

109<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION

# S. 1527

To amend the Public Health Service Act with respect to immunizations against vaccine-preventable diseases, including influenza, and for other purposes.

---

## IN THE SENATE OF THE UNITED STATES

JULY 28, 2005

Mr. KENNEDY (for himself and Mr. REED) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

---

## A BILL

To amend the Public Health Service Act with respect to immunizations against vaccine-preventable diseases, including influenza, 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 “Vaccine Access and  
5 Supply Act”.

6 **SEC. 2. CERTAIN AUTHORITIES REGARDING INFLUENZA**  
7 **AND OTHER VACCINES.**

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

1           (1) by redesignating section 317A as section  
2           317A-1; and

3           (2) by inserting after section 317 the following  
4           section:

5   **“SEC. 317A. CERTAIN AUTHORITIES REGARDING INFLU-**  
6                           **ENZA AND OTHER VACCINES.**

7           “(a) PURCHASE OF UNSOLD DOSES OF PERIODIC-  
8   CHANGE VACCINES.—

9                   “(1) PRODUCER-SPECIFIC NEGOTIATION ON  
10           SUPPLY FOR SEASON.—In the case of influenza vac-  
11           cine and each other periodic-change vaccine, the Sec-  
12           retary shall, for each applicable vaccine season, ne-  
13           gotiate with each producer of the vaccine to reach an  
14           agreement on the number of doses of the vaccine  
15           that the producer will manufacture for such season.  
16           The Secretary is not required under the preceding  
17           sentence to enter into such an agreement with any  
18           producer.

19                   “(2) PURCHASE OF PERCENTAGE OF UNSOLD  
20           DOSES.—With respect to the number of doses of a  
21           periodic-change vaccine manufactured for an appli-  
22           cable vaccine season by a producer in accordance  
23           with an agreement under paragraph (1), the Sec-  
24           retary shall purchase from the producer 50 percent  
25           of such doses that are unsold for the season.

1 “(3) PRICE PER DOSE.—

2 “(A) AVERAGE SALES PRICE.—Subject to  
3 subparagraph (B), the price per dose paid by  
4 the Secretary in a purchase of periodic-change  
5 vaccine under paragraph (2) shall be the aver-  
6 age sales price for the vaccine for the applicable  
7 vaccine season, as determined by the Secretary.

8 “(B) AUDITS; ADJUSTMENTS.—The Sec-  
9 retary may enter into an agreement under para-  
10 graph (1) with a producer regarding a periodic-  
11 change vaccine only if the agreement includes a  
12 provision that permits the Secretary to conduct  
13 audits of sales of such vaccine at wholesale by  
14 the producer. The average sales price deter-  
15 mined under subparagraph (A) for a dose of  
16 the vaccine for an applicable vaccine season  
17 shall be adjusted by the Secretary as deter-  
18 mined necessary by the Secretary on the basis  
19 of such audits and on the basis of any other in-  
20 formation available to the Secretary on sales of  
21 the vaccine at wholesale.

22 “(4) DEFINITIONS.—For purposes of this sec-  
23 tion:

24 “(A) The term ‘periodic-change vaccine’  
25 means a federally recommended vaccine (as de-

1           fined in subsection (g)) that is designed only for  
2           a single applicable vaccine season due to char-  
3           acteristics of the etiologic agent or agents for  
4           the disease involved, or due to characteristics of  
5           the vaccine, that adversely affect the extent to  
6           which the vaccine is safe and effective after  
7           such season. Such term includes influenza vac-  
8           cine.

9           “(B) The term ‘producer’ means a person  
10          who—

11                 “(i) manufactures an approved vac-  
12                 cine (as defined in subsection (g)); or

13                 “(ii) who intends to manufacture such  
14                 a vaccine and is determined by the Sec-  
15                 retary to have the capacity to meet legal  
16                 requirements applicable to such manufac-  
17                 turing.

18          “(C)(i) The term ‘vaccine season’, with re-  
19          spect to a periodic-change vaccine, means a  
20          consecutive number of months, not exceeding  
21          24 months, during which the Secretary rec-  
22          ommends that the public in general, or par-  
23          ticular populations, as the case may be, receive  
24          immunizations against the disease involved.

