

other forms of information technology, e.g., permitting electronic submissions of responses; and
5. Assess information collection costs.

Proposed Project

The National Firefighter Registry (NFR) for Cancer (OMB Control No. 0920-1348, Exp. 9/30/2024)—Revision—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In order to accurately monitor trends in cancer incidence and evaluate control measures among the U.S. fire service, Congress passed the Firefighter Cancer Registry Act of 2018. Under this legislation, CDC/NIOSH was directed to create a registry of U.S. firefighters for the purpose of monitoring cancer incidence and risk factors among the

current U.S. fire service. Funding for the project was authorized through this legislation for five years as of fiscal year 2019.

According to the Firefighter Cancer Registry Act of 2018, the main goal of the National Firefighter Registry (NFR) for Cancer is to develop and maintain . . . a voluntary registry of firefighters to collect relevant health and occupational information of such firefighters for purposes of determining cancer incidence. Results from the NFR will provide information for decision makers within the fire service and medical or public health community to devise and implement policies and procedures to lessen cancer risk and/or improve early detection of cancer among firefighters. Revisions to this collection include an update of the estimated annualized time burden and occupational wage information to reflect

current earnings based on the U.S. Bureau of Labor Statistics for 2022 and a more accurate number of respondents based on the first year of project enrollment. Additionally, minor updates to the enrollment questionnaire were made to improve readability and the overall user experience.

The below table outlines the estimated time burden for participants enrolling in the NFR. There are three corresponding documents to be completed as part of the enrollment process; the Informed Consent, User Profile, and Enrollment Questionnaire. The estimated time burden for the Informed Consent and User Profile are five minutes each, and an estimated twenty-minute burden for enrollment questionnaire. CDC requests OMB approval for an estimated 17,221 burden hours. There are no costs to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondents | Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total burden (in hours) |
|---------------------|--|-----------------------|------------------------------------|--|-------------------------|
| U.S. Firefighters | Informed Consent | 33,333 | 1 | 5/60 | 2,783 |
| U.S. Firefighters | NFR User Profile (web-portal registration) | 33,333 | 1 | 5/60 | 2,783 |
| U.S. Firefighters | NFR Enrollment Questionnaire | 33,333 | 1 | 20/60 | 11,111 |
| U.S. Firefighters | Records request | 34 | 1 | 960/60 | 544 |
| Total | | | | | 17,221 |

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS 3452-FN]

Medicare Program; Application by the Utilization Review Accreditation Commission (URAC) for Continued CMS Approval of Its Home Infusion Therapy (HIT) Accreditation Program

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

ACTION: Final notice.

SUMMARY: This final notice announces our decision to approve the Utilization Review Accreditation Commission (URAC) for continued recognition as a

national accrediting organization that accredits suppliers of home infusion therapy (HIT) services that wish to participate in the Medicare or Medicaid programs.

DATES: The approval announced in this final notice is effective March 27, 2024 through March 27, 2030.

FOR FURTHER INFORMATION CONTACT: Shannon Freeland, (410) 786-4348.

SUPPLEMENTARY INFORMATION:

I. Background

Home infusion therapy (HIT) is a treatment option for Medicare beneficiaries with a wide range of acute and chronic conditions. Section 5012 of the 21st Century Cures Act (Pub. L. 114-255, enacted December 13, 2016) added section 1861(iii) to the Social Security Act (the Act), establishing a new Medicare benefit for HIT services. Section 1861(iii)(1) of the Act defines “home infusion therapy” as professional services, including nursing services; training and education not otherwise covered under the Durable Medical Equipment (DME) benefit; remote monitoring; and other monitoring services. Home infusion therapy must

be furnished by a qualified HIT supplier and furnished in the individual’s home. Sections 1861(iii)(A) and (B) of the Act require that the individual (patient) must:

- Be under the care of an applicable provider (that is, physician, nurse practitioner, or physician assistant); and
- Have a plan of care established and periodically reviewed by a physician in coordination with the furnishing of home infusion drugs under Part B, which prescribes the type, amount, and duration of infusion therapy services that are to be furnished.

