the use of standardized APIs, like the open source and freely available HL7 FHIR APIs, with pharmacy data standards, *i.e.,* National Council for Prescription Drug Programs SCRIPT, to integrate REMS into prescriber and pharmacy workflows. The use case ultimately aims to reduce REMS implementation burden, improve the quality of REMS data for feedback and evaluation, and optimize safe medication use and health outcomes.

These activities demonstrate FDA's commitment to information systems modernization as well as openness to using FHIR in general.

More generally, FDA is exploring approaches to modernize submissions of clinical study data collected from RWD sources to the Agency using FHIR, while ensuring alignment with other FDA policy regarding RWD and the work of ASTP/ONC. Given the ubiquity of FHIR-based data elements generated, exchanged, and used in healthcare organizations, and considering the overlap between healthcare data and the information required for clinical research from RWD sources, FDA seeks input from interested parties regarding the range of challenges to be addressed when considering the use of FHIR for submission of clinical study data collected from RWD sources. Additionally, the Agency is seeking feedback on possible approaches and challenges to structuring and standardizing study data submissions with RWD sources using FHIR while aligning with the data interoperability and exchange standards adopted by HHS through ASTP/ONC. Please use the questions in section II to frame your comments. Also, please specify which types of RWD source(s) are pertinent to your comment (for example, EHRs, insurance claims), if applicable.

II. Request for Comments

FDA is requesting public comment on the questions below. Given the context of the currently supported data standards and models, technical guides, terminologies, and exchange formats used for clinical and nonclinical study data submission to FDA, those used for RWD sources such as EHRs, and the need to align with ASTP/ONC health IT development as described above:

1. What challenges do you see for the pharmaceutical industry regarding the *current state* of submitting clinical study data collected from RWD sources to FDA?

2. What opportunities and/or challenges do you see for the pharmaceutical industry on reaching a future state of clinical study data submissions collected from RWD sources using HL7 FHIR (*e.g.,* business processes, technical considerations)?

3. What are your suggestions on how, from a data standards perspective, FDA might reach a future state of clinical study data submissions collected from RWD sources that aligns with ASTP/ONC health IT goals for HL7 FHIR-based exchange?

4. Does USCDI version 3 provide enough information for collecting RWD for research purposes? Is there information that USCDI version 3 does not sufficiently address?

5. Under TEFCA, a variety of ''Exchange Purposes'' are authorized. If ''Research'' was added as an ''Exchange Purpose,'' what role could TEFCA play with using RWD for clinical research? How could TEFCA support more efficient collection and exchange of RWD for clinical research purposes? What challenges might exist with this approach?

III. References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

1. FDA, ''Real-World Evidence,'' web page, September 19, 2024. Available at: *https://www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence.*
2. FDA, ''Data Standards for Drug and Biological Product Submissions Containing Real-World Data,'' guidance for industry, December 2023. Available at: *https://www.fda.gov/media/153341/download.*
3. HHS, ''HHS Health IT Alignment Policy,'' web page, September 16, 2024. Available at: *https://www.healthit.gov/topic/hhs-health-it-alignment-policy.*
4. FDA, ''CBER–CDER Data Standards Program Action Plan,'' August 2024. Available at: *https://www.fda.gov/media/180870/download?attachment.*
5. Deady, M., R. Duncan, L.D. Jones, et al. ''Data Quality and Timeliness Analysis for Post-Vaccination Adverse Event Cases Reported Through Healthcare Data Exchange to FDA BEST Pilot Platform,'' *Front. Public Health,* 12:1379973, 2024. Available at: *https://www.frontiersin.org/journals/public-health/articles/10.3389/fpubh.2024.1379973/full.*
6. Deady, M., R. Duncan, M. Sonesen, et al. ''A Computable Phenotype Algorithm for Post-Vaccination Myocarditis/Pericarditis Detection Using Real-World Data: Validation Study,'' *J Med Internet Res,* 26:e54597, doi: 10.2196/54597, 2024. Available at: *https://www.jmir.org/2024/1/e54597.*
7. FDA, National Institutes of Health, and ONC Health IT, ''Common Data Model Harmonization (CDMH) and Open Standards for Evidence Generation,'' final report, 2020. Available at: *https://aspe.hhs.gov/sites/default/files/private/pdf/259016/CDMH-Final-Report-14August2020.pdf.*
8. HHS Office of the Assistant Secretary for Planning and Evaluation, ''Code Map Services for Interoperability of Common Data Models and Data Standards,'' web page, accessed November 20, 2024. Available at: *https://aspe.hhs.gov/code-map-services-interoperability-common-data-models-0.*

