patient-centeredness of laboratory services; revisions to the standards under which clinical laboratories are regulated; the impact of proposed revisions to the standards on medical and laboratory practice; and the modification of the standards and provision of non-regulatory guidelines to accommodate technological advances, such as new test methods, the electronic transmission of laboratory information, and mechanisms to improve the integration of public health and clinical laboratory practices.

Matters To Be Considered: The agenda will include agency updates from CDC, CMS, and FDA. In addition to the general updates, an update will be provided on the ongoing CLIAC workgroups. Presentations and CLIAC discussion will focus on the future of laboratory medicine, especially testing in non-traditional sites. There will be an extended public comment session focusing on anticipated changes in testing practices, personnel issues, and emerging technologies used in non-traditional testing sites. Agenda items are subject to change as priorities dictate.

It is the policy of CLIAC to accept written public comments and provide a brief period for oral public comments pertinent to agenda items. Public comment periods for each agenda item are scheduled immediately prior to the Committee discussion period for that item. In general, each individual or group requesting to present an oral comment will be limited to a total time of five minutes (unless otherwise indicated). Speakers should email *CLIAC@cdc.gov* or notify the contact person at least five business days prior to the meeting date. For individuals or groups unable to attend the meeting, CLIAC accepts written comments until the date of the meeting (unless otherwise stated). However, it is requested that comments be submitted at least five business days prior to the meeting date so that the comments may be made available to the Committee for their consideration and public distribution. All written comments will be included in the meeting Summary Report posted on the CLIAC website.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2022–05430 Filed 3–14–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10573 and CMS–10106]

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 May 16, 2022.

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, 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.*

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–10573 Reform of Requirements for Long-Term Care Facilities

CMS–10106 Medicare Authorization to Disclose Personal Health Information

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:* Revision of a currently approved collection; *Title of Information Collection:* Reform of Requirements for Long-Term Care Facilities; *Use:* According to our data, as of April 2, 2021, there were 15,372 LTC

facilities in the United States. These facilities are currently caring for 1,290,290 residents. Since the number of LTC facilities and residents varies yearly, for the purposes of this analysis, we utilized estimates of 15,600 for LTC facilities and 1.3 million residents. LTC facilities include skilled nursing facilities (SNFs) as defined in section 1819(a) of the Social Security Act in the Medicare program and nursing facilities (NFs) as defined in 1919(a) of the Act in the Medicaid program. SNFs and NFs provide skilled nursing care and related services for residents who require medical or nursing care, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons. In addition, NFs provide health-related care and services to individuals who because of their mental or physical condition require care and services (above the level of room and board) which can be made available to them only through institutional facilities, and is not primarily for the care and treatment of mental diseases. SNFs and NFs must care for their residents in such a manner and in such an environment as will promote maintenance or enhancement of the quality of life of each resident and must provide to residents services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, in accordance with a written plan of care, which describes the medical, nursing, and psychosocial needs of the resident and how such needs will be met and is updated periodically.

Under the authority of sections 1819 and 1919 of the Act, the Secretary proposed to reform the requirements that SNFs and NFs must meet to participate in the Medicare & Medicaid programs. These requirements would be set forth in 42 CFR 483 subpart B as Requirements for LTC Care Facilities. The requirements apply to an LTC facility as an entity as well as the services furnished to each individual under the care of the LTC facility, unless a requirement is specifically limited to Medicare or to Medicaid beneficiaries. To implement these requirements, State survey agencies generally conduct surveys of LTC facilities to determine whether or not they are complying with the requirements.

Ordinarily, we would be required to estimate the public reporting burden for information collection requirements (ICRs) for these regulations in accordance with chapter 35 of title 44, United States Code. However, sections 4204(b) and 4214(d) of Omnibus Budget Reconciliation Act of 1987, Public Law 100–203 (OBRA '87) provide for a waiver of Paperwork Reduction Act (PRA) requirements for some regulations. At the time that the 2016 LTC final rule (81 FR 68688) published, we believed that this waiver still applied to those updates we made to existing requirements in part 483 subpart B that were set forth by OBRA 87. However, we acknowledged that the 2016 final rule also extensively revised many of the existing requirements in part 483 subpart B and recognized that the revisions likely created new burdens for facilities. In addition, we noted that the 2016 final rule implemented several new requirements set forth by the Affordable Care Act, which were not included in the PRA waiver. Therefore, we provided burden estimates for the new ICRs finalized in the 2016 LTC final rule set forth by the Affordable Care Act, as well as those revisions to existing requirements in part 483 subpart B that were so extensive they could be considered new ICRs in concept. For the current or 2022 information collection request (ICR), we have provided updates to the burden in the 2019 ICR, as well as provided burden estimates for all of the new ICs finalized since 2016 that were in effect as of May 2021. The ICRs and the rules they were finalized in are indicated in table below.

