I

114TH CONGRESS
1ST SESSION

H. R. 786

To improve access, certainty, and innovation with respect to vaccines.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 5, 2015

Mrs. ELLMERS (for herself and Mr. BUTTERFIELD) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To improve access, certainty, and innovation with respect to vaccines.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Vaccine Access, Certainty, and Innovation Act of 2015''.

SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

TITLE I—DEVELOPMENT, LICENSURE, AND RECOMMENDATIONS

SEC. 101. REVIEW OF TRANSPARENCY AND CONSISTENCY OF ACIP RECOMMENDATION PROCESS.

(a) REVIEW.—The Director of the Centers for Disease Control and Prevention shall conduct a review of the transparency and consistency of the process used by the Advisory Committee on Immunization Practices in formulating and issuing recommendations pertaining to vaccines.

(b) CONSIDERATIONS.—The review under subsection (a) shall include assessment of—

(1) the criteria used to evaluate new and existing vaccines;

(2) the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) ap-

proach to the review and analysis of scientific and economic data, including the scientific basis for such approach; and

(3) the extent to which the processes used by the working groups of the Advisory Committee on Immunization Practices are transparent and consistent.

(c) STAKEHOLDERS.—In carrying out the review under subsection (a), the Director of the Centers for Disease Control and Prevention shall solicit input from vaccine stakeholders.

(d) REPORT.—Not later than 1 year after the date of enactment of this Act, the Director of the Centers for Disease Control and Prevention shall submit to the appropriate committees of the Congress and make publicly available a report on the results of the review under subsection (a), including recommendations on improving the transparency and consistency of the process described in such subsection.

(e) DEFINITION.—In this section, the term ''Advisory Committee on Immunization Practices'' means the advisory committee on immunization practices established by the Secretary of Health and Human Services pursuant to section 222 of the Public Health Service Act (42 U.S.C.

217a), acting through the Director of the Centers for Disease Control and Prevention.

SEC. 102. GUIDANCE ON VACCINE DEVELOPMENT.

(a) ISSUANCE.—Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services shall issue final guidance to facilitate the use of accelerated and expedited pathways for the development and licensure of vaccines to prevent—

(1) emerging, re-emerging, or rare infectious diseases with respect to which the low prevalence or nature of the disease may render the existence or collection of clinical outcome data unlikely or impractical; and

(2) infectious diseases with respect to which currently available vaccines are not addressing the full scope of public health needs.

(b) CONSIDERATIONS.—In developing the guidance required by this section, the Secretary of Health and Human Services shall consider issues relating to clinical development strategies for diseases described in subsection (a), including the development and acceptability of novel clinical and surrogate endpoints, the use of novel or accelerated study designs, the use of observational real-world data, the use of novel adjuvants, the use of new technologies or approaches to collecting and monitoring pa-

tient-level data, and the demonstration of efficacy through studies in healthy volunteers for the purpose of licensure.

SEC. 103. MEETINGS BETWEEN CDC AND VACCINE DEVELOPERS.

Section 310 of the Public Health Service Act (42 U.S.C. 242o) is amended by adding at the end the following:

''(c)(1) In this subsection, the term 'vaccine developer' means a nongovernmental entity engaged in—

''(A) the development or production of a vaccine; and

''(B) vaccine research.

''(2)(A) Upon the submission of a written request by a vaccine developer, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall convene a meeting of representatives of the vaccine developer and experts in immunization programs, epidemiology, and other relevant areas, including such experts from the Food and Drug Administration and the National Vaccine Program, at which the Director (or the Director's designee), for the purpose of informing the vaccine developer's understanding of public health needs and priorities, shall provide the perspectives of the Centers for Disease Control and Prevention and other relevant Federal agencies regarding—

''(i) public health needs, epidemiology, and implementation considerations with regard to a vaccine developer's potential vaccine profile; and

''(ii) potential implications of such perspectives for the vaccine developer's vaccine research and development planning.

''(B) The Director of the Centers for Disease Control and Prevention (or the Director's designee) shall convene a meeting requested under subparagraph (A) not later than 90 business days after receipt of the request for the meeting.

''(3)(A) Upon the submission of a written request by a vaccine developer, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall provide to the vaccine developer any age-based disease epidemiological analyses or data that—

''(i) are specified in the request;

''(ii) have been published;

''(iii) have been performed by or are in the possession of the Centers; and

''(iv) are not a trade secret or otherwise confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

''(B) The Secretary shall provide analyses requested by a vaccine manufacturer under subparagraph (A) not later than 90 business days after receipt of the request for the analyses.

''(4) The Secretary shall promptly notify a vaccine developer if—

''(A) the Secretary becomes aware of any change to information that was—

''(i) shared by the Secretary with the vaccine developer during a meeting under paragraph (2); or

''(ii) provided by the Secretary to the vaccine developer in one or more analyses under paragraph (3); and

''(B) the change may have implications for the vaccine developer's vaccine research and development.''.

SEC. 104. MODIFICATIONS TO PRIORITY REVIEW VOUCHER PROGRAM FOR TROPICAL DISEASES.

