

website by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>.

**FOR FURTHER INFORMATION CONTACT:** William N. Parham at (410) 786-4669.

**SUPPLEMENTARY INFORMATION:**

**Contents**

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-R-282 Medicare Advantage Appeals and Grievance Data Form

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

**Information Collection**

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Advantage Appeals and Grievance Data Form; *Use:* Part 422 of Title 42 of the Code of Federal Regulations (CFR) distinguishes between certain information a Medicare Advantage (MA) organization must provide to each enrollee (on an annual basis) and information that the MA organization must disclose to any MA eligible individual (upon request). This requirement can be found in § 1852(c)(2)(C) of the Social Security Act and in 42 CFR 422.111(c)(3) which states that MA organizations must disclose information pertaining to the number of disputes, and their disposition in the aggregate, with the categories of grievances and appeals, to any individual eligible to elect an MA

organization who requests this information.

The appeals and grievance data form is an OMB approved form for use by Medicare Advantage organizations to disclose grievance and appeal data, upon request, to individuals eligible to elect an MA organization. By utilizing the form, MA organizations will meet the disclosure requirements set forth in regulations at 42 CFR 422.111(c)(3). *Form Number:* CMS-R-282 (OMB control number: 0938-0778); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 949; *Total Annual Responses:* 63,740; *Total Annual Hours:* 5,964. (For policy questions regarding this collection contact Sabrina Edmonston at 410-786-3209.)

Dated: November 1, 2022.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2022-24097 Filed 11-3-22; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**[Document Identifiers: CMS-10003, CMS-1771, CMS-10789 and CMS-10379]**

**Agency Information Collection Activities: Submission for OMB Review; Comment Request**

**AGENCY:** Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the

information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments on the collection(s) of information must be received by the OMB desk officer by December 5, 2022.

**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.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>.

**FOR FURTHER INFORMATION CONTACT:** William Parham at (410) 786-4669.

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title:* Notice of Denial of Medical Coverage (or Payment); *Use:* Section 1852(g)(1)(B) of the Social Security Act (the Act) requires Medicare health plans to provide enrollees with a written notice in understandable language of the reasons for the denial and a description of the applicable appeals processes.

Medicare health plans, including Medicare Advantage plans, cost plans, and Health Care Prepayment Plans (HCPPs), are required to issue the Notice of Denial of Medical Coverage (or Payment) (NDMCP) when a request for either a medical service or payment is denied, in whole or in part. Additionally, the notices inform Medicare enrollees of their right to file an appeal, outlining the steps and timeframes for filing. All Medicare health plans are required to use these standardized notices. *Form Number:* CMS-10003 (OMB Control Number: 0938-0829); *Frequency:* Annually; *Affected Public:* Private Sector, Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 937; *Number of Responses:* 16,191,812; *Total Annual Hours:* 2,697,556. (For policy questions regarding this collection contact Sabrina Edmonston at 410-786-3209.)

**2. Type of Information Collection**  
*Request:* Extension of a currently approved collection; *Title:* Emergency and Foreign Hospital Services and Supporting Regulation in 42 CFR Section 424.103; *Use:* Section 1866 of the Social Security Act states that any provider of services shall be qualified to participate in the Medicare program and shall be eligible for payments under Medicare if it files an agreement with the Secretary to meet the conditions outlined in this section of the Act. Section 1814(d)(1) of the Social Security Act and 42 CFR 424.100, allows payment of Medicare benefits for a Medicare beneficiary to a nonparticipating hospital that does not have an agreement in effect with the Centers for Medicare and Medicaid Services. These payments can be made if such services were emergency services and if CMS would be required to make the payment if the hospital had an agreement in effect and met the conditions of payment. This form is used in connection with claims for emergency hospital services provided by hospitals that do not have an agreement in effect under Section 1866 of the Social Security Act.

42 CFR 424.103 (b) requires that before a non-participating hospital may be paid for emergency services rendered to a Medicare beneficiary, a statement must be submitted that is sufficiently comprehensive to support that an emergency existed. Form CMS-1771 contains a series of questions relating to the medical necessity of the emergency. The attending physician must attest that the hospitalization was required under the regulatory emergency definition (42 CFR 424.101 attached) and give clinical documentation to support the claim. A

photocopy of the beneficiary's hospital records may be used in lieu of the CMS-1771 if the records contain all the information required by the form.; *Form Number:* CMS-1771 (OMB Control Number: 0938-0023); *Frequency:* Annually; *Affected Public:* Private Sector, Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 100; *Number of Responses:* 200; *Total Annual Hours:* 50. (For policy questions regarding this collection contact Shauntari Cheely at 410-786-1818.)

**3. Type of Information Collection**  
*Request:* New Collection; *Title of Information Collection:* Customer Satisfaction Survey for Enterprise Portal Services (EPS) Users; *Use:* This EPS customer satisfaction survey will support EADG's goal of promoting improvements in the quality of EPS for all end-users and business owners. The collection of this information is necessary to enable EADG to obtain feedback in an efficient, timely manner, in accordance to our commitment to improving the quality and usability of our system. It will also allow for ongoing, collaborative, and actionable communications between EADG and all customers, stakeholders, and end-users.

The goal of this Generic clearance and its survey is to capture feedback from actual users of the system immediately after they finish using the system, while their user experience, negative or positive, is still fresh in their minds. This user feedback will allow our team to discover areas of improvement within EPS. It will help us improve the user experience, provide better service/support, improve marketing strategies, and identify gaps/issues that require resolution. For example, if we get several responses through the collection instrument stating that users feel that the EPS system is slow, we can use that feedback to invest efforts into increasing the EPS response times. As the feedback is analyzed and implemented over time, the survey questions will evolve to support implemented changes, providing the EPS team with the most up-to-date feedback on system improvement.

By using a Generic Instrument Collection, the survey will evolve over time. Within the CMS EPS, features are frequently added, and sometimes even removed. The team needs to be able to add new survey questions, specific to those new features, in order to capture valuable feedback on the effectiveness, ease-of-use, pain points, and areas of improvement for the 2 feature. When features are removed from the CMS EPS, questions relevant to those features must be modified or removed from the

survey as well. In general, given that the CMS EPS is a dynamic system, designed to meet enterprise needs that change over time, a Generic Instrument Collection will allow the survey to evolve as the system evolves, and remain relevant, capturing up-to-date feedback on the system. *Form Number:* CMS-10789 (OMB control number: 0938-New); *Frequency:* Quarter; *Affected Public:* Individuals and Households, Private Sector (Business or other for-profits, Not-for-Profit Institutions); *Number of Respondents:* 300,000; *Total Annual Responses:* 360,000; *Total Annual Hours:* 90,000. (For policy questions regarding this collection contact Corey L. Redden at 410-279-5152.)

**4. Type of Information Collection**  
*Request:* Revision of a previously approved information collection; *Title of Information Collection:* Rate Increase Disclosure and Review Reporting Requirements; *Use:* 45 CFR part 154 implements the annual review of unreasonable increases in premiums for health insurance coverage called for by section 2794. The regulation established a rate review program to ensure that all rate increases that meet or exceed an established threshold are reviewed by a state or the Centers for Medicare and Medicaid Services (CMS) to determine whether the rate increases are unreasonable. Accordingly, issuers offering non-grandfathered health insurance coverage in the individual and/or small group markets are required to submit Rate Filing Justifications to CMS. Section 154.103 exempts grandfathered health plan coverage as defined in 45 CFR 147.140, excepted benefits as described in section 2791(c) of the PHS Act and student health insurance coverage, as defined in § 147.145, from Federal rate review requirements.

The Rate Filing Justification consists of three parts. All issuers must continue to submit a Uniform Rate Review Template (URRT) (Part I of the Rate Filing Justification) for all single risk pool plans. Section 154.200(a)(1) establishes a 15 percent federal default threshold for reasonableness review. Issuers that submit a rate filing that includes a plan that meets or exceeds the threshold must include a written description justifying the rate increase, also known as the consumer justification narrative (Part II of the Rate Filing Justification). We note that the threshold set by CMS constitutes a minimum standard and most states currently employ stricter rate review standards and may continue to do so. Issuers offering a QHP or any single risk pool submission containing a rate

increase of any size must continue to submit an actuarial memorandum (Part III of the Rate Filing Justification). *Form Number:* CMS-10379 (OMB control number: 0938-1141); *Frequency:* Annually; *Affected Public:* Private Sector; Businesses or other for-profits, Not-for-profit institutions; *Number of Respondents:* 626; *Total Annual Responses:* 820; *Total Annual Hours:* 17,788. (For policy questions regarding this collection contact Lisa Cuzzo at 410-786-1746.)

Dated: November 1, 2022.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2022-24098 Filed 11-3-22; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Submission for OMB Review; Administration for Children and Families Uniform Project Description

**AGENCY:** Office of Administration, Office of Grants Policy, Administration for Children and Families, Department of Health and Human Services.

**ACTION:** Request for public comments.

**SUMMARY:** The Administration for Children and Families (ACF) is requesting a revision of the approved ACF Uniform Project Description (UPD) (Office of Management and Budget (OMB) # 0970-0139, expiration March 31, 2025).

**DATES:** *Comments due within 30 days of publication.* 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:

**Description:** The proposed information collection would revise the approved ACF UPD. The UPD provides a uniform format for applicants to submit project information in response to ACF discretionary Notices of Funding

Opportunity. The UPD requires applicants to describe how program objectives will be achieved and provide a rationale for the project's budgeted costs. All ACF discretionary grant programs are required to use the UPD.

ACF uses this information, along with other OMB-approved information collections (Standard Forms), to evaluate and rank applications. Use of the UPD protects the integrity of the ACF award selection process.

The UPD has been revised as follows:

(1) included a text field for the Geographic Location standardized text, which will allow ACF program offices to enter project-specific language; (2) under Organizational Capacity, inserted an option to allow submission of an Audit Summary report in lieu of a full audit report; (3) inserted a checkbox and standardized language to request current and pending funding support; (4) added a prior written approval requirement to Plan for Oversight of Federal Award Funds and Activities; (5) included Memoranda of Agreement (MOA) under Third Party Agreements; and (6) updated The Project Budget and Budget Justification standardized language related to salary limitation, budget preparation, fringe benefits, definition of supplies, contractual costs, accounting for real property, the Other Costs category, and Indirect Costs.

**Respondents:** Applicants responding to ACF Discretionary Notices of Funding Opportunity.

## ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
ACF Uniform Project Description .....	3,218	1	60	193,080

*Estimated Total Annual Burden Hours:* 64,360.

**Authority:** 45 CFR 75.203 and 75.204, and 45 CFR part 75, appendix I.

**Mary B. Jones,**

*ACF/OPRE Certifying Officer.*

[FR Doc. 2022-23976 Filed 11-3-22; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2022-N-0150]

#### Revocation of Two Authorizations of Emergency Use of In Vitro Diagnostic Devices 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 Authorizations (EUs) (the

Authorizations) issued to Cleveland Clinic Robert J. Tomsich Pathology and Laboratory Medicine Institute (Cleveland Clinic) for the Cleveland Clinic SARS-CoV-2 Assay and SelfCheck COVID-19 TaqPath Multiplex PCR. FDA revoked these Authorizations under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The revocations, which include an explanation of the reasons for each revocation, are reprinted in this document.

**DATES:** The Authorizations for the Cleveland Clinic SARS-CoV-2 Assay and SelfCheck COVID-19 TaqPath Multiplex PCR are revoked as of October 19, 2022.