

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](http://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-doxycycline-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

provided certain requirements established by the Secretary of the Department of Health and Human Services (the Secretary) are met. Section 1861(f) of the Social Security Act (the Act) establishes distinct criteria for facilities seeking designation as a psychiatric hospital under Medicare. Regulations concerning provider agreements and supplier approval are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488. The regulations at 42 CFR part 482 subpart A, B, C, and E, specify the minimum conditions that a psychiatric hospital must meet to participate in the Medicare program, the scope of covered services, and the conditions for Medicare payment for psychiatric hospitals.

Generally, to enter into a provider agreement with the Medicare program, a psychiatric hospital must first be certified by a State Survey Agency as complying with the conditions or requirements set forth in part 482 subpart A, B, C, and E of our regulations. Thereafter, the psychiatric hospital is subject to regular surveys by a State Survey Agency to determine whether it continues to meet the Medicare requirements. There is an alternative, however, to surveys by State agencies. Certification by a nationally recognized accreditation program can substitute for ongoing State review.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by an approved national accrediting organization (AO) that all applicable Medicare conditions are met or exceeded, we may treat the provider entity as having met those conditions, that is, we may “deem” the provider entity as having met the requirements. Accreditation by an AO is voluntary and is not required for Medicare participation.

If an AO is recognized by the Secretary as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body’s approved program may be deemed to meet the Medicare conditions. A national AO applying for approval of its accreditation program under part 488, subpart A, must provide CMS with reasonable assurance that the AO requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the approval of AOs are set forth at § 488.5. The regulations at § 488.5(e)(2)(i) require the AO to reapply for continued approval of its

accreditation program every 6 years or sooner as determined by CMS.

## II. Application Approval Process

Section 1865(a)(2) of the Act and our regulations at § 488.5 require that our findings concerning review and approval of an AO’s requirements consider, among other factors, the applying AO’s requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities that were not in compliance with the conditions or requirements; and their ability to provide us with the necessary data for validation.

Section 1865(a)(3)(A) of the Act provides a statutory timetable to ensure that our review of applications for CMS approval of an accreditation program is conducted in a timely manner. The Act provides us 210 days after the date of receipt of a complete application, with any documentation necessary to make the determination, to complete our survey activities and application process. Within 60 days after receiving a complete application, we must publish a notice in the **Federal Register** that identifies the national accrediting body making the request, describes the request, and provides no less than a 30-day public comment period. At the end of the 210-day period, we must publish a notice in the **Federal Register** approving or denying the application.

## III. Provisions of the Proposed Notice

On May 22, 2023 **Federal Register** (88 FR 32772), we published a proposed notice announcing CIHQ’s request for approval of its Medicare psychiatric hospital accreditation program. In the proposed notice, we detailed our evaluation criteria. In accordance with section 1865(a)(2) of the Act and regulations at § 488.5, we conducted a review of CIHQ’s Medicare psychiatric hospital accreditation application in accordance with the criteria specified by our regulations, which include, but are not limited to the following:

- *An onsite administrative review of CIHQ’s:* (1) Corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its psychiatric hospital surveyors; (4) ability to investigate and respond appropriately to complaints against accredited psychiatric hospitals; and (5) survey review and decision-making process for accreditation.

- The comparison of CIHQ’s Medicare psychiatric hospital accreditation program standards to our

current Medicare hospitals Conditions of Participation (CoPs) and psychiatric hospital special CoPs.

- A documentation review of CIHQ’s psychiatric hospital survey process to do the following:

- ++ Determine the composition of the survey team, surveyor qualifications, and CIHQ’s ability to provide continuing surveyor training.

- ++ Compare CIHQ’s processes to those we require of State Survey Agencies, including periodic re-survey and the ability to investigate and respond appropriately to complaints against accredited psychiatric hospitals.

- ++ Evaluate CIHQ’s procedures for monitoring psychiatric hospitals it has found to be out of compliance with CIHQ’s program requirements. (This pertains only to monitoring procedures when CIHQ identifies non-compliance. If noncompliance is identified by a State Survey Agency through a validation survey, the State Survey Agency monitors corrections as specified at § 488.9(c)(1)).

- ++ Assess CIHQ’s ability to report deficiencies to the surveyed hospital and respond to the psychiatric hospital’s plan of correction in a timely manner.

- ++ Establish CIHQ’s ability to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization’s survey process.

- ++ Determine the adequacy of CIHQ’s staff and other resources.

- ++ Confirm CIHQ’s ability to provide adequate funding for performing required surveys.

- ++ Confirm CIHQ’s policies with respect to surveys being unannounced.

- ++ Confirm CIHQ’s policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions.

- ++ Obtain CIHQ’s agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as we may require, including corrective action plans.

- ++ As authorized under § 488.8(h), CMS reserves the right to conduct onsite observations of accrediting organization operations at any time as part of the ongoing review and continuing oversight of an AO’s performance.

In accordance with section 1865(a)(3)(A) of the Act, the May 22, 2023 proposed notice also solicited public comments regarding whether CIHQ’s requirements met or exceeded the Medicare CoPs for psychiatric

hospitals. No comments were received in response to the proposed notice.

