

++ 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 we may require, including corrective action plans.

In accordance with section 1865(a)(3)(A) of the Act, the May 3, 2013 proposed notice also solicited public comments regarding whether ACHC's requirements met or exceeded the Medicare conditions of participation for hospices. We received no comments in response to our proposed notice.

IV. Provisions of the Final Notice

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

We compared ACHC's hospice requirements and survey process with the Medicare conditions of participation and survey process as outlined in the State Operations Manual (SOM). Our review and evaluation of ACHC's hospice application, which were conducted as described in section III of this final notice, yielded the following:

- To meet the requirement at § 418.3(2), ACHC amended its crosswalk and standards to accurately reflect the current regulatory language that the attending physician is identified by the individual, at the time he or she elects to receive hospice care, as having the most significant role in the determination and delivery of the individual's medical care.

- To meet the requirement at § 418.24(c)(3), ACHC amended its preamble to accurately reflect the current regulatory language that an election to receive hospice care will be considered to continue through the initial election period and through the subsequent election periods without a break in care as long as the individual is not discharged from the hospice under the provisions in § 418.26.

- To meet the requirement at § 418.70, ACHC revised its standard to accurately address the care/services provided directly and those provided under arrangement.

- To meet the requirement at § 418.76(c), ACHC revised its standards to address the requirement that hospice aide services can be provided by an individual only after the successful completion of a competency evaluation program.

- To meet the requirement at § 418.78, ACHC revised its standard to reflect that the hospice must use volunteers in defined roles.

- To meet the requirement at § 418.104(d), ACHC revised its standard to reflect that if the hospice discontinues operation, hospice policies must provide for retention and storage of clinical records.

- To meet the requirement at § 418.106(e)(2)(i)(A), ACHC revised its standard to reflect that the hospice will provide a copy of the hospice's written policies and procedures on the management and disposal of controlled drugs to the patient representative.

- To meet the requirement at § 418.106(e)(2)(i)(B), ACHC revised its standard to reflect the discussion of the hospice's policies and procedures managing the safe use and disposal of controlled drugs to the patient representative.

- To meet the requirement at § 418.108(b)(1)(ii), ACHC revised its standard to allow for pain control, symptom management, and respite purposes in a Medicare or Medicaid-certified nursing facility, in addition to a Medicare or Medicaid-certified hospice or hospital that also meets the standards specified in § 418.110(e).

- To meet the requirement at § 418.110(n)(2)(i), ACHC revised its standard to address techniques to identify staff behaviors, events, and environmental factors that may trigger circumstances that require the use of a restraint or seclusion.

- To meet the requirement at § 418.112(c), ACHC provided a clear definition of the management of crisis situations and temporary emergencies.

- To meet the requirement at § 418.202(g), ACHC amended its preamble to accurately reflect the requirement that homemaker services may include assistance in maintenance of a safe and healthy environment and services to enable the individual to carry out the treatment plan.

- To meet the requirements of Appendix M of the SOM, ACHC instituted processes and audits to ensure that the Medicare Enrollment Application Form CMS-855A is verified by the assigned Medicare Administrative Contractor (MAC) prior to conducting an initial survey.

B. Term of Approval

Based on our review and observations described in section III of this final notice, we have determined that ACHC's hospice accreditation program requirements meet or exceed our requirements. Therefore, we approve ACHC as a national accreditation organization for hospices that request participation in the Medicare program,

effective November 27, 2013 through November 27, 2019.

V. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program).

Dated: October 29, 2013.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects:

Title: DRA TANF Final Rule.

OMB No.: 0970-0338.

Description: When the Deficit Reduction Act of 2005 (DRA) reauthorized the Temporary Assistance for Needy Families (TANF) program, it imposed a new data requirement that States prepare and submit data verification procedures and replaced other data requirements with new versions including: the TANF Data Report, the SSP—MOE Data Report, the Caseload Reduction Documentation Process, and the Reasonable Cause/Corrective Compliance Documentation Process. The Continuing Appropriations Act, 2014 (Pub. L. 113-46) provides federal funds to operate Temporary Assistance for Needy Families (TANF) programs in the states, DC, Guam, Puerto Rico, the U.S. Virgin Islands, and for approved federally recognized tribes and Alaskan Native Villages through January 15, 2014. We are proposing to continue these information collections without change.

Respondents: The 50 States of the United States, the District of Columbia, Guam, Puerto Rico, and the Virgin Islands.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Preparation and Submission of Data Verification Procedures §§ 261.60–261.63	54	1	640	34,560
Caseload Reduction Documentation Process, ACF–202 §§ 261.41 & 261.44	54	1	120	6,480
Reasonable Cause/Corrective Compliance Documentation Process §§ 262.4, 262.6, & 262.7; § 261.51	54	2	240	25,920
TANF Data Report Part 265	54	4	2,201	475,416
SSP–MOE Data Report Part 265	29	4	714	82,824

Estimated Total Annual Burden Hours: 625,200.

In compliance with the requirements of Section 506(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. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: infocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

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.

Robert Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1213]

Draft Guidance for Industry: Use of Donor Screening Tests To Test Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products for Infection With *Treponema pallidum* (Syphilis); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled “Guidance for Industry: Use of Donor Screening Tests to Test Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) for Infection with *Treponema pallidum* (Syphilis),” dated October 2013. The draft guidance document provides establishments that make donor eligibility determinations for donors of HCT/Ps (HCT/P Establishments), with updated recommendations concerning donor testing for evidence of *Treponema pallidum* (*T. pallidum*) infection, the etiologic agent of syphilis. HCT/P Establishments must, as required under Federal regulations, test a donor specimen for evidence of *T. pallidum* infection using appropriate FDA-licensed, approved, or cleared donor screening tests, in accordance with the manufacturer's instructions, unless an exception to this requirement applies. The draft guidance clarifies that FDA does not consider diagnostic tests or pre-amendment devices (which have not been licensed, approved, or cleared) to be adequate for use in donor testing for *T. pallidum* infection under the criteria specified in Federal regulations. The recommendations in this guidance, when finalized, will supersede those recommendations for testing HCT/P donors for evidence of *T. pallidum* infection contained in the document entitled “Guidance for Industry:

Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps),” dated August 2007.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 3, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Paul E. Levine, Jr., Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled “Guidance for Industry: Use of Donor Screening Tests to Test Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) for Infection with *Treponema pallidum* (Syphilis),” dated October 2013. The draft guidance document provides HCT/P Establishments with