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PREVENT Pandemics Act (P.L. 117-328, Division FF, Title II)

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Kavya Sekar, Coordinator
Analyst in Health Policy

PREVENT Pandemics Act (P.L. 117-328, Division FF, Title II)

The Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act (PREVENT Pandemics Act) was enacted on December 29, 2022, as a part of Consolidated Appropriations Act, FY2023 (CAA, P.L. 117-328; Division FF; Title II). The act marks the first set of cross-cutting legislative reforms to address pandemic preparedness and response policy after the Coronavirus Disease 2019 (COVID-19) pandemic began. The law also addresses other issue areas with implications for pandemic preparedness and response, such as those related to general public health, medical supply chains, biomedical innovation, and research security.

The PREVENT Pandemics Act addresses mostly programs and agencies of the Department of Health and Human Services (HHS), especially some of the HHS agencies involved in pandemic preparedness and response, including the Centers for Disease Control and Prevention (CDC), the Administration for Strategic Preparedness and Response (ASPR, formerly Office of the Assistant Secretary for Preparedness and Response), the National Institutes of Health (NIH), and the U.S. Food and Drug Administration (FDA). The PREVENT Pandemics Act also establishes a new White House Office of Pandemic Preparedness and Response Policy to coordinate pandemic preparedness and response activities across the federal government.

A version of the PREVENT Pandemics Act (S. 3799) was passed by the Senate Committee on Health, Education, Labor, and Pensions in March 2022. With some changes from the Senate committee-passed bill, the PREVENT Pandemics Act was ultimately incorporated into the CAA (P.L. 117-328) alongside other health policy provisions. In summary, the subtitles of the PREVENT Pandemics Act focus on the following:

- **Strengthening Federal and State Preparedness.** Subtitle A addresses the roles and responsibilities of federal agencies and offices involved in pandemic preparedness and response, including CDC, ASPR, and the new White House Office of Pandemic Preparedness and Response. The subtitle also addresses state-level preparedness for infectious disease emergencies.
- **Improving Public Health Preparedness and Response Capacity.** Subtitle B addresses several public health issues related to the pandemic, including public health data sharing and modernization, health disparities, public health workforce programs, and other specific programs related to infectious diseases and emergency response.
- **Accelerating Research and Countermeasure Discovery.** Subtitle C addresses federal scientific and research and development (R&D) programs related to pandemic pathogens and other biological threats. The subtitle focuses in large part on research security issues, including laboratory biosafety and biosecurity, foreign influence, and the protection of sensitive or proprietary data and information in research. This subtitle also includes authorization for the new Advanced Research Projects Agency for Health (ARPA-H), an agency focused on high-risk, high-reward health research that was first funded in 2022.
- **Modernizing and Strengthening the Supply Chain for Vital Medical Products.** Subtitle C focuses on medical supply availability and distribution during public health emergencies. Several provisions in the subtitle address the Strategic National Stockpile, the federal stockpile of medical products maintained by ASPR for bioterrorist attacks and other public health emergencies. Provisions also address state stockpiles as well as programs and incentives for domestic manufacturing of critical medical products, such as generic medicines and antibiotics.
- **Enhancing Development and Combating Shortages of Medical Products.** Subtitle E addresses FDA's role in pandemic preparedness and response. First, the subtitle addresses FDA's review and regulation of medical products for emergencies. Second, the subtitle addresses FDA's role in mitigating medical product shortages and ensuring the quality of the U.S. medical supply chain.

This CRS report provides a section-by-section overview of the PREVENT Pandemics Act. The report is organized by subtitle of the act and includes general background followed by a summary of each provision.

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Introduction

The Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act (PREVENT Pandemics Act) was enacted on December 29, 2022, as a part of the Consolidated Appropriations Act, 2023 (P.L. 117-328; Division FF; Title II). The act marks the first set of cross-cutting legislative reforms to address pandemic preparedness and response policy after the Coronavirus Disease 2019 (COVID-19) pandemic began. The law also addresses other issue areas with implications for pandemic preparedness and response, such as those related to general public health, medical supply chains, biomedical innovation, and research security.

The PREVENT Pandemics Act addresses Department of Health and Human Services (HHS) programs, especially those of the key HHS agencies involved in pandemic preparedness and response, including the Centers for Disease Control and Prevention (CDC), the Administration for Strategic Preparedness and Response (ASPR, formerly Office of the Assistant Secretary for Preparedness and Response), the National Institutes of Health (NIH), and the U.S. Food and Drug Administration (FDA). The PREVENT Pandemics Act also establishes a new White House Office of Pandemic Preparedness and Response Policy to coordinate pandemic preparedness and response activities across the federal government.

A version of the PREVENT Pandemics Act (S. 3799) was first passed by the Senate Committee on Health, Education, Labor, and Pensions (HELP) in March 2022. According to the press release following the committee vote, the bill incorporated ideas from 41 different bills and 35 different Senators.¹ Regarding issues addressed by the bill, the press release stated

[The COVID-19 pandemic] has also put a harsh spotlight on some of the longstanding challenges the United States' public health preparedness systems face and brought to light unanticipated challenges. Broken supply chains and inadequate stockpiles led to shortages of masks, ventilators, and other medical products. Tests throughout the response have been either critically delayed or scarce, leaving workers, schools, and communities unable to make informed, timely decisions about how to keep themselves and those around them safe. Outdated and inconsistent public health data systems made it hard for federal, state, local, Tribal and territorial public health departments to get a full picture of the crisis and inform their responses. The nation's public health and health care workforce was overwhelmed. Mental health and substance use disorder challenges and health disparities, which were already damaging to so many communities, worsened during this crisis.

With some changes from the Senate committee-passed bill, the PREVENT Pandemics Act was ultimately incorporated into the Consolidated Appropriations Act, 2023 (P.L. 117-328) in Division FF, alongside many other health policy provisions.

The PREVENT Pandemics Act is a separate legislative effort from reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA). Some provisions of the PREVENT Pandemics Act address programs that have historically been included in PAHPA reauthorizations, such as CDC's public health emergency preparedness and biosurveillance programs, the Strategic National Stockpile, and other ASPR programs. However, with some exceptions, the PREVENT Pandemics Act made no changes to expiration dates from the last PAHPA reauthorization, the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (PAHPAIA; P.L.

¹ Senate Committee on Health, Education, Labor, and Pensions (HELP), "HELP Committee Passes Murray-Burr PREVENT Pandemics Act In Overwhelming Bipartisan Vote," press release, March 15, 2022, <https://www.help.senate.gov/chair/newsroom/press/help-committee-passes-murray-burr-prevent-pandemics-act-in-overwhelming-bipartisan-vote>.

116-22), including many expiration dates in 2023. Thus, House and Senate committees have considered PAHPA reauthorization bills in 2023.²

In addition, the PREVENT Pandemics Act addresses programs and issues that have not historically been addressed in past PAHPA reauthorizations, including CDC agency-wide leadership and strategic planning, foreign influence in HHS biomedical research, medical product shortages, and general public health programs and data sharing. The law includes formal authorization for the new Advanced Research Projects Agency for Health (ARPA-H), an agency focused on high-risk, high-reward health research that was first funded in 2022.³

This CRS report provides a section-by-section overview of the PREVENT Pandemics Act. The report is organized by subtitle of the act and includes general background followed by a summary of each provision.

The PREVENT Pandemics Act: At a Glance

In summary, the subtitles of the PREVENT Pandemics Act focus on the following:

- **Strengthening Federal and State Preparedness.** Subtitle A addresses the roles and responsibilities of federal agencies and offices involved in pandemic preparedness and response, including CDC, ASPR, and the new White House Office of Pandemic Preparedness and Response. The subtitle also addresses state-level preparedness for infectious disease emergencies.
- **Improving Public Health Preparedness and Response Capacity.** Subtitle B addresses several public health issues related to the pandemic, including public health data sharing and modernization, health disparities, public health workforce programs, and other specific programs related to infectious diseases or emergency response.
- **Accelerating Research and Countermeasure Discovery.** Subtitle C addresses federal scientific and research and development (R&D) programs related to pandemic pathogens and other biological threats. The subtitle focuses in large part on research security issues, including laboratory biosafety and biosecurity, foreign influence, and the protection of sensitive or proprietary data and information in research. This subtitle includes authorization for the new Advanced Research Projects Agency for Health (ARPA-H), an agency focused on high-risk, high-reward health research that was first funded in 2022.
- **Modernizing and Strengthening the Supply Chain for Vital Medical Products.** Subtitle D focuses on medical supply availability and distribution during public health emergencies. Several provisions in the subtitle address the Strategic National Stockpile, the federal stockpile of medical products maintained by ASPR for bioterrorist attacks and other public health emergencies. Provisions also address state stockpiles as well as programs and incentives for

² U.S. Senate HELP Committee, “S. 2333, Pandemic and All-Hazards Preparedness and Response Act,” press release, July 20, 2023, <https://www.help.senate.gov/hearings/s-2333-pandemic-and-all-hazards-preparedness-and-response-act>, and House Energy and Commerce Committee, “Health Subcommittee Chair Guthrie Opening Statement at Subcommittee Markup of 17 Bills,” press release, July 13, 2023, <https://energycommerce.house.gov/posts/health-subcommittee-chair-guthrie-opening-statement-at-subcommittee-markup-of-17-bills>.

³ See CRS Report R47074, *Advanced Research Projects Agency for Health (ARPA-H): Congressional Action and Selected Policy Issues*.

domestic manufacturing of critical medical products, such as generic medicines and antibiotics.

- **Enhancing Development and Combating Shortages of Medical Products.** Subtitle E addresses FDA's role in pandemic preparedness and response. First, the subtitle addresses FDA's review and regulation of medical products for emergencies. Second, the subtitle addresses FDA's role in mitigating shortages of medical products and ensuring the quality of the U.S. medical supply chain.

The PREVENT Pandemics Act is an authorizing law; it does not appropriate any funds. Some of the existing programs addressed in the law have not been funded in recent years. It remains to be seen whether new programs established by the law will be funded through future appropriations.

In this report, "Secretary" means "HHS Secretary" unless otherwise specified.

Subtitle A—Strengthening Federal and State Preparedness

Chapter 1—Federal Leadership and Accountability

Under the National Response Framework, HHS is the primary agency responsible for the public health and medical aspects of federal preparedness and response to emergencies.⁴ Within HHS, the Assistant Secretary for Preparedness and Response is established by statute as the principal advisor to the HHS Secretary on federal public health and medical preparedness and response.⁵ The Assistant Secretary leads the Administration for Strategic Preparedness and Response (ASPR), an HHS operating division that has significant responsibilities for leading public health emergency responses. However, other HHS agencies also play a major role in health emergency response. In particular, CDC has responsibilities and expertise related to controlling infectious diseases and responding to outbreaks. During the COVID-19 pandemic, some uncertainties arose around the respective roles of ASPR and CDC and their relationship with other federal agencies in the response.⁶ In addition, many have called into question CDC's preparedness for and leadership during the pandemic; the agency itself has acknowledged a need for reform.⁷ In 2021, the Government Accountability Office (GAO) added HHS's leadership and coordination of public health emergencies to its list of high-risk issue areas in need of reform.⁸

⁴ See Federal Emergency Management Agency, "Emergency Support Function #8 – Public Health and Medical Services Annex," https://www.fema.gov/sites/default/files/2020-07/fema_ESF_8_Public-Health-Medical.pdf.

⁵ PHSA Section 2811.

⁶ See, for example, U.S. Government Accountability Office (GAO), *COVID-19: HHS Should Clarify Agency Roles for Emergency Return of U.S. Citizens during a Pandemic*, GAO-21-334, April 19, 2021, <https://www.gao.gov/products/gao-21-334>.

⁷ See, for example, Senator Burr, "Modernizing CDC: Ensuring a Strategic Approach and Improving Accountability," May 2021, <https://www.help.senate.gov/imo/media/doc/Modernizing%20CDC%20-%20Ensuring%20a%20Strategic%20Approach%20and%20Improving%20Accountability.pdf>, and Jeneen Interlandi, "Covid Proved the C.D.C. Is Broken. Can It Be Fixed?," *The New York Times*, June 16, 2021. On agency reform, see CDC, "CDC Moving Forward," <https://www.cdc.gov/about/organization/cdc-moving-forward.html>.

⁸ GAO, *High-Risk Series: Efforts Made to Achieve Progress Need to Be Maintained and Expanded to Fully Address All Areas*, GAO-23-106203, April 20, 2023, <https://www.gao.gov/products/gao-23-106203>.

Sections 2101: Appointment and authority of the Director of the Centers for Disease Control and Prevention

Background

CDC, the federal government's focal point for disease prevention and control activities, was established administratively as funded by appropriations.⁹ CDC comprises several centers, institutes, and offices (CIOs) that focus on a wide array of health topics, including infectious diseases, noninfectious diseases, injury, disability, occupational health, environmental health, and public health emergency preparedness and response. In addition, CDC oversees the Agency for Toxic Substances and Disease Registry (ATSDR), a separate HHS operating division.¹⁰ Many of CDC's programs are based in general authorities in the Public Health Service Act (PHSA).¹¹ CDC has periodically developed agency-wide strategic plans, such as for 2022 to 2027.¹² Prior to the PREVENT Pandemics Act, neither the position of the CDC Director nor the requirement for a strategic plan was explicitly authorized in statute.

Provision

Section 2101 adds a new PHSA Section 305 to PHSA Title III, where many CDC authorities, including to collect data and to award public health grants, are currently based. The new section does three things:

First, PHSA Section 305 codifies the position of the CDC Director as a presidentially appointed and Senate-confirmed position, which becomes effective on January 20, 2025. The section also formally authorizes the CDC Director's role as Administrator of ATSDR. PHSA Section 305 tasks the CDC Director with exercising authorities and responsibilities related to public health both domestically and globally, including the prevention and control of diseases, as well as addressing injuries and occupational and environmental hazards. The section also makes the Director responsible for (1) the overall direction and management of the agency, (2) coordination among CDC CIOs, (3) overseeing strategic planning and performance, and (4) communicating the strategic plan and CDC's programs to public and private stakeholders, including through annual meetings. PHSA Section 305 also requires the Director to appear at hearings before specified congressional committees each fiscal year to address topics related to public health emergency preparedness and planning.

Second, PHSA Section 305 establishes requirements for CDC's strategic plan. One year after enactment, and every four years after, the CDC Director is required to submit a strategic plan to specified congressional committees and to post the plan online. The strategic plan must identify priorities and objectives related to (1) preventing, reducing, and eliminating communicable and noncommunicable diseases or conditions and addressing injuries and occupational and environmental hazards; (2) supporting state, local, territorial, and tribal (SLTT) health departments in these efforts; (3) containing, mitigating, and ending disease outbreaks; (4) enhancing global and domestic public health capacity, including public health data, surveillance, workforce, and laboratory capacity; and (5) other priorities identified by the Director. The plan must describe the capacity and capabilities needed to achieve identified priorities, as well as

⁹ Elizabeth W. Etheridge, *Sentinel for Health: A History of the Centers for Disease Control and Prevention* (University of California Press, 1992), pp. 16-17.

¹⁰ CDC, "Official Organizational Chart," February 2023, <https://www.cdc.gov/about/pdf/organization/cdc-org-chart.pdf>.

¹¹ See CRS In Focus IF12241, *The Centers for Disease Control and Prevention (CDC)*.

¹² See, CDC, "CDC's 2022-2027 Strategic Plan: Advancing Science and Health Equity," <https://www.cdc.gov/about/strategic-plan/index.html>.

progress made in achieving such capacity and capabilities. The plan must also incorporate descriptions related to strategic communications; partnerships with private and public sector entities, including SLTT public health departments; and coordination with other HHS and federal agencies. Strategic plans of CDC CIOs are to be prepared regularly and informed by the CDC-wide strategic plan.

Third, PHS Section 305 provides CDC with Other Transactions (OT) authority for infectious disease research, biosurveillance, infectious disease modeling, and public health preparedness and response. An OT is not a contract, grant, or cooperative agreement, and there is no one statutory or regulatory definition of “other transaction.” Typically, OT authority gives agencies more flexibility for engaging with private industry and other partners than allowed under regular federal funding awards (e.g., grants, contracts).¹³ The new authority specifies conditions for making awards over \$40 million and requires that CDC establish guidelines for using OT authority that include auditing requirements.

Section 2102: Advisory Committee to the Director of the Centers for Disease Control and Prevention

Background

From time to time, CDC has established under general authority an Advisory Committee to the Director of the Centers for Disease Control and Prevention. The committee is composed of nonfederal experts to advise on overall CDC policy and strategy. Most recently, CDC reestablished the committee in 2021.¹⁴

Provision

This provision adds a new PHS Section 305A, which codifies a requirement to establish the Advisory Committee to the Director to advise the CDC Director on policies and strategy to achieve CDC’s mission. The Advisory Committee is to be made up of 15 nonfederal members, 12 of whom are to be representatives of health disciplines relevant to CDC. Three members may be appointed from the general public and may include leaders in innovation, public policy, public relations, law, economics, or management.

The Advisory Committee is allowed to (1) advise on development of the strategic plan; (2) make recommendations regarding prioritizing agency activities in alignment with its strategic plan; (3) advise on ways to improve performance; (4) advise on funding awards like grants, cooperative agreements, contracts, and other transactions; (5) advise on CDC activities related to research, surveillance, and support to SLTT public health departments; and (6) appoint subcommittees.

¹³ See, for example, CRS Report R45521, *Department of Defense Use of Other Transaction Authority: Background, Analysis, and Issues for Congress*.

¹⁴ CDC, “Advisory Committee to the Director,” <https://www.cdc.gov/about/advisory-committee-director/index.html> and HHS, “Charter: Advisory Committee to the Director, Centers for Disease Control and Prevention,” https://www.cdc.gov/about/advisory-committee-director/pdf/HHS-2021-charter-signed_4.15.21.pdf.

Section 2103: Public health and medical preparedness and response coordination

Background

The HHS Secretary has the authority to declare a public health emergency at his or her discretion under conditions dictated under PHSA Section 319.¹⁵ Additional authorities and responsibilities related to public health emergency response are also detailed in this PHSA section, including the use of the Public Health Emergency Fund (PHEF). The PHEF is an emergency reserve fund available for PHEs (or expected PHEs) authorized in PHSA Section 319. The PHEF has not received appropriations in many years and has a balance of \$56,500 as of July 2023.¹⁶

PHSA Title XXVIII defines HHS responsibilities for preparedness and response to public health emergencies. Within this title, the position of the Assistant Secretary for Preparedness and Response is established in PHSA Section 2811 as the principal advisor to the HHS Secretary on federal public health and medical preparedness and response. As mentioned earlier, the Assistant Secretary leads the Administration for Strategic Preparedness and Response (ASPR).¹⁷ The duties of the ASPR include (1) providing leadership at the federal level for public health and medical preparedness and response; (2) developing and procuring advanced medical countermeasures (MCM), medical products that can be used to diagnose, prevent, or treat diseases related to chemical, biological, radiological, or nuclear (CBRN) threats; (3) coordinating activities, policies, and operations among and within different levels of government during responses; and (4) assessing threats to maintain preparedness and situational awareness for public health security.¹⁸

Provision

This provision contains several sections aimed at improving aspects of public health and medical preparedness and response coordination. Specifically, the provision amends PHSA sections as follows:

- Amends PHSA Section 319(b) to allow Public Health Emergency Fund (PHEF) funds to be used to support the initial deployment and distribution of SNS contents, and requires the HHS Secretary to report to Congress on expenditures from the PHEF each fiscal year as specified.¹⁹
- Amends PHSA Section 2801 to require that the HHS Secretary coordinate with other federal departments and agencies to carry out necessary public health and medical response activities to support the public health and medical response for SLTT agencies.²⁰
- Amends PHSA Section 2811(b) to clarify the roles and responsibilities of the Assistant Secretary in public health and medical response to public health emergencies.²¹ These amendments clarify that the Assistant Secretary is to assist

¹⁵ 42 U.S.C. §247d.

