

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

A BILL

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

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 “Vaccine Access, Cer-
5 tainty, and Innovation Act of 2015”.

6 **SEC. 2. TABLE OF CONTENTS.**

7 The table of contents for this Act is as follows:

Sec. 1. Short title.

Sec. 2. Table of contents.

TITLE I—DEVELOPMENT, LICENSURE, AND RECOMMENDATIONS

- Sec. 101. Review of transparency and consistency of ACIP recommendation process.
- Sec. 102. Guidance on vaccine development.
- Sec. 103. Meetings between CDC and vaccine developers.
- Sec. 104. Modifications to priority review voucher program for tropical diseases.
- Sec. 105. Guidance on changes to an approved application for biological products.
- Sec. 106. Expediting the process for export certifications for vaccines.
- Sec. 107. NIH vaccine research.

TITLE II—MEDICARE, MEDICAID, AND OTHER PROVISIONS

- Sec. 201. Requiring prompt updates to Medicare program upon issuance of ACIP recommendations.
- Sec. 202. GAO study and report on Medicare and Medicaid beneficiary access for vaccines.
- Sec. 203. Encouraging health plans to establish programs to increase adult immunization.

1 **TITLE I—DEVELOPMENT, LICEN-** 2 **SURE, AND RECOMMENDA-** 3 **TIONS**

4 **SEC. 101. REVIEW OF TRANSPARENCY AND CONSISTENCY** 5 **OF ACIP RECOMMENDATION PROCESS.**

6 (a) REVIEW.—The Director of the Centers for Dis-
7 ease Control and Prevention shall conduct a review of the
8 transparency and consistency of the process used by the
9 Advisory Committee on Immunization Practices in formu-
10 lating and issuing recommendations pertaining to vac-
11 cines.

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

14 (1) the criteria used to evaluate new and exist-
15 ing vaccines;

16 (2) the Grading of Recommendations, Assess-
17 ment, Development, and Evaluation (GRADE) ap-

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

4 (3) the extent to which the processes used by
5 the working groups of the Advisory Committee on
6 Immunization Practices are transparent and con-
7 sistent.

8 (c) STAKEHOLDERS.—In carrying out the review
9 under subsection (a), the Director of the Centers for Dis-
10 ease Control and Prevention shall solicit input from vac-
11 cine stakeholders.

12 (d) REPORT.—Not later than 1 year after the date
13 of enactment of this Act, the Director of the Centers for
14 Disease Control and Prevention shall submit to the appro-
15 priate committees of the Congress and make publicly
16 available a report on the results of the review under sub-
17 section (a), including recommendations on improving the
18 transparency and consistency of the process described in
19 such subsection.

20 (e) DEFINITION.—In this section, the term “Advisory
21 Committee on Immunization Practices” means the advi-
22 sory committee on immunization practices established by
23 the Secretary of Health and Human Services pursuant to
24 section 222 of the Public Health Service Act (42 U.S.C.

1 217a), acting through the Director of the Centers for Dis-
2 ease Control and Prevention.

3 **SEC. 102. GUIDANCE ON VACCINE DEVELOPMENT.**

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

9 (1) emerging, re-emerging, or rare infectious
10 diseases with respect to which the low prevalence or
11 nature of the disease may render the existence or
12 collection of clinical outcome data unlikely or im-
13 practical; and

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

17 (b) CONSIDERATIONS.—In developing the guidance
18 required by this section, the Secretary of Health and
19 Human Services shall consider issues relating to clinical
20 development strategies for diseases described in subsection
21 (a), including the development and acceptability of novel
22 clinical and surrogate endpoints, the use of novel or accel-
23 erated study designs, the use of observational real-world
24 data, the use of novel adjuvants, the use of new tech-
25 nologies or approaches to collecting and monitoring pa-

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

3 **SEC. 103. MEETINGS BETWEEN CDC AND VACCINE DEVEL-**
4 **OPERS.**

5 Section 310 of the Public Health Service Act (42
6 U.S.C. 242o) is amended by adding at the end the fol-
7 lowing:

8 “(c)(1) In this subsection, the term ‘vaccine devel-
9 oper’ means a nongovernmental entity engaged in—

10 “(A) the development or production of a vac-
11 cine; and

12 “(B) vaccine research.

