

requirement to cover EHB (45 CFR 147.150 and 156.115).

Medical Necessity Disclosure Under MHPAEA

MHPAEA specifically amends the Public Health Service (PHS) Act to require plan administrators or health insurance issuers to provide, upon request, the criteria for medical necessity determinations made with respect to MH/SUD benefits to current or potential participants, beneficiaries, or contracting providers. The Final Rules under MHPAEA set forth rules for providing criteria for medical necessity determinations. CMS administers MHPAEA with respect to self-insured, non-Federal governmental plans in all States, and health insurance issuers in two States.

Claims Denial Disclosure Under MHPAEA

MHPAEA specifically amends the PHS Act to require plan administrators or health insurance issuers to provide, upon request, the reason for any denial or reimbursement of payment for MH/SUD services to the participant or beneficiary involved in the case. The Final Rules under MHPAEA at 45 CFR 146.136(d)(2) implement MHPAEA. CMS administers MHPAEA with respect to self-insured, non-Federal governmental plans in all States and health insurance issuers in two States, and the regulation provides a safe harbor such that non-Federal governmental plans (and issuers offering coverage in connection with such plans) are deemed to comply with requirements of paragraph (d)(2) of 45 CFR 146.136 if they provide the reason for claims denial in a form and manner consistent with ERISA requirements found in 29 CFR 2560.503-1. Section 146.136(d)(3) clarifies that PHS Act section 2719 governing internal claims and appeals and external review as implemented by 45 CFR 147.136, covers MHPAEA claims denials and requires that, when a non-quantitative treatment limitation (NQTL) is the basis for a claims denial, that a non-grandfathered plan or issuer must provide the processes, strategies, evidentiary standard, and other factors used in developing and applying the NQTL with respect to med/surg benefits and MH/SUD benefits.

Disclosure Request Form

Group health plan participants, beneficiaries, covered individuals in the individual market, or persons acting on their behalf, may use this optional model form to request information from plans regarding the medical necessity

and claims denials disclosures referenced above. *Form Number:* CMS-10307 (OMB control number: 0938-1080); *Frequency:* On Occasion; *Affected Public:* State, Local, or Tribal Governments, Private Sector, Individuals; *Number of Respondents:* 282,657; *Total Annual Responses:* 1,125,558; *Total Annual Hours:* 93,797. (For policy questions regarding this collection contact Erik Gomez at 667-414-0682.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Privacy Act of 1974; System of Records

AGENCY: Administration for Children and Families, Department of Health and Human Services.

ACTION: Notice of a modified system of records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, as amended, the Department of Health and Human Services (HHS) is modifying an existing system of records maintained by the Administration for Children and Families (ACF), Office of Child Support Services (OCSS): System No. 09-80-0389, “OCSE Data Center General Support System,” being renamed “OCSS Data Exchange Platform.”

DATES: This Notice is applicable May 17, 2024, subject to a 30-day period in which to comment on the new and revised routine uses, described below. Please submit any comments by June 17, 2024.

ADDRESSES: The public should address written comments by mail or email to: Anita Alford, Senior Official for Privacy, Administration for Children and Families, 330 C St. SW, Washington, DC 20201, or by email to anita.alford@acf.hhs.gov.

FOR FURTHER INFORMATION CONTACT: General questions about these system of records should be submitted by mail or email to Venkata Kondapolu, Director, Division of Federal Systems, Office of Child Support Services, at 330 C St. SW—5th Floor, Washington, DC 20201,

or venkata.kondapolu@acf.hhs.gov, or by phone at 202-260-4712.