¹⁶ USASpending, “Public Health Emergency Fund,” accessed July 1, 2023, https://www.usaspending.gov/federal_account/075-1104.

¹⁷ Formerly the Office of the Assistant Secretary for Preparedness and Response, the office was renamed and reestablished as an HHS operating division, the Administration for Strategic Preparedness and Response, effective February 2023. See 88 *Federal Register* 10125.

¹⁸ PHSA Section 2811(b).

¹⁹ 42 U.S.C. §247d(b).

²⁰ 42 U.S.C. §300hh.

²¹ 42 U.S.C. §300hh-10(b).

the HHS Secretary in leading public health and medical response to public health emergencies consistent with the National Response Framework and other applicable provisions of law. This provision also directs the Assistant Secretary to conduct annual drills and operational exercises, including national-level and state-level, full-scale exercises at least once every four years. Such exercises are to assess the ability of the Strategic National Stockpile (see “Strategic National Stockpile: Sections 2402-240” for background) to provide MCMs and supplies in response to a PHE (including during a large-scale, long-term response) in coordination with state and local officials.

- Amends PHSA Section 2811(b) to further require the Assistant Secretary to coordinate HHS efforts to plan for medical product and supply needs in CBRN and other emergency responses.
- Amends PHSA Title Section 2811(b) by adding a requirement that the ASPR appear annually before Congress to report on various aspects of public health emergency preparedness and medical response.²²
- Amends PHSA Title Section 2801 to direct the HHS Secretary produce an annual report to Congress containing information on assessments of any PHE response; findings related to drills and exercises; the state of CBRN preparedness and response; and any challenges.²³

Lastly, this provision directs GAO to issue two reports within three years after enactment. For the first report, GAO is to review previous and current interagency agreements between the HHS Secretary and the heads of other federal departments or agencies involved in public health and medical emergency responses.²⁴ GAO is to examine several aspects of these agreements, including specific roles and responsibilities of each entity, how frequently these agreements were utilized, gaps or barriers to establishing or implementing these agreements, and recommendations on how to improve these agreements. For the second report, GAO is to review how the HHS Secretary has implemented and utilized the new authority to coordinate with other federal agencies for public health responses as added by Section 2103.²⁵

Section 2104: Office of Pandemic Preparedness and Response Policy

Background

The Executive Office of the President, created in 1939, provides support to the President in a number of policy areas. Existing subdivisions of the Executive Office include the Domestic Policy Council, the National Security Council, and the Office of Management and Budget, among many others.²⁶ At times, positions within the White House have been dedicated to biodefense and pandemic preparedness; however, such positions were established at the discretion of Presidents and have not been required by statute.²⁷

²² Ibid.

²³ 42 U.S.C. §300hh.

²⁴ Ibid.

²⁵ 42 U.S.C. §300hh(c) as introduced by the PREVENT Pandemic Act.

²⁶ The White House, *Executive Office of the President*, <https://www.whitehouse.gov/administration/executive-office-of-the-president/>.

²⁷ For general background, see Gail Wilensky, “The Importance of Reestablishing a Pandemic Preparedness Office at the White House,” *Journal of the American Medical Association*, vol. 1, no. 7 (July 9, 2020).

Provision

This provision establishes within the Executive Office of the President a new Office of Pandemic Preparedness and Response Policy. This office is to be headed by a Director appointed by the President. The functions of the Director include serving as the principal advisor to the President on all matters related to preparedness and response to pandemics and other biological threats; coordinating federal activities to prepare for and respond to these threats as specified; promoting the development of expertise within the federal government to ensure that the United States can detect, identify, and respond to these threats; consulting with relevant officials within the Executive Office of the President on preparedness and response activities; and identifying opportunities to leverage current and emerging technologies, and ensuring that federal after-action report (AAR) findings are implemented. The Director is to also lead an interdepartmental working group and appoint an Industry Liaison during a pandemic response.

In addition, the Director is directed to publish several reports:

- Within a year of its operation and in consultation with relevant federal agencies, the Director is required to publish a report on conditions that warrant special attention within the next five years involving current and emerging problems related to pandemics or other biological threats, and that discusses opportunities for developing and procuring MCMs. The report is to be revised at least once every five years.
- Within 18 months of enactment of PREVENT and every two years thereafter, the office is directed to issue a report to the President and Congress on current emerging threats, roles, and responsibilities of the federal government; findings of the preceding review; barriers to addressing such findings; and current and planned activities to update federal policies, strategies, and procedures, and to support the development of federal expertise and improve federal preparedness and response capabilities using emerging technologies.

Lastly, this provision requires the Director to conduct a review of federal strategies, policies, procedures, and AARs to identify pandemic preparedness and response gaps and inefficiencies within one year of enactment of the PREVENT Pandemics Act.

Chapter 2—State and Local Readiness

State, local, tribal and territorial (SLTT) jurisdictions play a significant role in preparing for and responding to emergencies. SLTT agencies are responsible for a range of activities, including developing incident response plans in anticipation of emergencies; coordinating with local stakeholders to enhance response efforts; executing training, exercises, and drills to develop emergency response skillsets; and implementing emergency response plans during emergency incidents.²⁸ A variety of federal programs, grants, and guidance are available to assist jurisdictions in their preparedness and response efforts. This chapter focuses on enhancing the ability of SLTT to prepare for and respond to future public health emergencies.

²⁸ FEMA, “How Communities and States Deal with Emergencies and Disasters,” p. 2, https://training.fema.gov/emiweb/downloads/is7unit_2.pdf.

Section 2111: Improving State and local public health security

Background

The Public Health Emergency Preparedness (PHEP) cooperative agreement program is administered by the CDC as authorized in PHSA Section 319C-1.²⁹ Funding is provided according to a statutory formula to 62 grantees, comprising all 50 states, the District of Columbia, five territories, three freely associated states, and three major localities: New York City, Los Angeles County, and Chicago.³⁰ Funds distributed through the agreement are a source of funding for public health departments to bolster their ability to prepare for and respond to a variety of emergencies.³¹ Eligible grantees must submit an application as specified by statute.³²

Provision

This provision contains a number of amendments to PHSA Section 319C-1, which lists the requirements eligible entities must demonstrate when applying for the PHEP cooperative agreement.³³ These amendments include the following:

- Clarifications that applicants must specify how they will integrate information to account for individuals with behavioral needs both before and following a public health emergency.
- Clarifications that eligible entities must specify how they will coordinate with state education, child care, and other relevant agencies.
- The addition of a requirement that applicants must describe how they will provide technical assistance to certain facilities, such as residential care facilities and group homes, where there is an increased risk of infectious disease outbreaks in a PHE.
- A requirement that applicants must issue assurances that relevant staff will complete preparedness and response trainings as specified.

Section 2112: Supporting access to mental health and substance use disorder services during public health emergencies

Background

The Substance Abuse and Mental Health Services Administration (SAMHSA) is the federal agency primarily responsible for supporting community-based mental health and substance use treatment and prevention services. SAMHSA does not directly deliver treatment services. Rather, it supports state and local efforts in providing mental health and substance use (collectively known as *behavioral health*) services, primarily through funding and technical assistance. SAMHSA derives most of its statutory authority from Title V of the Public Health Service Act

²⁹ CDC, “Public Health Emergency Preparedness Program and Guidance,” <https://www.cdc.gov/orr/readiness/phep/index.htm>.

³⁰ Funded territories include American Samoa, Puerto Rico, U.S. Virgin Islands, Guam, and the Northern Marianas. Funded freely associated states include Micronesia, Palau, and Marshall Islands. For the purposes of this cooperative agreement, the District of Columbia and the Commonwealth of Puerto Rico receive funding allocations as per states. Territories, and the nation’s three most populous cities, receive funding allocations per different formulas. 42 U.S.C. §247d–3a.

³¹ CDC, “Public Health Emergency Preparedness Program and Guidance,” <https://www.cdc.gov/orr/readiness/phep/index.htm>.

³² 42 U.S.C. §247d–3a(b)(2)

³³ 42 U.S.C. §247d–3a(b)(2).

(PHSA). More specifically, PHSA Section 501³⁴ provides the enumerated authorities of the Assistant Secretary for Mental Health and Substance Use (Assistant Secretary). Prior to the PREVENT Pandemics Act, SAMHSA's general authorities did not include any explicit responsibilities related to public health emergencies.

Provision

Section 2112 amends PHSA Section 501 to add an explicit SAMHSA authority to support continued access to behavioral health services during a public health emergency. The provision requires SAMHSA to specify a strategy for supporting behavioral health services during or in response to a public health emergency in SAMHSA's quadrennial strategic plan, and to provide a description of such activities in its biennial report to Congress.

In addition, Section 2112 requires the Assistant Secretary of SAMHSA to issue a report to specified congressional committees reflecting recommendations from SAMHSA's internal advisory councils on how to improve behavioral health services during a public health emergency. The provision also requires GAO to submit to specified congressional committees a report on SAMHSA programs and activities supporting behavioral health services during the COVID-19 pandemic, due not later than December 30, 2025. This GAO report is to (1) examine the role of SAMHSA's internal advisory councils in supporting SAMHSA's public health emergency-related activities, (2) describe how SAMHSA grant awardees altered delivery of behavioral health services during the COVID-19 PHE and any barriers faced in delivering care, and (3) describe SAMHSA activities supporting the response to the COVID-19 PHE, including flexibilities provided to grant awardees or barriers faced in implementing activities.

Section 2113: Trauma care reauthorization

Background

The Patient Protection and Affordable Care Act (ACA, P.L. 111-148) amended and reauthorized a number of trauma care programs authorized in PHSA Title XII. These provisions were intended to address a number of recommendations that the Institute of Medicine (now National Academy of Medicine) made to improve the U.S. emergency and trauma care system.³⁵ These included designating ASPR as the lead within HHS for emergency and trauma care, authorizing grants to create regionalized systems for trauma care, allocating additional funds to facilities with large uncompensated care burdens, and improving the emergency care workforce, among other provisions. The programs were transferred to the ASPR in the ACA; however, these grant programs have not been funded since the transfer and modifications made in the ACA.

Provision

Section 2113 makes a number of modifications to PHSA Title XII. Specifically, the provision

- adds new language and a new purpose to the grants authorized in PHSA Section 1201—general grants related to improving trauma care—to add that grants can be made to states and consortia of states to improve emergency services and trauma care during a PHE;³⁶

³⁴ 42 U.S.C. §290aa.

³⁵ Institute of Medicine, *Emergency Medical Services at the Crossroads* (Washington, DC: The National Academies Press, 2006); Institute of Medicine, *Hospital-Based Emergency Care At the Breaking Point* (Washington, DC: The National Academies Press, 2006); and Institute of Medicine, *Emergency Care for Children: Growing Pains* (Washington, DC: The National Academies Press, 2006).

³⁶ 42 U.S.C. §300dd.

- amends PHSA Section 1202 to replace a rural trauma care grant with new language creating a program for trauma care in rural areas similar to the prior program, except that the new program requires the Secretary to award grants, adds language regarding trauma care (prior language authorized grants for emergency medical services), specifies eligible entities and granting priority, and requires grantees to submit reports to the HHS Secretary;³⁷
- amends PHSA Section 1204 regarding competitive grants for regionalized trauma systems to rename the section “Competitive Grants for Trauma Centers” and modify language in the general purposes of the grant and grant activities to (1) amend the eligible entities for the grant program to include consortia of trauma centers; (2) add new language about disseminating best practices, facilitating activities to conduct clinical research; (3) require matching funds as of October 1, 2025; and (4) require a report to be disseminated to certain specified congressional committees;³⁸ and
- amends PHSA Section 1232 to reauthorize funding from FY2023 through FY2027.³⁹

Section 2114: Assessment of containment and mitigation of infectious diseases

Background

In response to COVID-19, various jurisdictions executed public health emergency and medical preparedness and response plans. Although the plans may have shared unique elements, some jurisdictions used different infection control measures, such as recommendations for isolation and quarantine.⁴⁰

Provision

This provision directs GAO to conduct a study and deliver a report to Congress on the emergency preparedness and response plans of select states and territories that, in response to the COVID-19 pandemic, implemented preparedness and response plans that included isolation and quarantine recommendations or requirements. This study, due within 18 months of enactment of the PREVENT Pandemics Act, is to include a review of these plans, an assessment of the extent to which they facilitated or hindered state and territorial responses, and a description of the technical assistance provided by the federal government to help states and territories facilitate their response activities.

Section 2115: Consideration of unique challenges in noncontiguous States and territories

Background

Noncontiguous states and territories are those that are not connected by land or do not share a border with other states or territories.⁴¹ These jurisdictions can face unique challenges during

³⁷ 42 U.S.C. §300d-3.

³⁸ 42 U.S.C. §300d-5.

³⁹ 42 U.S.C. §300d-32.

⁴⁰ Rebecca Katz, Andrea Vaught, Adrienne Formentos, et al., “Raising the Yellow Flag: State Variation in Quarantine Laws,” *Journal of Public Health Management & Practice*, vol. 24, no. 4 (July 1, 2019).

⁴¹ Cornell Law School: Legal Information Institute, “noncontiguous,” *Wex Legal Dictionary*, (continued...)

public health emergencies. CDC’s Office of Island Affairs, which serves the territories and freely associated states, asserts that “public health issues affect these islands harder than most places because of their geographic location and limited local capacity. The remoteness, climate change vulnerabilities, and limited resources available heighten the public health challenges experienced in the [territories and freely associated states].”⁴²

Provision

This provision directs the HHS Secretary to conduct quarterly meetings, as appropriate, during any declared PHEs with noncontiguous states and territories regarding unique public health challenges associated with the PHE in such areas.

Subtitle B—Improving Public Health Preparedness and Response Capacity

Chapter 1—Improving Public Health Emergency Responses

Section 2201: Addressing factors related to improving health outcomes

Background

The PHSA currently includes many authorizations used for public health and health promotion programs designed to address health disparities. For example, PHSA Section 317 is a general and permanent authorization for preventive health services programs.⁴³ This authorization is used as a basis for many CDC public health programs, including, for example, programs to promote evidence-based strategies to improve nutrition and physical activity,⁴⁴ as well as to reduce health disparities among racial and ethnic populations with the highest burden of chronic disease.⁴⁵ During the COVID-19 pandemic, Congress provided relief funding designed to directly address health disparities exacerbated by the pandemic.⁴⁶

Provision

Section 2201 adds a new PHSA Section 317V, which authorizes two programs for improving health outcomes. The first program allows the HHS Secretary to award funding for evidence-based projects to improve health outcomes. Eligible funding recipients include SLTT health departments, other public and private entities, and partnerships or consortia among organizations.

<https://www.law.cornell.edu/wex>. Noncontiguous states and territories include Alaska, Hawaii, the five U.S. territories (American Samoa, Commonwealth of the Northern Mariana Islands, Guam, Puerto Rico, and the U.S. Virgin Islands), and three freely associated states (Federated States of Micronesia, Republic of Palau, and the Republic of the Marshall Island).

⁴² CDC, “Office of Island Affairs – Fact Sheet,” <https://www.cdc.gov/islandaffairs/factsheet.html>. CDC’s Office of Island Affairs helps connect the territories and freely associated states to CDC funding and resources.

⁴³ 42 U.S.C. §247b.

⁴⁴ CDC, “The State Physical Activity and Nutrition Program (SPAN),” CDC-RFA-DP-23-0012, March 28, 2023, p. 4, <https://www.grants.gov/web/grants/view-opportunity.html?oppId=342954>.

⁴⁵ CDC, *Racial and Ethnic Approaches to Community Health (REACH)*, CDC-RFA-DP-23-0014, April 11, 2023, p. 4, <https://www.grants.gov/web/grants/view-opportunity.html?oppId=342940>.

⁴⁶ For example, not less than \$2.5 billion of a \$22.4 billion testing and contact tracing appropriation was for testing and contact tracing strategies among “high-risk and underserved populations, including racial and ethnic minority populations and rural communities” in the Public Health and Social Services Emergency Fund account in P.L. 116-260, Division M.

Applicants must demonstrate a history of working with established community-based organizations to address health outcomes (if not already a community-based organization), and applicants must submit a plan based on a community needs assessment. Award recipients are to use funds for at least one of the following: (1) to support the implementation, evaluation, and dissemination of strategies to address factors related to health outcomes; (2) to establish, maintain, or improve technology platforms or networks to support coordination, information sharing, and technical assistance among entities; (3) to implement best practices for improving health outcomes and reducing disease among underserved populations; and (4) to support consideration of factors related to health outcomes in preparing for and responding to public health emergencies through outreach, education, research, and other relevant activities.

For the second program, the HHS Secretary may award funding to minority-serving institutions (as defined in the Higher Education Act of 1965), in consultation with the Office of Minority Health, ONC, and the Administrator of the Administration for Community Living. Awardees are to (1) identify or facilitate the development of best practices to support improved health outcomes for underserved populations; (2) provide technical assistance, training, and evaluation assistance to award recipients receiving funding for evidence-based projects to improve health outcomes (described in the paragraph above); (3) disseminate best practices; and (4) leverage, establish, or operate regional centers to develop, evaluate, and disseminate effective strategies on factors related to health outcomes, including supporting research and training related to such strategies.

For both programs authorized under the new PHSA Section 317V, funding may be awarded for a period up to five years and may be extended for an additional period up to three years. The Secretary is to submit a report on funded activities and related outcomes to specified congressional committees no later than September 30, 2026.

PHSA Section 317V authorizes an appropriation of \$35 million for each of FY2023 through FY2027. Of the amount for each fiscal year, 5% is reserved for tribal organizations, as specified.

Within four years of enactment, GAO is to report to specified congressional committees on the program authorized under PHSA Section 317V, including a review of the outcomes and effectiveness of the program and coordination with other HHS programs with similar goals to ensure that there was no unnecessary duplication of efforts.

Chapter 2—Improving State, Local, and Tribal Public Health Data

Background for Sections 2211-2216

The COVID-19 pandemic exposed the challenges associated with collecting and reporting national health data on a rapidly changing pandemic in the context of the U.S. federal public health system—where many of the laws and programs for public health data are based at the SLTT level.⁴⁷ In addition, the pandemic demonstrated some of the potential for modernized approaches to public health surveillance and data analysis, such as through surveillance using genome sequencing or by using newer modeling and forecasting methods to predict the trajectory of outbreaks.⁴⁸

⁴⁷ CRS Report R46588, *Tracking COVID-19: U.S. Public Health Surveillance and Data*.