ICRs Associated With Each Rule

Rule name and publication date	FR citation	ICRs
Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities; Final rule (CMS–3260–F) Published October 4, 2016.	81 FR 68688 ..	All ICRs, except as noted below.
Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency; IFC (CMS–3401–IFC) Published September 2, 2020.	85 FR 54820 ..	Section 483.80(h)—COVID–19 Testing.
Medicare and Medicaid Programs; COVID–19 Vaccine Requirements for Long Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs–IID) Residents, Clients, and Staff); IFC (CMS–3414–IFC) (May 2021 Vaccination IFC) Published May 13, 2021.	86 FR 26306 ..	Sections 483.80(d)(3)—COVID–19 immunizations and (g)(1)(viii)–(x).
Medicare and Medicaid Programs: CY 2022 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model Requirements and Model Expansion; Home Health and Other Quality Reporting Program Requirements; Home Infusion Therapy Services Requirements; Survey and Enforcement Requirements for Hospice Programs; Medicare Provider Enrollment Requirements; and COVID–19 Reporting Requirements for Long-Term Care Facilities (86 FR 62240) (CMS–1747–F and CMS–5531–F). Published November 9, 2021.	86 FR 62240 ..	Section 483.80(g).

The primary users of this information will be State agency surveyors, CMS, and the LTC facilities for the purposes of ensuring compliance with Medicare and Medicaid requirements as well as ensuring the quality of care provided to LTC facility residents. The ICs specified in the regulations may be used as a basis for determining whether a LTC is meeting the requirements to participate in the Medicare program. In addition, the information collected for purposes of ensuring compliance may be used to inform the data provided on CMS' Nursing Home Compare website and as such used by the public in considering nursing home selections for services. *Form Number:* CMS–10573 (OMB control number: 0938–1363); *Frequency:* Occasionally; *Affected Public:* Private Sector: Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 15,600; *Total Annual Responses:* 18,658,854; *Total Annual Hours:* 29,935,899. (For policy questions regarding this collection contact Diane Corning at 410–786–8486.)

2. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Medicare Authorization to Disclose Personal Health Information; *Use:* The ''Medicare Authorization to Disclose Personal Health Information'' will be used by Medicare beneficiaries to authorize Medicare to disclose their protected health information to a third

party. Medicare beneficiaries can submit the Medicare Authorization to Disclose Personal Health Information electronically at *Medicare.gov.* Beneficiaries may also submit the Medicare Authorization to Disclose Personal Health Information by mailing a complete and valid authorization form to Medicare. Beneficiaries can submit the Medicare Authorization to Disclose Personal Health Information verbally over the phone by calling Medicare. *Form Number:* CMS–10106 (OMB control number: 0938–0930); *Frequency:* Occasionally; *Affected Public:* Individuals or households; *Number of Respondents:* 1,000,000; *Total Annual Responses:* 1,000,000; *Total Annual Hours:* 250,000. (For policy questions regarding this collection contact Sam Jenkins at 410–786–3261.)

Dated: March 9, 2022.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2022–05360 Filed 3–14–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0367]

Compliance Policy Guide Sec. 540.525 Scombrotoxin (Histamine)-Forming Fish and Fishery Products—Decomposition and Histamine; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is reopening the comment period for the draft Compliance Policy Guide entitled ''Compliance Policy Guide Sec. 540.525 Scombrotoxin (Histamine)-forming Fish and Fishery Products—Decomposition and Histamine'' that published in the **Federal Register** of December 27, 2021. We are taking this action in response to a request from stakeholders to extend the comment period to allow additional time for interested parties to develop and submit data, other information, and comments before FDA begins work on the final guidance.

DATES: FDA is reopening the comment period for the draft Compliance Policy Guide announced in the **Federal Register** on December 27, 2021 (86 FR 73295). Submit either electronic or written comments on the draft guidance by April 14, 2022, to ensure that we consider your comments before we begin work on the final guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows.

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–2021–D–0367 for ''Compliance Policy Guide Sec. 540.525 Scombrotoxin (Histamine)-forming Fish and Fishery Products—Decomposition and Histamine.'' Received comments 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 information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Steven Bloodgood, Division of Seafood Safety (HFS–325), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–5316, email: *Steven.Bloodgood@fda.hhs.gov;* or Jessica Larkin, Center for Food Safety and Applied Nutrition, Office of Regulations and Policy (HFS–024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 27, 2021 (86 FR 73295), we published a notice announcing the availability of a draft Compliance Policy Guide (CPG) entitled ''Sec. 540.525 Scombrotoxin (Histamine)-forming Fish and Fishery Products—Decomposition and