#### IV. Provisions of the Final Notice

##### A. Differences Between CIHQ's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements

We compared CIHQ's psychiatric hospital accreditation program requirements and survey process with the Medicare CoPs at 42 CFR part 482 subpart A, B, C and E, and the survey and certification process requirements of parts 488 and 489. Our review and evaluation of CIHQ's psychiatric hospital application, which were conducted as described in section III of this final notice, yielded the following areas where, as of the date of this final notice, CIHQ has revised its standards and certification processes in order to meet the requirements at § 488.26(b). CIHQ revised its requirements to provide additional guidance and instruction to surveyors on determining the appropriate level of citation for Life Safety Code deficiencies.

##### B. Term of Approval

Based on our review and observations described in section III of this final notice, we have determined that CIHQ's psychiatric hospital accreditation program requirements meet or exceed our requirements, and its survey processes are also comparable. Therefore, we approve CIHQ as a national AO for psychiatric hospitals that request participation in the Medicare program, effective November 1, 2023 through November 1, 2027.

#### V. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Chyana Woodyard, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: September 22, 2023.

**Chyana Woodyard,**

*Federal Register Liaison, Centers for Medicare & Medicaid Services.*

[FR Doc. 2023–21724 Filed 9–29–23; 8:45 am]

**BILLING CODE P**

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Centers for Medicare & Medicaid Services

[CMS–9892–N]

##### Meeting Date for Ground Ambulance and Patient Billing (GAPB) Advisory Committee—October 31 and November 1, 2023

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

**ACTION:** Notice of meeting.

**SUMMARY:** This notice announces that the date for the third public meeting of the Ground Ambulance and Patient Billing (GAPB) Advisory Committee is October 31, 2023 and November 1, 2023. The GAPB Advisory Committee will make recommendations with respect to the disclosure of charges and fees for ground ambulance services and insurance coverage, consumer protection and enforcement authorities of the Departments of Labor, Health and Human Services, and the Treasury (the Departments) and relevant States, and the prevention of balance billing to consumers. The recommendations shall address options, best practices, and identified standards to prevent instances of balance billing; steps that can be taken by State legislatures, State insurance regulators, State attorneys general, and other State officials as appropriate, consistent with current legal authorities regarding consumer protection; and legislative options for Congress to prevent balance billing.

**DATES:**

*Virtual Meeting Date:* The GAPB Advisory Committee will hold a virtual meeting on Tuesday, October 31, 2023 and Wednesday, November 1, 2023 from 9:30 a.m. to 5:30 p.m., Eastern Daylight Time.

*Registration Link:* The virtual meeting will be open to the public and held via the Zoom webinar platform. Virtual attendance information will be provided upon registration. To register for this virtual meeting, please visit: [https://priforum.zoomgov.com/webinar/register/WN\\_n40NyMM\\_QOu3UFXuI1IWTw](https://priforum.zoomgov.com/webinar/register/WN_n40NyMM_QOu3UFXuI1IWTw). Attendance is open to the public subject to any technical or capacity limitations.

*Deadline for Registration:* All individuals who plan to attend the virtual public meeting must register to attend. The deadline to register for the public meeting is Monday, October 30, 2023. Interested parties are encouraged to register as far in advance of the meeting as possible.

A detailed agenda and materials will be available prior to the meeting on the GAPB Advisory Committee website at: <https://www.cms.gov/medicare/regulations-guidance/advisory-committees/ground-ambulance-patient-billing-gapb>.

A recording and a summary of the meeting will be made available on the GAPB Advisory Committee website approximately 45 calendar days after the meeting.

**ADDRESSES:** *Virtual Meeting Location:* The October 31, 2023 and November 1, 2023 public meeting will be held virtually via Zoom only.

**FOR FURTHER INFORMATION CONTACT:** Shaheen Halim, (410) 786–0641 or via email at [gapbadvisorycommittee@cms.hhs.gov](mailto:gapbadvisorycommittee@cms.hhs.gov).

Press inquiries may be submitted by phone at (202) 690–6145 or via email at [press@cms.hhs.gov](mailto:press@cms.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

#### I. Background

Section 117(a) of the No Surprises Act, enacted as part of the Consolidated Appropriations Act, 2021, div. BB, tit. I, Public Law 116–260 (December 27, 2020), requires the Secretaries of Labor, Department of Health and Human Services (HHS), and the Treasury to establish and convene an advisory committee for the purpose of reviewing options to improve the disclosure of charges and fees for ground ambulance services, better inform consumers of insurance options for such services, and protect consumers from balance billing. The Ground Ambulance and Patient Billing (GAPB) Advisory Committee is governed by the provisions of the Federal Advisory Committee Act (FACA), Public Law 92–463 (October 6, 1972), as amended, 5 U.S.C. app. 2. Information on past and current Committee activity can be found at: <https://www.cms.gov/medicare/regulations-guidance/advisory-committees/ground-ambulance-patient-billing-gapb>.