and the Japanese Pharmaceutical Manufacturers Association. The Standing Members of the ICH Association include Health Canada and Swissmedic. Additionally, the Membership of ICH has expanded to include other regulatory authorities and industry associations from around the world (*https://www.ich.org/*).

ICH works by involving technical experts from both regulators and industry parties in detailed technical harmonization work and the application of a science-based approach to harmonization through a consensus-driven process that results in the development of ICH guidelines. The regulators around the world are committed to consistently adopting these consensus-based guidelines, realizing the benefits for patients and for industry.

As a Founding Regulatory Member of ICH, FDA plays a major role in the development of each of the ICH guidelines, which FDA then adopts and issues as guidance for industry. FDA's guidance documents do not establish legally enforceable responsibilities. Instead, they describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

In the **Federal Register** of October 5, 2021 (86 FR 54982), FDA published a notice announcing the availability of a draft guidance entitled ''S1B(R1) Addendum to S1B Testing for Carcinogenicity of Pharmaceuticals.'' The notice gave interested persons an opportunity to submit comments by December 6, 2021.

After consideration of the comments received and revisions to the guideline, a final draft of the guideline was submitted to the ICH Assembly and endorsed by the regulatory agencies on August 4, 2022.

The final guidance provides guidance on expanding the testing scheme for assessing human carcinogenic risk of pharmaceuticals by introducing an additional approach that is not described in the original S1B Guideline and also adds a plasma exposure ratio-based approach for setting the high dose in the rasH2-Tg mouse model. This guidance finalizes the draft guidance issued on October 5, 2021.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.regulations.gov*.

Dated: October 27, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–23787 Filed 11–1–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Request for Public Comment on Proposed Update to the Bright Futures Periodicity Schedule as Part of the HRSA-Supported Preventive Services Guidelines for Infants, Children, and Adolescents

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

ACTION: Notice.

SUMMARY: This notice seeks public comment on a proposed update to the Periodicity Schedule of the Bright Futures Recommendations for Pediatric Preventive Health Care (''Bright Futures Periodicity Schedule''), as part of the HRSA-supported preventive service guidelines for infants, children, and adolescents. Please see *https://mchb.hrsa.gov/maternal-child-health-topics/child-health/bright-futures.html* for additional information. Specifically, the proposed update to the Bright Futures Periodicity Schedule is to extend the upper age range for the existing universal Human Immunodeficiency Virus (HIV) screening recommendation.

In the Bright Futures Periodicity Schedule, a ''dot'' with an ''arrow'' indicates a ''range during which a service may be provided.'' In the current Bright Futures Periodicity Schedule, the age range recommended for which adolescents may be provided universal screening for HIV is between the 15-year visit and 18-year visit. The proposed update to the Bright Futures Periodicity Schedule would indicate that the recommended age range for which adolescents may be provided universal screening for HIV is between the 15-year visit and 21-year visit. The proposed update also includes an accompanying footnote to provide updated information from the American Academy of Pediatrics (AAP) about more frequent screening for youth assessed as at high risk of HIV infection.

DATES: Members of the public are invited to provide written comments no later than December 2, 2022. All comments received on or before this date will be reviewed and considered by the Bright Futures Periodicity Schedule Working Group and provided for further consideration by HRSA in determining the recommended updates that it will support.

ADDRESSES: Members of the public interested in providing comments can do so by accessing the public comment web page at: *https://mchb.hrsa.gov/maternal-child-health-topics/child-health/bright-futures.html.*

FOR FURTHER INFORMATION CONTACT: Bethany Miller, HRSA, Maternal and Child Health Bureau, email: *BMiller@hrsa.gov,* telephone: (301) 945–5156.

SUPPLEMENTARY INFORMATION: The Bright Futures Periodicity Schedule is maintained through a national cooperative agreement, the Bright Futures Pediatric Implementation Program, with the AAP. If accepted by HRSA, the proposed update to the Bright Futures Periodicity Schedule will provide additional clinical guidance to providers and, under the Public Health Service Act and pertinent regulations, would require non-grandfathered group health plans and health insurance issuers to provide coverage without cost-sharing of such updated preventive care and screenings.