⁴⁸ CRS In Focus IF11789, *COVID-19 Variants: Vaccines, Diagnostics, and Therapeutics*, and U.S. Government Accountability Office, *Science & Tech Spotlight: COVID-19 Modeling*, GAO-20-582SP, June 4, 2020, <https://www.gao.gov/products/gao-20-582sp>.

Previously, through the Pandemic and All-Hazards Preparedness Act of 2006 (P.L. 109-417) and subsequent reauthorizations before the COVID-19 pandemic,⁴⁹ Congress has directed HHS in PHSA Section 319D to

establish near real-time electronic nationwide public health situational awareness capability through an interoperable network of systems to share data and information to enhance early detection of rapid response to, and management of, potentially catastrophic infectious disease outbreaks and other public health emergencies that originate domestically or abroad.

GAO reported that, as of March 2022, HHS had not yet established this capability or taken all statutorily required steps to plan for such a capability. The HHS Secretary had designated the Assistant Secretary for Preparedness and Response as responsible for developing the strategy.⁵⁰

CDC is the primary HHS agency that directly receives and analyzes public health surveillance data related to infectious diseases. CDC generally receives de-identified public health surveillance data—including on cases, testing, deaths, and hospitalizations—from all or a subset of U.S. jurisdictions based on data sharing agreements with those jurisdictions.⁵¹ U.S. jurisdictions have differing legal requirements and systems for collecting different types of public health data.⁵² Jurisdictions also generally rely on diverse health care entities—such as laboratories, hospitals, and outpatient health care facilities—to share data and meet reporting requirements. In the past, data sharing among entities has sometimes relied on outdated means of exchange, such as by fax machines or Excel spreadsheets. CDC has funded public health surveillance systems at the SLTT level and has encouraged jurisdictions to follow recommended standards for data collection.⁵³ Despite this funding and the recommended standards, SLTT jurisdictions collected public health data in different ways during and before the pandemic, which affected the timeliness and adequacy of data for response.⁵⁴

During the pandemic, Congress and the executive branch implemented federal-level public health data reporting requirements, including a laboratory test result reporting requirement in the CARES Act (P.L. 116-136; Section 18115) and hospital and nursing home requirements through CMS regulations.⁵⁵

⁴⁹ Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (P.L. 113-5) and the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (P.L. 116-22).

⁵⁰ GAO, *COVID-19: Pandemic Lessons Highlight Need for Public Health Situational Awareness Network*, GAO-22-104600, June 2022, <https://www.gao.gov/assets/730/721426.pdf>.

⁵¹ CRS Report R46588, *Tracking COVID-19: U.S. Public Health Surveillance and Data*, and CDC, “Where Does our Data Come From?,” https://www.cdc.gov/surveillance/data-modernization/basics/where_does_our_data_come_from.html.

⁵² Association of State and Territorial Health Officials, *Legal Landscape of Public Health Data: A Scan of State Laws Governing Public Health Data*, March 2023, <https://www.astho.org/globalassets/report/legal-landscape-of-ph-data-scan-of-state-laws.pdf>, and Macarena C. Garcia, Nedra Y. Garrett, Vivian Singletary, et al., “An Assessment of Information Exchange Practices, Challenges and Opportunities to Support U.S. Disease Surveillance in Three States,” *Journal of Public Health Management and Practice*, vol. 24, no. 6 (2018), pp. 546-553.

⁵³ U.S. Government Accountability Office, *COVID-19: Current and Future Federal Preparedness Requires Fixes to Improve Health Data and Address Improper Payments*, GAO-22-105397, April 27, 2022, pp. 49-54, <https://www.gao.gov/products/gao-22-105397>, and CRS Report R46588, *Tracking COVID-19: U.S. Public Health Surveillance and Data*.

⁵⁴ CDC, “Where Does our Data Come From?,” https://www.cdc.gov/surveillance/data-modernization/basics/where_does_our_data_come_from.html.

⁵⁵ 42 C.F.R. §482.42(e), 42 C.F.R. §485.640(d), and 42 C.F.R. §483.80(g)

Throughout the pandemic, Congress provided supplemental appropriations through six different COVID-19 relief laws that included funding for public health surveillance and data systems.⁵⁶ For example, much of the more than \$59 billion in COVID-19 grants that CDC has awarded to SLTT jurisdictions from these laws can be used, in part, for surveillance and data-related activities.⁵⁷ The American Rescue Plan Act of 2021 (ARPA; P.L. 117-2) provided specific funding to establish a Center for Forecasting and Outbreak Analytics at CDC (Section 2404), as well as for genomic sequencing and surveillance (Section 2402). CDC established the Center for Forecasting and Outbreak Analytics in April 2022 using \$200 million of the ARPA funds.⁵⁸ In addition, the Biden Administration announced that the \$1.75 billion genomic surveillance appropriation would be used as follows: \$1 billion for CDC and SLTT jurisdictions to expand sequencing capacity, \$400 million for new Centers of Excellence in Genomic Epidemiology that operate as partnerships between state public health agencies and academic institutions, and \$300 million to build a National Bioinformatics Infrastructure.⁵⁹

CDC has received a total of \$1.38 billion to date for its Data Modernization Initiative (DMI) from both regular and COVID-19 supplemental appropriations.⁶⁰ CDC's DMI is an effort to modernize the way public health data are collected, shared, and analyzed in the United States to enable rapid and comprehensive data on health threats.⁶¹ As a part of the DMI, CDC has partnered with the Office of the National Coordinator for Health Information Technology (ONC) to establish new standards and regulations for facilitating the modernization of data exchange between the health care and public health sectors, with feedback gathered from federal advisory committees.⁶² In addition, Congress required CDC data modernization activities and authorized a related grant program as a part of the Consolidated Appropriations Act, 2021 (P.L. 116-260; Division BB, Section 314), which enacted PHSA Section 2823.

Section 2211: Modernizing State, local, and tribal biosurveillance capabilities and infectious disease data

Provision

Section 2211 amends PHSA Section 319D, which addresses CDC and other HHS biosurveillance and public health emergency response capabilities.⁶³ The provision makes several amendments to clarify CDC's required capacities for responding to bioterrorism and other public health threats

⁵⁶ CRS Report R46711, *U.S. Public Health Service: COVID-19 Supplemental Appropriations in the 116th Congress*, and CRS Report R46834, *American Rescue Plan Act of 2021 (P.L. 117-2): Public Health, Medical Supply Chain, Health Services, and Related Provisions*.

⁵⁷ CDC, "CDC COVID-19 State, Tribal, Local and Territorial Funding," <https://www.cdc.gov/budget/fact-sheets/covid-19/funding/index.html>. Allowable uses of funds vary by grant, see links at the end of the website.

⁵⁸ CDC, "CDC Launches New Center for Forecasting and Outbreak Analytics," April 2022, <https://www.cdc.gov/media/releases/2022/p0419-forecasting-center.html>.

⁵⁹ The White House, "Fact Sheet: Biden Administration Announces \$1.7 Billion Investment to Fight COVID-19 Variants," press release, April 16, 2021, <https://www.whitehouse.gov/briefing-room/statements-releases/2021/04/16/fact-sheet-biden-administration-announces-1-7-billion-investment-to-fight-covid-19-variants/>.

⁶⁰ CDC, "Notable DMI Milestones: 2019-2023," <https://www.cdc.gov/surveillance/data-modernization/milestones.html> and CRS analysis of appropriations.

⁶¹ CDC "Data Modernization Initiative (DMI): The Basics," <https://www.cdc.gov/surveillance/data-modernization/basics/index.html>.

⁶² CDC, "Advancing Interoperability for Public Health," <https://www.cdc.gov/surveillance/policy-standards/interoperability.html>, and ONC, "Public Health Data Systems Task Force 2022," <https://www.healthit.gov/hitac/committees/public-health-data-systems-task-force-2022>.

⁶³ 42 U.S.C. §247d-4.

(in subsection a). These capacities include training personnel, improving communications facilities and networks, improving capabilities for public health surveillance and reporting, and improving laboratory facilities. Under prior law, such activities were allowed but not required.

In addition, Section 2211 makes several amendments to the existing authorizations for HHS to establish an integrated system of public health alert communications and surveillance networks (in subsection b), to establish a near real-time electronic nationwide public health situational awareness capability through an interoperable network of systems (in subsection c), and to implement a state or regional grant program for situational awareness systems (in subsection d). In particular, Section 2211 makes several amendments to address the privacy of information collected in such systems, including by adding requirements throughout PHSA Section 319D that information is collected in a manner that protects privacy and security as required by applicable federal and state law. Section 2211 makes many other amendments, including those related to incorporating tribal data systems into the networks, ensuring data quality, improving laboratory data reporting, improving data exchange, ensuring consultation with state officials, and ensuring that standards align with those in PHSA Section 2823, the CDC data modernization authorization.

Section 2211 requires the Secretary to convene a public meeting for providing input on the network (subsection c) within 180 days of enactment. It also requires the Secretary to update a strategy and implementation plan for the network every five years. Among other things, the strategy implementation plan is to implement applicable lessons learned from recent public health emergencies. In addition, the plan must identify and demonstrate measurable steps to further develop and integrate infectious disease detection, to support laboratory test result sharing, and to improve coordination among SLTT public health officials, clinical laboratories, and others with expertise in public health surveillance.

Nothing in the amended PHSA Section 319D(c) may be construed to (1) supplant relevant SLTT activities related to public health surveillance, or (2) alter the Secretary's data collection authority with respect to types of data. The Secretary is required to ensure that activities under the state grant program do not duplicate efforts of other HHS agencies.

Section 2211 amends PHSA Section 319D to authorize appropriations of \$25 million for each of FY2022 and FY2023 for CDC's facilities and capacities (subsection a), and \$136 million for each of FY2022 and FY2023 for the interoperable networks and public health situational awareness capabilities (in subsections b, c, and d).

Section 2212: Genomic sequencing, analytics, and public health surveillance of pathogens

Provision

Section 2212 includes two main provisions related to genomic sequencing and surveillance. First, the provision directs the HHS Secretary to issue guidance related to genomic sequencing of pathogens (subsection a). The guidance is to support collaboration among federal agencies related to genomic sequencing of pathogens, including the use of new and innovative approaches, to improve public health surveillance and response activities. The guidance is also to address secure sharing of sequence data and to ensure privacy protection consistent with state and federal law.

Second, Section 2212 formally authorizes a genomic sequencing, analytics, and surveillance program at CDC by adding a new PHSA Section 2824 (subsection b). The new PHSA Section 2824 requires CDC to strengthen and expand activities related to genomic sequencing of pathogens in consultation with NIH and other departments and agencies. CDC is to address technological and workforce capabilities for genomic sequencing, and to provide technical

assistance to SLTT public health agencies, including those receiving Epidemiology and Laboratory Capacity grants. The section authorizes CDC to award funding to entities with expertise in genomic sequencing for public health purposes, including academic laboratories, for achieving these goals. PHSA Section 2824 also authorizes funding awards to public health agencies to establish centers of excellence to promote innovation in pathogen genomics and molecular epidemiology. These centers are to develop new surveillance and epidemiology approaches, along with assisting in responses and developing training materials for other experts. To receive an award, public health agencies must partner with academic institutions with relevant expertise. This section does not authorize an appropriation.

Under Section 2212, CDC must report to specified congressional committees within 90 days after enactment and 90 days after expenditure of all funds outlining how funds under American Rescue Plan Act of 2021 (ARPA; P.L. 117-2) Section 2402 were expended as of that date. ARPA Section 2402 appropriated funding for genomic sequencing and surveillance.

Section 2213: Supporting State, local, and tribal public health data

Provision

Section 2213 is a multicomponent authorization that addresses several aspects of public health data policy. First, Section 2213 amends requirements under PHSA Section 2823(a)(2),⁶⁴ which authorizes the HHS Secretary to establish standards for CDC public health data systems and SLTT governments receiving grant funding under that section. The amendment adds specificity to the existing law by requiring the Secretary to develop such standards no later than two years after enactment. The amended PHSA Section 2823 further stipulates that, to eliminate duplicative efforts when creating these standards, the Secretary, in conjunction with the ONC, may draw upon input gathered (including from an existing advisory committee) and materials created prior to enactment. These standards must comply with existing federal laws pertaining to standards and implementation specifications for health information and technology. None of the amendments to PHSA Section 2823 may be construed to preempt relevant federal or state information privacy or security law.

Second, Section 2213 requires that, within one year of enactment, ONC conduct a study to review the use of standards for electronic ordering and reporting of laboratory test results. The study must focus on (1) the extent of laboratory standard use, (2) compliance and effects on interoperability, and (3) challenges to collection of demographic data and compliance with standards, among other things. Within two years of enactment, ONC must submit a report, based on this study, to select congressional committees, as specified.

Third, under Section 2213, the Secretary is required to facilitate the development of and updates to HHS interagency data use agreements between CDC, ASPR, other relevant agencies and offices within HHS, and other federal agencies to prepare for and respond to potential or declared public health emergencies. In carrying out this requirement, the Secretary must adhere to specific further requirements, including, for example, addressing methods of granting access to other agencies, considering minimum necessary principles of data sharing for appropriate use, and using privacy and security protections. The Secretary is further allowed to update data-related agreements and contracts between CDC, ASPR, and external entities, including, for example, SLTT health departments, laboratories, and health care providers, in order to prepare for and respond to public health emergencies. Within 90 days of enactment, the Secretary shall report to

⁶⁴ 42 U.S.C. §300hh-33.

select congressional committees on the status of agreements among stakeholders both internal and external to HHS.

Fourth, Section 2213 amends part A of PHSA Title III to add a new PHSA Section 310B, “Improving State, Local, and Tribal Information Sharing.” The new section allows the Secretary to conduct activities to improve the availability of relevant public health data on communicable disease and to facilitate information sharing between CDC, ASPR, and SLTT public health officials, in consultation with nonfederal public health officials. Such public health data can include data from health care facilities, laboratories, health information exchanges, and SLTT health departments. When possible, the Secretary shall ensure that the data disclosed are the minimum necessary for public health purposes. The Secretary shall consult with public health officials and relevant stakeholders to determine the most effective content, form, and manner for data sharing, consistent with existing federal law, to enable nonfederal health department communicable disease response, including the collection and reporting of demographic and other relevant data elements. Data gathered may be exempt from disclosure under FOIA (5 U.S.C. §552) if it identifies an individual or if there is even a small risk it could identify, alone or in combination with other available resources, an individual.

Fifth, Section 2213 additionally requires the Secretary to award funding for identifying, developing, or disseminating best practices in electronic health information and the use of designated standards and implementation specifications to improve the quality and completeness of public health data, including demographic data. Eligible entities for the program include SLTT governments, health care providers, academic medical centers, community-based organizations, other tribal organizations, and other appropriate public or private nonprofit entities. Award-receiving entities shall develop and test health care provider training best practices with regard to activities surrounding the use of standards and implementation specifications that assist in the capture, access, exchange, and use of electronic health information. Such electronic health information can include demographic information, disability status, veteran status, and functional status. These endeavors must include, at a minimum, those related to (1) using and improving data standards and implementation specifications, (2) improving communications with culturally diverse patients to better capture their demographic information, (3) developing methods for accurately recording patient responses, (4) educating providers on the importance of accurate data collection and recording and the utility of the data, and (5) providing information regarding how data will be de-identified if used for public health purposes, as applicable. Award recipients shall submit a report to the Secretary of best practices developed. The Secretary, within one year of the program’s completion, shall submit a report to Congress regarding the success of identified best practices and recommendations for improving public health and reducing disparities through improving the capture, access, exchange, and use of data. The Secretary shall ensure funded activities and programs are not unnecessarily duplicative. There is no authorization of appropriations for this program.

Finally, nothing in Section 2213 may be construed to (1) supplant relevant SLTT activities related to public health surveillance, (2) alter the Secretary’s data collection authority with respect to types of data, or (3) modify relevant federal and state information privacy or security law.

Section 2214: Epidemic forecasting and outbreak analytics

Provision

Section 2214 adds a new PHSA Section 2825, which formally authorizes epidemic forecasting and analytics activities at CDC to enhance the prediction, modeling and forecasting of potential public health emergencies and other infectious disease outbreaks. The Secretary is to identify

strategies to leverage the capabilities of other public and private entities in these efforts, including through collaborative partnerships. CDC may consider public health and other data sources related to public health emergencies and other infectious disease outbreaks in these efforts.

CDC is to report to specified congressional committees on the progress of activities within one year of enactment and then annually for the subsequent four years.

Section 2215: Public health data transparency

Provision

Section 2215 requires the HHS Secretary to issue a report within one year of enactment assessing CDC's collection and dissemination of public health data related to a public health emergency declared under PHSA Section 319 or a potential public health emergency. The report is to assess practices, objectives, and associated progress and challenges in achieving such objectives.

No later than 180 days after submitting the report, CDC is to submit a plan to specified congressional committees that includes (1) steps to improve the timely reporting and dissemination of de-identified public health data related to a public health emergency and associated barriers, (2) recommendations to Congress regarding gaps in practices and objectives, and (3) considerations regarding the requirements and limitations of data use agreements for such purposes, and any efforts undertaken to address those requirements and limitations.

Section 2216: GAO report on public health preparedness, response, and recovery data capabilities

Provision

Section 2216 directs GAO to conduct a study on HHS' efforts to ensure that data capabilities related to public health preparedness, response, and recovery for pandemic and other biological threats are not unnecessarily duplicative, overlapping, or fragmented. The study is to include (1) a comprehensive list of all relevant data collection efforts as identified by the department; (2) an analysis of duplication, overlap, or fragmentation in such programs; (3) documentation of HHS efforts to reduce duplication, improve coordination, and associated challenges; (4) reporting of any practices that threaten individual privacy and recommendations to improve privacy of individual, identifiable data; and (5) a description of the funding dedicated to each data collection program.

GAO must provide a briefing no later than six months after enactment and a complete report no later than 18 months after enactment to specified congressional committees. The report is to include recommendations for related data programs to (1) streamline data collection and reduce fragmentation and any associated challenges, (2) reduce duplication in such programs, and (3) improve information sharing across programs.

Chapter 3—Revitalizing the Public Health Workforce

COVID-19 pandemic preparedness and response have required mobilization of the public health workforce and the patient care workforce to test, treat, and vaccinate patients and to engage in outbreak control efforts. For both workforces, the pandemic revealed underlying challenges related to workforce shortages overall, in certain disciplines, and in specific geographic locations. In addition, the pandemic may have exacerbated issues related to clinician burnout. One survey found that 52% of providers reported experiencing burnout and 62% reported that worry or stress

during the pandemic had adversely affected their mental health.⁶⁵ The American Rescue Plan Act (P.L. 117-2) included additional funding for several new and existing health workforce programs.

Section 2221: Improving recruitment and retention of the frontline public health workforce

Background

PHSA Section 776 authorized the Public Health Workforce Loan Repayment Program, a loan repayment program to support public health professionals at federal state, local, and tribal public health agencies.⁶⁶ Individuals were eligible for loan repayment if they are in their final year of study for a degree in public health or a health profession and have accepted employment (or a related training fellowship) at an eligible public health agency. Individuals were also eligible if they have completed training during the preceding 10-year period. Eligible individuals had to be U.S. citizens, may not have had another service obligation, and must apply, and enter into a contract with the HHS Secretary. The section also specified the penalties for breach of contract. It specified that participants will receive \$35,000 in loan repayment for each year served, with a maximum total loan repayment award of \$105,000. The Secretary was allowed to provide additional payments for an individual's tax liability. Authorizations of appropriations for this program were from FY2010 through FY2015; this program has not been funded in recent years. No loan repayments have been made under this program in recent years.

