

110TH CONGRESS
2D SESSION

H. R. 4993

To amend the Public Health Service Act to increase the availability of vaccines, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 16, 2008

Mr. WAXMAN (for himself and Ms. ROYBAL-ALLARD) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Education and Labor, Ways and Means, and Oversight and Government Reform, 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 amend the Public Health Service Act to increase the availability of vaccines, 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 “Vaccines for the Unin-
5 sured Adult Act of 2008”.

1 **SEC. 2. CERTAIN AUTHORITIES REGARDING ADULT IMMU-**
2 **NIZATIONS.**

3 (a) IN GENERAL.—Part B of title III of the Public
4 Health Service Act (42 U.S.C. 243 et seq.) is amended—

5 (1) by redesignating section 317A as section
6 317A–1; and

7 (2) by inserting after section 317 the following
8 section:

9 **“SEC. 317A. CERTAIN AUTHORITIES REGARDING ADULT IM-**
10 **MUNIZATIONS.**

11 **“(a) IMMUNIZATION PROGRAM FOR ELIGIBLE**
12 **ADULTS.—**

13 **“(1) IN GENERAL.—**The Secretary shall by reg-
14 ulation establish a program for the distribution of
15 qualified adult vaccines through States with ap-
16 proved applications under paragraph (4)(C) and the
17 payment of a fee for the administration of such vac-
18 cines, under which program—

19 **“(A) each vaccine-eligible adult, in receiv-**
20 **ing an immunization with a qualified adult vac-**
21 **cine from a program-registered provider on or**
22 **after October 1, 2009, is entitled to receive the**
23 **immunization without charge for the cost of**
24 **such vaccine; and**

25 **“(B)(i) each program-registered provider**
26 **who administers such a vaccine to a vaccine-eli-**

1 gible adult on or after such date is entitled to
2 receive such vaccine under the program without
3 charge either for the vaccine or its delivery to
4 the provider and is entitled to receive payment
5 for the administration of such vaccine; and

6 “(ii) no vaccine is distributed under the
7 program to a provider, and no payment is made
8 for the administration of the vaccine by such a
9 provider, unless the provider is a program-reg-
10 istered provider.

11 “(2) RELATIONSHIP TO PROGRAM FOR DIS-
12 TRIBUTION OF PEDIATRIC VACCINES.—The provi-
13 sions of the program under section 1928 of the So-
14 cial Security Act (including provisions taking effect
15 on or after the effective date of this section, other
16 than subsection (f) of such section 1928) apply with
17 respect to immunizations for vaccine-eligible adults
18 under the program under paragraph (1) to the same
19 extent and in the same manner as such provisions
20 apply with respect to immunizations for vaccine-eli-
21 gible children under the program under such section
22 1928, except to the extent that such a provision con-
23 flicts with this subsection. The preceding sentence
24 may not be construed as having any effect on the
25 program under title XIX of the Social Security Act,

1 or as having the effect that, in the program under
2 paragraph (1), State plans comparable to State
3 plans under section 1902 of such Act are required.

4 “(3) VACCINE-ELIGIBLE ADULT.—

5 “(A) IN GENERAL.—For purposes of this
6 subsection, the term ‘vaccine-eligible adult’
7 means a federally vaccine-eligible adult or a
8 State vaccine-eligible adult.

9 “(B) FEDERALLY VACCINE-ELIGIBLE
10 ADULT.—For purposes of this subsection, the
11 term ‘federally vaccine-eligible adult’ means any
12 of the following:

13 “(i) An adult who is not insured.

14 “(ii) An adult who—

15 “(I) is administered a qualified
16 adult vaccine by a Federally-qualified
17 health center (as defined in section
18 1905(l)(2)(B) of the Social Security
19 Act), by any other entity that is a cov-
20 ered entity under section 340B(a)(4),
21 or by any public clinic; and

22 “(II) is not insured with respect
23 to the vaccine.

