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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program:

Addition to the Vaccine Injury Table to Include All Vaccines Against Seasonal Influenza

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: Through this notice, the Secretary of the U.S. Department of Health and Human Services (the Secretary) announces that all FDA-approved vaccines against seasonal influenza are covered under the National Vaccine Injury Compensation Program (VICP), which provides a system of no-fault compensation for certain individuals who have been injured by covered childhood vaccines. Prior to this publication, trivalent influenza vaccines were included under Category XIV on the Vaccine Injury Table (Table) and will continue to be listed in that category. This notice serves to include all vaccines against seasonal influenza (not already covered under Category XIV) as covered vaccines under Category XVII of the Table (new vaccines covered under the VICP). This notice ensures that petitioners may file petitions relating to all vaccines against seasonal influenza (not already covered under the VICP) with the VICP even before such vaccines are added as a separate and distinct category to the Table through rulemaking.

DATES: This notice is effective on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. As described below, all vaccines against seasonal influenza (except trivalent influenza vaccines, which are already covered under the VICP) will be covered under the VICP on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Vito Caserta, M.D., M.P.H., Acting Director, Division of Vaccine Injury Compensation, Healthcare Systems Bureau, Health Resources and Services Administration, Parklawn Building, Room 11C-26, 5600 Fishers Lane, Rockville, Maryland 20857; telephone number (301) 443-5287.

SUPPLEMENTARY INFORMATION: The statute authorizing the VICP provides for the inclusion of additional vaccines in the VICP when they are recommended by the Centers for Disease Control and Prevention (CDC) to the Secretary for routine administration to children. See section 2114(e)(2) of the Public Health Service (PHS) Act, 42 U.S.C. 300aa-14(e)(2). Consistent with section 13632(a)(3) of Public Law 103-66, the regulations governing the VICP provide that such vaccines will be included as covered vaccines in the Table as of the effective date of an excise tax to provide funds for the payment of compensation with respect to such vaccines (42 CFR 100.3(c)(5)).

By way of background, trivalent influenza vaccines (meaning they each contain three vaccine virus strains which are thought most likely to cause disease outbreaks during the influenza season) are routinely given to millions of individuals in the United States each year. Trivalent influenza vaccines include an inactivated (killed) virus vaccine administered using a syringe as

well as a live, attenuated product administered in a nasal spray. All trivalent vaccines have been covered under the VICP since July 1, 2005. On April 12, 2005, the Health Resources and Services Administration (HRSA) published a notice in the Federal Register announcing that such vaccines were covered under the category for new vaccines on the Table. See 70 FR 19092. Subsequently, the Secretary engaged in rulemaking to add trivalent influenza vaccines as a separate category on the Table (category XIV on the Table). See 76 FR 36367.

Since that time, quadrivalent influenza vaccines (meaning that they contain four vaccine virus strains which are thought most likely to cause disease outbreaks during the influenza season) have been approved by the Food and Drug Administration (FDA), and such vaccines are expected to be administered as an alternative to trivalent influenza vaccines during the upcoming and future flu seasons. On June 25, 2013, Public Law 113-15 was enacted, extending the applicable excise tax on trivalent influenza vaccines to also include any other vaccines against seasonal influenza. See Public Law 113-15 (amending 26 U.S.C. § 4132(a)(1)(N)).

The amendment included in Public Law 113-15 ensures that all FDA-approved seasonal influenza vaccines, including quadrivalent influenza vaccines, and other new seasonal influenza vaccines are covered under the VICP. Under the regulations governing the VICP, Category XVII of the Table specifies that “[a]ny new vaccine recommended by CDC for routine administration to children, after publication by the Secretary of a notice of coverage” is a covered vaccine under the Table (42 CFR 100.3(a), Item XVII). As explained in HRSA’s notice of coverage with respect to the coverage of trivalent influenza vaccines, the CDC recommended in its May 28, 2004, issue of the Morbidity and Mortality Weekly Report (MMWR) that influenza

vaccines be routinely administered to children between 6 and 23 months of age because children in this age group are at an increased risk for complications from influenza. That recommendation extends to seasonal influenza vaccines beyond trivalent vaccines. The latest CDC update of its annual influenza vaccination recommendation was published in the MMWR on September 20, 2013. MMWR 2013;62, No. 7. This report updated the 2012 recommendations by the CDC and its Advisory Committee on Immunization Practices regarding the use of influenza vaccines for the prevention and control of seasonal influenza. Routine annual influenza vaccination is recommended for all persons aged 6 months and older. For the 2013–14 influenza season, it is expected that trivalent live attenuated influenza vaccine (LAIV3) will be replaced by a quadrivalent LAIV formulation (LAIV4). Inactivated influenza vaccines (IIVs) will be available in both trivalent (IIV3) and quadrivalent (IIV4) formulations. No preferential recommendation was made for one influenza vaccine product over another for persons for whom more than one product is otherwise appropriate.

