TABLE 1—CURRENT FORM IN USE DURING IMPLEMENTATION THROUGH 2026

Information collection title	Total number of annual respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
NMSN—Part A—Notice to Withhold for Health Care Coverage—States	54	90,194	.17	827,891
NMSN—Part A—Notice to Withhold for Health Care Coverage—Employers	1,310,727	3.72	.17	828,904
State Medical Support Contacts and Program Requirement Matrix—States	54	1	1	54
NMSN—Part A—Notice to Withhold for Health Care Coverage e-NMSN record specification layout Electronic system to system—States	5	5,000	.01	250
NMSN—Part A—Notice to Withhold for Health Care Coverage e-NMSN record specification layout Electronic system to system—Employers	25	3.72	.01	1
Estimated Annual Burden				1,657,100

TABLE 2—REVISED FORM—ESTIMATED BURDEN AFTER 2026 IMPLEMENTATION

Information collection title	Total number of annual respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
NMSN—Part A—Notice to Withhold for Health Care Coverage—*States*	54	86,818	.17	796,989
NMSN—Part A—Notice to Withhold for Health Care Coverage—*Employers*	1,263,267	3.71	.17	796,742
NMSN—Part A—Notice to Withhold for Health Care Coverage e-NMSN record specification layout Electronic system to system—*States*	7	5,000	.01	350
NMSN—Part A—Notice to Withhold for Health Care Coverage e-NMSN record specification layout Electronic system to system—*Employers*	25	3.72	.01	1
Estimated Annual Burden				1,567,082

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: Section 466(a)(19) of the Social Security Act, 42 U.S.C. 666(a)(19); 45 U.S.C. 303.32 National Medical Notice; The Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PWRORA) Pub. L. 104–193; Child Support Performance and Incentives Act of 1998 (CSPIA) Pub. L. 105–200, section 401(c); 609(a)(5)(C) of the Employee Retirement Income Security Act of 1974 (ERISA), Pub. L. 93–406.

Mary C. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for Office of Management and Budget (OMB) Review; Refugee Assistance Program Estimates: Cash and Medical Assistance–ORR–1 (Office of Management and Budget #: 0970–0030)

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

ACTION: Request for public comments.

SUMMARY: The Office of Refugee Resettlement (ORR), Administration for Children and Families (ACF), U.S. Department of Health and Human Services is requesting revisions to an existing data collection, ORR–1 Cash and Medical Assistance (CMA) Program Estimates (Office of Management and Budget (OMB) #0970–0030, expiration June 30, 2025. The proposed revisions include minor revisions to the existing ORR–1 form and the addition of a template recipients must use in preparing their annual budget justification estimates in accordance with the refugee resettlement program regulations.

DATES: *Comments due* July 24, 2025. OMB must decide about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

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: The ORR–1, CMA Program Estimates, is the application for grants under the CMA program. The application is required by ORR program regulations at 45 CFR 400.11(b). The regulation specifies that states must submit, as their application for this program, estimates of the projected costs they anticipate incurring in providing CMA for eligible recipients and the costs of administering the program. Under the CMA program, states are

reimbursed for the costs of providing these services and benefits for 4 months after an eligible recipient arrives in this country. The eligible beneficiaries for these services and benefits are refugees, Amerasians, Cuban and Haitian Entrants, asylees, Afghans and Iraqi with Special Immigrant Visas, victims of a severe form of trafficking, and other populations specified by Congress. States that provide services for unaccompanied refugee minors also provide an estimate for the cost of these services for the year for which they are applying for grants.

The proposed revisions include minor changes to the existing ORR–1 form and the addition of a template recipients must use in preparing their annual budget justification estimates in accordance with the refugee resettlement program regulations. Currently, recipients must submit the ORR–1, CMA Program Estimates, as the application for grants under the CMA program. A budget justification in support of CMA estimates must be submitted along with the ORR–1 form; however, ORR does not currently provide a standardized budget justification template. As a result, submissions vary widely in format, content, and level of detail, making it challenging to extract and standardize information, which increases the burden on both ORR reviewers and recipients. This revision to the information collection process requires states and Replacement Designees (RD) to submit budget justifications in a standardized format via a Microsoft Excel workbook, with each tab of the justification in alignment with a specific line on the ORR–1. The ORR–1 form has been updated with minor revisions, including updated column and line titles to reflect current terminology, and a simplified structure that replaces unit cost estimates with total cost estimates. These revisions are a result of the standardization of the budget justification.

The revised instructions, which are now embedded within the standardized budget justification, provide guidance to recipients on how to fill out each section of the standardized budget justification. The recipients work through corresponding sections of the instructions and budget justification, and the standardized format makes clear what information is needed and at what level of detail. Upon completion of the budget justification, the values needed to populate the ORR–1 form are automatically calculated, and recipients are instructed to transfer specific data from the budget justification to the ORR–1 form in the system of record.

ORR conducted a pilot of the standardized budget justification. Feedback was positive, with participating states citing time savings in development of their budget justification and more streamlined and consistent review and analysis by ORR reviewers. The annual burden estimate has been revised to reflect this.

Respondents: State Agencies, the District of Columbia, and Replacement Designees under 45 CFR 400.301(c) administering or supervising the administration of programs under Title IV of the Act.

ANNUAL BURDEN ESTIMATES

Information collection	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Total burden hours
ORR–1, CMA Program Estimates	57	1	0.5	28.5

Authority: 8 U.S.C. 1522(a)(4).

Mary C. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–D–1106]

Q1 Stability Testing of Drug Substances and Drug Products; International Council for Harmonisation; Draft 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 draft guidance for industry entitled ''Q1 Stability Testing of Drug Substances and Drug Products.'' The draft guidance was prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The draft guidance outlines stability data expectations for drug substances and drug products to support drug product marketing, including marketing authorization applications and, where applicable, drug master files. This draft guidance is a consolidated revision of the ICH Q1A(R2), Q1B, Q1C, Q1D, Q1E, and Q5C series of stability guidances, published November 2003, March 1996, May 1997, January 2003, June 2004, and July 1996, respectively. The revision also provides stability related guidance for product categories such as advanced therapy medicinal products, vaccines, and other complex biological products including combination products that were not previously covered under the existing stability guidances. The draft guidance is intended to provide an internationally harmonized approach to conducting and presenting data on stability testing for drug substances and drug products, as well as providing alternative, scientifically justified approaches that may be encountered due to scientific considerations and characteristics of the data being evaluated.

DATES: Submit either electronic or written comments on the draft guidance by August 25, 2025 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