

Republic of Guinea (Guinea) and the Democratic Republic of the Congo (DRC). CDC issued an Order on March 2, 2021 requiring airlines to collect and transmit to CDC contact information for passengers who were in Guinea or DRC within the 21 days before their arrival or attempted arrival in the United States. This Order became effective on March 4, 2021. (86 FR 12685, March 4, 2021).

On April 29, 2021, as there were no new cases reported in the prior 42 days, no remaining hospitalized patients with Ebola, and no contacts of confirmed Ebola cases still requiring monitoring in the DRC, CDC rescinded all requirements of the March 2, 2021 Order pertaining to DRC; however, the requirements pertaining to Guinea remained in effect.

Since April 3, 2021, there have been no new confirmed Ebola cases reported in Guinea and all contacts of cases that were being monitored have passed the 21-day incubation period. CDC has determined that airline travelers destined for the United States who are departing from, or were otherwise present in, Guinea in the past 21 days are no longer at risk of exposure to Ebola virus. Therefore, the March 2, 2021 Order is rescinded in its entirety as of 12:01 a.m. Daylight Saving Time May 14, 2021.

Authority: This Notice is issued pursuant to Sections 361 and 365 of the Public Health Service Act, 42 U.S.C. 264 and 268, and implementing regulations at 42 CFR 71.4, 71.20, 71.31, and 71.32.

Dated: May 13, 2021.

Rochelle Walensky,
Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-R-185, CMS-10166, CMS-10178, CMS-10184, CMS-10417 and CMS-372(S)]

Agency Information Collection Activities: Proposed Collection; 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 (the 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 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates 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 must be received by July 19, 2021.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: CMS-P-0015A, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

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-185—Granting and Withdrawal of Deeming Authority to Private Nonprofit Accreditation Organizations and CLIA Exemption Under State Laboratory

CMS-10166—Fee-for-Service Improper Payment Rate Measurement in Medicaid and the Children's Health Insurance Program

CMS-10178—Medicaid and Children's Health Insurance (CHIP) Managed Care Payments and Related Information

CMS-10184—Payment Error Rate Measurement—State Medicaid and CHIP Eligibility

CMS-10417—Medicare Fee-for-Service Prepayment Review of Medical Records

CMS-372(S)—Annual Report on Home and Community Based Services Waivers and Supporting Regulations

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 currently approved collection; *Title of Information Collection:* Granting and Withdrawal of Deeming Authority to Private Nonprofit Accreditation Organizations and CLIA Exemption Under State Laboratory Programs; *Use:* The information required is necessary to determine whether a private accreditation organization/State licensure program standards and accreditation/licensure process is at least equal to or more stringent than those of the Clinical Laboratory Improvement Amendments of 1988 (CLIA). If an accreditation organization is approved, the laboratories that it accredits are "deemed" to meet the

CLIA requirements based on this accreditation. Similarly, if a State licensure program is determined to have requirements that are equal to or more stringent than those of CLIA, its laboratories are considered to be exempt from CLIA certification and requirements. The information collected will be used by HHS to: Determine comparability/equivalency of the accreditation organization standards and policies or State licensure program standards and policies to those of the CLIA program; to ensure the continued comparability/equivalency of the standards; and to fulfill certain statutory reporting requirements. *Form Number:* CMS-R-185 (OMB control number: 0938-0686); *Frequency:* Occasionally; *Affected Public:* Private Sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 9; *Total Annual Responses:* 9; *Total Annual Hours:* 5,464. (For policy questions regarding this collection contact Arlene Lopez at 410-786-6782.)

2. *Type of Information Collection Request:* Reinstatement without change of a currently approved collection; *Title of Information Collection:* Fee-for-Service Improper Payment Rate Measurement in Medicaid and the Children's Health Insurance Program; *Use:* The information collected from the selected States will be used by Federal contractors to conduct Medicaid and CHIP FFS data processing and medical record reviews on which State-specific improper payment rates will be calculated. The quarterly FFS claims and payments will provide the contractor with the actual claims to be sampled. The systems manuals, provider policies, and other supporting documentation will be used by the federal contractor when conducting the FFS data processing and medical record reviews. Further, the FFS claims and payments sampled for data processing and medical record reviews will serve as the basis for the eligibility reviews. Individuals for whom the state made the FFS claim or payments will have their underlying eligibility reviewed.

