

responsible for making sure that your comment does not include any sensitive or confidential information. In particular, your comment should not include any sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any "trade secret or any commercial or financial information which . . . is privileged or confidential"—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule § 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled "Confidential," and must comply with FTC Rule § 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. See FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted publicly at www.regulations.gov, we cannot redact or remove your comment unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule § 4.9(c), and the General Counsel grants that request.

The FTC Act and other laws that the Commission administers permit the collection of public comments to

consider and use in this proceeding, as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before August 24, 2020. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see <https://www.ftc.gov/site-information/privacy-policy>.

Josephine Liu,
Assistant General Counsel for Legal Counsel.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Case Plan Requirement, Title IV-E of the Social Security Act, (OMB #0970-0428)

AGENCY: Administration on Children, Youth and Families, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Administration on Children, Youth and Families (ACYF), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is requesting a 3-year extension of the information collection—Case Plan Requirement, Title IV-E of the Social Security Act, (OMB #0970-0428, expiration 3/31/2021). ACF is reporting a change to the information collection—the burden estimates in the previously-approved request were based on the number of children in foster care as the respondent instead of the agency completing the case plan. The burden estimates, therefore, are adjusted accordingly.

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: The case plan information collection is authorized in sections 422(b)(8)(A)(ii) and 471(a)(16), and defined in sections 475 and 475A of the Social Security Act (the Act). Statutory requirements in the Act mandate that states, territories, and tribes with an approved title IV-E plan develop a case plan and case review system for each child in the foster care system for whom the state, territory, or tribe receives title IV-E reimbursement of foster care maintenance payments.

The case review system assures that each child has a case plan designed to achieve placement in a safe setting that is the least restrictive, most family-like setting available and in close proximity to the child's parental home, consistent with the best interest and special needs of the child. States, territories, and tribes meeting these requirements also partly comply with title IV-B, section 422(b), of the Act, which assures certain protections for children in foster care.

The case plan is a written document that provides a narrative description of the child-specific program of care. Federal regulations at 45 CFR 1356.21(g) and sections 475 and 475A of the Act delineate the specific information that must be addressed in the case plan. ACF does not specify a format for the case plan nor does ACF require submission of the document to the federal government. Case plan information is recorded in a format developed and maintained by the state, territorial, or tribal title IV-E agency.

Respondents: State, territorial, and tribal title IV-E agencies.

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
Case Plan	64	26,427	4.8	8,118,374	2,706,125

Estimated Total Annual Burden Hours: 2,706,125.

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: 42 U.S.C. 622; 42 U.S.C. 671; 42 U.S.C. 675.

Mary B. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0589]

Hospital-Acquired Bacterial Pneumonia and Ventilator-Associated Bacterial Pneumonia: Developing Drugs for Treatment; 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 "Hospital-Acquired Bacterial Pneumonia and Ventilator-Associated Bacterial Pneumonia: Developing Drugs for Treatment." The purpose of this final guidance is to help sponsors and investigators in the clinical development of antibacterial drugs for the treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) based on comments that were received and current recommendations. This guidance finalizes the draft guidance of the same title issued on May 7, 2014.

DATES: The announcement of the guidance is published in the **Federal Register** on June 25, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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 as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2010-D-0589 for "Hospital-Acquired Bacterial Pneumonia and Ventilator-Associated Bacterial Pneumonia: Developing Drugs for Treatment." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the

information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillendale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Sunita Shukla, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6334, Silver Spring, MD 20993-0002, 301-796-6406.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled "Hospital-Acquired Bacterial