117TH CONGRESS
1st Session
HOUSE OF REPRESENTATIVES
REPORT
117–178

IMMUNIZATION INFRASTRUCTURE MODERNIZATION ACT OF 2021

NOVEMBER 30, 2021.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. PALLONE, from the Committee on Energy and Commerce, submitted the following

R E P O R T

[To accompany H.R. 550]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 550) to amend the Public Health Service Act with respect to immunization system data modernization and expansion, and for other purposes, having considered the same, reports favorably thereon with an amendment and recommends that the bill as amended do pass.

CONTENTS

The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Immunization Infrastructure Modernization Act of 2021".

SEC. 2. IMMUNIZATION INFORMATION SYSTEM DATA MODERNIZATION AND EXPANSION.

Subtitle C of title XXVIII of the Public Health Service Act (42 U.S.C. 300hh–31 et seq.) is amended by adding at the end the following:

"SEC. 2824. IMMUNIZATION INFORMATION SYSTEM DATA MODERNIZATION AND EXPANSION.

"(a) EXPANDING CDC AND PUBLIC HEALTH DEPARTMENT CAPABILITIES.—

"(1) IN GENERAL.—The Secretary shall—

"(A) conduct activities (including with respect to interoperability, population reporting, and bidirectional reporting) to expand, enhance, and improve immunization information systems that are administered by health departments or other agencies of State, local, Tribal, and territorial governments and used by health care providers; and

"(B) award grants or cooperative agreements to the health departments, or such other governmental entities as administer immunization information systems, of State, local, Tribal, and territorial governments, for the expansion, enhancement, and improvement of immunization information systems to assist public health departments in—

"(i) assessing current data infrastructure capabilities and gaps among health care providers to improve and increase consistency in patient matching, data collection, reporting, bidirectional exchange, and analysis of immunization-related information;

"(ii) providing for technical assistance and the efficient enrollment and training of health care providers, including at pharmacies and other settings where immunizations are being provided, such as long-term care facilities, specialty health care providers, community health centers, Federally qualified health centers, rural health centers, organizations serving adults 65 and older, and organizations serving homeless and incarcerated populations;

"(iii) improving secure data collection, transmission, bidirectional exchange, maintenance, and analysis of immunization information;

"(iv) improving the secure bidirectional exchange of immunization record data among Federal, State, local, Tribal, and territorial governmental entities and non-governmental entities, including by—

"(I) improving such exchange among public health officials in multiple jurisdictions within a State, as appropriate; and

"(II) by simplifying and supporting electronic reporting by any health care provider;

"(v) supporting the standardization of immunization information systems to accelerate interoperability with health information technology, including with health information technology certified under section 3001(c)(5) or with health information networks;

"(vi) supporting adoption of the immunization information system functional standards of the Centers for Disease Control and Prevention and the maintenance of security standards to protect individually identifiable health information;

"(vii) supporting and training immunization information system, data science, and informatics personnel;

"(viii) supporting real-time immunization record data exchange and reporting, to support rapid identification of immunization coverage gaps;

"(ix) improving completeness of data by facilitating the capability of immunization information systems to exchange data, directly or indirectly, with immunization information systems in other jurisdictions;

"(x) enhancing the capabilities of immunization information systems to evaluate, forecast, and operationalize clinical decision support tools in alignment with the recommendations of the Advisory Committee on Immunization Practices as approved by the Director of the Centers for Disease Control and Prevention;

"(xi) supporting the development and implementation of policies that facilitate complete population-level capture, consolidation, and access to accurate immunization information;

"(xii) supporting the procurement and implementation of updated software, hardware, and cloud storage to adequately manage information volume and capabilities;

"(xiii) supporting expansion of capabilities within immunization information systems for outbreak response;

"(xiv) supporting activities within the applicable jurisdiction related to the management, distribution, and storage of vaccine doses and ancillary supplies;

"(xv) developing information related to the use and importance of immunization record data and disseminating such information to health care providers and other persons authorized under State law to access such information, including payors and health care facilities; or

"(xvi) supporting activities to improve the scheduling and administration of vaccinations.

"(2) DATA STANDARDS.—In carrying out paragraph (1), the Secretary shall—

"(A) designate data and technology standards that must be followed by governmental entities with respect to use of immunization information systems as a condition of receiving an award under this section, with priority given to standards developed by—

"(i) consensus-based organizations with input from the public; and

"(ii) voluntary consensus-based standards bodies; and

"(B) support a means of independent verification of the standards used in carrying out paragraph (1).

"(3) PUBLIC-PRIVATE PARTNERSHIPS.—In carrying out paragraph (1), the Secretary may develop and utilize contracts and cooperative agreements for technical assistance, training, and related implementation support.

"(b) REQUIREMENTS.—

"(1) HEALTH INFORMATION TECHNOLOGY STANDARDS.—The Secretary may not award a grant or cooperative agreement under subsection (a)(1)(B) unless the applicant uses and agrees to use standards adopted by the Secretary under section 3004.

"(2) WAIVER.—The Secretary may waive the requirement under paragraph (1) with respect to an applicant if the Secretary determines that the activities under subsection (a)(1)(B) cannot otherwise be carried out within the applicable jurisdiction.

"(3) APPLICATION.—A State, local, Tribal, or territorial health department applying for a grant or cooperative agreement under subsection (a)(1)(B) shall submit an application to the Secretary at such time and in such manner as the Secretary may require. Such application shall include information describing—

"(A) the activities that will be supported by the grant or cooperative agreement; and

"(B) how the modernization of the immunization information systems involved will support or impact the public health infrastructure of the health department, including a description of remaining gaps, if any, and the actions needed to address such gaps.

"(c) STRATEGY AND IMPLEMENTATION PLAN.—Not later than 90 days after the date of enactment of this section, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a coordinated strategy and an accompanying implementation plan that identifies and demonstrates the measures the Secretary will utilize to—

"(1) update and improve immunization information systems supported by the Centers for Disease Control and Prevention; and

"(2) carry out the activities described in this section to support the expansion, enhancement, and improvement of State, local, Tribal, and territorial immunization information systems.

"(d) CONSULTATION; TECHNICAL ASSISTANCE.—

"(1) CONSULTATION.—In developing the strategy and implementation plan under subsection (c), the Secretary shall consult with—

"(A) health departments, or such other governmental entities as administer immunization information systems, of State, local, Tribal, and territorial governments;

"(B) professional medical, associations, public health associations, and associations representing pharmacists and pharmacies;

"(C) community health centers, long-term care facilities, and other appropriate entities that provide immunizations;

"(D) health information technology experts; and

"(E) other public or private entities, as appropriate.

"(2) TECHNICAL ASSISTANCE.—In connection with consultation under paragraph (1), the Secretary may—

"(A) provide technical assistance, certification, and training related to the exchange of information by immunization information systems used by health care and public health entities at the local, State, Federal, Tribal, and territorial levels; and

"(B) develop and utilize public-private partnerships for implementation support applicable to this section.

"(e) REPORT TO CONGRESS.—Not later than 1 year after the date of enactment of this section, the Secretary shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives that includes—

"(1) a description of any barriers to—

"(A) public health authorities implementing interoperable immunization information systems;

"(B) the exchange of information pursuant to immunization records; or

"(C) reporting by any health care professional authorized under State law, using such immunization information systems, as appropriate, and pursuant to State law; or

"(2) a description of barriers that hinder the effective establishment of a network to support immunization reporting and monitoring, including a list of recommendations to address such barriers; and

"(3) an assessment of immunization coverage and access to immunizations services and any disparities and gaps in such coverage and access for medically underserved, rural, and frontier areas.

"(f) DEFINITION.—In this section, the term 'immunization information system' means a confidential, population-based, computerized database that records immunization doses administered by any health care provider to persons within the geographic area covered by that database.

"(g) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $400,000,000, to remain available until expended.".

I. PURPOSE AND SUMMARY

H.R. 550, the "Immunization Infrastructure Modernization Act of 2021," authorizes the Secretary of Health and Human Services (the Secretary) to conduct activities, including designating data and technology standards, developing public-private partnerships, and awarding grants or cooperative agreements to health departments, in order to expand, enhance, and improve immunization information systems (IIS).