In addition to the Federal Review Contractor conducting a data processing and medical record review of the FFS claims and payments, the FFS sample selected from the state-submitted universe will also be leveraged to support the PERM eligibility reviews. The Federal Eligibility Review Contractor will review the underlying eligibility of individuals whose FFS claims and payments were sampled as part of the PERM FFS sample. *Form Number:* CMS-10166 (OMB control number: 0938-0974); *Frequency:*

Quarterly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 17; *Total Annual Responses:* 34; *Total Annual Hours:* 56,100. (For policy questions regarding this collection contact Daniel Weimer at 410-786-5240.)

3. *Type of Information Collection Request:* Reinstatement without change of a currently approved collection; *Title of Information Collection:* Medicaid and Children's Health Insurance (CHIP) Managed Care Payments and Related Information; *Use:* The information collected from the selected States will be used by Federal contractors to conduct Medicaid and CHIP managed care data processing reviews on which State-specific improper payment rates will be calculated. The quarterly capitation payments will provide the contractor with the actual claims to be sampled. The managed care contracts, rate schedules, and updates to both, will be used by the federal contractor when conducting the managed care claims reviews. Further, the managed care capitation payments sampled for data processing reviews will serve as the basis for the eligibility reviews. Individuals for whom the state made the managed care capitation will have their underlying eligibility reviewed.

Section 2(b)(1) of IPERA clarified that, when meeting IPIA and IPERA requirements, agencies must produce a statistically valid estimate, or an estimate that is otherwise appropriate using a methodology approved by the Director of the OMB. IPERIA further clarified requirements for agency reporting on actions to reduce improper payments and recover improper payments. The collection of information is necessary for CMS to produce national improper payment rates for Medicaid and CHIP as required by Public Law 107-300. *Form Number:* CMS-10178 (OMB control number: 0938-0994); *Frequency:* Quarterly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 17; *Total Annual Responses:* 34; *Total Annual Hours:* 19,550. (For policy questions regarding this collection contact Daniel Weimer at 410-786-5240.)

4. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Payment Error Rate Measurement—State Medicaid and CHIP Eligibility; *Use:* The Payment Error Rate Measurement (PERM) program was developed to implement the requirements of the Improper Payments Information Act (IPIA) of 2002 (Pub. L. 107-300), which requires the head of federal agencies to annually

review all programs and activities that it administers to determine and identify any programs that are susceptible to significant erroneous payments. If programs are found to be susceptible to significant improper payments, then the agency must estimate the annual amount of erroneous payments, report those estimates to the Congress, and submit a report on actions the agency is taking to reduce improper payments. IPIA was amended by Improper Payments Elimination and Recovery Act of 2010 (IPERA) (Pub. L. 111-204), the Improper Payments Elimination and Recovery Improvement Act of 2012 (IPERIA) (Pub. L. 112-248), and the Payment Integrity Information Act of 2019 (PIIA) (Pub. L. 116-117).

The eligibility case documentation collected from the States, through submission of hard copy case files and through access to state eligibility systems, will be used by CMS and its federal contractors to conduct eligibility case reviews on individuals who had claims paid on their behalf in order to determine the improper payment rate associated with Medicaid and CHIP eligibility to comply with the IPIA of 2002. Prior to the July 2017 Final Rule being published in response to the Affordable Care Act, states provided CMS only with information about their sampling and review process as well as the final review findings, which CMS has used in each PERM cycle to calculate IPIA-compliant state and federal improper payment rate for Medicaid and CHIP. Given changes brought forth in the July 2017 Final Rule, states will no longer be required to develop eligibility-specific universes, conduct case reviews, and report findings to CMS. A federal contractor will utilize the claims (fee-for-service and managed care universes) to identify a sample of individuals and will be responsible for conducting case reviews to support the PERM measurement. *Form Number:* CMS-10184 (OMB control number: 0938-1012); *Frequency:* Quarterly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 17; *Total Annual Responses:* 34; *Total Annual Hours:* 25,500. (For policy questions regarding this collection contact Daniel Weimer at 410-786-5240.)

5. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Fee-for-Service Prepayment Review of Medical Records; *Use:* The Medical Review program is designed to prevent improper payments in the Medicare FFS program. Whenever possible, Medicare Administrative Contractors (MACs) are

encouraged to automate this process; however, it may require the evaluation of medical records and related documents to determine whether Medicare claims are billed in compliance with coverage, coding, payment, and billing policies. Addressing improper payments in the Medicare fee-for-service (FFS) program and promoting compliance with Medicare coverage and coding rules is a top priority for the CMS. Preventing Medicare improper payments requires the active involvement of every component of CMS and effective coordination with its partners including various Medicare contractors and providers. The information required under this collection is requested by Medicare contractors to determine proper payment, or if there is a suspicion of fraud. Medicare contractors request the information from providers/suppliers submitting claims for payment when data analysis indicates aberrant billing patterns or other information which may present a vulnerability to the Medicare program. *Form Number:* CMS-10417; *Frequency:* Occasionally; *Affected Public:* Private Sector, State, Business, and Not-for Profits; *Number of Respondents:* 485,632; *Number of Responses:* 485,632; *Total Annual Hours:* 242,816. (For questions regarding this collection, contact Christine Grose at (410-786-1362).

6. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Annual Report on Home and Community Based Services Waivers and Supporting Regulations; *Use:* We use this report to compare actual data to the approved waiver estimates. In conjunction with the waiver compliance review reports, the information provided will be compared to that in the Medicaid Statistical Information System (MSIS) (CMS-R-284; OMB control number: 0938-0345) report and FFP claimed on a state's Quarterly Expenditure Report (CMS-64; OMB control number: 0938-1265), to determine whether to continue the state's home and community-based services waiver. States' estimates of cost and utilization for renewal purposes are based upon the data compiled in the CMS-372(S) reports. *Form Number:* CMS-372(S) (OMB control number: 0938-0272); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 48; *Total Annual Responses:* 253; *Total Annual Hours:* 11,132. (For policy

questions regarding this collection contact Ralph Lollar at 410-786-0777.)

Dated: May 13, 2021.

William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

120 Day Proposed Information Collection: Tribal Investment in Commercial Electronic Health Records

AGENCY: Indian Health Service, HHS.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Indian Health Service (IHS) takes this opportunity to provide information on a new Office of Management and Budget (OMB) information collection, Control Number 0917-XXXX, titled, "Tribal Investment in Commercial Electronic Health Records." This proposed information collection project has been granted an emergent review by OMB. The purpose of this notice is to provide the public a notice of the information sent directly to OMB.

A copy of the supporting statement is available at www.regulations.gov (see Docket ID IHS_FRDOC_0001).

DATES: September 15, 2021. Any comments regarding this information collection are best assured of having full effect if received within 120 days of the date of this publication.

Direct Your Comments to OMB: Send your comments and suggestions regarding the proposed information collection contained in this notice, especially regarding the estimated public burden and associated response time to: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for IHS.

FOR FURTHER INFORMATION CONTACT: To request additional information, please contact IHS by one of the following methods:

- *Mail:* Mitchell Thornbrugh, Director, Office of Information Technology, Indian Health Service, DHHS, 5600 Fishers Lane, Rockville, MD 20857.

- *Phone:* (240) 620-3117.
- *Email:* mitchell.thornbrugh@ihs.gov.

SUPPLEMENTARY INFORMATION: The IHS has requested emergency review of this information collection by OMB, as authorized by section 3507(j) of the Paperwork Reduction Act of 1995. The Agency gathers comments concerning: (a) The necessity of this information collection for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden (hours and cost) of the collection of information, including the validity of the methodology and assumptions used; (c) ways we could enhance the quality, utility, and clarity of the information to be collected; and (d) ways we could minimize the burden of the collection of the information on the respondents.

Please note that an agency may not conduct or sponsor, and an individual need not respond to, a collection of information unless it displays a valid OMB Control Number.

Title of Proposal: Tribal Investment in Commercial Electronic Health Records.

Type of Information Collection Request: EMERGENCY REQUEST.

OMB Control Number: To be assigned.

Need and Use of Information Collection: In the Explanatory Statement accompanying the 2021 Consolidation Appropriation Act, Congress directed IHS "to report back within 120 days of enactment of this Act with a list of Tribes that currently maintain their own non-RPMS electronic health record systems along with cost estimates required for those Tribes to implement, maintain, and make any necessary upgrades to these systems." Because the IHS does not routinely collect or maintain this information, the Agency needs to issue a data call to Tribes and Urban Indian Organizations in order to prepare the required report to the requesting Committees.

Status of the Proposed Information Collection: New request.

Form(s): Spreadsheet (or form).

Agency Form Numbers: None.

Members of Affected Public: Tribes and Urban Indian Organizations.

The table below provides: Type of data collection instrument, Estimated number of respondents, Number of responses per respondent, Annual number of responses, Average burden hour per response, and Total annual burden hour(s).