production of the syrup as required. Woodfield provided the syrup to Marshall and his DTO without any corresponding documentation that identified the ingredients of the syrup; practices that continued until February 2019 when Woodfield started creating paper records for some of the cough syrup batches Woodfield made for the DTO. From 2014 through February 2021, the conspiracy between the Marshall DTO produced and distributed, or attempted to produce and distribute, approximately 65,920 gallons of counterfeit cough syrup. The total amount of cash paid by Marshall and his DTO to Mr. Runsdorf was approximately at least $3 million.

As a result of this conviction, FDA sent Mr. Runsdorf, by certified mail, on January 23, 2024, a notice proposing to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(B), that Mr. Runsdorf was convicted of two felonies under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. The proposal informed Mr. Runsdorf of the proposed debarment and offered him an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Runsdorf received the proposal and notice of opportunity for a hearing on January 26, 2024. Mr. Runsdorf failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(a)(2)(B) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Runsdorf has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act.

As a result of the foregoing finding, Mr. Runsdorf is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application, effective (see **DATES**) (see sections 306(a)(2)(B) and 306(c)(2)(A)(ii) of the FD&C Act). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses in any capacity the services of Mr. Runsdorf during his debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Mr. Runsdorf provides services in any capacity to a person with an approved or pending drug product application during his period of debarment, he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug application from Mr. Runsdorf during his period of debarment, other than in connection with an audit under section 306 of the FD&C Act (section 306(c)(1)(B) of the FD&C Act). Note that, for purposes of sections 306 and 307 of the FD&C Act, a ''drug product'' is defined as a ''drug subject to regulation under section 505, 512, or 802 of this FD&C Act [(21 U.S.C. 355, 360b, or 382)] or under section 351 of the Public Health Service Act [(42 U.S.C. 262)]'' (section 201(dd) of the FD&C Act (21 U.S.C. 321(dd))).

Dated: May 2, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–09917 Filed 5–6–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–1032]

Risk Evaluation and Mitigation Strategy Logic Model: A Framework to Link Program Design With Assessment; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''REMS Logic Model: A Framework to Link Program Design With Assessment.'' The guidance describes FDA's risk evaluation and mitigation strategy (REMS) logic model. The REMS logic model is a framework that FDA recommends, which provides applicants with a systematic, structured approach to the design, implementation, and evaluation of a REMS. The aim of applying the REMS logic model is to develop clear goals, objectives, and strategies that align with the intended outcomes and to help applicants of new drug applications (NDAs), biologics license applications (BLAs), and abbreviated new drug applications (ANDAs) incorporate REMS assessment planning into the design of a REMS. The principles in this guidance apply to designing a REMS, developing a REMS assessment, and modifying a REMS.

DATES: Submit either electronic or written comments on the draft guidance by August 5, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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–2024–D–1032 for ''REMS Logic Model:

A Framework to Link Program Design With Assessment.'' Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Gita Toyserkani, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 1106, Silver Spring, MD, 20993–0002, 301–796–1783, or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''REMS Logic Model: A Framework to Link Program Design With Assessment.'' Section 505–1 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355–1) establishes FDA's REMS authority. A REMS is a required risk management strategy that can include one or more elements to ensure that the benefits of a drug outweigh its risks (see section 505–1(a) of the FD&C Act). A REMS can include a Medication Guide, a patient package insert, a communication plan, and certain packaging and safe disposal technologies for a drug that poses a serious risk of abuse or overdose. FDA also may require certain elements to assure safe use as part of the REMS for drugs or biological products (see section 505–1(f) of the FD&C Act).

A REMS, like other public health programs, involves a set of activities or interventions to achieve an intended outcome. Program evaluation is a systematic method of collecting, analyzing, and using data to examine the effectiveness and efficiency of those programs and to inform continuous program improvement. Several theories, frameworks, and logic models have been used to guide both program design and evaluation. In particular, logic models describe in detail how a program or intervention operationally works to achieve benefits and captures the logical flow and linkages that exist within the program or intervention and its proximal and distal outcomes. Leveraging this type of systematic approach is a critical aspect to the success and effectiveness of programs.

In 2013, FDA received feedback from the Office of the Inspector General (available at *https://oig.hhs.gov/oei/reports/OEI-04-11-00510.asp*) on the overall effectiveness of REMS. To address the feedback, FDA convened a public meeting on REMS standardization (78 FR 30313, May 22, 2013) (meeting materials available at *https://www.fda.gov/industry/prescription-drug-user-fee-amendments/background-materials-rems-standardization-and-evalution-public-meeting).* FDA sought stakeholder input on using a commonly cited framework for program planning and evaluation. FDA also encouraged applicants to consider using healthcare program assessment frameworks to assess REMS (see the draft guidance for industry entitled ''REMS Assessment: Planning and Reporting'' (available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/rems-assessment-planning-and-reporting*). FDA continued to explore and research the application of theories, frameworks, and models to develop a systematic approach to REMS design, implementation, and evaluation. Existing healthcare program evaluation frameworks, together with stakeholder feedback and FDA's research, informed the development of FDA's REMS logic model.

