1, review contents within the stock-*
20 *pile and assess whether such contents are con-*
21 *sistent with the recommendations made pursuant*
22 *to section 2811–1(c)(1)(A). Such review shall be*
23 *submitted annually, beginning on March 15,*
24 *2019, to the Committee on Health, Education,*
25 *Labor, and Pensions and the Committee on Ap-*

1 *propriations of the Senate and the Committee on*
2 *Energy and Commerce and the Committee on*
3 *Appropriations of the House of Representatives,*
4 *in a manner that does not compromise national*
5 *security.*

6 “(B) *ADDITIONS, MODIFICATIONS, AND RE-*
7 *PLENISHMENTS.—Each annual threat-based re-*
8 *view under subparagraph (A) shall, for each new*
9 *or modified countermeasure procurement or re-*
10 *plenishment, provide—*

11 “(i) *information regarding—*

12 “(I) *the quantities of the addi-*
13 *tional or modified countermeasure pro-*
14 *cured for, or contracted to be procured*
15 *for, the stockpile;*

16 “(II) *planning considerations for*
17 *appropriate manufacturing capacity*
18 *and capability to meet the goals of*
19 *such additions or modifications (with-*
20 *out disclosing proprietary informa-*
21 *tion), including consideration of the ef-*
22 *fect such additions or modifications*
23 *may have on the availability of such*
24 *products and ancillary medical sup-*
25 *plies in the health care system;*

1 “(III) the presence or lack of a
2 commercial market for the counter-
3 measure at the time of procurement;

4 “(IV) the emergency health secu-
5 rity threat or threats such counter-
6 measure procurement is intended to
7 address, including whether such pro-
8 curement is consistent with meeting
9 emergency health security needs associ-
10 ated with such threat or threats;

11 “(V) an assessment of whether the
12 emergency health security threat or
13 threats described in subclause (IV)
14 could be addressed in a manner that
15 better utilizes the resources of the stock-
16 pile and permits the greatest possible
17 increase in the level of emergency pre-
18 paredness to address such threats;

19 “(VI) whether such counter-
20 measure is replenishing an expired
21 countermeasure, is a different counter-
22 measure with the same indication that
23 is replacing an expired counter-
24 measure, or is a new addition to the
25 stockpile;

1 “(VII) a description of how such
2 additions or modifications align with
3 the countermeasures budget plan as re-
4 quired under section 2811(b)(7), in-
5 cluding expected life-cycle costs, ex-
6 penditures related to countermeasure
7 procurement to address the threat or
8 threats described in subclause (IV), re-
9 plenishment dates (including the abil-
10 ity to extend the maximum shelf life of
11 a countermeasure), and the manufac-
12 turing capacity required to replenish
13 such countermeasure; and

14 “(VIII) appropriate protocols and
15 processes for the deployment, distribu-
16 tion, or dispensing of the counter-
17 measure at the State and local level,
18 including plans for relevant capabili-
19 ties of State and local entities to dis-
20 pense, distribute, and administer the
21 countermeasure; and

22 “(ii) an assurance that for each coun-
23 termeasure produced or replenished under
24 this subsection, the Secretary completed a
25 review addressing each item listed under

1 *this subsection in advance of such procure-*
2 *ment or replenishment, which need not be*
3 *provided in advance of procurement.”;*

4 *(4) in paragraph (3), as so redesignated—*

5 *(A) in subparagraph (A), by inserting “and*
6 *the Public Health Emergency Medical Counter-*
7 *measures Enterprise established under section*
8 *2811–1” before the semicolon;*

9 *(B) in subparagraph (C), by inserting “,*
10 *and the availability, deployment, dispensing,*
11 *and administration of countermeasures” before*
12 *the semicolon; and*

13 *(C) by amending subparagraph (E) to read*
14 *as follows:*

15 *“(E) devise plans for effective and timely*
16 *supply-chain management of the stockpile, in*
17 *consultation with the Director of the Centers for*
18 *Disease Control and Prevention, the Assistant*
19 *Secretary for Preparedness and Response, the*
20 *Secretary of Transportation, the Secretary of*
21 *Homeland Security, the Secretary of Veterans*
22 *Affairs, and the heads of other appropriate Fed-*
23 *eral agencies, State, local, tribal, and territorial*
24 *agencies, and the public and private health care*
25 *infrastructure, as applicable, taking into account*

1 *the manufacturing capacity and other available*
2 *sources of products and appropriate alternatives*
3 *to supplies in the stockpile;” and*

4 *(5) by adding at the end the following:*

5 “(5) *GAO REPORT.—*

6 “(A) *IN GENERAL.—Not later than 3 years*
7 *after the date of enactment of the Pandemic and*
8 *All-Hazards Preparedness and Advancing Inno-*
9 *vation Act of 2018, and every 5 years thereafter,*
10 *the Comptroller General of the United States*
11 *shall conduct a review of any changes to the con-*
12 *tents or management of the stockpile since Janu-*
13 *ary 1, 2015. Such review shall include—*

