used by all Exchanges using the Federal eligibility and enrollment platform, unless otherwise specified in future guidance or rulemaking.

The 2014 final rule also amended the requirements for product renewal and re-enrollment (or non-renewal) notices to be sent by QHP issuers in the Exchanges and specifies content for these notices. The guidance document ''Updated Federal Standard Renewal and Product Discontinuation Notices, and Enforcement Safe Harbor for Product Discontinuation Notices in Connection with the Open Enrollment Period for Coverage in the Individual Market in the 2020 Benefit Year'' provides standard notices for product discontinuation and renewal to be sent by issuers of individual market QHPs and issuers in the individual market.

The Federal standard notices to be sent by issuers of individual market QHPs and issuers in the individual market have been revised to improve consumer understanding and update out-of-date information, and to include language to reference the potential for a bronze to silver crosswalk under 45 CFR 155.335(j)(4). The revised notices in this information collection will be required for notices provided in connection with coverage beginning in the 2024 plan year.

Issuers in the small group market may use the draft Federal standard small group notices released in the June 26, 2014 bulletin ''Draft Standard Notices When Discontinuing or Renewing a Product in the Small Group or Individual Market'', or any forms of the notice otherwise permitted by applicable laws and regulations. States that are enforcing the guaranteed renewability provisions of the Affordable Care Act may develop their own standard notices for product discontinuances, renewals, or both, provided the state-developed notices are at least as protective as the Federal standard notices. *Form Number:* CMS–10527 (OMB Control Number 0938–1254); *Frequency:* Annually; *Affected Public:* Private Sector, State Governments; *Number of Respondents:* 1,340; *Total Annual Responses:* 5,881; *Total Annual Hours:* 72,147. (For policy questions regarding this collection contact Russell Tipps at 301–492–4371.)

Dated: April 12, 2023.

William N. Parham, III,

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

[FR Doc. 2023–08069 Filed 4–14–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10398 #37]

Medicaid and Children's Health Insurance Program (CHIP) Generic Information Collection Activities: Proposed Collection; Comment Request; Correction

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

ACTION: Notice; correction.

SUMMARY: On April 10, 2023, we published a collection of information notice in the **Federal Register** concerning our revised Managed Care Rate Setting Guidance. The notice included an incorrect web address for obtaining copies of the supporting statement, the revised guide, and supporting documents.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of April 10, 2023, in FR Doc. 2023–07473, on page 21191, in the third column, correct the fourth paragraph under the **ADDRESSES** caption to read as follows:

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.*

Dated: April 12, 2023.

William N. Parham, III,

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

[FR Doc. 2023–08062 Filed 4–14–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2480]

Rare Disease Endpoint Advancement Pilot Program Workshop: Novel Endpoints for Rare Disease Drug Development; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a public workshop entitled ''Rare Disease Endpoint Advancement Pilot Program Workshop: Novel Endpoints for Rare Disease Drug Development.'' Convened by the Duke-Robert J. Margolis, MD Center for Health Policy (Duke-Margolis) and supported by a cooperative agreement between FDA and Duke-Margolis, the workshop will include discussions of the Rare Disease Endpoint Advancement (RDEA) Pilot Program and novel endpoint development for rare disease drug development.

DATES: The public workshop will be held virtually on June 7, 2023, and June 8, 2023, from 1 p.m. to 5 p.m., Eastern Time. Either electronic or written comments on this public workshop must be submitted by July 23, 2023. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held virtually using the Zoom platform. The link for the public workshop will be sent to registrants upon registration.

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 on July 23, 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–2022–N–2480 for ''Rare Disease Endpoint Advancement Pilot Program Workshop: Novel Endpoints for Rare Disease Drug Development.'' 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: Mary Jo Salerno, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240–402–0420, *RDEA.Meetings@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

This public workshop is intended to support the RDEA Pilot Program consistent with the requirements under section 3208 of the Food and Drug Omnibus Reform Act of 2022 (FDORA). Section 3208 of FDORA requires FDA to establish a pilot program to provide increased interaction with sponsors of rare disease drug development programs for purposes of advancing the development of efficacy endpoints, including surrogate and intermediate endpoints, for drugs intended to treat rare diseases. Section 3208 of FDORA also requires FDA to conduct up to three public workshops to discuss various topics relevant to the development of endpoints for rare diseases on or before September 30, 2026. This is the first of up to three public workshops to satisfy the FDORA requirement.

The public workshop is also intended to meet a performance goal under the FDA User Fee Reauthorization Act of 2022, in accordance with the PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027 letter (PDUFA VII Commitment Letter), which is available at *https://www.fda.gov/media/151712/download*. Specifically, section I.K.4 of the PDUFA VII Commitment Letter, ''Advancing Development of Drugs for Rare Diseases'' (*https://www.fda.gov/media/151712/download*), outlines commitments, including up to three public workshops to discuss various topics relevant to endpoint development for rare diseases.

II. Topics for Discussion at the Public Workshop

The purpose of this public workshop is to: (1) provide an overview of the RDEA Pilot Program (a joint program of the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research), (2) discuss the scientific and technical issues associated with developing study endpoints for rare diseases and highlight resources to assist with addressing these issues, (3) discuss lessons learned from previous PDUFA meeting programs that can be applied to the RDEA Pilot Program, and (4) provide opportunity for public comment on the RDEA Pilot Program and issues associated with rare disease endpoint development.

Meeting sessions will focus on: (1) the RDEA Pilot Program and process, (2) elements of RDEA proposal and meeting packages, (3) addressing issues in developing rare disease endpoints, and (4) experience with other FDA pilot programs. At the end of the public workshop, there will be an opportunity for public comment.

Meeting updates, the agenda, and background materials (if any) will be made available at *https://duke.is/5ca3k* prior to the workshop.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website: *https://duke.is/5ca3k*. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. Registration will end at 11:59 p.m. Eastern Time on June 6, 2023.

Registration is free, and persons interested in attending this public workshop must register to receive a link to the meeting. Registrants will receive a confirmation email after they register.

If you need special accommodations due to a disability, please contact *Margolisevents@duke.edu* no later than May 5, 2023. Please note, closed captioning will be available automatically.

Requests for Oral Comments: During online registration you may indicate if you wish to speak during a public comment session. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their comment and request time for joint commentary. All requests to make oral comments must be received by 11:59 p.m. Eastern Time on May 26, 2023. FDA will determine the amount of time

allotted to each commenter and the approximate time each comment is to begin and will select and notify participants by June 2, 2023.

Transcript: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at *https://duke.is/5ca3k*. The transcript will also be available at *https://www.regulations.gov* and may be viewed at the Dockets Management Staff (see **ADDRESSES**).

Dated: April 12, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–08066 Filed 4–14–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0249]

Authorization of Emergency Use of an In Vitro Diagnostic Device in Response to an Outbreak of Mpox; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of an Emergency Use Authorization (EUA) (the Authorization) under the Federal Food, Drug, and Cosmetic Act (FD&C Act) in response to an outbreak of mpox. FDA has issued an Authorization for an in vitro diagnostic device as requested by Cue Health, Inc. The Authorization contains, among other things, conditions on the emergency use of the authorized product. The Authorization follows the August 9, 2022, determination by the Secretary of Health and Human Services (HHS) that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves monkeypox virus. On the basis of such determination, the Secretary of HHS declared, on September 7, 2022, that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus,* pursuant to the FD&C Act, subject to terms of any authorization issued under that section. The Authorization, which includes an explanation of the reasons for issuance, is reprinted in this document.

DATES: The Authorization is effective as of March 17, 2023.

ADDRESSES: Submit written requests for single copies of an EUA to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, 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 Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Kim Sapsford-Medintz, Office of Product Evaluation and Quality, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3216, Silver Spring, MD 20993–0002, 301–796–0311 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) allows FDA to strengthen public health protections against biological, chemical, radiological, or nuclear agent or 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. With this EUA authority, FDA can help ensure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, radiological, or nuclear agent or agents when there are no adequate, approved, and available alternatives (among other criteria).

II. Criteria for EUA Authorization

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces, including personnel operating under the authority of title 10 or title 50, U.S. Code, of attack with (A) a biological, chemical, radiological, or nuclear agent or agents or (B) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces; [1] (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F–2 of the Public Health Service (PHS) Act (42 U.S.C. 247d–6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the **Federal Register** a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Under section 564(h)(1) of the FD&C Act, revisions to an authorization shall be made available on the internet website of FDA. Section 564 of the FD&C Act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use in an actual or potential emergency when the Secretary of HHS has declared that circumstances exist justifying the authorization of emergency use. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under sections 505, 510(k), 512, or 515 of the FD&C Act (21 U.S.C. 355, 360(k), 360b, or 360e) or section 351 of the PHS Act (42 U.S.C. 262), or conditionally approved under section 571 of the FD&C Act (21 U.S.C. 360ccc).

[1] In the case of a determination by the Secretary of Defense, the Secretary of HHS shall determine within 45 calendar days of such determination, whether to make a declaration under section 564(b)(1) of the FD&C Act, and, if appropriate, shall promptly make such a declaration.