

0077, Quality Assurance Requirements, in all correspondence related to this collection. Comments received generally will be posted without change to <http://www.regulations.gov>, including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check [www.regulations.gov](http://www.regulations.gov), approximately two-to-three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

**FOR FURTHER INFORMATION CONTACT:** Ms. Marilyn Chambers, Procurement Analyst, at 202–285–7380 or email [marilyn.chambers@gsa.gov](mailto:marilyn.chambers@gsa.gov).

**SUPPLEMENTARY INFORMATION:**

**A. OMB control number, Title, and any Associated Form(s)**

9000–0077, Quality Assurance Requirements.

**B. Needs and Uses**

Supplies and services acquired under Government contracts must conform to the contract's quality and quantity requirements. FAR Part 46 prescribes inspection, acceptance, warranty, and other measures associated with quality requirements. Standard inspection clauses require the contractor to provide and maintain an inspection system that is acceptable to the Government; give the Government the right to make inspections and test while work is in process; and require the contractor to keep complete, and make available to the Government, records of its inspection work. FAR clause 52.246–15, Certificate of Conformance, is not an inspection clause, but a requirement for the contractor to certify that supplies or services furnished are of the quality specified and conform in all respects with the contract requirements.

**C. Annual Burden**

**1. Inspection Clauses**

The FAR inspection clauses are used for quality assurance depending on the type of contract and the type of product or service being provided. The corresponding quality/inspection systems the contractors are required to implement have requirements for record keeping and in some cases documenting the quality or inspection system. These clauses do not require the transmittal or sending of documentation to the Government. Instead, the Government may review these records to confirm the contract quality requirements are being met. Definitive information was not available on how often the Government requests to see these records. The time

required to provide the records is estimated as follows:

*Respondents:* 1,590.

*Total Annual Responses:* 1,590.

*Total Burden hours:* 1,590.

**2. Certificate of Conformance**

FAR clause 52.246–15 is used in solicitations and contracts for supplies or services at the discretion of the contracting officer when it is in the Government's interest, small losses would be incurred in the event of a defect; or because of the contractor's reputation or past performance, it is likely that the supplies or services furnished will be acceptable and any defective work would be replaced, corrected, or repaired without contest. The clause requires the contractor to submit a prescribed certificate. The time required to submit the certificate is estimated as follows:

*Respondents:* 639.

*Total Annual Responses:* 639.

*Total Burden hours:* 320.

**D. Public Comment**

A 60-day notice published in the **Federal Register** at 84 FR 28813 on June 20, 2019. No comments were received.

*Obtaining Copies:* Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW, Washington, DC 20405, telephone 202–501–4755. Please cite OMB Control No. 9000–0077, Quality Assurance Requirements, in all correspondence.

Dated: August 27, 2019.

**Janet Fry,**

*Director, Federal Acquisition Policy, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.*

[FR Doc. 2019–18906 Filed 8–30–19; 8:45 am]

**BILLING CODE 6820–EP–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Agency for Healthcare Research and Quality**

**Notice of Meetings**

**AGENCY:** Agency for Healthcare Research and Quality (AHRQ), HHS.

**ACTION:** Notice of Five AHRQ subcommittee meetings.

**SUMMARY:** The subcommittees listed below are part of AHRQ's Health Services Research Initial Review Group Committee. Grant applications are to be reviewed and discussed at these

meetings. Each subcommittee meeting will commence in open session before closing to the public for the duration of the meeting.

**DATES:** See **SUPPLEMENTARY INFORMATION** for meeting dates of the individual subcommittees.

**ADDRESSES:** Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, Maryland 20852.

**FOR FURTHER INFORMATION CONTACT:** (to obtain a roster of members, agenda or minutes of the non-confidential portions of the meetings.) Heather Phelps, Acting Committee Management Officer, Office of Extramural Research Education and Priority Populations, Agency for Healthcare Research and Quality (AHRQ), 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 427–1128.

**SUPPLEMENTARY INFORMATION:** In accordance with section 10 (a)(2) of the Federal Advisory Committee Act (5 U.S.C. App. 2), AHRQ announces meetings of the above-listed scientific peer review groups, which are subcommittees of AHRQ's Health Services Research Initial Review Group Committees. Each subcommittee meeting will commence in open session before closing to the public for the duration of the meeting. The subcommittee meetings will be closed to the public in accordance with the provisions set forth in 5 U.S.C. App. 2 section 10(d), 5 U.S.C. 552b(c)(4), and 5 U.S.C. 552b(c)(6). The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

The meeting dates for the subcommittees are:

1. *Healthcare Effectiveness and Outcomes Research (HEOR)*  
*Date:* October 9th, 2019 (Open from 8:00 a.m. to 8:30 a.m. on October 9th and closed for remainder of the meeting)
2. *Health System and Value Research (HSVR)*  
*Date:* October 16th, 2019 (Open from 8:00 a.m. to 8:30 a.m. on October 16th and closed for remainder of the meeting)
3. *Health Care Research and Training (HCRT)*  
*Date:* October 17–18th, 2019 (Open from 8:00 a.m. to 8:30 a.m. on October 17th and closed for remainder of the meeting)

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