Dun and Bradstreet. It is a nine-digit identification number, which provides unique identifiers of single business entities. The D–U–N–S number can be obtained from: *https://iupdate.dnb.com/iUpdate/viewiUpdateHome.htm.*

C. Intergovernmental Review

Executive Order 12372, Intergovernmental Review of Federal Programs, is not applicable to these grant applications.

IV. Submission Information

1. Letter of Assurance

To receive funding, eligible entities must provide a Letter of Assurance containing all the information outlined in Section III above.

Letters of Assurance should be addressed to: Jennifer Johnson, Deputy Commissioner, Administration on Disabilities, Administration for Community Living.

Letters of Assurance should be submitted *electronically via email* to *PHWF@acl.hhs.gov.*

2. Submission Dates and Times

To receive consideration, Letters of Assurance must be submitted by 11:59 p.m. Eastern Time on February 11, 2022. Letters of Assurance should be submitted electronically via email and have an electronic time stamp indicating the date/time submitted.

VII. Agency Contacts

1. Programmatic and Submission Issues

Direct programmatic and submission inquiries to *PHWF@acl.hhs.gov.*

Dated: January 6, 2022.

Alison Barkoff,

Principal Deputy Administrator.

[FR Doc. 2022–00401 Filed 1–11–22; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–E–1817, FDA–2020–E–1818, and FDA–2020–E–1820]

Determination of Regulatory Review Period for Purposes of Patent Extension; ENHERTU; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA or the Agency) published a notice in the **Federal Register** of November 1, 2021, for the determination of a regulatory review period for purposes of patent extension for the human biological product, ENHERTU. This document corrects that notice by adjusting the applicable regulatory review period for the testing phase and approval phase of the product, ENHERTU.

DATES: All due dates for submission of comments, redetermination requests, and submission of petitions for due diligence as well as the dates used to determine the regulatory review periods for the products noted above remain the same as originally published.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION: On November 1, 2021, the Food and Drug Administration (FDA or the Agency) published a notice in the **Federal Register** determining the regulatory review period for the human biological product ENHERTU. This correction to the notice adjusts the applicable regulatory review period of the product with the number of days occurring during the testing phase and the approval phase of the product ENHERTU.

Correction

In the **Federal Register** of November 1, 2021 (86 FR 60252), in FR Doc. 2021–23725, appearing on page 60253, in the third column, in section II., ''Determination of Regulatory Review Period,'' in the first two sentences, the following correction is made:

FDA has determined that the applicable regulatory review period for ENHERTU is 1,395 days. Of this time, 114 days occurred during the testing phase of the regulatory review period, while 1,281 days occurred during the approval phase.

Dated: January 5, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–00404 Filed 1–11–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Updates to the Bright Futures Periodicity Schedule

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: Effective December 30, 2021, HRSA accepted recommended updates to the Bright Futures Periodicity Schedule, a HRSA-supported guideline for infants, children and adolescents for purposes of ensuring that non-grandfathered group and individual health insurance issuers provide coverage without cost sharing under the Public Health Service Act. The updates to the Bright Futures Periodicity Schedule are: A new category for sudden cardiac arrest and sudden cardiac death risk assessment, a new category for hepatitis B virus infection risk assessment, addition of suicide risk as an element of universal depression screening for children ages 12–21, and updated category title from ''Psychosocial/Behavioral Assessment'' to ''Behavioral/Social/Emotional Screening,'' with no revision to the ages in which the screening occurs (newborn to 21 years). Finally, two clarifying references related to dental fluoride varnish and fluoride supplementation have been added, with no associated recommended changes to clinical practice or health insurance coverage. Please see *https://mchb.hrsa.gov/maternal-child-health-topics/child-health/bright-futures.html* for additional information.

FOR FURTHER INFORMATION CONTACT: Savannah Kidd, M.S. MFT, HRSA/Maternal and Child Health Bureau by calling 301–287–2601 or by emailing at *SKidd@hrsa.gov.*

SUPPLEMENTARY INFORMATION: The Bright Futures program has been funded by HRSA since 1990. A primary focus of this program is for the funding recipient to maintain and recommend updates to the *Bright Futures Guidelines for Health Supervision of Infants, Children and Adolescents,* a set of materials and tools that provide theory-based and evidence-driven guidance for all preventive care screenings and well-child visits. One component of these tools is the Bright Futures Periodicity Schedule, a chart that identifies the recommended screenings, assessments, physical examinations, and procedures to be delivered within preventive checkups at each age milestone. Over the program's existence, the Bright Futures Periodicity Schedule has become the accepted schedule within the United States for preventive health services through the course of a child's development.

Section 2713 of the Public Health Service Act (42 U.S.C. 300gg–13), added by the Patient Protection and Affordable Care Act (Pub. L. 111–148), requires that non-grandfathered group health plans and health insurance issuers offering

group or individual health insurance coverage provide coverage without cost-sharing for certain preventive health services. Section 2713(a)(3) describes such services for infants, children, and adolescents as ''evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration.'' HHS, along with the Departments of Treasury and Labor, issued an Interim Final Rule on July 19, 2010 (75 FR 41726–41760) that identified two specific resources as the comprehensive guidelines supported by HRSA for infants, children, and adolescents to be covered by insurance without cost sharing by non-grandfathered group health plans and health insurance issuers: (1) The Bright Futures Periodicity Schedule and (2) the Recommended Uniform Screening Panel of the Advisory Committee on Heritable Disorders in Newborns and Children. The Interim Final Rule provided that a future change to these comprehensive guidelines is considered to be issued for purposes of Section 2713 on the date on which it is accepted by the HRSA Administrator or, if applicable, adopted by the Secretary of HHS.