24 “(iii) An adult who—

1 “(I) is administered a qualified
2 adult vaccine while incarcerated in a
3 Federal, State, or local penal or cor-
4 rectional institution, including an
5 adult who is held pending judicial or
6 administrative proceedings; and

7 “(II) is not insured with respect
8 to the vaccine.

9 “(C) STATE VACCINE-ELIGIBLE ADULT.—
10 For purposes of this subsection, the term ‘State
11 vaccine-eligible adult’ means, with respect to a
12 State and a qualified adult vaccine, an adult
13 who is within a class of adults for which the
14 State is purchasing the vaccine pursuant to
15 provisions that apply pursuant to paragraph
16 (2).

17 “(4) PARTICIPATION OF STATES.—

18 “(A) IN GENERAL.—In the case or each
19 State with an approved application under sub-
20 paragraph (C), the Secretary shall provide, in
21 accordance with provisions that apply pursuant
22 to paragraph (2), for the purchase and delivery
23 on behalf of the State, without charge to the
24 State, of such quantities of qualified adult vac-
25 cines as may be necessary for the administra-

tion of such vaccines to all vaccine-eligible adults in the State on or after October 1, 2009.

“(B) PROGRAM CRITERIA.—The Secretary, in accordance with provisions that apply pursuant to paragraph (2), shall establish criteria for State programs under paragraph (1).

“(C) STATE APPLICATION.—A State may participate in the program under paragraph (1) only if the State submits to the Secretary an application for such participation. The Secretary shall approve any such application that—

“(i) is submitted in such form and such manner as the Secretary may require; and

“(ii) demonstrates that the State is in compliance with criteria under subparagraph (B) and the requirement of subparagraph (D).

“(D) REQUIREMENT OF STATE MAINTENANCE OF IMMUNIZATION LAWS.—In the case of a State that had in effect as of July 1, 2008, a law that requires some or all health insurance policies or plans to provide some coverage with respect to an adult vaccine, the Secretary may

1 not approve the State’s application under sub-
2 paragraph (C) unless the State certifies to the
3 Secretary that the State has not modified or re-
4 pealed such law in a manner that reduces the
5 amount of coverage so required.

6 “(5) ADDITIONAL DEFINITIONS.—For purposes
7 of this subsection:

8 “(A) The term ‘adult’ means an individual
9 who is not a child as defined in section 1928 of
10 the Social Security Act.

11 “(B) The term ‘adult vaccine’ means a fed-
12 erally recommended vaccine for adults.

13 “(C)(i) The term ‘insured’, with respect to
14 an adult, means that the adult is enrolled
15 under, and entitled to benefits under, a health
16 insurance policy or plan, including a group
17 health plan, a prepaid health plan, or an em-
18 ployee welfare benefit plan under the Employee
19 Retirement Income Security Act of 1974.

20 “(ii) An adult is not insured with respect
21 to a qualified adult vaccine if the adult is enti-
22 tled to benefits under such a health insurance
23 policy or plan, but such benefits are not avail-
24 able with respect to the cost of such vaccine.

1 “(D) The term ‘qualified adult vaccine’
2 means an adult vaccine with respect to which a
3 contract is in effect pursuant to provisions that
4 apply pursuant to paragraph (2).

5 “(6) PAYMENT FOR VACCINE ADMINISTRA-
6 TION.—

7 “(A) IN GENERAL.—The amount of pay-
8 ment for vaccine administration under the pro-
9 gram under this section shall be the same as
10 the amount established under the physician fee
11 schedule under section 1848 of the Social Secu-
12 rity Act for payment for administration of a
13 vaccine under part B of title XVIII of such Act.

14 “(B) ADMINISTRATIVE CONTRACTS.—The
15 Secretary shall enter into such contracts or
16 agreements with qualified carriers or inter-
17 mediaries as may be necessary for the proc-
18 essing of claims for payment for vaccine admin-
19 istration under this section.

20 “(7) DIRECT SPENDING.—The requirement
21 under paragraph (1) that the Secretary carry out a
22 program constitutes budget authority in advance of
23 appropriations Acts, and represents the obligation of
24 the Federal Government to make outlays to provide
25 for immunizations of vaccine-eligible adults in ac-

1 cordance with this subsection, including with respect
2 to program-registered providers and with respect to
3 the purchase and delivery of qualified adult vaccines
4 on behalf of States and with respect to the payment
5 for vaccine administration.

6 “(b) EMERGENCY RESPONSE PLAN REGARDING
7 SHORTAGES.—

8 “(1) DEVELOPMENT OF PLAN.—The Secretary
9 shall develop and maintain a plan for the response
10 of the Secretary to potential shortages in supplies of
11 vaccines that would constitute public health emer-
12 gencies. The plan shall include provisions with re-
13 spect to—

14 “(A) communication among the relevant
15 entities;

16 “(B) distribution of available supplies of
17 the vaccine involved;

18 “(C) the designation of populations to be
19 given priority for immunizations;

20 “(D) interactions with State and local gov-
21 ernments;

22 “(E) the use of the vaccine stockpile; and

23 “(F) special considerations for specific vac-
24 cines.

1 “(2) COMPLETION OF PLAN.—The initial plan
2 under paragraph (1) shall be completed not later
3 than 12 months after the date of the enactment of
4 the Vaccines for the Uninsured Act of 2008.

5 “(3) STUDY ON REALLOCATION OF VACCINE.—
6 Not later than 1 year after the date of the enact-
7 ment of the Vaccines for the Uninsured Act of 2008,
8 the Secretary shall complete a study and submit a
9 report to the Congress on successful models and al-
10 ternatives for tracking and facilitating, in consulta-
11 tion with State and local health officials, reallocation
12 of vaccine at the local level in times of shortage or
13 emergency.

14 “(c) EDUCATION PROGRAM REGARDING ADULT IM-
15 MUNIZATIONS.—

16 “(1) IN GENERAL.—The Secretary shall develop
17 and implement a program to promote, among the
18 adult population, immunizations with federally rec-
19 ommended vaccines.

20 “(2) CONTENT OF PROGRAM.—The program
21 developed under paragraph (1) shall include the use
22 of a mass media campaign.

23 “(3) AUTHORIZATION OF APPROPRIATIONS.—
24 For the purpose of carrying out this subsection,
25 there are authorized to be appropriated such sums

1 as may be necessary for each of the fiscal years
2 2009 through 2013.

3 “(d) GENERAL DEFINITIONS.—For purposes of this
4 section:

5 “(1) The term ‘approved vaccine’ means a vac-
6 cine for which a biologics license under section 351
7 is in effect.

8 “(2) The term ‘federally recommended vaccine’,
9 with respect to an adult, means an approved vaccine
10 that—

11 “(A) is recommended by the Advisory
12 Committee on Immunization Practices (an advi-
13 sory committee established by the Secretary,
14 acting through the Director of the Centers for
15 Disease Control and Prevention) with respect to
16 adults generally; or

17 “(B) is recommended by such Advisory
18 Committee with respect to any group of adults
19 because of their health condition, their employ-
20 ment status, or any other factor.”.

21 (b) APPLICATION OF PEDIATRIC VACCINE MAINTENANCE OF EFFORT PROVISIONS TO ADULT VACCINES.—

23 (1) UNDER ERISA.—

1 (A) IN GENERAL.—Section 609(d) of Em-
2 ployee Retirement Income Security Act of 1974
3 (29 U.S.C. 1169(d)) is amended—

4 (i) in the heading, by inserting “OR
5 ADULT” after “PEDIATRIC”; and

6 (ii) by adding at the end the fol-
7 lowing: “A group health plan may not re-
8 duce its coverage of the costs of adult vac-
9 cines (as defined under section
10 317A(a)(5)(B) of the Public Health Serv-
11 ice Act) below the coverage provided by the
12 plan as of July 1, 2008.”.