SUPPLEMENTARY INFORMATION:

I. Explanation of Changes to System of Records 09-80-0381

In accordance with 5 U.S.C. 552a(e)(4) and (11), HHS is modifying an existing system of records maintained by ACF/OCSS: System No. 09-80-0389, being renamed “OCSS Data Exchange Platform.” The system of records covers records supporting State and Tribal child support programs, and the program’s external stakeholders, which are exchanged electronically using a secure data exchange platform (the OCSS Data Exchange Platform, or any successor system) provided by OCSS. The data exchange platform facilitates electronic exchanges of information about individual participants in child support cases, between State child support agencies and other external partners such as employers, health plan administrators, financial institutions, and central authorities in foreign treaty countries or foreign countries that are the subject of a declaration under 42 U.S.C. 659a. The child support agencies and other external partners use the data exchange platform to electronically submit information to and receive information from each other, through OCSS.

The System of Records Notice (SORN) for system of records 09-80-0389 has been modified as follows:

- The system of records name has been changed to “OCSS Data Exchange Platform” to reflect the name change of the “Office of Support Enforcement” to the “Office of Child Support Services” and to provide a more meaningful name for the system of records.
- The System Manager(s) section has been revised to change the office name to Office of Child Support Services.
- The Purpose(s) section has been revised to describe the system as a data exchange platform, rather than as a “gateway system,” and one purpose, at the end of the section, has been expanded to include the use of the data exchange platform by foreign authorities to transmit case information associated with child support disbursements transmitted from a foreign authority to the United States through the Central Authority Payment (CAP) service.
- The Categories of Records section has been revised to make these changes to Category (4):
 - The phrase “which includes” has been changed to “which may include.”
 - Under (4)(c), “agency’s case number” had been changed to “agency’s case identifier.”

- The Record Source Categories section has been revised as follows:
 - The description of State child support agencies transmitting payment information to the CAP program has been modified to “exchanging case-related information associated with child support disbursements transmitted to foreign authorities through the CAP service.”
 - An additional category has been added: “[F]oreign authorities exchanging case-related information associated with child support disbursements transmitted to State child support agencies through the CAP service.”
- The Routine Uses section has been updated as follows:
 - The word “enforcement” has been removed from routine uses 1, 2, 4, and 6.
 - Routine use 11 has been revised to include disclosure of information involving residents of foreign treaty countries or foreign reciprocating countries to State child support programs for child support purposes.
- The Policies and Practices for Retention and Disposal of Records section has been revised to include General Records Schedule 5.2, items 010 and 020 as the applicable disposition authority.

Venkata Kondapolu,

Director, Division of Federal Systems, Office of Child Support Services, Administration for Children and Families, U.S. Department of Health and Human Services.

SYSTEM NAME AND NUMBER:

OCSS Data Exchange Platform, 09–80–0389.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Office of Child Support Services, Administration for Children and Families, 330 C St. SW, 5th Floor, Washington, DC 20201.

SYSTEM MANAGER(S):

Director, Division of Federal Systems, Office of Child Support Services, Administration for Children and Families, Department of Health and Human Services, 330 C St. SW, 5th Floor, Washington, DC 20201, Venkata.Kondapolu@acf.hhs.gov, 202–260–4712.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 652, 654, 654a, 654b, 659, 659a, 666, 669a.

PURPOSE(S) OF THE SYSTEM:

The purpose of the system of records is to cover records supporting State and

Tribal child support programs, and the programs’ external stakeholders, which are exchanged electronically using a secure data exchange platform provided by OCSS. The platform facilitates electronic exchanges of information about individual participants in child support cases, between State child support agencies and other external partners such as employers, health plan administrators, financial institutions, and central authorities in foreign treaty countries or foreign countries that are the subject of a declaration under 42 U.S.C. 659a. The child support agencies and other external partners use the data exchange platform to electronically submit information to and receive information from each other, through OCSS.

