purposes of publication in the **Federal Register**.

Lynette Wilson,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2022–08253 Filed 4–15–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10440]

Agency Information Collection Activities: Proposed Collection; Comment Request; Correction

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

ACTION: Notice; correction.

SUMMARY: On April 6, 2022, CMS published a notice in the **Federal Register** that sought comment on a collection of information concerning CMS–10440 (OMB control number 0938–1191) entitled ''Data Collection to Support Eligibility Determinations for Insurance Affordability Programs and Enrollment through Health Insurance Marketplaces, Medicaid and Children's Health Insurance Program Agencies.'' In one other instance the title was correct and in another the title was incorrect. This document corrects the incorrect occurrence.

FOR FURTHER INFORMATION CONTACT: William N. Parham, III, (410) 786–4669.

SUPPLEMENTARY INFORMATION:

I. Background

In the April 6, 2022, issue of the **Federal Register** (87 FR 19957), we published a Paperwork Reduction Act notice requesting a 60-day public comment period for the information collection request identified under CMS–10440, OMB control number 0938–1191, and titled ''Data Collection to Support Eligibility Determinations for Insurance Affordability Programs and Enrollment through Health Insurance Marketplaces, Medicaid and Children's Health Insurance Program Agencies.''

II. Explanation of Error

In the April 6, 2022, notice, the title associated with the information collection request identified under CMS–10440 is correctly listed on page 19957, in the second column, in the third paragraph under ''Contents.'' However, the title on page 19958 in the first column, in the second paragraph, beginning on line 11, the ''Title of Information Collection:'' incorrectly reads, ''Medicare Coverage of Items and Services in FDA Investigational Device Exemption Clinical Studies—Revision of Medicare Coverage.'' This notice corrects the ''Title of Information Collection.'' All of the other information contained in the April 6, 2022, notice is correct. The related public comment period remains in effect and ends June 6, 2022.

III. Correction of Error

In the **Federal Register** of April 6, 2022, in FR Doc. 2022–07314, on page 19958, in the first column, in the second paragraph, under ''Title of Information Collection;'' in lines 11–15, correct ''Medicare Coverage of Items and Services in FDA Investigational Device Exemption Clinical Studies—Revision of Medicare Coverage'' to read, ''Data Collection to Support Eligibility Determinations for Insurance Affordability Programs and Enrollment through Health Insurance Marketplaces, Medicaid and Children's Health Insurance Program Agencies;''.

Dated: April 12, 2022.

William N. Parham, III,

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

[FR Doc. 2022–08221 Filed 4–15–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1775–N]

Medicare Program; Public Meeting on June 23, 2022 Regarding New and Reconsidered Clinical Diagnostic Laboratory Test Codes for the Clinical Laboratory Fee Schedule for Calendar Year 2023

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

ACTION: Notice.

SUMMARY: This notice announces a public meeting to receive comments and recommendations (including data on which recommendations are based) on the appropriate basis for establishing payment amounts for new or substantially revised Healthcare Common Procedure Coding System codes being considered for Medicare payment under the Clinical Laboratory Fee Schedule (CLFS) for calendar year (CY) 2023. This meeting also provides a forum for those who submitted certain reconsideration requests regarding final determinations made last year on new test codes and for the public to provide comment on the requests.

DATES:

CLFS Annual Public Meeting Date: The virtual meeting is scheduled for Thursday, June 23, 2022 from 9:00 a.m. to 5:00 p.m., E.D.T.

Deadline for Submission of Presentations and Written Comments: All presenters for the CLFS Annual Public Meeting must register and submit their presentations electronically to our CLFS dedicated email box, *CLFS_Annual_Public_Meeting@cms.hhs.gov,* by June 2, 2022 at 5:00 p.m., E.D.T. All written comments (non-presenter comments) must also be submitted electronically to our CLFS dedicated email box, *CLFS_Annual_Public_Meeting@cms.hhs.gov,* by June 2, 2022, at 5:00 p.m., E.D.T. Any presentations or written comments received after that date and time will not be included in the meeting and will not be reviewed.

Deadline for Submitting Requests for Special Accommodations: Requests for special accommodations must be received no later than June 2, 2022 at 5:00 p.m. E.D.T.

Publication of Proposed Determinations: We intend to publish our proposed determinations for new test codes and our proposed determinations for reconsidered codes (as described later in section II ''Format'' of this notice) for CY 2023 by early September 2022.

Deadline for Submission of Written Comments Related to Proposed Determinations: Comments in response to the proposed determinations for new and reconsidered codes will be due by early October 2022.

ADDRESSES: Due to the current COVID–19 public health emergency, the CLFS Annual Public Meeting will be held virtually and will not occur at the campus of the Centers for Medicare & Medicaid Services (CMS), Central Building, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Where to Submit Written Comments: Interested parties should submit all written comments on presentations and proposed determinations electronically to our CLFS dedicated email box, *CLFS_Annual_Public_Meeting@cms.hhs.gov* (the specific date for the publication of these determinations and the deadline for submitting comments regarding these determinations will be published on the CMS website).

FOR FURTHER INFORMATION CONTACT: Rasheeda Arthur, Ph.D., (410) 786–3434. Submit all inquiries to the CLFS dedicated email box, *CLFS_Annual_Public_Meeting@cms.hhs.gov* with the

subject entitled ''CLFS Annual Public Meeting Inquiry.''

SUPPLEMENTARY INFORMATION:

I. Background

Section 531(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554) required the Secretary of the Department of Health and Human Services (the Secretary) to establish procedures for coding and payment determinations for new clinical diagnostic laboratory tests under Part B of title XVIII of the Social Security Act (the Act) that permit public consultation in a manner consistent with the procedures established for implementing coding modifications for International Classification of Diseases, Tenth Revision, Clinical Modification (ICD–10–CM). The procedures and Clinical Laboratory Fee Schedule (CLFS) public meeting announced in this notice for new tests are in accordance with the procedures published on November 23, 2001 in the **Federal Register** (66 FR 58743) to implement section 531(b) of BIPA.

Section 942(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) added section 1833(h)(8) of the Act. Section 1833(h)(8)(A) of the Act requires the Secretary to establish by regulation procedures for determining the basis for, and amount of, payment for any clinical diagnostic laboratory test (CDLT) for which a new or substantially revised Healthcare Common Procedure Coding System (HCPCS) code is assigned on or after January 1, 2005. A code is considered to be substantially revised if there is a substantive change to the definition of the test or procedure to which the code applies (for example, a new analyte or a new methodology for measuring an existing analyte-specific test). (See section 1833(h)(8)(E)(ii) of the Act and 42 CFR 414.502).

Section 1833(h)(8)(B) of the Act sets forth the process for determining the basis for, and the amount of, payment for new tests. Pertinent to this notice, sections 1833(h)(8)(B)(i) and (ii) of the Act require the Secretary to make available to the public a list that includes any such test for which establishment of a payment amount is being considered for a year and, on the same day that the list is made available, cause to have published in the **Federal Register** notice of a meeting to receive comments and recommendations (including data on which recommendations are based) from the public on the appropriate basis for establishing payment amounts for the tests on such list. This list of codes for which the establishment of a payment amount under the CLFS is being considered for Calendar Year (CY) 2023 will be posted on the Centers for Medicare & Medicaid Services (CMS) website concurrent with the publication of this notice and may be updated prior to the CLFS Annual Public Meeting. The CLFS Annual Public Meeting list of codes can be found on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html?redirect=/ClinicalLabFeeSched/.* Section 1833(h)(8)(B)(iii) of the Act requires that we convene the public meeting not less than 30 days after publication of the notice in the **Federal Register**. The CLFS requirements regarding public consultation are codified at 42 CFR 414.506.