14 “(i) *an assessment of the comprehen-*
15 *siveness and completeness of each annual*
16 *threat-based review under paragraph (2),*
17 *including whether all newly procured or re-*
18 *plenished countermeasures within the stock-*
19 *pile were described in each annual review,*
20 *and whether, consistent with paragraph*
21 *(2)(B), the Secretary conducted the nec-*
22 *essary internal review in advance of such*
23 *procurement or replenishment;*

24 “(ii) *an assessment of whether the Sec-*
25 *retary established health security and*

1 *science-based justifications, and a descrip-*
2 *tion of such justifications for procurement*
3 *decisions related to health security needs*
4 *with respect to the identified threat, for ad-*
5 *ditions or modifications to the stockpile*
6 *based on the information provided in such*
7 *reviews under paragraph (2)(B), including*
8 *whether such review was conducted prior to*
9 *procurement, modification, or replenish-*
10 *ment;*

11 *“(iii) an assessment of the plans devel-*
12 *oped by the Secretary for the deployment,*
13 *distribution, and dispensing of counter-*
14 *measures procured, modified, or replenished*
15 *under paragraph (1), including whether*
16 *such plans were developed prior to procure-*
17 *ment, modification, or replenishment;*

18 *“(iv) an accounting of countermeasures*
19 *procured, modified, or replenished under*
20 *paragraph (1) that received advanced re-*
21 *search and development funding from the*
22 *Biomedical Advanced Research and Devel-*
23 *opment Authority;*

24 *“(v) an analysis of how such procure-*
25 *ment decisions made progress towards meet-*

1 *ing emergency health security needs related*
2 *to the identified threats for countermeasures*
3 *added, modified, or replenished under para-*
4 *graph (1);*

5 *“(vi) a description of the resources ex-*
6 *pended related to the procurement of coun-*
7 *termeasures (including additions, modifica-*
8 *tions, and replenishments) in the stockpile,*
9 *and how such expenditures relate to the*
10 *emergency health security needs of the stock-*
11 *pile;*

12 *“(vii) an assessment of the extent to*
13 *which additions, modifications, and replen-*
14 *ishments reviewed under paragraph (2)*
15 *align with previous relevant reports or re-*
16 *views by the Secretary or the Comptroller*
17 *General; and*

18 *“(viii) with respect to any change in*
19 *the Federal organizational management of*
20 *the stockpile, an assessment and comparison*
21 *of the processes affected by such change, in-*
22 *cluding planning for potential counter-*
23 *measure deployment, distribution, or dis-*
24 *persing capabilities and processes related to*
25 *procurement decisions, use of stockpiled*

1 *man-made threats that, as determined by the*
2 *Secretary, pose a significant level of risk to na-*
3 *tional security based on the characteristics of a*
4 *chemical, biological, radiological or nuclear*
5 *threat, or existing capabilities to respond to such*
6 *a threat (including medical response and treat-*
7 *ment capabilities and manufacturing infrastruc-*
8 *ture). Such initiatives shall accelerate and sup-*
9 *port the advanced research, development, and*
10 *procurement of, countermeasures and products,*
11 *as applicable, to address areas including—*

12 “(i) *chemical, biological, radiological,*
13 *or nuclear threats, including emerging in-*
14 *fectious diseases, for which insufficient ap-*
15 *proved, licensed, or authorized counter-*
16 *measures exist, or for which such threat, or*
17 *the result of an exposure to such threat,*
18 *may become resistant to countermeasures or*
19 *existing countermeasures may be rendered*
20 *ineffective;*

21 “(ii) *threats that consistently exist or*
22 *continually circulate and have significant*
23 *potential to become a pandemic, such as*
24 *pandemic influenza, which may include the*
25 *advanced research and development, manu-*

1 *facturing, and appropriate stockpiling of*
 2 *qualified pandemic or epidemic products,*
 3 *and products, technologies, or processes to*
 4 *support the advanced research and develop-*
 5 *ment of such countermeasures (including*
 6 *multiuse platform technologies for*
 7 *diagnostics, vaccines, and therapeutics;*
 8 *virus seeds; clinical trial lots; novel virus*
 9 *strains; and antigen and adjuvant mate-*
 10 *rial); and*

11 *“(iii) threats that may result pri-*
 12 *marily or secondarily from a chemical, bio-*
 13 *logical, radiological, or nuclear agent, or*
 14 *emerging infectious disease, and which may*
 15 *present increased treatment complications*
 16 *such as the occurrence of resistance to avail-*
 17 *able countermeasures or potential counter-*
 18 *measures, including antimicrobial resistant*
 19 *pathogens.”.*

20 **SEC. 405. REPORTING ON THE FEDERAL SELECT AGENT**
 21 **PROGRAM.**

22 *Section 351A(k) (42 U.S.C. 262a) is amended—*

23 *(1) by striking “The Secretary” and inserting*
 24 *the following:*

25 *“(1) IN GENERAL.—The Secretary”; and*

1 (2) *by adding at the end the following:*

2 “(2) *IMPLEMENTATION OF RECOMMENDATIONS*
3 *OF THE FEDERAL EXPERTS SECURITY ADVISORY*
4 *PANEL AND THE FAST TRACK ACTION COMMITTEE ON*
5 *SELECT AGENT REGULATIONS.—*

6 “(A) *IN GENERAL.—Not later than 1 year*
7 *after the date of the enactment of the Pandemic*
8 *and All-Hazards Preparedness and Advancing*
9 *Innovation Act of 2018, the Secretary shall re-*
10 *port to the congressional committees of jurisdic-*
11 *tion on the implementation of recommendations*
12 *of the Federal Experts Security Advisory Panel*
13 *concerning the select agent program.*

14 “(B) *CONTINUED UPDATES.—The Secretary*
15 *shall report to the congressional committees of*
16 *jurisdiction annually following the submission of*
17 *the report under subparagraph (A) until the rec-*
18 *ommendations described in such subparagraph*
19 *are fully implemented, or a justification is pro-*
20 *vided for the delay in, or lack of, implementa-*
21 *tion.”.*

1 **TITLE V—INCREASING COMMU-**
2 **NICATION IN MEDICAL COUN-**
3 **TERMEASURE ADVANCED RE-**
4 **SEARCH AND DEVELOPMENT**

5 **SEC. 501. MEDICAL COUNTERMEASURE BUDGET PLAN.**

6 *Section 2811(b)(7) (42 U.S.C. 300hh–10(b)(7)) is*
7 *amended—*

8 *(1) in the matter preceding subparagraph (A),*
9 *by striking “March 1” and inserting “March 15”;*

10 *(2) by striking subparagraph (A) and inserting*
11 *the following:*

12 *“(A) include consideration of the entire*
13 *medical countermeasures enterprise, including—*

14 *“(i) basic research and advanced re-*
15 *search and development;*

16 *“(ii) approval, clearance, licensure,*
17 *and authorized uses of products;*

18 *“(iii) procurement, stockpiling, main-*
19 *tenance, and potential replenishment (in-*
20 *cluding manufacturing capabilities) of all*
21 *products in the Strategic National Stock-*
22 *pile; and*

23 *“(iv) the availability of technologies*
24 *that may assist in the advanced research*
25 *and development of countermeasures and*

1 *opportunities to use such technologies to ac-*
2 *celerate and navigate challenges unique to*
3 *countermeasure research and development;”.*

4 *(3) by redesignating subparagraphs (D) and (E)*
5 *as subparagraphs (E) and (F), respectively; and*

6 *(4) by inserting after subparagraph (C), the fol-*
7 *lowing:*

8 *“(D) identify the full range of anticipated*
9 *medical countermeasure needs related to research*
10 *and development, procurement, and stockpiling,*
11 *including the potential need for indications, dos-*
12 *ing, and administration technologies, and other*
13 *countermeasure needs as applicable and appro-*
14 *priate;”.*

15 **SEC. 502. MATERIAL THREAT AND MEDICAL COUNTER-**
16 **MEASURE NOTIFICATIONS.**

17 *(a) CONGRESSIONAL NOTIFICATION OF MATERIAL*
18 *THREAT DETERMINATION.—Section 319F–2(c)(2)(C) (42*
19 *U.S.C. 247d–6b(c)(2)(C)) is amended by striking “The Sec-*
20 *retary and the Homeland Security Secretary shall prompt-*
21 *ly notify the appropriate committees of Congress” and in-*
22 *serting “The Secretary and the Secretary of Homeland Se-*
23 *curity shall send to Congress, on an annual basis, all cur-*
24 *rent material threat determinations and shall promptly no-*
25 *tify the Committee on Health, Education, Labor, and Pen-*

1 *sions and the Committee on Homeland Security and Gov-*
 2 *ernment Affairs of the Senate and the Committee on Energy*
 3 *and Commerce and the Committee on Homeland Security*
 4 *of the House of Representatives”.*

5 (b) *CONTRACTING COMMUNICATIONS.*—

6 (1) *CONTRACT DURATION.*—Section 319F–
 7 2(c)(7)(B)(ii)(III) (42 U.S.C. 247d–
 8 6b(c)(7)(B)(ii)(III)) is amended by adding at the end
 9 the following: “The Secretary shall notify the vendor
 10 within 90 days of a determination by the Secretary
 11 to renew such contract.”.

12 (2) *EXPEDITED AUTHORITIES.*—Section
 13 319L(c)(5)(B)(i) (42 U.S.C. 247d–7e(c)(5)(B)(i)) is
 14 amended by adding at the end the following: “Upon
 15 award, extension, or termination of any such con-
 16 tract, grant, cooperative agreement, and other trans-
 17 action, the Secretary shall provide a written notifica-
 18 tion to the receiving entity that includes a justifica-
 19 tion for such award, extension, or termination.”.