II. BACKGROUND AND NEED FOR LEGISLATION

IIS are confidential, population-based, computerized databases that record all immunization doses administered by providers to persons within a certain geopolitical area.[1] IIS are important tools in providing immunization care for patients by allowing providers to view a consolidated immunization history of a patient to determine appropriate vaccinations from childhood to adulthood, and often include features to automatically remind patients about vaccine schedules.[2] On the population level, public health officials can review aggregate data in IIS to determine overall vaccination levels to better guide public health decisions.[3]

IIS were first developed in the early 1990s by local jurisdictions and private entities, with varying data and technology platforms.[4] It was not until 2001 that the Centers for Disease Control and Prevention (CDC) published the first complete set of standards for IIS.[5] These standards provided minimum recommended technical functions for all IIS, including allowing input of all personal data

[1] Centers for Disease Control and Prevention, *About Immunization Information Systems* (https://www.cdc.gov/vaccines/programs/iis/about.html) (2021).

[2] Lynn Gibbs Sharp, et al., *Current Challenges and Future Possibilities for Immunization Information Systems*, Academic Pediatrics (May 3, 2021).

[3] *Supra* note 1.

[4] Public Health Informatics Institute, *IIS Technology Over Time: Impact and Changing Roles* (available online at https://phii.org/sites/default/files/iis_history_spotlight-_technology.pdf).

[5] Centers for Disease Control and Prevention, *IIS Minimum Functional Standards, 2001–2013 Historical Information* (https://www.cdc.gov/vaccines/programs/iis/func-stds-2001.html) (2012).

elements recommended by the National Vaccine Advisory Committee (NVAC), establishing a registry record for all newborn children in a jurisdiction within six weeks of birth, policies related to confidentiality and data security, and other important core functions.[6] These standards have evolved since 2001, and now include functions related to resolving duplicate and incomplete patient records, digital security, encryption, uptime, and disaster recovery standards, and interoperability standards between data systems.[7] Despite improvements to functional standards over the years, varying policies and interpretation, inconsistent and antiquated technology in state and local jurisdictions, incomplete provider participation, and less than full implementation of bidirectional data exchange have been cited by experts as challenges to improving data quality.[8]

H.R. 550 will improve immunization information data quality by providing grants to state and local public health departments to enhance these systems and requiring the Secretary to adopt data standards among grantees.

Grants included in H.R. 550 will be used to assist public health departments in improving data quality by: assessing data infrastructure capabilities and gaps among health care providers to increase consistency in patient matching, data collection, reporting, bidirectional exchange of information, and information analysis; providing technical assistance to health providers and efficiently enrolling them; improving data collection, transmission, exchange, maintenance, and analysis; supporting standardization of IIS to accelerate interoperability, including with electronic health record systems; supporting training of IIS, data science, and informatics personnel; supporting procurement and implementation of software, hardware, and cloud storage; supporting activities to improve the scheduling of vaccinations; and other relevant activities. In carrying out the grant activities, the Secretary is authorized to develop and utilize contracts and cooperative agreements for technical assistance, training, and related implementation support.

To improve data standards among state and local jurisdictions, H.R. 550 would require the Secretary to designate data and technology standards that must be followed by governmental entities as a condition of receiving grants, with priority given to data standards developed by consensus-based organizations with input from the public and voluntary consensus-based standards bodies. The Secretary would also be required to support a means of independent verification of standards used in carrying out grant activities.

The bill also requires the Secretary to submit to the Committee, within 90 days of enactment, a coordinated strategy and implementation plan for updating and improving IIS supported by CDC and carrying out the activities described in the bill. In developing the strategy and implementation plan, the Secretary is required to consult with health departments and other government entities that administer IIS, professional medical associations, public health as-

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[6] *Id.*

[7] Centers for Disease Control and Prevention, *Immunization Information Systems (IIS) Functional Standards, v.4.1* (https://www.cdc.gov/vaccines/programs/iis/functional-standards/func-stds-v4-1.html) (2020).

[8] *Supra* note 2.

sociations, and associations representing pharmacists and pharmacies, community health centers, long-term care facilities, and other appropriate entities that provide immunizations, health information technology (IT) experts, and other public and private entities, as appropriate. The bill further directs the Secretary to provide to the Committee within a year of enactment a report describing any barriers to implementing interoperable IIS, exchange of information pursuant to immunization records, or reporting by health care providers. The report also must describe any barriers that hinder the effective establishment of a network to support immunization reporting or monitoring with a list of recommendations to address such barriers, and an assessment of immunization coverage and access to any disparities and gaps in coverage and access for medically underserved, rural, and frontier areas.