13 “(2)(A) Upon the submission of a written request by
14 a vaccine developer, the Secretary, acting through the Di-
15 rector of the Centers for Disease Control and Prevention,
16 shall convene a meeting of representatives of the vaccine
17 developer and experts in immunization programs, epidemi-
18 ology, and other relevant areas, including such experts
19 from the Food and Drug Administration and the National
20 Vaccine Program, at which the Director (or the Director’s
21 designee), for the purpose of informing the vaccine devel-
22 oper’s understanding of public health needs and priorities,
23 shall provide the perspectives of the Centers for Disease
24 Control and Prevention and other relevant Federal agen-
25 cies regarding—

1 “(i) public health needs, epidemiology, and im-
2 plementation considerations with regard to a vaccine
3 developer’s potential vaccine profile; and

4 “(ii) potential implications of such perspectives
5 for the vaccine developer’s vaccine research and de-
6 velopment planning.

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

12 “(3)(A) Upon the submission of a written request by
13 a vaccine developer, the Secretary, acting through the Di-
14 rector of the Centers for Disease Control and Prevention,
15 shall provide to the vaccine developer any age-based dis-
16 ease epidemiological analyses or data that—

17 “(i) are specified in the request;

18 “(ii) have been published;

19 “(iii) have been performed by or are in the pos-
20 session of the Centers; and

21 “(iv) are not a trade secret or otherwise con-
22 fidential information subject to section 552(b)(4) of
23 title 5, United States Code, or section 1905 of title
24 18, United States Code.

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

5 “(4) The Secretary shall promptly notify a vaccine
 6 developer if—

7 “(A) the Secretary becomes aware of any
 8 change to information that was—

9 “(i) shared by the Secretary with the vac-
 10 cine developer during a meeting under para-
 11 graph (2); or

12 “(ii) provided by the Secretary to the vac-
 13 cine developer in one or more analyses under
 14 paragraph (3); and

15 “(B) the change may have implications for the
 16 vaccine developer’s vaccine research and develop-
 17 ment.”.

18 **SEC. 104. MODIFICATIONS TO PRIORITY REVIEW VOUCHER**

19 **PROGRAM FOR TROPICAL DISEASES.**

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

22 (1) in subsection (a)—

23 (A) in paragraph (3)—

1 (i) in the matter before subparagraph
2 (A), by striking “This term” and inserting
3 “In this section, this term”; and

4 (ii) in subparagraph (R), by striking
5 “designated by order of the Secretary” and
6 inserting “designated by the Secretary pur-
7 suant to paragraph (4)”;

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

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

12 “(4) DESIGNATION OF OTHER INFECTIOUS DIS-
13 EASES AS TROPICAL DISEASES.—

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

16 “(i) using a methodology that is made
17 available to the public on the Internet site
18 of the Food and Drug Administration, des-
19 ignates infectious diseases other than the
20 diseases specified in subparagraphs (A)
21 through (Q) of paragraph (3) to be trop-
22 ical diseases for purposes of this section;
23 and

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

1 are tropical diseases for purposes of this
2 section.

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

6 “(i) consider the potential impact of
7 the disease on the public health due to—

8 “(I) the potential rate of spread
9 of the disease; and

10 “(II) the potential severity of the
11 disease in terms of human morbidity
12 and mortality; and

13 “(ii) consult with experts in tropical
14 infectious diseases, including the Centers
15 for Disease Control and Prevention, the
16 Food and Drug Administration, medical
17 professionals, the clinical research commu-
18 nity, and the World Health Organization.

