

Questions and Answers.” We are issuing this guidance in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104–121, as amended by Pub. L. 110–28)¹ to help small businesses understand and comply with the Consumer Antiseptic Rub FR (84 FR 14847, April 12, 2019), which established that 28 active ingredients are not eligible for evaluation under FDA’s OTC Drug Review for use in consumer antiseptic rubs. Drug products containing these ineligible active ingredients will require approval under a new drug application or abbreviated new drug application before they can be marketed. In this final action, FDA also established that three active ingredients used in consumer antiseptic rubs are eligible for evaluation under the OTC Drug Review and granted requests to temporarily defer further rulemaking on these three ingredients to allow interested parties to complete the studies necessary to fill the safety and effectiveness data gaps identified for these three ingredients.

This guidance reviews the content and effect of the final action, including identifying which active ingredients were found eligible and which were found not eligible for evaluation under the OTC Drug Review for use in consumer antiseptic rubs. In addition, this guidance explains when and how manufacturers must comply with the final action.

This Level 2 guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on how small businesses can better understand and comply with the Consumer Antiseptic Rub FR. 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

This guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs> or <https://www.regulations.gov>.

Dated: December 23, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–28929 Filed 12–30–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Service Administration

Updates to the Bright Futures Periodicity Schedule

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

ACTION: Notice.

SUMMARY: Effective December 28, 2020, HRSA accepted a recommended update to the Bright Futures Periodicity Schedule, a HRSA-supported guideline for infants, children and adolescents, for purposes of health insurance coverage without cost sharing under the Public Health Service (PHS) Act. The update includes screening for Hepatitis C Virus Infection for individuals ages 18 to 21. Please see <https://mchb.hrsa.gov/maternal-child-health-topics/child-health/bright-futures.html> for additional information.

FOR FURTHER INFORMATION CONTACT:

Bethany D. Miller, MSW, M.Ed., HRSA/ Maternal and Child Health Bureau by calling (301) 495–5156 or by emailing at BMiller@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 update 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 PHS Act 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 in four identified areas. 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.

On December 28, 2020, the HRSA Administrator accepted the recommended update to the Bright Futures Periodicity Schedule. The Bright Futures recommendation included both a recommended clinical practice update and revisions to the footnotes on the Bright Futures Periodicity Schedule. The update includes screening for Hepatitis C Virus Infection for individuals age 18 to 21. The footnote revisions are applied to footnote 11 (Developmental Screening); footnote 12 (Autism Spectrum Disorder Screening) to update the title of the relevant revised policy statements and the electronic hyperlinks; and a new footnote referring to the supporting evidence for the recommendation for screening for hepatitis C virus infection. Therefore, 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) beginning on or after December 28, 2021.

The updated Bright Futures Periodicity schedule can be accessed at the following link: <https://>

¹ 5 U.S.C. 601 (note).

mchb.hrsa.gov/maternal-child-health-topics/child-health/bright-futures.html

Thomas J. Engels,
Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Committee on Training in Primary Care Medicine and Dentistry

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

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Training in Primary Care Medicine and Dentistry (ACTPCMD) will hold public meetings for the 2021 calendar year (CY). Information about ACTPCMD, agendas, and materials for these meetings can be found on the ACTPCMD website at <https://www.hrsa.gov/advisory-committees/primarycare-dentist/index.html>.

DATES: ACTPCMD meetings will be held on

- March 2, 2021, 10:00 a.m.–5:00 p.m. Eastern Time (ET) and March 3, 2021, 10:00 a.m.–2:00 p.m. ET;
- November 2, 2021, 8:30 a.m.–5:00 p.m. ET and November 3, 2021, 8:30 a.m.–2:00 p.m. ET.