There are also separate federal loan repayment programs for public health professionals, such as the CDC Educational Loan Repayment Program for Health Professionals, for CDC staff who have participated in selected CDC fellowship programs as authorized by PHSA Section 317F.⁶⁷

Provision

The provision amends PHSA Section 776 to make a number of changes to the loan repayment program. Notably, it removes eligibility for individuals at federal agencies; instead, the program is to recruit and retain individuals at state, local, and tribal public health agencies. The provision makes a number of technical changes to the loan repayment program, for example, to make graduates (or soon to be graduates) of additional degree programs eligible for loan repayment, including those with certificates and those with training in specified data science fields. It also requires a service commitment of at least three consecutive years; increases the annual loan repayment amount to \$50,000 per year and the maximum loan repayment amount to \$150,000 total; and adds requirements that the Secretary, when making awards, attempt to achieve a balance in geographical regions, urban and rural participation, and participation by employees at state, local, and tribal health departments. The provision also adds language that specifies eligible loan types and adds that the Secretary may waive or suspend penalties for individuals who fail to complete their service commitment.

⁶⁵ Scott Clement, Cece Pascual, and Monica Ullmanu, "Stress on the Front Lines of Covid-19: Health Care Workers Share the Hardest Part of Working During the Pandemic," *Washington Post*, April 6, 2021, <https://www.washingtonpost.com/health/2021/04/06/stress-front-lines-health-care-workers-share-hardest-parts-working-during-pandemic/>. Other studies have shown increased anxiety, depression, sleep problems, and distress among health care workers during the COVID-19 pandemic. See, for example, Ashley E. Muller, Elisabet V. Hafstad, Jan P. W. Himmels, et al., "The Mental Health Impact of the COVID-19 Pandemic on Healthcare Workers, and Interventions to Help Them: A Rapid Systematic Review," *Psychiatry Research*, vol. 293 (November 2020).

⁶⁶ 42 U.S.C. §295f-1.

⁶⁷ CDC, "Educational Loan Repayment Program for Health Professionals," <https://www.cdc.gov/fellowships/loanrepayment.html>.

The provision also establishes a pilot program known as the Bio-Preparedness Workforce Pilot Program to provide loan repayment for health professionals who have expertise in infectious disease and emergency preparedness and response activities as a part of PHSA Section 776. The pilot will be administered in the same way as the Public Health Loan Repayment program in PHSA Section 776, except that it would permit individuals to fulfill their service commitment in federal health care facilities, in nonprofit health care facilities located in health professional shortage areas, in entities funded by the Ryan White HIV/AIDS program or the Indian Health Service, or at any other entity determined appropriate by the Secretary. The provision requires that the new program not duplicate the efforts of other federal loan repayment programs, including the National Health Service Corps, and be evaluated with a report to Congress that includes recommendations on whether the program should be extended.

Finally, the provision authorizes an appropriation of \$100 million for each of FY2023 through FY2025, and requires a GAO study on the health care workforce that includes certain specified elements. This study would be completed no later than two years after enactment and is to be submitted to specified congressional committees.

Section 2222: Awards to support community health workers and community health

Background

PHSA Section 399V authorized CDC to award grants for using community health workers to promote positive health behaviors and outcomes for populations in medically underserved communities.⁶⁸ Community health workers funded through the program were to provide education and outreach related to health problems, health behaviors, health care program enrollment, and other health care services access. CRS has not identified a dedicated CDC community health worker grant program carried out using authority in PHSA 399V.⁶⁹ During the COVID-19 Pandemic, CDC funded a Community Health Workers for COVID Response and Resilient Communities (CCR) initiative using COVID-19 relief funds.⁷⁰ In addition, HRSA made awards to support 83 community health worker training program grantees using funding from ARPA.⁷¹

Provision

This provision amends PHSA Section 399V to replace the overall statutory purpose of the community health worker grant program. The amended section requires the Secretary to award grants, contracts, or cooperative agreements to eligible entities to support community health worker programs that target improving health behaviors in medically underserved communities, including by addressing ongoing and longer-term community health needs, and by building the capacity of the community health worker workforce. The provision amends PHSA Section 399V to add language to the existing community health worker program that makes grants, contracts, or cooperative agreements awarded subject to state laws or requirements regarding scope of licensure, registration, or certification for community health workers. The provision also makes

⁶⁸ 42 U.S.C. §280g-11.

⁶⁹ CDC has cited PHSA Section 399V as authorizing legislation for is Public Health Scientific Services budget activity; however, it is unclear what programs or activities are carried out using this authority.

⁷⁰ CDC, “Community Health Workers for COVID Response and Resilient Communities (CCR),” <https://www.cdc.gov/covid-community-health-workers/index.html>.

⁷¹ HHS, “With New American Rescue Plan Funding, HHS Expands and Strengthens the Community and Public Health Workforce,” press release, September 30, 2022, <https://www.hhs.gov/about/news/2022/09/30/new-american-rescue-plan-funding-hhs-expands-and-strengthens-community-and-public-health-workforce.html>.

technical corrections to PHSA Section 399V and adds language for grant purposes that include that the funds should be used to (1) recruit, hire, train, and retain community health workers that meet the needs of the community, and (2) focus on health conditions that are prevalent in the medically underserved community or in a community that would require additional support under a public health emergency. The provision also adds language regarding promoting health behaviors, reducing health disparities, and serving rural populations. The provision adds new subsections to PHSA Section 399V that authorize the Secretary to provide technical assistance to awardees, require the Secretary to disseminate best practices regarding the recruitment and retention of community health workers, and require a report to Congress about the effectiveness of the program. Finally, the provision amends the section's authorization of appropriations to authorize \$50 million for each of FY2023 through FY2027, defines a number of terms, and requires a GAO study that examines the duplication between training programs administered by HRSA.

Section 2223: Improving public health emergency response capacity

Background

The authority to directly hire individuals can allow federal agencies to quickly fill vacancies when a critical hiring need or severe candidate shortage exists.⁷² HHS and other stakeholders have asserted that the use of such an authority during a public health emergency would allow HHS to respond to an incident in a more rapid manner.⁷³

Provision

This provision amends PHSA Section 319 to add a new subsection that authorizes the HHS Secretary to directly appoint a limited number of individuals to positions in HHS to support an initial response to a declared public health emergency.⁷⁴ The HHS Secretary can make up to 400 appointments for critical hiring needs and up to 100 appointments for severe shortage of candidates per each fiscal year in which the HHS Secretary makes a PHE declaration (not including renewals). The Secretary must maintain records of the appointments and, under specified conditions, provide notices to Congress on the use of this authority, as well as provide annual reports to Congress. One year after the initial report, GAO shall submit a report to Congress on the use of this authority. The appointment authority is scheduled to expire on September 30, 2028.

Section 2224: Increasing educational opportunities for allied health professions

Background

PHSA Section 755 authorized grants or contracts to support training in allied health professions through a number of specified potential grantee activities, including expanding program enrollment; providing training; establishing community-based training, including in rural and underserved areas; curriculum development; interdisciplinary training; and providing trainee

⁷² U.S. Office of Personnel Management (OPM), "Direct Hire Authority," <https://www.opm.gov/policy-data-oversight/hiring-information/direct-hire-authority/#url=Fact-Shee>

⁷³ Department of Health and Human Services Emergency Fund, *Public Health and Social Services FY 2024: Justification of Estimates for Appropriations Committee*, p. 66, <https://www.hhs.gov/sites/default/files/fy-2024-phssecf-cj.pdf>.

⁷⁴ 42 U.S.C. §247d.

financial assistance, amongst other purposes.⁷⁵ The section did not specify “allied health fields,” but included language about training to work with geriatric populations and in maternal and child health, which was added in the CARES Act (P.L. 116-136) in 2020.⁷⁶ This section has not been funded in recent years.

Provision

The provision amends PHSA Section 755 to add new language describing the activities the grant is to support. The provision stipulates that grant funds be used to increase educational opportunities in physical therapy, occupational therapy, respiratory therapy, audiology, and speech language pathology, which may include offering scholarships or stipends, among other activities that aim to improve retention of individuals from disadvantaged communities in these health professions.

Section 2225: Public Health Service Corps annual and sick leave

Background

The United States Public Health Service (USPHS) Commission Corps is a uniformed service in HHS. It is composed of individuals from varying health professions who can augment emergency and disaster responses. Some members of the Corps serve as full-time federal employees while on duty (Regular Corps), while others are activated only at particular times (Ready Reserve Corps).⁷⁷ The amount of annual leave that officers may accumulate while on active duty is specified in law.⁷⁸ During the COVID-19 pandemic, many USPHS officers were deployed and unable to take annual leave. Under prior law, many deployed officers would have lost leave accumulated during the pandemic, as the amount was capped at 60 days.⁷⁹

Provision

This provision amends PHSA Section 219 to allow regulations authorizing accumulated annual leave for commissioned officers of the Regular Corps or Ready Reserves Corps on active duty to be updated from 60 to 120 days.⁸⁰

Section 2226: Leadership exchange pilot for public health and medical preparedness and response positions at the Department of Health and Human Services

Background

During public health emergency responses, HHS staff often support SLTT health agencies and work with other federal agencies, such as the Federal Emergency Management Agency (FEMA). Some have argued that increased practical experience in SLTT agencies or other federal

⁷⁵ 42 U.S.C. §294e.

⁷⁶ CRS Report R46334, *Selected Health Provisions in Title III of the CARES Act (P.L. 116-136)*.

⁷⁷ HHS, *Ready Reserve Corps Management*, CCI 322.06, June 14, 2021, https://dcp.psc.gov/ccmis/ccis/documents/CCI_322.06.pdf.

⁷⁸ PHSA §219; 42 U.S.C. §210-1.

⁷⁹ See “Letter from Military Coalition to Appropriations Committee Leaders,” September 18, 2020, available at <https://www.moaa.org/content/publications-and-media/news-articles/2020-news-articles/advocacy/leave-policy-change-is-good-news-for-usphs-commissioned-corps-members/>.

⁸⁰ 42 U.S.C. §210-1.

emergency agencies might help HHS staff provide better service and support during emergencies.⁸¹

Provision

This provision amends PHSA Title XXVIII by adding a new Section 2826, which gives the HHS Secretary the authority to, not a year later than the enactment of the PREVENT Pandemics Act, establish a voluntary pilot program to provide additional field training to certain HHS employees engaged in activities related to public health preparedness and response.⁸² The program will provide fellowships, details, and other relevant placements with federal agencies, departments, or state and local health departments for a maximum of two years and shall not exceed five years. The HHS Secretary shall issue guidance for identifying these opportunities. At the conclusion of this program, the HHS Secretary shall issue a report to Congress detailing the number of individuals who participated, a description of their professional growth, and an assessment of the program, including a recommendation on whether it should be continued.

Section 2227: Continuing educational support for health professionals serving in rural and underserved communities

Background

PHSA Section 752 required the Secretary to make grants or enter into contracts with eligible entities for specified activities to improve health care, increase retention and representation of minority faculty members, enhance practice environments, and disseminate information and education support to reduce professional isolation.⁸³ The provision specified eligible entities, required an application, and specified how funds must be used, including to provide distance education, continuing education, collaborative education, and telelearning activities with priority for training in primary care. The section authorized an appropriation of \$5 million for each of FY2010 through FY2014 and has not been funded in recent years.

Provision

The provision amends PHSA Section 752 to retitle the program “Continuing Education Support for Health Professionals Serving in Rural and Underserved Communities.” It amends the program to require the Secretary to make grants or contracts with eligible entities to support access to accredited continuing medical education for primary care physicians and health care providers at community health centers or rural health clinics. In addition to creating new application requirements, it amends the use of funds to specify that specialty training for primary care providers be prioritized and that the goal of this training is to improve retention and increase access to specialty care for community health center and rural health clinic patients. The provision (1) adds clarifying language stating that funds may be used for training with an in-person clinical training components, (2) specifies that grantees may not use more than 5% of the grant funding for administrative expenses, (3) requires that the amended program may not duplicate other HRSA activities, including those authorized under PHSA Section 330N. (PHSA Section 330N authorizes a grant program for technology-enabled learning and capacity building for health care entities in rural, frontier, or health care shortage areas, or that serve Native American populations, and has been funded under HRSA’s Office of Rural Health as the

⁸¹ See, for example, Center for Strategic and International Studies, *Building the CDC the Country Needs*, 2023, pp. 21-22, https://csis-website-prod.s3.amazonaws.com/s3fs-public/publication/230112_Morrison_Building_CDC.pdf?VersionId=kTKB3urWn1bfZpXuCqixfxzHfT8AUcIM.

⁸² 42 U.S.C. §300hh et seq.

⁸³ 42 U.S.C. §294b.

Telehealth Technology-Enabled Learning Program). Finally, the provision amends the authorization of appropriations in PHSA Section 752 to authorize \$5 million for each of FY2023 through FY2025.

Chapter 4—Enhancing Public Health Preparedness and Response

Section 2231: Centers for public health preparedness and response

Background

PHSA Section 319F authorized a program to fund Centers for Public Health Preparedness (the Centers) at accredited schools of public health.⁸⁴ These Centers were responsible for establishing degree program curricula and training programs on essential public health security capabilities consistent with the National Health Security Strategy. The Centers have been required to conduct research on public health preparedness and response systems, and to collaborate with SLTT health departments to assess community preparedness and response needs, evaluate programs and activities, and develop training and education materials. This program has been administered as CDC's Academic Centers for Public Health Preparedness, and has received roughly \$8 million to \$9 million per year in recent years.⁸⁵

Provision

Section 2231 amends PHSA Section 319F to replace the preexisting Centers for Public Health Preparedness authorization with a new Centers for Public Health Preparedness and Response program authorization.⁸⁶ Funded institutes of higher education and other nonprofit entities are required to coordinate with SLTT public health agencies and health care entities. Funds may be used to carry out activities to advance public health preparedness and response capabilities, including (1) identifying, translating, and disseminating research findings or strategies into evidence-based best practices related to public health preparedness; (2) improving awareness of such practices among stakeholders and the public; (3) utilizing and expanding technological and analytical capabilities to inform preparedness and response efforts; (4) participating in drills and exercises; and (5) providing technical assistance and expertise to SLTT public health agencies and other appropriate entities. CDC must support at least 10 Centers, subject to the availability of appropriations, to be distributed geographically throughout the United States.

Section 2231 also strikes Section 319G of the PHSA, which established a demonstration program to enhance bioterrorism training, coordination, and readiness.⁸⁷

Section 2232: Vaccine distribution plans

Background

The Pandemic and All-Hazards Preparedness Act (PAHPA, P.L. 109-417) amended PHSA Section 319A to authorize the HHS Secretary to track the initial distribution of federally purchased

⁸⁴ 42 U.S.C. §247d-6.

⁸⁵ See *Congressional Record*, vol. 168, no. 42 (March 9, 2022), p. H2673, and CDC, “FY2022 Operating Plan,” <https://www.cdc.gov/budget/documents/fy2022/fy-2022-cdc-operating-plan.pdf>.

⁸⁶ 42 U.S.C. §247d-6.

⁸⁷ 42 U.S.C. §247d-7.

influenza vaccine with the voluntary cooperation of vaccine manufacturers, wholesalers, and distributors during an influenza pandemic.⁸⁸

Provision

Section 2232 amends PHSA Section 319A to allow the HHS Secretary to track federally purchased vaccines used in response to other pandemics, in addition to influenza pandemics.

Section 2233: Coordination and collaboration regarding blood supply

Background

The nation's blood supply is largely managed by a network of independent blood centers and the American Red Cross.⁸⁹ These organizations collect blood product donations (e.g., whole blood, platelets) from individuals through scheduled appointments, walk-in appointments, and blood drives.

Coordination of blood availability and emergency preparedness is a collaborative effort between many stakeholders, with input from HHS, FDA, and other federal entities, as well as from nonfederal partners. The HHS Office of Infectious Disease and HIV/AIDS Policy (OIDP) supports the coordination of blood safety and emergency preparedness and response activities. OIDP staff serve as liaisons on a number of councils, task forces, advisory committees, and programs.⁹⁰

Provision

Section 2233 requires the Secretary of HHS to ensure coordination and collaboration between relevant federal departments and agencies related to the safety and availability of the blood supply. This section specifically requires coordination and collaboration between relevant agencies within HHS, the Department of Defense (DOD), and the Department of Veterans Affairs (VA). This section also requires the Secretary to consult and communicate with nonfederal stakeholders regarding issues related to the safety and availability of the blood supply.

Section 2234: Supporting laboratory capacity and international collaboration to address antimicrobial resistance

Background

PHSA Section 319E authorized a federal Antimicrobial Resistance Task Force, along with several activities for addressing antimicrobial resistance (AMR), including research and development for new drugs and diagnostics, education of health professionals, monitoring at federal health care facilities, and state-based activities.⁹¹ Separately, HHS agencies have many activities to address AMR that are funded through appropriations but are not specifically named in PHSA Section 319E. For example, CDC established a network of antimicrobial resistance laboratories starting in

⁸⁸ 42 U.S.C. §247d-1.

⁸⁹ For more information on independent blood centers, see <https://americasblood.org/about/>. For more information on the American Red Cross, see <https://www.redcross.org/give-blood.html>.

⁹⁰ OIDP maintain a list of its roles and responsibilities for the various entities; see <https://www.hhs.gov/oidp/topics/blood-tissue-safety/roles/index.html>.

⁹¹ 42 U.S.C. §247d-5.

2016—a program that currently includes laboratories in all 50 states and several cities.⁹² HHS also engages in international collaboration to address AMR.⁹³

Provision

Section 2234 adds a new subsection to PHSA Section 319E that provides formal authorization for a network of antibiotic resistance regional laboratories to be maintained by CDC, distributed throughout the United States. These laboratories are to (1) identify and monitor antimicrobial-resistant pathogens; (2) detect and identify such resistant pathogens, including by providing support at the request of other laboratories and during emergency responses; and (3) support diagnosis of resistant pathogens and determine the susceptibility to treatments.

The amended PHSA Section 319E also formally authorizes the HHS Secretary to engage in international collaboration for addressing AMR, including by (1) supporting research on AMR pathogens, including those not detected in the United States; (2) supporting surveillance, laboratory, and other response capacity; and (2) providing technical assistance for AMR infection control activities. The Secretary may award grants, contracts, or cooperative agreements to public and private entities, including nongovernmental organizations, for these activities.

Section 2235: One Health framework

Background

The concept of “One Health” recognizes that human health is linked to animal health and the environment. A One Health approach therefore involves cross-sectoral efforts to address health challenges such as zoonotic diseases (i.e., diseases that can be transmitted from animals to humans).⁹⁴ During the pandemic, CDC established a coordinating committee for One Health approaches to COVID-19, in collaboration with the U.S. Department of Agriculture (USDA) and the Department of the Interior (DOI).⁹⁵ Through appropriations report language (H.Rept. 116-450), CDC was previously directed to develop a National One Health Framework along with a standing coordination committee for federal One Health efforts.

