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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Submission for Office of Management and Budget Review; Office of Community Services Affordable Housing and Supportive Services Demonstration Data Collection (Office of Management and Budget #: 0970–0628)

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

**ACTION:** Request for public comments.

**SUMMARY:** The Office of Community Services (OCS), Administration for Children and Families (ACF), U.S. Department of Health and Human Services, is requesting an extension of approval for a recently approved information collection: OCS Affordable Housing and Supportive Services Demonstration (Office of Management and Budget (OMB) #: 0970–0628, Expiration Date: September 30, 2024). This information collection was originally approved for 6 months as an emergency approval. In addition to extending the approval, OCS seeks to update the burden estimates to accommodate an anticipated increase in the number of grant recipients, as well as to collect additional responses to several of the instruments. OCS also seeks to make updates to approved forms.

**DATES:** *Comments due October 3, 2024.* OMB must make a decision 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](http://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](mailto:infocollection@acf.hhs.gov). Identify all emailed

requests by the title of the information collection.

**SUPPLEMENTARY INFORMATION:** OCS is seeking to continue collecting the information requested from grant recipients under OMB #: 0970–0628. In order to determine best practices in the implementation of supportive services in the affordable housing context and describe how supportive services help residents to improve well-being and economic mobility, OCS will engage in the following activities:

- Conducting interviews with program directors and caseworkers to understand program implementation.
- Conducting focus groups with residents to understand their needs and how the services funded by this grant impacted their lives.
- Administering a self-sufficiency matrix to residents receiving intensive services to understand the impact of the program on various domains of well-being.
- Conducting a questionnaire with residents, to see if they were able to access more services due to the funding.
- Collecting information from program officers about the number and types of services/events provided, aggregate demographics of residents served, partner organizations and referrals, and how the housing community was impacted by the grant funding.
- Collecting narrative reports from program officers about the progress of implementation of the program.

This request is to extend the approved collection period to 3 years, which will permit OCS to complete the collection with current grant recipients as well as future grant recipients. With an extended timeline, OCS will request additional responses for several approved instruments to observe activities over the course of the full project period for grant recipients. The self-sufficiency matrix and service receipt questionnaires will be administered every 6 months during the project period. The semi-annual quantitative report mandatory and optional forms will be required every 6 months, with a final cumulative report. The quarterly narrative PPR will be requested every quarter of the project period.

OCS has developed substantially revised 2024 versions of the semi-annual quantitative report forms for the mandatory and optional reports to broaden the measures of service delivery and outcomes to better accommodate the universe of potential services offered by future cohorts of

grant recipients. The new mandatory form combines the direct services and referrals tabs of the original form into a single tab where grant recipients will report the number of individuals receiving services through AHSSD funding and through the organization’s other funding sources, alongside the information reported about referrals. The new optional form broadens the list of outcome measures that grant recipients can choose to report for the individuals they serve. In consideration of the overall reporting burden for grant recipients, the 2024 version of the forms continue draw upon the service and outcome categories that grant recipients already use to report their Community Services Block Grant-related activities (OMB# 0970–0492). Additionally, the 2024 version of the forms request cumulative counts across the grant period, negating the need for a separate final report.

Current grant recipients will be able to choose between using the current 2023 version of the forms and the revised 2024 version of the forms through the completion of their current project. New grant recipients will be required to use the 2024 version of the forms.

*Respondents:* There will be three types of respondents to the proposed instruments. First, the direct beneficiaries, the clients receiving supportive services, will participate in the service receipt questionnaire, self-sufficiency matrix, and focus groups, and they will also provide information about their characteristics, needs, and outcomes for the grant recipients’ semi-annual quantitative reporting. Second, the program directors and social services staff will respond to interview instruments tailored to their roles. Grant recipients will also be asked to complete quarterly narrative PPRs and semi-annual quantitative reports to describe their service delivery activities, and outcomes.

#### Annual Burden Estimates

Burden estimates show the total number of responses per respondent over the next 3 years. The current grant recipients (9 total) will be able to choose between using the 2023 version of the semi-annual quantitative report forms and the 2024 version of those forms through the completion of their current project. New grant recipients (9 new recipients estimated) will be required to use the 2024 version of the forms.

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Interviews with program directors .....	18	1	1.5	27	9
Interviews with caseworkers .....	36	1	1	36	12
Focus groups with residents .....	105	1	1.5	157.5	52.5
Self-sufficiency matrix .....	680	3	1.5	3,060	1,020
Service receipt questionnaire .....	680	3	.25	510	170
2023 Version—Semi-Annual Quantitative Report Mandatory Form .....	3	4	3	36	12
2024 Version—Semi-Annual Quantitative Report Mandatory Form .....	15	3	3	135	45
2023 Version—Semi-Annual Quantitative Report Optional Form .....	1	4	3	12	4
2024 Version—Semi-Annual Report Optional Form .....	5	3	3	45	15
Quarterly Narrative PPR .....	18	6	2	216	72

*Estimated Total Annual Burden Hours:* 1,411.5.

*Authority:* Section 1110, Social Security Act, 42 U.S.C. 1310.

**Mary C. Jones,**

*ACF/OPRE Certifying Officer.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2022–N–0150]

**Revocation of Authorization of Emergency Use of In Vitro Diagnostic Device for Detection and/or Diagnosis of COVID–19; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorization (EUA) (the Authorization) issued to Roche Molecular Systems, Inc. for the cobas SARS-CoV–2 & Influenza A/B nucleic acid test for use on the cobas Liat System, that includes the cobas SARS-CoV–2 & Influenza A/B Quality Control Kit. FDA revoked the Authorization under the Federal Food, Drug, and Cosmetic Act (FD&C Act) as requested by the Authorization holder. The revocation, which includes an explanation of the reasons for revocation, is reprinted at the end of this document.

**DATES:** The revocation of the Authorization for the Roche Molecular Systems, Inc.’s for the cobas SARS-CoV–2 & Influenza A/B nucleic acid test for use on the cobas Liat System, that includes the cobas SARS-CoV–2 &

Influenza A/B Quality Control Kit is effective as of July 3, 2024.

**ADDRESSES:** Submit written requests for a single copy of the revocation to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the revocation may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revocation.

**FOR FURTHER INFORMATION CONTACT:** Kim Sapsford-Medintz, Office of Product Evaluation and Quality, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3216, Silver Spring, MD 20993–0002, 301–796–0311 (this is not a toll-free number).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Section 564 of the FD&C Act (21 U.S.C. 360bbb-3) as amended by the Project BioShield Act of 2004 (Pub. L. 108–276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113–5) allows FDA to strengthen the public health protections against biological, chemical, radiological, or nuclear agent or agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations.

On September 14, 2020, FDA issued the Authorization to Roche Molecular Systems, Inc. for the cobas SARS-CoV–2 & Influenza A/B nucleic acid test for use on the cobas Liat System, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on

November 20, 2020 (85 FR 74346), as required by section 564(h)(1) of the FD&C Act.

Subsequent updates to the Authorization were made available on FDA’s website. The authorization of a device for emergency use under section 564 of the FD&C Act may, pursuant to section 564(g)(2) of the FD&C Act, be revoked when the criteria under section 564(c) of the FD&C Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the FD&C Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the FD&C Act).

**II. Authorization Revocation Request**

In a request received by FDA on June 21, 2024, Roche Molecular Systems, Inc., requested the revocation of, and on July 3, 2024, FDA revoked, the Authorization for the Roche Molecular Systems, Inc.’s cobas SARS-CoV–2 & Influenza A/B nucleic acid test for use on the cobas Liat System, that includes the cobas SARS-CoV–2 & Influenza A/B Quality Control Kit. Because Roche Molecular Systems, Inc., notified FDA that they have ceased the manufacture and distribution of the cobas SARS-CoV–2 & Influenza A/B nucleic acid test for use on the cobas Liat System, that includes the cobas SARS-CoV–2 & Influenza A/B Quality Control Kit and requested FDA revoke Roche Molecular Systems, Inc.’s, cobas SARS-CoV–2 & Influenza A/B nucleic acid test for use on the cobas Liat System, that includes the cobas SARS-CoV–2 & Influenza A/B Quality Control Kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization.

**III. Electronic Access**

An electronic version of this document and the full text of the