20 **SEC. 503. AVAILABILITY OF REGULATORY MANAGEMENT**
 21 **PLANS.**

22 Section 565(f) of the Federal Food, Drug and Cosmetic
 23 Act (21 U.S.C. 360bbb–4(f)) is amended—

24 (1) by redesignating paragraphs (3) through (6)
 25 as paragraphs (4) through (7), respectively;

1 (2) by inserting after paragraph (2) the fol-
2 lowing:

3 “(3) *PUBLICATION.*—*The Secretary shall make*
4 *available on the internet website of the Food and*
5 *Drug Administration information regarding regu-*
6 *latory management plans, including—*

7 “(A) *the process by which an applicant*
8 *may submit a request for a regulatory manage-*
9 *ment plan;*

10 “(B) *the timeframe by which the Secretary*
11 *is required to respond to such request;*

12 “(C) *the information required for the sub-*
13 *mission of such request;*

14 “(D) *a description of the types of develop-*
15 *ment milestones and performance targets that*
16 *could be discussed and included in such plans;*
17 *and*

18 “(E) *contact information for beginning the*
19 *regulatory management plan process.”;*

20 (3) *in paragraph (6), as so redesignated, in the*
21 *matter preceding subparagraph (A)—*

22 (A) *by striking “paragraph (4)(A)” and in-*
23 *serting “paragraph (5)(A)”;* *and*

24 (B) *by striking “paragraph (4)(B)” and in-*
25 *serting “paragraph (5)(B)”;* *and*

1 technologies” inserting “platform technologies, technologies
 2 to administer countermeasures, and technologies to improve
 3 storage and transportation of countermeasures”.

4 **SEC. 602. MEDICAL COUNTERMEASURE MASTER FILES.**

5 (a) *IN GENERAL.*—Chapter V of the Federal Food,
 6 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended
 7 by inserting after section 565A the following:

8 **“SEC. 565B. MEDICAL COUNTERMEASURE MASTER FILES.**

9 “(a) *PURPOSE.*—The purpose of this section is to sup-
 10 port and accelerate the development or manufacture of secu-
 11 rity countermeasures, qualified countermeasures, and quali-
 12 fied pandemic or epidemic products by facilitating and en-
 13 couraging submission of data and information to support
 14 such products to master files, and through clarifying the
 15 authority to cross-reference to data and information pre-
 16 viously submitted to the Secretary.

17 “(b) *APPLICABILITY OF REFERENCE.*—

18 “(1) *IN GENERAL.*—A person may submit data
 19 and information to the Secretary with the intent to
 20 reference, or to authorize, in writing, another person
 21 to reference, such data or information to support a
 22 medical countermeasure submission (including a sup-
 23 plement or amendment to any such submission),
 24 without requiring the master file holder to disclose the
 25 data and information to any such persons authorized

1 to reference the master file. Such data and informa-
2 tion shall be available for reference by the master file
3 holder or a person authorized by the master file hold-
4 er only in accordance with applicable privacy and
5 confidentiality protocols and regulations.

6 “(2) *MASTER FILE HOLDER.*—In this section, the
7 term ‘master file holder’ means a person who submits
8 data and information to the Secretary with the intent
9 to reference or authorize to reference such data or in-
10 formation to support a medical countermeasure sub-
11 mission, as described in paragraph (1).

12 “(c) *MEDICAL COUNTERMEASURE MASTER FILE CON-*
13 *TENT.*—

14 “(1) *IN GENERAL.*—A master file under this sec-
15 tion may include information to support and accel-
16 erate—

17 “(A) the development of medical counter-
18 measure submissions to support the approval, li-
19 censure, classification, clearance, conditional ap-
20 proval, or authorization of one or more security
21 countermeasures, qualified countermeasures, or
22 qualified pandemic or epidemic products; and

23 “(B) the manufacture of security counter-
24 measures, qualified countermeasures, or qualified
25 pandemic or epidemic products.

1 “(2) *REQUIRED UPDATES.*—*The Secretary may*
2 *require, as appropriate, that the master file holder en-*
3 *sure that the contents of such master file are updated*
4 *during the time such master file is referenced for a*
5 *medical countermeasure submission.*

6 “(d) *SPONSOR REFERENCE.*—

7 “(1) *IN GENERAL.*—*Each incorporation of infor-*
8 *mation or data contained in a master file by ref-*
9 *erence shall describe the incorporated material in a*
10 *manner in which the Secretary determines appro-*
11 *priate and that permits the review of such informa-*
12 *tion without necessitating resubmission of such infor-*
13 *mation or data. Master files shall be submitted in an*
14 *electronic format in accordance with section 745A*
15 *and as specified in applicable guidance.*

16 “(2) *REFERENCE BY A MASTER FILE HOLDER.*—
17 *A master file holder that is the sponsor of a medical*
18 *countermeasure submission shall notify the Secretary*
19 *in writing of the intent to reference the medical coun-*
20 *termeasure master file as a part of the submission.*

21 “(3) *REFERENCE BY AN AUTHORIZED PERSON.*—
22 *A sponsor of a medical countermeasure submission*
23 *may, where the Secretary determines appropriate, in-*
24 *corporate by reference all or part of the contents of a*

1 *medical countermeasure master file, if the master file*
2 *holder authorizes the incorporation in writing.*

3 “(e) *ACKNOWLEDGEMENT OF MASTER FILE BY THE*
4 *SECRETARY.—The Secretary shall provide the master file*
5 *holder with a written notification indicating that the Sec-*
6 *retary has reviewed and relied upon specified information*
7 *or data within a master file and the purposes for which*
8 *such information or data was incorporated by reference if*
9 *the Secretary has reviewed and relied upon such specified*
10 *information or data to support the approval, classification,*
11 *conditional approval, clearance, licensure, or authorization*
12 *of a security countermeasure, qualified countermeasure, or*
13 *qualified pandemic or epidemic product. The Secretary*
14 *may rely upon the data and information within the med-*
15 *ical countermeasure master file for which such written noti-*
16 *fication was provided in additional applications, as appli-*
17 *cable and appropriate and upon the request of the master*
18 *file holder so notified in writing or by an authorized person*
19 *of such holder.*