Section 1861(iii)(3)(D)(i)(III) of the Act requires that a qualified HIT supplier be accredited by an accrediting organization (AO) designated by the Secretary in accordance with section 1834(u)(5) of the Act.

Section 1834(u)(5)(A) of the Act identifies factors for designating HIT AOs and in reviewing and modifying the list of designated HIT AOs. These statutory factors are as follows:

- The ability of the accrediting organization to conduct timely reviews of HIT accreditation applications.

- The ability of the accrediting organization to take into account the capacities of HIT suppliers located in a rural area (as defined in section 1886(d)(2)(D) of the Act).

- Whether the accrediting organization has established reasonable fees to be charged to HIT suppliers applying for accreditation.

- Such other factors as the Secretary determines appropriate.

Section 1834(u)(5)(B) of the Act requires the Secretary to designate AOs to accredit HIT suppliers furnishing HIT no later than January 1, 2021. Section 1861(iii)(3)(D)(i)(III) of the Act requires a “qualified home infusion therapy supplier” to be accredited by a CMS-approved AO, pursuant to section 1834(u)(5) of the Act.

The Utilization Review Accreditation Commission’s (URAC’s) current term of approval for their Home Infusion Therapy accreditation program expires March 27, 2024.

II. Approval of Deeming Organization

Section 1834(u)(5) of the Act and regulations at 42 CFR 488.1010 require that our findings concerning review and approval of a national accrediting organization’s requirements consider, among other factors, the applying accrediting organization’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 found not in compliance with the conditions or requirements; and ability to provide CMS with the necessary data.

Our rules at 42 CFR 488.1020(a) require that we publish, after receipt of an organization’s complete application, a notice identifying the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period. Pursuant to our rules at 42 CFR 488.1010(d), we have 210 days from the receipt of a complete application to publish notice of approval or denial of the application.

III. Provisions of the Proposed Notice

In the November 9, 2023 **Federal Register** (88 FR 77321), we published a proposed notice announcing the URAC’s request for continued recognition as a national accrediting organization for suppliers providing home infusion therapy (HIT) services that wish to participate in the Medicare or Medicaid programs. In that proposed notice, we detailed our evaluation criteria. Under section 1834(u)(5) of the Act and in our regulations at 42 CFR

488.1010, we conducted a review of URAC’s Medicare HIT accreditation application in accordance with the criteria specified by our regulations, which include, but are not limited to, the following:

- An administrative review of URAC’s:
 - ++ Corporate policies;
 - ++ Financial and human resources available to accomplish the proposed surveys;
 - ++ Procedures for training, monitoring, and evaluation of its HIT surveyors;
 - ++ Ability to investigate and respond appropriately to complaints against accredited HITs; and
 - ++ Survey review and decision-making process for accreditation.

- The equivalency of URAC’s standards for HIT as compared with CMS’ HIT conditions for participation.

- URAC’s survey process to determine the following:
 - ++ The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training;
 - ++ The comparability of URAC’s to CMS’ standards and processes, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities;
 - ++ URAC’s processes and procedures for monitoring a HIT supplier found out of compliance with URAC’s program requirements;
 - ++ URAC’s capacity to report deficiencies to the surveyed HIT facilities and respond to the facility’s evidence of standards compliance in a timely manner;
 - ++ URAC’s capacity to provide CMS with electronic data and reports necessary for effective assessment and interpretation of the organization’s survey process;
 - ++ URAC’s capacity to adequately fund required surveys;
 - ++ URAC’s policies with respect to whether surveys are announced or unannounced, to ensure that surveys are unannounced; and
 - ++ URAC’s agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as CMS may require (including corrective action plans or URAC’s evidence of standards compliance).

- The adequacy of URAC’s staff and other resources, and its financial viability.
- URAC’s agreement or policies for voluntary and involuntary termination of suppliers.

- URAC’s agreement or policies for voluntary and involuntary termination of the HIT AO program.

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

In accordance with section 1834(u)(5) of the Act, the November 9, 2023, proposed notice also solicited public comments regarding whether URAC’s requirements met or exceeded the Medicare conditions for participation for HIT. No comments were received in response to our proposed notice.

