4. *Healthcare Safety and Quality Improvement Research (HSQR)*
   Date: October 10–11th, 2019 (Open from 7:30 a.m. to 8:00 a.m. on October 10th and closed for remainder of the meeting)
5. *Healthcare Information Technology Research (HITR)*
   Date: October 24th, 2019 (Open from 8:00 a.m. to 8:30 a.m. on October 24th and closed for remainder of the meeting)

Agenda items for these meetings are subject to change as priorities dictate.

Virginia L. Mackay-Smith,

Associate Director, AHRQ.

[FR Doc. 2019–18928 Filed 8–30–19; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2019–0077]

Draft Guideline for Prevention and Control of Infections in Neonatal Intensive Care Unit Patients: Draft Recommendations for the Prevention and Control of Staphylococcus aureus in Neonatal Intensive Care Unit Patients

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment.

SUMMARY: The Centers for Disease Control and Prevention (CDC), in the Department of Health and Human Services (HHS), announces the opening of a docket to obtain comment on the *Draft Guideline for Prevention and Control of Infections in Neonatal Intensive Care Unit Patients: Draft Recommendations for the Prevention and Control of* Staphylococcus aureus *in Neonatal Intensive Care Unit Patients* (''*Draft Guideline*''). The *Draft Guideline* provides new, evidence-based recommendations specific to the prevention and control of *Staphylococcus aureus* (*S. aureus*), including methicillin-resistant *S. aureus* (MRSA) and methicillin-sensitive *S. aureus* (MSSA), in neonatal intensive care unit (NICU) patients.

DATES: Written comments must be received on or before November 4, 2019.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2019–0077, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Division of Healthcare Quality Promotion, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention, Attn: Docket No. CDC–2019–0077, HICPAC Secretariat, 1600 Clifton Rd. NE, Mailstop A07, Atlanta, Georgia 30329.

Instructions: Submissions via *http://regulations.gov* are preferred. All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *http://regulations.gov,* including any personal information provided. For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Kendra Cox, Division of Healthcare Quality Promotion, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop A–07, Atlanta, Georgia 30329; Telephone: (404) 639–4000.

SUPPLEMENTARY INFORMATION:

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data.

Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on *https://www.regulations.gov.* Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. CDC will carefully consider all comments submitted in preparation of the final *Guideline for Prevention and Control of Infections in Neonatal Intensive Care Unit Patients* and may revise the final document as appropriate.

Background

The *Draft Guideline,* located in the ''Supporting & Related Material'' tab of the docket, provides new, evidence-based recommendations specific to the prevention and control of *S. aureus,* including MRSA and MSSA, in NICU patients, including active surveillance testing and decolonization.

The *Draft Guideline* is intended for use by infection prevention staff, healthcare epidemiologists, healthcare administrators, nurses, neonatologists, other healthcare providers, and persons responsible for developing, implementing, and evaluating infection prevention and control programs for NICUs. The guideline can also serve as a resource for societies or organizations to develop more detailed implementation guidance for the prevention of infection in NICU patients.

The Healthcare Infection Control Practices Advisory Committee (HICPAC) worked with national partners, academicians, public health professionals, healthcare providers, and other partners to develop this *Draft Guideline.* HICPAC includes representatives from public health, infectious diseases, regulatory and other federal agencies, professional societies, and other stakeholders.

The draft recommendations in this *Draft Guideline* are informed by a systematic review of the best available literature through February 2017 and of relevant references published since February 2017 suggested by subject matter experts. The Appendix, located in the ''Supporting & Related Material'' tab of the docket, contains search strategies, Evidence Tables containing study-level data examined, and GRADE Tables which aggregate the overall strength and direction of the evidence.

This *Draft Guideline* will not be a federal rule or regulation.

Dated: August 28, 2019.

Sandra Cashman,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2019–18907 Filed 8–30–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3240]

List of Bulk Drug Substances for Which There is a Clinical Need Under Section 503B of the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is