Information Collection: Medicare Part C and Part D Data Validation (42 CFR 422.516(g) and 423.514(j)); *Use:* This ''Medicare Part C and Part D Data Validation (42 CFR 422.516(g) and 423.514(j))'' forms will be used by Data Validation Contractors (DVCs) to evaluate the quality of data submitted by plans for the Medicare Parts C and D Reporting Requirements. The Centers for Medicare and Medicaid Services (CMS) established reporting requirements for Medicare Part C and Part D sponsoring organizations (Medicare Advantage Organizations [MAOs], Cost Plans, and Medicare Part D sponsors) under the authority described in 42 CFR 422.516(a) and 423.514(a), respectively. Under these reporting requirements, each sponsoring organization must submit Medicare Part C, Medicare Part D, or Medicare Part C and Part D data; *Form Number:* CMS–10305 (OMB control number: 0938–1115); *Frequency:* Yearly; *Affected Public:* Businesses or other for-profits; *Number of Respondents:* 840; *Total Annual Responses:* 840; *Total Annual Hours:* 10,920. (For policy questions regarding this collection contact Bindu Aryal at 667–414–0889 or *bindu.aryal@cms.hhs.gov.*)

William N. Parham, III,

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

[FR Doc. 2025–17019 Filed 9–4–25; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–4211–FN]

Medicare Program; Approved Renewal of Deeming Authority of the Utilization Review Accreditation Commission (URAC) for Medicare Advantage Health Maintenance Organizations and Local Preferred Provider Organizations

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

ACTION: Final notice.

SUMMARY: This final notice announces the Centers for Medicare & Medicaid Services decision to renew the Utilization Review Accreditation Commission's application for Medicare Advantage ''deeming authority'' of Health Maintenance Organizations and Preferred Provider Organizations for a term of 6 years.

DATES:

Effective Date: The notice is effective on October 13, 2025.

Applicability Date: The approval communicated in this notice is applicable July 10, 2025 through July 10, 2031.

FOR FURTHER INFORMATION CONTACT: Dawn Johnson Scott, (410) 786–3159 or Katie Schenck, (410) 786–0628.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services through a Medicare Advantage (MA) organization that contracts with the Center for Medicare & Medicaid Services (CMS). The regulations specifying the Medicare requirements that must be met for a Medicare Advantage organization (MAO) to enter into a contract with CMS are located at 42 CFR 422.503(b). These regulations implement Part C of Title XVIII of the Social Security Act (the Act), which specifies the services that an MAO must provide and the requirements that the organization must meet to be an MA contractor. Generally, for an entity to be an MAO, the organization must be licensed under State law, or otherwise authorized to operate under State law, as a risk bearing organization, as set forth in 42 CFR 422.400.

As a method of assuring compliance with certain Medicare requirements, an MAO may choose to become accredited by a CMS-approved accreditation organization (AO). By virtue of its accreditation by a CMS-approved AO, the MAO may be ''deemed'' compliant in one or more requirements set forth in section 1852(e)(4)(B) of the Act. For CMS to recognize an AO's accreditation program as establishing an MA plan's compliance with our requirements, the AO must, as set forth in § 422.157(a)(1), prove to CMS that their standards are at least as stringent as Medicare requirements for MAOs. MAOs that are licensed as health maintenance organizations (HMOs) or preferred provider organizations (PPOs) and are accredited by an approved AO may receive, at their request, ''deemed'' status for our requirements for the deemable areas. These areas include Quality Improvement, Anti-Discrimination, Confidentiality and Accuracy of Enrollee Records, Information on Advance Directives, and Provider Participation Rules.

At this time, we do not recognize accreditation of the following areas: Access to Services set out in § 422.156(b)(3) or the Part D areas of review set out at § 423.165(b) as part of the MA deeming program. AOs that apply for MA deeming authority are generally recognized by the health care industry as entities that accredit HMOs and PPOs. As specified at § 422.157(b)(2)(ii), the term for which an AO may be approved by CMS may not exceed 6 years. For continuing approval, the AO must apply to CMS to renew their deeming authority for a subsequent approval period.

The Utilization Review Accreditation Commission (URAC) was previously approved by CMS as an accreditation organization for MA deeming of HMOs and PPOs for a term from May 31, 2019 to June 2, 2025. On March 14, 2025, URAC submitted its initial application to renew its deeming authority, including materials requested by us that included information intended to address the requirements set out in regulations at §§ 422.158(a) and (b) that are prerequisites for receiving approval of its accreditation program.

