

Reauthorization Act of 2010 (Pub. L. 111–320, Section 301(b)).

Elizabeth Leo,

Grants Policy Branch Chief, Office of Grants Policy, Office of Administration.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for Office of Management and Budget Review; TANF Contingency Fund Application

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

ACTION: Request for public comments.

SUMMARY: The Office of Family Assistance, Administration for Children and Families (ACF), U.S. Department of Health and Human Services, is

proposing to collect data for state requests of Temporary Assistance for Needy Families (TANF) Contingency Fund provisional payments through the TANF Contingency Fund Application.

DATES: Comments due October 2, 2026.

ADDRESSES: The public may view and comment on this information collection request at: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202608-0970-010. 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 TANF Contingency Fund Application is an optional request for funds submitted by states to ACF. The proposed information collection will standardize the mechanism through which states request provisional payments monthly. To reduce response time and minimize burden hours, the proposed form consolidates guidance and existing resources. The form will require states to demonstrate eligibility, describe how they will fulfill award

requirements, and provide certification by the Governor or official designee. Authority to distribute provisional payments based on receipt of state requests for contingency funds is contained in section 403 of the Social Security Act (42 U.S.C. 603(b)(3), as amended by the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, Public Law 104–193, 110 Stat. 2105. States must submit a new application in the month prior to the month for which they request funds.

Respondents: The 50 states of the United States and the District of Columbia.

Annual Burden Estimates

The TANF Contingency Fund Application for the 50 states and the District of Columbia will create an optional monthly burden with an average of 15 states responding, although up to 50 states and the District of Columbia may be eligible. We estimate the annual burden to be an average of 3 hours per response, with an estimate of 7 responses per respondent each year.

Instrument	Annual number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
TANF Contingency Fund Application	15	7	3	315

Authority: 42 U.S.C. 603(b).

Mary C. Jones,

ACF OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–D–8693]

Pharmacokinetics in Patients With Impaired Hepatic Function: Study Design, Data Analysis, and Impact on Dosage; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry titled “Pharmacokinetics in Patients with Impaired Hepatic Function: Study Design, Data Analysis, and Impact on Dosage.” This guidance assists sponsors in the design and

analysis of studies that assess the influence of hepatic impairment on the pharmacokinetics and, where appropriate, the pharmacodynamics of a drug, including therapeutic biological products. When final, this guidance will represent FDA’s current thinking. FDA is also withdrawing the guidance for industry titled “Pharmacokinetics in Patients with Impaired Hepatic Function: Study Design, Data Analysis, and Impact on Dosing and Labeling” (May 2003), which formerly provided FDA’s thinking relating to studies to assess the effect of hepatic impairment on the pharmacokinetics or pharmacodynamics of a drug and recommendations to include hepatic impairment information in labeling.

DATES: Submit either electronic or written comments on the draft guidance by December 1, 2026 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments 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 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”).