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(Original Signature of Member)

117TH CONGRESS  
1ST SESSION

**H. R.** \_\_\_\_\_

To amend the Public Health Service Act with respect to immunization system data modernization and expansion, and for other purposes.

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IN THE HOUSE OF REPRESENTATIVES

Ms. KUSTER of New Hampshire introduced the following bill; which was referred to the Committee on \_\_\_\_\_

\_\_\_\_\_  
**A BILL**

To amend the Public Health Service Act with respect to immunization system data modernization and expansion, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Immunization Infra-  
5 structure Modernization Act of 2021”.

1 **SEC. 2. IMMUNIZATION INFORMATION SYSTEM DATA MOD-**  
2 **ERNIZATION AND EXPANSION.**

3 Subtitle C of title XXVIII of the Public Health Serv-  
4 ice Act (42 U.S.C. 300hh–31 et seq.) is amended by add-  
5 ing at the end the following:

6 **“SEC. 2823. IMMUNIZATION INFORMATION SYSTEM DATA**  
7 **MODERNIZATION AND EXPANSION.**

8 **“(a) EXPANDING CDC AND PUBLIC HEALTH DE-**  
9 **PARTMENT CAPABILITIES.—**

10 **“(1) IN GENERAL.—**The Secretary shall—

11 **“(A)** conduct activities (including with re-  
12 spect to interoperability, population reporting,  
13 and bidirectional reporting) to expand, enhance,  
14 and improve immunization information systems  
15 that are administered by health departments or  
16 other agencies of State, local, Tribal, and terri-  
17 torial governments and used by health care pro-  
18 viders; and

19 **“(B)** award grants or cooperative agree-  
20 ments to the health departments, or such other  
21 governmental entities as administer immuniza-  
22 tion information systems, of State, local, Tribal,  
23 and territorial governments, for the expansion,  
24 enhancement, and improvement of immuniza-  
25 tion information systems to assist public health  
26 departments in—

1           “(i) assessing current data infrastruc-  
2           ture capabilities and gaps among health  
3           care providers to improve and increase  
4           consistency in patient matching, data col-  
5           lection, reporting, bidirectional exchange,  
6           and analysis of immunization-related infor-  
7           mation;

8           “(ii) providing for the efficient enroll-  
9           ment and training of health care providers,  
10          including at pharmacies and other settings  
11          where immunizations are being provided,  
12          such as long-term care facilities, specialty  
13          health care providers, community health  
14          centers, Federally qualified health centers,  
15          rural health centers, organizations serving  
16          adults 65 and older, and organizations  
17          serving homeless and incarcerated popu-  
18          lations;

19          “(iii) improving secure data collection,  
20          transmission, bidirectional exchange, main-  
21          tenance, and analysis of immunization in-  
22          formation;

23          “(iv) improving the secure  
24          bidirectional exchange of immunization  
25          record data among Federal, State, local,

1 Tribal, and territorial governmental enti-  
2 ties and non-governmental entities, includ-  
3 ing by—

4 “(I) improving such exchange  
5 among public health officials in mul-  
6 tiple jurisdictions within a State, as  
7 appropriate; and

8 “(II) by simplifying and sup-  
9 porting electronic reporting by any  
10 health care provider;

11 “(v) supporting the standardization of  
12 immunization information systems to accel-  
13 erate interoperability with health informa-  
14 tion technology, including with health in-  
15 formation technology certified under sec-  
16 tion 3001(e)(5) or with health information  
17 networks;

18 “(vi) supporting adoption of the im-  
19 munization information system functional  
20 standards of the Centers for Disease Con-  
21 trol and Prevention and the maintenance  
22 of security standards to protect individ-  
23 ually identifiable health information as de-  
24 fined in section 160.103 of title 45, Code

1 of Federal Regulations (or any successor  
2 regulations);

3 “(vii) supporting and training immu-  
4 nization information system, data science,  
5 and informatics personnel;

6 “(viii) supporting real-time immuniza-  
7 tion record data exchange and reporting,  
8 to support rapid identification of immuni-  
9 zation coverage gaps;

10 “(ix) improving completeness of data  
11 by facilitating the capability of immuniza-  
12 tion information systems to exchange data,  
13 directly or indirectly, with immunization  
14 information systems in other jurisdictions;

15 “(x) enhancing the capabilities of im-  
16 munization information systems to evalu-  
17 ate, forecast, and operationalize clinical de-  
18 cision support tools in alignment with the  
19 recommendations of the Advisory Com-  
20 mittee on Immunization Practices as ap-  
21 proved by the Director of the Centers for  
22 Disease Control and Prevention;

23 “(xi) supporting the development and  
24 implementation of policies that facilitate  
25 complete population-level capture, consoli-

1                    dation, and access to accurate immuniza-  
2                    tion information;

3                    “(xii) supporting the procurement and  
4                    implementation of updated software, hard-  
5                    ware, and cloud storage to adequately  
6                    manage information volume and capabili-  
7                    ties;

8                    “(xiii) supporting expansion of capa-  
9                    bilities within immunization information  
10                   systems for outbreak response;

11                   “(xiv) supporting activities within the  
12                   applicable jurisdiction related to the man-  
13                   agement, distribution, and storage of vac-  
14                   cine doses and ancillary supplies; and

15                   “(xv) developing information related  
16                   to the use and importance of immunization  
17                   record data and disseminating such infor-  
18                   mation to health care providers and other  
19                   persons authorized under State law to ac-  
20                   cess such information, including payors  
21                   and health care facilities.