Provision

Section 2235 requires CDC, in coordination with other federal departments and agencies, to (1) develop or update a One Health framework to address zoonotic diseases and advance public health preparedness, and (2) coordinate with USDA and DOI to develop a One Health coordination mechanism at the federal level to strengthen One Health collaboration across the government. The Secretary must report to specified congressional committees no later than one year after enactment to provide an update on these activities.

Section 2236: Supporting children during public health emergencies

Background

The National Advisory Committee on Children and Disasters (NACCD) is composed of individuals from both the private and public sector who evaluate issues and programs and provide

⁹² CDC, “CDC’s Antimicrobial Resistance (AR) Laboratory Networks,” <https://www.cdc.gov/drugresistance/laboratories.html>.

⁹³ HHS Office of Global Affairs, “Antimicrobial Resistance,” <https://www.hhs.gov/about/agencies/oga/global-health-security/antimicrobial-resistance/index.html>.

⁹⁴ CDC, “One Health Basics,” <https://www.cdc.gov/onehealth/basics/index.html>.

⁹⁵ CDC, “Federal One Health Coordination,” <https://www.cdc.gov/onehealth/what-we-do/federal-coordination.html>.

advice to the HHS Secretary and the Assistant Secretary for Preparedness and Response on supporting the preparedness, response, and recovery efforts aimed at the specific needs of children.⁹⁶ NACCD was first authorized by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA, P.L. 113-5) in PHSA Section 2811A⁹⁷ and was subsequently reauthorized by the Pandemic and All-Hazards Preparedness and Advancing Innovation Act (PAHPAIA, P.L. 116-22).

Provision

Section 2236 amends PHSA Section 2811A to include developmental needs among those evaluated by the National Advisory Committee on Children and Disasters. The provision further expands the duties of the committee to provide advice and consultation on continuity of care and education for children, parents, and caregivers during all-hazard emergencies. In addition, this provision updates the composition of the committee to include at least four nonfederal members representing child care settings, state or local educational agencies, individuals with expertise in children with disabilities, and parents.

Subtitle C—Accelerating Research and Countermeasure Discovery

Chapter 1—Fostering Research and Development and Improving Coordination

Background for Sections 2301-2304

At the onset of the pandemic, researchers in both the public and private sectors undertook efforts to rapidly study the biology of the virus and to develop new medical products. Prior to the pandemic, the federal government had established agencies, programs, and responsibilities for researching and developing new *medical countermeasures* (MCMs), that is, medical products that may be used to treat, prevent, or diagnose conditions associated with emerging infectious diseases or chemical, biological, radiological, or nuclear (CBRN) agents. MCMs include biologics (e.g., vaccines, monoclonal antibodies), drugs (e.g., antimicrobials, antivirals), and medical devices (e.g., diagnostic tests, PPE).⁹⁸

Agencies involved in MCM R&D include the National Institutes of Health (NIH), the Biomedical Advanced Research and Development Authority (BARDA), and the Department of Defense (DOD), among others. Each of these agencies plays a differing, sometimes overlapping, role in R&D for new MCMs. The PREVENT Pandemics Act primarily addresses NIH's role in MCM R&D, particularly the role of the National Institute of Allergy and Infectious Diseases (NIAID)—the main NIH institute that invests in emerging infectious disease and biodefense research. NIH and NIAID generally focus on the early stages of R&D for new medical countermeasures,

⁹⁶ ASPR, “About the National Advisory Committee on Children and Disasters (NACCD),” <https://aspr.hhs.gov/AboutASPR/WorkingwithASPR/BoardsandCommittees/Pages/NACCD/About-Us.aspx>.

⁹⁷ 42 U.S.C. §300hh-10b.

⁹⁸ For additional information, see CRS Report R46427, *Development and Regulation of Medical Countermeasures for COVID-19 (Vaccines, Diagnostics, and Treatments): Frequently Asked Questions*.

including basic research to better understand the biology of viruses and immunity, and preclinical R&D to develop and test potential MCM candidates.⁹⁹

In addition, the pandemic highlighted other scientific and R&D challenges. In the early stages of an outbreak with a novel virus, researchers may need access to pathogen samples in order to study the virus and develop MCMs.¹⁰⁰ Many scientists faced challenges gaining access to pathogen samples in the early stages of the COVID-19 outbreak.¹⁰¹ The pandemic also highlighted challenges with developing and scaling up diagnostic testing in the early stages of an outbreak.¹⁰² In addition, the pandemic demonstrated the challenge of making health guidance and recommendations in the context of a changing novel virus whose health impact is not fully known. For example, throughout the pandemic, scientists have continued to learn more about COVID-19 immunity, its durability, and differences between immunity induced by vaccination compared with infection. COVID-19 immunity has also changed as the virus has evolved over time.¹⁰³

Section 2301: Research centers for pathogens of pandemic concern

Provision

Section 2301 adds a new PHSA Section 447D, which authorizes a Research Centers for Pathogens of Pandemic Concern program to be administered by the National Institute of Allergy and Infectious Diseases (NIAID). In collaboration with other NIH Institutes and Centers, ASPR, and BARDA, NIAID is to establish or continue a multidisciplinary research program through support for research centers to advance the discovery and preclinical development of medical products for priority virus families and other viral pandemic threats. Funding may be awarded to public and private entities for (1) conducting basic research through preclinical development of new medical products; (2) identifying potential targets for therapeutic candidates; (3) identifying existing medical products with therapeutic potential; and (4) carrying out or supporting other research related to medical products. NIAID is also to collaborate with other federal departments and agencies to identify priority virus families and other viral pandemic threats, and with BARDA to provide updates and identify any advanced R&D needs for medical products supported by the centers.

⁹⁹ CRS Report R46427, *Development and Regulation of Medical Countermeasures for COVID-19 (Vaccines, Diagnostics, and Treatments): Frequently Asked Questions*.

¹⁰⁰ Cormac M. Kinsella, Pauline Dianne Santos, Ignacio Postigo-Hidalgo, et al., “Preparedness Needs Research: How Fundamental Science and International Collaboration Accelerated the Response to COVID-19,” *PLOS Pathogens*, vol. 16, no. 10 (October 9, 2020).

¹⁰¹ Ewen Callaway, “China Coronavirus: Labs Worldwide Scramble to Analyse Live Samples,” *Nature*, January 31, 2020, <https://www.nature.com/articles/d41586-020-00262-7>.

¹⁰² U.S. Government Accountability Office, *COVID-19: Continued Attention Needed to Enhance Federal Preparedness, Response, Service Delivery, and Program Integrity*, GAO-21-551, July 2021, pp. 17-18, <https://www.gao.gov/assets/gao-21-551.pdf>.

¹⁰³ See, for example, David M. Morens, Gregory K. Folkers, and Anthony S. Fauci, “The Concept of Classical Herd Immunity May Not Apply to COVID-19,” *The Journal of Infectious Diseases*, vol. 226, no. 2 (March 21, 2022), pp. 195-198, and COVID-19 Forecasting Team, “Past SARS-CoV-2 Infection Protection Against Re-Infection: A Systematic Review and Meta-Analysis,” *The Lancet*, vol. 401, no. 10379 (March 11, 2023), pp. P833-842.

Section 2302: Improving medical countermeasure research coordination

Provision

Section 2302 amends PHSA Section 402, which specifies the duties of the NIH Director.¹⁰⁴ The amended PHSA Section 402 requires the NIH Director to consult with ASPR, BARDA, CDC, and others, as appropriate, regarding research needs to advance medical countermeasures for public health threats, including emerging infectious diseases and CBRN agents.

Section 2303: Accessing specimen samples and diagnostic tests

Provision

Section 2303 requires the HHS Secretary to issue guidance regarding access to pathogen samples for research and development. It also adds a new authority, PHSA Section 319B, which addresses diagnostic test development during emergencies. Within one year after enactment, the HHS Secretary is required to make publicly available policies and procedures for accessing pathogen specimens (or other surrogates or alternatives as specified) that support public health preparedness and response activities, or that support biomedical research for developing and validating medical products to address emerging infectious diseases. The guidance must include (1) the method for requesting such samples; (2) considerations for sample availability and use of suitable surrogates or alternatives to such pathogens, including applicable safeguard and security measures; and (3) information required in order to receive such samples or suitable surrogates or alternatives.

The new PHSA Section 319B allows the HHS Secretary to contract with public and private entities to increase capacity in the rapid development, validation, manufacture, and dissemination of diagnostic tests to SLTT health departments and other entities—thereby supporting immediate public health response activities to address an emerging infectious disease with respect to a PHE under PHSA Section 319, or to address an emerging infectious disease that has significant potential to cause such a public health emergency.

Section 2304: National Academies of Sciences, Engineering, and Medicine study on natural immunity in relation to the COVID-19 pandemic

Provision

Section 2304 requires the HHS Secretary to contract with the National Academies of Sciences, Engineering, and Medicine (NASEM) to conduct a study related to the current scientific evidence on the durability of immunity to COVID-19. The study is to include (1) an assessment of scientific evidence related to the durability of immunity resulting from SARS-CoV-2 infection, COVID-19 vaccination, or both, including any differences between population groups; (2) an assessment of the extent to which the federal government makes publicly available the scientific evidence used by relevant federal departments and agencies to inform public health recommendations related to immunity resulting from SARS-CoV-2 infection and COVID-19 vaccination; and (3) a summary of scientific studies and evidence related to SARS-CoV-2 infection-acquired immunity from a sample of other countries or multilateral organizations. NASEM is to submit the report on the study no later than 18 months after enactment to specified congressional committees. This section does not authorize an appropriation.

¹⁰⁴ 42 U.S.C. §282.

Chapter 2—Improving Biosafety and Biosecurity

The provisions set forth in Subtitle C, Chapter 2, of the PREVENT Pandemics Act prescribe a series of policies and requirements for the executive branch and federal agencies to address biosafety- and biosecurity-related issues pertaining to research, training, and oversight of life science research.

The United States has multiple, overlapping policies to manage biosafety and biosecurity issues associated with emerging technologies and life sciences research. These policies provide guidance and oversight for life sciences research, depending on the types of experiments and biological agents used. While some oversight mechanisms are required by law for all public and private research entities, others are mandatory only if the research is funded by the federal government. Some biosafety and biosecurity standards are informed by guidance and best practices issued by federal agencies and other scientific organizations rather than by law. Privately funded research, or research conducted outside the United States, may therefore not be covered by certain U.S. oversight mechanisms. Two reports released in 2023 evaluate U.S. policies related to research with enhanced potential pandemic pathogens (ePPP) and broader biosafety and biosecurity issues related to life-sciences research: one from the U.S. Government Accountability Office (GAO) and another from the National Science Advisory Board for Biosecurity (NSABB). Both reports recommend expanding oversight to include privately funded research. For more information, see CRS Report R47114, *Oversight of Gain of Function Research with Pathogens: Issues for Congress*, and CRS Insight IN12109, *Improved Oversight of Pathogen Research: Recent Recommendations*.

Section 2311: Improving control and oversight of select biological agents and toxins

Background

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188) required HHS to establish and regulate a list of biological agents and toxins that have the potential to pose a severe threat to public health and safety. The Agricultural Bioterrorism Protection Act of 2002 (Title II, Subtitle B, of P.L. 107-188) required the U.S. Department of Agriculture (USDA) to establish and regulate a list of biological agents that have the potential to pose a severe threat to animal health and safety, plant health and safety, or to the safety of animal or plant products. These two laws provide the legal basis for the Federal Select Agents Program (FSAP), managed by the Division of Select Agents and Toxins at the CDC and the Division of Agriculture Select Agents and Toxins at USDA. CDC and USDA share responsibility for some agents because they potentially threaten both humans and animals. 42 U.S.C. §262a and 7 U.S.C. §8401 require CDC and USDA to review and republish the lists of select agents and toxins on at least a biennial basis.¹⁰⁵

FSAP focuses on both the people who have access to select agents and the facilities where select agents are used and stored. Entities possessing select agents are required under 42 U.S.C. §262a and 7 U.S.C. §8401 to develop explicit biosecurity and biosafety plans and procedures that are reviewed and certified by FSAP.¹⁰⁶

¹⁰⁵ Federal Select Agent Program, <https://www.selectagents.gov/sat/index.htm>.

¹⁰⁶ An entity is defined as any government agency (federal, state, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity. An entity is thus not limited to a single (continued...)

Provision

The provision amends PHS Section 351A to further specify who is required by law to have proper training under the FSAP program.¹⁰⁷ This includes individuals who are involved in the handling and use of select agents and toxins, individuals whose responsibilities routinely put them in close proximity to laboratory facilities that handle select agents and toxins, and individuals who perform administrative or oversight functions of facilities that transfer, possess, or use select agents and toxins.

The provision also makes various amendments to account for risks associated with the accidental release or theft of agents regulated by FSAP. The provision amends the establishment of appropriate regulatory safeguards for such agents. In addition to the risk of use in domestic or international terrorism, the provision expands the scope to include risks posed by the release, theft, or loss of a select agent or toxin. It requires the HHS Secretary or USDA Secretary to notify specified committees of any release, loss, or theft of a select agent or toxin reported within 72 hours. Within 14 days after such a notification, an update to such committees is required describing any actions taken or planned to mitigate the potential threat that the release, loss, or theft may pose to public health and safety, as well as any actions taken or planned to review the circumstances of such release, loss, or theft, and to prevent similar events.

The provision also requires an annual report submitted by the Secretary to selected congressional committees. The report should summarize the number and nature of notifications received, describe actions taken to address such incidents, and identify any gaps, challenges, or limitations regarding safety and security practices, as well as actions taken to address such gaps, challenges, or limitations.

The provision also reauthorizes appropriations for the FSAP program through FY2027.

Section 2312: Strategy for federal high-containment laboratories

Background

CDC and NIH co-publish the Biosafety in Microbiological and Biomedical Laboratories (BMBL) guidelines, which serve as the overarching guidance document for U.S. biosafety practices for protecting workers and preventing exposures in biological laboratories. The BMBL provides guidance for addressing the safe handling and containment of infectious microorganisms and hazardous biological materials.¹⁰⁸ Adherence to the BMBL is a term and condition that some grant awardees must meet in order to receive funding from certain federal agencies.

The BMBL describes biosafety levels (BSLs), which are designations applied to projects or activities conducted in laboratories, in ascending order of containment based on the degree of the health-related risk associated with the work being conducted.¹⁰⁹ Each biosafety level (BSL 1-4) builds upon the previous level. Each level describes a minimum set of safety practices and procedures, required safety equipment, and administrative and engineering controls. The appropriate BSL for a research project is determined by the institution in which the work is being conducted, in consultation with the principal investigator, depending on the specific organism and

facility or to a single laboratory. An entity may possess one or multiple facilities, each facility containing one or multiple laboratories.

¹⁰⁷ 42 U.S.C. §262a

¹⁰⁸ Paul J. Meehan and Jeffrey Potts, *Biosafety in Microbiological and Biomedical Laboratories*, U.S. Department of Health and Human Services, 6th Edition, 2020, <https://www.cdc.gov/labs/BMBL.html>.

¹⁰⁹ Department of Health and Human Services, Science Safety Security, <https://www.phe.gov/s3/BioriskManagement/biosafety/Pages/Biosafety-Levels.aspx>.

types of experiment to be performed. In 2020, 190 entities with BSL-3 laboratories and eight entities with BSL-4 laboratories were registered with FSAP in the United States, operated by a variety of actors (federal, commercial, academia, and private).¹¹⁰ Not all of these laboratories are research labs; for example, they could also include clinical and public health laboratories that deal with select agents.¹¹¹

Provision

The provision requires the Director of the Office of Science and Technology Policy (OSTP), within a year of the enactment, to establish a strategy for the management, maintenance, and oversight of federally owned laboratory facilities operating at BSL 3 or 4, including equivalent classification levels and facilities with BSL 4 capabilities. This strategy is to include an assessment of the needs of the federal government in relation to BSL 3 or 4 laboratories, as well as a summary of BSL 3 or 4 laboratory capacities established with federal funds but not managed by the federal government. The strategy is not intended to supersede the current authorities of relevant federal departments or agencies that have oversight of the management and maintenance of federally owned or operated facilities.

Section 2313: National Science Advisory Board for Biosecurity

Background

The National Science Advisory Board for Biosecurity (NSABB) is a federal advisory committee governed by the provisions of the Federal Advisory Committee Act.¹¹² The purpose of the NSABB is to provide, as requested, advice, guidance, and recommendations related to biosecurity and dual-use research, taking into consideration both national security concerns and the needs of the research community to foster continued rapid progress in public health and agricultural research. The NSABB consists of up to 25 voting members with a broad range of expertise. Prior to the PREVENT Pandemics Act, the NSABB was authorized by 42 U.S.C. §217a, Section 222 of the Public Health Service (PHS) Act, as amended, and the Pandemic and All-Hazards and Preparedness Act (P.L. 109-417), Section 205, codified at 42 U.S.C. §262a.¹¹³

During its first meeting in 2005, the NSABB was charged with examining the potential biosecurity concerns raised by the synthesis of select agents and by synthetic biology in general, and with recommending strategies for addressing these concerns.¹¹⁴ In January 2020, and again in February 2022, the HHS Secretary charged the NSABB with evaluating and providing recommendations on the effectiveness of the current oversight frameworks for research involving enhanced pathogens of pandemic potential and dual-use research of concern.¹¹⁵

¹¹⁰ Federal Select Agent Program, *2020 Annual Report of the Federal Select Agent Program*, 2020, https://www.selectagents.gov/resources/publications/docs/FSAP_Annual_Report_2020_508.pdf.

¹¹¹ This is a subset of the total number of BSL 3-4 laboratories in operation; laboratories that do not work with select agents would not need to register under the Select Agent Program. Therefore, the total number of BSL 3-4 laboratories may be higher.

¹¹² National Science Advisory Board for Biosecurity, <https://osp.od.nih.gov/biotechnology/national-science-advisory-board-for-biosecurity-nsabb/#about>.

¹¹³ National Science Advisory Board for Biosecurity, <https://osp.od.nih.gov/policies/national-science-advisory-board-for-biosecurity-nsabb/>.

¹¹⁴ National Science Advisory Board for Biosecurity, <https://osp.od.nih.gov/policies/national-science-advisory-board-for-biosecurity-nsabb#tab3/>.

¹¹⁵ National Science Advisory Board for Biosecurity, <https://osp.od.nih.gov/biotechnology/national-science-advisory-board-for-biosecurity-nsabb/#about>.

Provision

The provision provides a new formal authorization for the NSABB and its role. The provision amends Part A of Title IV of the Public Health Service Act to add a new Section 404O, which requires the HHS Secretary, acting through the NIH Director, to establish the NSABB.¹¹⁶ The provision prescribes the advice that NSABB is to provide. This advice includes oversight of federally conducted or federally supported dual-use biomedical research, as well as activities previously prescribed under Section 205 of the Pandemic and All-Hazards Preparedness Act (P.L. 109-417), including advice and recommendations regarding training for workers in high containment biological laboratories and periodic evaluations of biological laboratory capacity nationwide. The provision also describes certain strategies to improve the safety and security of biomedical research that NSABB is to consider. These strategies include leveraging or using new technologies and scientific advancements to (1) reduce safety and security risks associated with such research, (2) improve the containment of pathogens, and (3) improve outreach to, and education and training of, researchers, laboratory personnel, and other appropriate individuals regarding the safety and security risks associated with such research and mitigation of such risks.