Section 524 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360n) is amended—

(1) in subsection (a)—

(A) in paragraph (3)—

(i) in the matter before subparagraph (A), by striking ''This term'' and inserting ''In this section, this term''; and

(ii) in subparagraph (R), by striking ''designated by order of the Secretary'' and inserting ''designated by the Secretary pursuant to paragraph (4)'';

(B) by redesignating paragraph (4) as paragraph (5); and

(C) by inserting after paragraph (3) the following:

''(4) DESIGNATION OF OTHER INFECTIOUS DISEASES AS TROPICAL DISEASES.—

''(A) IN GENERAL.—The Secretary shall establish a process under which the Secretary—

''(i) using a methodology that is made available to the public on the Internet site of the Food and Drug Administration, designates infectious diseases other than the diseases specified in subparagraphs (A) through (Q) of paragraph (3) to be tropical diseases for purposes of this section; and

''(ii) publishes on such Internet site a complete, updated list of the diseases that

are tropical diseases for purposes of this section.

''(B) CONSIDERATIONS.—In designating an infectious disease as a tropical disease under subparagraph (A), the Secretary shall—

''(i) consider the potential impact of the disease on the public health due to—

''(I) the potential rate of spread of the disease; and

''(II) the potential severity of the disease in terms of human morbidity and mortality; and

''(ii) consult with experts in tropical infectious diseases, including the Centers for Disease Control and Prevention, the Food and Drug Administration, medical professionals, the clinical research community, and the World Health Organization.

''(C) REVIEW.—Every 5 years, or more frequently as determined necessary by the Secretary, the Secretary shall review, provide modifications to, and re-publish the list published under subparagraph (A) and any revisions made to the methodology for designation of diseases under such subparagraph.'';

(2) in subsection (b)—

(A) in paragraph (2), by striking ''The sponsor of a tropical disease'' and inserting:

''(A) IN GENERAL.—The sponsor of a tropical disease'';

(B) by inserting after such paragraph (2)(A) the following:

''(B) NOTIFICATION OF TRANSFER.—Each person to whom a priority review voucher is transferred shall notify the Secretary of such change in ownership of the voucher not later than 30 business days after such transfer.'';

(C) in paragraph (4), by striking ''The sponsor of a human drug application'' and inserting:

''(A) IN GENERAL.—The sponsor of a human drug application''; and

(D) by inserting after paragraph (4)(A), as designated by subparagraph (D), the following:

''(B) TRANSFER AFTER NOTICE.—The sponsor of a human drug application that provides notification of intent under subparagraph (A) may transfer the voucher after such notification is provided, if such sponsor has not yet submitted the human drug application de-

scribed in the notification. Upon such a transfer, notwithstanding subparagraph (A), such sponsor shall not remain legally committed to pay a user fee because of the sponsor's notification of intent under such subparagraph.''; and

(3) in subsection (c), by amending paragraph (2) to read as follows:

''(2) FEE AMOUNT.—The amount of the priority review user fee shall be determined each fiscal year by the Secretary based on the difference between—

''(A) the average cost incurred by the agency in the review of a human drug application subject to priority review in the previous fiscal year; and

''(B) the average cost incurred by the Food and Drug Administration in the review of a human drug application that is not subject to priority review in the previous fiscal year.''.

SEC. 105. GUIDANCE ON CHANGES TO AN APPROVED APPLICATION FOR BIOLOGICAL PRODUCTS.

Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services shall issue final guidance that—

(1) addresses changes in a licensed biological product or the labeling, production process, quality controls, equipment, facilities, or responsible personnel for such a product established in the application for the product that was approved under section 351 of the Public Health Service Act (42 U.S.C. 262);

(2) does not address such changes for specified biotechnology or specified synthetic biological products listed in section 601.2(c) of title 21 of the Code of Federal Regulation; and

(3) updates and supersedes the guidance entitled ''Changes to an Approved Application: Biological Products,'' that was issued by the Food and Drug Administration in July, 1997.

SEC. 106. EXPEDITING THE PROCESS FOR EXPORT CERTIFICATIONS FOR VACCINES.

Section 801(e)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(e)(4)) is amended—

(1) in the matter following clause (ii) in subparagraph (A), by striking ''within 20 days of the receipt of a request for such certification'' and inserting ''within 20 business days of the receipt of a request for such certification, except that in the case of a vaccine the Secretary shall issue such certifi-

cation within 10 business days of the receipt of a request for such certification''; and

(2) in subparagraph (B), by striking ''within the 20 days prescribed by subparagraph (A)'' and inserting ''within the period prescribed by subparagraph (A)''.

SEC. 107. NIH VACCINE RESEARCH.

(a) IN GENERAL.—Subpart 6 of part C of title IV of the Public Health Service Act (42 U.S.C. 285f et seq.) is amended by adding at the end the following:

''SEC. 447D. ADVANCEMENT OF VACCINE DEVELOPMENT.

''In carrying out the general purpose described in section 446, the Director of the Institute shall conduct or support translational science, research, and research training to advance the development of vaccines for the prevention of diseases, including the advancement of vaccine development programs into clinical trials.''.