1           “(ii) The term ‘applicable vaccine season’,  
2           with respect to a periodic-change vaccine,  
3           means the vaccine season that is applicable to  
4           such vaccine.

5           “(5) DIRECT SPENDING.—The requirement  
6           under paragraph (2) that the Secretary make pur-  
7           chases of doses of periodic-change vaccine con-  
8           stitutes budget authority in advance of appropria-  
9           tions Acts, and represents the obligation of the  
10          United States to make outlays for such purchases in  
11          accordance with this subsection.

12          “(b) IMMUNIZATION PROGRAM FOR ELIGIBLE  
13          ADULTS.—

14                 “(1) IN GENERAL.—The Secretary shall by reg-  
15                 ulation establish a program for the distribution of  
16                 qualified adult vaccines through States with ap-  
17                 proved applications under paragraph (4)(C), under  
18                 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, 2006, is entitled to receive the  
23                         immunization without charge for the cost of  
24                         such vaccine; and

1           “(B)(i) each program-registered provider  
2           who administers such a vaccine to a vaccine-eli-  
3           gible adult on or after such date is entitled to  
4           receive such vaccine under the program without  
5           charge either for the vaccine or its delivery to  
6           the provider; and

7           “(ii) no vaccine is distributed under the  
8           program to a provider unless the provider is a  
9           program-registered provider.

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

1 to State plans under section 1902 of such Act are  
2 required.

3 “(3) VACCINE-ELIGIBLE ADULT.—

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

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

12 “(i) An adult who is not insured.

13 “(ii) An adult who—

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

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

23 “(iii) An adult who—

24 “(I) is administered a qualified  
25 adult vaccine while incarcerated in a

1 Federal, State, or local penal or cor-  
2 rectional institution, including an  
3 adult who is held pending judicial or  
4 administrative proceedings; and

5 “(II) is not insured with respect  
6 to the vaccine.

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

15 “(4) PARTICIPATION OF STATES.—

16 “(A) IN GENERAL.—In the case or each  
17 State with an approved application under sub-  
18 paragraph (C), the Secretary shall provide, in  
19 accordance with provisions that apply pursuant  
20 to paragraph (2), for the purchase and delivery  
21 on behalf of the State, without charge to the  
22 State, of such quantities of qualified adult vac-  
23 cines as may be necessary for the administra-  
24 tion of such vaccines to all vaccine-eligible  
25 adults in the State on or after October 1, 2006.

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

5           “(C) STATE APPLICATION.—A State may  
6           participate in the program under paragraph (1)  
7           only if the State submits to the Secretary an  
8           application for such participation. The Sec-  
9           retary shall approve any such application  
10          that—

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

14                   “(ii) demonstrates that the State is in  
15                   compliance with criteria under subpara-  
16                   graph (B).

17          “(5) ADDITIONAL DEFINITIONS.—For purposes  
18          of this subsection:

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

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

24                   “(C)(i) The term ‘insured’, with respect to  
25                   an adult, means that the adult is enrolled

1 under, and entitled to benefits under, a health  
2 insurance policy or plan, including a group  
3 health plan, a prepaid health plan, or an em-  
4 ployee welfare benefit plan under the Employee  
5 Retirement Income Security Act of 1974.

6 “(ii) An adult is not insured with respect  
7 to a qualified adult vaccine if the adult is enti-  
8 tled to benefits under such a health insurance  
9 policy or plan, but such benefits are not avail-  
10 able with respect to the cost of such vaccine.

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

15 “(6) DIRECT SPENDING.—The requirement  
16 under paragraph (1) that the Secretary carry out a  
17 program constitutes budget authority in advance of  
18 appropriations Acts, and represents the obligation of  
19 the Federal Government to make outlays to provide  
20 for immunizations of vaccine-eligible adults in ac-  
21 cordance with this subsection, including with respect  
22 to program-registered providers and with respect to  
23 the purchase and delivery of qualified adult vaccines  
24 on behalf of States.

