

Beneficiary and Family-Centered Care-Quality Improvement Organization (BFCC-QIO) Contracts have been signed with QIOs for their respective geographic areas (which includes all United States & Territories). The second type of QIOs and Quality Innovation Network-QIOs focus on health care quality improvement efforts.

The scope of information collection by the BFCC-QIOs includes the number of Medicare beneficiaries with expedited appeals, reconsideration appeals and Beneficiary Complaint cases which are then reported into the CMS System of Record. Medicare beneficiaries or their appointed representatives have the right to appeal the provider's decision to discharge or end services if beneficiaries believe their Medicare Part A Medicare services (e.g. hospital discharge, skilled nursing home care, home health, etc.) are ending too soon. They also have the right to file a Beneficiary Complaint case when they have concerns about the quality of care they received. *Form Number: CMS-R-70* (OMB control number: 0938-0426); *Frequency: Reporting—On occasion; Affected Public: Business or other for-profits; Number of Respondents: 50,000; Total Annual Responses: 398,388; Total Annual Hours: 521,599.* (For policy questions regarding this collection contact *Malini.Krishnan@cms.hhs.gov*).

4. Type of Information Collection Request: Reinstatement without change of a previously approved collection; **Title of Information Collection:** Information Collection Requirements in 42 CFR 478.18, 478.34, 478.36, 478.42, QIO Reconsiderations and Appeals; **Use:** The Peer Review Improvement Act of 1982 amended Title XI of the Social Security Act to create the Utilization and Quality Control Peer Review Organization (PRO) program. Under this program, a PRO is designated in each State to ensure that care provided to Medicare patients is reasonable, medically necessary, and of a quality that meets professionally recognized standards of care. A **Federal Register** notice dated May 24, 2002, renamed the PROs as Quality Improvement Organizations (QIOs).

Beneficiary and Family-Centered Care-Quality Improvement Organization (BFCC-QIO) Contracts have been signed

with QIOs for their respective geographic areas (which includes all United States & Territories). The second type of QIOs are Quality Innovation Network-QIOs, and focus on health care quality improvement efforts.

The scope of this information collection includes that from the BFCC-QIOs for the number of Medicare beneficiary level 2 appeals. Medicare beneficiaries or their appointed representatives have the right to appeal the provider's decision to discharge or end services if beneficiaries believe that their Medicare Part A Medicare services (e.g. hospital discharge, skilled nursing home care, home health, etc.) are ending too soon. Medicare beneficiaries have the right to file a reconsideration of a BFCC-QIO appeals review determination. *Form Number: CMS-R-72* (OMB control number: 0938-0443); *Frequency: Reporting—On occasion; Affected Public: Individuals or Households and Business or other for-profit institutions; Number of Respondents: 20,129; Total Annual Responses: 60,729; Total Annual Hours: 22,014.* (For policy questions regarding this collection contact *Malini.Krishnan@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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SUMMARY: The Office of Child Support Enforcement (OCSE) is requesting a 3-year extension of the Provision of Services in Intergovernmental IV-D; Federally Approved Forms (Office of Management and Budget (OMB) #0970-0085, expiration February 28, 2026). There are no changes requested to these forms.

DATES: *Comments due December 22, 2025.*

ADDRESSES: The public may view and comment on this information collection request at: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202511-0970-004. 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: Public Law 113-183, the Preventing Sex Trafficking and Strengthening Families Act amends section 466(f) of the Social Security Act, requiring all states to enact any amendments to the Uniform Interstate Family Support Act “officially adopted as of September 30, 2008, by the National Conference of Commissioners on Uniform State Laws” (referred to as UIFSA 2008). Section 311(b) of UIFSA requires the states to use forms mandated by federal law. 45 CFR 303.7(a)(4) also requires child support programs to use federally approved forms in intergovernmental IV-D cases unless a country has provided alternative forms.

Respondents: State agencies administering a child support program under title IV-D of the Social Security Act.

Annual Burden Estimates

Annual burden estimates have been updated to reflect a decrease in the nationwide child support case load since the most recent full OMB review and approval process in 2023. Therefore, the annual number of responses per respondent has decreased, resulting in an overall decrease in estimated annual burden. The number of respondents and estimated time per response has not changed.

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
Transmittal #1—Initial Request	54	14,216	0.17	130,503
Transmittal #1—Initial Request Acknowledgement	54	14,216	0.05	38,383
Transmittal #2—Subsequent Action	54	10,662	0.08	46,060
Transmittal #3—Request for Assistance/Discovery	54	2,132	0.08	9,210
Uniform Support Petition (English and Spanish)	54	5,686	0.05	15,352

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
General Testimony	54	5,686	0.33	101,325
Declaration in Support of Establishing Parentage	54	2,132	0.15	17,269
Child Support Locate Request	54	142	0.05	383
Notice of Determination of Controlling Order	54	1	0.25	14
Letter of Transmittal Requesting Registration (English and Spanish)	54	8,529	0.08	36,845
Personal Information Form for UIFSA § 311	54	5,686	0.05	15,352
Child Support Agency Confidential Information Form	54	17,059	0.05	46,059
Request for Change of Support Payment Location Pursuant to UIFSA 319(b)	54	71	0.05	192
Estimated Total Annual Burden Hours	456,947

Authority: 45 CFR 303.7.

Mary C. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-N-0668]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Small Dispensers Assessment Under the Drug Supply Chain Security Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by December 22, 2025.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The title of this information collection is “Small Dispensers Assessment Under the Drug Supply Chain Security Act.” Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Small Dispensers Assessment Under the Drug Supply Chain Security Act

OMB Control Number 0910-NEW

I. Information Collection Authority

On November 27, 2013, the Drug Supply Chain Security Act (DSCSA) (Title II of Pub. L. 113-54) was signed into law. The DSCSA outlines steps to achieve interoperable, electronic tracing of products at the package level¹ to identify and trace certain prescription drugs as they are distributed in the United States. Section 202 of the DSCSA added the new sections 581 and 582 to the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee and 360eee-1).

Under enhanced drug distribution security requirements in section 582(g)(1), dispensers and other trading partners will be required to, among other requirements, exchange transaction information and transaction statements in a secure, interoperable, electronic manner for each package; implement systems and processes for package level verification, including the standardized numerical identifier; and implement systems and processes to facilitate gathering the information necessary to produce the transaction information and statement for each

¹ As defined by section 581(11) of the FD&C Act, generally, the term “package” means the smallest individual saleable unit or smallest container of product for distribution by a manufacturer or repackager that is intended by the manufacturer for ultimate sale to the dispenser of such product.

transaction going back to the manufacturer if FDA or a trading partner requests an investigation in the event of a recall or a suspect or illegitimate product. These enhanced drug distribution security requirements are also referred to as “enhanced product tracing or enhanced verification.”

We have developed a web page to provide more information to industry regarding the DSCSA. It is available at <https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa>.

Under section 582(g)(3), FDA is required to enter into a contract with a private, independent consulting firm with expertise to conduct a technology and software assessment that looks at the feasibility of dispensers with 25 or fewer full-time employees (FTEs) conducting interoperable, electronic tracing of products at the package level. FDA’s proposed study entitled, “Small Dispensers Assessment under the Drug Supply Chain Security Act” (DSCSA Small Dispensers Assessment) is intended to fulfill this requirement.

As described in section 582(g)(3)(C), issues to be addressed in the assessment questions are related to the accessibility of the necessary software and hardware to such dispensers; whether the necessary software and hardware is prohibitively expensive to obtain, install, and maintain for such dispensers; and if the necessary hardware and software can be integrated into business practices. Respondents will submit information by answering the assessment questions using a link provided on FDA’s website.

II. DSCSA Small Dispensers Assessment

A. Eligibility Requirements

Assessment respondents will include self-identified individuals representing dispensers with a total of 25 or fewer FTEs (small dispenser) and individuals representing small dispensers’ third-