(b) REVIEW OF NIH VACCINE RESEARCH.—

(1) IN GENERAL.—Not later than one year after the date of enactment of this Act, the Director of the National Institutes of Health shall—

(A) conduct a review on vaccine research being conducted or supported by the Institutes; and

(B) publish a report on the results of such review.

(2) CONTENTS.—At a minimum, the report under paragraph (1)(B) shall—

(A) describe intramural and extramural vaccine research and development programs that are being conducted or supported by the National Institutes of Health, including those that are translational or clinical phase studies;

(B) provide a summary of funding allocations made to conduct or support the matters described in section 447D of the Public Health Service Act, as added by subsection (a), and identify projected funding needs with regard to future research or support with regard to these matters; and

(C) identify funding and collaborations with the private sector through—

(i) the Small Business Innovation Research and Small Business Technology Transfer programs; and

(ii) cooperative research and development agreements.

TITLE II—MEDICARE, MEDICAID, AND OTHER PROVISIONS

SEC. 201. REQUIRING PROMPT UPDATES TO MEDICARE PROGRAM UPON ISSUANCE OF ACIP RECOMMENDATIONS.

In the case that the advisory committee on immunization practices established by the Secretary of Health and Human Services pursuant to section 222 of the Public Health Service Act (42 U.S.C. 217a) issues a recommendation for a vaccine or an update to a recommendation for a vaccine that the Secretary is using under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) with respect to coverage of vaccines or immunizations under such title, the Secretary shall determine whether or not to update policies under such title with respect to such coverage on a date that is not later than 60 business days after the date on which such advisory committee issues such recommendation or update.

SEC. 202. GAO STUDY AND REPORT ON MEDICARE AND MEDICAID BENEFICIARY ACCESS FOR VACCINES.

(a) STUDY.—The Comptroller General of the United States (in this section referred to as the ''Comptroller General'') shall conduct a study on the impact of reimbursement rates under the Medicare program under parts

B, C, and D of title XVIII of the Social Security Act and under the Medicaid program under title XIX of such Act on access by targeted individuals to vaccines recommended by the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention. Such study shall include an analysis and determination of—

(1) the reimbursement rates for vaccines under such parts of the Medicare program and under the Medicaid program, including those rates paid by a PDP sponsor under part D of title XVIII of such Act, Medicare Advantage organizations under part C of such title, and Medicaid managed care organizations (as defined in section 1903(m)(1)(A) of the Social Security Act (42 U.S.C. 1396b(m)(1)(A));

(2) the number of targeted individuals during the 3-year period prior to the study who were eligible for a vaccination recommended by the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention;

(3) the number of such targeted individuals who actually received a vaccination described in paragraph (2), with a particular breakdown of adults, the elderly, and populations located in rural or underserved communities; and

(4) the extent to which the reimbursement rates under such parts of the Medicare program and under the Medicaid program for vaccinations described in paragraph (2) affect their use by physicians or access for such targeted individuals.

(b) TARGETED INDIVIDUALS.—For purposes of subsection (a), the term ''targeted individual'' means and individual who is—

(1)(A) entitled to benefits under part A of title XVIII of the Social Security Act or enrolled in part B of such Act; or

(B) eligible for medical assistance under title XIX of such Act; and

(2) within a vulnerable population.

(c) REPORT.—Not later than 2 years after the date of enactment of this Act, the Comptroller General shall submit to the appropriate committees of the Congress a report containing the results of the study conducted under subsection (a), including—

(1) a summary of the findings of the study; and

(2) recommendations based on the results of the study, including recommendations for such legislative and administrative action as the Comptroller General determines appropriate.

SEC. 203. ENCOURAGING HEALTH PLANS TO ESTABLISH PROGRAMS TO INCREASE ADULT IMMUNIZATION.

(a) PRIVATE HEALTH PLANS.—Section 2718 of the Public Health Service Act (42 U.S.C. 300gg–18) is amended by adding at the end the following new subsection:

''(f) PROGRAMS TO INCREASE ADULT IMMUNIZATION.—

''(1) IN GENERAL.—For purposes of this section, for plan years beginning on or after the date of enactment of the Vaccine Access, Certainty, and Innovation Act of 2015, activities that improve health care quality described in subsection (a)(2) shall include programs to increase adult immunization.

''(2) ADMINISTRATION.—Not later than December 31, 2016, the Secretary shall establish standardized methodologies, including definitions, for which activities, and in what regard such activities, constitute programs to increase adult immunization in accordance with this subsection. The Secretary shall consult with relevant stakeholders in establishing such methodologies.''.

(b) MEDICARE ADVANTAGE AND PART D PLANS.—Section 1857(e) of the Social Security Act (42 U.S.C.

1395w–27(e)) is amended by adding at the end the following new paragraph:

"(5) INCLUSION OF EXPENDITURES ON PROGRAMS TO INCREASE ADULT IMMUNIZATION IN MINIMUM MEDICAL LOSS RATIO CALCULATION.—For purposes of calculating the minimum medical loss ratio under paragraph (4), for plan years beginning at least 12 months after the date of enactment of this Act, the numerator shall include any expenditures on programs to increase adult immunization.".

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