- § 418.56(c)(2), to address the requirement the frequency of services necessary to meet the specific patient and family needs.
- § 418.110(c)(1), to require an inpatient hospice to address real or potential threats to the health and safety of the patients, others, and property.
- § 418.110)(d)(1)(i), to address the requirement that hospice must meet applicable provisions and must proceed in accordance with the Life Safety Code (National Fire Protection Association (NFPA) 101 and Tentative Interim amendments TIA 12–1, TIA 12–2, TIA 12–3 and TIA 12–4.)
- § 418.110(d)(5), to address the requirement when a sprinkler system is shut down for more than 10 hours.
- § 418.110(d)(5)(i), to address the requirement to evacuate the building or portion of the building affected by the system outage until the system is back in service.
- § 418.110(d)(5)(ii), to address the requirement to establish a fire watch until the system is back in service.
- § 418.110(d)(6), to require both existing and new buildings to have an outside window or door in every sleeping room and, for any building constructed after July 5, 2016, to require that the sill height must not exceed 36 inches above the floor.
- § 418.110(e), to address the requirement that except as otherwise provided in this section, the hospice must meet the applicable provisions and must proceed in accordance with the Health Care Facilities Code (NFPA 99 and Tentative Interim Amendments TIA 12–2, TIA 12–3, TIA 12–4, TIA 12–5 and TIA 12–6).
- § 418.11(e)(1), to address the requirement that Chapters 7, 8, 12, and 13 of the adopted Health Care Facilities Code do not apply to a hospice.
- § 418.110(e)(2), to address the requirement that if application of the Health Care Facilities Code required under paragraph (e) of this section would result in unreasonable hardship for hospice, CMS may waive specific provisions of the Health Care Facilities Code, but only if the waiver does not adversely affect the health and safety of patients.
- § 418.110(q) through § 418.110(q)(1)(xi), address the requirement that the standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C 552(a) and 1 CFR part 51.

B. Term of Approval

Based on our review and observations described in section III of this final notice, we approve ACHC as a national accreditation organization for hospices that request participation in the Medicare program, effective November 27, 2019 through November 27, 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. 35 *et seq.*).

Dated: November 5, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2019–25429 Filed 11–22–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3390–PN]

Medicare Program; Application From Accreditation Commission for Health Care for Initial CMS-Approval of Its Home Infusion Therapy Accreditation Program

AGENCY: Centers for Medicare and Medicaid Services, HHS.

ACTION: Notice with request for comment.

SUMMARY: This proposed notice acknowledges the receipt of an application from Accreditation Commission for Health Care for initial recognition as a national accrediting organization for suppliers of home infusion therapy services that wish to participate in the Medicare program. The statute requires that within 60 days of receipt of an organization's complete application, the Centers for Medicare & Medicaid Services (CMS) publish a notice that identifies the national accrediting body making the request, describes the nature of the request, and provides at least a 30-day public comment period.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on December 26, 2019.

ADDRESSES: In commenting, please refer to file code CMS–3390–PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3390–PN, P.O. Box 8016,Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3390–PN, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Christina Mister-Ward, (410)786–2441 Lillian Williams, (410)786–8636.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov* . Follow the search instructions on that website to view public comments.

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. The individual 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, that 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 AOs and in reviewing and modifying the list of designated AOs. These statutory factors are as follows:

• The ability of the organization to conduct timely reviews of accreditation applications.

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

• Whether the organization has established reasonable fees to be charged to 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 not 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, under section 1834(u)(5) of the Act.

On March 1, 2019, we published a solicitation notice entitled, ''Medicare Program; Solicitation of Independent Accrediting Organizations To Participate in the Home Infusion Therapy Supplier Accreditation Program'' (84 FR 7057). This notice informed national AOs that accredit HIT suppliers of an opportunity to submit applications to participate in the HIT supplier accreditation program. We stated that complete applications would be considered for the January 1, 2021 designation deadline if received by February 1, 2020.

Regulations for the approval and oversight of AOs for HIT organizations are located at 42 CFR part 488, subpart L. The requirements for HIT suppliers are located at 42 CFR part 486, subpart I.

II. Approval of Accreditation Organizations

Section 1834(u)(5) of the Act and the regulations at § 488.1010 require that our findings concerning review and approval of a national 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 found not in compliance with the conditions or requirements; and ability to provide CMS with the necessary data.

Section 488.1020(a) requires 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. In accordance with § 488.1010(d), we have 210 days from the receipt of a complete application to publish notice of approval or denial of the application.

The purpose of this proposed notice is to inform the public of Accreditation Commission for Health Care's (ACHC's) initial request for CMS's approval of its HIT accreditation program. This notice also solicits public comment on whether ACHC's requirements meet or exceed the Medicare conditions of participation for HIT services.

III. Evaluation of Deeming Authority Request

ACHC submitted all the necessary materials to enable us to make a determination concerning its request for initial approval of its HIT accreditation program. This application was determined to be complete on September 26, 2019. Under section 1834(u)(5) of the Act and § 488.1010 (Application and re-application procedures for national HIT AOs), our review and evaluation of ACHC will be conducted in accordance with, but not necessarily limited to, the following factors:

• The equivalency of ACHC's standards for HIT as compared with CMS' HIT conditions for certification.

• ACHC'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 ACHC's to CMS standards and processes, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

++ ACHC's processes and procedures for monitoring a HIT supplier found out of compliance with ACHC's program requirements. .

++ ACHC's capacity to report deficiencies to the surveyed supplier and respond to the supplier's plan of correction in a timely manner.

++ ACHC's capacity to provide CMS with electronic data and reports necessary for effective assessment and interpretation of the organization's survey process.

++ The adequacy of ACHC's staff and other resources, and its financial viability.

++ ACHC's capacity to adequately fund required surveys.

++ ACHC's policies with respect to whether surveys are announced or unannounced, to assure that surveys are unannounced.

++ ACHC'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).

• ACHC's agreement or policies for voluntary and involuntary termination of suppliers.

• ACHC agreement or policies for voluntary and involuntary termination of the HIT AO program.

• ACHC'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.

IV. Collection of Information Requirements

This document does not impose information collection and 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*).

V. Response to Public Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Upon completion of our evaluation, including evaluation of comments received as a result of this notice, we will publish a final notice in the **Federal Register** announcing the result of our evaluation.

Dated: November 4, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2019–25430 Filed 11–22–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Form ACF–196, TANF Financial Reporting Form for States

AGENCY: Office of Family Assistance; Administration for Children and Families; HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF) is requesting to renew approval of the ACF–196 Temporary Assistance for Needy Families (TANF) Financial Reporting Form. The ACF–196 is the form used by states to estimate funding needs and request grant awards under the TANF program. In addition, the form is used to report data in substantiation of state claims and to certify the availability of the legislatively mandated state match. ACF will use the financial data provided by states to estimate quarterly funding needs, calculate award amounts, and assess compliance with statutory and regulatory requirements relating to administrative costs and state matching requirements. No changes are proposed to the form.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: Copies of the proposed collection of information can be obtained and comments may be forwarded by emailing *infocollection@acf.hhs.gov.* Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation (OPRE), 330 C Street SW, Washington, DC 20201, Attn: ACF Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: This information collection is authorized under Section 411(a)(3) of the Social Security Act. This request is for renewal of approval to the ACF–196 form for periodic financial reporting under the TANF program. States participating in the TANF program are required by statute to report financial data on a quarterly basis. This form meets the legal standard and provides essential data on the use of federal funds. Failure to collect the data would seriously compromise ACF's ability to monitor program expenditures, estimate funding needs, and to prepare budget submissions required by Congress. Financial reporting under the TANF program is governed by 45 CFR part 265.

Respondents: TANF Agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
ACF–196	51	4	10	2,040

Estimated Total Annual Burden Hours: 2,040.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: U.S.C. Section 402 of the Social Security Act (42 U.S.C. 602).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–25432 Filed 11–22–19; 8:45 am]

BILLING CODE 4184–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–3592]

Certificates of Confidentiality; Draft Guidance for Sponsors, Sponsor-Investigators, Researchers, Industry, and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance entitled ''Certificates of Confidentiality; Guidance for Sponsors, Sponsor-Investigators, Researchers, Industry, and Food and Drug Administration Staff.'' This draft guidance is intended to explain FDA implementation of the revised statutory provisions applicable to the request for, and issuance of, a Certificate of Confidentiality (CoC). The 21st Century Cures Act (Cures Act) amended the statutory provisions relating to the issuance of CoCs. A CoC is intended to help protect the privacy of human subject research participants from whom sensitive and identifiable information is being collected or used in furtherance of the research. Historically, a CoC generally protected a researcher from being compelled in a legal proceeding to disclose identifiable sensitive information about the research participant, created or compiled for the research. As amended, a CoC prohibits a researcher from disclosing such information unless a specified exception applies.

DATES: Submit either electronic or written comments on the draft guidance by January 9, 2020 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance. Submit electronic or written comments on the proposed information collection burden in the draft guidance by January 24, 2020.

ADDRESSES: You may submit either electronic or written comments on any guidance at any time as follows: