

115TH CONGRESS
2D SESSION

H. R. 6378

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 26, 2018

Received

AN ACT

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,*

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

2 (a) SHORT TITLE.—This Act may be cited as the
 3 “Pandemic and All-Hazards Preparedness and Advancing
 4 Innovation Act of 2018”.

5 (b) TABLE OF CONTENTS.—The table of contents for
 6 this Act is as follows:

Sec. 1. Short title; table of contents.

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 all-hazards preparedness and response by public health emergency volunteers.
- Sec. 208. Clarifying State liability law for volunteer health care professionals.
- Sec. 209. Report on adequate national blood supply.
- Sec. 210. Report on the public health preparedness and response capabilities and capacities of hospitals, long-term care facilities, and other health care facilities.

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. National advisory committees on disasters.
- 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.
- Sec. 505. Additional strategies for combating antibiotic resistance.

TITLE VI—ADVANCING TECHNOLOGIES FOR MEDICAL
COUNTERMEASURES

- Sec. 601. Administration of countermeasures.
- Sec. 602. Updating definitions of other transactions.
- Sec. 603. Medical countermeasure master files.
- Sec. 604. Animal rule report.
- Sec. 605. Review of the benefits of genomic engineering technologies and their
potential role in national security.
- Sec. 606. Report on vaccines development.
- Sec. 607. Strengthening mosquito abatement for safety and health.

TITLE VII—MISCELLANEOUS PROVISIONS

- Sec. 701. Reauthorizations and extensions.
- Sec. 702. Location of materials in the stockpile.
- Sec. 703. Cybersecurity.
- Sec. 704. Technical amendments.
- Sec. 705. Formal strategy relating to children separated from parents and
guardians as a result of zero tolerance policy.
- Sec. 706. Reporting relating to children separated from parents and guardians
as a result of zero tolerance policy.
- Sec. 707. Technical correction.
- Sec. 708. Savings clause.

1 TITLE I—STRENGTHENING THE
2 NATIONAL HEALTH SECURITY
3 STRATEGY

4 SEC. 101. NATIONAL HEALTH SECURITY STRATEGY.

5 Section 2802 of the Public Health Service Act (42
6 U.S.C. 300hh–1) is amended—

7 (1) in subsection (a)—

8 (A) in paragraph (1)—

9 (i) by striking “2014” and inserting

10 “2018”; and

1 (ii) by striking the second sentence
2 and inserting the following: “Such Na-
3 tional Health Security Strategy shall de-
4 scribe potential emergency health security
5 threats and identify the process for achiev-
6 ing the preparedness goals described in
7 subsection (b) to be prepared to identify
8 and respond to such threats and shall be
9 consistent with the national preparedness
10 goal (as described in section 504(a)(19) of
11 the Homeland Security Act of 2002), the
12 National Incident Management System (as
13 defined in section 501(7) of such Act), and
14 the National Response Plan developed pur-
15 suant to section 504 of such Act, or any
16 successor plan.”;

17 (B) in paragraph (2), by inserting before
18 the period at the end of the second sentence the
19 following: “, and an analysis of any changes to
20 the evidence-based benchmarks and objective
21 standards under sections 319C–1 and 319C–2”;
22 and

23 (C) in paragraph (3)—

24 (i) by striking “2009” and inserting
25 “2022”;

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

(iii) by striking “and identifying strategies” and inserting “identifying strategies”; and

(iv) by inserting before the period at the end “, and identifying current capabilities to meet the requirements of section 2803”; and

(2) in subsection (b)—

(A) in paragraph (2)—

(i) in subparagraph (A), by striking “and investigation” and inserting “investigation, and related information technology activities”;

(ii) in subparagraph (B), by striking “and decontamination” and inserting “decontamination, relevant health care services and supplies, and transportation and disposal of medical waste”; and

(iii) by adding at the end the following:

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

2 (B) in paragraph (3)—

3 (i) in the matter preceding subpara-
4 graph (A), by striking “including mental
5 health” and inserting “including phar-
6 macies, mental health facilities,”; and

7 (ii) in subparagraph (F), by inserting
8 “or exposures to agents that could cause a
9 public health emergency” before the pe-
10 riod;

11 (C) in paragraph (5), by inserting “and
12 other applicable compacts” after “Compact”;
13 and

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

15 “(9) ZOONOTIC DISEASE, FOOD, AND AGRI-
16 CULTURE.—Improving coordination among Federal,
17 State, local, tribal, and territorial entities (including
18 through consultation with the Secretary of Agri-
19 culture) to prevent, detect, and respond to outbreaks
20 of plant or animal disease (including zoonotic dis-
21 ease) that could compromise national security result-
22 ing from a deliberate attack, a naturally occurring
23 threat, the intentional adulteration of food, or other
24 public health threats, taking into account inter-
25 actions between animal health, human health, and

1 animals’ and humans’ shared environment as di-
2 rectly related to public health emergency prepared-
3 ness and response capabilities, as applicable.

4 “(10) GLOBAL HEALTH SECURITY.—Assessing
5 current or potential health security threats from
6 abroad to inform domestic public health prepared-
7 ness and response capabilities.”.

8 **TITLE II—IMPROVING**
9 **PREPAREDNESS AND RESPONSE**

10 **SEC. 201. IMPROVING BENCHMARKS AND STANDARDS FOR**
11 **PREPAREDNESS AND RESPONSE.**

12 (a) EVALUATING MEASURABLE EVIDENCE-BASED
13 BENCHMARKS AND OBJECTIVE STANDARDS.—Section
14 319C–1 of the Public Health Service Act (42 U.S.C.
15 247d–3a) is amended by inserting after subsection (j) the
16 following:

17 “(k) EVALUATION.—

18 “(1) IN GENERAL.—Not later than 2 years
19 after the date of enactment of the Pandemic and
20 All-Hazards Preparedness and Advancing Innovation
21 Act of 2018 and every 2 years thereafter, the Sec-
22 retary shall conduct an evaluation of the evidence-
23 based benchmarks and objective standards required
24 under subsection (g). Such evaluation shall be sub-
25 mitted to the congressional committees of jurisdic-

tion together with the National Health Security Strategy under section 2802, at such time as such strategy is submitted.

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

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

“(B) a discussion of changes to any evidence-based benchmarks and objective standards, and the effect of such changes on the ability to track whether entities are meeting or making progress toward the goals under this section and, to the extent practicable, the applicable goals of the National Health Security Strategy under section 2802;

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

“(D) recommendations, as applicable and appropriate, to improve evidence-based benchmarks and objective standards to more accu-

1 rately assess the ability of entities receiving
 2 awards under this section to better achieve the
 3 goals under this section and section 2802.”.

4 (b) EVALUATING THE PARTNERSHIP FOR STATE AND
 5 REGIONAL HOSPITAL PREPAREDNESS.—Section 319C–
 6 2(i)(1) of the Public Health Service Act (42 U.S.C. 247–
 7 3b(i)(1)) is amended by striking “section 319C–1(g), (i),
 8 and (j)” and inserting “section 319C–1(g), (i), (j), and
 9 (k)”.

10 **SEC. 202. AMENDMENTS TO PREPAREDNESS AND RE-**
 11 **SPONSE PROGRAMS.**

12 (a) COOPERATIVE AGREEMENT APPLICATIONS FOR
 13 IMPROVING STATE AND LOCAL PUBLIC HEALTH SECU-
 14 RITY.—Section 319C–1 of the Public Health Service Act
 15 (42 U.S.C. 247d–3a) is amended—

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

19 (2) in subsection (b)(2)(A)—

20 (A) in clause (vi), by inserting “, including
 21 public health agencies with specific expertise
 22 that may be relevant to public health security,
 23 such as environmental health agencies,” after
 24 “stakeholders”;

1 (B) by redesignating clauses (vii) through
2 (ix) as clauses (viii) through (x);

3 (C) by inserting after clause (vi) the fol-
4 lowing:

5 “(vii) a description of how, as applica-
6 ble, such entity may integrate information
7 to account for individuals with behavioral
8 health needs following a public health
9 emergency;”;

10 (D) in clause (ix), as so redesignated, by
11 striking “; and” and inserting a semicolon;

12 (E) in clause (x), as so redesignated, by in-
13 serting “and” after the semicolon; and

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

15 “(xi) a description of how the entity
16 will partner with health care facilities, in-
17 cluding hospitals and nursing homes and
18 other long-term care facilities, to promote
19 and improve public health preparedness
20 and response; and

21 “(xii) a description of how, as appro-
22 priate and practicable, the entity will in-
23 clude critical infrastructure partners, such
24 as utility companies within the entity’s ju-
25 risdiction, in planning pursuant to this

1 subparagraph to help ensure that critical
2 infrastructure will remain functioning dur-
3 ing, or return to function as soon as prac-
4 ticable after, a public health emergency.”.

5 (b) EXCEPTION RELATING TO APPLICATION OF CER-
6 TAIN REQUIREMENTS.—

7 (1) IN GENERAL.—Section 319C–1(g) of the
8 Public Health Service Act (42 U.S.C. 247d–3a(g)) is
9 amended—

10 (A) in paragraph (5)—

11 (i) by striking “Beginning with fiscal
12 year 2009” and inserting “Beginning with
13 fiscal year 2019”;

14 (ii) by striking “for the immediately
15 preceding fiscal year” and inserting “for
16 either of the two immediately preceding
17 fiscal years”; and

18 (iii) by striking “2008” and inserting
19 “2018”; and

20 (B) by amending subparagraph (A) of
21 paragraph (6) to read as follows:

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

1 “(i) For one (but not both) of the
2 first two fiscal years immediately following
3 a fiscal year in which an entity experienced
4 a failure described in subparagraph (A) or
5 (B) of paragraph (5) by the entity, an
6 amount equal to 10 percent of the amount
7 the entity was eligible to receive for the re-
8 spective fiscal year.

9 “(ii) For one (but not both) of the
10 first two fiscal years immediately following
11 the third consecutive fiscal year in which
12 an entity experienced such a failure, in lieu
13 of applying clause (i), an amount equal to
14 15 percent of the amount the entity was el-
15 igible to receive for the respective fiscal
16 year.”.

17 (2) EFFECTIVE DATE.—The amendments made
18 by paragraph (1) shall apply with respect to cooper-
19 ative agreements awarded on or after the date of en-
20 actment of this Act.

21 (c) PARTNERSHIP FOR STATE AND REGIONAL HOS-
22 PITAL PREPAREDNESS TO IMPROVE SURGE CAPACITY.—
23 Section 319C–2 of the Public Health Service Act (42
24 U.S.C. 247d–3b) is amended—

25 (1) in subsection (a)—

1 (A) by inserting “, acting through the As-
2 sistant Secretary for Preparedness and Re-
3 sponse,” after “The Secretary”; and

4 (B) by striking “preparedness for public
5 health emergencies” and inserting “prepared-
6 ness for, and response to, public health emer-
7 gencies in accordance with subsection (c)”;

8 (2) in subsection (b)(1)(A)—

9 (A) by striking “partnership consisting of”
10 and inserting “coalition that includes”;

11 (B) in clause (ii), by striking “; and” and
12 inserting a semicolon; and

13 (C) by adding at the end the following:

14 “(iv) one or more emergency medical serv-
15 ice organizations or emergency management or-
16 ganizations; and”;

17 (3) in subsection (d)—

18 (A) in paragraph (1)(B), by striking “part-
19 nership” each place it appears and inserting
20 “coalition”; and

21 (B) in paragraph (2)(C), by striking “med-
22 ical preparedness” and inserting “preparedness
23 and response”;

24 (4) in subsection (f), by striking “partnership”
25 and inserting “coalition”;

1 (5) in subsection (g)(2)—

2 (A) by striking “Partnerships” and insert-
3 ing “Coalitions”;

4 (B) by striking “partnerships” and insert-
5 ing “coalitions”; and

6 (C) by inserting “and response” after
7 “preparedness”; and

8 (6) in subsection (i)(1)—

9 (A) by striking “An entity” and inserting
10 “A coalition”; and

11 (B) by striking “such partnership” and in-
12 serting “such coalition”.

13 (d) PUBLIC HEALTH SECURITY GRANTS AUTHORIZA-
14 TION OF APPROPRIATIONS.—Section 319C–1(h)(1)(A) of
15 the Public Health Service Act (42 U.S.C. 247d–
16 3a(h)(1)(A)) is amended by striking “\$641,900,000 for
17 fiscal year 2014” and all that follows through the period
18 at the end and inserting “\$685,000,000 for each of fiscal
19 years 2019 through 2023 for awards pursuant to para-
20 graph (3) (subject to the authority of the Secretary to
21 make awards pursuant to paragraphs (4) and (5)).”.

22 (e) PARTNERSHIP FOR STATE AND REGIONAL HOS-
23 PITAL PREPAREDNESS AUTHORIZATION OF APPROPRIA-
24 TIONS.—Section 319C–2(j) of the Public Health Service
25 Act (42 U.S.C. 247d–3b(j)) is amended—

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

3 “(1) IN GENERAL.—

4 “(A) AUTHORIZATION OF APPROPRIA-
5 TIONS.—For purposes of carrying out this sec-
6 tion and section 319C–3, in accordance with
7 subparagraph (B), there is authorized to be ap-
8 propriated \$385,000,000 for each of fiscal years
9 2019 through 2023.

10 “(B) RESERVATION OF AMOUNTS FOR RE-
11 GIONAL SYSTEMS.—

12 “(i) IN GENERAL.—Subject to clause
13 (ii), of the amount appropriated under sub-
14 paragraph (A) for a fiscal year, the Sec-
15 retary may reserve up to 5 percent for the
16 purpose of carrying out section 319C–3.

17 “(ii) RESERVATION CONTINGENT ON
18 CONTINUED APPROPRIATIONS FOR THIS
19 SECTION.—If for fiscal year 2019 or a sub-
20 sequent fiscal year, the amount appro-
21 priated under subparagraph (A) is such
22 that, after application of clause (i), the
23 amount remaining for the purpose of car-
24 rying out this section would be less than
25 the amount available for such purpose for

1 the previous fiscal year, the amount that
2 may be reserved under clause (i) shall be
3 reduced such that the amount remaining
4 for the purpose of carrying out this section
5 is not less than the amount available for
6 such purpose for the previous fiscal year.

7 “(iii) SUNSET.—The authority to re-
8 serve amounts under clause (i) shall expire
9 on September 30, 2023.”;

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

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

18 **SEC. 203. REGIONAL HEALTH CARE EMERGENCY PRE-**
19 **PAREDNESS AND RESPONSE SYSTEMS.**

20 (a) IN GENERAL.—Part B of title III of the Public
21 Health Service Act (42 U.S.C. 243 et seq.) is amended
22 by inserting after section 319C–2 the 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, in ad-
9 vance of, and immediately following a public health emer-
10 gency, including threats posed by one or more chemical,
11 biological, radiological, or nuclear agents, including emerg-
12 ing infectious diseases.

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, the 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 lating to practices and protocols for all-hazards pub-
3 lic 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 and health care coalitions estab-
19 lished under section 319C–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) and (e) and information resulting from
10 applicable reports required under the Pandemic and
11 All-Hazards Preparedness and Advancing Innovation
12 Act of 2018 (including any amendments made by
13 such Act), to address new and emerging public
14 health threats.

15 “(c) CONSIDERATIONS.—In identifying, developing,
16 and updating guidelines under subsection (b), the Assist-
17 ant Secretary for Preparedness and Response shall—

18 “(1) include input from hospitals and health
19 care facilities (including health care coalitions under
20 section 319C–2), State, local, tribal, and territorial
21 public health departments, and health care or sub-
22 ject matter experts (including experts with relevant
23 expertise in chemical, biological, radiological, or nu-
24 clear threats, including emerging infectious dis-

1 eases), as the Assistant Secretary determines appro-
2 priate, to meet the goals under section 2802(b)(3);

3 “(2) consult and engage with appropriate
4 health care providers and professionals, including
5 physicians, nurses, first responders, health care fa-
6 cilities (including hospitals, primary care clinics,
7 community health centers, mental health facilities,
8 ambulatory care facilities, and dental health facili-
9 ties), pharmacies, emergency medical providers,
10 trauma care providers, environmental health agen-
11 cies, public health laboratories, poison control cen-
12 ters, blood banks, tissue banks, and other experts
13 that the Assistant Secretary determines appropriate,
14 to meet the goals under section 2802(b)(3);

15 “(3) consider feedback related to financial im-
16 plications for hospitals, health care facilities, public
17 health agencies, laboratories, blood banks, tissue
18 banks, and other entities engaged in regional pre-
19 paredness planning to implement and follow such
20 guidelines, as applicable; and

21 “(4) consider financial requirements and poten-
22 tial incentives for entities to prepare for, and re-
23 spond to, public health emergencies as part of the
24 regional health care emergency preparedness and re-
25 sponse system.

1 “(d) TECHNICAL ASSISTANCE.—The Assistant Sec-
2 retary for Preparedness and Response, in consultation
3 with the Director of the Centers for Disease Control and
4 Prevention and the Assistant Secretary of Labor for Occu-
5 pational Safety and Health, may provide technical assist-
6 ance and consultation toward meeting the guidelines de-
7 scribed in subsection (b).

8 “(e) DEMONSTRATION PROJECT FOR REGIONAL
9 HEALTH CARE PREPAREDNESS AND RESPONSE SYS-
10 TEMS.—

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

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

23 (b) GAO REPORT TO CONGRESS.—

24 “(1) REPORT.—Not later than 3 years after the
25 date of enactment of this Act, the Comptroller Gen-

1 eral of the United States (referred to in this sub-
2 section as the “Comptroller General”) shall submit
3 to the Committee on Health, Education, Labor, and
4 Pensions and the Committee on Finance of the Sen-
5 ate and the Committee on Energy and Commerce
6 and the Committee on Ways and Means of the
7 House of Representatives, a report on the extent to
8 which hospitals and health care facilities have imple-
9 mented the recommended guidelines under section
10 319C–3(b) of the Public Health Service Act (as
11 added by subsection (a)), including an analysis and
12 evaluation of any challenges hospitals or health care
13 facilities experienced in implementing such guide-
14 lines.

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 section 319C–3(b) of the Pub-
20 lic Health Service Act to improve regional emer-
21 gency health care preparedness and response
22 capability, including hospital and health care
23 facility capacity and medical surge capabilities
24 to prepare for, and respond to, public health
25 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 of
9 the Public Health Service Act (42 U.S.C.
10 247d–3b) or in programs under the Centers for
11 Medicare & Medicaid Services (including inno-
12 vative health care delivery and payment mod-
13 els), and input from private sector financial in-
14 stitutions.

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

19 (A) the Assistant Secretary for Prepared-
20 ness and Response;

21 (B) the Director of the Centers for Disease
22 Control and Prevention;

23 (C) the Administrator of the Centers for
24 Medicare & Medicaid Services;

1 (D) the Assistant Secretary for Mental
2 Health and Substance Use;

3 (E) the Assistant Secretary of Labor for
4 Occupational Safety and Health; and

5 (F) the Secretary of Veterans Affairs.

6 (c) ANNUAL REPORTS.—Section 319C–2(i)(1) of the
7 Public Health Service Act (42 U.S.C. 247d–3b(i)(1)) is
8 amended by inserting after the first sentence the following
9 “In submitting reports under this paragraph an entity
10 shall include information on the progress that the entity
11 has made toward the implementation of section 319C–3
12 (or barriers to progress, if any).”.

13 (d) NATIONAL HEALTH SECURITY STRATEGY INCOR-
14 PORATION OF REGIONALIZED EMERGENCY PREPARED-
15 NESS AND RESPONSE.—Subparagraph (G) of section
16 2802(b)(3) of the Public Health Service Act (42 U.S.C.
17 300hh–1(b)(3)) is amended to read as follows:

18 “(G) Optimizing a coordinated and flexible
19 approach to the emergency response and med-
20 ical surge capacity of hospitals, other health
21 care facilities, critical care, trauma care (which
22 may include trauma centers), and emergency
23 medical systems.”.

24 (e) IMPROVING STATE AND LOCAL PUBLIC HEALTH
25 SECURITY.—

1 (1) STATE AND LOCAL SECURITY.—Section
 2 319C–1(e) of the Public Health Service Act (42
 3 U.S.C. 247d–3a(e)) is amended by striking “, and
 4 local emergency plans.” and inserting “, local emer-
 5 gency plans, and any regional health care emergency
 6 preparedness and response system established pursu-
 7 ant to the applicable guidelines under section 319C–
 8 3.”.

9 (2) PARTNERSHIPS.—Section 319C–2(d)(1)(A)
 10 of the Public Health Service Act (42 U.S.C. 247d-
 11 3b(d)(1)(A)) is amended—

12 (A) in clause (i), by striking “; and” and
 13 inserting “;”;

14 (B) by redesignating clause (ii) as clause
 15 (iii); and

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

17 “(ii) among one or more facilities in a
 18 regional health care emergency system
 19 under section 319C–3; and”.

20 **SEC. 204. MILITARY AND CIVILIAN PARTNERSHIP FOR**
 21 **TRAUMA READINESS.**

22 Title XII of the Public Health Service Act (42 U.S.C.
 23 300d et seq.) is amended by adding at the end the fol-
 24 lowing new part:

1 **“PART I—MILITARY AND CIVILIAN PARTNERSHIP**
2 **FOR TRAUMA READINESS GRANT PROGRAM**

3 **“SEC. 1291. MILITARY AND CIVILIAN PARTNERSHIP FOR**
4 **TRAUMA READINESS GRANT PROGRAM.**

5 “(a) MILITARY TRAUMA TEAM PLACEMENT PRO-
6 GRAM.—

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

15 “(2) LIMITATIONS.—In the case of a grant
16 awarded under paragraph (1) to an eligible high
17 acuity trauma center, such grant—

18 “(A) shall be for a period of at least 3
19 years and not more than 5 years (and may be
20 renewed at the end of such period); and

21 “(B) shall be in an amount that does not
22 exceed \$1,000,000 per year.

23 “(3) AVAILABILITY OF FUNDS.—Notwith-
24 standing section 1552 of title 31, United States
25 Code, or any other provision of law, funds available
26 to the Secretary for obligation for a grant under this

1 subsection shall remain available for expenditure for
2 100 days after the last day of the performance pe-
3 riod of such grant.

4 “(b) MILITARY TRAUMA CARE PROVIDER PLACE-
5 MENT PROGRAM.—

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

13 “(2) LIMITATIONS.—In the case of a grant
14 awarded under paragraph (1) to an eligible trauma
15 center, such grant—

16 “(A) shall be for a period of at least 1 year
17 and not more than 3 years (and may be re-
18 newed at the end of such period); and

19 “(B) shall be in an amount that does not
20 exceed, in a year—

21 “(i) \$100,000 for each military trau-
22 ma care provider that is a physician at
23 such eligible trauma center; and

1 “(ii) \$50,000 for each other military
2 trauma care provider at such eligible trauma
3 center.

4 “(c) GRANT REQUIREMENTS.—

5 “(1) DEPLOYMENT AND PUBLIC HEALTH EMER-
6 GENCIES.—As a condition of receipt of a grant
7 under this section, a grant recipient shall agree to
8 allow military trauma care providers providing care
9 pursuant to such grant to—

10 “(A) be deployed by the Secretary of De-
11 fense for military operations, for training, or
12 for response to a mass casualty incident; and

13 “(B) be deployed by the Secretary of De-
14 fense, in consultation with the Secretary of
15 Health and Human Services, for response to a
16 public health emergency pursuant to section
17 319.

18 “(2) USE OF FUNDS.—Grants awarded under
19 this section to an eligible trauma center may be used
20 to train and incorporate military trauma care pro-
21 viders into such trauma center, including incorpora-
22 tion into operational exercises and training drills re-
23 lated to public health emergencies, expenditures for
24 malpractice insurance, office space, information
25 technology, specialty education and supervision,

1 trauma programs, research, and applicable license
2 fees for such military trauma care providers.

3 “(d) RULE OF CONSTRUCTION.—Nothing in this sec-
4 tion shall be construed to affect any other provision of law
5 that preempts State licensing requirements for health care
6 professionals, including with respect to military trauma
7 care providers.

8 “(e) REPORTING REQUIREMENTS.—

9 “(1) REPORT TO THE SECRETARY AND THE
10 SECRETARY OF DEFENSE.—Each eligible trauma
11 center or eligible high acuity trauma center awarded
12 a grant under subsection (a) or (b) for a year shall
13 submit to the Secretary and the Secretary of De-
14 fense a report for such year that includes informa-
15 tion on—

16 “(A) the number and types of trauma
17 cases managed by military trauma teams or
18 military trauma care providers pursuant to such
19 grant during such year;

20 “(B) the ability to maintain the integration
21 of the military trauma providers or teams of
22 providers as part of the trauma center, includ-
23 ing the financial effect of such grant on the
24 trauma center;

1 “(C) the educational effect on resident
2 trainees in centers where military trauma teams
3 are assigned;

4 “(D) any research conducted during such
5 year supported by such grant; and

6 “(E) any other information required by the
7 Secretaries for the purpose of evaluating the ef-
8 fect of such grant.

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

16 “(A) maintaining military trauma care
17 providers’ readiness and ability to respond to
18 and treat battlefield injuries;

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

21 “(C) the capability of trauma centers and
22 military trauma care providers to increase med-
23 ical surge capacity, including as a result of a
24 large scale event;

1 “(D) the ability of grant recipients to
2 maintain the integration of the military trauma
3 providers or teams of providers as part of the
4 trauma center;

5 “(E) efforts to incorporate military trauma
6 care providers into operational exercises and
7 training and drills for public health emer-
8 gencies; and

9 “(F) the capability of military trauma care
10 providers to participate as part of a medical re-
11 sponse during or in advance of a public health
12 emergency, as determined by the Secretary, or
13 a mass casualty incident.

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

15 “(1) ELIGIBLE TRAUMA CENTER.—The term
16 ‘eligible trauma center’ means a Level I, II, or III
17 trauma center that satisfies each of the following:

18 “(A) Such trauma center has an agree-
19 ment with the Secretary of Defense to enable
20 military trauma care providers to provide trau-
21 ma care and related acute care at such trauma
22 center.

23 “(B) Such trauma center utilizes a risk-ad-
24 justed benchmarking system and metrics to

1 measure performance, quality, and patient out-
2 comes.

3 “(C) Such trauma center demonstrates a
4 need for integrated military trauma care pro-
5 viders to maintain or improve the trauma clin-
6 ical capability of such trauma center.

7 “(2) ELIGIBLE HIGH ACUITY TRAUMA CEN-
8 TER.—The term ‘eligible high acuity trauma center’
9 means a Level I trauma center that satisfies each of
10 the following:

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

15 “(B) At least 20 percent of patients treat-
16 ed at such trauma center in the most recent 3-
17 month period for which data are available are
18 treated for a major trauma at such trauma cen-
19 ter.

20 “(C) Such trauma center utilizes a risk-ad-
21 justed benchmarking system and metrics to
22 measure performance, quality, and patient out-
23 comes.

24 “(D) Such trauma center is an academic
25 training center—

1 “(i) affiliated with a medical school;

2 “(ii) that maintains residency pro-
3 grams and fellowships in critical trauma
4 specialties and subspecialties, and provides
5 education and supervision of military trau-
6 ma team members according to those spe-
7 cialties and subspecialties; and

8 “(iii) that undertakes research in the
9 prevention and treatment of traumatic in-
10 jury.

11 “(E) Such trauma center serves as a med-
12 ical and public health preparedness and re-
13 sponse leader for its community, such as by
14 participating in a partnership for State and re-
15 gional hospital preparedness established under
16 section 319C–2 or 319C–3.

17 “(3) MAJOR TRAUMA.—The term ‘major trau-
18 ma’ means an injury that is greater than or equal
19 to 15 on the injury severity score.

20 “(4) MILITARY TRAUMA TEAM.—The term
21 ‘military trauma team’ means a complete military
22 trauma team consisting of military trauma care pro-
23 viders.

24 “(5) MILITARY TRAUMA CARE PROVIDER.—The
25 term ‘military trauma care provider’ means a mem-

1 ber of the Armed Forces who furnishes emergency,
 2 critical care, and other trauma acute care services
 3 (including a physician, surgeon, physician assistant,
 4 nurse, nurse practitioner, respiratory therapist,
 5 flight paramedic, combat medic, or enlisted medical
 6 technician), or other military trauma care provider
 7 as the Secretary determines appropriate.

8 “(g) AUTHORIZATION OF APPROPRIATIONS.—To
 9 carry out this section, there are authorized to be appro-
 10 priated \$15,000,000 for each of fiscal years 2019 through
 11 2023, of which—

12 “(1) $\frac{2}{3}$ of the amount made available each fis-
 13 cal year shall be made available for grants under
 14 subsection (a); and

15 “(2) $\frac{1}{3}$ of the amount made available each fis-
 16 cal year shall be made available for grants under
 17 subsection (b).”.

18 **SEC. 205. PUBLIC HEALTH AND HEALTH CARE SYSTEM SIT-**
 19 **UATIONAL AWARENESS AND BIOSURVEIL-**
 20 **LANCE CAPABILITIES.**

21 (a) FACILITIES, CAPACITIES, AND BIOSURVEILLANCE
 22 CAPABILITIES.—Section 319D of the Public Health Serv-
 23 ice Act (42 U.S.C. 247d–4) is amended—

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

4 (2) in subsection (a)—

5 (A) in the subsection heading, by striking
 6 “FACILITIES; CAPACITIES” and inserting “IN
 7 GENERAL”;

8 (B) in paragraph (1), by striking “and im-
 9 proved” and inserting “, improved, and appro-
 10 priately maintained”;

11 (C) in paragraph (3), in the matter pre-
 12 ceding subparagraph (A), by striking “expand,
 13 enhance, and improve” and inserting “expand,
 14 improve, enhance, and appropriately maintain”;
 15 and

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

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

1 lineation between, obligations and expenditures in-
2 curred for the construction, renovation, equipping,
3 and security upgrades of facilities and associated
4 contracts under this subsection, and the obligations
5 and expenditures incurred to establish and improve
6 the situational awareness and biosurveillance net-
7 work under subsection (b), and shall identify the
8 agency or agencies incurring such obligations and
9 expenditures.”;

10 (3) in subsection (b)—

11 (A) in the subsection heading, by striking
12 “NATIONAL” and inserting “ESTABLISHMENT
13 OF SYSTEMS OF PUBLIC HEALTH”;

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

17 (C) in paragraph (2)—

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

20 (ii) by inserting “and in a form read-
21 ily usable for analytical approaches” after
22 “in a secure manner”; and

23 (D) by amending paragraph (3) to read as
24 follows:

25 “(3) STANDARDS.—

1 “(A) IN GENERAL.—Not later than 1 year
2 after the date of the enactment of the Pan-
3 demic and All-Hazards Preparedness and Ad-
4 vancing Innovation Act of 2018, the Secretary,
5 in cooperation with health care providers, State,
6 local, tribal, and territorial public health offi-
7 cials, and relevant Federal agencies (including
8 the Office of the National Coordinator for
9 Health Information Technology and the Na-
10 tional Institute of Standards and Technology),
11 shall, as necessary, adopt technical and report-
12 ing standards, including standards for inter-
13 operability as defined by section 3000, for net-
14 works under paragraph (1) and update such
15 standards as necessary. Such standards shall be
16 made available on the internet website of the
17 Department of Health and Human Services, in
18 a manner that does not compromise national se-
19 curity.

20 “(B) DEFERENCE TO STANDARDS DEVEL-
21 OPMENT ORGANIZATIONS.—In adopting and im-
22 plementing standards under this subsection and
23 subsection (c), the Secretary shall give def-
24 erence to standards published by standards de-

1 velopment organizations and voluntary con-
2 sensus-based standards entities.”;

3 (4) in subsection (c)—

4 (A) in paragraph (1)—

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

10 (ii) by inserting “, and improve as ap-
11 plicable and appropriate,” after “shall es-
12 tablish”;

13 (iii) by striking “of rapid” and insert-
14 ing “of, rapid”; and

15 (iv) by striking “such connectivity”
16 and inserting “such interoperability”;

17 (B) by amending paragraph (2) to read as
18 follows:

19 “(2) COORDINATION AND CONSULTATION.—In
20 establishing and improving the network under para-
21 graph (1) the Secretary shall—

22 “(A) facilitate coordination among agencies
23 within the Department of Health and Human
24 Services that provide, or have the potential to
25 provide, information and data to, and analyses

1 for, the situational awareness and biosurveil-
2 lance network under paragraph (1), including
3 coordination among relevant agencies related to
4 health care services, the facilitation of health
5 information exchange (including the Office of
6 the National Coordinator for Health Informa-
7 tion Technology), and public health emergency
8 preparedness and response; and

9 “(B) consult with the Secretary of Agri-
10 culture, the Secretary of Commerce (and the
11 Director of the National Institute of Standards
12 and Technology), the Secretary of Defense, the
13 Secretary of Homeland Security, the Secretary
14 of Veterans Affairs, and the heads of other
15 Federal agencies, as the Secretary determines
16 appropriate.”;

17 (C) in paragraph (3)—

18 (i) by redesignating subparagraphs
19 (A) through (E) as clauses (i) through (v),
20 respectively, and adjusting the margins ac-
21 cordingly;

22 (ii) in clause (iv), as so redesign-
23 nated—

1 (I) by inserting “immunization
2 information systems,” after “poison
3 control,”; and

4 (II) by striking “and clinical lab-
5 oratories” and inserting “, clinical
6 laboratories, and public environmental
7 health agencies”;

8 (iii) by striking “The network” and
9 inserting the following:

10 “(A) IN GENERAL.—The network”; and

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

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

1 such review to the congressional committees of
2 jurisdiction.”;

3 (D) in paragraph (5)—

4 (i) by redesignating subparagraphs
5 (A) through (D) as clauses (i) through
6 (iv), respectively, and adjusting the mar-
7 gins accordingly;

8 (ii) by striking “In establishing” and
9 inserting the following:

10 “(A) IN GENERAL.—In establishing”;

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

13 “(B) PUBLIC MEETING.—

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

1 “(ii) EXPERTS.—The public meeting
2 shall include representatives of relevant
3 Federal agencies (including representatives
4 from the Office of the National Coordi-
5 nator for Health Information Technology
6 and the National Institute of Standards
7 and Technology); State, local, tribal, and
8 territorial public health officials; stake-
9 holders with expertise in biosurveillance
10 and situational awareness; stakeholders
11 with expertise in capabilities relevant to
12 biosurveillance and situational awareness,
13 such as experts in informatics and data
14 analytics (including experts in prediction,
15 modeling, or forecasting); and other rep-
16 resentatives as the Secretary determines
17 appropriate.