H.R. 550 authorizes appropriations of $400,000,000 to carry out the activities described in the bill, to remain available until expended.

III. Committee Hearings

For the purposes of section 3(c) of rule XIII of the Rules of the House of Representatives, the following hearing was used to develop or consider H.R. 550:

The Subcommittee on Health held a legislative hearing on June 15, 2021 entitled "Booster Shot: Enhancing Public Health through Vaccine Legislation." The Subcommittee received testimony from the following witnesses:

- Phyllis Arthur, Vice President, Infectious Diseases and Emerging Science Policy, Biotechnology Innovation Organization;
- Rebecca Coyle, Executive Director, American Immunization Registry Association;
- Yvonne Maldonado, M.D., Chair, Committee on Infectious Diseases, American Academy of Pediatrics; and
- Lijen (L.J.) Tan, Ph.D., Chief Strategy Officer, Immunization Action Coalition.

IV. Committee Consideration

Representatives Ann Kuster (D–NH) and Larry Bucshon (R–IN) introduced H.R. 550, the "Immunization Infrastructure Modernization Act of 2021," on January 28, 2021, and it was referred to the Committee on Energy and Commerce. Subsequently, on February 2, 2021, H.R. 550 was referred to the Subcommittee on Health. A legislative hearing was held on the bill on June 15, 2021.

On July 15, 2021, the Subcommittee on Health met in open markup session, pursuant to notice, to consider H.R. 550 and 18 other bills. During consideration of the bill, a manager's amendment offered by Representative Bucshon was agreed to by a voice vote. Upon conclusion of consideration of the bill, the Subcommittee on Health agreed to report the bill favorably to the full Committee, amended, by a voice vote.

On July 21, 2021, the full Committee met in open markup session, pursuant to notice, to consider H.R. 550 and 23 other bills. No amendments were offered to H.R. 550. Upon conclusion of consideration of the bill, the full Committee agreed to a motion on

final passage offered by Representative Pallone (D–NJ), Chairman of the Committee, to order H.R. 550 reported favorably to the House, as amended, by a voice vote.

V. COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list each record vote on the motion to report legislation and amendments thereto. The Committee advises that there were no record votes taken on H.R. 550.

VI. OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII and clause 2(b)(1) of rule X of the Rules of the House of Representatives, the oversight findings and recommendations of the Committee are reflected in the descriptive portion of the report.

VII. NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

Pursuant to 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee adopts as its own the estimate of new budget authority, entitlement authority, or tax expenditures or revenues contained in the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

VIII. CONGRESSIONAL BUDGET OFFICE ESTIMATE

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, September 21, 2021.

Hon. FRANK PALLONE, JR.,
Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 550, the Immunization Infrastructure Modernization Act of 2021.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Sarah Sajewski.

Sincerely,

PHILLIP L. SWAGEL,
Director.

Enclosure.

H.R. 550, Immunization Infrastructure Modernization Act of 2021
As ordered reported by the House Committee on Energy and Commerce on July 21, 2021

By Fiscal Year, Millions of Dollars	2021	2021-2026	2021-2031
Direct Spending (Outlays)	0	0	0
Revenues	0	0	0
Increase or Decrease (-) in the Deficit	0	0	0
Spending Subject to Appropriation (Outlays)	0	396	not estimated

Statutory pay-as-you-go procedures apply?	No	Mandate Effects	
Increases on-budget deficits in any of the four consecutive 10-year periods beginning in 2032?	No	Contains intergovernmental mandate?	No
		Contains private-sector mandate?	No

H.R. 550 would authorize $400 million for the Secretary of Health and Human Services to improve and expand immunization information systems (IIS). The bill instructs the Secretary to award grants to state, local, tribal, and territorial public health departments for IIS improvements, to designate data and technology standards for IIS, and to submit a Congressional report.

For this estimate, CBO assumes H.R. 550 will be enacted near the beginning of fiscal year 2022. Based on historical spending on similar activities, CBO estimates that implementing H.R. 550 would increase federal spending by $396 million over the 2022–2026 period, subject to the availability of appropriated funds.

The CBO staff contact for this estimate is Sarah Sajewski. The estimate was reviewed by Leo Lex, Deputy Director of Budget Analysis.