The provision prescribes NSABB's membership, which is to include voting members appointed by the HHS Secretary with expertise in biology, infectious diseases, public health ethics, national security, and other fields, as appropriate. Representatives from several federal departments and agencies, including HHS, DOD, DHS, and others, are to serve as nonvoting members.

Section 2314: Research to improve biosafety

Provision

The provision directs the HHS Secretary to conduct or support research to improve the safe conduct of biomedical research involving pathogens of pandemic potential or agents and toxins listed under FSAP (PHSA §351A(a)(1)).¹¹⁷ It further requires the Secretary to submit a report within five years to selected congressional committees on any research conducted or supported, relevant findings, and steps the Secretary is taking to disseminate those findings.

Section 2315: Federally funded research with enhanced pathogens of pandemic potential

Background

In January 2017, OSTP released *Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight*,¹¹⁸ which described attributes of federal agency review and reporting processes for the additional oversight of federally funded research that is anticipated to create, transfer, or use enhanced pathogens with pandemic potential. HHS soon after released its *Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens* (P3CO).¹¹⁹

¹¹⁶ 42 U.S.C. §281 et seq.

¹¹⁷ 2 U.S.C. §262a(a)(1)).

¹¹⁸ Office of Science and Technology Policy, *Recommended Policy Guidance for Potential Pandemic Pathogen Care and Oversight* (P3CO), 2017, <https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/p3co-finalguidancestatement.pdf>.

¹¹⁹ U.S. Department of Health and Human Services, Department of Health and Human Services (HHS) *Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens*, 2017, <https://www.phe.gov/s3/dualuse/Documents/P3CO.pdf>.

Sections III and IV of the HHS P3CO framework establish an additional review process for HHS-sponsored research proposals that have gone through the normal scientific review process, have been determined to be scientifically sound, and are reasonably anticipated to create, transfer, or use ePPP.¹²⁰ To be subject to this extra scrutiny, an ePPP must satisfy two criteria:

1. It is likely highly transmissible and likely capable of wide and uncontrollable spread in human populations.
2. It is likely highly virulent and likely to cause significant morbidity and/or mortality in humans.

If a research proposal meets these criteria, it may be required to go through an independent, HHS-level, multidisciplinary P3CO review committee.

Based on this review, the P3CO review committee reports to the HHS funding agency (e.g., NIH) whether the research is acceptable, not acceptable, acceptable on the condition that certain experiments are modified, or acceptable on the condition that certain risk mitigation measures are employed at the federal and institutional level. The funding agency makes the final determination on whether the project will be funded and must report its decision to HHS and OSTP.

Section 19010 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act (P.L. 116-136) required GAO to examine the extent to which HHS oversight addresses biosafety and biosecurity risks—including consideration of dual-use research of concern (DURC), FSAP, and P3CO—and whether these programs are duplicative. The resulting GAO report, released in January 2023, made two recommendations related to P3CO and one related to FSAP:¹²¹

- Develop and document a standard for “reasonably anticipated” to ensure consistency in identifying research for departmental review that is “reasonably anticipated to create, transfer or use enhanced potential pandemic pathogens.”
- Identify and share nonsensitive information with researchers, Congress, and the public about the departmental review process for research involving enhanced potential pandemic pathogens, including information on who is involved in the review process, their expertise, and how the evaluation criteria are applied.
- When adding a new pathogen to FSAP—which may burden diagnostic and treatment facilities with additional reporting and inspection requirements—the Director of the Centers for Disease Control and Prevention should assess and document the risk posed by the limitations of the existing FSAP exemptions for public health emergencies and seek legislative authority as needed. Currently, exemptions are for a maximum of 60 days.

GAO also repeated its recommendation from a 2009 report for HHS to identify a single government entity to assess the risk posed by the lack of oversight of privately funded research.

In January 2020, and again in February 2022, the Secretary of HHS charged the NSABB with evaluating and providing recommendations on the effectiveness of the current oversight frameworks for research involving enhanced pathogens of pandemic potential and dual-use research of concern. The resulting NSABB report, released in March 2023, made 12

¹²⁰ An ePPP is defined as a potential pandemic pathogen resulting from the enhancement of the transmissibility and/or virulence of a pathogen; which can occur via GOF-type research.

¹²¹ U.S. Government Accountability Office, *Public Health Preparedness: HHS Could Improve Oversight of Research Involving Enhanced Potential Pandemic Pathogens*, GAO-23-105455, January 2023, <https://www.gao.gov/products/gao-23-105455>.

recommendations based on 12 findings from two working groups focused on the implementation of P3CO and DURC.¹²² Selected recommendations include the following:

- Clarify definitions of research and expand the scope of biological agents requiring review under P3CO and DURC.
- Remove certain exclusions for surveillance and vaccine development research.
- Specify roles and responsibilities for investigators and institutions.
- Make P3CO consistent with the 1979 Belmont Report on guidelines for the protection of human research subjects.
- Monitor for ePPP throughout the entire research life cycle.
- Increase transparency in the review/approval process.
- Ensure equivalent review, evaluation, and ongoing oversight of research funded at international institutions.
- Engage stakeholders and publishing groups to address information hazards.
- Develop an integrated approach to oversight of research that raises significant biosafety and biosecurity concerns.
- Expand oversight to nonfederally funded research at institutions and private companies.

The GAO and NSABB reports each provided a separate set of recommendations based on their findings; however, when considered together, three broad focus areas emerge:¹²³

- Clarifying language and developing standards to identify research that requires review under the P3CO policy.
- Increasing transparency around the P3CO review and approval processes.
- Expanding oversight to include privately funded research.

Both reports were released after the PREVENT Pandemics Act was enacted into law, and their findings and recommendations could influence how the provisions of the act are implemented and interpreted.

Provision

The provision requires the Director of OSTP, in consultation with the heads of relevant federal departments and agencies, within a year of enactment to conduct a review of existing policies related to federally funded research “reasonably anticipated to involve the creation, transfer, or use of enhanced pathogens of pandemic potential.”¹²⁴ In addition, it requires OSTP to establish or update policies that would consistently provide review and oversight of such research. Further, the provision requires OSTP to review and update such policies every four years.

The provision bans the HHS Secretary from funding research involving pathogens of pandemic potential or biological agents or toxins listed under FSAP by a foreign entity located in a country of concern, as determined by the Director of National Intelligence or other appropriate federal

¹²² National Science Advisory Board for Biosecurity, *Proposed Biosecurity Oversight Framework for the Future of Science*, Washington, DC, 2023, <https://osp.od.nih.gov/wp-content/uploads/2023/03/NSABB-Final-Report-Proposed-Biosecurity-Oversight-Framework-for-the-Future-of-Science.pdf>.

¹²³ CRS Insight IN12109, *Improved Oversight of Pathogen Research: Recent Recommendations*, by Todd Kuiken.

¹²⁴ Note: The term *enhanced pathogens of pandemic potential* is and has been used to describe certain types of gain-of-function research involving both naturally occurring and experimentally induced changes in viruses to better understand transmission, infection, and pathogenesis.

agencies. It also allows the Secretary to lift a prohibition on foreign funding under certain circumstances, and only after notifying Congress prior to lifting the ban.

Chapter 3—Preventing Undue Foreign Influence in Biomedical Research

Background for Sections 2321-2326

Since 2016, NIH investigations have found issues of foreign influence among its research funding recipients, including (1) undisclosed sources of foreign research support, (2) undisclosed conflicts of interest associated with foreign countries and organizations, and (3) violations of the rules and integrity of the peer review process for NIH funding applications.¹²⁵ For example, in some cases, funding recipients received duplicative project funding from a foreign country or organization; in other cases, peer reviewers shared confidential application information with scientists in foreign countries.¹²⁶ An NIH working group found that foreign talent recruitment programs—especially China’s Thousand Talents program—have encouraged such actions and interference.¹²⁷

In light of these issues, Congress has funded the HHS Office of the Inspector General (OIG) to examine NIH’s policies and practices and recommend changes. To date, HHS OIG has explored issues related to controls for sensitive genomic research data;¹²⁸ the vetting process for peer reviewers;¹²⁹ financial conflicts of interest policies;¹³⁰ pre-award risk assessments,¹³¹ and cybersecurity,¹³² among others. These reports have highlighted potential weaknesses in NIH’s ability to address security concerns associated with its funded research.

NIH has since amended some of its policies and raised awareness of the issues among funding recipients.¹³³ In addition, a 2021 presidential memorandum¹³⁴ and a provision of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 (NDAA; P.L. 116-283, §223) required changes at all federal research agencies to address research security and

¹²⁵ NIH, “About Foreign Interference,” <https://grants.nih.gov/policy/foreign-interference/about-foreign-interference>.

¹²⁶ NIH, “About Foreign Interference,” <https://grants.nih.gov/policy/foreign-interference/about-foreign-interference>.

¹²⁷ Lawrence A. Tabak and M. Roy Wilson, “Foreign Influences on Research Integrity,” *117th Meeting of the Advisory Committee to the Director*, December 13, 2018, <https://acd.od.nih.gov/documents/presentations/12132018ForeignInfluences.pdf>.

¹²⁸ HHS Office of the Inspector General (OIG), *Opportunities Exist for the National Institutes of Health to Strengthen Controls in Place To Permit and Monitor Access to Its Sensitive Data, Audit* (A-18-18-09350, February 5, 2019, <https://oig.hhs.gov/oas/reports/region18/181809350.asp>).

¹²⁹ HHS OIG, *Vetting Peer Reviewers at NIH’s Center for Scientific Review: Strengths and Limitations*, OEI-01-19-00160, September 25, 2019, <https://oig.hhs.gov/oei/reports/oei-01-19-00160.asp>.

¹³⁰ HHS OIG, *The National Institutes of Health Has Limited Policies, Procedures, and Controls in Place for Helping to Ensure That Institutions Report All Sources of Research Support, Financial Interests, and Affiliations*, A-03-19-03003, September 25, 2019, <https://oig.hhs.gov/oas/reports/region3/31903003.asp>.

¹³¹ HHS OIG, *The National Human Genome Research Institute Should Strengthen Procedures in Its Pre-Award Process to Assess Risk for Certain Foreign and Higher Risk Applicants*, A-05-20-00026, August 30, 2021, <https://oig.hhs.gov/oas/reports/region5/52000026.asp>.

¹³² HHS OIG, *National Institutes of Health Grant Program Cybersecurity Requirements Need Improvement*, A-18-20-06300, September 19, 2022, <https://oig.hhs.gov/oas/reports/region18/182006300.asp>.

¹³³ NIH, “Foreign Interference,” <https://grants.nih.gov/policy/foreign-interference.htm>.

¹³⁴ White House, *Presidential Memorandum on United States Government-Supported Research and Development National Security Policy*, National Security Presidential Memorandum - 33, January 14, 2021, <https://trumpwhitehouse.archives.gov/presidential-actions/presidential-memorandum-united-states-government-supported-research-development-national-security-policy/>.

disclosure of foreign ties. NIH has made policy changes accordingly.¹³⁵ Congress also addressed cross-cutting federal research security issues through P.L. 117-167, commonly referred to the CHIPS and Science Act, enacted in 2022.¹³⁶

Issues surrounding the COVID-19 pandemic and investigations into the origins of the virus have focused attention on NIH's research security policies. For example, increased attention on NIH's funding and oversight of so-called "gain-of-function" research, which can make a virus more transmissible or pathogenic,¹³⁷ has invoked broader discussions about oversight of synthetic or other emerging biology research and its national security implications in general.¹³⁸ Another example is increased interest in NIH's ability to monitor subrecipients of grants located in foreign countries. For instance, HHS OIG has found that NIH did not effectively monitor funding awards made to EcoHealth Alliance and its funding subrecipient at the Wuhan Institute of Virology in China.¹³⁹

NIH funds research carried out by NIH staff (intramural research) at its own facilities and awards research funding through grants, contracts, and other agreements to nonfederal entities such as universities (extramural research).¹⁴⁰ Other HHS agencies also conduct research and award funding for medical and health research.

Section 2321: Foreign talent recruitment programs

Provision

Section 2321 requires the HHS Secretary to prohibit NIH intramural research personnel from participation in foreign talent recruitment programs with some exemptions for international conferences and programs to be approved by NIH as specified. The Secretary is also required to make disclosure of foreign talent recruitment program participation a requirement for those involved in HHS extramural research grants, contracts or other agreements. These requirements are to be consistent with existing requirements related to foreign talent recruitment programs established in the CHIPS and Science Act (P.L. 117-167) codified at 42 U.S.C. §19231 et seq.

Section 2322: Securing identifiable, sensitive information and addressing other national security risks related to research

Provision

Section 2322 requires the HHS Secretary to ensure that NIH and HHS biomedical research is done in a manner that appropriately considers national security risks, including national security implications of genomic sequencing and data, as well as identifiable and sensitive information involved in research, along with the potential misuse of such data. This is to be done in consultation with the Director of National Intelligence, the Secretary of State, the Secretary of Defense, and other national security experts. Within two years of enactment, the HHS Secretary is to develop a comprehensive framework and policies for assessing and managing national security

¹³⁵ NIH, "Requirements for Disclosure of Other Support, Foreign Components and Conflicts of Interest," <https://grants.nih.gov/policy/foreign-interference/requirements-for-disclosure>.

¹³⁶ See Division B, Title VI, Subtitle D of P.L. 117-167.

¹³⁷ CRS Report R47114, *Oversight of Gain of Function Research with Pathogens: Issues for Congress*.

¹³⁸ CRS Report R47265, *Synthetic/Engineering Biology: Issues for Congress*.

¹³⁹ HHS OIG, *The National Institutes of Health and EcoHealth Alliance Did Not Effectively Monitor Awards and Subawards, Resulting in Missed Opportunities to Oversee Research and Other Deficiencies*, A-05-21-00025, January 25, 2023, <https://oig.hhs.gov/oas/reports/region5/52100025.asp>.

¹⁴⁰ CRS Report R41705, *The National Institutes of Health (NIH): Background and Congressional Issues*.

risks before and after making research funding awards, as well as risks associated with granting access to data that may pose national security concerns.

One year after developing the comprehensive framework, the HHS Secretary must develop or implement controls to ensure that (1) researchers have complied with the framework and policies; (2) funding consideration for projects that may have national security implications takes into account the extent to which the country involved poses a risk to the integrity of the U.S. biomedical research enterprise; and (3) committees responsible for reviewing data access requests for projects that may have national security risks include members with national security expertise. Data access and sharing policies related to human genomic data are to be updated two years after developing the comprehensive framework and policies.

The HHS Secretary is required to provide a briefing on these efforts to specified congressional committees no later than one year after enactment.

Section 2323: Duties of the Director

Provision

Section 2323 amends the duties of the NIH Director as specified in PHS Act Section 402.¹⁴¹ Specifically, it adds that the NIH Director is required to (1) consult with the HHS Office of National Security, ASPR, the Director of National Intelligence, and the FBI Director and others regarding national security implications of biomedical research conducted or supported by NIH; (2) ensure that NIH award recipients and their collaborators (both domestic and nondomestic) have appropriate technology practices and policies in place to maintain security of identifiable, sensitive information; and (3) ensure that recipients of NIH awards are in compliance with the terms and conditions of such award, including through activities to ensure compliance by any award subrecipients.

Section 2324: Protecting America's biomedical research enterprise

Provision

Section 2324 requires the HHS Secretary to develop, in consultation with specified federal national security heads and other experts, a set of strategies and frameworks to protect federally funded biomedical R&D from national security risks and other threats. The Secretary is to identify ways to improve protection from national security risks related to (1) intellectual property, other proprietary information, and identifiable and sensitive information involved in biomedical R&D; (2) foreign talent programs and countries seeking to exploit U.S. technology and other proprietary information; (3) national and information security risks associated with the peer review process; and (4) emerging areas of biomedical R&D that would compromise national security if subject to undue foreign influence. The Secretary is required to report on such findings and recommendations to specified congressional committees no later than one year after enactment.

Section 2325: GAO study

Provision

Section 2325 requires GAO to conduct a study to assess the extent to which HHS provides funding to entities that use such funds for human genomic sequencing services or genetic

¹⁴¹ 42 U.S.C. §282.

services¹⁴² provided by entities organized under the laws of a country (or countries) of concern, as determined by the Director of National Intelligence or other appropriate agency head. GAO is required to consider (1) the extent to which countries of concern could obtain genomic information of U.S. citizens and use such information in a manner inconsistent with the national security interests of the United States; (2) whether HHS or the funding recipient sought to provide the funding to a domestic recipient and barriers to the use of domestic entities; (3) whether data use agreements or other security measures are sufficient to protect the identifiable, sensitive information of the people of the United States and national security interests. GAO is to make recommendations to address any national security vulnerabilities identified. GAO is to submit the report to specified congressional committees no later than two years after enactment in unclassified form, to the extent practicable, but may include a classified annex.

Section 2326: Report on progress to address undue foreign influence

Provision

Section 2326 requires the HHS Secretary to submit a report to specified congressional committees no later than one year after enactment on actions taken to (1) address cases of noncompliance with disclosure requirements or research misconduct related to foreign influence, including the number of noncompliance cases investigated by or reported to NIH and the number of cases referred to HHS OIG and other intelligence agencies, along with enforcement actions taken; and (2) prevent, address, and mitigate instances of noncompliance with disclosure requirements or research misconduct related to foreign influence.

Chapter 4—Advanced Research Projects Agency–Health

Section 2331: Advanced Research Projects Agency–Health

Background

Through FY2022 appropriations (P.L. 117-103), Congress provided \$1 billion to establish the Advanced Research Projects Agency for Health (ARPA-H) at HHS. ARPA-H advances “high-potential, high-impact biomedical and health research that cannot be readily accomplished through traditional research or commercial activity.”¹⁴³ First proposed in the Biden Administration’s FY2022 budget request for NIH, ARPA-H is modelled after other “ARPAs” in the federal government, especially the Defense Advanced Research Projects Agency. In 2022, the HHS Secretary established ARPA-H within NIH, with its Director reporting to the HHS Secretary.¹⁴⁴

Throughout 2022, both the House and Senate considered separate bills to authorize ARPA-H. In the Senate, the PREVENT Pandemics Act (S. 3799, as amended in committee) incorporated the previously introduced Advanced Research Project Authority for Health Act (S. 3819) as Section 331. In the House, H.R. 5585 was passed on June 22, 2022. The two bills differed primarily in ARPA-H’s placement within HHS and the means of ensuring its independence. Independence at the agency level to shape a distinct mission and culture, along with autonomy of program managers to select and fund projects, are viewed as key components of the ARPA model.¹⁴⁵ H.R.

¹⁴² “Genetic services” as defined in the Genetic Information Nondiscrimination Act of 2008 (42 U.S.C. §2000ff(6)).

¹⁴³ ARPA-H, *FY2024 Congressional Justification*, p. 6, https://arpa-h.gov/assets/files/ARPA-H_FY_2024.pdf.