Dated: April 16, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–06967 Filed 4–22–25; 8:45 am]

BILLING CODE 4164–01–P

[7] See U.S. Medication REMS FHIR IG web page at *https://build.fhir.org/ig/HL7/fhir-medication-rems-ig/.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–5706]

Voluntary Quality Management Maturity Prototype Assessment Protocol Evaluation Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for a limited number of drug manufacturing establishments to participate in the second year of the voluntary Quality Management Maturity Prototype Assessment Protocol Evaluation Program involving the use of a refined prototype assessment protocol to evaluate quality management maturity (QMM). The Center of Drug Evaluation and Research (CDER) implemented this voluntary program for manufacturers of CDER-regulated drug products to gain additional experience with, and further refine as necessary, the prototype assessment protocol and process, to help enable consistent and meaningful assessment of participating establishments' quality management practices, and to provide useful feedback to participants. This notice announces CDER's intent to continue the voluntary QMM Prototype Assessment Protocol Evaluation

Program, outlines the types of establishments CDER is seeking for participation, and describes the process for submitting a request to participate in the program.

DATES: CDER intends to accept requests to participate in the voluntary QMM Prototype Assessment Protocol Evaluation Program through June 9, 2025. See the ''Participation'' section of this document for instructions on submitting a request to participate and the selection process.

FOR FURTHER INFORMATION CONTACT: For questions about the voluntary QMM Prototype Assessment Protocol Evaluation Program: Djamila Harouaka, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4160, Silver Spring, MD 20993–0002, 240–402–0224, *CDER-QMM@fda.hhs.gov.* To submit a request to participate in the program: Conchetta Newton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4144, 240–402–6551, *CDER-QMM@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

QMM refers to the extent to which drug manufacturing establishments implement quality management practices that prioritize patients, drive continual improvement, and enhance supply chain reliability through the strategic integration of business decisions and manufacturing operations with quality practices and technological advancements. CDER is in the process of developing a voluntary program to promote QMM at drug manufacturing establishments, which would encourage drug manufacturers to implement or improve their quality management practices.[1]

Between October 2020 and March 2022, CDER conducted two pilot programs to assess the QMM of drug manufacturing establishments. The first pilot program evaluated the maturity of seven domestic manufacturers of finished dosage forms for the U.S. market.[2] The second pilot program evaluated the maturity of eight foreign manufacturers of active pharmaceutical ingredients (APIs).[3] Each pilot program was conducted by a different contractor. These pilot programs provided valuable insights for CDER to develop a protocol to assess establishments' QMM, understand assessor behaviors during interviews of establishment personnel, and gather participant feedback on assessment questions, reports, and outcomes.[4]

Using the findings from these two pilot programs, a review of the literature on quality management, evaluations of existing external programs assessing elements of quality culture or pharmaceutical quality, surveys of external stakeholders, and feedback from partner offices and centers within FDA, CDER developed a prototype assessment protocol to evaluate an establishment's QMM.[5] This prototype assessment protocol included a series of questions in five practice areas: management commitment to quality,[6] business continuity, technical excellence, advanced pharmaceutical quality system, and employee empowerment and engagement. Within each practice area, the prototype assessment protocol explores key elements of the establishment's QMM. Examples of some topics covered under the practice areas include management review and resource management (management commitment to quality), supply planning and demand forecasting (business continuity), continual improvement[7] (advanced pharmaceutical quality system), data governance and process optimization (technical excellence), and rewards and recognition (employee engagement and empowerment).

