or more additional components in certain of its stress testing scenarios the Board will notify the company in writing and include a basis for its determination. Within 14 calendar days of receipt of this notification the company may request in writing that the Board reconsider the requirement that company include the additional component(s) or additional scenario(s), including an explanation as to why the request for reconsideration should be granted. The Board will respond in writing within 14 calendar days of receipt of the company's request. This request would be submitted via the Federal Reserve's IntraLinks system.

Recordkeeping Requirements

Section 238.144(c)(1) requires a Category II SLHC, Category III SLHC, or a SLHC with average total consolidated assets of greater than $250 billion to establish and maintain a system of controls, oversight, and documentation, including policies and procedures, that are designed to ensure that its stress testing processes are effective in meeting the relevant requirements. These policies and procedures must, at a minimum, describe the covered company's stress testing practices and methodologies, and processes for validating and updating the company's stress test practices and methodologies consistent with applicable laws and regulations.

Frequency: Ongoing, annual, bi-annual, or event-generated.

Respondents: Foreign SLHCs with average total consolidated assets of greater than $250 billion and domestic covered SLHCs with average total consolidated assets of greater than $100 billion.

Total estimated number of respondents: 1.

Total estimated change in burden: 31.

Total estimated annual burden hours: 14,430.[1]

Board of Governors of the Federal Reserve System, September 22, 2023.

Erin M. Cayce,

Assistant Secretary of the Board.

[FR Doc. 2023–21160 Filed 9–27–23; 8:45 am]

BILLING CODE 6210–01–P

[1] More detailed information regarding this collection, including more detailed burden estimates, can be found in the OMB Supporting Statement posted at *https://www.federalreserve.gov/apps/reportingforms/home/review.* On the page displayed at the link, you can find the OMB Supporting Statement by referencing the collection identifier, FR LL.

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a proposal to implement the Ad Hoc Clearance for Board-Wide Use (FR 3100; OMB No. 7100–NEW).

FOR FURTHER INFORMATION CONTACT: Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, *nuha.elmaghrabi@frb.gov,* (202) 452–3884.

Office of Management and Budget (OMB) Desk Officer for the Federal Reserve Board, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. The OMB inventory, as well as copies of the PRA Submission, supporting statements (which contain more detailed information about the information collections and burden estimates than this notice), and approved collection of information instrument(s) are available at *https://www.reginfo.gov/public/do/PRAMain.* These documents are also available on the Federal Reserve Board's public website at *https://www.federalreserve.gov/apps/reportingforms/home/review* or may be requested from the agency clearance officer, whose name appears above.

Final Approval Under OMB Delegated Authority To Implement the Following Information Collection Collection

Collection title: Ad Hoc Clearance for Board-Wide Use.

Collection identifier: FR 3100.

OMB control number: 7100–NEW.

Effective Date: October 30, 2023.

General description of collection: Information under this ad hoc information collection would be collected from Board-regulated entities, other stakeholders, and the public (collectively, respondents) through to-be-defined surveys, interviews, and focus groups, and other similar activities about a variety of financial service-related topics and the Board's operations. The clearance would help the Board understand respondents' perspectives, experiences, and expectations regarding the financial system and Board operations and would be used to inform the Board's initiatives to promote financial system stability, supervise and regulate financial institutions and financial activities, and promote consumer protection and community development.

Frequency: As needed.

Respondents: Individuals, institutions, state and local governments, and other persons of interest to the Board.

Total estimated number of respondents: 850.

Total estimated annual burden hours: 17,000.[1]

Current actions: On May 15, 2023, the Board published an initial notice in the **Federal Register** (88 FR 30972) requesting public comment for 60 days on the implementation of the FR 3100. The comment period for this notice expired on July 14, 2023. The Board did not receive any comments. The collection will be implemented as proposed.

Board of Governors of the Federal Reserve System, September 22, 2023.

Erin M. Cayce,

Assistant Secretary of the Board.

[FR Doc. 2023–21157 Filed 9–27–23; 8:45 am]

BILLING CODE 6210–01–P

[1] More detailed information regarding this collection, including more detailed burden estimates, can be found in the OMB Supporting Statement posted at *https://www.federalreserve.gov/apps/reportingforms/home/review.* On the page displayed at the link, you can find the OMB Supporting Statement by referencing the collection identifier, FR 3100.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1795–N]

Medicare Program; Town Hall Meeting on the Fiscal Year 2025 Applications for New Medical Services and Technologies Add-On Payments

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

ACTION: Notice of meeting.

SUMMARY: This notice announces a town hall meeting in accordance with the Social Security Act (the Act) to discuss fiscal year (FY) 2025 applications for add-on payments for new medical services and technologies under the hospital inpatient prospective payment system (IPPS). Interested parties are invited to this virtual meeting to present their comments, recommendations, and data regarding whether the FY 2025 new medical services and technologies applications meet the substantial clinical improvement criterion.