¹⁴⁴ CRS Report R47074, *Advanced Research Projects Agency for Health (ARPA-H): Congressional Action and Selected Policy Issues*.

¹⁴⁵ Azoulay et al., “Funding Breakthrough Research: Promises and Challenges of the ‘ARPA Model,’” pp. 9-10.

5585 would have made ARPA-H an independent agency within HHS; S. 3819 would have placed the new agency within NIH with some provisions aimed at creating independence from other NIH programs. For more information on ARPA-H, see CRS Report R47568, *Advanced Research Projects Agency for Health (ARPA-H): Overview and Selected Issues*.

Provision

Section 2331 establishes ARPA-H as focused on driving breakthroughs in biomedical science and medicine. It also grants the agency many of the common authorities and flexibilities provided to other ARPA agencies, such as hiring flexibilities and funding authorities (e.g., other transaction authorities). The authorization includes the following key provisions:

- ARPA-H is established as a part of NIH. The ARPA-H Director reports directly to the HHS Secretary.
- ARPA-H is required to have offices or facilities in at least three geographic areas. ARPA-H cannot be located on NIH's existing campus.
- The Director is to ensure that staff have not worked at NIH in the prior three years, but can grant an exemption for individuals who are uniquely qualified to advance ARPA-H's goals.
- ARPA-H is to prioritize awards to domestic recipients and cannot award funding to nondomestic recipients organized under the laws of Russia, Iran, North Korea, China, or other countries determined to be a covered foreign country under Section 119C of the National Security Act of 1947.

Subtitle D—Modernizing and Strengthening the Supply Chain for Vital Medical Products

The COVID-19 pandemic affected the medical product supply chain globally and domestically. Although concerns about the U.S. medical product supply chain predate the emergence of COVID-19, the pandemic underscored the importance of understanding, developing, and protecting the medical product supply chain. The sections within this subtitle address several of the concerns noted by stakeholders¹⁴⁶ during the pandemic, including reducing U.S. reliance on foreign sources of medical products, increasing the federal government's ability to oversee the supply chain and mitigate future disruptions, providing enhancements to the Strategic National Stockpile (SNS), and increasing production of critical medical products.

Section 2401: Warm-base manufacturing capacity for medical countermeasures

Background

Within ASPR, the Biomedical Advanced Research Development Authority (BARDA) coordinates and supports the advanced research, development, manufacturing, and initial procurement of medical countermeasures for use in emergency situations. Established in 2006 by the Pandemic and All-Hazards Preparedness Act (PAHPA, P.L. 109-417), BARDA collaborates with public and private sector stakeholders to achieve its mission.

Warm-base manufacturing refers to the capacity of a manufacturing facility to rapidly produce critical medical countermeasures for use during a public health crisis. Improving this capacity

¹⁴⁶ See, for example, CRS Report R46507, *FDA's Role in the Medical Product Supply Chain and Considerations During COVID-19*.

involves the research, utilization, and incorporation of advanced manufacturing and platform technologies in existing and new manufacturing facilities.¹⁴⁷

Provision

Section 2401 contains several amendments to PHSA Section 319L¹⁴⁸ focusing on enhancing domestic surge manufacturing capabilities and capacity related to certain products. Specifically, this provision directs BARDA to take the following actions:

- Support, maintain, and improve domestic manufacturing surge capacity and capability to increase the availability of medical countermeasures for use in public health crises.
- Facilitate communication between various private and public stakeholders regarding the development of domestic manufacturing capabilities with regard to various medical countermeasures.
- Authorize BARDA to award contracts, grants, and other cooperative agreements or enter into other transactions to support domestic manufacturing surge capacity and capabilities through the use of advanced manufacturing techniques. Among other requirements, award recipients are required to annually submit reports on the maintenance of these capacities and to ensure their ability to rapidly manufacture countermeasures as required by the Secretary.
- Direct BARDA to consult with the FDA to ensure that manufacturing facilities, pursuant to these grants, are including current good manufacturing practices.

In addition, this provision extends the authorization for BARDA's Medical Countermeasure Innovation Partner program through FY2028.

Strategic National Stockpile: Sections 2402-2409

Background for Sections 2402-2409

The Strategic National Stockpile (SNS) is an inventory of medical countermeasures that can be deployed to state, local, tribal, and territorial (SLTT) jurisdictions for use in emergencies when existing supplies are depleted or unavailable. The SNS formulary contains a wide range of products to respond to a variety of different hazards. The HHS Secretary is statutorily required¹⁴⁹ to conduct an annual threat-based review of the products within the SNS to assess whether they are consistent with the recommendations issued by the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE).¹⁵⁰ The HHS Secretary is also required to adhere to several procedures to ensure the contents, security, and the safe deployment of the products within the SNS.¹⁵¹

SLTT health officials may request emergency medical countermeasures (such as antibiotics, antitoxins, medical supplies and equipment) from the SNS. These requests can be placed through select officials in these jurisdictions. During the COVID-19 pandemic, existing guidance and

¹⁴⁷ GAO, *HHS Has Funded Flexible Manufacturing Activities for Medical Countermeasures, but It Is Too Soon to Assess Their Effect*, March 2014, p. 10, <https://www.gao.gov/assets/gao-14-329.pdf>.=10.

¹⁴⁸ 42 U.S.C. §247d-7e.

¹⁴⁹ 42 U.S.C. §247d-6b(2).

¹⁵⁰ The PHEMCE is a United States interdepartmental committee that facilitates the coordination of the research, development, and procurement of medical countermeasures in response to emergency situations. 42 U.S. Code §300hh-10a

¹⁵¹ 42 U.S.C. §247d-6b.

policies detailing how SLTT stakeholders could access supplies were somewhat dated.¹⁵² Tribes, tribal organizations, and urban Indian organizations reportedly had difficulties accessing PPE and other materials, including through the SNS.¹⁵³ Officials in these jurisdictions reportedly were sometimes unable to request supplies directly from the SNS and instead coordinated their efforts with state or territorial health officials as directed by the ASPR.¹⁵⁴

The SNS employs several methods to manage stockpile assets, including vendor-managed inventory (VMI). Under the VMI program, SNS pays vendors to store and manage some SNS supplies. This arrangement allows a vendor to rotate its product through this inventory on its way to other commercial markets to prevent expiration of the product. Delivery of supplies from vendor-managed inventory takes between 24 and 36 hours.¹⁵⁵

Currently, state, local, tribal, and territorial governments are not required to maintain their own stockpile of medical and ancillary equipment to prepare for and respond to localized emergencies. State, local, and territorial health jurisdictions may choose to use funding from federal grant programs to stockpile medical countermeasures and prepare for sub-state distribution of stockpile materials.¹⁵⁶

Sections 2402 to 2409 contain several amendments to existing programs and authorizations for novel programs, which overall are designed to improve SNS inventory management, increase visibility, and enhance distribution of SNS contents.

Section 2402: Supply chain considerations for the Strategic National Stockpile

Provision

This provision directs the HHS Secretary to consider the impact that the addition, modification, or replenishment of MCMs in the SNS may have on the availability of those products or ancillary medical supplies. This provision also directs the HHS Secretary to conduct an assessment of the entire supply chain for these products, as directed.

Section 2403: Strategic National Stockpile equipment maintenance

Provision

Section 2403 amends PHSA Section 319F-2(a)(3) to require the HHS Secretary to also consider, among other items, that the contents of the stockpile are in working condition and ready for deployment.¹⁵⁷

¹⁵² See CDC, Receiving, Distributing and Dispensing Strategic National Stockpile Assets: A Guide to Preparedness, Version 11, https://www.orau.gov/sns/v11/ReceivingDistributingDispensingSNSAssets_V11.pdf.

¹⁵³ “Senate Indian Affairs Committee Holds Hearing on Native American Health During the New Coronavirus,” July 1, 2020, <https://plus.cq.com/doc/congressionaltranscripts-5947593?0&searchId=DNWVg7bB>.

¹⁵⁴ See CRS Report R47400, *The Strategic National Stockpile: Overview and Issues for Congress*.

¹⁵⁵ *Ibid.*

¹⁵⁶ *Ibid.*

¹⁵⁷ 42 U.S.C. §247d-6b(a)(3).

Section 2404: Improving transparency and predictability of processes of the Strategic National Stockpile¹⁵⁸

Provision

Section 2404 requires the HHS Secretary, within 60 days of enactment, to issue guidance describing the process by which the Secretary deploys SNS contents. This guidance must include information related to the process by which entities request SNS contents, facts considered by the Secretary when making distribution decisions, and points of contact that requesting entities may use for information related to SNS requests and received materials.

Further, this section amends PHSA Section 319F-2(a)(3) to add a new subsection that requires the Secretary to convene meetings with SLTT jurisdictions, relevant industry, federal agencies, and other stakeholders to coordinate and share information related to maintenance and use of the SNS.¹⁵⁹

Section 2405: Improving supply chain flexibility for the Strategic National Stockpile

Provision

Section 2405 amends PHSA Section 319F-2 to authorize the HHS Secretary to execute contracts or cooperative agreements for vendor-managed inventory (VMI) of stockpiled supplies.¹⁶⁰ The amended section gives the Secretary the authority to dictate the terms and conditions of such contracts with respect to procurement, maintenance, storage, and delivery of stockpiled items, and maintenance of domestic manufacturing capacity of such products. This section also directs the HHS Secretary to issue a report to Congress no later than two years after enactment on VMI contracts and cooperative agreements, which must include the amount and recipient of each award, the products covered through the award, and how the Secretary works with recipients to ensure the situational awareness of manufacturing capacity and inventory of such products. This section also amends the requirement for a GAO report so that an assessment of VMI contracts is included in the report. The provision also sets a deadline of March 15 of each year for annual notice to Congress on the determination of material threats. Lastly, this section authorizes SNS appropriations of \$610 million for each of FY2019 and FY2021, and \$750 million for each of FY2022 and FY2023.

Section 2406: Reimbursement for certain supplies

Provision

Section 2406 amends PHSA Section 319F-2(a) to amend the process for selling surplus or expiring supplies in the SNS.¹⁶¹ This section states that the Secretary may make SNS contents available for purchase only if (1) the contents are in excess of what is required for appropriate stockpile maintenance, (2) the costs for maintaining such excess are not appropriate to meet the needs of the stockpile, and (3) making such supplies available for purchase does not compromise national security. This section further dictates the reimbursement and collection mechanisms that

¹⁵⁸ As of the date of publication of this report, this guidance is now available. See, ASPR, “Requesting SNS Assets,” <https://aspr.hhs.gov/SNS/Pages/Requesting-SNS-Assets.aspx>.

¹⁵⁹ 42 U.S.C. §247d-6b(a)(3).

¹⁶⁰ 42 U.S.C. §247d-6b.

¹⁶¹ 42 U.S.C. §247d-6b(a).

may be implemented by the Secretary to reimburse for the cost of acquiring and maintaining such supplies. This section also requires the HHS Secretary to issue a report to Congress within two years of enactment, and annually thereafter, on the use of this authority. This authority sunsets on September 30, 2028.

Section 2407: Action reporting on stockpile depletion

Provision

Section 2407 amends PHSA Section 319 by requiring the Secretary to submit a report to Congress no later than 30 days after a deployment of SNS contents in response to an incident, and every 30 days thereafter until the expiration of such incident(s), on the stockpile deployment, the contents that remain in the stockpile following deployment, and plans to replenish the stockpile.¹⁶²

Section 2408: Provision of medical countermeasures to Indian programs and facilities

Provision

Section 2408 amends PHSA Section 319F-2(a)(3) by specifying that the Secretary will consult with and provide assistance to tribal officials, as well as state and local officials, related to the SNS.¹⁶³ This section also establishes a new PHSA section (319F-5) that requires the Secretary to make SNS contents available directly to Indian tribes and tribal organizations.

Section 2409: Grants for State strategic stockpiles

Provision

Section 2409 amends Section 319F-2 of the PHSA to establish a pilot program to support state medical countermeasure stockpiles.¹⁶⁴ These grants are to be administered by the Secretary in consultation with the ASPR and the CDC Director, and to support not fewer than five states or consortia of states in establishing, expanding, or maintaining a stockpile of drugs, vaccines, biological products, medical devices, and other medical materials determined by the grantee to be necessary to respond to a public health emergency, emergency, or major disaster. Funds may not be used to stockpile security countermeasures, unless approved by the Secretary. Grantees must agree to a nonfederal contribution ratio through FY2023 to FY2025 and thereafter as specified. Awards made under this authority are meant to supplement, not supplant, the use of the SNS.

This section also requires the Secretary to issue guidance and technical assistance related to maintaining and replenishing stockpiles, including strategies and best practices related to types of materials to be stockpiled, stockpile management procedures, and procurement requirements. Grantees must submit an annual report to the Secretary on the implementation of the plan required by this statute, and the Secretary must submit an annual report to Congress on the program. This section authorizes appropriations of \$3.5 billion for each of FY2023 and FY2024, to remain available until expended. Finally, this section requires a GAO report on the state stockpiles established pursuant to this section no later than three years after the first awards under this section are issued.

¹⁶² 42 U.S.C. §247d.

¹⁶³ 42 U.S.C. §247d-6b(a)(3).

¹⁶⁴ 42 U.S.C. §247d-6b.

Domestic medical supply manufacturing: Sections 2410-2411

Background for Sections 2410-2411

Throughout the COVID-19 pandemic, the drug supply chain faced several issues, including shortages of raw materials, disruptions in manufacturing, and transportation challenges. These issues were caused by a combination of factors, including factory shutdowns, border closures, and increased demand for certain medications.¹⁶⁵ As a result, some stakeholders have stated that using domestic production of certain medications, among other actions, may reduce reliance on foreign products during public health crises and strengthen the drug supply chain.¹⁶⁶

Section 2410: Study on incentives for domestic production of generic medicines

Provision

Section 2410 requires the HHS Secretary, acting through the Assistant Secretary for Planning and Evaluation (ASPE) to conduct a study on the feasibility, sustainment, potential effectiveness, and utility of providing incentives for increased domestic product and capacity of specified generic drugs and their active pharmaceutical ingredients not later than one year after the enactment of this act.

Section 2411: Increased manufacturing capacity of certain critical antibiotic drugs

Provision

Section 2411 authorizes the HHS Secretary, in consultation with the ASPR and the FDA, to award contracts to increase the domestic manufacturing capacity of certain antibiotic drugs (or their active pharmaceutical ingredients or key starting materials) with identified supply chain vulnerabilities. These grants shall be eligible to certain drug manufacturers after submission of an application that includes elements such as the manufacturer's strategic plan for achieving, maintaining, and sustaining increased manufacturing facilities. Grantees are to be required to submit follow-up reports as required by the HHS Secretary. The HHS Secretary is to be required to submit a biennial report on any activities authorized under this provision, as specified. This authority is to cease to be effective three years after the enactment and have no force or effect three years after enactment.

Subtitle E—Enhancing Development and Combating Shortages of Medical Products

At the onset of the pandemic, few treatment options were available for COVID-19 and no vaccines were available to prevent the disease. Increased demand for personal protective equipment (PPE) and other medical supplies disrupted medical product supply chains, resulting in

¹⁶⁵ Mariana P. Socal, Joshua M. Sharfstein, and Jeremy A. Greene, "The Pandemic and the Supply Chain: Gaps in Pharmaceutical Production and Distribution," *American Journal of Public Health*, vol. 111, no. 4 (April 2021), pp. 635-639, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7958046/>.

¹⁶⁶ See, for example, FDA, "Executive Order 13944 List of Essential Medicines, Medical Countermeasures, and Critical Inputs," <https://www.fda.gov/about-fda/reports/executive-order-13944-list-essential-medicines-medical-countermeasures-and-critical-inputs>.

shortages. This situation highlighted larger issues about U.S. reliance on foreign sources of medical products and the federal government’s ability to oversee the supply chain and mitigate future disruptions.¹⁶⁷ The U.S. Food and Drug Administration (FDA), the focus of this subtitle, is the primary federal agency responsible for regulating most medical products and has key responsibilities in responding to medical supply shortages.

A critical part of the COVID-19 public health response was the development new MCMs to address COVID-19, including biologics (e.g., vaccines, monoclonal antibodies), drugs (e.g., antimicrobials, antivirals), and medical devices (e.g., diagnostic tests, PPE).¹⁶⁸ Medical product development and regulatory review is a difficult and high-risk endeavor that takes years in typical circumstances. In response to public health emergencies, federal law allows certain aspects of medical product development and review to be expedited. Expedited medical product development and review also carries certain potential risks, such as a more limited safety profile for new products upon authorization. In the context of a health emergency such as a pandemic, and pursuant to its authority, FDA evaluates the risks and benefits of introducing new or modified products to the market on an abbreviated timeline.¹⁶⁹

In addition, FDA plays a key role in monitoring and addressing medical supply shortages, although its authority varies by product type. Various stakeholders have noted that during the COVID-19 pandemic, a number of overlapping factors (e.g., unexpected demand spike increases for certain medical products, disruptions to the medical supply chain, and global trade interruptions) led to acute medical product shortages.¹⁷⁰

Chapter 1—Development and Review

Throughout the COVID-19 pandemic, stakeholders expressed concern at the lack of novel therapies to treat COVID-19.¹⁷¹ FDA regulates the safety, effectiveness, and quality of MCMs through premarket and postmarket activities. With respect to its premarket work, FDA granted marketing approval, clearance, and emergency use authorization (EUA) to COVID-19 therapeutics, vaccines, diagnostics, and other medical devices (e.g., respirators and ventilators).¹⁷² In addition, FDA issued numerous guidance documents to facilitate COVID-19 MCM development and marketing authorization.

A number of regulatory flexibilities were utilized during the COVID-19 pandemic to both encourage the development of novel medical countermeasures and accelerate the review process for these products so they could be more quickly deployed. This chapter includes a number of

¹⁶⁷ For additional information, see CRS Report R46628, *COVID-19 and Domestic PPE Production and Distribution: Issues and Policy Options*; CRS Report R46507, *FDA’s Role in the Medical Product Supply Chain and Considerations During COVID-19*; and CRS In Focus IF11488, *Personal Protective Equipment (PPE) and COVID-19: FDA Regulation and Related Activities*.

¹⁶⁸ For additional information, see CRS Report R46427, *Development and Regulation of Medical Countermeasures for COVID-19 (Vaccines, Diagnostics, and Treatments): Frequently Asked Questions*.

¹⁶⁹ CRS Report R46427, *Development and Regulation of Medical Countermeasures for COVID-19 (Vaccines, Diagnostics, and Treatments): Frequently Asked Questions*.

¹⁷⁰ Johns Hopkins University, *The Pandemic and The Supply Chain: Addressing Gaps in Pharmaceutical Production and Distribution*, November 2020, https://www.jhsph.edu/research/affiliated-programs/johns-hopkins-drug-access-and-affordability-initiative/publications/Pandemic_Supply_Chain.pdf.

¹⁷¹ Phillip C. Robinson, David F.L. Liew, Helen L. Tanner, et al., “COVID-19 Therapeutics: Challenges and Directions for the Future,” *PNAS*, vol. 119, no. 15 (March 1, 2022).