18 “(iii) TOPICS.—Such public meeting
19 shall include a discussion of—

20 “(I) data elements, including
21 minimal or essential data elements,
22 that are voluntarily provided for such
23 network, which may include elements
24 from public health and public and pri-

1 vate health care entities, to the extent
2 practicable;

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

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

11 “(IV) considerations for State,
12 local, tribal, and territorial capabilities
13 and infrastructure related to data ex-
14 change and interoperability;

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

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

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

24 (I) in clause (i), as so redesign-
25 nated—

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

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

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

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

15 (IV) by adding at the end the fol-
16 lowing:

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

24 (E) by redesignating paragraph (6) as
25 paragraph (7);

1 (F) by inserting after paragraph (5) the
2 following:

3 “(6) STRATEGY AND IMPLEMENTATION
4 PLAN.—

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

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

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

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

22 “(I) develop, implement, and
23 evaluate the network described in
24 paragraph (1), utilizing elements de-
25 scribed in paragraph (3)(A);

1 “(II) modernize and enhance bio-
2 surveillance activities, including strat-
3 egies to include innovative tech-
4 nologies and analytical approaches
5 (including prediction and forecasting
6 for pandemics and all-hazards) from
7 public and private entities;

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

19 “(IV) test and evaluate capabili-
20 ties of the interoperable network of
21 systems to improve situational aware-
22 ness and biosurveillance capabilities;

23 “(iv) includes performance measures
24 and the metrics by which performance
25 measures will be assessed with respect to

1 the measurable steps under clause (iii);
2 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 Na-
14 tional Biodefense Science Board, develop a
15 budget plan based on the strategy and imple-
16 mentation plan under this section. Such budget
17 plan shall include—

18 “(i) a summary of resources pre-
19 viously expended to establish, improve, and
20 utilize the nationwide public health situa-
21 tional awareness and biosurveillance net-
22 work under paragraph (1);

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

1 strategy and implementation plan under
2 subparagraph (A);

3 “(iii) the identification of gaps and in-
4 efficiencies in nationwide public health sit-
5 uational awareness and biosurveillance ca-
6 pabilities, resources, and authorities need-
7 ed to 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 “surveil-
21 lance 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”;
4 and

5 (II) by striking the period and
6 inserting “; and”; and

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

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

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

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

21 (5) in subsection (d)—

22 (A) in paragraph (1)—

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

1 (ii) by inserting “immunization pro-
2 grams,” after “poison control centers,”;
3 and

4 (B) in paragraph (2)—

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

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

9 (iii) by adding after subparagraph (C)
10 the following:

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

14 (C) by striking paragraph (5) and insert-
15 ing the following:

16 “(5) TECHNICAL ASSISTANCE.—The Secretary
17 may provide technical assistance to States, localities,
18 tribes, and territories or a consortium of States, lo-
19 calities, tribes, and territories receiving an award
20 under this subsection regarding interoperability and
21 the technical standards set forth by the Secretary.”;

22 (6) by redesignating subsections (f) and (g) as
23 subsections (i) and (j), respectively; and

24 (7) by inserting after subsection (e) the fol-
25 lowing:

1 “(f) PERSONNEL AUTHORITIES.—

2 “(1) SPECIALLY QUALIFIED PERSONNEL.—In
3 addition to any other personnel authorities, to carry
4 out subsections (b) and (c), the Secretary may—

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

16 “(B) compensate individuals appointed
17 under subparagraph (A) in the same manner
18 and subject to the same terms and conditions in
19 which individuals appointed under 9903 of title
20 5, United States Code, are compensated, with-
21 out regard to the provisions of chapter 51 and
22 subchapter III of chapter 53 of such title relat-
23 ing to classification and General Schedule pay
24 rates.

1 “(2) LIMITATIONS.—The Secretary shall exer-
2 cise the authority under paragraph (1) in a manner
3 that is consistent with the limitations described in
4 section 319F–1(e)(2).

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

11 “(h) INDEPENDENT EVALUATION.—Not later than 3
12 years after the date of enactment of the Pandemic and
13 All-Hazards Preparedness and Advancing Innovation Act
14 of 2018, the Comptroller General of the United States
15 shall conduct an independent evaluation, and submit to
16 the Secretary and the congressional committees of juris-
17 diction a report concerning the activities conducted under
18 subsections (b) and (c), and provide recommendations, as
19 applicable and appropriate, on necessary improvements to
20 the biosurveillance and situational awareness network.”.

21 (b) AUTHORIZATION OF APPROPRIATIONS.—Sub-
22 section (i) of section 319D of the Public Health Service
23 Act (42 U.S.C. 247d–4), as redesignated by subsection
24 (a)(6), is amended by striking “\$138,300,000 for each of
25 fiscal years 2014 through 2018” and inserting

1 “\$161,800,000 for each of fiscal years 2019 through
2 2023”.

3 (c) BIOLOGICAL THREAT DETECTION REPORT.—The
4 Secretary of Health and Human Services shall, in coordi-
5 nation with the Secretary of Defense and the Secretary
6 of Homeland Security, not later than 180 days after the
7 date of enactment of this Act, report to the Committee
8 on Energy and Commerce, the Committee on Armed Serv-
9 ices, and the Committee on Homeland Security of the
10 House of Representatives and the Committee on Health,
11 Education, Labor, and Pensions, the Committee on Armed
12 Services, and the Committee on Homeland Security and
13 Governmental Affairs of the Senate on the state of Fed-
14 eral biological threat detection efforts, including the fol-
15 lowing—

16 (1) an identification of technological, oper-
17 ational, and programmatic successes and failures of
18 domestic detection programs supported by Federal
19 departments and agencies for intentionally-intro-
20 duced or accidentally-released biological threat
21 agents and naturally occurring infectious diseases;

22 (2) a description of Federal efforts to facilitate
23 the exchange of information related to the informa-
24 tion described in paragraph (1) among Federal de-

1 departments and agencies that utilize biological threat
2 detection technology;

3 (3) a description of the capabilities of detection
4 systems in use by Federal departments and agencies
5 including the capability to—

6 (A) rapidly detect, identify, characterize,
7 and confirm the presence of biological threat
8 agents;

9 (B) recover live biological agents from col-
10 lection devices;

11 (C) determine the geographical distribution
12 of biological agents;

13 (D) determine the extent of environmental
14 contamination and persistence of biological
15 agents; and

16 (E) provide advanced molecular diagnostics
17 to State, local, tribal, and territorial public
18 health and other laboratories that support bio-
19 logical threat detection activities;

20 (4) a description of Federal interagency coordi-
21 nation related to biological threat detection;

22 (5) a description of efforts by Federal depart-
23 ments and agencies that utilize biological threat de-
24 tection technology to collaborate with State, local,
25 tribal, and territorial public health laboratories and

1 other users of biological threat detection systems, in-
2 cluding collaboration regarding the development of—

3 (A) biological threat detection require-
4 ments or standards;

5 (B) a standardized integration strategy;

6 (C) training requirements or guidelines;

7 (D) guidelines for a coordinated public
8 health response, including preparedness capa-
9 bilities, and, as applicable, for coordination with
10 public health surveillance systems; and

11 (E) a coordinated environmental remedi-
12 ation plan, as applicable; and

13 (6) recommendations related to research, ad-
14 vanced research, development, and procurement for
15 Federal departments and agencies to improve and
16 enhance biological threat detection systems, includ-
17 ing recommendations on the transfer of biological
18 threat detection technology among Federal depart-
19 ments and agencies, as necessary and appropriate.

20 **SEC. 206. STRENGTHENING AND SUPPORTING THE PUBLIC**
21 **HEALTH EMERGENCY RAPID RESPONSE**
22 **FUND.**

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

25 (1) in subsection (b)—

1 (A) in paragraph (1)—

2 (i) in the first sentence, by inserting
3 “or if the Secretary determines there is the
4 significant potential for a public health
5 emergency, to allow the Secretary to rap-
6 idly respond to the immediate needs result-
7 ing from such public health emergency or
8 potential public health emergency” before
9 the period; and

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

14 (B) by redesignating paragraph (2) as
15 paragraph (3);

16 (C) by inserting after paragraph (1) the
17 following:

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

20 “(A) facilitate coordination between and
21 among Federal, State, local, tribal, and terri-
22 torial entities and public and private health
23 care entities that the Secretary determines may
24 be affected by a public health emergency or po-
25 tential public health emergency referred to in

1 paragraph (1) (including communication of
2 such entities with relevant international enti-
3 ties, as applicable);

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

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

19 “(D) strengthen biosurveillance capabilities
20 and laboratory capacity to identify, collect, and
21 analyze information regarding such public
22 health emergency or potential public health
23 emergency, including the systems under section
24 319D;

1 “(E) support initial emergency operations
2 and assets related to preparation and deploy-
3 ment of intermittent disaster response per-
4 sonnel under section 2812, and the Medical Re-
5 serve Corps under section 2813; and

6 “(F) carry out other activities, as the Sec-
7 retary determines applicable and appropriate.”;
8 and

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

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

24 “(5) GAO REPORT.—Not later than 4 years
25 after the date of enactment of the Pandemic and

1 All-Hazards Preparedness and Advancing Innovation
2 Act of 2018, the Comptroller General of the United
3 States shall—

4 “(A) conduct a review of the Fund under
5 this section, including its uses and the re-
6 sources available in the Fund; and

7 “(B) submit to the Committee on Health,
8 Education, Labor, and Pensions of the Senate
9 and the Committee on Energy and Commerce
10 of the House of Representatives a report on
11 such review, including recommendations related
12 to such review, as applicable.”; and

13 (2) in subsection (c)—

14 (A) by inserting “rapidly respond to public
15 health emergencies or potential public health
16 emergencies and” after “used to”; and

17 (B) by striking “section.” and inserting
18 “Act or funds otherwise provided for emergency
19 response.”.

20 **SEC. 207. IMPROVING ALL-HAZARDS PREPAREDNESS AND**
21 **RESPONSE BY PUBLIC HEALTH EMERGENCY**
22 **VOLUNTEERS.**

23 (a) IN GENERAL.—Section 319I of the Public Health
24 Service Act (42 U.S.C. 247d–7b) is amended—

1 (1) in the section heading, by striking
2 “**HEALTH PROFESSIONS VOLUNTEERS**” and in-
3 serting “**VOLUNTEER HEALTH PROFESSIONAL**”;

4 (2) in subsection (a), by adding at the end the
5 following: “Such health care professionals may in-
6 clude members of the National Disaster Medical
7 System, members of the Medical Reserve Corps, and
8 individual health care professionals.”;

9 (3) in subsection (i) by adding at the end “In
10 order to inform the development of such mechanisms
11 by States, the Secretary shall make available infor-
12 mation and material provided by States that have
13 developed mechanisms to waive the application of li-
14 censing requirements to applicable health profes-
15 sionals seeking to provide medical services during a
16 public health emergency. Such information shall be
17 made publicly available in a manner that does not
18 compromise national security.”; and

19 (4) in subsection (k) by striking “2014 through
20 2018” and inserting “2019 through 2023”.

21 (b) **ALL-HAZARDS PUBLIC HEALTH EMERGENCY**
22 **PREPAREDNESS AND RESPONSE PLAN.**—Section 319C-
23 1(b)(2)(A)(iv) of the Public Health Service Act (42 U.S.C.
24 247d-3a(b)(2)(A)(iv)) is amended to read as follows:

1 “(iv) a description of the mechanism the
2 entity will implement to utilize the Emergency
3 Management Assistance Compact, or other mu-
4 tual aid agreement, for medical and public
5 health mutual aid, and, as appropriate, the ac-
6 tivities such entity will implement pursuant to
7 section 319I to improve enrollment and coordi-
8 nation of volunteer health care professionals
9 seeking to provide medical services during a
10 public health emergency, which may include—

11 “(I) providing a public method of
12 communication for purposes of volunteer
13 coordination (such as a phone number);

14 “(II) providing for optional registra-
15 tion to participate in volunteer services
16 during processes related to State medical
17 licensing, registration, or certification or
18 renewal of such licensing, registration or
19 certification; or

20 “(III) other mechanisms as the State
21 determines appropriate;”.

1 **SEC. 208. CLARIFYING STATE LIABILITY LAW FOR VOLUN-**
2 **TEER HEALTH CARE PROFESSIONALS.**

3 (a) IN GENERAL.—Title II of the Public Health Serv-
4 ice Act (42 U.S.C. 202 et seq.) is amended by inserting
5 after section 224 the following:

6 **“SEC. 225. HEALTH CARE PROFESSIONALS ASSISTING DUR-**
7 **ING A PUBLIC HEALTH EMERGENCY.**

8 “(a) LIMITATION ON LIABILITY.—Notwithstanding
9 any other provision of law, a health care professional who
10 is a member of the Medical Reserve Corps under section
11 2813 or who is included in the Emergency System for Ad-
12 vance Registration of Volunteer Health Professionals
13 under section 319I and who—

14 “(1) is responding—

15 “(A) to a public health emergency deter-
16 mined under section 319(a), during the initial
17 period of not more than 90 days (as determined
18 by the Secretary) of the public health emer-
19 gency determination (excluding any period cov-
20 ered by a renewal of such determination); or

21 “(B) to a major disaster or an emergency
22 as declared by the President under section 401
23 of the Robert T. Stafford Disaster Relief and
24 Emergency Assistance Act (42 U.S.C. 5170) or
25 under section 201 of the National Emergencies

1 Act (50 U.S.C.1621) during the initial period of
2 such declaration; and

3 “(2) is alleged to be liable for an act or omis-
4 sion—

5 “(A) during the initial period of a deter-
6 mination or declaration described in paragraph
7 (1) and related to the treatment of individuals
8 in need of health care services due to such pub-
9 lic health emergency, major disaster, or emer-
10 gency;

11 “(B) in the State or States for which such
12 determination or declaration is made;

13 “(C) in the health care professional’s ca-
14 pacity as a member of the Medical Reserve
15 Corps or a professional included in the Emer-
16 gency System for Advance Registration of Vol-
17 unteer Health Professionals under section 319I;
18 and

19 “(D) in the course of providing services
20 that are within the scope of the license, reg-
21 istration, or certification of the professional, as
22 defined by the State of licensure, registration,
23 or certification; and

24 “(3) prior to the rendering of such act or omis-
25 sion, was authorized by the State’s authorization of

1 deploying such State’s Emergency System for Ad-
2 vance Registration of Volunteer Health Professionals
3 described in section 319I or the Medical Reserve
4 Corps established under section 2813, to provide
5 health care services,

6 shall be subject only to the State liability laws of the State
7 in which such act or omission occurred, in the same man-
8 ner and to the same extent as a similar health care profes-
9 sional who is a resident of such State would be subject
10 to such State laws, except with respect to the licensure,
11 registration, and certification of such individual.

12 “(b) VOLUNTEER PROTECTION ACT.—Nothing in
13 this section shall be construed to affect an individual’s
14 right to protections under the Volunteer Protection Act
15 of 1997.

16 “(c) PREEMPTION.—This section shall supercede the
17 laws of any State that would subject a health care profes-
18 sional described in subsection (a) to the liability laws of
19 any State other than the State liability laws to which such
20 individual is subject pursuant to such subsection.

21 “(d) DEFINITIONS.—In this section:

22 “(1) The term ‘health care professional’ means
23 an individual licensed, registered, or certified under
24 Federal or State laws or regulations to provide
25 health care services.

1 “(2) The term ‘health care services’ means any
2 services provided by a health care professional, or by
3 any individual working under the supervision of a
4 health care professional, that relate to—

5 “(A) the diagnosis, prevention, or treat-
6 ment of any human disease or impairment; or

7 “(B) the assessment or care of the health
8 of human beings.

9 “(e) EFFECTIVE DATE.—

10 “(1) IN GENERAL.—This section shall take ef-
11 fect 90 days after the date of the enactment of the
12 Pandemic and All-Hazards Preparedness and Ad-
13 vancing Innovation Act of 2018.

14 “(2) APPLICATION.—This section shall apply to
15 a claim for harm only if the act or omission that
16 caused such harm occurred on or after the effective
17 date described in paragraph (1).”.

18 “(b) GAO STUDY.—Not later than one year after the
19 date of enactment of this Act, the Comptroller General
20 of the United States shall conduct a review of—

21 (1) the number of health care providers who
22 register under the Emergency System for Advance
23 Registration of Volunteer Health Professionals
24 under section 319I of the Public Health Service Act

1 (42 U.S.C. 247d–7b) in advance to provide services
2 during a public health emergency;

3 (2) the number of health care providers who are
4 credentialed to provide services during the period of
5 a public health emergency declaration, including
6 those who are credentialed through programs estab-
7 lished in the Emergency System for Advance Reg-
8 istration of Volunteer Health Professionals under
9 such section 319I and those credentialed by authori-
10 ties within the State in which the emergency oc-
11 curred;

12 (3) the average time to verify the credentials of
13 a health care provider during the period of a public
14 health emergency declaration, including the average
15 time pursuant to the Emergency System for Ad-
16 vance Registration of Volunteer Health Professionals
17 under such section 319I and for an individual’s cre-
18 dentials to be verified by an authority within the
19 State; and

20 (4) the Emergency System for Advance Reg-
21 istration of Volunteer Health Professionals program
22 in States, including whether physician or medical
23 groups, associations, or other relevant provider orga-
24 nizations utilize such program for purposes of volun-
25 teering during public health emergencies.

1 **SEC. 209. REPORT ON ADEQUATE NATIONAL BLOOD SUP-**
2 **PLY.**

3 Not later than 1 year after the date of the enactment
4 of this Act, the Secretary of Health and Human Services
5 shall submit to Congress a report containing recommenda-
6 tions related to maintaining an adequate national blood
7 supply, including—

8 (1) challenges associated with the continuous
9 recruitment of blood donors (including those newly
10 eligible to donate);

11 (2) ensuring the adequacy of the blood supply
12 in the case of public health emergencies;

13 (3) implementation of the transfusion trans-
14 mission monitoring system; and

15 (4) other measures to promote safety and inno-
16 vation, such as the development, use, or implementa-
17 tion of new technologies, processes, and procedures
18 to improve the safety and reliability of the blood
19 supply.

20 **SEC. 210. REPORT ON THE PUBLIC HEALTH PREPARED-**
21 **NESS AND RESPONSE CAPABILITIES AND CA-**
22 **PACITIES OF HOSPITALS, LONG-TERM CARE**
23 **FACILITIES, AND OTHER HEALTH CARE FA-**
24 **CILITIES.**

25 (a) STUDY.—

1 (1) IN GENERAL.—Not later than one year
2 after the date of enactment of this Act, the Sec-
3 retary of Health and Human Services shall enter
4 into an agreement with an appropriate entity to con-
5 duct a study regarding the public health prepared-
6 ness and response capabilities and medical surge ca-
7 pacities of hospitals, long-term care facilities, and
8 other health care facilities to prepare for, and re-
9 spond to, public health emergencies, including nat-
10 ural disasters.

11 (2) CONSULTATION.—In conducting the study
12 under paragraph (1), the entity shall consult with
13 Federal, State, local, tribal, and territorial public
14 health officials (as appropriate), and health care
15 providers and facilities with experience in public
16 health preparedness and response activities.

17 (3) EVALUATION.—The study under paragraph
18 (1) shall include—

19 (A) an evaluation of the current bench-
20 marks and objective standards, as applicable,
21 related to programs that support hospitals,
22 long-term care facilities, and other health care
23 facilities, and their effect on improving public
24 health preparedness and response capabilities
25 and medical surge capacities, including the

1 Hospital Preparedness Program, the Public
2 Health Emergency Preparedness cooperative
3 agreements, and the Regional Health Care
4 Emergency Preparedness and Response Sys-
5 tems under section 319C–3 of the Public
6 Health Service Act (as added by section 203);

7 (B) the identification of gaps in prepared-
8 ness, including with respect to such benchmarks
9 and objective standards, such as those identified
10 during recent public health emergencies, for
11 hospitals, long-term care facilities, and other
12 health care facilities to address future potential
13 public health threats;

14 (C) an evaluation of coordination efforts
15 between the recipients of Federal funding for
16 programs described in subparagraph (A) and
17 entities with expertise in emergency power sys-
18 tems and other critical infrastructure partners
19 during a public health emergency, to ensure a
20 functioning critical infrastructure, to the great-
21 est extent practicable, during a public health
22 emergency;

23 (D) an evaluation of coordination efforts
24 between the recipients of Federal funding for
25 programs described in subparagraph (A) and

1 environmental health agencies with expertise in
2 emergency preparedness and response planning
3 for hospitals, long-term care facilities and other
4 health care facilities; and

5 (E) an evaluation of current public health
6 preparedness and response capabilities and
7 medical surge capacities related to at-risk indi-
8 viduals during public health emergencies, in-
9 cluding an identification of gaps in such pre-
10 paredness as they relate to such individuals.

11 (b) REPORT.—

12 (1) IN GENERAL.—The agreement under sub-
13 section (a) shall require the entity to submit to the
14 Secretary of Health and Human Services and the
15 congressional committees of jurisdiction, not later
16 than 3 years after the date of enactment of this Act,
17 a report on the results of the study conducted pur-
18 suant to this section.

19 (2) CONTENTS.—The report under paragraph
20 (1) shall—

21 (A) describe the findings and conclusions
22 of the evaluation conducted pursuant to sub-
23 section (a); and

24 (B) provide recommendations for improv-
25 ing public health preparedness and response ca-

pability and medical surge capacity for hospitals, long-term care facilities, and other health care facilities, including—

(i) improving the existing benchmarks and objective standards for the Federal grant programs described in subsection (a)(3)(A) or developing new benchmarks and standards for such programs; and

(ii) identifying best practices for improving public health preparedness and response programs and medical surge capacity at hospitals, long-term care facilities, and other health care facilities, including recommendations for the evaluation under subparagraphs (C) and (D) of subsection (a)(3).

TITLE III—REACHING ALL COMMUNITIES

SEC. 301. STRENGTHENING AND ASSESSING THE EMERGENCY RESPONSE WORKFORCE.

(a) NATIONAL DISASTER MEDICAL SYSTEM.—

(1) STRENGTHENING THE NATIONAL DISASTER MEDICAL SYSTEM.—Clause (ii) of section 2812(a)(3)(A) of the Public Health Service Act (42

1 U.S.C. 300hh–11(a)(3)(A)) is amended to read as
2 follows:

3 “(ii) be present at locations, and for
4 limited periods of time, specified by the
5 Secretary on the basis that the Secretary
6 has determined that a location is at risk of
7 a public health emergency during the time
8 specified, or there is a significant potential
9 for a public health emergency.”.

10 (2) REVIEW OF THE NATIONAL DISASTER MED-
11 ICAL SYSTEM.—Section 2812(b)(2) of the Public
12 Health Service Act (42 U.S.C. 300hh–11(b)(2)) is
13 amended to read as follows:

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

16 “(A) REVIEW.—Not later than 180 days
17 after the date of enactment of the Pandemic
18 and All-Hazards Preparedness and Advancing
19 Innovation Act of 2018, the Secretary, in co-
20 ordination with the Secretary of Homeland Se-
21 curity, the Secretary of Defense, and the Sec-
22 retary of Veterans Affairs, shall conduct a joint
23 review of the National Disaster Medical System.
24 Such review 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
6 (c);

7 “(iii) the capacity of the workforce de-
8 scribed in clause (ii) to respond to all haz-
9 ards, including capacity to simultaneously
10 respond to multiple public health emer-
11 gencies and the capacity to respond to a
12 nationwide public health emergency;

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

15 “(v) gaps that may exist in such
16 workforce and recommendations for ad-
17 dressing such gaps.

18 “(B) UPDATES.—As part of the National
19 Health Security Strategy under section 2802,
20 the Secretary shall update the findings from the
21 review under subparagraph (A) and provide rec-
22 ommendations to modify the policies of the Na-
23 tional Disaster Medical System as necessary.”.

24 (3) NOTIFICATION OF SHORTAGE.—Section
25 2812(c) of the Public Health Service Act (42 U.S.C.

1 300hh–11(c)) is amended by adding at the end the
2 following:

3 “(3) NOTIFICATION.—Not later than 30 days
4 after the date on which the Secretary determines the
5 number of intermittent disaster-response personnel
6 of the National Disaster Medical System is insuffi-
7 cient to address a public health emergency or poten-
8 tial public health emergency, the Secretary shall sub-
9 mit to the congressional committees of jurisdiction a
10 notification detailing—

11 “(A) the impact such shortage could have
12 on meeting public health needs and emergency
13 medical personnel needs during a public health
14 emergency; and

15 “(B) any identified measures to address
16 such shortage.

17 “(4) CERTAIN APPOINTMENTS.—

18 “(A) IN GENERAL.—If the Secretary deter-
19 mines that the number of intermittent disaster
20 response personnel within the National Disaster
21 Medical System under this section is insuffi-
22 cient to address a public health emergency or
23 potential public health emergency, the Secretary
24 may appoint candidates directly to personnel
25 positions for intermittent disaster response

1 within such system. The Secretary shall provide
2 updates on the number of vacant or unfilled po-
3 sitions within such system to the congressional
4 committees of jurisdiction each quarter for
5 which this authority is in effect.

6 “(B) SUNSET.—The authority under this
7 paragraph shall expire on September 30,
8 2021.”.

9 (4) AUTHORIZATION OF APPROPRIATIONS.—

10 Section 2812(g) of the Public Health Service Act
11 (42 U.S.C. 300hh–11(g)) is amended by striking
12 “\$52,700,000 for each of fiscal years 2014 through
13 2018” and inserting “\$57,400,000 for each of fiscal
14 years 2019 through 2023”.

15 (b) VOLUNTEER MEDICAL RESERVE CORPS.—

16 (1) IN GENERAL.—Section 2813(a) of the Pub-
17 lic Health Service Act (42 U.S.C. 42 U.S.C. 300hh–
18 15(a)) is amended by striking the second sentence
19 and inserting “The Secretary may appoint a Direc-
20 tor to head the Corps and oversee the activities of
21 the Corps chapters that exist at the State, local,
22 tribal, and territorial levels.”.

23 (2) AUTHORIZATION OF APPROPRIATIONS.—

24 Section 2813(i) of the Public Health Service Act (42

1 U.S.C. 300hh–15(i)) is amended by striking “2014
2 through 2018” and inserting “2019 through 2023”.

3 (c) STRENGTHENING THE EPIDEMIC INTELLIGENCE
4 SERVICE.—Section 317F of the Public Health Service Act
5 (42 U.S.C. Sec. 247b–7) is amended—

6 (1) in subsection (a)—

7 (A) in paragraph (1)—

8 (i) by inserting “or preparedness and
9 response activities, including rapid re-
10 sponse to public health emergencies and
11 significant public health threats” after
12 “conduct prevention activities”; and

13 (ii) by striking “\$35,000” and insert-
14 ing “\$50,000”; and

15 (B) in paragraph (2)(B), by striking “3
16 years” and inserting “2 years”; and

17 (2) in subsection (c)—

18 (A) by striking “For the purpose of car-
19 rying out this section” and inserting the fol-
20 lowing:

21 “(1) IN GENERAL.—For the purpose of car-
22 rying out this section, except as described in para-
23 graph (2)”; and

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

1 “(2) EPIDEMIC INTELLIGENCE SERVICE PRO-
2 GRAM.—For purposes of carrying out this section
3 with respect to qualified health professionals serving
4 in the Epidemic Intelligence Service, as authorized
5 under section 317G, there are authorized to be ap-
6 propriated \$1,000,000 for each of fiscal years 2019
7 through 2023.”.

8 (d) SERVICE BENEFIT FOR NATIONAL DISASTER
9 MEDICAL SYSTEM VOLUNTEERS.—

10 (1) IN GENERAL.—Section 2812(c) of the Pub-
11 lic Health Service Act (42 U.S.C. 300hh–11(c)), as
12 amended by subsection (a)(3), is further amended by
13 adding at the end the following:

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

22 (2) PUBLIC SAFETY OFFICER BENEFITS.—Sec-
23 tion 1204(9) of title I of the Omnibus Crime Control
24 and Safe Streets Act of 1968 (34 U.S.C. 10284(9))
25 is amended—

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

3 (B) in subparagraph (D), by striking the
4 period and inserting “; or”; and

5 (C) by inserting after subparagraph (D)
6 the following:

7 “(E) an individual appointed to the Na-
8 tional Disaster Medical System under section
9 2812 of the Public Health Service Act (42
10 U.S.C. 300hh–11) who is performing official
11 duties of the Department of Health and Human
12 Services, if those official duties are—

13 “(i) related to responding to a public
14 health emergency or potential public health
15 emergency, or other activities for which the
16 Secretary of Health and Human Services
17 has activated such National Disaster Med-
18 ical System; and

19 “(ii) determined by the Secretary of
20 Health and Human Services to be haz-
21 ardous.”.

22 (3) SUNSET.—The amendments made by para-
23 graphs (1) and (2) shall cease to have force or effect
24 on October 1, 2021.

25 (e) MISSION READINESS REPORT TO CONGRESS.—

1 (1) REPORT.—Not later than one year after the
2 date of enactment of this section, the Comptroller
3 General of the United States (referred to in this
4 subsection as the “Comptroller General”) shall sub-
5 mit to the Committee on Health, Education, Labor,
6 and Pensions of the Senate and the Committee on
7 Energy and Commerce of the House of Representa-
8 tives, a report on the medical surge capacity of the
9 United States in the event of a public health emer-
10 gency, including the capacity and capability of the
11 current health care workforce to prepare for, and re-
12 spond to the full range of public health emergencies
13 or potential public health emergencies, and rec-
14 ommendations to address any gaps identified in such
15 workforce.

16 (2) CONTENTS.—The Comptroller General shall
17 include in the report under paragraph (1)—

18 (A) the number of health care providers
19 who have volunteered to provide health care
20 services during a public health emergency, in-
21 cluding members of the National Disaster Med-
22 ical System, the Disaster Medical Assistant
23 Teams, the Medical Reserve Corps, and other
24 volunteer health care professionals in the
25 verification network pursuant to section 319I of

1 the Public Health Service Act (42 U.S.C.
2 247d–7b);

3 (B) the capacity of the workforce described
4 in subparagraph (A) to respond to a public
5 health emergency or potential public health
6 emergency, including the capacity to respond to
7 multiple concurrent public health emergencies
8 and the capacity to respond to a nationwide
9 public health emergency;

10 (C) the preparedness and response capa-
11 bilities and mission readiness of the workforce
12 described in subparagraph (A) taking into ac-
13 count areas of health care expertise and consid-
14 erations for at-risk individuals (as defined in
15 section 2802(b)(4)(B) of the Public Health
16 Service Act (42 U.S.C. 300hh–1(b)(4)(B));

17 (D) an assessment of the effectiveness of
18 efforts to recruit, retain, and train such work-
19 force; and

20 (E) identification of gaps that may exist in
21 such workforce and recommendations for ad-
22 dressing such gaps, the extent to which the As-
23 sistant Secretary for Preparedness and Re-
24 sponse plans to address such gaps, and any rec-

1 ommendations from the Comptroller General to
2 address such gaps.

3 **SEC. 302. HEALTH SYSTEM INFRASTRUCTURE TO IMPROVE**
4 **PREPAREDNESS AND RESPONSE.**

5 (a) COORDINATION OF PREPAREDNESS.—Section
6 2811(b)(5) of the Public Health Service Act (42 U.S.C.
7 300hh–10(b)(5)) is amended by adding at the end the fol-
8 lowing: “Such logistical support shall include working with
9 other relevant Federal, State, local, tribal, and territorial
10 public health officials and private sector entities to identify
11 the critical infrastructure assets, systems, and networks
12 needed for the proper functioning of the health care and
13 public health sectors that need to be maintained through
14 any emergency or disaster, including entities capable of
15 assisting with, responding to, and mitigating the effect of
16 a public health emergency, including a public health emer-
17 gency determined by the Secretary pursuant to section
18 319(a), an emergency or major disaster declared by the
19 President under the Robert T. Stafford Disaster Relief
20 and Emergency Assistance Act, or the National Emer-
21 gencies Act, including by establishing methods to exchange
22 critical information and deliver products consumed or used
23 to preserve, protect, or sustain life, health, or safety, and
24 sharing of specialized expertise.”.

1 (b) MANUFACTURING CAPACITY.—Section
2 2811(d)(2)(C) of the Public Health Service Act (42
3 U.S.C. 300hh–10(d)(2)(C)) is amended by inserting “,
4 and ancillary medical supplies to assist with the utilization
5 of such countermeasures or products,” after “products”.

6 (c) EVALUATION OF BARRIERS TO RAPID DELIVERY
7 OF MEDICAL COUNTERMEASURES.—

8 (1) RAPID DELIVERY STUDY.—The Assistant
9 Secretary for Preparedness and Response may con-
10 duct a study on issues that have the potential to ad-
11 versely affect the handling and rapid delivery of
12 medical countermeasures to individuals during public
13 health emergencies occurring in the United States.

14 (2) NOTICE TO CONGRESS.—Not later than 9
15 months after the date of the enactment of this Act,
16 the Assistant Secretary for Preparedness and Re-
17 sponse shall notify the Committee on Energy and
18 Commerce of the House of Representatives and the
19 Committee on Health, Education, Labor, and Pen-
20 sions of the Senate if the Assistant Secretary for
21 Preparedness and Response does not plan to conduct
22 the study under paragraph (1) and shall provide
23 such committees a summary explanation for such de-
24 cision.

1 (3) REPORT TO CONGRESS.—Not later than 1
2 year after the Assistant Secretary for Preparedness
3 and Response conducts the study under paragraph
4 (1), such Assistant Secretary shall submit a report
5 to the Committee on Energy and Commerce of the
6 House of Representatives and the Committee on
7 Health, Education, Labor, and Pensions of the Sen-
8 ate containing the findings of such study.

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

10 (a) AT-RISK INDIVIDUALS IN THE NATIONAL
11 HEALTH SECURITY STRATEGY.—Section 2802(b)(4)(B)
12 of the Public Health Service Act (42 U.S.C. 300hh–
13 1(b)(4)(B)) is amended—

14 (1) by striking “this section and sections 319C–
15 1, 319F, and 319L,” and inserting “this Act,”; and

16 (2) by striking “special” and inserting “access
17 or functional”.

18 (b) COUNTERMEASURE CONSIDERATIONS.—Section
19 319L(c)(6) of the Public Health Service Act (42 U.S.C.
20 247d–7e(c)(6)) is amended—

21 (1) by striking “elderly” and inserting “senior
22 citizens”; and

23 (2) by inserting “with relevant characteristics
24 that warrant consideration during the process of re-

1 searching and developing such countermeasures and
2 products” before the period.

3 (c) BIOSURVEILLANCE OF EMERGING PUBLIC
4 HEALTH THREATS.—Section 2814 is amended—

5 (1) in paragraph (7), by striking “; and” and
6 inserting a semicolon;

7 (2) in paragraph (8), by striking the period and
8 inserting “; and”; and

9 (3) by adding at the end the following:

10 “(9) facilitate coordination to ensure that, in
11 implementing the situational awareness and bio-
12 surveillance network under section 319D, the Sec-
13 retary considers incorporating data and information
14 from Federal, State, local, tribal, and territorial
15 public health officials and entities relevant to detect-
16 ing emerging public health threats that may affect
17 at-risk individuals, such as pregnant and postpartum
18 women and infants, including adverse health out-
19 comes of such populations related to such emerging
20 public health threats.”.

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

4 Part B of title III of the Public Health Service Act
5 (42 U.S.C. 243 et seq.) is amended by inserting after sec-
6 tion 319D the following:

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

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

20 “(b) **EXPERTISE.**—The team described in subsection
21 (a) shall include one or more pediatricians, which may be
22 a developmental-behavioral pediatrician, and may also in-
23 clude behavioral scientists, child psychologists, epidemiolo-
24 gists, biostatisticians, health communications staff, and
25 individuals with other areas of expertise, as the Secretary
26 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, includ-
 5 ing pursuant to section 319C–3; and

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

9 **SEC. 305. NATIONAL ADVISORY COMMITTEES ON DISAS-**
 10 **TERS.**

11 (a) REAUTHORIZING THE NATIONAL ADVISORY COM-
 12 MITTEE ON CHILDREN AND DISASTERS.—Section 2811A
 13 of the Public Health Service Act (42 U.S.C. 300hh–10a)
 14 is amended—

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

17 (2) in subsection (d)—

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

20 (B) by striking paragraph (2) and insert-
 21 ing the following:

22 “(2) REQUIRED NON-FEDERAL MEMBERS.—The
 23 Secretary, in consultation with such other heads of
 24 Federal agencies as may be appropriate, shall ap-

1 point to the Advisory Committee under paragraph
2 (1) at least 13 individuals, 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 exper-
8 tise in pediatric disaster planning, prepared-
9 ness, response, or recovery;

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

20 “(D) other members as the Secretary de-
21 termines 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
2 be an individual with expertise in schools
3 or child care settings;

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

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

13 “(3) FEDERAL MEMBERS.—The Advisory Com-
14 mittee under paragraph (1) shall include the fol-
15 lowing Federal members or their designees (who
16 may be non-voting members, as determined by the
17 Secretary):

18 “(A) The Assistant Secretary for Pre-
19 paredness and Response.

20 “(B) The Director of the Biomedical Ad-
21 vanced Research and Development Authority.

22 “(C) The Director of the Centers for Dis-
23 ease Control and Prevention.

24 “(D) The Commissioner of Food and
25 Drugs.

1 “(E) The Director of the National Insti-
2 tutes of Health.

3 “(F) The Assistant Secretary of the Ad-
4 ministration for Children and Families.

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

7 “(H) The Administrator of the Federal
8 Emergency Management Agency.

9 “(I) The Administrator of the Administra-
10 tion for Community Living.

11 “(J) The Secretary of Education.