V. Provisions of the Final Notice

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

We compared URAC’s HIT accreditation requirements and survey process with the Medicare Conditions for Coverage of 42 CFR part 486, and the survey and certification process requirements of part 488. Our review and evaluation of URAC’s HIT application, which were conducted as described in section III. of this final notice, yielded the following areas where, as of the date of this notice, URAC has completed revising its standards and certification processes to meet the conditions at §§ 486.500 to 486.525.

- Section 486.520(a), to address the requirement of all patients must be under the care of an applicable provider.

- Section 486.520(b), to address the requirement that the plan of care must be established by a physician prescribing the type, amount, and duration for HIT.

- Section 486.520(c), to address the requirement that the plan of care must be periodically reviewed by the physician.

- Section 486.525(a), to address the requirement that the HIT suppliers to be available 7 days a week, 24 hours a day basis in accordance with the plan of care.

- Section 486.525(a)(1), to provide professional services, including nursing services.

- Section 486.525(a)(2), to address the requirement for patient education and training to be available for patients on a 7 day a week, 24 hour a day basis in accordance with the plan of care.

- Section 486.525(a)(3), to address the requirement of remote monitoring for the provision of HIT and home infusion drugs.

- Section 486.525(b), to address the requirement of all home infusion therapy suppliers must provide home

infusion therapy services in accordance with nationally recognized standards of practice, and in accordance with all applicable State and Federal laws and regulations.

B. Term of Approval

Based on the review and observations described in section III. of this final notice, we have determined that URAC's requirements for HITs meet or exceed our requirements. Therefore, we approve URAC as a national accreditation organization for HITs that request participation in the Medicare program, effective March 27, 2024 through March 27, 2030.

VI. 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. chapter 35).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, 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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for Office of Management and Budget (OMB) Review; Interstate Administrative Subpoena and Notice of Lien (Office of Management and Budget OMB #: 0970-0152)

AGENCY: Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families (ACF) is requesting a 3-year extension with proposed revisions to the Interstate Administrative Subpoena and Notice of Lien forms (Office of Management and Budget #0970-0152, expiration 6/30/2024). The forms are updated to reflect the name change of the Federal child support program office from the Office of Child Support Enforcement to the Office of Child Support Services.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular

information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function. You can also obtain copies of the proposed collection of information by emailing infocollection@acf.hhs.gov. Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The Administrative Subpoena is used by State child support agencies to obtain income and other financial information regarding noncustodial parents for purposes of establishing, enforcing, and modifying child support orders. The Notice of Lien imposes liens in cases with overdue support and allows a State child support agency to file liens across State lines, when it is more efficient than involving the other State's IV-D agency.

Section 452(a)(11) of the Social Security Act requires the Secretary of the Department of Health and Human Services to promulgate forms for administrative subpoenas and imposition of liens used by State child support agencies in interstate cases. Section 454(9)(E) of the Social Security Act requires each State to cooperate with any other State in using the Federal forms for issuance of administrative subpoenas and imposition of liens in interstate child support cases.

Respondents: State, local, or Tribal agencies administering a child support program under title IV-D of the Social Security Act.

ANNUAL BURDEN ESTIMATES

| Instrument | Annual number of respondents | Annual number of responses per respondent | Average burden hours per response | Annual burden hours |
|-------------------------------|------------------------------|---|-----------------------------------|---------------------|
| Administrative Subpoena | 54 | 462 | .5 | 12,474 |
| Notice of Lien | 54 | 29,762 | .5 | 803,574 |

Estimated Total Annual Burden Hours: 816,048.

Authority: 42 U.S.C. 652; 42 U.S.C. 654.

Mary C. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-2343]

Hazard Analysis and Risk-Based Preventive Controls for Human Food; Draft Guidance for Industry; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA, we, or the Agency) is extending the comment period for two chapters of a multichapter draft guidance entitled "Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry," which were announced in the **Federal Register** of September 27, 2023. The relevant draft chapters are entitled "Chapter 11—