Plans), Prescription Drug Plan sponsors (PDPs), and Programs of All-Inclusive Care for the Elderly (PACE) organizations report financial information demonstrating the organization has a fiscally sound operation. The FSRR is designed to capture financial data of these contracting entities. The Division of Finance and Benefits (DFB) within the Medicare Advantage Contract Administration Group (MCAG) of CMS is assigned the responsibility of reviewing ongoing financial performance of the contracting entities.

All contracting organizations must submit audited annual financial statements one time per year. In addition to the audited annual submission, Health Plans with a negative net worth and/or a net loss and the amount of that loss is greater than one-half of the organization's total net worth submit quarterly financial statements for fiscal soundness monitoring. Part D organizations are required to submit three (3) quarterly financial statements. Lastly, PACE organizations are required to file four (4) quarterly financial statements for the first three (3) years in the program. After the first three (3) years, PACE organizations with a negative net worth and/or a net loss and the amount of that loss is greater than one-half of the organization's total net worth must submit quarterly financial statements for fiscal soundness monitoring. *Form Number:* CMS–906 (OMB control number: 0938–0496); *Frequency:* Quarterly and Yearly; *Affected Public:* Private Sector (Business or other for-profits, Not-for-Profit Institutions); *Number of Respondents:* 936; *Total Annual Responses:* 1,958; *Total Annual Hours:* 652. (For policy questions regarding this collection contact Christa M. Zalewski at (410) 786–1971.)

Dated: March 1, 2022.

William N. Parham, III,

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

[FR Doc. 2022–04644 Filed 3–3–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10108]

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 3, 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 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–10108 Medicaid Managed Care Regulations

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:* Medicaid Managed Care Regulations; *Use:* Information collected includes information about managed care programs, grievances and appeals, enrollment broker contracts, and managed care organizational capacity to provide health care services. Medicaid enrollees use the information collected and reported to make informed choices regarding health care, including how to access health care services and the grievance and appeal system. States use the information collected and reported as part of its contracting process with managed care entities, as well as its compliance oversight role. We use the

information collected and reported in an oversight role of state Medicaid managed care programs.

Among the proposed changes, this iteration also accommodates the use of reporting templates for existing reporting requirements at 42 CFR 438.207(d) for network adequacy and access and § 438.74 for medical loss ratio. The templates are intended to help states by articulating the specific data elements needed and by providing an easy to use format that facilitates CMS' tracking and analysis. The data gathered from these reports will enable CMS to ensure state compliance with regulatory requirements.

Form Number: CMS–10108 (OMB control number: 0938–0920); *Frequency:* Occasionally; *Affected Public:* Individuals or households, Private sector (business or other for-profit and not-for-profit institutions), and State, local or Tribal Government; *Number of Respondents:* 609; *Total Annual Responses:* 13,742,805; *Total Annual Hours:* 1,682,411. (For policy questions regarding this collection contact Amy Gentile at 410–786–3499.)

Dated: March 1, 2022.

William N. Parham, III,

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

[FR Doc. 2022–04645 Filed 3–3–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0150]

Revocation of Two 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 Bio-Rad Laboratories for the BioPlex 2200 SARS–CoV–2 IgG, and Quotient Suisse SA for the MosaiQ COVID–19 Antibody Magazine. 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 Authorizations are revoked as of January 11, 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 July 1, 2021, FDA issued an EUA to Bio-Rad Laboratories for the BioPlex 2200 SARS–CoV–2 IgG, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on October 28, 2021 (86 FR 59738), as required by section 564(h)(1) of the FD&C Act. On September 25, 2020, FDA issued an EUA to Quotient Suisse SA for the MosaiQ COVID–19 Antibody Magazine, 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 updates 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 FD&C Act, be revoked when the criteria under section 564(c) of the FD&C Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the FD&C Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the FD&C Act).

II. EUA Revocation Requests

In a request received by FDA on December 20, 2021, Bio-Rad Laboratories requested revocation of, and on January 11, 2022, FDA revoked, the Authorization for the BioPlex 2200 SARS–CoV–2 IgG. Because Bio-Rad Laboratories notified FDA that Bio-Rad Laboratories has not commercialized the authorized product in the United States and requested FDA revoke the BioPlex 2200 SARS–CoV–2 IgG, FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization.

In a request received by FDA on December 22, 2021, Quotient Suisse SA requested termination of, and on January 11, 2022, FDA revoked, the Authorization for the MosaiQ COVID–19 Antibody Magazine. Because Quotient Suisse SA notified FDA that Quotient Suisse SA has decided not to continue to commercially support the product and requested FDA terminate the MosaiQ COVID–19 Antibody Magazine, FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization.

III. Electronic Access

An electronic version of this document and the full text of the revocations are available on the internet at *https://www.regulations.gov/.*

IV. The Revocations

Having concluded that the criteria for revocation of the Authorizations under section 564(g)(2)(C) of the FD&C Act are met, FDA has revoked the EUA of Bio-Rad Laboratories for the BioPlex 2200 SARS–CoV–2 IgG and of Quotient Suisse SA for the MosaiQ COVID–19 Antibody Magazine. The revocations in their entirety follow and provide an explanation of the reasons for each revocation, as required by section 564(h)(1) of the FD&C Act.

BILLING CODE 4164–01–P