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

19 “(4) TERM OF APPOINTMENT.—Each member
20 of the Advisory Committee appointed under para-
21 graph (2) shall serve for a term of 3 years, except
22 that the Secretary may adjust the terms of the Advi-
23 sory Committee appointees serving on the date of
24 enactment of the Pandemic and All-Hazards Pre-
25 paredness and Advancing Innovation Act of 2018, or

1 appointees who are initially appointed after such
 2 date of enactment, in order to provide for a stag-
 3 gered term of appointment for all members.

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

9 (3) in subsection (e), by adding at the end “At
 10 least one meeting per year shall be an in-person
 11 meeting.”;

12 (4) by redesignating subsection (f) as sub-
 13 section (g);

14 (5) by inserting after subsection (e) the fol-
 15 lowing:

16 “(f) COORDINATION.—The Secretary shall coordinate
 17 duties and activities authorized under this section in ac-
 18 cordance with section 2811D.”; and

19 (6) in subsection (g), as so redesignated, by
 20 striking “2018” and inserting “2023”.

21 (b) AUTHORIZING THE NATIONAL ADVISORY COM-
 22 MITTEE ON SENIORS AND DISASTERS.—Subtitle B of title
 23 XXVIII of the Public Health Service Act (42 U.S.C.
 24 300hh et seq.) is amended by inserting after section
 25 2811A the following:

1 **“SEC. 2811B. NATIONAL ADVISORY COMMITTEE ON SEN-**
2 **IORES 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
7 on Seniors and Disasters (referred to in this section as
8 the ‘Advisory Committee’).

9 “(b) DUTIES.—The Advisory Committee shall—

10 “(1) provide advice and consultation with re-
11 spect to the activities carried out pursuant to section
12 2814, as applicable and appropriate;

13 “(2) evaluate and provide input with respect to
14 the medical and public health needs of seniors re-
15 lated to preparation for, response to, and recovery
16 from all-hazards emergencies; and

17 “(3) provide advice and consultation with re-
18 spect to State emergency preparedness and response
19 activities relating to seniors, including related drills
20 and exercises pursuant to the preparedness goals
21 under section 2802(b).

22 “(c) ADDITIONAL DUTIES.—The Advisory Committee
23 may provide advice and recommendations to the Secretary
24 with respect to seniors and the medical and public health
25 grants and cooperative agreements as applicable to pre-

1 paredness and response activities under this title and title
2 III.

3 “(d) MEMBERSHIP.—

4 “(1) IN GENERAL.—The Secretary, in consulta-
5 tion with such other heads of agencies as appro-
6 priate, shall appoint not more than 17 members to
7 the Advisory Committee. In appointing such mem-
8 bers, the Secretary shall ensure that the total mem-
9 bership of the Advisory Committee is an odd num-
10 ber.

11 “(2) REQUIRED MEMBERS.—The Advisory
12 Committee shall include Federal members or their
13 designees (who may be non-voting members, as de-
14 termined by the Secretary) and non-Federal mem-
15 bers, as follows:

16 “(A) The Assistant Secretary for Pre-
17 paredness and Response.

18 “(B) The Director of the Biomedical Ad-
19 vanced Research and Development Authority.

20 “(C) The Director of the Centers for Dis-
21 ease Control and Prevention.

22 “(D) The Commissioner of Food and
23 Drugs.

24 “(E) The Director of the National Insti-
25 tutes of Health.

1 “(F) The Administrator of the Centers for
2 Medicare & Medicaid Services.

3 “(G) The Administrator of the Administra-
4 tion for Community Living.

5 “(H) The Administrator of the Federal
6 Emergency Management Agency.

7 “(I) The Under Secretary for Health of
8 the Department of Veterans Affairs.

9 “(J) At least 2 non-Federal health care
10 professionals with expertise in geriatric medical
11 disaster planning, preparedness, response, or
12 recovery.

13 “(K) At least 2 representatives of State,
14 local, territorial, or tribal agencies with exper-
15 tise in geriatric disaster planning, preparedness,
16 response, or recovery.

17 “(L) Representatives of such other Federal
18 agencies (such as the Department of Energy
19 and the Department of Homeland Security) as
20 the Secretary determines necessary to fulfill the
21 duties of the Advisory Committee.

22 “(e) MEETINGS.—The Advisory Committee shall
23 meet not less frequently than biannually. At least one
24 meeting per year shall be an in-person meeting.

1 “(f) COORDINATION.—The Secretary shall coordinate
 2 duties and activities authorized under this section in ac-
 3 cordance with section 2811D.

4 “(g) SUNSET.—

5 “(1) IN GENERAL.—The Advisory Committee
 6 shall terminate on September 30, 2023.

7 “(2) EXTENSION OF COMMITTEE.—Not later
 8 than October 1, 2022, the Secretary shall submit to
 9 Congress a recommendation on whether the Advisory
 10 Committee should be extended.”.

11 (c) NATIONAL ADVISORY COMMITTEE ON INDIVID-
 12 UALS WITH DISABILITIES AND DISASTERS.—Subtitle B
 13 of title XXVIII of the Public Health Service Act (42
 14 U.S.C. 300hh et seq.), as amended by subsection (b), is
 15 further amended by inserting after section 2811B the fol-
 16 lowing:

17 **“SEC. 2811C. NATIONAL ADVISORY COMMITTEE ON INDIVID-**
 18 **UALS WITH DISABILITIES AND DISASTERS.**

19 “(a) ESTABLISHMENT.—The Secretary, in consulta-
 20 tion with the Secretary of Homeland Security, shall estab-
 21 lish a national advisory committee to be known as the Na-
 22 tional Advisory Committee on Individuals with Disabilities
 23 and Disasters (referred to in this section as the ‘Advisory
 24 Committee’).

25 “(b) DUTIES.—The Advisory Committee shall—

1 “(1) provide advice and consultation with re-
2 spect to activities carried out pursuant to section
3 2814, as applicable and appropriate;

4 “(2) evaluate and provide input with respect to
5 the medical, public health, and accessibility needs of
6 individuals with disabilities related to preparation
7 for, response to, and recovery from all-hazards emer-
8 gencies; and

9 “(3) provide advice and consultation with re-
10 spect to State emergency preparedness and response
11 activities, including related drills and exercises pur-
12 suant to the preparedness goals under section
13 2802(b).

14 “(c) MEMBERSHIP.—

15 “(1) IN GENERAL.—The Secretary, in consulta-
16 tion with such other heads of agencies and depart-
17 ments as appropriate, shall appoint not more than
18 17 members to the Advisory Committee. In appoint-
19 ing such members, the Secretary shall ensure that
20 the total membership of the Advisory Committee is
21 an odd number.

22 “(2) REQUIRED MEMBERS.—The Advisory
23 Committee shall include Federal members or their
24 designees (who may be non-voting members, as de-

1 terminated by the Secretary) and non-Federal mem-
2 bers, as follows:

3 “(A) The Assistant Secretary for Pre-
4 paredness and Response.

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

7 “(C) The Director of the Biomedical Ad-
8 vanced Research and Development Authority.

9 “(D) The Director of the Centers for Dis-
10 ease Control and Prevention.

11 “(E) The Commissioner of Food and
12 Drugs.

13 “(F) The Director of the National Insti-
14 tutes of Health.

15 “(G) The Administrator of the Federal
16 Emergency Management Agency.

17 “(H) The Chair of the National Council on
18 Disability.

19 “(I) The Chair of the United States Access
20 Board.

21 “(J) The Under Secretary for Health of
22 the Department of Veterans Affairs.

23 “(K) At least 2 non-Federal health care
24 professionals with expertise in disability accessi-
25 bility before, during, and after disasters, med-

1 ical and mass care disaster planning, prepared-
2 ness, response, or recovery.

3 “(L) At least 2 representatives from State,
4 local, territorial, or tribal agencies with exper-
5 tise in disaster planning, preparedness, re-
6 sponse, or recovery for individuals with disabil-
7 ities.

8 “(M) At least 2 individuals with a dis-
9 ability with expertise in disaster planning, pre-
10 paredness, response, or recovery for individuals
11 with disabilities.

12 “(d) MEETINGS.—The Advisory Committee shall
13 meet not less frequently than biannually. At least one
14 meeting per year shall be an in-person meeting.

15 “(e) DISABILITY DEFINED.—For purposes of this
16 section, the term ‘disability’ has the meaning given such
17 term in section 3 of the Americans with Disabilities Act
18 of 1990.

19 “(f) COORDINATION.—The Secretary shall coordinate
20 duties and activities authorized under this section in ac-
21 cordance with section 2811D.

22 “(g) SUNSET.—

23 “(1) IN GENERAL.—The Advisory Committee
24 shall terminate on September 30, 2023.

1 “(2) RECOMMENDATION.—Not later than Octo-
2 ber 1, 2022, the Secretary shall submit to Congress
3 a recommendation on whether the Advisory Com-
4 mittee should be extended.”.

5 (d) ADVISORY COMMITTEE COORDINATION.—Sub-
6 title B of title XXVIII of the Public Health Service Act
7 (42 U.S.C. 300hh et seq.), as amended by subsection (c),
8 is further amended by inserting after section 2811C the
9 following:

10 **“SEC. 2811D. ADVISORY COMMITTEE COORDINATION.**

11 “(a) IN GENERAL.—The Secretary shall coordinate
12 duties and activities authorized under sections 2811A,
13 2811B, and 2811C, and make efforts to reduce unneces-
14 sary or duplicative reporting, or unnecessary duplicative
15 meetings and recommendations under such sections, as
16 practicable. Members of the advisory committees author-
17 ized under such sections, or their designees, shall annually
18 meet to coordinate any recommendations, as appropriate,
19 that may be similar, duplicative, or overlapping with re-
20 spect to addressing the needs of children, seniors, and in-
21 dividuals with disabilities during public health emer-
22 gencies. If such coordination occurs through an in-person
23 meeting, it shall not be considered the required in-person
24 meetings under any of sections 2811A(e), 2811B(e), or
25 2811C(d).

1 “(b) COORDINATION AND ALIGNMENT.—The Sec-
2 retary, acting through the employee designated pursuant
3 to section 2814, shall align preparedness and response
4 programs or activities to address similar, dual, or overlap-
5 ping needs of children, seniors, and individuals with dis-
6 abilities, and any challenges in preparing for and respond-
7 ing to such needs.

8 “(c) NOTIFICATION.—The Secretary shall annually
9 notify the congressional committees of jurisdiction regard-
10 ing the steps taken to coordinate, as appropriate, the rec-
11 ommendations under this section, and provide a summary
12 description of such coordination.”.

13 **SEC. 306. GUIDANCE FOR PARTICIPATION IN EXERCISES**
14 **AND DRILLS.**

15 Not later than 2 years after the date of enactment
16 of this Act, the Secretary of Health and Human Services
17 shall issue final guidance regarding the ability of per-
18 sonnel funded by programs authorized under this Act (in-
19 cluding the amendments made by this Act) to participate
20 in drills and operational exercises related to all-hazards
21 medical and public health preparedness and response.
22 Such drills and operational exercises may include activities
23 that incorporate medical surge capacity planning, medical
24 countermeasure distribution and administration, and pre-
25 paring for and responding to identified threats for that

1 region. Such personnel may include State, local, tribal,
 2 and territorial public health department or agency per-
 3 sonnel funded under this Act (including the amendments
 4 made by this Act). The Secretary shall consult with the
 5 Department of Homeland Security, the Department of
 6 Defense, the Department of Veterans Affairs, and other
 7 applicable Federal departments and agencies as necessary
 8 and appropriate in the development of such guidance. The
 9 Secretary shall make the guidance available on the inter-
 10 net website of the Department of Health and Human
 11 Services.

12 **TITLE IV—PRIORITIZING A** 13 **THREAT-BASED APPROACH**

14 **SEC. 401. ASSISTANT SECRETARY FOR PREPAREDNESS AND** 15 **RESPONSE.**

16 Section 2811 of the Public Health Service Act (42
 17 U.S.C. 300hh–10) is amended—

18 (1) in subsection (b)—

19 (A) in the matter preceding paragraph (1)
 20 by inserting “utilize experience related to public
 21 health emergency preparedness and response,
 22 biodefense, medical countermeasures, and other
 23 relevant topics to” after “shall”; and

24 (B) in paragraph (4) by adding at the end
 25 the following:

1 “(I) THREAT AWARENESS.—Coordinate
2 with the Director of the Centers for Disease
3 Control and Prevention, the Director of Na-
4 tional Intelligence, the Secretary of Homeland
5 Security, the Assistant to the President for Na-
6 tional Security Affairs, the Secretary of De-
7 fense, and other relevant Federal officials, such
8 as the Secretary of Agriculture, to maintain a
9 current assessment of national security threats
10 and inform preparedness and response capabili-
11 ties based on the range of the threats that have
12 the potential to result in a public health emer-
13 gency.”; and

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

15 “(f) PROTECTION OF NATIONAL SECURITY FROM
16 THREATS.—

17 “(1) IN GENERAL.—In carrying out the duties
18 under subsection (b)(3), the Assistant Secretary for
19 Preparedness and Response shall implement stra-
20 tegic initiatives or activities to address threats, in-
21 cluding pandemic influenza, that pose a significant
22 level of risk to public health and national security
23 based on the characteristics of such threat, which
24 may also include a chemical, biological, radiological,
25 or nuclear agent, including threats with a significant

1 potential to become a pandemic. Such initiatives
2 shall include activities to accelerate and support the
3 advanced research, development, manufacturing ca-
4 pacity, procurement, and stockpiling of counter-
5 measures, including initiatives under section
6 319L(c)(4)(F). Such activities may also include
7 those related to readiness to respond to pandemic in-
8 fluenza threats by supporting the development and
9 manufacturing of influenza virus seeds, clinical trial
10 lots, and stockpiles of novel influenza strains.

11 “(2) AUTHORIZATION OF APPROPRIATIONS.—

12 “(A) IN GENERAL.—For purposes of car-
13 rying out this subsection, there is authorized to
14 be appropriated \$250,000,000 for each of fiscal
15 years 2019 through 2023.

16 “(B) SUPPLEMENT, NOT SUPPLANT.—
17 Funds appropriated under this subsection shall
18 be used to supplement and not supplant funds
19 provided under section 319L(e) and section
20 319F–2(g).

21 “(C) DOCUMENTATION REQUIRED.—The
22 Assistant Secretary for Preparedness and Re-
23 sponse shall, as required under subsection
24 (b)(7), document amounts expended for pur-
25 poses of carrying out this subsection, including

1 amounts appropriated to the Public Health and
2 Social Services Emergency Fund under title II
3 of Division H of the Consolidated Appropria-
4 tions Act, 2018 (Public Law 115–141), as ap-
5 plicable to section 319L(c)(4)(F).”.

6 **SEC. 402. PUBLIC HEALTH EMERGENCY MEDICAL COUN-**
7 **TERMEASURES ENTERPRISE.**

8 (a) IN GENERAL.—Title XXVIII is amended by in-
9 serting after section 2811 of the Public Health Service
10 Act (42 U.S.C. 300hh–10) the following:

11 **“SEC. 2811–1. PUBLIC HEALTH EMERGENCY MEDICAL**
12 **COUNTERMEASURES ENTERPRISE.**

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

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

21 “(1) The Assistant Secretary for Preparedness
22 and Response.

23 “(2) The Director of the Centers for Disease
24 Control and Prevention.

1 “(3) The Director of the National Institutes of
2 Health.

3 “(4) The Commissioner of Food and Drugs.

4 “(5) The Secretary of Defense.

5 “(6) The Secretary of Homeland Security.

6 “(7) The Secretary of Agriculture.

7 “(8) The Secretary of Veterans Affairs.

8 “(9) The Director of National Intelligence.

9 “(10) Representatives of any other Federal
10 agency, which may include the Director of the Bio-
11 medical Advanced Research and Development Au-
12 thority, the Director of the Strategic National Stock-
13 pile, the Director of the National Institute of Allergy
14 and Infectious Diseases, and the Director of the Of-
15 fice of Public Health Preparedness and Response, as
16 the Secretary determines appropriate.

17 “(c) FUNCTIONS.—

18 “(1) IN GENERAL.—The functions of the
19 PHEMCE shall include the following:

20 “(A) Utilize a process to make rec-
21 ommendations to the Secretary regarding re-
22 search, advanced research, development, pro-
23 curement, stockpiling, deployment, distribution,
24 and utilization with respect to countermeasures,
25 as defined in section 319F–2(c), including

1 prioritization based on the health security needs
2 of the United States. Such recommendations
3 shall be informed by, when available and prac-
4 ticable, the National Health Security Strategy
5 pursuant to section 2802, the Strategic Na-
6 tional Stockpile needs pursuant to section
7 319F-2, and assessments of current national
8 security threats, including chemical, biological,
9 radiological and nuclear threats, including
10 emerging infectious diseases. In the event that
11 members of the PHEMCE do not agree upon a
12 recommendation, the Secretary shall provide a
13 determination regarding such recommendation.

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

22 “(C) Assist the Secretary in developing
23 strategies related to logistics, deployment, dis-
24 tribution, dispensing, and use of counter-
25 measures that may be applicable to the activi-

1 ties of the strategic national stockpile under
2 section 319F–2(a).

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

6 “(2) INPUT.—In carrying out subparagraphs
7 (B) and (C) of paragraph (1), the PHEMCE shall
8 solicit and consider input from State, local, tribal,
9 and territorial public health departments or officials,
10 as appropriate.”.

11 (b) PUBLIC HEALTH EMERGENCY MEDICAL COUN-
12 TERMEASURES ENTERPRISE STRATEGY AND IMPLEMEN-
13 TATION PLAN.—Section 2811(d) of the Public Health
14 Service Act (42 U.S.C. 300hh–10(d)) is amended—

15 (1) in paragraph (1)—

16 (A) by striking “Not later than 180 days
17 after the date of enactment of this subsection,
18 and every year thereafter” and inserting “Not
19 later than March 15, 2020, and biennially
20 thereafter”; and

21 (B) by striking “Director of Biomedical”
22 and all that follows through “Food and Drugs”
23 and inserting “Public Health Emergency Med-
24 ical Countermeasures Enterprise established
25 under section 2811–1”; and

1 (2) in paragraph (2)(J)(v), by striking “one-
2 year period” and inserting “2-year period”.

