

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services**

[CMS-4188-FN]

Medicare Program; Approved Renewal of Deeming Authority of the Utilization Review Accreditation Commission for Medicare Advantage Health Maintenance Organizations and Local Preferred Provider Organizations**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.**ACTION:** Final notice.

SUMMARY: This notice announces our decision to renew the Medicare Advantage “deeming authority” of the Utilization Review Accreditation Commission (URAC) for health maintenance organizations and preferred provider organizations for a term of 6 years.

DATES: The renewal announced in this notice is effective on May 31, 2019 through June 2, 2025.

FOR FURTHER INFORMATION CONTACT: Greg McDonald, (410) 786-8941; or Nick Proy, (410) 786-8407.

SUPPLEMENTARY INFORMATION:**I. Background**

Under the Medicare program, eligible beneficiaries may receive covered services through a Medicare Advantage (MA) organization that contracts with 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 part 422. 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. Other relevant sections of the Act are Parts A and B of Title XVIII and Part A of Title XI pertaining to the provision of services by Medicare certified providers and suppliers. Generally, for an entity to be an MA organization, the organization must be licensed by the state as a risk bearing organization, as set forth in 42 CFR part 422.

As a method of assuring compliance with certain Medicare requirements, an MA organization may choose to become accredited by a CMS-approved accrediting organization (AO). By virtue of its accreditation by a CMS-approved AO, the MA organization 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 prove to CMS that its standards are at least as stringent as Medicare requirements for MA organizations. MA organizations that are licensed as health maintenance organizations (HMOs) or preferred provider organizations (PPOs) and are accredited by an approved accrediting organization may receive, at their request, deemed status for CMS requirements with respect to the deemeable areas. At this time, recognition of accreditation does not include the Part D areas of review set out at 42 CFR 423.165(b). AOs that apply for MA deeming authority are generally recognized by the health care industry as entities that accredit HMOs and PPOs. As we specify 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 approved as a CMS-approved accreditation organization for MA deeming of HMOs and PPOs on May 26, 2012, and that term lapsed on May 25, 2018, prior to our decision on its renewal application. On October 13, 2017, URAC submitted an application to renew its deeming authority. On that same date, URAC submitted materials requested by CMS that included information intended to address the requirements set out at § 422.158(a) through (b) that are prerequisites for receiving approval of its accreditation program from CMS. CMS subsequently requested that additional materials, including revisions, be submitted by URAC to satisfy these requirements. URAC submitted all the necessary materials to enable us to make a determination concerning its request for approval as an accreditation organization, and the renewal application was determined to be complete on November 8, 2018.

II. Provisions of the Proposed Notice

In the December 26, 2018 **Federal Register** (83 FR 66271), we published a proposed notice announcing URAC’s request to renew its Medicare Advantage deeming authority for HMOs and PPOs. In the December 26, 2018 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 the AO’s accreditation requirements and standards with the Medicare requirements (for example, a crosswalk) in the following 5 areas: Quality Improvement, Anti-Discrimination, Confidentiality and Accuracy of Enrollee Records, Information on Advance Directives, and 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 MA organizations of deficiencies and to monitor the correction of those deficiencies; and

- The procedures used to enforce compliance with accreditation requirements.

- Detailed information about the individuals who perform surveys for the accreditation organization, 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; and

- ++ The organization’s policies and practice with respect to the 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 with respect to 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 with respect to the withholding or removal of accreditation for failure to meet the accreditation organization'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 approves the accreditation organization.
- A list of all currently accredited MA organizations 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 accreditation organization.
- The name and address of each person with an ownership or control interest in the accreditation organization.
- CMS also considers URAC's past performance in the deemинг program and results of recent deemинг validation reviews, or look-behind audits conducted as part of continuing federal oversight of the deemинг program under § 422.157(d).

In accordance with section 1865(a)(3)(A) of the Act, the December 26, 2018 proposed notice (83 FR 66271) also 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. We received no public comments in response to the December 26, 2018 proposed notice (83 FR 66271).

III. 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 continued CMS approval were conducted as described in section II. of this final notice, and yielded the following:

- URAC amended its crosswalk to ensure current URAC standards are

clearly cross-walked to our regulations, including the following regulatory requirements for Quality Improvement; Antidiscrimination, Confidentiality and Accuracy of Enrollee Records, Information on Advanced Directives, and Provider Participation Rules: §§ 422.101(f); 422.205(b); 422.110(a) through (b); 422.118(a); 422.128(b); 422.152(a) and (b), (e) through (g); 422.202(a) through (d); 422.206(a) through (b); 422.208(c), (e) through (g); 422.210(b); 422.212(a) through (d); and 422.216(f) through (h).

- URAC submitted additional information and/or documentation regarding its survey process that was intended to address: § 422.158(a)(2), (a)(3)(ii), (a)(3)(iii)(A) through (C), (a)(4)(ii) and (iii), (a)(6) through (10), and (b)(2).

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 approve URAC as a national accreditation organization with deemинг authority for MA HMOs and PPOs, effective May 21, 2019.

V. Collection of Information Requirements

This notice announces the new term of approval for the URAC. It does not impose any 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.*).

VI. Regulatory Impact Statement

In accordance with the provisions of Executive Order 12866, this regulation was not reviewed by the Office of Management and Budget.

Dated: May 2, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0801]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Exports; Notification and Recordkeeping Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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: Fax written comments on the collection of information by June 20, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0482. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Lansdown St., North Bethesda, MD 20852, 301-796-7726, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Exports; Notification and Recordkeeping Requirements—21 CFR 1.101

OMB Control Number 0910-0482—Extension

Section 801 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381) charges the Secretary of Health and Human Services, through FDA, with the responsibility of helping to ensure that exports of unapproved new drugs, biologics, devices, animal drugs, food, cosmetics, and tobacco products which are not to be sold in the United States