In 2024, CDER evaluated nine establishments in the voluntary QMM Prototype Assessment Protocol Evaluation Program.[8] CDER used the prototype assessment protocol to collect information on each establishment's practices, behaviors, and responses to specific questions in five practice areas. The information collected was evaluated using an objective rubric. Trained assessors conducted 5-day assessments and provided establishments with a QMM report following the assessment. Each QMM report highlighted the establishment's strengths and opportunities for improvement. Feedback from voluntary participants indicated that engagement with the QMM assessment team and the QMM reports were favorably received and provided value to the establishments. However, participants also indicated that certain aspects of the prototype assessment protocol were repetitive and suggested that the protocol should be streamlined.

The 2024 QMM Prototype Assessment Protocol Evaluation Program provided CDER with experience in the successful application of the prototype assessment tool across a group of volunteer establishments that reasonably reflected the diversity of the industry. The rubric effectively differentiated the maturity of quality management practices across the nine establishments assessed in 2024. Using the feedback received and insights gained from 2024, CDER modified its prototype QMM assessment tool to be clearer and more concise and updated the rubric. We also modified how some of the questions are framed for greater clarity. CDER intends to evaluate these improvements and further refine the prototype protocol as necessary by continuing the voluntary program and offering the opportunity to establishments that wish to volunteer to participate in 2025. This notice announces CDER's intent to continue the voluntary QMM Prototype Assessment Protocol Evaluation Program, outlines the types of establishments CDER is seeking for participation, and describes the process for submitting a request to participate in the program.

[1] In 2023, CDER solicited comments to inform the development of a future QMM program. Then, in 2024, CDER initiated a voluntary QMM Prototype Assessment Protocol Evaluation Program. See 88 FR 63587, September 15, 2023, and 89 FR 4950, January 25, 2024, respectively.

[2] Quality Management Maturity for Finished Dosage Forms Pilot Program for Domestic Drug Product Manufacturers; Program Announcement, 85 FR 65824, October 16, 2020, *https://www.federalregister.gov/d/2020-22976.*

[3] Quality Management Maturity for Active Pharmaceutical Ingredients Pilot Program for Foreign Facilities; Program Announcement, 85 FR 65828, October 16, 2020, *https://www.federalregister.gov/d/2020-22977.*

[4] Maguire, J., A. Fisher, D. Harouaka, et al., ''Lessons from CDER's Quality Management Maturity Pilot Programs,'' AAPS J, 25(14), January 10, 2023, *https://doi.org/10.1208/s12248-022-00777-z.*

[5] For additional information, see CDER's ''Quality Management Maturity (QMM) Program: Practice Areas and Prototype Assessment Protocol Development'' (2023), available at *https://www.fda.gov/media/171705/download.*

[6] Note that this practice area was previously referred to as 'leadership' (89 FR 4950 at 4951). We have since modified this to ''management commitment to quality'' to align with what the practice area was titled at the time that specific prototype was developed and as discussed in our 2023 QMM white paper: CDER's Quality Management

Maturity (QMM) Program: Practice Areas and Prototype Assessment Protocol Development (see *https://www.fda.gov/media/171705/download*). ''Management Commitment to Quality'' more accurately reflects the topic areas covered in this practice area.

[7] Note that the example in the previous **Federal Register** Notice (89 FR 4950 at 4951) was ''corrective action and preventive action process'' (89 FR 4950 at 4951). That has since been replaced with ''Continual improvement'' as an example to align with modifications that were made to the prototype assessment protocol.

[8] See 89 FR 4950, January 25, 2024.

II. Participation

A. Establishment Characteristics

CDER will consider the following establishment characteristics when identifying potential participants for this voluntary QMM Prototype Assessment Protocol Evaluation Program:

- The potential participant is an establishment as defined in 21 CFR 207.1 that registers with FDA under section 510 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and manufactures, prepares, propagates, compounds, or processes drugs, or APIs used in such drugs, subject to approval or licensure under section 505 of the FD&C Act or section 351 of the Public Health Service Act, or that are marketed pursuant to section 505G of the FD&C Act without an approved application under section 505 of the FD&C Act (often referred to as over-the-counter (OTC) monograph drug products).
- The establishment has received at least one human drug surveillance inspection.[9]
- The current inspection classification for the establishment at the time of the request to participate is No Action Indicated or Voluntary Action Indicated.
- The establishment manufactures, prepares, propagates, compounds, or processes at least one CDER-regulated drug (API or finished drug product) that is currently in commercial distribution in the United States.
- The establishment is willing to participate in an onsite or hybrid assessment.