3 **SEC. 403. STRATEGIC NATIONAL STOCKPILE.**

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

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

8 (2) in paragraph (1)—

9 (A) by inserting “the Assistant Secretary
10 for Preparedness and Response and” after “col-
11 laboration with”;

12 (B) by inserting “and optimize” after
13 “provide for”;

14 (C) by inserting “and, as informed by ex-
15 isting recommendations of, or consultations
16 with, the Public Health Emergency Medical
17 Countermeasure Enterprise established under
18 section 2811–1, make necessary additions or
19 modifications to the contents of such stockpile
20 or stockpiles based on the review conducted
21 under paragraph (2)” before the period of the
22 first sentence; and

23 (D) by striking the second sentence;

24 (3) by inserting after paragraph (1) the fol-
25 lowing:

1 “(2) THREAT-BASED REVIEW.—

2 “(A) IN GENERAL.—The Secretary shall
3 conduct an annual threat-based review (taking
4 into account at-risk individuals) of the contents
5 of the stockpile under paragraph (1), including
6 non-pharmaceutical supplies, and, in consulta-
7 tion with the Public Health Emergency Medical
8 Countermeasures Enterprise established under
9 section 2811–1, review contents within the
10 stockpile and assess whether such contents are
11 consistent with the recommendations made pur-
12 suant to section 2811–1(c)(1)(A). Such review
13 shall be submitted annually, beginning on
14 March 15, 2019, to the Committee on Health,
15 Education, Labor, and Pensions and the Com-
16 mittee on Appropriations of the Senate and the
17 Committee on Energy and Commerce and the
18 Committee on Appropriations of the House of
19 Representatives, in a manner that does not
20 compromise national security.

21 “(B) ADDITIONS, MODIFICATIONS, AND
22 REPLENISHMENTS.—Each annual threat-based
23 review under subparagraph (A) shall, for each
24 new or modified countermeasure procurement
25 or replenishment, provide—

1 “(i) information regarding—

2 “(I) the quantities of the addi-
3 tional or modified countermeasure
4 procured for, or contracted to be pro-
5 cured for, the stockpile;

6 “(II) planning considerations for
7 appropriate manufacturing capacity
8 and capability to meet the goals of
9 such additions or modifications (with-
10 out disclosing proprietary informa-
11 tion), including consideration of the
12 effect such additions or modifications
13 may have on the availability of such
14 products and ancillary medical sup-
15 plies in the health care system;

16 “(III) the presence or lack of a
17 commercial market for the counter-
18 measure at the time of procurement;

19 “(IV) the emergency health secu-
20 rity threat or threats such counter-
21 measure procurement is intended to
22 address, including whether such pro-
23 curement is consistent with meeting
24 emergency health security needs asso-
25 ciated with such threat or threats;

1 “(V) an assessment of whether
2 the emergency health security threat
3 or threats described in subclause (IV)
4 could be addressed in a manner that
5 better utilizes the resources of the
6 stockpile and permits the greatest
7 possible increase in the level of emer-
8 gency preparedness to address such
9 threats;

10 “(VI) whether such counter-
11 measure is replenishing an expiring or
12 expired countermeasure, is a different
13 countermeasure with the same indica-
14 tion that is replacing an expiring or
15 expired countermeasure, or is a new
16 addition to the stockpile;

17 “(VII) a description of how such
18 additions or modifications align with
19 projected investments under previous
20 countermeasures budget plans under
21 section 2811(b)(7), including expected
22 life-cycle costs, expenditures related to
23 countermeasure procurement to ad-
24 dress the threat or threats described
25 in subclause (IV), replenishment dates

1 (including the ability to extend the
2 maximum shelf life of a counter-
3 measure), and the manufacturing ca-
4 pacity required to replenish such
5 countermeasure; and

6 “(VIII) appropriate protocols and
7 processes for the deployment, distribu-
8 tion, or dispensing of the counter-
9 measure at the State and local level,
10 including plans for relevant capabili-
11 ties of State and local entities to dis-
12 pense, distribute, and administer the
13 countermeasure; and

14 “(ii) an assurance, which need not be
15 provided in advance of procurement, that
16 for each countermeasure procured or re-
17 plenished under this subsection, the Sec-
18 retary completed a review addressing each
19 item listed under this subsection in ad-
20 vance of such procurement or replenish-
21 ment.”;

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

23 (A) in subparagraph (A), by inserting
24 “and the Public Health Emergency Medical

1 Countermeasures Enterprise established under
2 section 2811–1” before the semicolon;

3 (B) in subparagraph (C), by inserting “,
4 and the availability, deployment, dispensing,
5 and administration of countermeasures” before
6 the semicolon;

7 (C) by amending subparagraph (E) to read
8 as follows:

9 “(E) devise plans for effective and timely
10 supply-chain management of the stockpile, in
11 consultation with the Director of the Centers
12 for Disease Control and Prevention, the Assist-
13 ant Secretary for Preparedness and Response,
14 the Secretary of Transportation, the Secretary
15 of Homeland Security, the Secretary of Vet-
16 erans Affairs, and the heads of other appro-
17 priate Federal agencies; State, local, tribal, and
18 territorial agencies; and the public and private
19 health care infrastructure, as applicable, taking
20 into account the manufacturing capacity and
21 other available sources of products and appro-
22 priate alternatives to supplies in the stockpile;”;

23 (D) in subparagraph (G), by striking “;
24 and” and inserting a semicolon;

1 (E) in subparagraph (H), by striking the
2 period and inserting a semicolon; and

3 (F) by adding at the end the following:

4 “(I) ensure that each countermeasure or
5 product under consideration for procurement
6 pursuant to this subsection receives the same
7 consideration regardless of whether such coun-
8 termeasure or product receives or had received
9 funding under section 319L, including with re-
10 spect to whether the countermeasure or product
11 is most appropriate to meet the emergency
12 health security needs of the United States; and

13 “(J) provide assistance, including technical
14 assistance, to maintain and improve State and
15 local public health preparedness capabilities to
16 distribute and dispense medical counter-
17 measures and products from the stockpile, as
18 appropriate.”; and

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

20 “(5) GAO REPORT.—

21 “(A) IN GENERAL.—Not later than 3 years
22 after the date of enactment of the Pandemic
23 and All-Hazards Preparedness and Advancing
24 Innovation Act of 2018, and every 5 years
25 thereafter, the Comptroller General of the

1 United States shall conduct a review of any
2 changes to the contents or management of the
3 stockpile since January 1, 2015. Such review
4 shall include—

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

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

1 to procurement, modification, or replenish-
2 ment;

3 “(iii) an assessment of the plans de-
4 veloped by the Secretary for the deploy-
5 ment, distribution, and dispensing of coun-
6 termeasures procured, modified, or replen-
7 ished under paragraph (1), including
8 whether such plans were developed prior to
9 procurement, modification, or replenish-
10 ment;

11 “(iv) an accounting of counter-
12 measures procured, modified, or replen-
13 ished under paragraph (1) that received
14 advanced research and development fund-
15 ing from the Biomedical Advanced Re-
16 search and Development Authority;

17 “(v) an analysis of how such procure-
18 ment decisions made progress toward
19 meeting emergency health security needs
20 related to the identified threats for coun-
21 termeasures added, modified, or replen-
22 ished under paragraph (1);

23 “(vi) a description of the resources ex-
24 pended related to the procurement of coun-
25 termeasures (including additions, modifica-

1 tions, and replenishments) in the stockpile,
2 and how such expenditures relate to the
3 ability of the stockpile to meet emergency
4 health security needs;

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

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

21 “(ix) an assessment of whether the
22 processes and procedures described by the
23 Secretary pursuant to section 403(b) of
24 the Pandemic and All-Hazards Prepared-
25 ness and Advancing Innovation Act of

1 2018 are sufficient to ensure counter-
2 measures and products under consideration
3 for procurement pursuant to subsection (a)
4 receive the same consideration regardless
5 of whether such countermeasures and
6 products receive or had received funding
7 under section 319L, including with respect
8 to whether such countermeasures and
9 products are most appropriate to meet the
10 emergency health security needs of the
11 United States.

12 “(B) SUBMISSION.—Not later than 6
13 months after completing a classified version of
14 the review under subparagraph (A), the Comp-
15 troller General shall submit an unclassified
16 version of the review to the congressional com-
17 mittees of jurisdiction.”.

18 (b) ADDITIONAL REPORTING.—In the first threat-
19 based review submitted after the date of enactment of this
20 Act pursuant to paragraph (2) of section 319F–2(a) of
21 the Public Health Service Act (42 U.S.C. 247d–6b(a)), as
22 amended by subsection (a), the Secretary shall include a
23 description of the processes and procedures through which
24 the Director of Strategic National Stockpile and the Di-
25 rector of the Biomedical Advanced Research and Develop-

1 ment Authority coordinate with respect to counter-
2 measures and products procured under such section
3 319F–2(a), including such processes and procedures in
4 place to ensure countermeasures and products under con-
5 sideration for procurement pursuant to such section
6 319F–2(a) receive the same consideration regardless of
7 whether such countermeasures and products receive or
8 had received funding under section 319L of the Public
9 Health Service Act (42 U.S.C. 247d–7e), and whether
10 such countermeasures and products are the most appro-
11 priate to meet the emergency health security needs of the
12 United States.

13 (c) AUTHORIZATION OF APPROPRIATIONS, STRA-
14 TEGIC NATIONAL STOCKPILE.—Section 319F–2(f)(1) of
15 the Public Health Service Act (42 U.S.C. 247d–6b(f)(1))
16 is amended by striking “\$533,800,000 for each of fiscal
17 years 2014 through 2018” and inserting “\$610,000,000
18 for each of fiscal years 2019 through 2023, to remain
19 available until expended”.

20 **SEC. 404. PREPARING FOR PANDEMIC INFLUENZA, ANTI-**
21 **MICROBIAL RESISTANCE, AND OTHER SIG-**
22 **NIFICANT THREATS.**

23 (a) STRATEGIC INITIATIVES.—Section 319L(c)(4)
24 (247d–7e(c)(4)) is amended by adding at the end the fol-
25 lowing:

“(F) STRATEGIC INITIATIVES.—The Secretary, acting through the Director of BARDA, may implement strategic initiatives, including by building on existing programs and by awarding contracts, grants, and cooperative agreements, or entering into other transactions, to support innovative candidate products in pre-clinical and clinical development that address priority, naturally occurring and man-made threats that, as determined by the Secretary, pose a significant level of risk to national security based on the characteristics of a chemical, biological, radiological or nuclear threat, or existing capabilities to respond to such a threat (including medical response and treatment capabilities and manufacturing infrastructure). Such initiatives shall accelerate and support the advanced research, development, and procurement of, countermeasures and products, as applicable, to address areas including—

“(i) chemical, biological, radiological, or nuclear threats, including emerging infectious diseases, for which insufficient approved, licensed, or authorized countermeasures exist, or for which such threat,

1 or the result of an exposure to such threat,
2 may become resistant to countermeasures
3 or existing countermeasures may be ren-
4 dered ineffective;

5 “(ii) threats that consistently exist or
6 continually circulate and have significant
7 potential to become a pandemic, such as
8 pandemic influenza, which may include the
9 advanced research and development, manu-
10 facturing, and appropriate stockpiling of
11 qualified pandemic or epidemic products,
12 and products, technologies, or processes to
13 support the advanced research and devel-
14 opment of such countermeasures (including
15 multiuse platform technologies for
16 diagnostics, vaccines, and therapeutics;
17 virus seeds; clinical trial lots; novel virus
18 strains; and antigen and adjuvant mate-
19 rial); and

20 “(iii) threats that may result pri-
21 marily or secondarily from a chemical, bio-
22 logical, radiological, or nuclear agent, or
23 emerging infectious diseases, and which
24 may present increased treatment complica-
25 tions such as the occurrence of resistance

1 to available countermeasures or potential
2 countermeasures, including antimicrobial
3 resistant pathogens.”.

4 (b) EMERGING INFECTIOUS DISEASE PROGRAM.—
5 Section 319L of the Public Health Service Act (42 U.S.C.
6 247d–7e) is amended—

7 (1) by redesignating subsections (d), (e), and
8 (f) as subsections (e), (f), and (g), respectively; and

9 (2) by inserting after subsection (c) the fol-
10 lowing new subsections:

11 “(d) EMERGING INFECTIOUS DISEASE PROGRAM.—

12 “(1) IN GENERAL.—The Secretary, acting
13 through the Director of BARDA, shall establish and
14 implement a program that supports—

15 “(A) advanced research and development
16 activities for qualified pandemic or epidemic
17 products; and

18 “(B) manufacturing infrastructure activi-
19 ties with respect to an emerging infectious dis-
20 ease.

21 “(2) FUNDING.—

22 “(A) IN GENERAL.—To carry out para-
23 graph (1), there is authorized to be appro-
24 priated \$250,000,000 for each of fiscal years

1 2019 through 2023, to remain available until
2 expended.

3 “(B) SUPPLEMENT NOT SUPPLANT.—Any
4 funds provided to the Secretary under this
5 paragraph shall be used to supplement and not
6 supplant any other Federal funds provided to
7 carry out paragraph (1).”.

8 **SEC. 405. REPORTING ON THE FEDERAL SELECT AGENT**
9 **PROGRAM.**

10 Section 351A(k) of the Public Health Service Act (42
11 U.S.C. 262a(k)) is amended—

12 (1) by striking “The Secretary” and inserting
13 the following:

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

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

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

20 “(A) IN GENERAL.—Not later than 1 year
21 after the date of the enactment of the Pan-
22 demic and All-Hazards Preparedness and Ad-
23 vancing Innovation Act of 2018, the Secretary
24 shall report to the congressional committees of
25 jurisdiction on the implementation of rec-

ommendations of the Federal Experts Security
Advisory Panel concerning the select agent pro-
gram.

“(B) CONTINUED UPDATES.—The Sec-
retary shall report to the congressional commit-
tees of jurisdiction annually following the sub-
mission of the report under subparagraph (A)
until the recommendations described in such
subparagraph are fully implemented, or a jus-
tification is provided for the delay in, or lack of,
implementation.”.

TITLE V—INCREASING COMMU- NICATION IN MEDICAL COUN- TERMEASURE ADVANCED RE- SEARCH AND DEVELOPMENT

SEC. 501. MEDICAL COUNTERMEASURE BUDGET PLAN.

Section 2811(b)(7) of the Public Health Service Act
(42 U.S.C. 300hh–10(b)(7)) is amended—

(1) in the matter preceding subparagraph (A),
by striking “March 1” and inserting “March 15”;

(2) in subparagraph (A)—

(A) in clause (ii), by striking “; and” and
inserting “;”; and

(B) by striking clause (iii) and inserting
the following:

1 “(iii) procurement, stockpiling, main-
2 tenance, and potential replenishment (in-
3 cluding manufacturing capabilities) of all
4 products in the Strategic National Stock-
5 pile;

6 “(iv) the availability of technologies
7 that may assist in the advanced research
8 and development of countermeasures and
9 opportunities to use such technologies to
10 accelerate and navigate challenges unique
11 to countermeasure research and develop-
12 ment; and

13 “(v) potential deployment, distribu-
14 tion, and utilization of medical counter-
15 measures; development of clinical guidance
16 and emergency use instructions for the use
17 of medical countermeasures; and, as appli-
18 cable, potential post-deployment activities
19 related to medical countermeasures;”;

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

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;”.

6 **SEC. 502. MATERIAL THREAT AND MEDICAL COUNTER-**
 7 **MEASURE NOTIFICATIONS.**

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

22 (b) CONTRACTING COMMUNICATION.—Section 319F–
 23 2(c)(7)(B)(ii)(III) of the Public Health Service Act (42
 24 U.S.C. 247d–6b(c)(7)(B)(ii)(III)) is amended by adding
 25 at the end the following: “The Secretary shall notify the

1 vendor within 90 days of a determination by the Secretary
2 to renew, extend, or terminate such contract.”.

3 **SEC. 503. AVAILABILITY OF REGULATORY MANAGEMENT**
4 **PLANS.**

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

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

9 (2) by inserting after paragraph (2) the fol-
10 lowing:

11 “(3) PUBLICATION.—The Secretary shall make
12 available on the internet website of the Food and
13 Drug Administration information regarding regu-
14 latory management plans, including—

15 “(A) the process by which an applicant
16 may submit a request for a regulatory manage-
17 ment plan;

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

20 “(C) the information required for the sub-
21 mission of such request;

22 “(D) a description of the types of develop-
23 ment milestones and performance targets that
24 could be discussed and included in such plans;
25 and

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

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

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

7 (B) by striking “paragraph (4)(B)” and
8 inserting “paragraph (5)(B)”; and

9 (4) in paragraph (7)(A), as so redesignated, by
10 striking “paragraph (3)(A)” and inserting “para-
11 graph (4)(A)”.

12 **SEC. 504. THE BIOMEDICAL ADVANCED RESEARCH AND DE-**
13 **VELOPMENT AUTHORITY AND THE BIO-**
14 **SHIELD SPECIAL RESERVE FUND.**

15 (a) BIOSHIELD SPECIAL RESERVE FUND.—Section
16 319F–2(g)(1) of the Public Health Service Act (42 U.S.C.
17 247d–6b(g)(1)) is amended—

18 (1) by striking “\$2,800,000,000 for the period
19 of fiscal years 2014 through 2018” and inserting
20 “\$7,100,000,000 for the period of fiscal years 2019
21 through 2028, to remain available until expended”;
22 and

23 (2) by striking the second sentence.

24 (b) THE BIOMEDICAL ADVANCED RESEARCH AND
25 DEVELOPMENT AUTHORITY.—Subsection (e)(2) of section

1 319L of the Public Health Service Act (42 U.S.C. 247d–
 2 7e), as redesignated by section 404(b), is amended by
 3 striking “\$415,000,000 for each of fiscal years 2014
 4 through 2018” and inserting “\$611,700,000 for each of
 5 fiscal years 2019 through 2023”.

6 **SEC. 505. ADDITIONAL STRATEGIES FOR COMBATING ANTI-**
 7 **BIOTIC RESISTANCE.**

8 Part B of title III of the Public Health Service Act
 9 (42 U.S.C. 243 et seq.) is amended by inserting after sec-
 10 tion 319E the following:

11 **“SEC. 319E-1. ADVISORY COUNCIL ON COMBATING ANTI-**
 12 **BIOTIC-RESISTANT BACTERIA.**

13 “(a) DEFINITIONS.—In this section:

14 “(1) ACTION PLAN.—The term ‘Action Plan’
 15 means the Action Plan described in section
 16 319E(a)(1).

17 “(2) ADVISORY COUNCIL.—The term ‘Advisory
 18 Council’ means the Presidential Advisory Council on
 19 Combating Antibiotic-Resistant Bacteria established
 20 by Executive Order 13676 of September 18, 2014
 21 (79 Fed. Reg. 56931; relating to combating anti-
 22 biotic-resistant bacteria).

23 “(3) NATIONAL STRATEGY.—The term ‘Na-
 24 tional Strategy’ means the National Strategy for
 25 Combating Antibiotic-Resistant Bacteria issued by

1 the White House in September 2014, and any subse-
2 quent update to such strategy or a successor strat-
3 egy.

4 “(b) ADVISORY COUNCIL.—The Advisory Council
5 shall provide advice, information, and recommendations to
6 the Secretary regarding programs and policies intended to
7 support and evaluate the implementation of Executive
8 Order 13676 of September 18, 2014 (79 Fed. Reg. 56931;
9 relating to combating antibiotic-resistant bacteria), includ-
10 ing the National Strategy, and the Action Plan.

11 “(c) MEETINGS AND DUTIES.—

12 “(1) MEETINGS.—The Advisory Council shall
13 meet as the Chair determines appropriate but not
14 less than twice per year, and, to the extent prac-
15 ticable, in conjunction with meetings of the task
16 force described in section 319E.

17 “(2) RECOMMENDATIONS.—The Advisory Coun-
18 cil shall make recommendations to the Secretary, in
19 consultation with the Secretary of Agriculture and
20 the Secretary of Defense, regarding programs and
21 policies intended to—

22 “(A) preserve the effectiveness of anti-
23 biotics by optimizing their use;

24 “(B) advance research to develop improved
25 methods for combating antibiotic resistance and

1 conducting antimicrobial stewardship, as de-
2 fined in section 319E(h)(3);

3 “(C) strengthen surveillance of antibiotic-
4 resistant bacterial infections;

5 “(D) prevent the transmission of anti-
6 biotic-resistant bacterial infections;

7 “(E) advance the development of rapid
8 point-of-care and agricultural diagnostics;

9 “(F) further research on new treatments
10 for bacterial infections;

11 “(G) develop alternatives to antibiotics for
12 animal health purposes;

13 “(H) maximize the dissemination of up-to-
14 date information on the appropriate and proper
15 use of antibiotics to the general public and
16 human and animal health care providers; and

17 “(I) improve international coordination of
18 efforts to combat antibiotic resistance.

19 “(3) COORDINATION.—The Advisory Council
20 shall, to the greatest extent practicable, coordinate
21 activities carried out by the Council with the Anti-
22 microbial Resistance Task Force established under
23 section 319E(a) (commonly referred to as the ‘Com-
24 bating Antibiotic-Resistant Bacteria Task Force’).”.

1 **TITLE VI—ADVANCING TECH-**
2 **NOLOGIES FOR MEDICAL**
3 **COUNTERMEASURES**

4 **SEC. 601. ADMINISTRATION OF COUNTERMEASURES.**

5 Section 319L(c)(4)(D)(iii) of the Public Health Serv-
6 ice Act (42 U.S.C. 247d–7e(c)(4)(D)(iii)) is amended by
7 striking “and platform technologies” and inserting “plat-
8 form technologies, technologies to administer counter-
9 measures, and technologies to improve storage and trans-
10 portation of countermeasures”.

11 **SEC. 602. UPDATING DEFINITIONS OF OTHER TRANS-**
12 **ACTIONS.**

13 Section 319L of the Public Health Service Act (42
14 U.S.C. 247d–7e) is amended—

15 (1) in subsection (a)(3), by striking “, such as”
16 and all that follows through “Code”;

17 (2) in subsection (c)(5)(A)—

18 (A) in clause (i), by striking “under this
19 subsection” and all that follows through “Code”
20 and inserting “(as defined in subsection (a)(3))
21 under this subsection”; and

22 (B) in clause (ii)—

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

1 “(I) IN GENERAL.—To the max-
 2 imum extent practicable, competitive
 3 procedures shall be used when enter-
 4 ing into transactions to carry out
 5 projects under this subsection.”; and
 6 (ii) in subclause (II)—

7 (I) by striking “\$20,000,000”
 8 and inserting “\$100,000,000”;

9 (II) by striking “senior procure-
 10 ment executive for the Department
 11 (as designated for the purpose of sec-
 12 tion 16(c) of the Office of Federal
 13 Procurement Policy Act (41 U.S.C.
 14 414(c)))” and inserting “Assistant
 15 Secretary for Financial Resources”;
 16 and

17 (III) by striking “senior procure-
 18 ment executive under” and inserting
 19 “Assistant Secretary for Financial Re-
 20 sources under”.

21 **SEC. 603. MEDICAL COUNTERMEASURE MASTER FILES.**

22 (a) IN GENERAL.—The purpose of this section (in-
 23 cluding section 565B of the Federal Food, Drug, and Cos-
 24 metic Act, as added by subsection (b)) is to support and
 25 advance the development or manufacture of security coun-

1 termeasures, qualified countermeasures, and qualified
2 pandemic or epidemic products by facilitating and encour-
3 aging submission of data and information to support such
4 products to medical countermeasure master files, and
5 through clarifying the authority to cross-reference to data
6 and information previously submitted to the Secretary of
7 Health and Human Services (referred to in this section
8 as the “Secretary”).

9 (b) MEDICAL COUNTERMEASURE MASTER FILES.—
10 Chapter V of the Federal Food, Drug, and Cosmetic Act
11 (21 U.S.C. 351 et seq.) is amended by inserting after sec-
12 tion 565A the following:

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

14 **“(a) APPLICABILITY OF REFERENCE.—**

15 **“(1) IN GENERAL.—**A person may submit data
16 and information in a master file to the Secretary
17 with the intent to reference, or to authorize, in writ-
18 ing, another person to reference, such data or infor-
19 mation to support a medical countermeasure submis-
20 sion (including a supplement or amendment to any
21 such submission), without requiring the master file
22 holder to disclose the data and information to any
23 such persons authorized to reference the master file.
24 Such data and information shall be available for ref-
25 erence by the master file holder or by a person au-

1 thorized by the master file holder, in accordance
2 with applicable privacy and confidentiality protocols
3 and regulations.

4 “(2) REFERENCE OF CERTAIN MASTER
5 FILES.—In the case that data or information within
6 a medical countermeasure master file is used only to
7 support the conditional approval of an application
8 filed under section 571, such master file may be re-
9 lied upon to help support the effectiveness of a prod-
10 uct that is the subject of a subsequent medical coun-
11 termeasure submission only if such application is
12 supplemented by additional data or information to
13 support review and approval in a manner consistent
14 with the standards applicable to such review and ap-
15 proval for such countermeasure, qualified counter-
16 measure, or qualified pandemic or epidemic product.

17 “(b) MEDICAL COUNTERMEASURE MASTER FILE
18 CONTENT.—

19 “(1) IN GENERAL.—A master file under this
20 section may include data or information to sup-
21 port—

22 “(A) the development of medical counter-
23 measure submissions to support the approval,
24 licensure, classification, clearance, conditional
25 approval, or authorization of one or more secu-

1 rity countermeasures, qualified counter-
2 measures, or qualified pandemic or epidemic
3 products; and

4 “(B) the manufacture of security counter-
5 measures, qualified countermeasures, or quali-
6 fied pandemic or epidemic products.

7 “(2) REQUIRED UPDATES.—The Secretary may
8 require, as appropriate, that the master file holder
9 ensure that the contents of such master file are up-
10 dated during the time such master file is referenced
11 for a medical countermeasure submission.

12 “(c) SPONSOR REFERENCE.—

13 “(1) IN GENERAL.—Each incorporation of data
14 or information within a medical countermeasure
15 master file shall describe the incorporated material
16 in a manner in which the Secretary determines ap-
17 propriate and that permits the review of such infor-
18 mation within such master file without necessitating
19 re-submission of such data or information. Master
20 files shall be submitted in an electronic format in ac-
21 cordance with sections 512(b)(4), 571(a)(4), and
22 745A, as applicable, and as specified in applicable
23 guidance.

24 “(2) REFERENCE BY A MASTER FILE HOLD-
25 ER.—A master file holder that is the sponsor of a

1 medical countermeasure submission shall notify the
2 Secretary in writing of the intent to reference the
3 medical countermeasure master file as a part of the
4 submission.

5 “(3) REFERENCE BY AN AUTHORIZED PER-
6 SON.—A person submitting an application for review
7 may, where the Secretary determines appropriate,
8 incorporate by reference all or part of the contents
9 of a medical countermeasure master file, if the mas-
10 ter file holder authorizes the incorporation in writ-
11 ing.

12 “(d) ACKNOWLEDGEMENT OF THE RELIANCE UPON
13 A MASTER FILE BY THE SECRETARY.—

14 “(1) IN GENERAL.—The Secretary shall provide
15 the master file holder with a written notification in-
16 dicating that the Secretary has reviewed and relied
17 upon specified data or information within a master
18 file and the purposes for which such data or infor-
19 mation was incorporated by reference if the Sec-
20 retary has reviewed and relied upon such specified
21 data or information to support the approval, classi-
22 fication, conditional approval, clearance, licensure, or
23 authorization of a security countermeasure, qualified
24 countermeasure, or qualified pandemic or epidemic
25 product. The Secretary may rely upon the data and

1 information within the medical countermeasure mas-
2 ter file for which such written notification was pro-
3 vided in additional applications, as applicable and
4 appropriate and upon the request of the master file
5 holder so notified in writing or by an authorized per-
6 son of such holder.

7 “(2) CERTAIN APPLICATIONS.—If the Secretary
8 has reviewed and relied upon specified data or infor-
9 mation within a medical countermeasure master file
10 to support the conditional approval of an application
11 under section 571 to subsequently support the ap-
12 proval, clearance, licensure, or authorization of a se-
13 curity countermeasure, qualified countermeasure, or
14 qualified pandemic or epidemic product, the Sec-
15 retary shall provide a brief written description to the
16 master file holder regarding the elements of the ap-
17 plication fulfilled by the data or information within
18 the master file and how such data or information
19 contained in such application meets the standards of
20 evidence under subsection (c) or (d) of section 505,
21 subsection (d) of section 512, or section 351 of the
22 Public Health Service Act (as applicable) unless
23 such disclosure includes any trade secret or con-
24 fidential commercial information.

1 “(e) RULES OF CONSTRUCTION.—Nothing in this
2 section shall be construed to—

3 “(1) limit the authority of the Secretary to ap-
4 prove, license, clear, conditionally approve, or au-
5 thorize drugs, biological products, or devices pursu-
6 ant to, as applicable, this Act or section 351 of the
7 Public Health Service Act (as such applicable Act is
8 in effect on the day before the date of enactment of
9 the Pandemic and All-Hazards Preparedness and
10 Advancing Innovation Act of 2018), including the
11 standards of evidence, and applicable conditions, for
12 approval under the applicable Act;

13 “(2) alter the standards of evidence with re-
14 spect to approval, licensure, or clearance, as applica-
15 ble, of drugs, biological products, or devices under
16 this Act or section 351 of the Public Health Service
17 Act, including, as applicable, the substantial evi-
18 dence standards under sections 505(d) and 512(d)
19 or this Act and section 351(a) of the Public Health
20 Service Act; or

21 “(3) alter the authority of the Secretary under
22 this Act or the Public Health Service Act to deter-
23 mine the types of data or information previously
24 submitted by a sponsor or any other person that
25 may be incorporated by reference in an application,

1 request, or notification for a drug, biological prod-
2 uct, or device submitted under sections 505(i),
3 505(b), 505(j), 512(b)(1), 512(b)(2), 512(j), 564,
4 571, 520(g), 515(c), 513(f)(2), or 510(k) of this
5 Act, or subsection (a) or (k) of section 351 of the
6 Public Health Service Act, including a supplement
7 or amendment to any such submission, and the re-
8 quirements associated with such reference.

9 “(f) DEFINITIONS.—In this section:

10 “(1) The term ‘master file holder’ means a per-
11 son who submits data and information to the Sec-
12 retary with the intent to reference or authorize an-
13 other person to reference such data or information
14 to support a medical countermeasure submission, as
15 described in subsection (a).

16 “(2) The term ‘medical countermeasure submis-
17 sion’ means an investigational new drug application
18 under section 505(i), a new drug application under
19 section 505(b), or an abbreviated new drug applica-
20 tion under section 505(j) of this Act, a biological
21 product license application under section 351(a) of
22 the Public Health Service Act or a biosimilar biologi-
23 cal product license application under section 351(k)
24 of the Public Health Service Act, a new animal drug
25 application under section 512(b)(1) or abbreviated

1 new animal drug application under section
2 512(b)(2), an application for conditional approval of
3 a new animal drug under section 571, an investiga-
4 tional device application under section 520(g), an
5 application with respect to a device under section
6 515(c), a request for classification of a device under
7 section 513(f)(2), a notification with respect to a de-
8 vice under section 510(k), or a request for an emer-
9 gency use authorization under section 564 to sup-
10 port—

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

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

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

24 (c) STAKEHOLDER INPUT.—Not later than 18
25 months after the date of enactment of this Act, the Sec-

1 retary, acting through the Commissioner of Food and
2 Drugs and in consultation with the Assistant Secretary
3 for Preparedness and Response, shall solicit input from
4 stakeholders, including stakeholders developing security
5 countermeasures, qualified countermeasures, or qualified
6 pandemic or epidemic products, and stakeholders devel-
7 oping technologies to assist in the development of such
8 countermeasures with respect to how the Food and Drug
9 Administration can advance the use of tools and tech-
10 nologies to support and advance the development or manu-
11 facture of security countermeasures, qualified counter-
12 measures, and qualified pandemic or epidemic products,
13 including through reliance on cross-referenced data and
14 information contained within master files and submissions
15 previously submitted to the Secretary as set forth in sec-
16 tion 565B of the Federal Food, Drug, and Cosmetic Act,
17 as added by subsection (b).

18 (d) GUIDANCE.—Not later than 2 years after the
19 date of enactment of this Act, the Secretary, acting
20 through the Commissioner of Food and Drugs, shall pub-
21 lish draft guidance about how reliance on cross-referenced
22 data and information contained within master files under
23 section 565B of the Federal Food, Drug, and Cosmetic
24 Act, as added by subsection (b) or submissions otherwise
25 submitted to the Secretary may be used for specific tools

1 or technologies (including platform technologies) that have
2 the potential to support and advance the development or
3 manufacture of security countermeasures, qualified coun-
4 termasures, and qualified pandemic or epidemic products.
5 The Secretary, acting through the Commissioner of Food
6 and Drugs, shall publish the final guidance not later than
7 3 years after the enactment of this Act.

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 subsections (c) and (d) of section 565
12 of the of the Federal Food, Drug, and Cosmetic Act (21
13 U.S.C. 360bbb–4) (referred to in this section as the “ani-
14 mal rule”) as a component of medical countermeasure ad-
15 vanced development under the Biomedical Advanced Re-
16 search and Development Authority and regulatory review
17 by the Food and Drug Administration. In conducting such
18 study, the Comptroller General shall examine the fol-
19 lowing:

20 (1) The extent to which advanced development
21 and review of a medical countermeasure are coordi-
22 nated between the Biomedical Advanced Research
23 and Development Authority and the Food and Drug
24 Administration, including activities that facilitate
25 appropriate and efficient design of studies to sup-

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

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

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

23 (4) The extent to which the guidance issued
24 under section 565(c) of the Federal Food Drug and
25 Cosmetic Act (21 U.S.C. 360bbb–4(c)), entitled,

1 “Product Development Under the Animal Rule:
2 Guidance for Industry” (issued in October 2015),
3 has assisted in achieving the purposes described in
4 paragraphs (1), (2), and (3).

5 (b) CONSULTATIONS.—In conducting the study under
6 subsection (a), the Comptroller General of the United
7 States shall consult with—

8 (1) the Federal agencies responsible for advanc-
9 ing, reviewing, and procuring medical counter-
10 measures, including the Office of the Assistant Sec-
11 retary for Preparedness and Response, the Bio-
12 medical Advanced Research and Development Au-
13 thority, the Food and Drug Administration, and the
14 Department of Defense;

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

19 (3) other biodefense stakeholders, as applicable.

20 (c) REPORT.—Not later than 3 years after the date
21 of enactment of this Act, the Comptroller General of the
22 United States shall submit to the Committee on Health,
23 Education, Labor, and Pensions of the Senate and the
24 Committee on Energy and Commerce of the House of
25 Representatives a report containing the results of the

1 study conducted under subsection (a) and recommenda-
2 tions to improve the application and consistency of the re-
3 quirements under subsections (c) and (d) of section 565
4 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
5 360bbb-4) to support and expedite the research and devel-
6 opment of medical countermeasures, as applicable.

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

12 **SEC. 605. REVIEW OF THE BENEFITS OF GENOMIC ENGI-**
13 **NEERING TECHNOLOGIES AND THEIR POTEN-**
14 **TIAL ROLE IN NATIONAL SECURITY.**

15 (a) MEETING.—

16 (1) IN GENERAL.—Not later than 1 year after
17 the date of enactment of this Act, the Secretary of
18 Health and Human Services (referred to in this sec-
19 tion as the “Secretary”) shall convene a meeting to
20 discuss the potential role advancements in genomic
21 engineering technologies (including genome editing
22 technologies) may have in advancing national health
23 security. Such meeting shall be held in a manner
24 that does not compromise national security.

1 (2) ATTENDEES.—The attendees of the meeting
2 under paragraph (1)—

3 (A) shall include—

4 (i) representatives from the Office of
5 the Assistant Secretary for Preparedness
6 and Response, the National Institutes of
7 Health, the Centers for Disease Control
8 and Prevention, and the Food and Drug
9 Administration; and

10 (ii) representatives from academic,
11 private, and nonprofit entities with exper-
12 tise in genome engineering technologies,
13 biopharmaceuticals, medicine, or bio-
14 defense, and other relevant stakeholders;
15 and

16 (B) may include—

17 (i) other representatives from the De-
18 partment of Health and Human Services,
19 as the Secretary determines appropriate;
20 and

21 (ii) representatives from the Depart-
22 ment of Homeland Security, the Depart-
23 ment of Defense, the Department of Agri-
24 culture, and other departments, as the Sec-
25 retary may request for the meeting.