II. Provisions of the Proposed Notice

In the May 16, 2025 **Federal Register** (90 FR 21041), we published a proposed notice announcing URAC's request to renew its Medicare Advantage deeming authority for HMOs and PPOs. In the May 16, 2025 proposed notice, we detailed our evaluation criteria. Under section 1852(e)(4) of the Act and § 422.158 (Federal review of accrediting organizations), we conducted a review of URAC's application in accordance with the criteria specified by our regulations which include, but are not limited to the following:

- The types of MA plans that it would review as part of its accreditation process.
- A detailed comparison of URAC's accreditation requirements and standards with the Medicare requirements (for example, a crosswalk) in the following five deemable areas: (1) Quality Improvement; (2) Anti-Discrimination; (3) Confidentiality and Accuracy of Enrollee Records; (4) Information on Advance Directives; and (5) Provider Participation Rules.
- Detailed information about the organization's survey process, including—

++ Frequency of surveys and whether surveys are announced or unannounced.

++ Copies of survey forms, and guidelines and instructions to surveyors.

++ Descriptions of—

—The survey review process and the accreditation status decision making process.

—The procedures used to notify accredited MAOs of deficiencies and to monitor the correction of those deficiencies.

—The procedures used to enforce compliance with accreditation requirements.

• Detailed information about the individuals who perform surveys for the AO, including—

++ The size and composition of accreditation survey teams for each type of plan reviewed as part of the accreditation process.

++ The education and experience requirements surveyors must meet.

++ The content and frequency of the in-service training provided to survey personnel.

++ The evaluation systems used to monitor the performance of individual surveyors and survey teams.

++ The organization's policies and practice for participation, in surveys or in the accreditation decision process, by an individual who is professionally or financially affiliated with the entity being surveyed.

• A description of the organization's data management and analysis system for its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system.

• A description of the organization's procedures for responding to and investigating complaints against accredited organizations, including policies and procedures regarding coordination of these activities with appropriate licensing bodies and ombudsmen programs.

• A description of the organization's policies and procedures for the withholding or removal of accreditation for failure to meet the AO's standards or requirements, and other actions the organization takes in response to noncompliance with its standards and requirements.

• A description of all types (for example, full, partial) and categories (for example, provisional, conditional, temporary) of accreditation offered by the organization, the duration of each type and category of accreditation and a statement identifying the types and categories that would serve as a basis for accreditation if CMS approve the AO.

• A list of all currently accredited MAOs and the type, category, and expiration date of the accreditation held by each of them.

• A list of all full and partial accreditation surveys scheduled to be performed by the AO.

• The name and address of each person with an ownership or control interest in the AO.

• CMS also considered URAC's past performance in the deeming program and results of recent deeming validation reviews or equivalency reviews conducted as part of continuing Federal oversight of the deeming program under § 422.157(d).

In accordance with section 1865(a)(3)(A) of the Act, the May 16, 2025 proposed notice solicited public comments regarding whether URAC's requirements met or exceeded the Medicare conditions of participation as an accrediting organization for MA HMOs and PPOs.

III. Analysis of and Responses to Public Comments on the Proposed Notice

We received no public comments on the proposed notice.

IV. Provisions of the Final Notice

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

We compared the standards and survey process contained in URAC's application with the Medicare conditions for accreditation. Our review and evaluation of URAC's application for our continued approval were conducted as described in section II. of this final notice, and yielded the following:

• Under § 422.158(a)(2), URAC submitted a crosswalk and standards that clearly cross-walked to our regulations, and any applicable oversight protocols, in each of five deemable areas: (1) Quality Improvement; (2) Anti-discrimination; (3) Confidentiality and Accuracy of Enrollee Records; (4) Information on Advance Directives: and (5) Provider Participation rules.

• URAC submitted additional information and/or documentation regarding its survey process that was intended to address our regulations at §§ 422.158(a)(1) through (11), and (b)(1) through (3).

B. Term of Approval

Based on the review and observations described in section II. of this final notice, we have determined that URAC's accreditation program requirements meet or exceed our requirements. Therefore, we approved URAC as a national accreditation organization with deeming authority for MA HMOs and PPOs on July 10, 2025 for a term of approval to continue through July 10, 2031. We informed URAC of their renewal via a letter dated July 10, 2025.

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), Mehmet Oz, having reviewed and approved this document, authorizes Trenesha Fultz-Mimms, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Trenesha Fultz-Mimms,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2025–17037 Filed 9–4–25; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0734]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Manufactured Food Regulatory Program Standards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by October 6, 2025.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0601. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD