DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received within 30 days of this notice.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Advanced Education Nursing Traineeship (AENT) Program Application.

OMB No.: 0915–xxxx—NEW

Abstract: The Health Resources and Services Administration (HRSA) provides advanced education nursing training grants to educational institutions to increase the numbers of advanced education nurses through the AENT Program. The AENT Program is governed by Title VIII, Section 811(a)(2) of the Public Health Service Act (42 U.S.C. 296j(a)(2)). This new request includes the Program Specific AENT Tables. The proposed AENT Tables will include data on the distribution of graduates from the organization who are working in rural, underserved, and public health settings, as well as the distribution of graduates who received traineeship support and are working in rural, underserved, and public health settings; and the number of projected students to receive traineeship support by their enrollment status (full-time or part-time), the degree program (master's, post-nursing master's certificate, or doctoral), and the specialty in which they are enrolled (nurse practitioner or nurse midwifery) by budget year one and by budget year two.

Need and Proposed Use of the Information: HRSA will use this information gathered from the tables in determining the amount of traineeship support to be awarded per student, per institution, and to succinctly capture data for the number of projected students for determining eligibility for Special Consideration and Statutory Funding Preference.

Likely Respondents: Eligible applicants are schools of nursing, nursing centers, academic health centers, state or local governments, and other public or private nonprofit entities determined appropriate by the Secretary that submit an application and are accredited for the provision of primary care nurse practitioner and nurse midwifery programs accredited by a national nurse education accrediting agency recognized by the Secretary of the U.S. Department of Education. The school must be located in the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Northern Mariana Islands, American Samoa, Guam, the U.S. Virgin Islands, the Federated States of Micronesia, the Republic of the Marshall Islands, or the Republic of Palau.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Type of respondent	Form name	Number of respondent	Number responses per respondent	Average burden per response (in hours)	Total hour burden
Grantee	Table 1a: Rural, Underserved, or Public health Practice Settings: Graduate Data.	70	1	3.19	223.3
Grantee	Table 1b: Rural, Underserved, or Public health Practice Settings: Graduates Supported Data.	70	1	3.19	223.3
Grantee	Table 2a: Number of Projected Master's Degree and Post Nursing Master's Certificate Student To Receive Traineeship Support by Role (budget year 1 and budget year 2).	70	1	3.11	217.7
Grantee	Table 2b: Number of Projected Doctoral (PhD and/or DNP) Degree Nursing Students To Receive Traineeship Support by Role (budget year 1 and budget year 2).	70	1	3.11	217.7
Total		70			882

Dated: November 4, 2013.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2013–27006 Filed 11–8–13; 8:45 am]

BILLING CODE 4165–15–P

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 November 12, 2013. 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 November 12, 2013.

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., Pub. L. 113–