DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10398 #13, #24, #73, #74, and #75]

Medicaid and Children's Health Insurance Program (CHIP) Generic Information Collection Activities: Proposed Collection; Comment Request

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

ACTION: Notice.

SUMMARY: On May 28, 2010, the Office of Management and Budget (OMB) issued Paperwork Reduction Act (PRA) guidance [1] related to the ''generic'' clearance process. Generally, this is an expedited process by which agencies may obtain OMB's approval of collection of information requests that are ''usually voluntary, low-burden, and uncontroversial collections,'' do not raise any substantive or policy issues, and do not require policy or methodological review. The process requires the submission of an overarching plan that defines the scope of the individual collections that would fall under its umbrella. On October 23, 2011, OMB approved our initial request to use the generic clearance process under control number 0938–1148 (CMS–10398). It was last approved on April 26, 2021, via the standard PRA process which included the publication of 60- and 30-day **Federal Register** notices. The scope of the April 2021 umbrella accounts for Medicaid and CHIP State plan amendments, waivers, demonstrations, and reporting. This **Federal Register** notice seeks public comment on one or more of our collection of information requests that we believe are generic and fall within the scope of the umbrella. Interested persons are invited to submit 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 January 21, 2022.

ADDRESSES: When commenting, please reference the applicable form number (see below) and the OMB control number (0938–1148). 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: CMS–10398 (#74)/OMB control number: 0938–1148, 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 access CMS' website 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: Following is a summary of the use and burden associated with the subject information collection(s). More detailed information can be found in the collection's supporting statement and associated materials (see **ADDRESSES**).

Generic Information Collections

1. *Title of Information Collection:* Medicaid Accountability—Nursing Facility, Outpatient Hospital and Inpatient Hospital Upper Payment Limits; *Type of Information Collection Request:* Revision of a currently approved collection; *Use:* Starting in 2013, CMS required states to submit annual upper payment limit (UPL) demonstrations on an annual basis. Previously this information was collected or updated only when a state was proposing an amendment to a reimbursement methodology in its Medicaid state plan. Specifically, in 2013, we required that states submit UPL demonstrations for inpatient hospital services, outpatient hospital services, and nursing facilities. In 2014, states were then required to submit annual UPL demonstrations for the services listed above as well as clinics, physician services (for states that reimburse targeted physician supplemental payments), Intermediate care facilities for individuals with intellectual disabilities (ICF/IID), psychiatric residential treatment facilities (PRTFs) and institutes for mental disease (IMDs). These annual demonstrations included provider specific data reporting on all payments made to the providers, including supplemental payments.

Through this process, States were also asked as part of the submission to identify the source of the non-federal share of funding. for the payments described in the UPL. This is consistent with the overall requirements to identify sources of non-federal funding set forth in section 1903(d)(1) of the Social Security Act. Such information will allow CMS and the State to have a better understanding of the variables surrounding rate levels, supplemental payments, and total providers participating in the programs and the funding supporting each of the payments described in the UPL demonstration.

In early 2021 CMS developed and revised the templates in conjunction with the States and a CMS contractor for use with each of the 3 services of the UPL demonstration within this package—Nursing Facility, Outpatient Hospital, and Inpatient Hospital. These templates are helping to standardize the data collection and allow the States to quickly transfer data from their existing UPL demonstration reporting tools into the new UPL demonstration templates for reporting to CMS. These templates have allowed the States to report the UPL demonstrations more efficiently with embedded formulas to help complete required areas of the UPL demonstrations, saving States time and effort in their reporting. Standardizing the templates has helped CMS to review the annual UPL demonstrations, by being able to look at one template format, instead of up to 54 different templates in each UPL demonstration types.

In this December 2021 revision, CMS is moving its Guidance and Instruction documents into an online format within the MACFin system. The Guidance and Instruction documents for each of the service type have been revised and will be collected online, a change from the previous collection of information where States responded via a Word type document and sent those responses to a dedicated UPL email box. Now States will be able to fill in the Guidance and Instruction documents as needed online. These two documents are now

[1] *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/assets/inforeg/PRA_Gen_ICRs_5-28-2010.pdf.*

combined in the online format and answered online as shown in the attached materials. Attached here are a walkthrough of the proposed changes for each service type and separate files for each of the screen pictures of the proposed questions and logical flow of the questions, that will become the online format for each service type. After answering the new online Guidance and Instructions, State personnel will then upload their UPL templates directly into the MACFin system for processing.

CMS has revised the Guidance and Instruction and the UPL templates. These changes are minor but substantive. The Guidance and Instruction documents were revised to accommodate an online format and to clarify the questions and data sources States use in calculating the UPL. Some additional questions have been asked (3), some eliminated (10), and others have been clarified, but the overall burden for States of 40 hours for each UPL package remains the same, though CMS anticipates the changes will save burden to States, as the online system will allow for a logical flow to the questions and only ask the relevant questions for each State's UPL submission.