B. Requests To Participate

Drug product manufacturers that meet the establishment characteristics described in Section II.A and are interested in participating in the voluntary QMM Prototype Assessment Protocol Evaluation Program should submit a request directly to Conchetta Newton (see **FOR FURTHER INFORMATION CONTACT**). To be considered for this program, a request should include all the following information:

(1) A contact person (name and email).

(2) Manufacturing establishment address.

(3) FDA Establishment Identifier and Data Universal Numbering System Numbers.

(4) A brief description of the business operations (*e.g.,* manufacturing, testing, re/packaging, re/labeling, sterilizing, storing, distributing, or salvaging) conducted at the establishment. Please indicate whether you produce APIs, generic drugs, innovator drugs, OTC drugs, biological drug products, and if you are a contract manufacturing or contract testing organization.

(5) Confirmation that the establishment features the characteristics discussed in Section II.A of this notice.

To be eligible to participate in this 2025 program, establishments should submit a request to participate within the request acceptance period as discussed in the **DATES** section. This applies to all establishments regardless of whether they previously submitted a request to participate in the 2024 QMM Prototype Assessment Protocol Evaluation Program.

C. Selection Process

CDER intends to select participants that reasonably reflect the diversity of the industry. CDER intends to notify each establishment of a decision on their request to participate within 45 days after the close of the request acceptance period as discussed in the **DATES** section when this notice closes. CDER intends to select up to nine volunteer participants for this program.

D. CDER-Participant Interactions

CDER intends to notify participants of their selection and confirm participation. This notification would include information about a virtual orientation session in which CDER would share additional information with participating establishments including the program timelines, milestones, and expectations. Participating establishments would also receive a pre-assessment questionnaire, which provides specific topic areas that would be addressed during the assessment, help to prepare in advance of the assessment, and help determine which personnel would be most appropriate to provide supporting information. CDER intends to provide each establishment with options for dates to schedule the 5-day assessment.

Teams of three assessors would conduct each assessment. The QMM assessment team would be composed of CDER staff not including personnel from FDA's Office of Inspections and Investigations charged with the responsibility of ensuring compliance with current good manufacturing practice. In advance of the assessment, the establishment would receive an agenda to ensure the appropriate people are present at the requested times. The entire leadership team would not need to be present for the full assessment. If necessary, personnel may participate remotely.

Following completion of the assessment, each participating establishment would receive a report that provides, for each practice area: their score, a narrative, areas of strength, and opportunities for improvement. After reviewing the report, participating establishments would meet with the QMM assessment team to discuss any questions or comments they have regarding the report.

In the post-assessment phase of this program, participating establishments will be encouraged to select at least one opportunity to improve from the QMM report and develop an improvement plan with defined goal(s) based on that opportunity. Approximately 3 months after receipt of the QMM report, participating establishments will share their improvement plan with CDER and meet to discuss their plan and path forward. Approximately 6 months after receipt of the QMM report, CDER will schedule a final meeting with the participating establishment to discuss any progress made toward achieving their improvement goal(s). CDER will also solicit feedback from each participating establishment on the assessment, the report, and any suggestions or input they wish to share. This information will help CDER evaluate use of its QMM assessment tool and process to determine whether it enables a meaningful assessment of the establishment's quality management practices and if the feedback provided to the establishment was useful.

Dated: April 16, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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[9] Inspections conducted by FDA or by Mutual Recognition Agreement partners and classified by FDA fulfill this criterion. We also updated the original characteristic (''The establishment has received at least one human drug surveillance inspection in the prior 5 years,'' as published in 89 FR 4950 at 4951) to remove the 5-year timeframe and expand the number of potential establishments that could be eligible to participate.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0647]

Issuance of Priority Review Voucher; Material Threat Medical Countermeasure Product; EBANGA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.