committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2023–21567 Filed 9–29–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2023–0080]

Guidelines for the Use of Doxycycline Post-Exposure Prophylaxis for Bacterial Sexually Transmitted Infection (STI) Prevention; Request for Comment and Informational Presentation

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

ACTION: Notice with comment period.

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 proposed guidelines for the use of doxycycline post-exposure prophylaxis (PEP) for prevention of bacterial sexually transmitted infections (STI). The proposed guidelines for bacterial STI prevention include post-exposure prophylaxis with doxycycline (doxycycline PEP) because it has demonstrated benefit in reducing chlamydia, gonorrhea, and syphilis infections and represents a new approach to addressing STI prevention in populations at increased risk for these infections. Doxycycline PEP, when offered, should be implemented in the context of a comprehensive sexual health approach including risk reduction counseling, STI screening and treatment, recommended vaccination, and linkage to HIV pre-exposure prophylaxis (PrEP), HIV care, or other services, as appropriate. The purpose of the proposed guidelines is to provide updated clinical guidance for healthcare providers to inform the use of doxycycline PEP for preventing bacterial STI infections. CDC has made available a pre-recorded informational presentation to provide information about the studies considered when developing the proposed guideline, explain the public comment process, and provide an overview of important monitoring for antibiotic use and antibiotic resistance that the agency will be considering to address potential risks.

DATES: Written comments must be received on or before November 16, 2023. An Informational Presentation has been pre-recorded and is available at *https://npin.cdc.gov/.*

ADDRESSES: You may submit comments, identified by Docket No. CDC–2023–0080 by either of the methods listed below. Do not submit comments by email. CDC does not accept comments by email.

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* [Division of STD Prevention, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop US12–2, Atlanta, GA 30329, Attn: Docket No. CDC–2023–0080].

Instructions: 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.*

The informational presentation can be accessed at *https://npin.cdc.gov/.*

FOR FURTHER INFORMATION CONTACT: John R. Papp, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop U12–3, Atlanta, GA 30329; Telephone: 404–639–8000; Email: *jwp6@cdc.gov.*

SUPPLEMENTARY INFORMATION: CDC's proposed guidelines for the use of post-exposure prophylaxis with doxycycline for bacterial STI prevention in the United States is available under the Supporting and Related Materials tab in the docket for this notice, Docket No. CDC–2023–0080, on *http://www.regulations.gov.*

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data. In addition, CDC invites comments specifically on the following questions proposed in this Notice:

- Based on the evidence presented in the full guidelines document (see the Supporting and Related Materials tab in the docket), does the evidence support the proposed guidelines for the use of post-exposure prophylaxis with doxycycline for bacterial STI prevention, including but not limited to risks and benefits? If not, please state the reason why and, if available, provide additional evidence for consideration.
- Are CDC's proposed guidelines for the use of post-exposure prophylaxis with doxycycline bacterial STI prevention clearly written? If not, what changes do you propose to make it clear?
- If implemented as currently drafted, do you believe the proposed guidelines for the use of post-exposure prophylaxis with doxycycline for bacterial STI prevention would result in improved prevention of bacterial STIs in the United States? If not, please provide an explanation and supporting data or evidence.
- How can these proposed guidelines most effectively reach and be received by populations who would benefit from this intervention?

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.

Background

Incidence of sexually transmitted infections (STIs) caused by *Neisseria gonorrhoeae* (causative agent of gonorrhea), *Chlamydia trachomatis* (causative agent of chlamydia), and *Treponema pallidum* (causative agent of syphilis) continues to increase in the United States. Novel approaches are needed to address the STI epidemic, especially for populations disproportionately affected (1). Post-exposure prophylaxis (PEP) involves taking a medication to prevent an infection after a possible exposure and is a common strategy for prevention of HIV and other infections. PEP is a form of chemoprophylaxis and distinct from pre-exposure prophylaxis (PrEP) which involves taking a medication before exposure occurs. Doxycycline, a broad-spectrum tetracycline antibiotic, is used as pre- or post-exposure prophylaxis to prevent infections such as malaria and Lyme disease (2). Doxycycline is well

absorbed and tolerated, with a half-life of approximately 12 hours (3). Adverse effects most associated with doxycycline are photosensitivity and gastrointestinal symptoms including esophageal erosion and ulceration (4). Most adverse effects resolve when the medication is stopped. Doxycycline is the recommended treatment regimen for chlamydia and an alternative treatment for syphilis in non-pregnant patients with severe penicillin allergy or when penicillin is not available (5).

The 2021 CDC STI Treatment Guidelines included a systematic review of the available literature on STI PEP and concluded that further studies were necessary to determine whether it would be an effective strategy for bacterial STI prevention (5). Since that time, promising results from several randomized trials on doxycycline PEP indicated the need to re-address this topic (6, 7). The new guidelines will offer an important resource for healthcare providers to inform the use of doxycycline PEP for preventing bacterial STI infections. CDC plans to use multiple surveillance systems to monitor impacts of the proposed guidelines including potential impacts on antibiotic use and antibiotic resistance in both STI and non-STI pathogens.