13 (B) MONITORING BY IG.—The Inspector
14 General of the Department of Labor shall sub-
15 mit an annual report to the Congress on imple-
16 mentation and enforcement of the requirement
17 of section 609(d) of the Employee Retirement
18 Income Security Act of 1974 (29 U.S.C.
19 1169(d)), as amended by subparagraph (A),
20 that a group health plan not reduce its coverage
21 of the costs of adult vaccines below the coverage
22 provided by the plan as of July 1, 2008.

23 (2) UNDER IRC.—

24 (A) IN GENERAL.—Section 4980B(f)(1) of
25 the Internal Revenue Code of 1986 is amended

1 by inserting after “1993,” the following: “the
2 coverage of the costs of adult vaccines (as de-
3 fined in section 317A(a)(5)(B) of the Public
4 Health Service Act) is not reduced below the
5 coverage provided by the plan as of July 1,
6 2008,”.

7 (B) MONITORING BY IG.—The Inspector
8 General of the Department of the Treasury
9 shall submit an annual report to the Congress
10 on implementation and enforcement of the re-
11 quirement of section 4980B(f)(1) of the Inter-
12 nal Revenue Code of 1986, as amended by sub-
13 paragraph (A), that a group health plan not re-
14 duce its coverage of the costs of adult vaccines
15 below the coverage provided by the plan as of
16 July 1, 2008.

17 (3) UNDER PHSA.—

18 (A) IN GENERAL.—Section 13631(d) of
19 the Omnibus Budget Reconciliation Act of 1993
20 (Public Law 103–66; relating to title XXII of
21 the Public Health Service Act) is amended—

22 (i) in the heading, by inserting “OR
23 ADULT” after “PEDIATRIC”; and

24 (ii) in paragraph (1), by adding at the
25 end the following: “Such requirement also

1 includes, with respect to a group health
2 plan for plan years beginning after the
3 date of the enactment of this sentence, the
4 requirement that the group health plan not
5 reduce its coverage of the costs of adult
6 vaccines (as defined in section
7 317A(a)(5)(B) of the Public Health Serv-
8 ice Act) below the coverage provided by the
9 plan as of July 1, 2008.”.

10 (B) MONITORING BY IG.—The Inspector
11 General of the Department of Health and
12 Human Services shall submit an annual report
13 to the Congress on implementation and enforce-
14 ment of the requirement of section 13631(d) of
15 the Omnibus Budget Reconciliation Act of 1993
16 (Public Law 103–66), as amended by subpara-
17 graph (A), that a group health plan not reduce
18 its coverage of the costs of adult vaccines below
19 the coverage provided by the plan as of July 1,
20 2008.

21 (4) EFFECTIVE DATE.—The amendments made
22 by paragraphs (1)(A), (2)(A), and (3)(A) shall apply
23 to group health plans for plan years beginning after
24 the date of the enactment of this Act.

1 **SEC. 3. AMENDMENTS TO PROGRAM OF VACCINE-RELATED**
2 **GRANTS TO STATES.**

3 Section 317 of the Public Health Service Act (42
4 U.S.C. 247b) is amended—

5 (1) in subsection (j), by adding at the end the
6 following:

7 “(3)(A) For grants described in subsection (l)
8 (relating to immunizing individuals without charge),
9 there are authorized to be appropriated
10 \$500,000,000 for fiscal year 2009 and such sums as
11 may be necessary for each subsequent fiscal year.

12 “(B) Of the amount appropriated pursuant to
13 this paragraph for each of fiscal years 2009 and
14 2010, the Secretary shall reserve not less than
15 \$80,000,000 for the purpose of providing immuniza-
16 tions for adults who have not, prior to fiscal year
17 2009, been served by immunization programs car-
18 ried out with grants made pursuant to this section.”;
19 and

20 (2) by adding at the end the following:

21 “(l)(1) In making grants under subsection (a), the
22 Secretary may make grants for preventive health service
23 programs to provide immunizations without charge.

24 “(2) Subject to paragraphs (3) through (5), grants
25 made pursuant to this subsection shall be made in accord-
26 ance with criteria of the Secretary issued under para-

1 graphs (1) and (2) of subsection (j) for immunization pro-
2 grams. The preceding sentence may not be construed as
3 terminating the authority of the Secretary to modify such
4 criteria.

