nonparticipating hospital that does not have an agreement in effect with the Centers for Medicare and Medicaid Services. These payments can be made if such services were emergency services and if CMS would be required to make the payment if the hospital had an agreement in effect and met the conditions of payment. This form is used in connection with claims for emergency hospital services provided by hospitals that do not have an agreement in effect under Section 1866 of the Social Security Act.

42 CFR 424.103(b) requires that before a non-participating hospital may be paid for emergency services rendered to a Medicare beneficiary, a statement must be submitted that is sufficiently comprehensive to support that an emergency existed. Form CMS–1771 contains a series of questions relating to the medical necessity of the emergency. The attending physician must attest that the hospitalization was required under the regulatory emergency definition (*42 CFR 424.101* attached) and give clinical documentation to support the claim. A photocopy of the beneficiary's hospital records may be used in lieu of the CMS–1771 if the records contain all the information required by the form.; *Form Number:* CMS–1771 (OMB Control Number: 0938–0023); *Frequency:* Annually; *Affected Public:* Private Sector, Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 100; *Number of Responses:* 200; *Total Annual Hours:* 50. (For policy questions regarding this collection contact Shauntari Cheely at 410–786–1818.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2026–07634 Filed 4–17–26; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10950]

Agency Information Collection Activities: Proposed Collection; Comment Request

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

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by June 22, 2026.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. Electronically. You may send your comments electronically to *http://www.regulations.gov*. Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. By *regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier: __/OMB Control Number: __, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing*.

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* New collection (Request for a OMB control number); *Title of Information Collection:* Submissions of Acute Hospital Care at Home (AHCAH) Waiver Submission and Data Collection; *Use:* This information collection request was approved under OMB control number of 0938–1384. The AHCAH information collection request is being separated from the 1135 waiver information collection request. The Acute Hospital Care at Home initiative has been codified in legislation, Consolidate Appropriations Act, 2025, and is no longer under the 1135 waiver authority. Any changes to this document would be based on the legislative authority and not based on an 1135 waiver.

Acute Hospital Care at Home is a waiver initiative established by CMS on November 23, 2020 in response to the unprecedented strain on hospital capacity due to the severe national increase in coronavirus disease 2019 (COVID–19) witnessed. This waiver, which is granted at the individual hospital/CMS Certification Number (CCN) level, waives § 482.23(b) and (b)(1) of the Hospital Conditions of Participation (CoPs) which require nursing services to be provided on premises 24 hours a day, 7 days a week and the immediate availability of a registered nurse for care of any patient. In exchange for this flexibility, hospitals will utilize models of at-home hospital care that have seen prior success in several leading hospital institutions and networks. This care and its results have been reported in leading academic

journals, including a major study funded by a Healthcare Innovation Award from the Center for Medicare and Medicaid Innovation (CMMI). This extensive research has shown that quality and safety are at least as high as that received by similar patients admitted to traditional brick and mortar hospitals.

This program clearly differentiates the delivery of acute hospital care at home from traditional home health services. Home health care provides important skilled nursing and other services, Acute Hospital Care at Home is for beneficiaries who require acute inpatient admission to a hospital and who require at least daily rounding by a physician and medical team monitoring their care needs on an ongoing basis. A minimum of two in-person visits will occur daily by either registered nurses or mobile integrated health paramedics, based on the patient's nursing plan and hospital policies. Hospitals may only treat patients with this waiver if they are admitted from their Emergency Department or if they are transferred from inpatient hospital beds. There is no payment change, and hospitals are not permitted to bill Medicare or its beneficiaries for any costs outside of a typical inpatient admission.

CMS is seeking to obtain continued OMB approval for information. All approved hospitals have submitted this information via an online portal at *CMS QualityNet* the previously mentioned website. To date, 433 hospitals individual hospitals/CCNs have submitted waiver requests and 396 of these hospitals have been approved. At this time, 65 hospitals have completed the online expedited waiver request, and 331 hospitals have completed the online detailed waiver request. When a hospital submits a waiver request, it completes one of two online forms found on the waiver landing page, depending on its level of experience with this type of care. Experienced hospitals, defined as treating at least 25 patients with acute hospital care at home previously, have an expedited submission that is based on a series of attestations. Additionally, all hospitals with an approved waiver are asked to submit data for patient admissions and discharges, escalations of care back to the brick-and-mortar hospital, and unexpected patient mortalities to CMS on a monthly (Tier 1) or weekly (Tier 2). This data is submitted voluntarily through the same online portal as the waiver submission and is not a requirement of ongoing participation in the Waiver. Of note, without further Congressional action, this waiver submission process will end September 30, 2030. *Form Number:* CMS–10950 (OMB control number: 0938–NEW); *Frequency:* Occasionally; *Affected Public:* Private Sector: Business or other for-profits and Not-for-profit institutions and State, Local or Tribal Governments; *Number of Respondents:* 1,947; *Total Annual Responses:* 1,947; *Total Annual Hours:* 1,947. (For policy questions regarding this collection, contact Danielle Adams at 410–786–8818.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2026–07583 Filed 4–17–26; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–D–6130]

Establishing Impurity Specifications for Antibiotics; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft guidance for industry entitled ''Establishing Impurity Specifications for Antibiotics.'' The draft guidance provides recommendations regarding the establishment of specifications for organic impurities in antibiotics manufactured by fermentation and semi-synthesis. This draft guidance applies to antibiotic drugs subject to approval under new drug applications (NDAs) and abbreviated new drug applications (ANDAs) and associated type II drug substance drug master files (DMFs) referenced in antibiotic NDAs and ANDAs. This guidance also applies to nonprescription antibiotic drugs, often referred to as over-the-counter (OTC) monograph drugs. By providing these recommendations, FDA intends to clarify effective control strategies, support the development of high-quality antibiotic products, and promote consistency in quality standards.

DATES: Submit either electronic or written comments on the draft guidance by June 22, 2026. to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions''.

Instructions: All submissions received must include the Docket No. FDA–2025–D–6130 for ''Establishing Impurity Specifications for Antibiotics.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states