The UPL templates have been revised to clarify definitions and instructions in filling out the UPL templates. The nursing facility template adds a tab to give States the option to use the Medicare created Patient Driven Payment Model (PDPM) as an option for the nursing facility UPL reporting. The new PDPM tab gives states the option of this new payment methodology, but does not require new data to be collected. None of the changes add burden to States, and CMS anticipates the new MACFin system will make it easier for States to upload and track their required UPL submissions. *Form Number:* CMS–10398 (#13) (OMB control number: 0938–1148); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 54; *Total Annual Responses:* 54; *Total Annual Hours:* 2,160. (For policy questions regarding this collection contact: Richard Kimball at 410–786–2278.)

2. *Title of Information Collection:* Medicaid Accountability—Upper Payment Limits for Clinics, Physician Services, ICF/IID, PRTFs, and IMDs; *Type of Information Collection Request:* Revision of a currently approved collection; *Use:* Starting in 2013, CMS required states to submit annual upper payment limit (UPL) demonstrations on an annual basis. Previously this information was collected or updated only when a state was proposing an amendment to a reimbursement methodology in its Medicaid state plan. Specifically, in 2013, we required that states submit UPL demonstrations for inpatient hospital services, outpatient hospital services, nursing facilities. In 2014, states were required to submit annual UPL demonstrations for the services listed above and clinics, physician services (for states that reimburse targeted physician supplemental payments), intermediate care facilities for Individuals with Intellectual Disabilities (ICF/IID), psychiatric residential treatment facilities (PRTFs) and institutes for mental disease (IMDs). These annual demonstrations included provider specific data reporting on all payments made to the providers, including supplemental payments.

Through this process, States are also asked as part of the submission to identify the source of non-federal funding for the payments described in the UPL. This is consistent with overall requirements to identify sources of non-federal funding set forth in section 1903(d)(1) of the Social Security Act. Such information will allow CMS and the state to have a better understanding of the variables surrounding rate levels, supplemental payments and total providers participating in the programs and the funding supporting each of the payments described in the UPL demonstration.

In early 2021 CMS developed and revised the templates in conjunction with the States and a CMS contractor for use with each of the 5 services of the UPL demonstration within this package—Intermediate care facilities for individuals with intellectual disabilities (ICF/IID), Clinic services, Medicaid qualified practitioner services (Physician), other Psychiatric Residential Treatment Facilities (PRTFs), and Institutes for mental diseases (IMDs). These templates are helping to standardize the data collection and allow the states to quickly transfer data from their existing UPL demonstration reporting tools into the new UPL demonstration templates for reporting to CMS. These templates have allowed the states to report the UPL demonstrations more efficiently with embedded formulas to help complete required areas of the UPL demonstrations, saving States time and effort in their reporting. Standardizing the templates has helped CMS to review the annual UPL demonstrations, by being able to look at one template format, instead of up to 54 different templates in each UPL demonstration types. Instructions on the use of the templates are attached to each template, along with a data dictionary.

In this December 2021 revision, CMS is moving its Guidance and Instruction documents into an online format within the MACFin system. The Guidance and Instruction documents for each of the service type have been revised and will be collected online, a change from the previous collection of information where States responded via a Word type document and sent those responses to a dedicated UPL email box. Now States will be able to fill in the Guidance and Instruction documents as needed online. These two documents are now combined in the online format and answered online as shown in the attached materials. Attached here are a walkthrough of the proposed changes for each service type and separate files for each of the screen pictures of the proposed questions and logical flow of the questions, that will become the online format for each service type. After answering the new online Guidance and Instructions, State personnel will then upload their UPL templates directly into the MACFin system for processing.

CMS has revised the Guidance and Instruction and the UPL templates. The IMD guidance and instructions were previously the same as the inpatient hospital guidance and instructions. Now the IMD has its own specific guidance and instructions.

These changes are minor but substantive. The Guidance and Instruction documents were revised as noted in the changes document to accommodate an online format and to clarify the questions and data sources States use in calculating the UPL. Some additional questions have been asked (50), some eliminated (36), and others have been clarified, but the overall burden for States of 40 hours for each UPL package remains the same, though CMS anticipates the changes will save burden to States, as the online system will allow for a logical flow to the questions and only ask the relevant questions for each State's UPL submission.

The UPL templates have been revised to clarify definitions and instructions in filling out the UPL templates. None of the changes add burden to States, and CMS anticipates the new MACFin system will make it easier for States to upload and track their required UPL submissions.

The standard funding questions have been revised for consistency with language in reviewing state plan amendments, instead of referring to the SMDL, we now refer to the state plan pages relevant to the funding

questions—attachments 4.19–A, 4.19–B, and 4.–19–D. The questions concerning the source of funding have not changed, therefore there is no change in the burden to States. *Form Number:* CMS–10398 (#24) (OMB control number: 0938–1148); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 54; *Total Annual Responses:* 54; *Total Annual Hours:* 2,160. (For policy questions regarding this collection contact: Richard Kimball at 410–786–2278.)