Two bases of payment are used to establish payment amounts for new CDLTs. The first basis, called ''crosswalking,'' is used when a new CDLT is determined to be comparable to an existing test, multiple existing test codes, or a portion of an existing test code. New CDLTs that were assigned new or substantially revised codes prior to January 1, 2018, are subject to provisions set forth under § 414.508(a). For a new CDLT that is assigned a new or significantly revised code on or after January 1, 2018, CMS assigns to the new CDLT code the payment amount established under § 414.507 of the comparable existing CDLT. Payment for the new CDLT code is made at the payment amount established under § 414.507. (See § 414.508(b)(1)).

The second basis, called ''gapfilling,'' is used when no comparable existing CDLT is available. When using this method, instructions are provided to each Medicare Administrative Contractor (MAC) to determine a payment amount for its Part B geographic area for use in the first year. In the first year, for a new CDLT that is assigned a new or substantially revised code on or after January 1, 2018, the MAC-specific amounts are established using the following sources of information, if available: (1) Charges for the test and routine discounts to charges; (2) resources required to perform the test; (3) payment amounts determined by other payers; (4) charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant; and (5) other criteria CMS determines appropriate. In the second year, the test code is paid at the median of the MAC-specific amounts. (See § 414.508(b)(2)).

Under section 1833(h)(8)(B)(iv) of the Act and § 414.506(d)(1) CMS, taking into account the comments and recommendations (and accompanying data) received at the CLFS Annual Public Meeting, develops and makes available to the public a list of proposed determinations with respect to the appropriate basis for establishing a payment amount for each code, an explanation of the reasons for each determination, the data on which the determinations are based, and a request for public written comments on the proposed determinations. Under section 1833(h)(8)(B)(v) of the Act and § 414.506(d)(2), taking into account the comments received on the proposed determinations during the public comment period, CMS then develops and makes available to the public a list of final determinations of payment amounts for tests along with the rationale for each determination, the data on which the determinations are based, and responses to comments and suggestions received from the public.

Section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) added section 1834A to the Act. The statute requires extensive revisions to the Medicare payment, coding, and coverage requirements for CDLTs. Pertinent to this notice, Section 1834A(c)(3) of the Act requires the Secretary to consider recommendations from the expert outside advisory panel established under section 1834A(f)(1) of the Act when determining payment using crosswalking or gapfilling processes. In addition, section 1834A(c)(4) of the Act requires the Secretary to make available to the public an explanation of the payment rates for the new test codes, including an explanation of how the gapfilling criteria and panel recommendations are applied. These requirements are codified in § 414.506(d) and (e).

After the final determinations have been posted on the CMS website, the public may request reconsideration of the basis and amount of payment for a new CDLT as set forth in § 414.509. Pertinent to this notice, those requesting that we reconsider the basis for payment or the payment amount as set forth in § 414.509(a) and (b), may present their reconsideration requests at the following year's CLFS Annual Public Meeting provided the requestor made the request to present at the CLFS Annual Public Meeting in the written reconsideration request. For purposes of this notice, we refer to these codes as the ''reconsidered codes.'' The public may comment on the reconsideration requests. (See the CY 2008 Physician Fee Schedule final rule with comment period published in the **Federal Register** on November 27, 2007 (72 FR

66275 through 66280) for more information on these procedures).

II. Format

We are following our usual process, including an annual public meeting to determine the appropriate basis and payment amount for new and reconsidered codes under the CLFS for CY 2023. However, due to the COVID–19 public health emergency, the public meeting will be conducted virtually and will not occur on-site at the CMS Central Building.

This meeting is still open to the public. Registration is only required for those interested in presenting public comments during the meeting. During the virtual meeting, registered persons from the public may discuss and make recommendations for specific new and reconsidered codes for the CY 2023 CLFS.

The Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests (Advisory Panel on CDLTs) will participate in this CLFS Annual Public Meeting by gathering information and asking questions to presenters, and will hold its next public meeting, virtually on July 18, 2022 and July 19, 2022. The public meeting for the Advisory Panel on CDLTs will focus on the discussion of and recommendations for test codes presented during the June 23, 2022 CLFS Annual Public Meeting. The Panel meeting also will address any other CY 2023 CLFS issues that are designated in the Panel's charter and specified on the meeting agenda. The announcement for the next meeting of the Advisory Panel on CDLTs is included in a separate notice published elsewhere in this issue of the **Federal Register**.

