

A. Components of the Review Process

The review of NCQA's renewal application for approval of MA deeming authority includes, but is not limited to, the following components:

- The types of MA plans that it would review as part of its accreditation process.
- A detailed comparison of NCQA'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 for 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 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 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 will also consider NCQA'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).

B. Notice Upon Completion of Evaluation

Upon completion of our evaluation, including a review of comments received as a result of this proposed notice, we will publish a notice in the **Federal Register** announcing the result of our evaluation. Section 1852(e)(4)(C) of the Act provides a statutory timetable to ensure that our review of deeming applications is conducted in a timely manner. The Act provides us with 210 calendar days after the date of receipt of a completed application to complete our survey activities and application review process. At the end of the 210-day period, we will publish an approval or denial of the application in the **Federal Register**.

III. Collection of Information Requirements

This document does not impose any new or revised "collection of information" requirements or burden. Consequently, there is no need for

review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*). With respect to the PRA and this section of the preamble, collection of information is defined under 5 CFR 1320.3(c) of the PRA's implementing regulations.

IV. Response to 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.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Seema Verma, having reviewed and approved this document, authorizes Lynette Wilson, who is the **Federal Register** Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Lynette Wilson,

Federal Register Liaison, Department of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; State Plan for Grants to States for Refugee Resettlement (OMB #0970-0351)

AGENCY: Office of Refugee Resettlement, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF), Office of Refugee Resettlement (ORR) is requesting a 3-year extension of the ACF form ORR-0135 State Plan for Grants to States for Refugee Resettlement (OMB #0970-0351, expiration 3/31/2021). ORR is proposing changes 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, ACF 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: A State Plan is a required comprehensive narrative description of the nature and scope of a state's or Replacement Designee's (RD) Refugee Resettlement Program and provides assurances that the program will be administered in conformity with the specific requirements stipulated in 45 CFR 400.4–400.9. The State Plan must include all applicable state or RD procedures, designations, and certifications for each requirement as well as supporting documentation. The plan assures ORR that the state or RD is

capable of administering refugee assistance and coordinating employment and other social services for eligible caseloads in conformity with specific requirements.

Changes proposed to the previously approved State Plan for Grants to States for Refugee Resettlement information collection are described below. ORR is proposing:

- Streamlining/formatting changes to multiple sections of the form including technical corrections to regulatory citations and removing a number of requirements related to the now obsolete Wilson-Fish Alternative Program (superseded by the Wilson-Fish TANF Coordination Program, which will have its own separate reporting requirements).
- adding a number of requirements related to Replacement Designees (RDs) to ensure that they are administering the Refugee Resettlement Program with transparency and equity and to the same standard as a state, including quarterly consultation process, Refugee Medical

Assistance, Unaccompanied Refugee Minors (URM), and emergency planning to ensure ORR populations receive all necessary information and services to the extent possible.

- requesting additional information related to the Refugee Support Services (RSS) program; ORR's current template does not provide sufficient detailed information for ORR to ascertain how a grantee intends to provide RSS services to its client base.
- improving the URM section to correct inefficiencies, eliminate unnecessary items, and address the needs of victims of trafficking and Special Immigrant Juveniles now eligible for the URM program. In particular, ORR is soliciting states' and RDs' plans for placing children referred by ORR and ensuring alignment with federal capacity priorities.

Respondents: State agencies and RDs under 45 CFR 400.301(c) administering or supervising the administration of programs.

ANNUAL BURDEN ESTIMATES

| Instrument | Total number of respondents | Total number of responses per respondent | Average burden hours per response | Total burden hours | Annual burden hours |
|--|-----------------------------|--|-----------------------------------|--------------------|---------------------|
| State Plan for Grants to States for Refugee Resettlement | 62 | 3 | 18 | 3,348 | 1,116 |

Estimated Total Annual Burden Hours: 1,116.

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: 8 U.S.C. 1522 of the Immigration and Nationality Act (the Act) [Title IV, Sec. 412 of the Act] for each state agency requesting federal funding for refugee resettlement under 8 U.S.C. 524 [Title IV, Sec. 414 of the Act].

Mary Jones,
ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–2268]

Insanitary Conditions at Compounding Facilities; Guidance for Industry; 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 final guidance for industry entitled “Insanitary Conditions at Compounding Facilities.” Drug products compounded under insanitary conditions could become contaminated and cause serious adverse events, including death, in patients. FDA is issuing this guidance to help compounding facilities and State regulatory agencies understand some examples of what FDA considers to be insanitary conditions that could cause a drug to become contaminated or rendered injurious to health. These examples are intended to help compounding facilities take action to

prevent the occurrence of these and other insanitary conditions, as well as to implement appropriate corrective actions when such conditions already exist.

DATES: The announcement of the guidance is published in the **Federal Register** on November 9, 2020.

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

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such