When its preventive care and screening recommendations have been

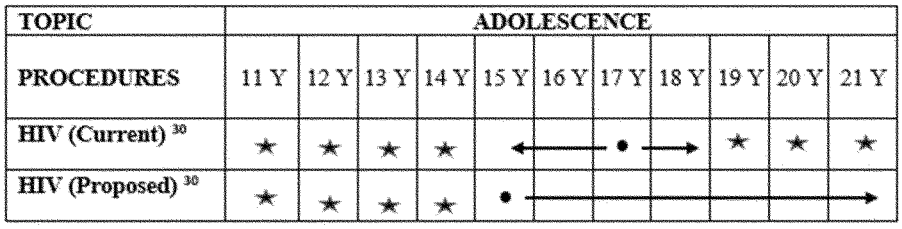
accepted by HRSA, the Bright Futures Periodicity Schedule is part of the HRSA-supported preventive service guidelines for infants, children, and adolescents. The development of the Periodicity Schedule is maintained through a national cooperative agreement, the Bright Futures Pediatric Implementation Program, with AAP. Under Section 2713 of the Public Health Service Act (42 U.S.C. 300gg–13) and pertinent regulations, non-grandfathered group health plans and health insurance issuers must provide coverage, without cost sharing, for certain preventive services for plan years (in the individual market, policy years) that begin on or after the date that is 1 year after the date the recommendation or guideline is issued. These include HRSA-supported preventive health services provided for in the Bright Futures Periodicity Schedule as part of the HRSA-supported preventive services guidelines for infants, children, and adolescents.

Through the cooperative agreement with the AAP, the Bright Futures Pediatric Implementation Program is required to administer a process for developing and regularly recommending, as needed, updates to the Bright Futures Periodicity Schedule through a process that includes a comprehensive, objective, and transparent review of available evidence that incorporates opportunity for public comment. Accordingly, the Program reviews the evidence to determine whether updates are needed, develops recommended updates, seeks and considers public comments, and makes recommendations to HRSA.

The AAP convenes a panel of pediatric primary care experts, the Bright Futures Periodicity Schedule Working Group, to review the latest evidence, develop draft recommended updates, seek and consider public comment, and propose updates to the Bright Futures Periodicity Schedule. Comments received from the public will be reviewed and discussed by the Bright Futures Periodicity Schedule Working Group.

The proposed update to the Bright Futures Periodicity Schedule would indicate that the recommended age range for which adolescents may be provided universal screening for HIV is between the 15-year visit and 21-year visit. In the current Bright Futures Periodicity Schedule, the age range recommended for which adolescents may be offered universal screening for HIV is between the 15-year visit and 18-year visit. Early detection of an infection with HIV in adolescents and young adults can lead to improved health outcomes and reduce the further spread of HIV by individuals who are not yet aware they are infected. Universal screening is a type of screening that a provider may recommend without first identifying a specific risk factor or symptom.

The current and proposed update to HIV screening is reflected in the chart below:



All such screenings (universal and risk-based) within this age range are within the scope of the guideline. The proposed update also includes an accompanying footnote to provide updated information from the AAP about more frequent screening for youth assessed as at high risk of HIV infection. The full footnote reads:

''Screen adolescents for HIV at least once between the ages of 15 and 21 making every effort to preserve confidentiality of the adolescent, as per ''Human Immunodeficiency Virus (HIV) Infection: Screening'' (*https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/human-immunodeficiency-virus-hiv-infection-screening*), and after initial screening, youth at increased risk of HIV infection should be retested annually or more frequently, as per ''Adolescents and Young Adults: The Pediatrician's Role in HIV Testing and Pre- and Postexposure HIV Prophylaxis'' (*https://doi.org/10.1542/peds.2021-055207*).''

Authority: 2713(a)(3) of the Public Health Service Act, 42 U.S.C. 300gg–13(a)(3).

Carole Johnson,

Administrator.

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BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Committee on Infant and Maternal Mortality (Formerly the Advisory Committee on Infant Mortality)

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

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Infant and Maternal Mortality (ACIMM or Committee) has scheduled a public meeting. Information about ACIMM and the agenda for this meeting can be found on the ACIMM website at *https://www.hrsa.gov/advisory-committees/infant-mortality/index.html.*

DATES: December 7, 2022, from 11 a.m. to 6 p.m. Eastern Time.

ADDRESSES: This meeting will be held via webinar. *The webinar link and log-in information will be available at the ACIMM website before the meeting: https://www.hrsa.gov/advisory-committees/infant-mortality/index.html.*

FOR FURTHER INFORMATION CONTACT: Vanessa Lee, MPH, Designated Federal Officer, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Room 18N84, Rockville, Maryland 20857; 301–443–0543; or *SACIM@hrsa.gov.*

SUPPLEMENTARY INFORMATION: ACIMM is authorized by section 222 of the Public Health Service Act (42 U.S.C. 217a), as amended. The Committee is governed by provisions of Public Law 92–463, as amended, (5 U.S.C. App. 2), which sets