20 “(f) *RULES OF CONSTRUCTION.—Nothing in this sec-*
21 *tion shall be construed to—*

22 “(1) *alter the authority of the Secretary to ap-*
23 *prove, license, classify, clear, conditionally approve,*
24 *or authorize drugs, biological products, or devices*
25 *pursuant to this Act or section 351 of the Public*

1 *Health Service Act (as authorized prior to the date of*
2 *enactment of the Pandemic and All-Hazards Pre-*
3 *paredness and Advancing Innovation Act of 2018),*
4 *including the standards of evidence, and applicable*
5 *conditions, for approval under the applicable Act; or*

6 “(2) *alter the authority of the Secretary under*
7 *this Act or the Public Health Service Act to determine*
8 *the types of information or data previously submitted*
9 *by a sponsor or any other person that may be incor-*
10 *porated by reference in an application, request, or no-*
11 *tification for a drug, biological product, or device sub-*
12 *mitted under sections 505(i), 505(b), 505(j),*
13 *512(b)(1), 512(b)(2), 564, 571, 520(g), 515(c),*
14 *513(f)(2), or 510(k) of this Act, or subsection (a) or*
15 *(k) of section 351 of the Public Health Service Act,*
16 *including a supplement or amendment to any such*
17 *submission, and the requirements associated with*
18 *such reference.*

19 “(g) *DEFINITIONS.—In this section:*

20 “(1) *The term ‘medical countermeasure submis-*
21 *sion’ means an investigational new drug application*
22 *under section 505(i), a new drug application under*
23 *section 505(b), or an abbreviated new drug applica-*
24 *tion under section 505(j) of this Act, a biological*
25 *product license application under section 351(a) of*

1 *the Public Health Service Act or a biosimilar biological*
2 *product license application under section 351(k)*
3 *of the Public Health Service Act, a new animal drug*
4 *application under section 512(b)(1) or abbreviated*
5 *new animal drug application under section 512(b)(2),*
6 *an application for conditional approval of a new ani-*
7 *mal drug under 571, an investigational device appli-*
8 *cation under section 520(g), an application with re-*
9 *spect to a device under section 515(c), a request for*
10 *classification of a device under section 513(f)(2), a*
11 *notification with respect to a device under section*
12 *510(k), or request for an emergency use authorization*
13 *under section 564 to support—*

14 *“(A) the approval, licensure, classification,*
15 *clearance, conditional approval, or authorization*
16 *of a security countermeasure, qualified counter-*
17 *measure, or qualified pandemic or epidemic*
18 *product; or*

19 *“(B) a new indication to an approved secu-*
20 *rity countermeasure, qualified countermeasure,*
21 *or qualified pandemic or epidemic product.*

22 *“(2) The terms ‘qualified countermeasure’, ‘secu-*
23 *rity countermeasure’, and ‘qualified pandemic or epi-*
24 *demic product’ have the meanings given such terms in*

1 *sections 319F-1, 319F-2, and 319F-3, respectively, of*
2 *the Public Health Service Act.”.*

3 *(b) STAKEHOLDER INPUT.—Not later than 18 months*
4 *after the date of enactment of this Act, the Secretary of*
5 *Health and Human Services (referred to in this section as*
6 *the “Secretary”), acting through the Commissioner of Food*
7 *and Drugs and in consultation with the Assistant Secretary*
8 *for Preparedness and Response, shall solicit input from*
9 *stakeholders, including stakeholders developing security*
10 *countermeasures, qualified countermeasures, or qualified*
11 *pandemic or epidemic products, and stakeholders devel-*
12 *oping technologies to assist in the development of such coun-*
13 *termeasures with respect to how the Food and Drug Admin-*
14 *istration can advance the use of tools and technologies to*
15 *support and accelerate the development or manufacture of*
16 *security countermeasures, qualified countermeasures, and*
17 *qualified pandemic or epidemic products, including through*
18 *the reliance on cross-referenced data and information con-*
19 *tained within master files and submissions previously sub-*
20 *mitted to the Secretary as set forth in section 565B of the*
21 *Federal Food, Drug, and Cosmetic Act, as added by sub-*
22 *section (a).*

23 *(c) GUIDANCE.—Not later than 2 years after the after*
24 *the date of enactment of this Act, the Secretary, acting*
25 *through the Commissioner of Food and Drugs, shall publish*

1 *draft guidance about how reliance on cross-referenced data*
2 *and information contained within master files under sec-*
3 *tion 565B of the Federal Food, Drug, and Cosmetic Act,*
4 *as added by subsection (a) or submissions otherwise sub-*
5 *mitted to the Secretary may be used for specific tools or*
6 *technologies (including platform technologies) that have the*
7 *potential to support and accelerate the development or man-*
8 *ufacture of security countermeasures, qualified counter-*
9 *measures, qualified pandemic or epidemic products. The*
10 *Secretary, acting through the Commissioner of Food and*
11 *Drugs, shall publish the final guidance not later than 3*
12 *years after the enactment of this Act.*