19 “(C) REVIEW.—Every 5 years, or more
20 frequently as determined necessary by the Sec-
21 retary, the Secretary shall review, provide modi-
22 fications to, and re-publish the list published
23 under subparagraph (A) and any revisions
24 made to the methodology for designation of dis-
25 eases under such subparagraph.”;

1 (2) in subsection (b)—

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

4 “(A) IN GENERAL.—The sponsor of a trop-
5 ical disease”;

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

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

13 (C) in paragraph (4), by striking “The
14 sponsor of a human drug application” and in-
15 serting:

16 “(A) IN GENERAL.—The sponsor of a
17 human drug application”; and

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

20 “(B) TRANSFER AFTER NOTICE.—The
21 sponsor of a human drug application that pro-
22 vides notification of intent under subparagraph
23 (A) may transfer the voucher after such notifi-
24 cation is provided, if such sponsor has not yet
25 submitted the human drug application de-

1 scribed in the notification. Upon such a trans-
2 fer, notwithstanding subparagraph (A), such
3 sponsor shall not remain legally committed to
4 pay a user fee because of the sponsor's notifica-
5 tion of intent under such subparagraph.”; and
6 (3) in subsection (c), by amending paragraph
7 (2) to read as follows:

8 “(2) FEE AMOUNT.—The amount of the pri-
9 ority review user fee shall be determined each fiscal
10 year by the Secretary based on the difference be-
11 tween—

12 “(A) the average cost incurred by the
13 agency in the review of a human drug applica-
14 tion subject to priority review in the previous
15 fiscal year; and

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

20 **SEC. 105. GUIDANCE ON CHANGES TO AN APPROVED APPLI-**
21 **CATION FOR BIOLOGICAL PRODUCTS.**

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

1 (1) addresses changes in a licensed biological
2 product or the labeling, production process, quality
3 controls, equipment, facilities, or responsible per-
4 sonnel for such a product established in the applica-
5 tion for the product that was approved under section
6 351 of the Public Health Service Act (42 U.S.C.
7 262);

8 (2) does not address such changes for specified
9 biotechnology or specified synthetic biological prod-
10 ucts listed in section 601.2(c) of title 21 of the Code
11 of Federal Regulation; and

12 (3) updates and supersedes the guidance enti-
13 tled “Changes to an Approved Application: Biologi-
14 cal Products,” that was issued by the Food and
15 Drug Administration in July, 1997.

16 **SEC. 106. EXPEDITING THE PROCESS FOR EXPORT CERTIFI-**
17 **CATIONS FOR VACCINES.**

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

20 (1) in the matter following clause (ii) in sub-
21 paragraph (A), by striking “within 20 days of the
22 receipt of a request for such certification” and in-
23 serting “within 20 business days of the receipt of a
24 request for such certification, except that in the case
25 of a vaccine the Secretary shall issue such certifi-

1 cation within 10 business days of the receipt of a re-
 2 quest for such certification”; and

3 (2) in subparagraph (B), by striking “within
 4 the 20 days prescribed by subparagraph (A)” and
 5 inserting “within the period prescribed by subpara-
 6 graph (A)”.

7 **SEC. 107. NIH VACCINE RESEARCH.**

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

11 **“SEC. 447D. ADVANCEMENT OF VACCINE DEVELOPMENT.**

12 “In carrying out the general purpose described in sec-
 13 tion 446, the Director of the Institute shall conduct or
 14 support translational science, research, and research train-
 15 ing to advance the development of vaccines for the preven-
 16 tion of diseases, including the advancement of vaccine de-
 17 velopment programs into clinical trials.”.

18 (b) REVIEW OF NIH VACCINE RESEARCH.—

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

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

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

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

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

10 (B) provide a summary of funding alloca-
11 tions made to conduct or support the matters
12 described in section 447D of the Public Health
13 Service Act, as added by subsection (a), and
14 identify projected funding needs with regard to
15 future research or support with regard to these
16 matters; and

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

19 (i) the Small Business Innovation Re-
20 search and Small Business Technology
21 Transfer programs; and

22 (ii) cooperative research and develop-
23 ment agreements.