All comments received will be carefully reviewed and considered. The proposed guidelines are also undergoing peer review. All comments will be addressed in the final guidelines and the proposed guidelines will be revised as appropriate. CDC will publish another notice announcing the availability of the final guidelines.

References

1. STI National Strategic Plan, 2021–2025 [internet]. Available from: *www.hhs.gov/programs/topic-sites/sexually-transmitted-infections/plan-overview/index.html.*
2. Nadelman RB, Nowakowski J, Fish D, Falco RC, Freeman K, McKenna D, et al. Prophylaxis with single-dose doxycycline for the prevention of Lyme disease after an Ixodes scapularis tick bite. N Engl J Med. 2001 Jul 12;345(2):79–84.
3. Peyriere H, Makinson A, Marchandin H, Reynes J. Doxycycline in the management of sexually transmitted infections. J Antimicrob Chemother. 2018 Mar 1;73(3):553–63.
4. Sloan B, Scheinfeld N. The use and safety of doxycycline hyclate and other second-generation tetracyclines. Expert Opin Drug Saf. 2008 Sep;7(5):571–7.
5. Workowski K, Bachmann L, Chan P, Johnston C, Muzny C, Park I, et al. Sexually Transmitted Infections Treatment Guidelines, 2021. MMWR. 2021; 70:1–187.
6. Luetkemeyer AF, Donnell D, Dombrowski JC, Cohen S, Grabow C, Brown CE, et al. Postexposure Doxycycline to Prevent Bacterial Sexually Transmitted Infections. N Engl J Med. 2023 Apr 6;388(14):1296–306.
7. Jean-Michel Molina, Beatrice Bercot, Lambert Assoumou, Algarte-Genin Michele, Emma Rubenstein, Gilles Pialoux, et al. ANRS 174 DOXYVAC: An Open-Label Randomized Trial to Prevent STIs in MSM on PrEP. CROI [internet]. 2023 Feb 19; Seattle, Washington. Available from: *https://www.croiconference.org/abstract/anrs-174-doxyvac-an-open-label-randomized-trial-to-prevent-stis-in-msm-on-prep/.*

Dated: September 27, 2023.

Kathryn L. Wolff,

Chief of Staff, Centers for Disease Control and Prevention.

[FR Doc. 2023–21725 Filed 9–29–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–R–26, CMS–R–185, CMS–116, CMS–2746 and CMS–10261]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice; partial withdrawal.

SUMMARY: On Monday, September 25, 2023, the Centers for Medicare & Medicaid Services (CMS) published a notice document entitled, ''Agency Information Collection Activities: Submission for OMB Review; Comment Request.'' That notice invited public comments on five separate information collection requests, under Document Identifiers: CMS–R–26, CMS–R– 185, CMS–116, CMS–2746 and CMS–10261. Through the publication of this document, we are withdrawing the portion of the notice requesting public comment on the information collection request titled, ''Clinical Laboratory Improvement Amendments (CLIA) Regulations.'' Form number: CMS–R–26 (OMB control number: 0938–0612). We are also withdrawing the portion of the notice requesting public comment on the information collection request titled, ''Granting and Withdrawal of Deeming Authority to Private Nonprofit Accreditation Organizations and CLIA Exemption Under State Laboratory Programs.'' Form number: CMS–R–185 (OMB control number 0938–0686).

DATES: The original comment period for the document that published on September 25, 2023, remains in effect and ends October 25, 2023.

SUPPLEMENTARY INFORMATION:

In FR document, 2023–20739, published on September 25, 2023 (88 FR 65689), we are withdrawing item 1 '' Clinical Laboratory Improvement Amendments (CLIA) Regulations'' which begins on page 65689. We are also withdrawing item 2 '' Granting and Withdrawal of Deeming Authority to Private Nonprofit Accreditation Organizations and CLIA Exemption Under State Laboratory Programs.'' which begin on page 65690. These items were published in error. Both items will be republished at a later date, thereby providing the public a full 30-day comment period as required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Dated: September 27, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2023–21669 Filed 9–29–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3443–FN]

Medicare and Medicaid Programs; Application From the Center for Improvement in Healthcare Quality for Initial CMS Approval of Its Psychiatric Hospital

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces our decision to approve the Center for Improvement in Healthcare Quality (CIHQ) as a national accrediting organization (AO) for psychiatric hospitals that wish to participate in the Medicare or Medicaid programs.

DATES: The decision announced in this notice is applicable on November 1, 2023 through November 1, 2027.

FOR FURTHER INFORMATION CONTACT: Donald Howard, (410) 786–6764 or Lillian Williams, (410) 786–8636.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services from a psychiatric hospital