13 **SEC. 603. PRIORITY ZOO NOTIC ANIMAL DRUGS.**

14 *Chapter V of the Federal Food, Drug, and Cosmetic*
15 *Act (21 U.S.C. 351 et seq.) is amended by inserting after*
16 *section 512 the following:*

17 **“SEC. 512A. PRIORITY ZOO NOTIC ANIMAL DRUGS.**

18 *“(a) DESIGNATION OF A NEW ANIMAL DRUG AS A PRI-*
19 *ORITY ZOO NOTIC ANIMAL DRUG.—*

20 *“(1) IN GENERAL.—The Secretary shall, at the*
21 *request of the sponsor of an application for approval*
22 *of a new animal drug under section 512(b)(1) or an*
23 *application for conditional approval of a new animal*
24 *drug under section 571, expedite the development and*
25 *review of such new animal drug if preliminary clin-*

1 *ical evidence indicates that the new animal drug,*
2 *alone or in combination with 1 or more other animal*
3 *drugs, has the potential to prevent or treat a zoonotic*
4 *disease in animals, including a vector borne-disease,*
5 *that has the potential to cause serious adverse health*
6 *consequences for, or serious or life-threatening diseases*
7 *in, humans.*

8 *“(2) REQUEST FOR DESIGNATION.—The sponsor*
9 *of a new animal drug may request the Secretary to*
10 *designate a new animal drug described in paragraph*
11 *(1) as a priority zoonotic animal drug. A request for*
12 *the designation may be made concurrently with, or at*
13 *any time after, the opening of an investigational new*
14 *animal drug file under section 512(j) or the filing of*
15 *an application under section 512(b)(1) or 571.*

16 *“(3) DESIGNATION.—*

17 *“(A) IN GENERAL.—Not later than 60 cal-*
18 *endar days after the receipt of a request under*
19 *paragraph (2), the Secretary shall determine*
20 *whether the new animal drug that is the subject*
21 *of the request meets the criteria described in*
22 *paragraph (1). If the Secretary determines that*
23 *the new animal drug meets the criteria, the Sec-*
24 *retary shall designate the new animal drug as a*
25 *priority zoonotic animal drug and shall take*

1 *such actions as are appropriate to expedite the*
2 *development and review of the application for*
3 *approval or conditional approval of such new*
4 *animal drug.*

5 *“(B) ACTIONS.—The actions to expedite the*
6 *development and review of an application under*
7 *subparagraph (A) may include, as appro-*
8 *priate—*

9 *“(i) taking steps to ensure that the de-*
10 *sign of clinical trials is as efficient as prac-*
11 *ticable, when scientifically appropriate,*
12 *such as by utilizing novel trial designs or*
13 *drug development tools (including biomark-*
14 *ers) that may reduce the number of animals*
15 *needed for studies;*

16 *“(ii) providing timely advice to, and*
17 *interactive communication with, the spon-*
18 *sor (which may include meetings with the*
19 *sponsor and review team) regarding the de-*
20 *velopment of the new animal drug to ensure*
21 *that the development program to gather the*
22 *nonclinical and clinical data necessary for*
23 *approval is as efficient as practicable;*

24 *“(iii) involving senior managers and*
25 *review staff with experience in zoonotic or*

1 *vector-borne disease to facilitate collabo-*
2 *rative, cross-disciplinary review, including,*
3 *as appropriate, across agency centers; and*
4 “*(iv) implementing additional admin-*
5 *istrative or process enhancements, as nec-*
6 *essary, to facilitate an efficient review and*
7 *development program.*”.

8 **SEC. 604. ANIMAL RULE REPORT.**

9 *(a) STUDY.—The Comptroller General of the United*
10 *States shall conduct a study on the application of the re-*
11 *quirements under section 565(d) of the of the Federal Food,*
12 *Drug, and Cosmetic Act (21 U.S.C. 360bbb–4(d)) (referred*
13 *to in this section as the “animal rule”) as a component*
14 *of medical countermeasure advanced development under the*
15 *Biomedical Advanced Research and Development Authority*
16 *and regulatory review by the Food and Drug Administra-*
17 *tion. In conducting such study, the Comptroller General*
18 *shall examine the following:*

19 *(1) The extent to which advanced development*
20 *and review of a medical countermeasure are coordi-*
21 *nated between the Biomedical Advanced Research and*
22 *Development Authority and the Food and Drug Ad-*
23 *ministration, including activities facilitate appro-*
24 *priate and efficient design of studies to support ap-*
25 *proval, licensure, and authorization under the animal*

1 *rule, consistent with the recommendations in the ani-*
2 *mal rule guidance, issued pursuant to section 565(c)*
3 *of the Federal Food Drug and Cosmetic Act (21*
4 *U.S.C. 360bbb–4(c)) and entitled “Product Develop-*
5 *ment Under the Animal Rule Guidance for Industry”*
6 *(issued in October 2015), to resolve discrepancies in*
7 *the design of adequate and well-controlled efficacy*
8 *studies conducted in animal models related to the*
9 *provision of substantial evidence of effectiveness for*
10 *the product approved, licensed, or authorized under*
11 *the animal rule.*

