to eligible individuals and entities, as described in Section 1311(i)(2) of the ACA and 45 CFR 155.210(a) and (c), to carry out certain Navigator duties in states with an FFE. Entities or individuals that receive a cooperative agreement award must be capable of carrying out, at a minimum, all Navigator duties required by the ACA and HHS regulations. The primary regulations that establish requirements for Navigator grant awardees are 45 CFR 155.210 and 155.215. Under the terms and conditions of the Navigator program cooperative agreements, awardees must provide progress reports on a weekly, monthly, and quarterly basis, and a final report at the end of the five-year period of performance. *Form Number:* CMS–10463 (OMB control number: 0938–1215); *Frequency:* Annually, Monthly, Quarterly, Weekly; *Affected Public:* Private Sector; Businesses or other for-profits, Not-for-profit institutions; *Number of Respondents:* 44; *Total Annual Responses:* 120,236; *Total Annual Hours:* 457,857. (For questions regarding this collection contact Gian Johnson at 301–492–4323.)

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Data Collection to Support Eligibility Determinations for Small Businesses in the Small Business Health Options Program; *Use:* On March 23, 2010, the President signed into law H.R. 3590, the Patient Protection and Affordable Care Act, Public Law 111–148, as amended by the Health Care and Education Reconciliation Act of 2010, Public Law 111–152. The Patient Protection and Affordable Care Act (PPACA) expands access to health insurance coverage through improvements to the Medicaid and Children's Health Insurance (CHIP) programs, the establishment of Affordable Insurance Exchanges (Exchanges), and the coordination between Medicaid, CHIP, and Exchanges. Small business employers may participate in and provide health coverage through the Small Business Health Options Program (SHOP), so long as the small business employer obtains a positive eligibility determination from SHOP. Employers will work with SHOP-registered agents/brokers or Issuers offering Qualified Health Plans (QHPs) and Qualified Dental Plans (SADPs), to enroll in SHOP coverage and to select coverage options to offer their employees. SHOP Exchanges became operational on October 1, 2013.

HHS has developed a single, streamlined form that employers use to obtain a SHOP eligibility determination, which is included as an appendix to this Information Collection Request. 45 CFR 155.731 provides more detail about this ''single employer application,'' which is used to determine employer eligibility. Since publication of the last package, no updates have been made in regulation concerning what information should be collected on the single employer application to determine employer eligibility under 45 CFR 155.731. When an employer completes the SHOP Eligibility Determination Form, the form and its results are retained by SHOP for future use, if needed (*e.g.,* reconciliation with issuer records, SHOP employer appeals, etc.). *Form Number:* CMS–10439 (OMB control number: 0938–1193); *Frequency:* Annually; *Affected Public:* Private Sector—Business or other for-profits, Not-for-profit institutions; *Number of Respondents:* 2,100; *Number of Responses:* 2,100; *Total Annual Hours:* 336. (For questions regarding this collection, contact Mary Guy at 410–786–2772).

5. *Type of Information Collection Request:* Reinstatement with change of a previously approved information collection; *Title of Information Collection:* State-based Exchange Annual Reporting Tool (SMART); *Use:* The ACA § 1313(a)(1) and its implementing regulations require State Exchanges to keep an accurate accounting of all activities, receipts, and expenditures, and to submit a report annually to CMS concerning such accounting. Instructions governing specific facets of the activities covered by the report are contained both in the ACA and 45 CFR 155.1200, 155.1210. CMS uses the SMART as the reporting tool to ensure compliance with regulatory requirements.

CMS uses the information collected from the SMART to determine if a state is maintaining a compliant, operational Exchange. It also provides a mechanism to collect innovative approaches to meeting challenges encountered by states during the preceding year, as well as to provide information to CMS regarding potential changes in priorities and approaches for the upcoming year. If CMS determines a state to be non-compliant through the review of required documentation, it will issue a formal letter asking the state to develop and submit a Corrective Action Plan (CAP). CMS may also provide technical assistance to help State Exchanges address potential areas of non-compliance, as needed. *Form Number:* CMS–10507 (OMB control number: 0938–1244); *Frequency:* Annually; *Affected Public:* State, Local or Tribal Government; *Number of Respondents:* 23; *Number of Responses:* 23; *Total Annual Hours:* 4,792. (For questions regarding this collection, contact Tiffany Y. Animashaun at *Tiffany.Animashaun@cms.hhs.gov.*)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB #: 0970–0338]

Submission for Office of Management and Budget Review; Caseload Reduction Documentation Process

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 Administration for Children and Families (ACF) is requesting a three-year extension of the form ACF–202: Caseload Reduction Report (Office of Management and Budget (OMB) #0970–0338, expiration October 31, 2026). There are substantive changes requested to the instructions and form.