22                   “(2) DATA STANDARDS.—In carrying out para-  
23                   graph (1), the Secretary shall—

24                   “(A) designate data and technology stand-  
25                   ards that must be followed by governmental en-

1           tities with respect to use of immunization infor-  
2           mation systems as a condition of receiving an  
3           award under this section, with priority given to  
4           standards developed by—

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

7                   “(ii) voluntary consensus-based stand-  
8                   ards bodies; and

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

12                 “(3) PUBLIC-PRIVATE PARTNERSHIPS.—In car-  
13                 rying out paragraph (1), the Secretary may develop  
14                 and utilize contracts and cooperative agreements for  
15                 technical assistance, training, and related implemen-  
16                 tation support.

17                 “(b) REQUIREMENTS.—

18                   “(1) HEALTH INFORMATION TECHNOLOGY  
19                   STANDARDS.—The Secretary may not award a grant  
20                   or cooperative agreement under subsection (a)(1)(B)  
21                   unless the applicant uses and agrees to use stand-  
22                   ards adopted by the Secretary under section 3004.

23                   “(2) WAIVER.—The Secretary may waive the  
24                   requirement under paragraph (1) with respect to an  
25                   applicant if the Secretary determines that the activi-

1 ties under subsection (a)(1)(B) cannot otherwise be  
2 carried out within the applicable jurisdiction.

3 “(3) APPLICATION.—A State, local, Tribal, or  
4 territorial health department applying for a grant or  
5 cooperative agreement under subsection (a)(1)(B)  
6 shall submit an application to the Secretary at such  
7 time and in such manner as the Secretary may re-  
8 quire. Such application shall include information de-  
9 scribing—

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

12 “(B) how the modernization of the immu-  
13 nization information systems involved will sup-  
14 port or impact the public health infrastructure  
15 of the health department, including a descrip-  
16 tion of remaining gaps, if any, and the actions  
17 needed to address such gaps.

18 “(c) STRATEGY AND IMPLEMENTATION PLAN.—Not  
19 later than 90 days after the date of enactment of this sec-  
20 tion, the Secretary shall submit to the Committee on En-  
21 ergy and Commerce of the House of Representatives and  
22 the Committee on Health, Education, Labor, and Pen-  
23 sions of the Senate a coordinated strategy and an accom-  
24 panying implementation plan that identifies and dem-  
25 onstrates the measures the Secretary will utilize to—



1           “(1) update and improve immunization infor-  
2           mation systems supported by the Centers for Dis-  
3           ease Control and Prevention; and

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

8           “(d) CONSULTATION; TECHNICAL ASSISTANCE.—

9           “(1) CONSULTATION.—In developing the strat-  
10          egy and implementation plan under subsection (c),  
11          the Secretary shall consult with—

12                 “(A) health departments, or such other  
13                 governmental entities as administer immuniza-  
14                 tion information systems, of State, local, Tribal,  
15                 and territorial governments;

16                 “(B) professional medical, associations,  
17                 public health associations, and associations rep-  
18                 resenting pharmacists and pharmacies;

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

22                 “(D) health information technology ex-  
23                 perts; and

24                 “(E) other public or private entities, as ap-  
25                 propriate.

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

4           “(A) provide technical assistance, certifi-  
5 cation, and training related to the exchange of  
6 information by immunization information sys-  
7 tems used by health care and public health enti-  
8 ties at the local, State, Federal, Tribal, and ter-  
9 ritorial levels; and

10           “(B) develop and utilize public-private  
11 partnerships for implementation support appli-  
12 cable to this section.

13           “(e) REPORT TO CONGRESS.—Not later than 1 year  
14 after the date of enactment of this section, the Secretary  
15 shall submit a report to the Committee on Health, Edu-  
16 cation, Labor, and Pensions of the Senate and the Com-  
17 mittee on Energy and Commerce of the House of Rep-  
18 resentatives that includes—

19           “(1) a description of any barriers to—

20           “(A) public health authorities imple-  
21 menting interoperable immunization informa-  
22 tion systems;

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

1           “(C) reporting by any health care profes-  
2           sional authorized under State law, using such  
3           immunization information systems, as appro-  
4           priate, and pursuant to State law; or

5           “(2) a description of barriers that hinder the  
6           effective establishment of a network to support im-  
7           munization reporting and monitoring, including a  
8           list of recommendations to address such barriers;  
9           and

10          “(3) an assessment of immunization coverage  
11          and access to immunizations services and any dis-  
12          parities and gaps in such coverage and access for  
13          medically underserved, rural, and frontier areas.

14          “(f) DEFINITION.—In this section, the term ‘immuni-  
15          zation information system’ means a confidential, popu-  
16          lation-based, computerized database that records immuni-  
17          zation doses administered by any health care provider to  
18          persons within the geographic area covered by that data-  
19          base.

20          “(g) AUTHORIZATION OF APPROPRIATIONS.—To  
21          carry out this section, there is authorized to be appro-  
22          priated \$400,000,000, to remain available until ex-  
23          pended.”.