1 (3) TOPICS.—The meeting under paragraph (1)
2 shall include a discussion of—

3 (A) the current state of the science of
4 genomic engineering technologies related to na-
5 tional health security, including—

6 (i) medical countermeasure develop-
7 ment, including potential efficiencies in the
8 development pathway and detection tech-
9 nologies; and

10 (ii) the international and domestic
11 regulation of products utilizing genome ed-
12 iting technologies; and

13 (B) national security implications, includ-
14 ing—

15 (i) capabilities of the United States to
16 leverage genomic engineering technologies
17 as a part of the medical countermeasure
18 enterprise, including current applicable re-
19 search, development, and application ef-
20 forts underway within the Department of
21 Defense;

22 (ii) the potential for state and non-
23 state actors to utilize genomic engineering
24 technologies as a national health security
25 threat; and

1 (iii) security measures to monitor and
2 assess the potential threat that may result
3 from utilization of genomic engineering
4 technologies and related technologies for
5 the purpose of compromising national
6 health security.

7 (b) REPORT.—Not later than 270 days after the
8 meeting described in subsection (a) is held, the Assistant
9 Secretary for Preparedness and Response shall issue a re-
10 port to the congressional committees of jurisdiction on the
11 topics discussed at such meeting, and provide rec-
12 ommendations, as applicable, to utilize innovations in
13 genomic engineering (including genome editing) and re-
14 lated technologies as a part of preparedness and response
15 activities to advance national health security. Such report
16 shall be issued in a manner that does not compromise na-
17 tional security.

18 **SEC. 606. REPORT ON VACCINES DEVELOPMENT.**

19 Not later than one year after the date of the enact-
20 ment of this Act, the Secretary of Health and Human
21 Services shall submit to the Committee on Health, Edu-
22 cation, Labor, and Pensions of the Senate and the Com-
23 mittee on Energy and Commerce of the House of Rep-
24 resentatives a report describing efforts and activities to
25 coordinate with other countries and international partners

1 during recent public health emergencies with respect to
 2 the research and advanced research on, and development
 3 of, qualified pandemic or epidemic products (as defined
 4 in section 319F–3 of the Public Health Service Act (42
 5 U.S.C. 247d–6d)). Such report may include information
 6 regarding relevant work carried out under section
 7 319L(c)(5)(E) of the Public Health Service Act (42
 8 U.S.C. 247d–7e(c)(5)(E)), through public-private partner-
 9 ships, and through collaborations with other countries to
 10 assist with or expedite the research and development of
 11 qualified pandemic or epidemic products. Such report shall
 12 not include information that may compromise national se-
 13 curity.

14 **SEC. 607. STRENGTHENING MOSQUITO ABATEMENT FOR**
 15 **SAFETY AND HEALTH.**

16 (a) REAUTHORIZATION OF MOSQUITO ABATEMENT
 17 FOR SAFETY AND HEALTH PROGRAM.—Section 317S of
 18 the Public Health Service Act (42 U.S.C. 247b–21) is
 19 amended—

20 (1) in subsection (a)(1)(B)—

21 (A) by inserting “including programs to
 22 address emerging infectious mosquito-borne dis-
 23 eases,” after “subdivisions for control pro-
 24 grams,”; and

1 (B) by inserting “or improving existing
2 control programs” before the period at the end;
3 (2) in subsection (b)—

4 (A) in paragraph (1), by inserting “, in-
5 cluding improvement,” after “operation”;

6 (B) in paragraph (2)—

7 (i) in subparagraph (A)—

8 (I) in clause (ii), by striking “or”
9 at the end;

10 (II) in clause (iii), by striking the
11 semicolon at the end and inserting “,
12 including an emerging infectious mos-
13 quito-borne disease that presents a se-
14 rious public health threat; or”; and

15 (III) by adding at the end the
16 following:

17 “(iv) a public health emergency due to
18 the incidence or prevalence of a mosquito-
19 borne disease that presents a serious pub-
20 lic health threat;”; and

21 (ii) by amending subparagraph (D) to
22 read as follows:

23 “(D)(i) is located in a State that has re-
24 ceived a grant under subsection (a); or

1 “(ii) that demonstrates to the Secretary
2 that the control program is consistent with ex-
3 isting State mosquito control plans or policies,
4 or other applicable State preparedness plans.”;

5 (C) in paragraph (4)(C), by striking “that
6 extraordinary” and all that follows through the
7 period at the end and inserting the following:
8 “that—

9 “(i) extraordinary economic conditions
10 in the political subdivision or consortium of
11 political subdivisions involved justify the
12 waiver; or

13 “(ii) the geographical area covered by
14 a political subdivision or consortium for a
15 grant under paragraph (1) has an extreme
16 mosquito control need due to—

17 “(I) the size or density of the po-
18 tentially impacted human population;

19 “(II) the size or density of a
20 mosquito population that requires
21 heightened control; or

22 “(III) the severity of the mos-
23 quito-borne disease, such that ex-
24 pected serious adverse health out-

1 comes for the human population jus-
2 tify the waiver.”; and

3 (D) by amending paragraph (6) to read as
4 follows:

5 “(6) NUMBER OF GRANTS.—A political subdivi-
6 sion or a consortium of political subdivisions may
7 not receive more than one grant under paragraph
8 (1).”; and

9 (3) in subsection (f)—

10 (A) in paragraph (1) by striking “for fiscal
11 year 2003, and such sums as may be necessary
12 for each of fiscal years 2004 through 2007”
13 and inserting “for each of fiscal years 2019
14 through 2023”;

15 (B) in paragraph (2), by striking “the
16 Public Health Security and Bioterrorism Pre-
17 paredness and Response Act of 2002” and in-
18 serting “this Act and other medical and public
19 health preparedness and response laws”; and

20 (C) in paragraph (3)—

21 (i) in the heading, by striking “2004”
22 and inserting “2019”; and

23 (ii) by striking “2004” and inserting
24 “2019”.

1 (b) EPIDEMIOLOGY-LABORATORY CAPACITY

2 GRANTS.—Section 2821 of the Public Health Service Act

3 (42 U.S.C. 300hh–31) is amended—

4 (1) in subsection (a)(1), by inserting “, includ-

5 ing mosquito and other vector-borne diseases,” after

6 “infectious diseases”; and

7 (2) by amending subsection (b) to read as fol-

8 lows:

9 “(b) AUTHORIZATION OF APPROPRIATIONS.—There

10 are authorized to be appropriated to carry out this section

11 \$40,000,000 for each of fiscal years 2019 through 2023.”.

12 **TITLE VII—MISCELLANEOUS**

13 **PROVISIONS**

14 **SEC. 701. REAUTHORIZATIONS AND EXTENSIONS.**

15 (a) VACCINE TRACKING AND DISTRIBUTION.—Sec-

16 tion 319A(e) of the Public Health Service Act (42 U.S.C.

17 247d–1(e)) is amended by striking “2014 through 2018”

18 and inserting “2019 through 2023”.

19 (b) TEMPORARY REASSIGNMENT.—Section 319(e)(8)

20 of the Public Health Service Act (42 U.S.C. 247d(e)(8))

21 is amended by striking “2018” and inserting “2023”.

22 (c) STRATEGIC INNOVATION PARTNER.—Section

23 319L(c)(4)(E)(ix) of the Public Health Service Act (42

24 U.S.C. 247d–7e(c)(4)(E)(ix)) is amended by striking

25 “2022” and inserting “2023”.

1 (d) LIMITED ANTITRUST EXEMPTION.—

2 (1) IN GENERAL.—Section 405 of the Pandemic
3 and All-Hazards Preparedness Act (42 U.S.C.
4 247d–6a note) is amended—

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

7 (B) by transferring such section to the
8 Public Health Service Act (42 U.S.C. 201 et
9 seq.), to appear after section 319L of such Act
10 (42 U.S.C. 247d–7e);

11 (C) in subsection (a)(1)(A)—

12 (i) by striking “Secretary of Health
13 and Human Services (referred to in this
14 subsection as the ‘Secretary’)” and insert-
15 ing “Secretary”;

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

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

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

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

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

5 (e) INAPPLICABILITY OF CERTAIN PROVISIONS.—
6 Subsection (e)(1) of section 319L of the Public Health
7 Service Act (42 U.S.C. 247d–7e) is amended—

8 (1) by amending subparagraph (A) to read as
9 follows:

10 “(A) NON-DISCLOSURE OF INFORMA-
11 TION.—

12 “(i) IN GENERAL.—Information de-
13 scribed in clause (ii) shall be deemed to be
14 information described in section 552(b)(3)
15 of title 5, United States Code.

16 “(ii) INFORMATION DESCRIBED.—The
17 information described in this clause is in-
18 formation relevant to programs of the De-
19 partment of Health and Human Services
20 that could compromise national security
21 and reveal significant and not otherwise
22 publicly known vulnerabilities of existing
23 medical or public health defenses against
24 chemical, biological, radiological, or nuclear
25 threats, and is comprised of—

1 “(I) specific technical data or sci-
2 entific information that is created or
3 obtained during the countermeasure
4 and product advanced research and
5 development carried out under sub-
6 section (c);

7 “(II) information pertaining to
8 the location security, personnel, and
9 research materials and methods of
10 high-containment laboratories con-
11 ducting research with select agents,
12 toxins, or other agents with a material
13 threat determination under section
14 319F–2(c)(2); or

15 “(III) security and vulnerability
16 assessments.”;

17 (2) by redesignating subparagraph (C) as sub-
18 paragraph (D);

19 (3) by inserting after subparagraph (B) the fol-
20 lowing:

21 “(C) REPORTING.—One year after the
22 date of enactment of the Pandemic and All-
23 Hazards Preparedness and Advancing Innova-
24 tion Act of 2018, and annually thereafter, the
25 Secretary shall report to the Committee on

1 Health, Education, Labor, and Pensions of the
2 Senate and the Committee on Energy and Com-
3 merce of the House of Representatives on the
4 number of instances in which the Secretary has
5 used the authority under this subsection to
6 withhold information from disclosure, as well as
7 the nature of any request under section 552 of
8 title 5, United States Code that was denied
9 using such authority.”; and
10 (4) in subparagraph (D), as so redesignated, by
11 striking “12” and inserting “17”.

12 **SEC. 702. LOCATION OF MATERIALS IN THE STOCKPILE.**

13 Subsection (d) of section 319F–2 of the Public
14 Health Service Act (42 U.S.C. 247d–6b) is amended to
15 read as follows:

16 “(d) DISCLOSURES.—No Federal agency may dis-
17 close under section 552 of title 5, United States Code any
18 information identifying the location at which materials in
19 the stockpile described in subsection (a) are stored, or
20 other information regarding the contents or deployment
21 capability of the stockpile that could compromise national
22 security.”.

23 **SEC. 703. CYBERSECURITY.**

24 (a) STRATEGY FOR PUBLIC HEALTH PREPAREDNESS
25 AND RESPONSE TO CYBERSECURITY THREATS.—

1 (1) STRATEGY.—Not later than 18 months
2 after the date of enactment of this Act, the Sec-
3 retary of Health and Human Services (referred to in
4 this section as the “Secretary”) shall prepare and
5 submit to the relevant committees of Congress a
6 strategy for public health preparedness and response
7 to address cybersecurity threats (as defined in sec-
8 tion 102 of Cybersecurity Information Sharing Act
9 of 2015 (6 U.S.C. 1501)) that present a threat to
10 national health security. Such strategy shall in-
11 clude—

12 (A) identifying the duties, functions, and
13 preparedness goals for which the Secretary is
14 responsible in order to prepare for and respond
15 to such cybersecurity threats, including metrics
16 by which to measure success in meeting pre-
17 paredness goals;

18 (B) identifying gaps in public health capa-
19 bilities to achieve such preparedness goals; and

20 (C) strategies to address identified gaps
21 and strengthen public health emergency pre-
22 paredness and response capabilities to address
23 such cybersecurity threats.

24 (2) PROTECTION OF NATIONAL SECURITY.—

25 The Secretary shall make such strategy available to

1 the Committee on Health, Education, Labor, and
2 Pensions of the Senate, the Committee on Energy
3 and Commerce of the House of Representatives, and
4 other congressional committees of jurisdiction, in a
5 manner that does not compromise national security.

6 (b) COORDINATION OF PREPAREDNESS FOR AND RE-
7 SPONSE TO ALL-HAZARDS PUBLIC HEALTH EMER-
8 GENCIES.—Subparagraph (D) of section 2811(b)(4) of the
9 Public Health Service Act (42 U.S.C. 300hh–10(b)(4)) is
10 amended to read as follows:

11 “(D) POLICY COORDINATION AND STRA-
12 TEGIC DIRECTION.—Provide integrated policy
13 coordination and strategic direction, before,
14 during, and following public health emergencies,
15 with respect to all matters related to Federal
16 public health and medical preparedness and
17 execution and deployment of the Federal re-
18 sponse for public health emergencies and inci-
19 dents covered by the National Response Plan
20 described in section 504(a)(6) of the Homeland
21 Security Act of 2002 (6 U.S.C. 314(a)(6)), or
22 any successor plan; and such Federal responses
23 covered by the National Cybersecurity Incident
24 Response Plan developed under section 228(c)
25 of the Homeland Security Act of 2002 (6

1 U.S.C. 149(c)), including public health emer-
2 gencies or incidents related to cybersecurity
3 threats that present a threat to national health
4 security.”.

5 **SEC. 704. TECHNICAL AMENDMENTS.**

6 (a) PUBLIC HEALTH SERVICE ACT.—Title III of the
7 Public Health Service Act (42 U.S.C. 241 et seq.) is
8 amended—

9 (1) in paragraphs (1) and (5) of section 319F–
10 1(a) (42 U.S.C. 247d–6a(a)), by striking “section
11 319F(h)” each place such term appears and insert-
12 ing “section 319F(e)”; and

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

16 (b) PUBLIC HEALTH SECURITY GRANTS.—Section
17 319C–1(b)(2) of the Public Health Service Act (42 U.S.C.
18 247d–3a(b)(2)) is amended—

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

21 (2) in subparagraph (F), by striking “make sat-
22 isfactory annual improvement and describe” and in-
23 serting “makes satisfactory annual improvement and
24 describes”.

1 (c) EMERGENCY USE INSTRUCTIONS.—Subpara-
2 graph (A) of section 564A(e)(2) of the Federal Food,
3 Drug, and Cosmetic Act (21 U.S.C. 360bbb–3a(e)(2)) is
4 amended by striking “subsection (a)(1)(C)(i)” and insert-
5 ing “subsection (a)(1)(C)”.

6 (d) PRODUCTS HELD FOR EMERGENCY USE.—Sec-
7 tion 564B(2) of the Federal Food, Drug, and Cosmetic
8 Act (21 U.S.C. 360bbb–3b) is amended—

9 (1) in subparagraph (B), by inserting a comma
10 after “505”; and

11 (2) in subparagraph (C), by inserting “or sec-
12 tion 564A” before the period at the end.

13 (e) TRANSPARENCY.—Section 507(c)(3) of the Fed-
14 eral Food, Drug, and Cosmetic Act (21 U.S.C. 357(c)(3))
15 is amended—

16 (1) by striking “Nothing in” and inserting the
17 following:

18 “(A) IN GENERAL.—Nothing in”;

19 (2) by striking “disclose any” and inserting
20 “disclose or direct—

21 “(i) any”;

22 (3) by striking the period and inserting “; or”;

23 and

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

1 “(ii) in the case of a drug develop-
2 ment tool that may be used to support the
3 development of a qualified countermeasure,
4 security countermeasure, or qualified pan-
5 demic or epidemic product, as defined in
6 sections 319F–1, 319F–2, and 319F–3,
7 respectively, of the Public Health Service
8 Act, any information that the Secretary
9 determines has a significant potential to
10 affect national security.

11 “(B) PUBLIC ACKNOWLEDGMENT.—In the
12 case that the Secretary, pursuant to subpara-
13 graph (A), does not make information publicly
14 available, the Secretary shall provide on the
15 internet website of the Food and Drug Admin-
16 istration an acknowledgement of the informa-
17 tion that has not been disclosed, pursuant to
18 subparagraph (A).”.

19 **SEC. 705. FORMAL STRATEGY RELATING TO CHILDREN**
20 **SEPARATED FROM PARENTS AND GUARD-**
21 **IANAS AS A RESULT OF ZERO TOLERANCE POL-**
22 **ICY.**

23 Not later than 14 days after the date of enactment
24 of this Act, the Assistant Secretary for Preparedness and
25 Response and the Assistant Secretary for the Administra-

tion on Children and Families shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a formal strategy to reunify with their parent or guardian, if the parent or guardian chooses such reunification, each child who—

(1) as a result of the initiative announced on April 6, 2018, and due to prosecution under section 1325(a) of title 8, United States Code;

(2) was separated from their parent or guardian and placed into a facility funded by the Department of Health and Human Services; and

(3) can be safely reunited with such parent or guardian.

**SEC. 706. REPORTING RELATING TO CHILDREN SEPARATED
FROM PARENTS AND GUARDIANS AS A RESULT OF ZERO TOLERANCE POLICY.**

Beginning on the date of enactment of this Act, the Assistant Secretary for Preparedness and Response and the Assistant Secretary for the Administration on Children and Families shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate weekly reports on the status and welfare of the children who, as a result of the “zero toler-

1 ance” policy, were separated from their parent or guard-
2 ian and are awaiting reunification with their parent or
3 guardian, as well as the number of such children in facili-
4 ties funded by the Department of Health and Human
5 Services.

6 **SEC. 707. TECHNICAL CORRECTION.**

7 Section 801(e)(4)(E)(iii) of the Federal Food, Drug,
8 and Cosmetic Act (21 U.S.C. 381(e)(4)(E)(iii)) is amend-
9 ed by striking “subparagraph” both places it appears in
10 subclause (I) and subclause (II) and inserting “para-
11 graph”.

12 **SEC. 708. SAVINGS CLAUSE.**

13 Nothing in this Act shall be construed as reducing
14 or limiting the authorities vested in any other Federal
15 agency by any other Federal law.

 Passed the House of Representatives September 25,
2018.

Attest:

KAREN L. HAAS,
Clerk.