DATES: The public may view and comment on this information collection request at: *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202511-0970-001.* 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.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. 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: Section 407(b)(3) of the Social Security Act requires ACF to reduce a state's required work participation rate for a fiscal year (FY)

by the state's caseload reduction credit for that FY. 42 U.S.C. 607(b)(3). The caseload reduction credit gives a state credit for reducing its caseload between a base year and a comparison year. 42 U.S.C. 607(b)(3)(A). States submit data for the calculation of their caseload reduction credit by completing form ACF–202. Section 301 of the Fiscal Responsibility Act of 2023 (FRA) recalibrates the caseload reduction credit by amending Section 407(b)(3) of the Social Security Act (42 U.S.C. 607(b)(3)) and changing the base-year caseload from FY 2005 to FY 2015. The FRA, Public Law 118–15, § 301 (2023), 137 Stat. 34. ACF proposes to revise the Caseload Reduction Documentation Process as required by the FRA by striking ''2005'' and inserting ''2015.'' Fiscal Responsibility Act of 2023, Public Law 118–15, § 301 (2023), 137 Stat. 34. There are additional minor changes to the instructions and form to update the reporting due date for FY 2026, update submission and general instructions, and change 'State' to lowercase, where applicable.

Respondents: State TANF agencies.

Annual Burden Estimates: The following table includes all information collections currently approved under this OMB #. This revision request only proposes changes to the content of the second row: *Caseload Reduction Credit Documentation Process, Form ACF–202 §§ 261.41 & 261.44.* Burden estimates have been revised to reflect that states spend less time on revisions than initial submissions, and that not all states submit each form each year.

Instrument	Total number of respondents	Total number of responses per respondent (over 3 years)	Average burden hours per response	Total burden (over 3 years)	Annual burden hours
Work Verification Plan §§ 261.60–261.63	10	1	30	900	300
Caseload Reduction Credit Documentation Process, ACF–202 §§ 261.41 & 261.44	54	1	40	6,480	2,160
Reasonable Cause/Corrective Compliance Documentation Process §§ 262.4, 262.6, & 262.7; § 261.51	9	1	240	6,480	2,160
TANF Data Report Part 265	54	4	2,100	1,360,800	453,600
SSP–MOE Data Report—Part 265	29	4	714	248,472	82,824
TANF Sampling and Statistical Methods Manual § 265.5	30	4	48	17,280	5,760
Estimated Total Annual Burden Hours					546,804

Authority: 42 U.S.C. 607(b)(3); Fiscal Responsibility Act of 2023, Public Law 118–5, 301, 137 Stat. 34.

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2025–20397 Filed 11–19–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0605]

Scientific Considerations in Demonstrating Biosimilarity to a Reference Product: Updated Recommendations for Assessing the Need for Comparative Efficacy Studies; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft guidance for industry entitled ''Scientific Considerations in Demonstrating Biosimilarity to a Reference Product: Updated Recommendations for Assessing the Need for Comparative Efficacy Studies.'' This draft guidance describes considerations regarding a comparative clinical study or studies with efficacy endpoints (a comparative efficacy study or CES) intended to support a demonstration that a proposed therapeutic protein product is biosimilar to a reference product for the purpose of submitting a marketing application under the Public Health Service Act (PHS Act).

DATES: Submit either electronic or written comments on the draft guidance by January 20, 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'').

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–2011–D–0605 for ''Scientific Considerations in Demonstrating Biosimilarity to a Reference Product: Updated Recommendations for Assessing the Need for Comparative Efficacy Studies.'' Received comments