The platform supports, for example:

- The Electronic Income Withholding Order (e-IWO) program, which provides the means to electronically exchange income withholding order information between State child support agencies and employers.
- The Electronic National Medical Support Notice (e-NMSN) program, which allows State child support agencies, employers, and health plan administrators to electronically send and receive National Medical Support Notices used to enroll children in medical insurance plans pursuant to child support orders.
- The Federally Assisted State Transmitted (FAST) Levy program, which allows States and financial institutions to exchange information about levy actions through an electronic process.
- The Central Authority Payment (CAP) service, which allows States and foreign authorities to exchange details of child support disbursements transmitted between the United States and the authorized entity of the foreign treaty country or foreign country subject of a declaration under 42 U.S.C. 659a for distribution of the support payment by the foreign authority or the State child support agency in accordance with the terms of the order.

Multiple child support program partners utilize the platform to electronically send and receive information:

State child support agencies use the platform to transmit e-IWOs to employers and e-NMSNs to employers and health plan administrators. State child support agencies also use the platform to create levy actions for distribution to multiple financial institutions, and to transmit information about child support disbursements between U.S. States and foreign authorities through the CAP service.

Employers use the platform to respond to State child support agencies regarding e-IWOs and to provide information about health insurance coverage provided by the employer. Employers and health plan administrators use the platform to respond to State child support agencies regarding e-NMSNs.

Financial institutions use the platform to receive and respond to levy actions from multiple State child support agencies.

U.S. States and foreign authorities use the platform to transmit case information associated with child support disbursements transmitted between the United States and a foreign authority through the CAP service.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The records in the system of records are about custodial and noncustodial parents, legal guardians, and third-party caretakers who are participants in child support program cases and whose names and Social Security numbers (SSNs) are used to retrieve the records. Children’s personal identifiers are not used to retrieve records in this system of records, so children are not subject individuals for purposes of this system of records.

CATEGORIES OF RECORDS IN THE SYSTEM:

The categories of records exchanged in the platform include:

1. Child support case information used to populate an e-IWO, which may include:
 - a. Name of State, Tribe, territory, or private individual entity issuing an e-IWO;
 - b. Order ID and Case ID;
 - c. Remittance ID;
 - d. Employer/income withholder name, address, Federal employer identification number (FEIN), telephone number, FAX number, email, or website;
 - e. Employee/obligor’s name, Social Security number (SSN), date of birth;
 - f. Custodial parent’s/obligee’s name;
 - g. Child(ren)’s name(s) and date(s) of birth;
 - h. Income withholding amounts for current child support, past-due child support, current cash medical support, past-due cash medical support, current spousal support, past-due spousal support;
 - i. Child support State disbursement unit or Tribal order payee name and address;
 - j. Judge/issuing official’s name, title, and signature; and
 - k. Employee/obligor termination date, last known telephone number, last

known address, new employer/income withholder's name and address.

2. Child support case information used to populate an e-NMSN, and medical insurance information included in e-NMSN responses from employers and health plan administrators, which may include:

- a. Custodial parent/obligee's name and mailing address;
- b. Substituted official/agency name and address (if custodial parent/obligee's address is left blank);
- c. Name, telephone number, and mailing address of representative of child(ren);
- d. Child(ren)'s name(s), gender, date of birth, and SSN;
- e. Employee's name, SSN, and mailing address;
- f. Plan administrator name, contact person, FAX number and telephone number;
- g. Employer and/or employer representative name, FEIN, and telephone number;
- h. Date of medical support termination, reason for termination, and child(ren) to be terminated from medical support;
- i. Medical insurance provider name, group number, policy number, address;
- j. Dental insurance provider name, group number, policy number, address;
- k. Vision insurance provider name, group number, policy number, address;
- l. Prescription drug insurance provider name, group number, policy number, address;
- m. Mental health insurance provider name, group number, policy number, address;
- n. Other insurance, specified by name, group number, policy number, address; and
- o. Plan administrator name, title, telephone number and address.

3. Child support case information used to administer the FAST Levy program, which includes:

- a. Requesting State agency name, address, and State Federal Information Processing Standard (FIPS) code;
- b. Financial institution's name and FEIN;
- c. Obligor's name, SSN, and date of birth;
- d. Account number of account from which to withhold funds;
- e. Withholding amount; and
- f. Contact name, phone number, and email for point of contact in requesting State.

