

monotherapy in patients unable to tolerate UDCA.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference and/or video conference meeting will be available at the location of the advisory committee meeting and at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link. The meeting presentations will also be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform. The online presentation of materials will include slide presentations with audio and video components in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. All electronic and written submissions to the Docket (see **ADDRESSES**) on or before August 29, 2024, will be provided to the Committee. Oral presentations from the public will be scheduled between approximately 1:30 p.m. to 2:30 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, whether they would like to present online or in-person, and an indication of the approximate time requested to make their presentation on or before August 21, 2024. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. Similarly, room for interested persons to participate in-person may be limited. If the number of registrants requesting to speak in-person during the open public hearing is greater than can be reasonably accommodated in the venue for the in-person portion of the advisory committee meeting, FDA may conduct a lottery to determine the speakers who will be invited to participate in-person.

The contact person will notify interested persons regarding their request to speak by August 22, 2024. Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

For press inquiries, please contact the Office of Media Affairs at fdaoma@fda.hhs.gov or 301-796-4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Jessica Seo (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform in conjunction with the physical meeting room (see location). This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. The conditions for issuance of a waiver under 21 CFR 10.19 are met.

Dated: August 7, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; COVID-19 Provider Relief Programs Single and Commercial Audits and Delinquent Audit Reporting Submission Activities—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than September 11, 2024.

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 Review—Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Joella Roland, the HRSA Information Collection Clearance Officer, at paperwork@hrsa.gov or call (301) 443-3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: COVID-19 Provider Relief Programs Single and Commercial Audits and Delinquent Audit Reporting Submission Activities, OMB No. 0906-0083—Revision

Abstract: The Coronavirus Aid, Relief, and Economic Security Act (Pub. L. 116-136); the Paycheck Protection Program and Health Care Enhancement Act (Pub. L. 116-139); the Coronavirus Response and Relief Supplemental Appropriations Act (Pub. L. 116-260); the Families First Coronavirus Response

Act (Pub. L. 116–127); and the American Rescue Plan Act of 2021 (Pub. L. 117–2) provided the Department of Health and Human Services the authority to administer the Provider Relief Programs (PRP) (*i.e.*, Provider Relief Fund; American Rescue Plan Act Rural Distribution; COVID–19 Coverage Assistance Fund; and COVID–19 Claims Reimbursement to Health Care Providers and Facilities for Testing, Treatment, and Vaccine Administration for the Uninsured). The Department of Health and Human Services, through HRSA, administered the PRP. The PRP issued payments to eligible health care providers for expenses or lost revenues attributable to COVID–19 and claims reimbursement for COVID–19 testing, treatment, and vaccine administration for uninsured individuals. Recipients of these funds agreed to the Terms and Conditions applicable to each Program, which require, among other Terms, compliance with reporting requirements as specified by the Secretary of Health and Human Services and the statutes listed above. Recipients are eligible health care providers who include public entities, Medicare or Medicaid enrolled suppliers and providers, and for-profit and non-profit entities that provide diagnosis, testing, vaccination, or care for individuals with possible or actual cases of COVID–19. The Single Audit Act requires entities that expend \$750,000 or more of federal assistance during the entity’s fiscal year to conduct an independent audit. Requirements for

these audits are set forth in regulations at 45 CFR Subpart F. Requirements differ for non-profit and commercial/for-profit entities, and non-profit entities are required to submit their audits to the Federal Audit Clearinghouse. HRSA has established a Commercial Audit Reporting Portal to collect audits from commercial/for-profit organizations. In late calendar year 2023, HRSA developed a delinquent audit follow-up process to ensure that all providers required to submit an audit do so. The delinquent audit follow-up process includes educating PRP recipients on the 45 CFR 75 Subpart F requirements and following up on overdue audit report submissions. In February 2024, OMB approved HRSA’s emergency ICR for the Commercial Audit Reporting Portal and the delinquent audit follow-up process. Collectively, these activities will help ensure the fiscal and program integrity of the PRP.

A 60-day notice published in the **Federal Register** on May 2, 2024, vol. 89, No. 86; pp. 35842–35843. There were no public comments.

Need and Proposed Use of the Information: HRSA will use the collected information to ensure all PRP recipients who expended over \$750,000 in funding during the recipient’s fiscal year submit an audit and resolve audit findings, which may include recovery of any funds used not in accordance with the Terms and Conditions of the programs.

Likely Respondents: PRP recipients who expended over \$750,000 in funding during their fiscal year.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

The February 2024 emergency ICR also included the Commercial Audit Compliance and Delinquent Audit Follow-up General and Targeted emails, which will continue to be used. These burden hours associated with these emails were erroneously left out of burden table in the 60-day notice and have been added back into the 30-day **Federal Register** notice. The Delinquent Audit Follow-up General Email Blast was also updated to include more details regarding audit requirements for PRP payments.

Total Estimated Annualized Burden Hours:

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Provider Relief Bureau Commercial Audit Reporting Portal	21,000	1	21,000	0.75	15,750
Commercial Audit Compliance Email	500	1	500	0.25	125
Delinquent Audit Follow-up General Email Blast and Attestation	42,000	6	252,000	0.25	63,000
Delinquent Audit Follow-up Targeted Email and Attestation	21,000	2	42,000	0.25	10,500
Questioned Cost Attestation	7,000	10	70,000	5.00	350,000
Total	91,500	385,500	439,375

Maria G. Button,
Director, Executive Secretariat.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Supplemental Funding for Regional Pediatric Pandemic Network Award Recipients

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice of supplemental funding.

SUMMARY: Per Congressional Report language accompanying the Further Consolidated Appropriations Act, 2024, HRSA is awarding supplemental funds in FY 2024 to two Regional Pediatric Pandemic Network (RPPN) Program recipients to increase activities to coordinate among the Nation’s pediatric hospitals and their communities to prepare for and coordinate research-informed responses to future pandemics. The current RPPN program period of performance ends on August 31, 2026.