1       “(c) INFORMATION ON LOCATION OF SUPPLIES OF  
2 VACCINES; EMERGENCY AUTHORITY OF SECRETARY.—

3           “(1) IN GENERAL.—If the Secretary publishes  
4 in the Federal Register a declaration that there is  
5 a shortage of an approved vaccine that constitutes a  
6 public health emergency, each person who is a man-  
7 ufacturer or distributor of the vaccine shall provide  
8 to the Secretary such information as the Secretary  
9 may require with respect to the location of supplies  
10 of the vaccine, including supplies in the possession  
11 of the person, supplies scheduled to be received by  
12 the person, and supplies sold by the person. Any  
13 such person who fails to comply with an order of the  
14 Secretary under the preceding sentence is liable to  
15 the United States for a civil penalty not exceeding  
16 \$1,000 for each day for which the person is in viola-  
17 tion of the order.

18           “(2) AVAILABILITY TO STATES.—Upon the re-  
19 quest of a State, the Secretary shall provide to the  
20 State the information collected by the Secretary  
21 under paragraph (1) that relates to the State.

22       “(d) EMERGENCY RESPONSE PLAN REGARDING  
23 SHORTAGES.—The Secretary shall develop and maintain  
24 a plan for the response of the Secretary to potential short-  
25 ages in supplies of vaccines that would constitute public

1 health emergencies. The plan shall include provisions with  
2 respect to communication among the relevant entities; dis-  
3 tribution of available supplies of the vaccine involved; the  
4 designation of populations to be given priority for immuni-  
5 zations; interactions with State and local governments; use  
6 of the vaccine stockpile; and special considerations for spe-  
7 cific vaccines. The initial plan shall be completed not later  
8 than 12 months after the date of the enactment of the  
9 Vaccine Access and Supply Act.

10       “(e) RESEARCH.—For the purpose of carrying out re-  
11 search toward the development of new vaccines for human  
12 use, including vaccines to prevent or control pandemic in-  
13 fections, there are authorized to be appropriated  
14 \$250,000,000 for fiscal year 2006, and such sums as may  
15 be necessary for each of the fiscal years 2007 through  
16 2010. Such authorization is in addition to any other au-  
17 thorizations of appropriations for such purpose.

18       “(f) EDUCATION PROGRAM REGARDING ADULT IM-  
19 MUNIZATIONS.—

20               “(1) IN GENERAL.—The Secretary shall develop  
21 and implement a program to promote, among the  
22 adult population, immunizations with federally rec-  
23 ommended vaccines.

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

4           “(3) AUTHORIZATION OF APPROPRIATIONS.—  
5 For the purpose of carrying out this subsection,  
6 there are authorized to be appropriated such sums  
7 as may be necessary for each of the fiscal years  
8 2006 through 2010.

9           “(g) GENERAL DEFINITIONS.—For purposes of this  
10 section:

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

14           “(2)(A) The term ‘federally recommended vac-  
15 cine’, with respect to an adult, means an approved  
16 vaccine recommended by the Advisory Committee on  
17 Immunization Practices (an advisory committee es-  
18 tablished by the Secretary, acting through the Direc-  
19 tor of the Centers for Disease Control and Preven-  
20 tion).

21           “(B) The term ‘federally recommended vaccine’,  
22 with respect to a child, means a vaccine on the list  
23 referred to in section 1928(e) of the Social Security  
24 Act.”.

1 (b) IMMUNIZATIONS FOR ELIGIBLE ADULTS; CON-  
2 TINUED COVERAGE UNDER GROUP HEALTH PLANS.—  
3 With respect to the program under section 317A(b) of the  
4 Public Health Service Act (as added by subsection (a) of  
5 this section) (referred to in this subsection as the “adult  
6 program”):

7 (1) Pursuant to paragraph (2) of such section,  
8 the provisions of section 1928 of the Social Security  
9 Act (referred to in this section as the “pediatric pro-  
10 gram”) that apply with respect to the adult program  
11 include subsection (f) of the pediatric program (re-  
12 lating to State maintenance of immunization laws).

13 (2) Section 609(d) of the Employee Retirement  
14 Income Security Act, and the effective date for such  
15 section (under section 4301(d) of Public Law 103–  
16 66), apply with respect to the adult program to the  
17 same extent and in the same manner as such section  
18 and effective date apply with respect to the pediatric  
19 program. For purposes of such section 609(d) as ap-  
20 plied pursuant to the preceding sentence, the ref-  
21 erence in such section to May 1, 1993, shall be con-  
22 sidered a reference to July 1, 2005.