3. *Title of Information Collection:* Supplemental Payment Reporting under the Consolidated Appropriations Act; *Type of Information Collection Request:* Extension of a currently approved collection; *Use:* Through passage of Division CC, Title II, Section 202 of the Consolidated Appropriations Act (CAA), Congress added subsection (bb) to section 1903 of the Act, which requires the Secretary of Health and Human Services to establish a system for states to submit reports on supplemental payments as defined in section 1903(bb)(2) of the Act. States are required to submit ''reports, as determined appropriate by the Secretary, on supplemental payment data, as a requirement for a State plan or State plan amendment [SPA] that would provide for a supplemental payment'' as required by section 1903(bb)(1) of the Act.

CMS is implementing section 202 of the CAA of 2021 by adding new screens to the CMS–64 in the MBES system for states to report all supplemental payments. States will be expected to use the form starting for their first quarter Federal fiscal year 2022 expenditures beginning on January 15, 2022. The statute requires CMS to set up a data collection system for all state supplemental payments. *Form Number:* CMS–10398 (#73) (OMB control number: 0938–1148); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 54; *Total Annual Responses:* 54; *Total Annual Hours: 3,240.* (For policy questions regarding this collection contact: Richard Kimball at 410–786–2278.)

4. *Title of Information Collection:* Coverage of Routine Patient Cost for Items & Services in Qualifying Clinical Trials; *Type of Information Collection Request:* New collection; *Use:* Section 210 of the Consolidated Appropriations Act of 2021 amended section 1905(a) of the Social Security Act (the Act) to add a new mandatory benefit at 1905(a)(30). The new benefit mandates coverage of routine patient services and costs furnished in connection with participation by Medicaid beneficiaries in qualifying clinical trials. Routine costs for services provided in connection with participation in a qualifying clinical trial generally include any item or service provided to the individual under the qualifying clinical trial, including any item or service provided to prevent, diagnose, monitor, or treat complications resulting from participation in the qualified clinical trial, to the extent that the provision of such items or services to the individual would otherwise be covered under the state plan or waiver.

We propose that States and territories review the preprints completed for a Medicaid beneficiary to receive coverage of routine patient services and costs furnished in connection with participation in qualifying clinical trials. Completion of the preprint pages verifies in the Medicaid state plan that the mandatory clinical trials benefit is being furnished by a state. Completion of the preprint verifies that the requirements of a federally sponsored clinical trial is appropriate for the Medicaid beneficiary. *Form Number:* CMS–10398 (#74) (OMB control number: 0938–1148); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 56; *Total Annual Hours:* 56. (For policy questions regarding this collection contact Kirsten Jensen at 410–786–8146.)

5. *Title of Information Collection:* American Rescue Plan (ARP) 1135 State Plan Amendment; *Type of Information Collection Request:* New collection; *Use:* Section 9811 of the ARP established new mandatory benefits at section 1905(a)(4)(E) for COVID–19 vaccine and vaccine administration and section 1905(a)(4)(F) for COVID–19 testing and treatment for both Medicaid and CHIP. The effective date time period for these mandatory benefits is March 11, 2021, ending on the last day of the first calendar quarter that begins one year after the last day of the emergency period described in section 1135(g)(1)(B) of the Social Security Act (the Act). Given that regular state plan rules do not allow for effective dates prior to the first day of the quarter in which the state plan amendment (SPA) was submitted, we are allowing states to use Section 1135 SPA process waiver authority to allow states to meet the required timeframes of these provisions. The SPAs will implement mandatory Medicaid coverage and reimbursement for COVID–19 vaccine and vaccine administration and COVID–19 testing and treatment are considered part of the Agency's emergency response to COVID. CMS has issued guidance for each of these provisions.

In large part, states have already been providing these services throughout the course of the pandemic and these SPAs will reflect what states have been doing. CMS is primarily using an attestation approach for states to affirm that they are in compliance with the requirements of the provisions.

Form Number: CMS–10398 (#75) (OMB control number: 0938–1148); *Frequency:* Once and on occasion; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 56; *Total Annual Hours: 168.* (For policy questions regarding this collection contact Kirsten Jensen at 410–786–8146.)

Dated: January 4, 2022.

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

Office of the Secretary

Tenth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19

ACTION: Notice of amendment.

SUMMARY: The Secretary issues this amendment pursuant to section 319F–3 of the Public Health Service Act to expand the authority for certain Qualified Persons authorized to prescribe, dispense, and administer seasonal influenza vaccines under section VI of this Declaration.

DATES: This amendment is effective as of January 7, 2022.

FOR FURTHER INFORMATION CONTACT: L. Paige Ezernack, Office of the Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201; 202–260–0365, *paige.ezernack@hhs.gov.*

SUPPLEMENTARY INFORMATION: The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (the Secretary) to issue a Declaration to provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of,