1 **TITLE II—MEDICARE, MEDICAID,**
2 **AND OTHER PROVISIONS**

3 **SEC. 201. REQUIRING PROMPT UPDATES TO MEDICARE**
4 **PROGRAM UPON ISSUANCE OF ACIP REC-**
5 **OMMENDATIONS.**

6 In the case that the advisory committee on immuniza-
7 tion practices established by the Secretary of Health and
8 Human Services pursuant to section 222 of the Public
9 Health Service Act (42 U.S.C. 217a) issues a rec-
10 ommendation for a vaccine or an update to a recommenda-
11 tion for a vaccine that the Secretary is using under title
12 XVIII of the Social Security Act (42 U.S.C. 1395 et seq.)
13 with respect to coverage of vaccines or immunizations
14 under such title, the Secretary shall determine whether or
15 not to update policies under such title with respect to such
16 coverage on a date that is not later than 60 business days
17 after the date on which such advisory committee issues
18 such recommendation or update.

19 **SEC. 202. GAO STUDY AND REPORT ON MEDICARE AND**
20 **MEDICAID BENEFICIARY ACCESS FOR VAC-**
21 **CINES.**

22 (a) STUDY.—The Comptroller General of the United
23 States (in this section referred to as the “Comptroller
24 General”) shall conduct a study on the impact of reim-
25 bursement rates under the Medicare program under parts

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

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

15 (2) the number of targeted individuals during
16 the 3-year period prior to the study who were eligi-
17 ble for a vaccination recommended by the Advisory
18 Committee on Immunization Practices of the Cen-
19 ters for Disease Control and Prevention;

20 (3) the number of such targeted individuals who
21 actually received a vaccination described in para-
22 graph (2), with a particular breakdown of adults,
23 the elderly, and populations located in rural or un-
24 derserved communities; and

1 (4) the extent to which the reimbursement rates
2 under such parts of the Medicare program and
3 under the Medicaid program for vaccinations de-
4 scribed in paragraph (2) affect their use by physi-
5 cians or access for such targeted individuals.

6 (b) TARGETED INDIVIDUALS.—For purposes of sub-
7 section (a), the term “targeted individual” means and in-
8 dividual who is—

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

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

14 (2) within a vulnerable population.

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

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

21 (2) recommendations based on the results of
22 the study, including recommendations for such legis-
23 lative and administrative action as the Comptroller
24 General determines appropriate.

1 **SEC. 203. ENCOURAGING HEALTH PLANS TO ESTABLISH**
2 **PROGRAMS TO INCREASE ADULT IMMUNIZA-**
3 **TION.**

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

8 “(f) PROGRAMS TO INCREASE ADULT IMMUNIZA-
9 TION.—

10 “(1) IN GENERAL.—For purposes of this sec-
11 tion, for plan years beginning on or after the date
12 of enactment of the Vaccine Access, Certainty, and
13 Innovation Act of 2015, activities that improve
14 health care quality described in subsection (a)(2)
15 shall include programs to increase adult immuniza-
16 tion.

17 “(2) ADMINISTRATION.—Not later than Decem-
18 ber 31, 2016, the Secretary shall establish standard-
19 ized methodologies, including definitions, for which
20 activities, and in what regard such activities, con-
21 stitute programs to increase adult immunization in
22 accordance with this subsection. The Secretary shall
23 consult with relevant stakeholders in establishing
24 such methodologies.”.

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

1 1395w-27(e)) is amended by adding at the end the fol-
2 lowing new paragraph:

3 “(5) INCLUSION OF EXPENDITURES ON PRO-
4 GRAMS TO INCREASE ADULT IMMUNIZATION IN MIN-
5 IMUM MEDICAL LOSS RATIO CALCULATION.—For
6 purposes of calculating the minimum medical loss
7 ratio under paragraph (4), for plan years beginning
8 at least 12 months after the date of enactment of
9 this Act, the numerator shall include any expendi-
10 tures on programs to increase adult immunization.”.

○