23 (3) Section 4980B(f)(1) of the Internal Rev-  
24 enue Code of 1986 (as added by section 13422(a) of  
25 Public Law 103–66) applies with respect to adult

1 vaccines (as defined in the adult program) to the  
2 same extent and in the same manner as such section  
3 applies with respect to pediatric vaccines. For pur-  
4 poses of such section 4980B(f)(1) as applied pursu-  
5 ant to the preceding sentence, the reference in such  
6 section to May 1, 1993, shall be considered a ref-  
7 erence to July 1, 2005. This paragraph applies with  
8 respect to plan years beginning after the date of the  
9 enactment of this Act.

10 (4) Section 13631(d) of Public Law 103–66  
11 (relating to title XXII of the Public Health Service  
12 Act) applies with respect to the adult program to the  
13 same extent and in the same manner as such section  
14 applies with respect to the pediatric program. For  
15 purposes of such section 13631(d) as applied pursu-  
16 ant to the preceding sentence, the reference in such  
17 section to May 1, 1993, shall be considered a ref-  
18 erence to July 1, 2005.

19 **SEC. 3. PROGRAM FOR DISTRIBUTION OF PEDIATRIC VAC-**  
20 **CINES.**

21 (a) **INCLUSION OF ALL PUBLIC CLINICS.**—Section  
22 1928(b)(2)(A)(iii)(I) of the Social Security Act (42 U.S.C.  
23 1396s(b)(2)(A)(iii)(I)) is amended—

24 (1) by striking “or a rural health clinic” and in-  
25 serting “, a rural health clinic”; and

1           (2) by inserting “or a public clinic,” after  
2           “1905(l)(1)),”.

3           (b) **AUTHORITY TO REMOVE CERTAIN LIMITATIONS**  
4 **ON PAYMENTS TO MANUFACTURERS.**—Section  
5 1928(d)(3)(B) of the Social Security Act (42 U.S.C.  
6 1396s(d)(3)(B)) is amended by adding at the end the fol-  
7 lowing: “In the case of a contract entered into on or after  
8 the date of the enactment of the Vaccine Access and Sup-  
9 ply Act, the limitation established in the preceding sen-  
10 tence with respect to the price per dose of a pediatric vac-  
11 cine does not apply if the Secretary determines that the  
12 limitation is having a significant adverse effect on the  
13 availability of sufficient supplies of the vaccine.”.

14           (c) **SALES FROM 6-MONTH SUPPLY.**—Section  
15 1928(d)(6) of the Social Security Act (42 U.S.C.  
16 1396s(d)(6)) is amended by inserting before the last sen-  
17 tence the following: “The Secretary may sell such quan-  
18 tities of vaccines from such supply as the Secretary deter-  
19 mines appropriate. Proceeds received from such sales shall  
20 be available to the Secretary only for the purposes of pro-  
21 curing pediatric vaccine stockpiles under this section and  
22 shall remain available until expended.”.

1 **SEC. 4. AMENDMENTS TO PROGRAM OF VACCINE-RELATED**  
2 **GRANTS TO STATES.**

3 Section 317(j) of the Public Health Service Act (42  
4 U.S.C. 247b(j)) is amended by adding at the end the fol-  
5 lowing paragraph:

6 “(3)(A)(i) For fiscal year 2006, the Secretary shall  
7 make grants described in paragraphs (1) and (2) (relating  
8 to immunizing individuals without charge) in an aggregate  
9 amount not exceeding \$515,536,000.

10 “(ii) Of the amount available under subparagraph  
11 (A) for fiscal year 2006, the Secretary shall reserve not  
12 less than \$80,000,000 for the purpose of providing immu-  
13 nizations for adults who have not, prior to fiscal year  
14 2006, been served by immunization programs carried out  
15 with grants made pursuant to paragraph (1) or (2).

16 “(B)(i) For fiscal year 2007 and each subsequent fis-  
17 cal year, the Secretary shall make grants described in  
18 paragraphs (1) and (2) in an aggregate amount equal to  
19 the sum of the amounts determined under subclauses (I)  
20 and (II), as follows:

21 “(I) Of the aggregate amount provided in such  
22 grants for fiscal year 2006, the Secretary shall de-  
23 termine the portion that was obligated to purchase  
24 vaccines. The amount determined under this sub-  
25 clause is such portion as increased to offset the per-  
26 centage increase in the average sales price for such

1 vaccines for the most recent five-year period for  
2 which data are available, taking into account reports  
3 under subparagraph (F) (in the case of fiscal year  
4 2007 and subsequent fiscal years).

5 “(II) Of the aggregate amount provided in such  
6 grants for fiscal year 2006, the Secretary shall de-  
7 termine the portion that was obligated for purposes  
8 other than the purchase of vaccines. The amount de-  
9 termined under this subclause is such portion as in-  
10 creased to offset the percentage increase in the Con-  
11 sumer Price Index for all urban consumers (all  
12 items; United States city average) for the most re-  
13 cent five-year period for which data are available.

14 “(ii) Of the amount available under clause (i) for a  
15 fiscal year, the Secretary shall, for the purpose described  
16 in subparagraph (A)(ii), reserve not less than the amount  
17 specified in such subparagraph as increased in accordance  
18 with the same methodology as applies under clause (i).

19 “(C) Subject to subparagraphs (D) through (F)),  
20 grants made pursuant to this paragraph shall be made in  
21 accordance with criteria of the Secretary issued under  
22 paragraphs (1) and (2) for immunization programs. The  
23 preceding sentence may not be construed as terminating  
24 the authority of the Secretary to modify such criteria.

1       “(D) The purposes for which grants made pursuant  
2 to this paragraph may be expended by a State or political  
3 subdivision include the following:

4           “(i) Conducting assessments to determine the  
5 number of adults in the area involved who need im-  
6 munizations and the barriers to providing immuniza-  
7 tions to such adults.

8           “(ii) Developing and implementing strategies to  
9 increase the rate of immunizations in populations in  
10 which a significant number of individuals have not  
11 received immunizations with the federally rec-  
12 ommended vaccines (as defined in section 317A(g))  
13 for the populations.

14           “(iii) Educating care givers, health care profes-  
15 sionals, and the public about the need to be immu-  
16 nized.

17           “(iv) Consulting with health care providers with  
18 respect to ensuring proper and timely immunizations  
19 for their patients.

20           “(v) Investigating and responding to outbreaks  
21 of vaccine-preventable diseases.

22           “(vi) Developing and modifying plans to re-  
23 spond to potential shortages in supplies of vaccines.

1           “(vii) Preparing reports under subparagraph  
2           (F) and any additional reports that are submitted to  
3           the Secretary pursuant to this paragraph.

4           “(E) A condition for the receipt by a State of a grant  
5           made pursuant to this paragraph for a fiscal year is that  
6           the State have (or agree to develop, in the case of a grant  
7           for fiscal year 2006) a State plan that—

8           “(i) ensures the distribution and administration  
9           of vaccines in the event that the Secretary declares  
10          a shortage of approved vaccines as a public health  
11          emergency; and

12          “(ii) includes plans for communication and co-  
13          ordination between—

14               “(I) State and local public health depart-  
15               ments;

16               “(II) community health centers;

17               “(III) hospitals;

18               “(IV) private physicians licensed within the  
19               State; and

20               “(V) to the extent practicable, vaccine  
21               manufacturers and suppliers.

22          “(F) A condition for the receipt of a grant made pur-  
23          suant to this paragraph for a fiscal year is that the appli-  
24          cant involved agree to submit to the Secretary a report  
25          that specifies for such year the quantity of each type of

1 vaccine purchased with the grant and the per-dose cost  
2 of the vaccine.

3 “(G) The requirements under subparagraphs (A) and  
4 (B) that the Secretary make grants constitutes budget au-  
5 thority in advance of appropriations Acts, and represents  
6 the obligation of the Federal Government to make outlays  
7 to provide for immunizations without charge pursuant to  
8 the grants in accordance with this paragraph.”.

9 **SEC. 5. ONE-YEAR NOTICE ON DISCONTINUING MANUFAC-**  
10 **TURE OF VACCINE.**

11 Subchapter A of chapter V of the Federal Food,  
12 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-  
13 ed by inserting after section 506C the following section:

14 **“SEC. 506D. DISCONTINUANCE OF VACCINE.**

15 “(a) IN GENERAL.—

16 “(1) NOTICE TO SECRETARY.—A manufacturer  
17 of a vaccine approved by the Secretary shall notify  
18 the Secretary of a discontinuance of the manufac-  
19 ture of the vaccine at least 12 months prior to the  
20 date of the discontinuance.