12 *(2) The consistency of the application of the ani-*
13 *mal rule among and between review divisions within*
14 *the Food and Drug Administration.*

15 *(3) The flexibilities pursuant to the animal rule*
16 *to address variations in countermeasure development*
17 *and review processes, including the extent to which*
18 *qualified animal models are adopted and used within*
19 *the Food and Drug Administration in regulatory de-*
20 *cisionmaking with respect to medical counter-*
21 *measures.*

22 *(4) The extent to which the guidance issued*
23 *under section 565(c) of the Federal Food Drug and*
24 *Cosmetic Act (21 U.S.C. 360bbb–4(c)), entitled,*
25 *“Product Development Under the Animal Rule Guid-*

1 *ance for Industry” (issued in October 2015), has as-*
2 *sisted in achieving the purposes described in para-*
3 *graphs (1), (2), and (3).*

4 *(b) CONSULTATIONS.—In conducting the study under*
5 *subsection (a), the Comptroller General of the United States*
6 *shall consult with—*

7 *(1) the Federal agencies responsible for advanc-*
8 *ing, reviewing, and procuring medical counter-*
9 *measures, including the Office of the Assistant Sec-*
10 *retary for Preparedness and Response, the Biomedical*
11 *Advanced Research and Development Authority, the*
12 *Food and Drug Administration, and the Department*
13 *of Defense;*

14 *(2) manufacturers involved in the research and*
15 *development of medical countermeasures to address*
16 *biological, chemical, radiological, and nuclear threats;*
17 *and*

18 *(3) other biodefense stakeholders, as applicable.*

19 *(c) REPORT.—Not later than 3 years after the date of*
20 *enactment of this Act, the Comptroller General of the United*
21 *States shall submit to the Committee on Health, Education,*
22 *Labor, and Pensions of the Senate and the Committee on*
23 *Energy and Commerce of the House of Representatives a*
24 *report containing the results of the study conducted under*
25 *subsection (a) and recommendations to improve the appli-*

1 cation and consistency of the requirements under sub-
 2 sections (c) and (d) of section 565 of the Federal Food, Drug
 3 and Cosmetic Act (21 U.S.C. 360bbb-4) to support and ex-
 4 pedite the research and development of medical counter-
 5 measures, as applicable.

6 (d) *PROTECTION OF NATIONAL SECURITY.*—The
 7 Comptroller General of the United States shall conduct the
 8 study and issue the assessment and report under this section
 9 in a manner that does not compromise national security.

10 **SEC. 605. REVIEW OF THE BENEFITS OF GENOMIC ENGI-**
 11 **NEERING TECHNOLOGIES AND THEIR POTEN-**
 12 **TIAL ROLE IN NATIONAL SECURITY.**

13 (a) *MEETING.*—

14 (1) *IN GENERAL.*—Not later than 1 year after
 15 the date of enactment of this Act, the Secretary of
 16 Health and Human Services (referred to in this sec-
 17 tion as the “Secretary”) shall convene a meeting to
 18 discuss the potential role advancements in genomic
 19 engineering technologies (including genome editing
 20 technologies) may have in advancing national health
 21 security. Such meeting shall be held in a manner that
 22 does not compromise national security.

23 (2) *ATTENDEES.*—The attendees of the meeting
 24 under paragraph (1)—

25 (A) shall include—

1 (i) representatives from the Office of
2 the Assistant Secretary for Preparedness
3 and Response, the National Institutes of
4 Health, the Centers for Disease Control and
5 Prevention, and the Food and Drug Admin-
6 istration; and

7 (ii) representatives from academic, pri-
8 vate, and non-profit entities with expertise
9 in genome engineering technologies, bio-
10 pharmaceuticals, medicine, or biodefense,
11 and other relevant stakeholders; and

12 (B) may include—

13 (i) other representatives from the De-
14 partment of Health and Human Services,
15 as the Secretary determines appropriate;
16 and

17 (ii) representatives from the Depart-
18 ment of Homeland Security, the Depart-
19 ment of Defense, the Department of Agri-
20 culture, and other departments, as the Sec-
21 retary may request for the meeting.

22 (3) TOPICS.—The meeting under paragraph (1)
23 shall include a discussion of—

1 (A) *the current state of the science of*
2 *genomic engineering technologies related to na-*
3 *tional health security, including—*

4 (i) *medical countermeasure develop-*
5 *ment, including potential efficiencies in the*
6 *development pathway and detection tech-*
7 *nologies; and*

8 (ii) *the international and domestic reg-*
9 *ulation of products utilizing genome editing*
10 *technologies; and*

11 (B) *national security implications, includ-*
12 *ing—*

13 (i) *capabilities of the United States to*
14 *leverage genomic engineering technologies as*
15 *a part of the medical countermeasure enter-*
16 *prise, including current applicable research,*
17 *development, and application efforts under-*
18 *way within the Department of Defense;*

19 (ii) *the potential for state and non-*
20 *state actors to utilize genomic engineering*
21 *technologies as a national health security*
22 *threat; and*

23 (iii) *security measures to monitor and*
24 *assess the potential threat of genomic engi-*

1 neering technologies and related tech-
2 nologies.