4. Child support case information used to administer the CAP service, which may include:

- a. Obligor/non-custodial parent's name and SSN;

- b. Foreign authority name, FIPS locator code, and foreign authority's child support case identifier;

- c. U.S. State name and State child support agency's case identifier;
- d. Amount and date of payment;
- e. Medical support indicator; and
- f. Employment termination indicator.

RECORD SOURCE CATEGORIES:

The sources of the information in the system of records include:

- State child support agencies initiating e-IWO, e-NMSN, and FAST Levy program transactions in domestic child support cases and exchanging case-related information associated with child support disbursements transmitted to foreign authorities through the CAP service.
- Employers or authorized third parties responding to e-IWOs and e-NMSNs.
- Health plan administrators responding to e-NMSNs.
- Financial institutions responding to FAST Levy requests.
- Foreign authorities exchanging case-related information associated with child support disbursements transmitted to State child support agencies through the CAP service.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to the disclosures authorized directly in the Privacy Act at 5 U.S.C. 552a(b)(1) and (b)(2) and (b)(4) through (b)(11), these routine uses specify circumstances under which the agency may disclose information from this system of records to a non-HHS officer or employee without the consent of the data subject. ACF will prohibit redisclosures, or may permit only certain redisclosures, as required or authorized by law. Each proposed disclosure or redisclosure of information permitted directly in the Privacy Act or under these routine uses will be evaluated to ensure that the disclosure or redisclosure is legally permissible.

Any information defined as "return" or "return information" under 26 U.S.C. 6103 (Internal Revenue Code) is not disclosed unless authorized by a statute, the Internal Revenue Service (IRS), or IRS regulations.

1. Disclosure to Financial Institution to Collect Past-Due Support.

Pursuant to 42 U.S.C. 652(l), information pertaining to an individual owing past-due child support may be disclosed to a financial institution doing business in two or more States to identify an individual who maintains an account at the institution for the

purpose of collecting past-due support. Information pertaining to requests by the State child support agencies for the placement of a lien or levy of such accounts may also be disclosed.

2. Disclosure of Financial Institution Information to State Child Support Agency for Assistance in Collecting Past-Due Support.

Pursuant to 42 U.S.C. 652(l), the results of a comparison between information pertaining to an individual owing past-due child support and information provided by multistate financial institutions may be disclosed to a State child support agency for the purpose of assisting the State agency in collecting past-due support. Information pertaining to responses to requests by a State child support agency for the placement of a lien or levy of such accounts may also be disclosed.

3. Disclosure to Employer to Enforce Child Support Obligations.

Pursuant to 42 U.S.C. 666(b), information pertaining to an individual owing current or past-due child support may be disclosed to an employer for the purpose of collecting current or past-due support by way of an e-IWO.

4. Disclosure of Employer Information to State Child Support Agency in Response to an e-IWO.

Information pertaining to a response by an employer to an e-IWO issued by a State child support agency for the collection of child support may be disclosed to the State child support agency.

5. Disclosure to Employer and Health Plan Administrator to Enforce Medical Support Obligations.

Pursuant to 42 U.S.C. 666(a)(19), information pertaining to participants in a child support case may be disclosed to an employer or a health plan administrator for the purpose of enforcing medical support for a child by way of an e-NMSN.

6. Disclosure of Employer and Health Plan Administrator Information to State Child Support Agency in Response to an e-NMSN.

Information pertaining to a response by an employer or a health plan administrator to an e-NMSN issued by a State child support agency for the enforcement of medical support may be disclosed to the State child support agency.

7. Disclosure to Department of Justice or in Proceedings.

Records may be disclosed to the Department of Justice (DOJ) or to a court or other adjudicative body in litigation or other proceedings when HHS or any of its components, or any employee of HHS acting in the employee's official capacity, or any employee of HHS acting

in the employee's individual capacity where the DOJ or HHS has agreed to represent the employee, or the United States Government, is a party to the proceedings or has an interest in the proceedings and, by careful review, HHS determines that the records are both relevant and necessary to the proceedings.