21 “(2) DIRECTOR OF CENTERS FOR DISEASE  
22 CONTROL AND PREVENTION.—Promptly after receiv-  
23 ing a notice under paragraph (1), the Secretary shall  
24 inform the Director of the Centers for Disease Con-  
25 trol and Prevention of the notice. Promptly after de-

1       termining that a reduction under subsection (b) ap-  
2       plies with respect to such a notice, the Secretary  
3       shall inform such Director of the reduction.

4               “(3) RELATIONSHIP TO SEPARATE NOTICE PRO-  
5       GRAM.—In the case of a vaccine that is approved by  
6       the Secretary and is a drug described in section  
7       506C(a), this section applies to the vaccine in lieu  
8       of section 506C.

9               “(b) REDUCTION IN NOTIFICATION PERIOD.—The  
10       notification period required under subsection (a) for a  
11       manufacturer may be reduced if the manufacturer certifies  
12       to the Secretary that good cause exists for the reduction,  
13       such as a situation in which—

14               “(1) a public health problem may result from  
15       continuation of the manufacturing for the 12-month  
16       period;

17               “(2) a biomaterials shortage prevents the con-  
18       tinuation of the manufacturing for the 12-month pe-  
19       riod;

20               “(3) a liability problem may exist for the manu-  
21       facturer if the manufacturing is continued for the  
22       12-month period;

23               “(4) continuation of the manufacturing for the  
24       12-month period may cause substantial economic  
25       hardship for the manufacturer;

1           “(5) the manufacturer has filed for bankruptcy  
2           under chapter 7 or 11 of title 11, United States  
3           Code; or

4           “(6) the manufacturer can continue the dis-  
5           tribution of the vaccine involved for 12 months.

6           “(c) DISTRIBUTION.—To the maximum extent prac-  
7           ticable, the Secretary shall distribute information on the  
8           discontinuation of the manufacture of vaccines to appro-  
9           priate physician and patient organizations.”.

10 **SEC. 6. PROGRAM FOR PEDIATRIC VACCINE STOCKPILE;**

11                           **PARTICIPATION OF MANUFACTURERS OF**  
12                           **VACCINES.**

13           (a) IN GENERAL.—Not later than 30 days after the  
14           date of the enactment of this Act, the Secretary of Health  
15           and Human Services, in consultation with the Chairman  
16           of the Securities and Exchange Commission, shall submit  
17           to the Congress a plan to facilitate the participation of  
18           manufacturers of pediatric vaccines in the program oper-  
19           ated by the Secretary to maintain a six-month supply of  
20           such vaccines (commonly referred to as the pediatric vac-  
21           cine stockpile). With respect to the purchase of pediatric  
22           vaccines for such program, the plan shall include, as nec-  
23           essary, provisions for the accounting-rules treatment of  
24           amounts paid by the Secretary to such manufacturers that

1 will permit the manufacturers to treat the amounts as rev-  
 2 enue upon receipt of the amounts.

3 (b) DEFINITION.—For purposes of subsection (a),  
 4 the term “pediatric vaccine” means a vaccine on the list  
 5 referred to in section 1928(e) of the Social Security Act.

6 **SEC. 7. PROHIBITION ON MEDICAID COST-SHARING FOR**  
 7 **VACCINES RECOMMENDED BY ADVISORY**  
 8 **COMMITTEE ON IMMUNIZATION PRACTICES.**

9 (a) IN GENERAL.—Section 1916 of the Social Secu-  
 10 rity Act (42 U.S.C. 1396o) is amended by adding at the  
 11 end the following:

12 “(h) The State plan shall require that no provider  
 13 participating under the State plan may impose a copay-  
 14 ment, cost sharing charge, or similar charge for admin-  
 15 istering to an adult individual who is eligible for medical  
 16 assistance under such plan a vaccine that is included on  
 17 the recommended vaccine schedule for adults that is estab-  
 18 lished (and periodically reviewed and appropriately re-  
 19 vised) by the Advisory Committee on Immunization Prac-  
 20 tices of the Centers for Disease Control and Prevention  
 21 and that is otherwise covered under the State plan.”.

22 (b) EFFECTIVE DATE.—The amendment made by  
 23 subsection (a) shall take effect on October 1, 2005.

○