Due to time constraints, presentations must be brief, lasting no longer than 10 minutes. Written presentations must be electronically submitted to CMS on or before June 2, 2022. Presentation slots are typically assigned based upon chronological order of receipt of presentation materials. In the event there is not enough time for presentations by everyone who is interested in presenting, we will only accept written presentations from those who submitted written presentations within the submission window and were unable to present due to time constraints. Presentations should be sent via email to our CLFS dedicated email box, *CLFS_Annual_Public_Meeting@cms.hhs.gov.* In addition, individuals may also submit requests after the CLFS Annual Public Meeting to obtain electronic versions of the presentations. Requests for electronic copies of the presentations after the public meeting should be sent via email to our CLFS dedicated email box, noted above.

Presenters should submit all presentations using a standard PowerPoint template that is available on the CMS website, at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Laboratory_Public_Meetings.html,* under the ''Meeting Notice and Agenda'' heading.

For reconsidered and new codes, presenters should address all of the following five items:

(1) Reconsidered or new code(s) with the most current code descriptor.

(2) Test purpose and method with a brief comment on how the new test is different from other similar analyte or methodologies found in tests already on the CLFS.

(3) Test costs.

(4) Charges.

(5) Recommendation with rationale for one of the two bases (crosswalking or gapfilling) for determining payment for reconsidered and new tests.

In addition, presenters should provide the data on which their recommendations are based. Presentations regarding reconsidered and new test codes that do not address the above five items for presenters may be considered incomplete and may not be considered by CMS when making a determination. However, we may request missing information following the meeting to prevent a recommendation from being considered incomplete.

Taking into account the comments and recommendations (and accompanying data) received at the CLFS Annual Public Meeting, we intend to post our proposed determinations with respect to the appropriate basis for establishing a payment amount for each new test code and our proposed determinations with respect to the reconsidered codes along with an explanation of the reasons for each determination, the data on which the determinations are based, and a request for public written comments on these determinations on our website by early September 2022. This website can be accessed at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html?redirect=/ClinicalLabFeeSched/.* Interested parties may submit written comments on the proposed determinations for new and reconsidered codes by early October 2022, electronically to our CLFS dedicated email box, *CLFS_Annual_Public_Meeting@cms.hhs.gov* (the specific date for the publication of the determinations on the CMS website, as well as the deadline for submitting comments regarding the determinations, will be published on the CMS website). Final determinations for new test codes to be included for payment on the CLFS for CY 2023 and reconsidered codes will be posted our website in November 2022, along with the rationale for each determination, the data on which the determinations are based, and responses to comments and suggestions received from the public. The final determinations with respect to reconsidered codes are not subject to further reconsideration. With respect to the final determinations for new test codes, the public may request reconsideration of the basis and amount of payment as set forth in § 414.509.

III. Registration Instructions

The Division of Ambulatory Services in the CMS Center for Medicare is coordinating the CLFS Annual Public Meeting registration. Beginning May 2, 2022 and ending June 2, 2022, registration may be completed by presenters only. Individuals who intend to view and/or listen to the meeting do not need to register. Presenter registration may be completed by sending an email to our CLFS dedicated email box, *CLFS_Annual_Public_Meeting@cms.hhs.gov.* The subject of the email should state ''Presenter Registration for CY 2023 CLFS Annual Laboratory Meeting.'' All of the following information must be submitted when registering:

- Speaker name.
- Organization or company name.
- Telephone numbers.
- Email address that will be used by the presenter in order to connect to the virtual meeting.
- New or Reconsidered Code (s) for which presentation is being submitted.
- Presentation.

Registration details may not be revised once they are submitted. If registration details require changes, a new registration entry must be submitted by the date specified in the **DATES** section of this notice. Also, registration information must reflect individual-level content and not reflect an organization entry. In addition, each individual may only register one person at a time. That is, one individual may not register multiple individuals at the same time.