8. Disclosure to Congressional Office.

Information may be disclosed to a congressional office from the record of an individual in response to a written inquiry from the congressional office made at the written request of the individual.

9. Disclosure to Contractor to Perform Duties.

Records may be disclosed to a contractor performing or working on a contract for HHS and who has a need to have access to the information in the performance of its duties or activities for HHS in accordance with law and with the contract.

10. Disclosure in the Event of a Security Breach.

a. Information may be disclosed to appropriate agencies, entities, and persons when (1) HHS suspects or has confirmed that there has been a breach of the system of records; (2) HHS has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, HHS (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with HHS's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

b. Information may be disclosed to another Federal agency or Federal entity, when HHS determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

11. Disclosure to a Foreign Reciprocating Country, Foreign Treaty Country, and State Child Support Program for Child Support Purposes.

Pursuant to 42 U.S.C. 652(n), 653(a)(2), 653(c)(5) and 659a(c)(2), child support case information involving residents of the United States and residents of foreign treaty countries or

foreign countries that are the subject of a declaration under 42 U.S.C. 659a may be disclosed to the foreign authority and to State child support programs.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

The records are stored electronically.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are retrieved by the parent's, guardian's or third-party caretaker's name or SSN.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Because the platform is not a source system but facilitates access to records from other systems which are the official sources of the records, the records are retained and disposed of in accordance with General Records Schedule 5.2 Transitory and Intermediary Records, Items 010 and 020 (DAA-GRS-2022-0009-0001 and DAA-GRS-2022-0009-0002), which provides these disposition periods:

- Item 010 Transitory records:

Destroy when no longer needed for business use, or according to an agency predetermined time period or business rule.

- Item 020 Intermediary records:

Destroy upon creation or update of the final record, or when no longer needed for business use, whichever is later.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

The platform leverages cloud service providers that maintain an authority to operate in accordance with applicable laws, rules, and policies, including Federal Risk and Authorization Management Program (FedRAMP) requirements. Specific administrative, technical, and physical controls are in place to ensure that the records collected, maintained, and transmitted using the platform are secure from unauthorized access. Access to the records within the system is restricted to authorized personnel who are advised of the confidentiality of the records and the civil and criminal penalties for misuse and who sign a nondisclosure oath to that effect. Agency personnel are provided privacy and security training before being granted access to the records and annually thereafter. Additional safeguards include protecting the facilities where records are stored or accessed with security guards, badges and cameras; limiting access to electronic databases to authorized users based on roles and either two-factor authentication or user ID and password (as appropriate); using a secured

operating system protected by encryption, firewalls, and intrusion detection systems; reviewing security controls on a periodic basis; and using secure destruction methods prescribed in NIST SP 800-88 to dispose of eligible records. All safeguards conform to the HHS Information Security and Privacy Program, <https://www.hhs.gov/ocio/securityprivacy/index.html>.

RECORD ACCESS PROCEDURES:

To request access to a record about you in this system of records, submit a written access request to the System Manager identified in the "System Manager" section of this System of Records Notice (SORN). The request must reasonably describe the record sought and must include (for contact purposes and identity verification purposes) your full name, current address, telephone number and/or email address, date and place of birth, and signature, and (if needed by the agency) sufficient particulars contained in the records (such as, your SSN) to enable the System Manager to distinguish between records on subject individuals with the same name. In addition, to verify your identity, your signature must be notarized, or the request must include your written certification that you are the individual who you claim to be and that you understand that the knowing and willful request for or acquisition of a record pertaining to an individual under false pretenses is a criminal offense subject to a fine of up to \$5,000. You may request that copies of the records be sent to you, or you may request an appointment to review the records in person (including with a person of your choosing, if you provide written authorization for agency personnel to discuss the records in that person's presence). You may also request an accounting of disclosures that have been made of records about you, if any.