IX. Federal Mandates Statement

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

X. Statement of General Performance Goals and Objectives

Pursuant to clause 3(c)(4) of rule XIII, the general performance goal or objective of this legislation is to improve data sharing and modernization of IIS through developing a plan and strategy to improve such systems, designating data and technology standards, and awarding grants to help departments to carry out activities necessary to improve IIS.

XI. Duplication of Federal Programs

Pursuant to clause 3(c)(5) of rule XIII, no provision of H.R. 550 is known to be duplicative of another Federal program, including any program that was included in a report to Congress pursuant to section 21 of Public Law 111–139 or the most recent Catalog of Federal Domestic Assistance.

XII. Committee Cost Estimate

Pursuant to clause 3(d)(1) of rule XIII, the Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

XIII. Earmarks, Limited Tax Benefits, and Limited Tariff Benefits

Pursuant to clause 9(e), 9(f), and 9(g) of rule XXI, the Committee finds that H.R. 550 contains no earmarks, limited tax benefits, or limited tariff benefits.

XIV. Advisory Committee Statement

No advisory committee within the meaning of section 5(b) of the Federal Advisory Committee Act was created by this legislation.

XV. Applicability to Legislative Branch

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

XVI. Section-by-Section Analysis of the Legislation

Section 1. Short title

Section 1 designates that the Act may be cited as the "Immunization Infrastructure Modernization Act of 2021."

Sec. 2. Immunization Information System data modernization and expansion

Section 2 amends the Public Health Service Act by creating a new Section 2824 to modernize and expand IIS infrastructure.

Subsection (a) of Section 2824 requires the Secretary to conduct activities to expand, enhance, and improve IIS administered by health departments or other agencies of State, local, Tribal, and territorial governments and used by health care providers. Subsection (a) also requires the Secretary to award grants or cooperative agreements to health departments or other government entities to assist public health departments in: (1) assessing current data infrastructure capabilities and gaps among health care providers to improve and increase consistency in patient matching, data collection, reporting, bidirectional exchange, and analysis of immunization-related information; (2) providing technical assistance and training to health care providers; (3) improving secure data collection, transmission, bidirectional exchange, maintenance, and analysis of immunization information; (4) improving the secure bidirectional exchange of immunization record data among Federal, State, local, Tribal, and territorial governmental entities and nongovernmental entities; (5) supporting the standardization of IIS to accelerate interoperability with health information technology (IT); (6) supporting adoption of CDC's functional IIS standards, and the maintenance of security standards to protect individually identifiable health information; (7) supporting and training IIS, data science, and informatics personnel; (8) supporting real-time immu-

nization record data exchange and reporting to support rapid identification of immunization coverage gaps; (9) improving completeness of data by facilitating IIS to exchange data with IIS in other jurisdictions; (10) enhancing the capabilities of IIS to evaluate, forecast, and operationalize clinical decision support tools; (11) supporting the development and implementation of policies that facilitate complete population-level capture, consolidation, and access to accurate immunization information; (12) supporting the procurement and implementation of software, hardware, and cloud storage; (13) strengthening outbreak response capabilities; (14) improving the management, distribution, and storage of vaccine doses and ancillary supplies; (15) developing and disseminating information related to the use and importance of immunization record data and disseminating it to health care providers and other relevant entities; and (16) supporting activities to improve the scheduling and administration of vaccinations.

Section (a)(2) requires the Secretary to designate data and technology standards that must be followed by governmental entities with respect to the use of IIS as a condition of receiving an award, and prioritizes standards developed by consensus-based organizations with input from the public and voluntary consensus-based bodies. The Secretary is also required to support the independent verification of the adopted standards.

Subsection (a)(3) authorizes the Secretary to develop and utilize contracts and cooperative agreements for technical assistance, training, and related implementation support.

Subsection (b) prohibits the Secretary from issuing an award unless the applicant uses and agrees to use standards adopted by the Secretary under Section 3004 of the Public Health Service Act. Such prohibition can only be waived if the Secretary determines that grant activities cannot otherwise be carried out within the applicable jurisdiction. Subsection (b) also includes requirements related to the application for awards, such as a description of the activities to be carried out under the award, and how the activities will support or impact the public health department, and what gaps would remain.

Subsection (c) requires the Secretary to submit, within 90 days of enactment, a coordinated strategy and implementation plan to the House Committee on Energy and Commerce and the Senate Committee on Health, Education, Labor, and Pensions.

Subsection (d) requires the Secretary, in developing the strategy and implementation plan described in subsection (c), to consult with health departments or other government entities that administer IIS; professional medical, public health, and pharmacist or pharmacy associations; community health centers, long-term care facilities, and other appropriate entities that provide immunizations; health IT experts; and other public or private entities, as appropriate. Subsection (d) also authorizes the Secretary to provide technical assistance, certification, and training related to IIS information exchange and develop public-private partnerships for implementation support.

Subsection (e) requires the Secretary to submit, within one year of enactment, a report to the House Committee on Energy and Commerce and the Senate Committee on Health, Education, Labor, and Pensions that includes a description of barriers to the imple-

mentation of interoperable IIS, exchange of information, or health professionals reporting to an IIS; barriers that hinder the effective establishment of a network to support immunization reporting and monitoring and a list of recommendations to address such barriers; and an assessment of immunization coverage and access to immunizations services and any disparities and gaps in such coverage and access for medically underserved, rural, and frontier areas.

Subsection (f) defines the term "immunization information system."

Subsection (g) authorizes appropriations of $400,000,000 to carry out the section, to remain available until expended.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (new matter is printed in italics and existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

TITLE XXVIII—NATIONAL ALL-HAZARDS PREPAREDNESS FOR PUBLIC HEALTH EMERGENCIES

* * * * * * *

Subtitle C—Strengthening Public Health Surveillance Systems

* * * * * * *

SEC. 2824. IMMUNIZATION INFORMATION SYSTEM DATA MODERNIZATION AND EXPANSION.

(a) EXPANDING CDC AND PUBLIC HEALTH DEPARTMENT CAPABILITIES.—

(1) IN GENERAL.—The Secretary shall—

(A) conduct activities (including with respect to interoperability, population reporting, and bidirectional reporting) to expand, enhance, and improve immunization information systems that are administered by health departments or other agencies of State, local, Tribal, and territorial governments and used by health care providers; and

(B) award grants or cooperative agreements to the health departments, or such other governmental entities as administer immunization information systems, of State, local, Tribal, and territorial governments, for the expansion, enhancement, and improvement of immunization information systems to assist public health departments in—

(i) assessing current data infrastructure capabilities and gaps among health care providers to improve and increase consistency in patient matching, data collec-

tion, reporting, bidirectional exchange, and analysis of immunization-related information;

(ii) providing for technical assistance and the efficient enrollment and training of health care providers, including at pharmacies and other settings where immunizations are being provided, such as long-term care facilities, specialty health care providers, community health centers, Federally qualified health centers, rural health centers, organizations serving adults 65 and older, and organizations serving homeless and incarcerated populations;

(iii) improving secure data collection, transmission, bidirectional exchange, maintenance, and analysis of immunization information;

(iv) improving the secure bidirectional exchange of immunization record data among Federal, State, local, Tribal, and territorial governmental entities and nongovernmental entities, including by—

(I) improving such exchange among public health officials in multiple jurisdictions within a State, as appropriate; and

(II) by simplifying and supporting electronic reporting by any health care provider;

(v) supporting the standardization of immunization information systems to accelerate interoperability with health information technology, including with health information technology certified under section 3001(c)(5) or with health information networks;

(vi) supporting adoption of the immunization information system functional standards of the Centers for Disease Control and Prevention and the maintenance of security standards to protect individually identifiable health information;

(vii) supporting and training immunization information system, data science, and informatics personnel;

(viii) supporting real-time immunization record data exchange and reporting, to support rapid identification of immunization coverage gaps;

(ix) improving completeness of data by facilitating the capability of immunization information systems to exchange data, directly or indirectly, with immunization information systems in other jurisdictions;

(x) enhancing the capabilities of immunization information systems to evaluate, forecast, and operationalize clinical decision support tools in alignment with the recommendations of the Advisory Committee on Immunization Practices as approved by the Director of the Centers for Disease Control and Prevention;

(xi) supporting the development and implementation of policies that facilitate complete population-level capture, consolidation, and access to accurate immunization information;

(xii) supporting the procurement and implementation of updated software, hardware, and cloud storage to

adequately manage information volume and capabilities;

(xiii) supporting expansion of capabilities within immunization information systems for outbreak response;

(xiv) supporting activities within the applicable jurisdiction related to the management, distribution, and storage of vaccine doses and ancillary supplies;

(xv) developing information related to the use and importance of immunization record data and disseminating such information to health care providers and other persons authorized under State law to access such information, including payors and health care facilities; or

(xvi) supporting activities to improve the scheduling and administration of vaccinations.

(2) DATA STANDARDS.—In carrying out paragraph (1), the Secretary shall—

(A) designate data and technology standards that must be followed by governmental entities with respect to use of immunization information systems as a condition of receiving an award under this section, with priority given to standards developed by—

(i) consensus-based organizations with input from the public; and

(ii) voluntary consensus-based standards bodies; and

(B) support a means of independent verification of the standards used in carrying out paragraph (1).

(3) PUBLIC-PRIVATE PARTNERSHIPS.—In carrying out paragraph (1), the Secretary may develop and utilize contracts and cooperative agreements for technical assistance, training, and related implementation support.

(b) REQUIREMENTS.—

(1) HEALTH INFORMATION TECHNOLOGY STANDARDS.—The Secretary may not award a grant or cooperative agreement under subsection (a)(1)(B) unless the applicant uses and agrees to use standards adopted by the Secretary under section 3004.

(2) WAIVER.—The Secretary may waive the requirement under paragraph (1) with respect to an applicant if the Secretary determines that the activities under subsection (a)(1)(B) cannot otherwise be carried out within the applicable jurisdiction.

(3) APPLICATION.—A State, local, Tribal, or territorial health department applying for a grant or cooperative agreement under subsection (a)(1)(B) shall submit an application to the Secretary at such time and in such manner as the Secretary may require. Such application shall include information describing—

(A) the activities that will be supported by the grant or cooperative agreement; and

(B) how the modernization of the immunization information systems involved will support or impact the public health infrastructure of the health department, including a description of remaining gaps, if any, and the actions needed to address such gaps.

(c) STRATEGY AND IMPLEMENTATION PLAN.—Not later than 90 days after the date of enactment of this section, the Secretary shall

submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a coordinated strategy and an accompanying implementation plan that identifies and demonstrates the measures the Secretary will utilize to—

(1) update and improve immunization information systems supported by the Centers for Disease Control and Prevention; and

(2) carry out the activities described in this section to support the expansion, enhancement, and improvement of State, local, Tribal, and territorial immunization information systems.

(d) CONSULTATION; TECHNICAL ASSISTANCE.—

(1) CONSULTATION.—In developing the strategy and implementation plan under subsection (c), the Secretary shall consult with—

(A) health departments, or such other governmental entities as administer immunization information systems, of State, local, Tribal, and territorial governments;

(B) professional medical, associations, public health associations, and associations representing pharmacists and pharmacies;

(C) community health centers, long-term care facilities, and other appropriate entities that provide immunizations;

(D) health information technology experts; and

(E) other public or private entities, as appropriate.

(2) TECHNICAL ASSISTANCE.—In connection with consultation under paragraph (1), the Secretary may—

(A) provide technical assistance, certification, and training related to the exchange of information by immunization information systems used by health care and public health entities at the local, State, Federal, Tribal, and territorial levels; and

(B) develop and utilize public-private partnerships for implementation support applicable to this section.

(e) REPORT TO CONGRESS.—Not later than 1 year after the date of enactment of this section, the Secretary shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives that includes—

(1) a description of any barriers to—

(A) public health authorities implementing interoperable immunization information systems;

(B) the exchange of information pursuant to immunization records; or

(C) reporting by any health care professional authorized under State law, using such immunization information systems, as appropriate, and pursuant to State law; or

(2) a description of barriers that hinder the effective establishment of a network to support immunization reporting and monitoring, including a list of recommendations to address such barriers; and

(3) an assessment of immunization coverage and access to immunizations services and any disparities and gaps in such coverage and access for medically underserved, rural, and frontier areas.

(f) DEFINITION.—In this section, the term "immunization information system" means a confidential, population-based, computerized database that records immunization doses administered by any health care provider to persons within the geographic area covered by that database.

(g) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $400,000,000, to remain available until expended.

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