5 “(3) Grants made pursuant to this subsection may
6 be expended to improve the ability of a State health au-
7 thority, a political subdivision of a State, or another public
8 entity to improve an immunization program, including
9 through the following:

10 “(A) Conducting assessments to determine the
11 number of adults in the area involved who need im-
12 munizations and the barriers to providing immuniza-
13 tions to such adults.

14 “(B) Developing and implementing strategies to
15 increase the rate of immunizations in populations in
16 which a significant number of individuals have not
17 received immunizations with the federally rec-
18 ommended vaccines (as defined in section 317A(d))
19 for the populations.

20 “(C) Educating care givers, health care profes-
21 sionals, and the public about the need to be immu-
22 nized.

23 “(D) Consulting with health care providers with
24 respect to ensuring proper and timely immunizations
25 for their patients.

1 “(E) Investigating and responding to outbreaks
2 of vaccine-preventable diseases.

3 “(F) Developing and modifying plans to re-
4 spond to potential shortages in supplies of vaccines.

5 “(G) Preparing reports under paragraph (5)
6 and any additional reports that are submitted to the
7 Secretary pursuant to this paragraph.

8 “(4) A condition for the receipt of a grant by a State,
9 a political subdivision of a State, or another public entity
10 made pursuant to this paragraph for a fiscal year is that
11 the State, political subdivision, or public entity have (or
12 agree to develop, in the case of a grant for fiscal year
13 2008) a State plan that—

14 “(A) ensures the distribution and administra-
15 tion of vaccines in the event that the Secretary de-
16 clares a shortage of approved vaccines as a public
17 health emergency; and

18 “(B) includes plans for communication and co-
19 ordination between—

20 “(i) State and local public health depart-
21 ments;

22 “(ii) community health centers;

23 “(iii) hospitals;

24 “(iv) private physicians licensed within the
25 State; and

1 “(v) to the extent practicable, vaccine man-
 2 ufacturers and suppliers.

3 “(5) A condition for the receipt of a grant made pur-
 4 suant to this paragraph for a fiscal year is that the appli-
 5 cant involved agree to submit to the Secretary a report
 6 that specifies for such year the quantity of each type of
 7 vaccine purchased with the grant and the per-dose cost
 8 of the vaccine”.

9 **SEC. 4. PROHIBITION ON MEDICAID COST-SHARING FOR**
 10 **VACCINES RECOMMENDED BY ADVISORY**
 11 **COMMITTEE ON IMMUNIZATION PRACTICES.**

12 (a) IN GENERAL.—Section 1916 of the Social Secu-
 13 rity Act (42 U.S.C. 1396o) is amended—

14 (1) in subsection (a), by striking “and (i)” and
 15 inserting “, (i), and (j)”; and

16 (2) by adding at the end the following new sub-
 17 section:

18 “(j) The State plan shall require that no provider
 19 participating under the State plan may impose a copay-
 20 ment, cost sharing charge, or similar charge for admin-
 21 istering to an adult individual who is eligible for medical
 22 assistance under such plan a federally recommended vac-
 23 cine (as defined in section 317A(d) of the Public Health
 24 Service Act).”.

1 (b) CONFORMING AMENDMENT.—Section
2 1916A(a)(1) of such Act (42 U.S.C. 1396o–1(a)(1)) is
3 amended by inserting “(other than subsection (j))” after
4 “Notwithstanding sections 1916”.

5 (c) EFFECTIVE DATE.—The amendment made by
6 subsection (a) shall take effect on the date of the enact-
7 ment of this Act.

8 **SEC. 5. MEDICARE AND MEDICAID PROGRAMS; STANDARDS**
9 **TO MEASURE USAGE AND COVERAGE OF**
10 **ADULT IMMUNIZATIONS.**

11 (a) IN GENERAL.—The Secretary of Health and
12 Human Services, acting through the Administrator of the
13 Centers for Medicare & Medicaid Services, shall establish
14 standards for the measurement of use by beneficiaries
15 under the Medicare and Medicaid programs of routinely
16 recommended adult immunizations.

17 (b) STUDY FOR USE OF STANDARDS AS A QUALITY
18 MEASURE.—The Secretary of Health and Human Serv-
19 ices, acting through the Administrator of the Centers for
20 Medicare & Medicaid Services, shall conduct a study to
21 determine the feasibility and advisability of including adult
22 immunization by Medicare and Medicaid beneficiaries, as
23 a performance measure under quality initiatives conducted
24 by the Secretary under the Medicare and Medicaid pro-
25 grams.

1 (c) MEASUREMENT OF USAGE BY HEALTH CARE
 2 WORKERS.—The Secretary of Health and Human Serv-
 3 ices, acting through the Administrator of the Centers for
 4 Medicare & Medicaid Services, shall establish standards
 5 for the measurement of use by health care workers, as
 6 defined by the Secretary for purposes of this section,
 7 working in a provider of services (as defined in section
 8 1861(u) of the Social Security Act (42 U.S.C. 1395x(u))
 9 of adult immunizations for influenza.

10 (d) ASSESSMENT OF BEST PRACTICES TO IMPROVE
 11 COVERAGE OF ADULT IMMUNIZATIONS.—The Secretary
 12 of Health and Human Services, acting through the Agency
 13 for Healthcare Research and Quality, shall conduct a
 14 study of the best practices of health insurers and managed
 15 care organizations to encourage the use of adult immuni-
 16 zations by enrollees of such insurers and organizations.

17 **SEC. 6. STUDY ON ADULT IMMUNIZATION FOR INFLUENZA**
 18 **FOR HEALTH CARE WORKERS AS A QUALITY**
 19 **INDICATOR FOR PURPOSES OF ACCREDITA-**
 20 **TION.**

21 (a) STUDY.—The Secretary of Health and Human
 22 Services shall conduct a study to determine the feasibility
 23 and advisability of including as a requirement of accredita-
 24 tion of a provider of services (as defined in section 1861(u)
 25 of the Social Security Act (42 U.S.C. 1395x(u)) compli-

1 ance with recommended adult immunizations, including
2 influenza, for all health care workers employed by the pro-
3 vider of services. Any such requirement should include a
4 provision for informed refusal by the health care worker
5 of the immunization and appropriate documentation of
6 usage and refusal of such immunizations.

7 (b) REPORT.—Not later than one year after the date
8 of the enactment of this Act, the Secretary shall submit
9 to Congress a report on the study conducted under sub-
10 section (a), and shall include in that report a description
11 of the difficulties of implementing such a requirement as
12 well as recommendations for the resolution of those dif-
13 ficulties.

14 **SEC. 7. FEHBP COVERAGE OF QUALIFIED IMMUNIZATION**
15 **SERVICES.**

16 (a) IN GENERAL.—Section 8902 of title 5, United
17 States Code, is amended by adding at the end the fol-
18 lowing:

19 “(p)(1) A contract may not be made or a plan ap-
20 proved which does not (A) offer qualified immunization
21 services to eligible enrollees, and (B) provide for the waiv-
22 er of any deductible that might otherwise apply with re-
23 spect to any such services provided to any such enrollee.

24 “(2) For purposes of this subsection—

1 “(A) the term ‘qualified immunization services’
2 means the provision and administration of all feder-
3 ally recommended vaccines (as defined in section
4 317A(d) of the Public Health Service Act); and

5 “(B) the term ‘eligible enrollee’, as used with
6 respect to a health benefits plan, means an indi-
7 vidual enrolled in such plan under this chapter who
8 is 18 years of age or older.”.

9 (b) EFFECTIVE DATE.—The amendment made by
10 this section shall apply to services provided under any con-
11 tract entered into or renewed for any contract year begin-
12 ning later than 9 months after the date of the enactment
13 of this Act.

○