DATES:

Meeting Dates: The New Technology Town Hall meeting announced in this notice will be held virtually on Wednesday, December 13, 2023, and Thursday, December 14, 2023 (the number of new technology applications submitted will determine if a second day for the meeting is necessary; see the **SUPPLEMENTARY INFORMATION** section for details regarding the second day of the meeting and the posting of the final schedule). The New Technology Town Hall meeting will begin each day at 9 a.m. eastern standard time (EST) and check-in via online platform will begin at 8:30 a.m. EST.

Deadline for Registration of Presenters at the New Technology Town Hall Meeting: The deadline to register to present at the New Technology Town Hall meeting is 5 p.m., EST on Monday, November 6, 2023.

Deadline for Submission of Agenda Item(s) or Written Comments for the New Technology Town Hall Meeting: Written comments and agenda items (public comments to be delivered at the New Technology Town Hall meeting) for discussion at the New Technology Town Hall meeting, including agenda items by presenters (presentation slide decks), must be received by 5 p.m. EST on Monday, November 13, 2023.

Deadline for Requesting Special Accommodations: The deadline to submit requests for special accommodations is 5 p.m., EST on Monday, November 20, 2023.

Deadline for Submission of Written Comments after the New Technology Town Hall Meeting for Consideration in the Fiscal Year (FY) 2025 Hospital Inpatient Prospective Payment System/Long Term Care PPS (IPPS/LTCH PPS) Proposed Rule: Individuals may submit written comments after the New Technology Town Hall meeting, as specified in the **ADDRESSES** section of this notice, on whether the service or technology represents a substantial clinical improvement. These comments must be received by 5 p.m. EST on Monday, December 18, 2023, to ensure consideration in the FY 2025 IPPS/LTCH PPS proposed rule.

ADDRESSES:

Meeting Location: The New Technology Town Hall meeting will be held virtually via live stream technology or webinar and listen-only via toll-free teleconference. Live stream or webinar and teleconference dial-in information will be provided through an upcoming listserv/email notice and will appear on the final meeting agenda, which will be posted on the New Technology website when available at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html.* Continue to check the website for updates.

Registration and Special Accommodations: Individuals wishing to present at the meeting must follow the instructions located in section III. of this notice. Individuals who need special accommodations should send an email to *newtech@cms.hhs.gov.*

Submission of Agenda Item(s) or Written Comments for the New Technology Town Hall Meeting: Each presenter must submit an agenda item(s) regarding whether a FY 2025 application meets the substantial clinical improvement criterion. Written comments, questions or other statements must not exceed three single-spaced typed pages and may be sent via email to *newtech@cms.hhs.gov.*

FOR FURTHER INFORMATION CONTACT:

Drew Kasper, (410) 786–8926, *drew.kasper@cms.hhs.gov* and *newtech@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on the Add-On Payments for New Medical Services and Technologies Under the IPPS

Effective for discharges beginning on or after October 1, 2001, section 1886(d)(5)(K)(i) of the Act requires the Secretary to establish (after notice and opportunity for public comment) a mechanism to recognize the costs of new services and technologies under the hospital inpatient prospective payment system (IPPS). In addition, section 1886(d)(5)(K)(vi) of the Act specifies that a medical service or technology will be considered ''new'' if it meets criteria established by the Secretary (after notice and opportunity for public comment). For further discussion on the new technology add-on payment criteria, we refer readers to the new technology add-on payment final rule (66 FR 46912, September 7, 2001), as well as the FY 2012 IPPS/LTCH PPS final rule (76 FR 51572 through 51574), the FY 2020 IPPS/LTCH PPS final rule (84 FR 42288 through 42300), and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58736 through 58742).

As finalized in the FY 2020 and FY 2021 IPPS/LTCH PPS final rules, technologies which are eligible for the alternative new technology pathway for transformative new devices or the alternative new technology pathway for certain antimicrobials do not need to meet the requirement under 42 CFR 412.87(b)(1) that the technology represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. These medical devices or products will also be considered not substantially similar to an existing technology for purposes of new technology add-on payment under the IPPS. See the FY 2020 IPPS/LTCH PPS final rule (84 FR 42292 through 42297) and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58737 through 58739) for additional information.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42289 through 42292), we codified in our regulations at § 412.87 the following aspects of how we evaluate substantial clinical improvement for purposes of new technology add-on payments under the IPPS to determine if a new technology meets the substantial clinical improvement requirement:

- The totality of the circumstances is considered when making a determination that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries.
- A determination that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries means—

++ The new medical service or technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments;

++ The new medical service or technology offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods, and there must also be evidence that use of the new medical service or technology to make a diagnosis affects the management of the patient; or

++ The use of the new medical service or technology significantly improves clinical outcomes relative to services or technologies previously available as demonstrated by one or more of the following:

—A reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication.