CONTESTING RECORD PROCEDURES:

To request correction of a record about you in this system of records, submit a written amendment request to the System Manager identified in the "System Manager" section of this SORN. The request must contain the same information required for an access request and include verification of your identity in the same manner required for an access request. In addition, the request must reasonably identify the record and specify the information contested, the corrective action sought, and the reasons for requesting the correction; and should include supporting information to show how the

record is inaccurate, incomplete, untimely, or irrelevant.

NOTIFICATION PROCEDURES:

To find out if the system of records contains a record about you, submit a written notification request to the System Manager identified in the "System Manager" section of this SORN. The request must identify this system of records, contain the same information required for an access request, and include verification of your identity in the same manner required for an access request.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

87 FR 69026 (Nov. 17, 2022).

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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 Device 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 Inc., for the Bio-Rad SARS-CoV-2 ddPCR Kit, and Fast Track Diagnostics Luxembourg S.á.r.l. (A Siemens Healthineers Company), for the FTD SARS-CoV-2. FDA revoked the Authorizations under the Federal Food, Drug, and Cosmetic Act (FD&C Act) as requested by the Authorization holders. The revocations, which include an explanation of the reasons for each revocation, are reprinted at the end of this document.

DATES: The revocation of the Authorization for the Bio-Rad Laboratories Inc.'s Bio-Rad SARS-CoV-2 ddPCR Kit is effective as of March 27, 2024. The revocation of the Authorization for the Fast Track Diagnostics Luxembourg S.á.r.l.'s (A Siemens Healthineers Company) FTD SARS-CoV-2 is effective as of April 18, 2024.

ADDRESSES: Submit written requests for a single copy of the revocations 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 revocations may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revocations.

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) 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, 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. On May 1, 2020, FDA issued the Authorization to Bio-Rad Laboratories Inc., for the Bio-Rad SARS-CoV-2 ddPCR Kit, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on July 14, 2020 (85 FR 42409), as required by section 564(h)(1) of the FD&C Act.

On May 5, 2020, FDA issued the Authorization to Fast Track Diagnostics Luxembourg S.á.r.l. (a Siemens Healthineers Company) for the FTD SARS-CoV-2, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on July 14, 2020 (85 FR 42409), 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. Authorizations Revocation Requests

In a request received by FDA on March 16, 2024, Bio-Rad Laboratories Inc., requested the revocation of, and on March 27, 2024, FDA revoked, the Authorization for the Bio-Rad Laboratories Inc.'s Bio-Rad SARS-CoV-2 ddPCR Kit. Because Bio-Rad Laboratories Inc., notified FDA that they ceased United States distribution of the Bio-Rad SARS-CoV-2 ddPCR Kit and requested FDA revoke Bio-Rad Laboratories Inc.'s Bio-Rad SARS-CoV-2 ddPCR Kit, 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 April 11, 2024, Fast Track Diagnostics Luxembourg S.á.r.l. (a Siemens Healthineers Company), requested the deregister of, and on April 18, 2024, FDA revoked, the Authorization for Fast Track Diagnostics Luxembourg S.á.r.l.'s FTD SARS-CoV-2. Because Fast Track Diagnostics Luxembourg S.á.r.l. notified FDA that they have ceased United States distribution of the FTD SARS-CoV-2 and requested FDA deregister the Fast Track Diagnostics Luxembourg S.á.r.l.'s FTD SARS-CoV-2, 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 Inc.'s Bio-Rad SARS-CoV-2 ddPCR Kit, and Fast Track Diagnostics Luxembourg S.á.r.l.'s (a Siemens Healthineers Company) FTD SARS-CoV-2. The revocations in their entirety follow and provide an explanation of the reasons for revocation, as required by section 564(h)(1) of the FD&C Act.

BILLING CODE 4164-01-P