A public comment period was announced and occurred from September 13, 2021, through October 13, 2021 (86 FR 50894, September 13, 2021),[1] to allow public comment on the proposed recommended updates affecting clinical practice and health insurance coverage requirements. A total of 27 respondents gave 57 comments during the public comment period. The Bright Futures grantee, the American Academy of Pediatrics, received and considered the public comments. The annual report (Tab A) provides a description of the comments, including a detailed tabulation of each comment.

On December 30, 2021, the HRSA Administrator accepted the American Academy of Pediatrics' recommended several updates to the Bright Futures Periodicity Schedule. The Bright Futures recommendations included recommended clinical practice updates, along with revisions to the footnotes on the Bright Futures Periodicity Schedule that do not require changes to clinical practice or health insurance coverage. The updates to the Bright Futures Periodicity Schedule are: (1) A new category for sudden cardiac arrest and sudden cardiac death risk assessment, (2) a new category for hepatitis B virus infection risk assessment, (3) addition of suicide risk as an element of universal depression screening for children ages 12–21, and (4) updated category title from ''Psychosocial/Behavioral Assessment'' to ''Behavioral/Social/Emotional Screening,'' with no revision to the ages in which the screening occurs (newborn to 21 years). Finally, two clarifying references related to dental fluoride varnish and fluoride supplementation have been added with no associated recommended changes to clinical practice. In light of these updates, all non-grandfathered group health plans and health insurance issuers offering group or individual health insurance coverage must cover without cost-sharing the services and screenings listed on the updated Bright Futures Periodicity Schedule for plan years (in the individual market, policy years) that begin in 2023, which can be accessed at the following link: *https://mchb.hrsa.gov/maternal-child-health-topics/child-health/bright-futures.html*.

Diana Espinosa,

Acting Administrator.

[FR Doc. 2022–00461 Filed 1–11–22; 8:45 am]

BILLING CODE 4165–15–P

[1] *See https://www.federalregister.gov/documents/2021/09/13/2021-19630/opportunity-for-comments-on-proposed-updates-to-the-bright-futures-periodicity-schedule-as-part-of.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Update to the Women's Preventive Services Guidelines

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: On December 30, 2021, HRSA approved updates to the HRSA-supported Women's Preventive Services Guidelines (Guidelines) that address health needs specific to women. The Guidelines are based on clinical recommendations from the Women's Preventive Services Initiative (WPSI), a coalition of experts and health professional organizations convened by the American College of Obstetricians and Gynecologist (ACOG) under a cooperative agreement awarded by HRSA. Under the Public Health Service Act and pertinent regulations, preventive care and screenings for women provided for in comprehensive guidelines supported by HRSA are required to be covered without cost sharing by group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage. This 2021 update adds one additional service, Preventing Obesity in Midlife Women, and revises five services: Breastfeeding Services and Supplies, Contraception, Screening for Human Immunodeficiency Virus Infection, Counseling for Sexually Transmitted Infections, and Well-Woman Preventive Visits. This notice serves as an announcement of the decision to update the Guidelines as further described below. Please see *https://www.hrsa.gov/womens-guidelines/index.html* for additional information.

FOR FURTHER INFORMATION CONTACT: Kimberly Sherman, HRSA, Maternal and Child Health Bureau, telephone (301) 443–8283, email: *wellwomancare@hrsa.gov.*

SUPPLEMENTARY INFORMATION: The updated 2021 HRSA-supported Women's Preventive Services Guidelines, along with information related to their development and implementation, are available at *https://www.hrsa.gov/womens-guidelines/index.html.* A summary of information regarding the updates to the comprehensive guidelines supported by HRSA on December 30, 2021, is set out below.

Women's Preventive Services Guidelines

The first HRSA-supported Guidelines, based on recommendations of the Institute of Medicine, were established in 2011. The Guidelines were subsequently updated following review and recommendations by the ACOG under the WPSI cooperative agreement, awarded by HRSA in 2016. The purpose of WPSI is to improve adult women's health across the lifespan by engaging a coalition of experts and health professional organizations to recommend updates to the HRSA-supported Guidelines. Following such review and recommendations, HRSA decides whether or not to support, in whole or in part, the recommended updates to the Guidelines. In March 2021, HRSA awarded a subsequent cooperative agreement to ACOG to provide recommendations as appropriate over a 5-year period to update the HRSA-supported Guidelines. Under the cooperative agreement, ACOG, through the WPSI, engages in a process to consider and review new and existing Guidelines developed by a multidisciplinary group of women's health experts and professional organizations.

Under section 2713 of the Public Health Service Act, 42 U.S.C. 300gg–13, group health plans and issuers of non-grandfathered group and individual