

Information Collection: Collection Requirements for Compendia for Determination of Medically-accepted Indications for Off-label Uses of Drugs and Biologicals in an Anti-cancer Chemotherapeutic Regimen; *Use:* Section 182(b) of the Medicare Improvement of Patients and Providers Act (MIPPA) amended section 1861(t)(2)(B) of the Social Security Act (42 U.S.C. 1395x(t)(2)(B)) by adding at the end the following new sentence: 'On and after January 1, 2010, no compendia may be included on the list of compendia under this subparagraph unless the compendia has a publicly transparent process for evaluating therapies and for identifying potential conflicts of interest.' CMS implemented this statutory provision that compendia have a "publicly transparent process for evaluating therapies and for identifying potential conflicts of interests" by amending 42 CFR 414.930 to include the MIPPA requirements and by defining the key components of publicly transparent processes for evaluating therapies and for identifying potential conflicts of interests.

All compendia were required to comply with these provisions as of January 1, 2010, to remain on the list of recognized compendia. In addition, any compendium that is the subject of a future request for inclusion on the list of recognized compendia will be required to comply with these provisions. No compendium can be on the list if it does not fully meet the standard described in section 1861(t)(2)(B) of the Act, as revised by section 182(b) of the MIPPA. *Form Number:* CMS-10302 (OMB control number: 0938-1078); *Frequency:* Annually; *Affected Public:* Business and other for-profits and Not-for-profit institutions; *Number of Respondents:* 845; *Total Annual Responses:* 900; *Total Annual Hours:* 5,135. (For policy questions regarding this collection contact Sarah Fulton at 410-786-2749.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10415]

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 (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 August 10, 2026.

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: __, 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, 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 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**).

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 Collections

1. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery; *Use:* This collection of information is necessary to enable the Agency to garner customer and stakeholder feedback in an efficient, timely manner, in accordance with our commitment to improving service delivery. The information collected from our customers and stakeholders will help ensure that users have an effective, efficient, and satisfying experience with the Agency's programs. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where

communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management. Collecting voluntary customer feedback is the least burdensome, most effective way for the Agency to determine whether or not its public websites are useful to and used by its customers. Generic clearance is needed to ensure that the Agency can continuously improve its websites through regular surveys developed from these pre-defined questions. Surveying the Agency websites on a regular, ongoing basis will help ensure that users have an effective, efficient, and satisfying experience on any of the websites, maximizing the impact of the information and resulting in optimum benefit for the public. The surveys will ensure that this communication channel meets customer and partner priorities, builds the Agency's brands, and contributes to the Agency's health and human services impact goals. *Form Number:* CMS-10415 (OMB control number 0938-1185); *Frequency:* Occasionally; *Affected Public:* Individuals and Households; *Number of Respondents:* 2,000,000; *Number of Responses:* 2,000,000; *Total Annual Hours:* 60,000. (For policy questions regarding this collection contact Aaron Lartey at 410-786-7866.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3486-N]

Announcement of the Approval of COLA as an Accreditation Organization for the Specialty of Histocompatibility Under the Clinical Laboratory Improvement Amendments of 1988

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces the application of the Commission on Laboratory Accreditation (COLA) for

approval as an accreditation organization for clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program for the specialty of Histocompatibility. We have determined that COLA meets or exceeds the applicable CLIA requirements. Consequently, we are granting COLA deeming authority for the specialty of Histocompatibility for a period of 5 years.

DATES: This notice is applicable from July 10, 2026 to June 10, 2031.

FOR FURTHER INFORMATION CONTACT: Sam Cyrus, (443) 896-4827.

SUPPLEMENTARY INFORMATION:

I. Background

On October 31, 1988, the Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Pub. L. 100-578). CLIA amended section 353 of the Public Health Service Act. We issued a final rule implementing the accreditation provisions of CLIA on July 31, 1992 (57 FR 33992). Under those provisions, CMS may grant deeming authority to an accreditation organization if its requirements for laboratories accredited under its program are equal to or more stringent than the applicable CLIA program requirements in 42 CFR part 493 (Laboratory Requirements). Subpart E of part 493 (Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program) specifies the requirements an accreditation organization must meet to be approved by CMS as an accreditation organization under CLIA.

II. Notice of Approval of COLA for the Specialty of Histocompatibility

In this notice, we approve the Commission on Laboratory Accreditation (COLA) as an organization that may accredit laboratories for purposes of establishing their compliance with CLIA requirements for the specialty of Histocompatibility. We have examined the initial COLA application and all subsequent submissions to determine its accreditation program's equivalency with the requirements for approval of an accreditation organization under subpart E of part 493. We have determined that COLA meets or exceeds the applicable CLIA requirements. We have also determined that COLA has provided reasonable assurance that it will ensure that its accredited laboratories will meet or exceed the applicable requirements in subparts H, I, J, K, M, Q, and the applicable sections

of subpart R. Therefore, we grant COLA approval as an accreditation organization under subpart E of part 493, for the period stated in the **DATES** section of this notice for the specialty of Histocompatibility. As a result of this determination, any laboratory that is accredited by COLA during the time period stated in the **DATES** section of this notice may be deemed to meet the CLIA requirements for the specialty of Histocompatibility, and therefore, will generally not be subject to routine inspections by a State survey agency to determine its compliance with CLIA requirements. The accredited laboratory, however, is subject to validation and complaint investigation surveys performed by CMS, or its agent(s).

III. Evaluation of COLA's Request for Approval as an Accreditation Organization Under CLIA for the Specialty of Histocompatibility

The following describes the process used to determine that COLA's accreditation program meets the necessary requirements to be approved by CMS and that, as such, CMS may approve COLA as an accreditation program with deeming authority under the CLIA program for the specialty of Histocompatibility. In reviewing these materials, we reached the following determinations for each applicable part of the CLIA regulations:

Subpart E—Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program

COLA submitted its mechanism for monitoring compliance with all requirements equivalent to condition-level requirements, a list of all current laboratories and the expiration date of their accreditation, and a detailed comparison of the individual accreditation requirements with the comparable condition-level requirements. We have determined that COLA policies and procedures for oversight of laboratories performing laboratory testing for the specialty of Histocompatibility are equivalent to those required under the CLIA regulations in the matters of inspection and investigating complaints. COLA submitted documentation regarding its requirements for monitoring and inspecting laboratories and describing its standards regarding data management, the inspection process, procedures for removal or withdrawal of accreditation, notification requirements for laboratories out of compliance, and accreditation organization resources. We have determined that COLA's requirements for monitoring and