¹⁷² FDA, Emergency Use Authorization, “Coronavirus Disease 2019 (COVID-19) EUA Information,” <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covid19euas>.

provisions that encourage and enhance the ability of the FDA to safely accelerate product development and review.

Section 2501: Accelerating countermeasure development and review

Background

Section 565 of the Federal Food, Drug and Cosmetic Act (FFDCA) outlined the responsibility of the HHS Secretary, in consultation with the ASPR, to ensure appropriate involvement of the FDA with accelerating the development, stockpiling, approval, licensure, and clearance of countermeasures.¹⁷³ These responsibilities included promoting expertise and situational awareness within the FDA, developing specialized teams within the FDA with expertise on countermeasures, and providing technical assistance to manufacturers and others. Prior to the PREVENT Pandemics Act, FDA did not have specific authority to expedite the development or review of such countermeasures, though FDA used some of its existing regulatory mechanisms to expedite review of COVID-19 products during the pandemic.¹⁷⁴

Provision

Section 2501 amends FFDCA Section 565 to add a new subsection that authorizes the HHS Secretary, at his or her discretion and at the request of a countermeasure sponsor during specified incidents, to take certain actions to expedite the development and review of countermeasures for approval, licensure, clearance, or authorization of products. These actions may include expedited review of sponsor submissions, expedited and increased sponsor engagement, and expedited issuance of guidance to industry stakeholders.

Section 2502: Third-party test evaluation during emergencies

Background

During the COVID-19 pandemic, FDA relied on its Emergency Use Authorization (EUA) authority to increase access to many medical products.¹⁷⁵ This authority enabled access to numerous medical products, but particularly to COVID-19 tests, in an expedited manner, using abbreviated requirements for marketing authorization.¹⁷⁶ More than 400 COVID-19 tests received EUA during the pandemic, including molecular diagnostic, antigen, and serology tests, among others. The volume of EUA submissions was said to be challenging for the agency during a time when it was prioritizing many other COVID-19-related review activities.

Provision

Section 2502 adds a new FFDCA Section 565(i) to allow the Secretary to consult or enter into cooperative agreements with experts when evaluating in vitro diagnostics that are the subject of EUA submissions to determine whether they meet the criteria for EUA issuance. These experts may conduct evaluations and provide recommendations relating to the scope and conditions of the authorization. In so doing, they must consider whether the diagnostic meets the conditions in

¹⁷³ 21 U.S.C. §360bbb-4.

¹⁷⁴ See FDA, “Coronavirus Treatment Acceleration Program,” <https://www.fda.gov/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap>.

¹⁷⁵ See generally FFDCA §564 (21 U.S.C. §360bbb-3).

¹⁷⁶ The criteria for issuing an EUA are found at FFDCA §564(c)(2) and include, for example, that based on the totality of scientific evidence, the product being evaluated may be effective in treating or preventing the disease that is the subject of the emergency, and that the known and potential benefits of the product outweigh the known and potential risks of the product.

FFDCA Section 564(c)(2) for issuance of an EUA, and recommendations must be submitted to the Secretary in writing. Not later than one year after enactment, the HHS Secretary is required to publish draft guidance on the consultations occurring under Section 565(i), including considerations around compensation and conflict of interest, among others. A revised draft or final guidance must be published not later than one year after public comment closes for the initial draft guidance.

Section 2503: Platform technologies

Background

Platform technologies are tools that can be adapted and reused to develop a range of medical products, including drugs, vaccines, and diagnostics. Use of these technologies may reduce the time and cost required to develop subsequent products.¹⁷⁷ The FDA has recognized the potential benefits of platform technologies in drug development and has encouraged their use through various initiatives and policies.¹⁷⁸

Provision

This provision adds a new section in the FFDCA (FFDCA §506K) that establishes a program for the designation of certain technologies as platform technologies under certain conditions, such as

- the technology is used in the development of certain drug products;
- preliminary evidence suggests that the technology has the potential to be used in multiple drug products; and
- data suggest that the technology has a reasonable likelihood to bring significant efficiencies to the drug development, manufacturing, and review processes.

An individual or product sponsor may request designation of a platform technology either with or at any time during a drug product submission that uses this technology. Upon receipt of the request, the Secretary shall determine whether the technology meets the specified criteria for the designation. Upon such a determination, the Secretary may take certain actions to expedite the development and review of an application that uses this technology, including engaging with sponsors early, providing timely advice to drug sponsors, and considering inspectional findings that incorporate the use of such technology. The HHS Secretary may also choose to not designate a technology as a platform technology, or to revoke an earlier designation.

The Secretary must allow the sponsor of a drug application to reference data from another application that uses the same platform technology. Sponsors of multiple approved drug products that incorporate or use a designated platform technology may submit a single supplemental application for proposed changes to the technology that may be applicable to other products using the same technology.

The Secretary must also issue draft guidance on the implementation of this section not later than one year after the date of enactment and must issue a report not later than September 30, 2026, and annually for the next three years on the number of platform technology designations, resources used, and efficiencies gained, among other program metrics.

¹⁷⁷ Michael Siedler, “Implementation of a Platform Approach for Early Biologics Development,” *American Pharmaceutical Review*, September 1, 2011, <https://www.americanpharmaceuticalreview.com/Featured-Articles/37325-Implementation-of-a-Platform-Approach-for-Early-Biologics-Development/>.

¹⁷⁸ FDA, “Emerging Technology Program,” last updated Nov. 14, 2022, <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/emerging-technology-program>.

Section 2504: Increasing EUA decision transparency

Background

During the COVID-19 pandemic, FDA used EUAs to make a variety of medical products available. GAO has noted that although FDA's EUA decisions are communicated via authorization letters and subsequent publicly available data, the underlying evidence that FDA used to support its authorization has not always been transparent.¹⁷⁹ FDA noted that it had tried to improve its transparency regarding EUA decisions, but that certain federal laws may have limited what information the agency was able to share.¹⁸⁰ Prior to the PREVENT Pandemic Act, Section 564(h) of the FFDCA¹⁸¹ required that FDA publish a notice of EUA authorization, termination or revocation for certain product classes in the Federal Register.

Provision

Section 2504 amends the existing FDA requirement to publish a notice of each EUA authorization, termination, or revocation in FFDCA Section 564(h).¹⁸² Specifically, the section broadens the types of products for which notices are required. The provision also directs the Secretary to make any EUA revisions available on an FDA website, which may include a summary of the data and information supporting such revisions. The provision also clarifies that EUA revisions and accompanying documents are authorized disclosures under federal law.¹⁸³

Section 2505: Improving FDA guidance and communication

Background

FDA regularly communicates with the public and other stakeholders through various publications, including guidance documents and external stakeholder (including product sponsor) communications.¹⁸⁴ Though FDA guidance documents are nonbinding, they represent FDA's current policy interpretations regarding regulatory issues.¹⁸⁵ Communications with external stakeholders may include, for example, correspondence with product sponsors developing novel medical products.¹⁸⁶

In a 2021 policy brief, Senator Burr noted that “[d]uring the COVID-19 public health emergency, FDA quickly published guidance and other regulatory documents” that “helped speed the development and availability of medical countermeasures to turn the tide on the pandemic response.”¹⁸⁷ Consequently, the brief recommended that FDA strengthen its regulatory readiness by “adopt[ing] [its] best practices that emerged during the pandemic related to providing

¹⁷⁹ GAO, *Federal Efforts Accelerate Vaccine and Therapeutic Development, but More Transparency Needed on Emergency Use Authorizations*, November 2020, p. 29, <https://www.gao.gov/assets/gao-21-207.pdf>.

¹⁸⁰ *Ibid.* at 33.

¹⁸¹ 21 U.S.C. §360bbb-3(h).

¹⁸² 21 U.S.C. §360bbb-3(h).

¹⁸³ Specifically 18 U.S.C. §1905.

¹⁸⁴ For FDA's regulations governing guidance documents, see generally 21 C.F.R. §10.115, and FDA, “Guidances,” January 24, 2022, <https://www.fda.gov/industry/fda-basics-industry/guidances>.

¹⁸⁵ *Ibid.*

¹⁸⁶ See, for example, FDA, CDER, CBER, *Best Practices for Communication Between IND Sponsors and FDA During Drug Development: Guidance for Industry and Review Staff*, December 2017, pp. 3-5, at <https://www.fda.gov/media/94850/download>.

¹⁸⁷ Richard Burr, *Strengthening FDA's Regulatory Readiness: Implementing Lessons Learned from the COVID-19 Pandemic*, policy brief, September 30, 2021, p. 3, at <https://www.help.senate.gov/imo/media/doc/Burr%20Policy%20Brief%20-%20Strengthening%20FDA's%20Regulatory%20Readiness.pdf>.

guidance to and interacting with sponsors” to increase future communication speed and transparency.¹⁸⁸

Provision

Section 2505 stipulates that the Secretary shall develop and publish a report detailing best practices for guidance document prioritization, development, issuance, and use across FDA and other applicable agencies. In addition, the Secretary shall develop and publish an implementation plan that addresses streamlining guidance document creation and FDA regulatory submission processes, implementing innovative guidance measures, and transitioning or updating appropriate guidance issued during COVID-19.

The Secretary shall also develop and publish a report detailing FDA’s nonguidance document communication practices with external stakeholders. The report shall include a review of the types and methods of these communications, related best practices, and a corresponding implementation plan, with further details as specified. The Secretary shall consult with stakeholders, as specified, pursuant to the development and publication of the reports and implementation plans.

In fulfilling these responsibilities, the Secretary may update an existing report or plan, and may further combine the reports and implementation plans discussed above into one or more documents. Within one year of enactment, the Secretary must publish a draft of the reports and plans, and no later than 180 days following the draft publications, the Secretary must publish a final report and plan and begin implementing plan best practices.

Chapter 2—Mitigating Shortages

As the federal regulator of drugs and devices, FDA plays a critical role in overseeing aspects of the U.S. medical product supply chain. Drug and device manufacturers are required, by law, to report to FDA certain supply chain-related information, with some exceptions for emergency circumstances. For example, establishments that manufacture drugs and devices are required to register with FDA and list the drugs and devices they manufacture for U.S. commercial distribution. This registration helps FDA maintain a catalog of all drugs, biologics, and devices in commercial distribution in the United States. FDA relies on establishment registration and listing information to carry out various programs and activities, including establishment inspections, postmarketing surveillance, recalls, drug quality reports, adverse event reports, monitoring of drug and device shortages and availability, supply chain security, and identification of products marketed without an approved application.

To enhance FDA’s capacity to assess the medical product supply chain and device manufacturing, Congress created requirements for reporting drug and device manufacturing interruptions and for tracking drugs as they are distributed to consumers. To help prevent and mitigate shortages, manufacturers of certain drugs and devices must notify FDA of any interruptions or discontinuances in their manufacturing. FDA is required to take certain mitigating actions in response to such notification. For example, FDA must prioritize and expedite facility inspections and review of certain regulatory submissions. Notably, drug manufacturers are required to report such interruptions or discontinuances at any time, whereas device manufacturers are subject to this requirement only in the context of a public health emergency.

¹⁸⁸ Ibid., pp. 5-6.

In addition, to make the public aware of supply chain disruptions, FDA is required by law to maintain public, up-to-date lists of drugs and devices that are in short supply. FDA publishes these lists based on the information it receives from various entities.¹⁸⁹

Section 2511: Ensuring registration of foreign drug and device manufacturers

Background

FDA upholds registration requirements for manufacturers of the various medical products that it regulates.¹⁹⁰ Although these requirements have granted the FDA some insight into the medical supply chain, numerous stakeholders have reported data gaps. These gaps, they say, have consequently made monitoring product development throughout the manufacturing lifecycle a challenge.¹⁹¹

Provision

Section 2511 amends FFDCA Section 510(i) to expand the requirement for certain foreign drug and device manufacturers to register with the United States, specifying that the registration requirements stated therein are applicable regardless if the product undergoes further preparation, propagation, compounding, or processing at a separate foreign facility prior to importation or offer for importation within the United States.¹⁹² This section also directs the HHS Secretary to update appropriate regulations to implement the updated registration requirements.

Section 2512: Extending expiration dates for certain drugs

Background

Federal regulations require that the expiration dates for drug products are determined by appropriate stability testing.¹⁹³ These expiration dates reflect the period of time in which a drug product retains its medicinal properties when properly stored. In some instances, manufacturers of an approved drug product may apply to FDA to extend the product expiration date based on available data.¹⁹⁴ In some instances, and in response to drug shortages, FDA has approved extensions of expiration dates for certain products.¹⁹⁵

Provision

Section 2512 directs the HHS Secretary to issue or revise guidance related to expiration dates for certain drug and biologic product applications. The guidance is to address (1) the submission of stability data testing results in such applications with considerations for streamlining data requirements to allow for faster review of longer expiration dates; (2) the labeling of a drug product with the longest feasible expiration date supported by data; and (3) the use of innovative approaches for product stability modelling. The Secretary must also submit a report to Congress two years after enactment (and another two years later) that includes information on drug

¹⁸⁹ CRS In Focus IF11058, *Drug Shortages: Causes, FDA Authority, and Policy Options*.

¹⁹⁰ FDA, “Registration and Listing,” last updated February 2, 2023 at <https://www.fda.gov/industry/fda-basics-industry/registration-and-listing>.

¹⁹¹ For more details, see CRS Report R46507, *FDA’s Role in the Medical Product Supply Chain and Considerations During COVID-19*, at p. 20.

¹⁹² 21 U.S.C. §360(i).

¹⁹³ 21 C.F.R. §211.137 and 21 C.F.R. §211.166.

¹⁹⁴ FDA, “Changes to an Approved NDA or ANDA,” April 2004, p. 31, <https://www.fda.gov/media/71846/download>.

¹⁹⁵ FDA, “Expiration Date Extension,” last updated April 27, 2023, <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/expiration-dating-extension>.

products for which the HHS Secretary has requested the manufacturer to change the expiration date and the circumstances of such requests.

Section 2513: Combating counterfeit devices.

Background

Leading up to and during the COVID-19 pandemic, there was concern about the import and marketing of counterfeit medical products, especially counterfeit medical devices (e.g., COVID-19 OTC tests).¹⁹⁶ Although authorities addressing counterfeit drugs were in place prior to the pandemic, similar authorities were not in place for medical devices. In early 2020, the Safeguarding Therapeutics Act (H.R. 5663/S. 4225) was introduced to provide authority to the FDA to destroy specified counterfeit medical devices refused admission into the United States and to add a definition for the term “counterfeit device” in the FFDCA; this bill became law in January 2021.¹⁹⁷

Provision

Section 2513 amends FFDCA Section 301 to prohibit three actions related to counterfeit devices:

- (1) “forging, counterfeiting, simulating, falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification upon any device or container, packaging, or labeling”;
- (2) “making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark or imprint of another or any likeness of any of the foregoing upon any device or container, packaging, or labeling thereof so as to render such device a counterfeit device”; and
- (3) “the doing of any act which causes a device to be a counterfeit device, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit device.”¹⁹⁸

In addition, this provision amends FFDCA Section 303¹⁹⁹ to create and clarify penalties for certain of these prohibited acts.

Section 2514: Preventing medical device shortages

Background

As mandated by the CARES Act (P.L. 116-136), device manufacturers are required to report to FDA during or prior to a public health emergency any permanent discontinuance of production, or interruption in production, likely to lead to a significant disruption in the supply of a device, including the reasons for the discontinuance or interruption.²⁰⁰ This information must be reported to FDA at least six months prior to occurrence, or as soon as is practical.²⁰¹ In contrast to the

¹⁹⁶ See, for example, FDA, “Counterfeit At-Home OTC COVID-19 Diagnostic Tests,” <https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/counterfeit-home-otc-covid-19-diagnostic-tests>.

¹⁹⁷ P.L. 116-304, amending §§801 and 201 of the FFDCA.

¹⁹⁸ 21 U.S.C. §331.

¹⁹⁹ 21 U.S.C. §333.

²⁰⁰ FFDCA §506J(a); 21 U.S.C. §356j(a).

²⁰¹ FFDCA §506J(b); 21 U.S.C. §356j(b). Per FDA guidance, FDA interprets “as soon as is practicable” to mean no later than seven calendar days after the discontinuance or interruption in manufacturing occurs. FDA, *Guidance for Industry and Food and Drug Administration Staff: Notifying CDRH of a Permanent Discontinuance or Interruption in* (continued...)

agency's authority to compel manufacturers of certain drugs to report discontinuances or interruptions in production,²⁰² FDA did not have such authority for medical devices prior to the CARES Act. Rather, FDA relied on manufacturers to voluntarily report such information to the agency.

FDA has issued guidance to help affected manufacturers implement this provision in the context of COVID-19; this guidance expired when the public health emergency (PHE) ended.²⁰³ In addition to outlining the requirements specified in statute, the guidance specified additional voluntary information that would help the agency identify shortages.²⁰⁴ In January 2022, the agency published draft guidance to elaborate on the requirements during *any* public health emergency, not only those that are COVID-specific.²⁰⁵ This broader guidance is in effect going forward but notably continues to be in effect only during specified public health emergencies.

Provision

Section 2514 amends FFDCA Section 506J to allow FDA to receive voluntary notifications of interruptions of or discontinuances in manufacture of certain devices, as specified, from device manufacturers, including the reasons for such interruptions or discontinuances.²⁰⁶ The Secretary is required, not later than one year after enactment, to publish draft guidance on these voluntary notifications, including recommended timeframes and processes for the notifications, and possible mitigating actions that the Secretary may take, among other things. The Secretary is further required to publish final guidance not later than one year after the close of comments on the draft guidance. In addition, the Secretary is required, not later than one year after enactment, to issue or revise draft guidance on the device shortage notification requirements under Section 506J, including a list of device types for which shortage notifications are required.

Section 2515: Technical corrections

Section 2515 offers a number of technical corrections to various sections of the CARES Act and the FFDCA.

Manufacturing of a Device Under Section 506J of the FD&C Act During the COVID-19 Public Health Emergency, p. 5, June 2020, <https://www.fda.gov/media/137712/download> (hereinafter FDA, *Guidance: Notifying CDRH of a Permanent Discontinuation or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act During the COVID-19 Public Health Emergency*).

²⁰² 21 U.S.C. §356c.

²⁰³ FDA, *Guidance: Notifying CDRH of a Permanent Discontinuation or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act During the COVID-19 Public Health Emergency*.

²⁰⁴ FDA, *Guidance: Notifying CDRH of a Permanent Discontinuation or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act During the COVID-19 Public Health Emergency*, November 2020, pp. 11-12, <https://www.fda.gov/media/137712/download>.

²⁰⁵ FDA, *Notifying FDA of a Permanent Discontinuation or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act*, January 2022, <https://www.fda.gov/media/155245/download>.

²⁰⁶ 21 U.S.C. §356c.

Author Information

Kavya Sekar, Coordinator
Analyst in Health Policy

Todd Kuiken
Analyst in Science and Technology Policy

Hassan Z. Sheikh
Analyst in Health Policy

Amanda K. Sarata
Specialist in Health Policy

Johnathan H. Duff
Analyst in Health Policy

Jared S. Sussman
Analyst in Health Policy

Elayne J. Heisler
Acting Section Research Manager

Nora Wells
Analyst in Health Policy

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