DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10398 #59, #64, and #94]

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 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. 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 September 9, 2025.

ADDRESSES: When commenting, please reference the applicable form number (CMS–10398 #__) 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 #__/OMB control number: 0938–1148, Room C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

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/medicare/regulations-guidance/legislation/paperwork-reduction-act-1995/pra-listing.*

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 Collection

1. *Title of Information Collection:* Medicaid Section 1115 Severe Mental Illness (SMI) and Children with Serious Emotional Disturbance (SED) Demonstrations; *Type of Information Collection Request:* Revision of an existing generic information collection request; *Use:* In November 2018, CMS announced the opportunity for section 1115(a) demonstration projects, mandated under section 1203 of the 21st Century Cures Act, aimed at improving care for adult Medicaid beneficiaries with serious mental illness (SMI) and children with a serious emotional disturbance (SED). Participating states are eligible to receive federal financial participation for institutions of mental disease (IMD) stays subject to requirements that include ensuring quality of care in IMDs, improving connections to community-based care following stays in acute care settings, ensuring a continuum of care is available to address more chronic mental health care needs of beneficiaries with SMI/SED, providing a full array of crisis stabilization services, and engaging beneficiaries with SMI or SED treatment as soon as possible.

Primary data collection includes virtual interviews with (1) the state Medicaid Agency and/or the single state agency for behavioral health and (2) providers in the states that have approved section 1115 SMI/SED demonstrations. We will conduct three rounds of interviews: Initial Implementation Interviews will be conducted with state Medicaid directors and directors of the single state agency for mental health, or their designees; Provider Interviews will expand our understanding of SMI/SED demonstration implementation experience; and Follow-up Implementation Interviews.

As of April 2025, 15 states and the District of Columbia have an approved SMI/SED demonstration, and 3 states have a pending application. Since it is possible that all 50 states and the District of Columbia could submit SMI/SED demonstration applications, this 2025 revision proposes to: (1) increase the number of possible initial implementation interviews with state officials from 20 states to 50 states and the District of Columbia (N=51); (2) increase the number of provider interviews from 80 (in 20 states) to 100 (in 25 states) or up to 4 interviewees per state; and (3) add follow-up implementation interviews for up to 50 states and the District of Columbia. No follow-up interviews are planned with providers because that data collection was intended to learn providers' experiences and organizational changes after the demonstration was implemented.

Form Number: CMS–10398 #59 (OMB control number: 0938–1148)*; Frequency:* Once*; Affected Public:* Private Sector and State, Local, or Tribal Governments*; Number of Respondents:* 151*; Total Annual Responses:* 329*; Total Annual Hours:* 481. (For policy questions regarding this collection contact Raven Smith at 410–786–3731.)

2. *Title of Information Collection:* Section 1115 Federal Meta Analysis Substance Use Disorder (SUD) Demonstrations; *Type of Information Collection Request:* Revision of an existing generic information collection request; *Use:* Starting in 2015, in response to the opioid epidemic, CMS offered states the flexibility to test Medicaid coverage of a full SUD treatment service array in the context of overall SUD service delivery transformation through the authority of section 1115 demonstrations, provided states met specific requirements. A key component of the section 1115 demonstration is that states could apply to receive federal financial participation (FFP) for the continuum of services to treat addiction to opioids or other substances, including institutions for mental diseases (IMDs), which are normally ineligible for FFP if the facility has more than 16 beds.

This 2025 revision increases the ''MCO and Behavioral Health Provider Stakeholder Interviews'' from 80 interviews (in 10 states) to 160 interviews (in 20 states) and seeks approval for a follow-up round of interviews (referred to as Follow-up Implementation Interviews) with SUD state Medicaid directors, single state agency representatives, or other state officials who are involved in SUD demonstration implementation. These interviews will occur only with state officials; no providers will be included in the ''Follow-up Implementation Interviews.'' This revision also adds a thank you letter template for the initial Demonstration Characteristics and Implementation Interviews as well as templates for the email correspondence and interview protocol for the Follow-up Implementation Interviews.

Form Number: CMS–10398 #64 (OMB control number: 0938–1148)*; Frequency:* Once*; Affected Public:* Private Sector and State, Local, or Tribal Governments*; Number of Respondents:* 211*; Total Annual Responses:* 384*; Total Annual Hours:* 668. (For policy questions regarding this collection contact Raven Smith at 410–786–3731.)

3. *Title of Information Collection:* Streamlining Medicaid Enterprise Systems (MES) Advance Planning Documents (APD) Templates; *Type of Information Collection Request:* New generic information collection request; *Use:* This collection of information request proposes to move an active collection (CMS–10536, OMB 0938–1268) entitled, ''Medicaid Eligibility and Enrollment (E&E) Implementation Advance Planning Document (IAPD) Template'' under OMB control number 0938–1148 (CMS–10398 #94). We also propose to revise the collection's title as indicated above. The revised title better encapsulates the efforts to streamline and create efficiencies across MES instead of limiting it only to E&E implementations.

While the MES APD Template is currently approved by OMB under 0938–1268, we also propose to revise that template and add six new templates that have not been approved by OMB under any control number. The templates aim to streamline the process and ensure consistency across state submissions. We intend to discontinue 0938–1268 sometime after this new collection of information request (CMS–10398 #94) is approved by OMB under 0938–1148.

Form Number: CMS–10398 #94 (OMB control number: 0938–1148); *Frequency:* Monthly, once, and occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 3,314; *Total Annual Hours:* 86,096. (For policy questions regarding this collection contact: Loren Palestino at 410–786–8842.)

Evell Barco Holland,

Senior Technical Advisor, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2025–16343 Filed 8–25–25; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–E–5010]

Determination of Regulatory Review Period for Purposes of Patent Extension; LUMISIGHT

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for LUMISIGHT and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by October 27, 2025. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by February 23, 2026. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 27, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–E–5010 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; LUMISIGHT.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the