After registering, a confirmation email will be sent upon receipt of the registration. The email will provide information to the presenter in preparation for the meeting. Registration is only required for individuals giving a presentation during the meeting. Presenters must register by the deadline

specified in the **DATES** section of this notice.

If you are not presenting during the CLFS Annual Public Meeting, you may view the meeting via webinar or listen-only by teleconference. If you would like to listen to or view the meeting, teleconference dial-in and webinar information will appear on the final CLFS Annual Public Meeting agenda, which will be posted on the CMS website when available at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html?redirect=/ClinicalLabFeeSched/.*

IV. Special Accommodations

Individuals viewing or listening to the meeting who are hearing or visually impaired and have special requirements, or a condition that requires special assistance, should send an email to the resource box (*CDLT_Annual_Public_Meeting@cms.hhs.gov*). The deadline for submitting this request is listed in the **DATES** section of this notice.

V. Collection of Information Requirements

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. 3501 *et seq.*).

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

Dated: April 13, 2022.

Lynette Wilson,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2022–08259 Filed 4–15–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0049]

Revocation of Five Authorizations of Emergency Use of In Vitro Diagnostic Devices for Detection and/or Diagnosis of COVID–19; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorizations (EUAs) (the Authorizations) issued to BillionToOne, Inc. for the qSanger-COVID–19 Assay, RTA Laboratories Biological Products Pharmaceutical and Machinery Industry (RTA) for the Diagnovital SARS–CoV–2 Real-Time PCR Kit, DiaSorin Inc. for the DiaSorin LIAISON SARS–CoV–2 IgM Assay, and CENTOGENE US, LLC for both the CentoFast-SARS–CoV–2 RT–PCR Assay and CentoSure SARS–CoV–2 RT–PCR Assay. FDA revoked these Authorizations under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The revocations, which include an explanation of the reasons for each revocation, are reprinted in this document.

DATES: The Authorization for the qSanger-COVID–19 Assay is revoked as of March 10, 2022. The Authorization for the Diagnovital SARS–CoV–2 Real-Time PCR Kit is revoked as of March 14, 2022. The Authorization for the DiaSorin LIAISON SARS–CoV–2 IgM Assay is revoked as of March 15, 2022. The Authorizations for the CentoFast-SARS–CoV–2 RT–PCR Assay and CentoSure SARS–CoV–2 RT–PCR Assay are revoked as of March 17, 2022.

ADDRESSES: Submit written requests for a single copy of the revocations to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the revocations may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revocations.

FOR FURTHER INFORMATION CONTACT: Jennifer J. Ross, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993–0002, 240–402–8155 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb-3) as amended by the Project BioShield Act of 2004 (Pub. L. 108–276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113–5) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. On September 4, 2020, FDA issued an EUA to BillionToOne, Inc. for the qSanger-COVID–19 Assay, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on November 20, 2020 (85 FR 74346), as required by section 564(h)(1) of the FD&C Act. On June 12, 2020, FDA issued an EUA to RTA for the Diagnovital SARS–CoV–2 Real-Time PCR Kit, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on November 20, 2020 (85 FR 74346), as required by section 564(h)(1) of the FD&C Act. On September 29, 2020, FDA issued an EUA to DiaSorin Inc. for the DiaSorin LIAISON SARS–CoV–2 IgM Assay, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on April 23, 2021 (86 FR 21749), as required by section 564(h)(1) of the FD&C Act. On July 1, 2020, FDA issued an EUA to CENTOGENE US, LLC for the CentoFast-SARS–CoV–2 RT–PCR Assay, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on November 20, 2020 (85 FR 74346), as required by section 564(h)(1) of the FD&C Act. On September 29, 2020, FDA issued an EUA to CENTOGENE US, LLC for the CentoSure SARS–CoV–2 RT–PCR Assay, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on April 23, 2021 (86 FR 21749), as required by section 564(h)(1) of the FD&C Act. Subsequent changes to the Authorizations were made available on FDA's website. The authorization of a device for emergency use under section 564 of the FD&C Act may, pursuant to section 564(g)(2) of the