

109TH CONGRESS
1ST SESSION

H. R. 4358

To amend the Public Health Service Act to provide for emergency distributions of influenza vaccine.

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 17, 2005

Mr. DEFazio (for himself, Mr. HINCHey, Mrs. MALONEY, Mr. McNULTY, Mr. KUCINICH, Mr. ALLEN, Mr. GUTIERREZ, Mr. CROWLEY, Ms. LEE, Mr. HOLDEN, Mr. KILDEE, and Mr. SANDERS) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Public Health Service Act to provide for emergency distributions of influenza vaccine.

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 “Influenza Vaccine
5 Emergency Act”.

1 **SEC. 2. EMERGENCY DISTRIBUTIONS OF INFLUENZA VAC-**
2 **CINE.**

3 Part B of title III of the Public Health Service Act
4 (42 U.S.C. 243 et seq.) is amended by inserting after sec-
5 tion 319K the following section:

6 **“SEC. 319L. EMERGENCY AUTHORITIES REGARDING SUP-**
7 **PLY OF INFLUENZA VACCINE.**

8 “(a) CONTINGENCY CLAUSES IN SALES CON-
9 TRACTS.—In entering into a contract for the sale of influ-
10 enza vaccine in interstate commerce, a manufacturer or
11 distributor of such vaccine shall include in the contract
12 a provision in writing expressing the policy that the sale
13 to the purchaser under the contract is subject to the fol-
14 lowing conditions:

15 “(1) If the Secretary publishes in the Federal
16 Register a declaration that there is a public health
17 emergency by reason of a shortage of influenza vac-
18 cine, the Secretary has the authority, in lieu of such
19 purchaser, to take title to such quantities of the vac-
20 cine as the Secretary determines to be necessary for
21 purposes of the public health, subject to subsection
22 (c)(2).

23 “(2) If by reason of the Secretary using the au-
24 thority under paragraph (1) the purchaser does not
25 receive, or loses possession of, a quantity of influ-
26 enza vaccine for which the purchaser has made pay-

1 ment, the manufacturer or distributor (as the case
2 may be) will provide to the purchaser a refund for
3 such quantity.

4 “(b) COMPENSATION.—In the case of a contract for
5 the sale of influenza vaccine with respect to which the Sec-
6 retary uses the authority referred to in subsection (a)(1),
7 the Secretary shall pay to the manufacturer or distributor
8 involved the same amount as, under the contract, the man-
9 ufacturer or distributor received or would have received
10 for the quantity of vaccine involved.

11 “(c) AGENCY PROCEDURES.—With respect to the in-
12 fluenza season involved:

13 “(1) If the Secretary makes an emergency dec-
14 laration under subsection (a)(1), the Secretary shall
15 determine the extent of compliance with guidelines
16 for the distribution of influenza vaccine that have
17 been established by the Secretary.

18 “(2) The Secretary may not use the authority
19 referred to in subsection (a)(1) with respect to any
20 contract unless the Secretary has published in the
21 Federal Register, not earlier than 30 days after
22 making the emergency declaration under such sub-
23 section, a determination that the extent of compli-
24 ance with such guidelines has not been sufficient to
25 constitute an adequate response to the emergency.

1 “(d) DISTRIBUTION OF VACCINE.—If the Secretary
2 meets the condition described in subsection (c)(2) for the
3 use of the authority referred to in subsection (a)(1):

4 “(1) The Secretary may, in lieu of such author-
5 ity, order any manufacturer or distributor of influ-
6 enza vaccine to honor its contracts with States or
7 political subdivisions of States for the sale of such
8 vaccine, in any case in which the manufacturer or
9 distributor has conflicting obligations under its con-
10 tracts for sale of the vaccine.

11 “(2) Any influenza vaccine to which the Sec-
12 retary takes title under subsection (a)(1) shall be
13 provided—

14 “(A) to States and political subdivisions of
15 States in accordance with the immunization
16 program under section 317(j); and

17 “(B) to such other public or private enti-
18 ties as the Secretary determines to be appro-
19 priate as a response to the emergency involved.

20 “(e) RULES OF CONSTRUCTION.—

21 “(1) EMERGENCY DECLARATION.—The Sec-
22 retary shall be considered to have made an emer-
23 gency declaration under subsection (a)(1) if the Sec-
24 retary publishes in the Federal Register a declara-
25 tion described in such subsection.

1 “(2) EMERGENCY SHORTAGE.—

2 “(A) OVERALL QUANTITY VS. DELIVERY
3 WAITING TIME.—Without regard to whether the
4 Secretary considers as adequate the total quan-
5 tity of influenza vaccine that has been or is
6 being manufactured for the influenza season in-
7 volved, the Secretary may make an emergency
8 declaration under subsection (a)(1) if the Sec-
9 retary determines that the delivery waiting time
10 for States or political subdivisions of States to
11 receive the vaccine for the season is a period
12 whose duration constitutes a significant threat
13 to children, adolescents, or adults who are
14 served by the immunization program under sec-
15 tion 317(j).

16 “(B) DELIVERY WAITING TIME.—A deliv-
17 ery waiting time under subparagraph (A) for a
18 State or political subdivision of a State to re-
19 ceive influenza vaccine is the time elapsing be-
20 tween the date on which the State or subdivi-
21 sion enters into a contract to purchase such
22 vaccine and the date on which the State or sub-
23 division (or other entity designated under the
24 contract) takes custody of the vaccine, less any
25 period in which payment is due under the con-

1 tract and the State or subdivision has not made
2 payment, or in which the State or subdivision
3 otherwise is in significant violation of the con-
4 tract.

5 “(f) DEFINITIONS.—For purposes of this subsection,
6 the terms ‘influenza season’ and ‘influenza vaccine’ have
7 the meanings given such terms by the Secretary.”.

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