3 (b) *REPORT.*—Not later than 180 days after the meet-
4 ing described in subsection (a) is held, the Assistant Sec-
5 retary for Preparedness and Response shall issue a report
6 to the congressional committees of jurisdiction on the topics
7 discussed at such meeting, and provide recommendations,
8 as applicable, to utilize innovations in genomic engineering
9 (including genome editing) and related technologies as a
10 part of preparedness and response activities to advance na-
11 tional health security. Such report shall be issued in a man-
12 ner that does not compromise national security.

13 **TITLE VII—MISCELLANEOUS**
14 **PROVISIONS**

15 **SEC. 701. REAUTHORIZATIONS AND EXTENSIONS.**

16 (a) *VETERANS AFFAIRS.*—Section 8117(g) of title 38,
17 United States Code, is amended by striking “2014 through
18 2018” and inserting “2019 through 2023”.

19 (b) *VACCINE TRACKING AND DISTRIBUTION.*—Section
20 319A(e) (42 U.S.C. 247d–1(e)) is amended by striking
21 “2014 through 2018” and inserting “2019 through 2023”.

22 (c) *TEMPORARY REASSIGNMENT.*—Section 319(e)(8)
23 (42 U.S.C. 247d(e)(8)) is amended by striking “2018” and
24 inserting “2023”.

1 (d) *STRATEGIC INNOVATION PARTNER.*—Section
2 319L(c)(4)(E)(ix) (42 U.S.C. 247d–7e(c)(4)(E)(ix)) is
3 amended by striking “2022” and inserting “2023”.

4 (e) *PUBLIC DISCLOSURE EXEMPTION.*—Section
5 319L(e)(1)(C) (42 U.S.C. 247d–7e(e)(1)(C)) is amended by
6 striking “12” and inserting “17”.

7 (f) *LIMITED ANTITRUST EXEMPTION.*—

8 (1) *IN GENERAL.*—Section 405 of the *Pandemic*
9 *and All-Hazards Preparedness Act* (42 U.S.C. 247d–
10 6a note) is amended—

11 (A) by redesignating such section as section
12 319L–1;

13 (B) transferring such section to the *Public*
14 *Health Service Act* (42 U.S.C. 201 et seq.), to
15 appear after section 319L of such Act (42 U.S.C.
16 247d–7e);

17 (C) in subsection (a)(1)—

18 (i) by striking “Secretary of Health
19 and Human Services (referred to in this
20 subsection as the ‘Secretary’)” and inserting
21 “Secretary”;

22 (ii) by striking “of the *Public Health*
23 *Service Act* (42 U.S.C. 247d–6b)) (as
24 amended by this Act”;

1 (iii) by striking “of the Public Health
2 Service Act (42 U.S.C. 247d– 6a)) (as
3 amended by this Act”; and

4 (iv) by striking “of the Public Health
5 Service Act (42 U.S.C. 247d–6d)”; and

6 (D) in subsection (b), by striking “12-year”
7 and inserting “17-year”.

8 (2) *EFFECTIVE DATE.*—The amendment made by
9 paragraph (1)(D) shall take effect as if enacted on
10 December 17, 2012.

11 (3) *CONFORMING AMENDMENT.*—The table of
12 contents in section 1(b) of the Pandemic and All-Haz-
13 ards Preparedness Act (Public Law 109–417) is
14 amended by striking the item related to section 405.

15 **SEC. 702. TECHNICAL AMENDMENTS.**

16 (a) *PUBLIC HEALTH SERVICE ACT.*—Title III (42
17 U.S.C. 241 et seq.) is amended—

18 (1) in paragraphs (1) and (5) of section 319F–
19 1(a) (42 U.S.C. 247d–6a(a)), by striking “section
20 319F(h)” each place such term appears and inserting
21 “section 319F(e)”; and

22 (2) in section 319K(a) (42 U.S.C. 247d–7d(a)),
23 by striking “section 319F(h)(4)” and inserting “sec-
24 tion 319F(e)(4)”.

1 (b) *PUBLIC HEALTH SECURITY GRANTS*.—Section
2 319C–1(b)(2) (42 U.S.C. 247d–3a(b)(2)) is amended—

3 (1) in subparagraph (C), by striking “individ-
4 uals,” and inserting “individuals,”; and

5 (2) in subparagraph (F), by striking “make sat-
6 isfactory annual improvement and describe” and in-
7 serting “makes satisfactory annual improvement and
8 describes”.

9 (c) *FEDERAL FOOD, DRUG, AND COSMETIC ACT*.—The
10 Federal Food, Drug, and Cosmetic Act is amended—

11 (1) in section 564A(e)(2)(A) (21 U.S.C. 360bbb–
12 3a(e)(2)(A)), by striking “subsection (a)(1)(C)(i)”
13 and inserting “subsection (a)(1)(C)”; and

14 (2) in section 564B(2)(C) (21 U.S.C. 360bbb–
15 3b(2)(C)), by inserting “or section 564A”.

Calendar No. 467

115TH CONGRESS
2^D SESSION

S. 2852

A BILL

To reauthorize certain programs under the Pandemic and All-Hazards Preparedness Reauthorization Act.

JUNE 18, 2018

Reported with an amendment