This draft guidance describes FDA's REMS logic model, which uses common logic model principles adapted for use in a REMS and makes explicit the scientific evidence, assumptions, and underlying logic that support the program and the various processes behind it. The REMS logic model provides applicants [1] with a recommended systematic, structured approach to design, implement, and evaluate a REMS. The REMS logic model delineates the relationship between the goal, objectives, strategies, and intended outcomes. The logic model includes the three phases of a REMS life cycle: design, implement, and evaluate. Each phase is further separated into two or more steps. Application of the REMS logic model begins with the design phase (situation context, program goal). The next phase is the implement phase (inputs, activities, outputs). The last phase is the evaluate phase (outcome, impact). The REMS logic model, although described in sequential steps, is an iterative process that involves moving back and forth or toggling between steps and phases to address uncertainties,

[1] For the purposes of the ''REMS Logic Model: A Framework to Link Program Design With Assessment'' guidance, the term *applicant* refers to sponsors of investigational new drug applications and applicants of NDAs, BLAs, and ANDAs.

validating assumptions, incorporating new information, and refining the program.

This draft guidance is being issued to fulfill the performance goals (available at *https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vii-fiscal-years-2023-2027*) under the sixth reauthorization of the Prescription Drug User Fee Act (PDUFA VII). This REMS logic model guidance is the first in a series of planned guidances for industry and FDA staff to optimize REMS design and improve the way a REMS is assessed.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''REMS Logic Model: A Framework to Link Program Design With Assessment.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 for the submission of investigational new drug applications have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 for the submission of new drug applications and abbreviated new drug applications have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 for the submission of biologics license applications have been approved under OMB control number 0910–0338. The collections of information in 21 CFR part 208 pertaining to Medication Guides for prescription drug and biological products have been approved under OMB control number 0910–0393. The collections of information in 21 CFR 201.56 and 201.57 for the content and format requirements for labeling of drugs and biologics have been approved under OMB control number 0910–0572. The collections of information in 21 CFR part 316 regarding orphan drug product development are approved under OMB control number 0910–0167. The collections of information pertaining to Prescription Drug User Fee Program have been approved under OMB control number 0910–0297.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: May 2, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–09928 Filed 5–6–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Rural Communities Opioid Response Program Performance Measures

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than July 8, 2024.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Joella Roland, the HRSA Information Collection Clearance Officer, at (301) 443–3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Rural Communities Opioid Response Program (RCORP) Performance Measures, OMB No. 0906–0044—Revision

Abstract: HRSA administers RCORP, which is authorized by section 711(b)(5) of the Social Security Act (42 U.S.C. 912(b)(5)) and is a multi-initiative program that aims to: (1) support treatment for and prevention of substance use disorder (SUD), including opioid use disorder (OUD); and (2) reduce morbidity and mortality associated with SUD, including OUD, by improving access to and delivering prevention, treatment, and recovery support services to high-risk rural communities. To support this purpose, RCORP grant initiatives include:

- RCORP—Implementation grants fund established networks and consortia to deliver SUD/OUD prevention, treatment, and recovery activities in high-risk rural communities.
- RCORP—Psychostimulant Support grants aim to strengthen and expand access to prevention, treatment, and recovery services for individuals in rural areas who misuse psychostimulants, to enhance their ability to access treatment and move toward recovery.
- RCORP—Medication Assisted Treatment Access grants aim to establish new access points in rural facilities where none currently exist.
- RCORP—Behavioral Health Care support grants aim to expand access to and quality of behavioral health care services at the individual-, provider-, and community-levels.
- RCORP Overdose Response recipients address immediate needs in rural areas through improving access to, capacity for, and sustainability of prevention, treatment, and recovery services for SUD.
- RCORP Child and Adolescent Behavioral Health grants aim to establish and expand sustainable behavioral health care services for children and adolescents aged 5–17 years who live in rural communities.
- RCORP-Neonatal Abstinence Syndrome grants aim to reduce the incidence and impact of Neonatal Abstinence Syndrome in rural communities by improving systems of care, family supports, and social determinants of health.
- Note that additional grant initiatives may be added pending fiscal year 2025 and future fiscal year appropriations.

HRSA currently collects information about RCORP grants using approved