This notice serves to satisfy the regulation's publication requirement. Through this notice, all vaccines against seasonal influenza (beyond trivalent influenza vaccines, which are already covered under Category XIV on the Table) are included as covered vaccines under Category XVII of the Table (new vaccines).

Under section 2114(e) of the PHS Act, as amended by section 13632(a) of the Omnibus Budget Reconciliation Act of 1993, coverage for a vaccine recommended by the CDC for routine administration to children shall take effect upon the effective date of the tax enacted to provide

funds for compensation with respect to the vaccine included as a covered vaccine in the Table. Under Public Law 113-15, the excise tax for vaccines against seasonal influenza (beyond trivalent influenza vaccines) “shall apply to sales and uses on or after the later of: (A) the first day of the first month which begins more than 4 weeks after the date of the enactment of this Act [i.e., Public Law 113-15]; or (B) the date on which the Secretary of Health and Human Services lists any vaccines against seasonal influenza (other than any vaccine against seasonal influenza listed by the Secretary prior to the date of the enactment of this Act) for purposes of compensation for any vaccine-related injury or death through the Vaccine Injury Compensation Trust Fund.” Public Law 113-15, § 1. The law further provides that if the vaccines were sold before or on the effective date of the excise tax, but delivered after this date, the delivery date of such vaccines shall be considered the sale date. Id.

Under this statutory language, the effective date of the excise tax for seasonal influenza vaccines other than trivalent influenza vaccines is the later of August 1, 2013 (which is the first day of the first month beginning more than 4 weeks after the effective date of Public Law 113-15, which was June 25, 2013), or the date on which the Secretary publishes a notice of coverage under the VICP for seasonal influenza vaccines not previously covered under the VICP. This publication is the notice referred to in the latter requirement. Because this publication is made after August 1, 2013, the effective date of coverage for all vaccines against seasonal influenza (beyond trivalent influenza vaccines, which are already covered by the VICP) is the effective date of this publication, [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Petitions filed concerning vaccine-related injuries or deaths associated with all vaccines against seasonal influenza vaccines must be filed within the applicable statute of limitations. The filing limitations applicable to petitions filed with the VICP are set out in section 2116(a) of the PHS Act (42 U.S.C. 300aa-16(a)). In addition, section 2116(b) of the PHS Act lays out specific exceptions to these statutes of limitations that apply when the effect of a revision to the Table makes a previously ineligible person eligible to receive compensation or when an eligible person's likelihood of obtaining compensation significantly increases. Under this provision, persons who may be eligible to file petitions based on the addition of a new category of vaccines under Category XVII of the Table may file a petition for compensation not later than 2 years after the effective date of the revision if the injury or death occurred not more than 8 years before the effective date of the revision of the Table (42 U.S.C. 300aa-16(b)). Thus, persons whose petitions may not be timely under the limitations periods described in section 2116(a) of the PHS Act, may still file petitions concerning vaccine-related injuries or deaths associated with seasonal influenza vaccines (with the exception of trivalent influenza vaccines that are already covered under the VICP) until November 12, 2015, as long as the vaccine-related injury or death occurred on or before November 12, 2021 (8 years prior to the effective date of the addition of non-trivalent seasonal influenza vaccines as covered vaccines).

The Table will be amended through subsequent rulemaking to include all vaccines against seasonal influenza in place of only trivalent influenza vaccines under Category XIV of the Table. Once that is done, the Table's coverage provisions (codified at 42 CFR 100.3(c)) will explain that trivalent influenza vaccines are included on the Table as of July 1, 2005, and that other

seasonal influenza vaccines are included on the Table as of [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Dated: November 5, 2013

Mary K. Wakefield,
Administrator

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