ADDRESSES: Meetings may be held in-person, by teleconference, and/or Adobe Connect webinar. For updates on how the meeting will be held, visit the ACTPCMD website 30 business days before the date of the meeting, where instructions for joining meetings either in-person or remotely will also be posted. In-person ACTPCMD meetings will be held at 5600 Fishers Lane, Rockville, Maryland 20857. For meeting information updates, go to the ACTPCMD website meeting page at <https://www.hrsa.gov/advisory-committees/interdisciplinary-community-linkages/meetings/index.html>.

FOR FURTHER INFORMATION CONTACT:

Shane Rogers, Designated Federal Official, Division of Medicine and Dentistry, Bureau of Health Workforce, HRSA, 5600 Fishers Lane, Room 15N142, Rockville, Maryland 20857; 301-443-5260; or SRogers@hrsa.gov.

SUPPLEMENTARY INFORMATION: The ACTPCMD provides advice and recommendations to the Secretary of HHS (Secretary) on policy, program development, and other matters of significance concerning the activities under Section 747 of Title VII of the Public Health Service (PHS) Act, as it existed upon the enactment of Section 749 of the PHS Act in 1998. The ACTPCMD prepares an annual report describing the activities of the committee, including findings and recommendations made by the committee concerning the activities under Section 747, as well as training programs in oral health and dentistry. The annual report is submitted to the Secretary as well as the Chairman and ranking members of the Senate Committee on Health, Education, Labor and Pensions and the House of Representatives Committee on Energy and Commerce. The ACTPCMD develops, publishes, and implements performance measures and guidelines for longitudinal evaluations of programs authorized under Title VII, Part C of the PHS Act, and recommends

appropriation levels for programs under this Part. Since priorities dictate meeting times, be advised that start times, end times, and agenda items are subject to change. For CY 2021 meetings, agenda items may include, but are not limited to inter-professional team-based education, practice, and retention in underserved rural communities, as well as matters pertaining to policy, program development, and other matters of significance concerning medicine and dentistry activities authorized under Title VII of the PHS Act. Refer to the ACTPCMD website listed above for all current and updated information concerning the CY 2021 ACTPCMD meetings, including draft agendas and meeting materials that will be posted 30 calendar days before the meeting.

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting(s). Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement or make oral comments to the ACTPCMD should be sent to Shane Rogers using the contact information above at least 5 business days before the meeting date(s).

Individuals who need special assistance or another reasonable accommodation should notify Shane Rogers using the contact information listed above at least 10 business days

before the meeting(s) they wish to attend.

If a meeting is held in-person, it will occur in a federal government building and attendees must go through a security check to enter. Non-U.S. citizen attendees must notify HRSA of their planned attendance at an in-person meeting at least 20 business days prior to the meeting in order to facilitate their entry into the building. All attendees are required to present government-issued identification prior to entry.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2020-28919 Filed 12-30-20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the National Advisory Council on Nurse Education and Practice

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

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the National Advisory Council on Nurse Education and Practice (NACNEP) will hold public meetings for the 2021 calendar year (CY). Information about NACNEP, agendas, and materials for these meetings can be found on the NACNEP website at <https://www.hrsa.gov/advisory-committees/nursing/index.html>.

DATES: NACNEP meetings will be held on

- March 9, 2021, 8:30 a.m.–5:00 p.m. Eastern Time (ET) and March 10, 2021, 8:30 a.m.–2:00 p.m. ET;
- July 13, 2021, 8:30 a.m.–5:00 p.m. ET and July 14, 2021, 8:30 a.m.–5:00 p.m. ET;
- December 7, 2021, 8:30 a.m.–5:00 p.m. ET and December 8, 2021, 8:30 a.m.–5:00 p.m. ET.

ADDRESSES: Meetings may be held in-person, by teleconference, and/or Adobe Connect webinar. For updates on how the meeting will be held, visit the NACNEP website 30 business days before the date of the meeting, where instructions for joining meetings either in-person or remotely will also be posted. In-person NACNEP meetings will be held at 5600 Fishers Lane, Rockville, Maryland 20857. For meeting