—A decreased rate of at least one subsequent diagnostic or therapeutic intervention (for example, due to reduced rate of recurrence of the disease process).

—A decreased number of future hospitalizations or physician visits.

—A more rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time; an improvement in one or more activities of daily living; an improved quality of life; or, a demonstrated greater medication adherence or compliance.

++ The totality of the circumstances otherwise demonstrates that the new medical service or technology substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.

• Evidence from the following published or unpublished information sources from within the United States or elsewhere may be sufficient to establish that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries: Clinical trials, peer reviewed journal articles; study results; meta-analyses; consensus statements; white papers; patient surveys; case studies; reports; systematic literature reviews; letters from major healthcare associations; editorials and letters to the editor; and public comments. Other appropriate information sources may be considered.

• The medical condition diagnosed or treated by the new medical service or technology may have a low prevalence among Medicare beneficiaries.

• The new medical service or technology may represent an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of a subpopulation of patients with the medical condition diagnosed or treated by the new medical service or technology.

Section 1886(d)(5)(K)(viii) of the Act requires that as part of the process for evaluating new medical services and technology applications, the Secretary shall do the following:

• Provide for public input regarding whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of Medicare beneficiaries before publication of a proposed rule.

• Make public and periodically update a list of all the services and technologies for which an application is pending.

• Accept comments, recommendations, and data from the public regarding whether the service or technology represents a substantial improvement.

• Provide for a meeting at which organizations representing hospitals, physicians, manufacturers, and any other interested party may present comments, recommendations, and data to the clinical staff of CMS as to whether the service or technology represents a substantial improvement before publication of a proposed rule.

The opinions and presentations provided during this meeting will assist us as we evaluate the new medical services and technology applications for FY 2025.

II. New Technology Town Hall Meeting Format and Conference Call Information

A. Format of the Town Hall Meeting

As noted in section I. of this notice, we are required to provide for a meeting at which organizations representing hospitals, physicians, manufacturers, and any other interested party may present comments, recommendations, and data to the clinical staff of CMS concerning whether the service or technology represents a substantial clinical improvement. This meeting will allow for a discussion of the substantial clinical improvement criterion for the FY 2025 applications for new technology add-on payments. Information regarding the applications can be found on our website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html.*

The majority of the meeting will be reserved for presentations of comments, recommendations, and data from registered presenters. The time for each presenter's comments will be approximately 10 minutes, with additional time reserved for questions, and will be based on the number of registered presenters. Individuals who would like to present must register and submit their agenda item(s) via email to *newtech@cms.hhs.gov* by the dates specified in the **DATES** section of this notice.

Depending on the number of applications received, we will determine if a second meeting day is necessary. The final schedule for the New Technology Town Hall meeting will be posted on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html* by November 20, 2023 to inform the public of the number of days of the meeting.

In addition, written comments will also be accepted and presented at the meeting if they are received via email to *newtech@cms.hhs.gov* by the date specified in the **DATES** section of this notice. Written comments may also be submitted after the meeting for our consideration. If the comments are to be considered before the publication of the FY 2025 IPPS/LTCH PPS proposed rule, the comments must be received via email to *newtech@cms.hhs.gov* by the date specified in the **DATES** section of this notice.

B. Conference Call and Webinar Information

As noted previously, the New Technology Town Hall meeting will be held virtually. There will be an option to participate in the New Technology Town Hall Meeting via webinar and a toll-free teleconference phone line. Information on the option to participate via webinar and a teleconference dial-in will be provided through an upcoming listserv/email notice and will appear on the final meeting agenda, which will be posted on the New Technology website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html.* Continue to check the website for updates.

C. Disclaimer

We cannot guarantee reliability for a webinar.

III. Registration Instructions

The Division of New Technology in CMS is coordinating the meeting registration for the New Technology Town Hall meeting on substantial clinical improvement. While there is no registration fee, individuals planning to present at the New Technology Town Hall meeting must register to present.

Registration for presenters may be completed by sending an email to *newtech@cms.hhs.gov,* by the date specified in the **DATES** section of this notice. Please include the name and email address of the presenter(s), as well as address, telephone number, and the

name of the technology for which they will be presenting.

Registration for attendees not presenting at the meeting is not required.

IV. Collection of Information

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Chyana Woodyard, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Chyana Woodyard,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2023–21186 Filed 9–27–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2030]

Agency Information Collection Activities; Proposed Collection; Comment Request; Application for Food and Drug Administration Approval To Market a New Drug

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. 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 of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with applications for FDA approval to market a new drug or generic drug.

DATES: Either electronic or written comments on the collection of information must be submitted by November 27, 2023.

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 November 27, 2023. 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–2020–N–2030 for ''Application for Food and Drug Administration Approval to Market a New Drug.'' 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 information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its 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: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined