(OMB control number: 0938–0599); *Frequency:* Yearly, quarterly, and semi-annually; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 50; *Total Annual Responses:* 50; *Total Annual Hours:* 34. (For policy questions regarding this collection contact Eric Powell at 312–886–0791.)

William N. Parham, III,

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

[FR Doc. 2024–03675 Filed 2–22–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10164 A/B]

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 (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 April 23, 2024.

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, 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.*

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–10164 A/B Medicare Electronic Data Interchange (EDI) Registration and Electronic Data Interchange Enrollment Form

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: Reinstatement with change of a previously approved collection; *Title of Information Collection:* Medicare Electronic Data Interchange (EDI) Registration and Electronic Data Interchange Enrollment Form; *Use:* The purpose of this collection is to obtain information that will be subsequently used during transaction exchange for identification of Medicare providers/suppliers and authorization of requested electronic data interchange (EDI) functions. The EDI Registration Form and the Medicare Enrollment Forms are completed by Medicare providers/suppliers and submitted to CMS Medicare Administrative Contractors (MACs). Authorization is needed for providers/suppliers to send/receive Health Insurance Portability and Accountability Act (HIPAA) standard transactions directly (or through a designated 3rd party) to/from Medicare contractors. Medicare contractors will use the information for initial set-up and maintenance of the access privileges. CMS has allowed each MAC to create their own organization specific forms given they are comparable in terms of content of forms 10164A and 10164B, to transmit data files electronically between themselves and their trading partners. The Standards for Electronic Transactions final rule, 45 CFR part 162 subpart K § 162.1101 through subpart R § 162.1802, (hereinafter referred to as ''Transactions Rule'') published August 17, 2000, adopted standards for health care transactions and code sets. Subsequent to the Transactions Rule, CMS–0003–P and CMS–0005–P proposed modifications to the adopted standards essential to permit initial implementation of the standards throughout the entire healthcare industry. Currently, MACs have a process in place to enroll providers for electronic billing and other EDI transactions. In support of the HIPAA Transactions Rule, the purpose of this Paperwork Reduction Act (PRA) request is to establish a prescribed amount of data that must be submitted by providers/suppliers that is sufficient to address all HIPAA transactions. *Form Number:* CMS–10164 A/B (OMB control number: 0938–0983); *Frequency:* Once; *Affected Public:* Private and Business or other for-profits; *Number of Respondents:* 1,181,209; *Number of Responses:* 1,181,209; *Total Annual Hours:* 393,706. (For policy questions regarding this collection contact

Charlene Parks at (410)-786–8684 or *Charlene.Parks@cms.hhs.gov*).

William N. Parham, III,

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

[FR Doc. 2024–03676 Filed 2–22–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2113]

Taylor McLaren: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Taylor McLaren for a period of 5 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Mr. McLaren was convicted of one felony count under Federal law for conspiracy to smuggle goods into the United States. The factual basis supporting Mr. McLaren's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. McLaren was given notice of the proposed debarment and was given an opportunity to request a hearing to show why he should not be debarred. As of January 8, 2024 (30 days after receipt of the notice), Mr. McLaren had not responded. Mr. McLaren's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.

DATES: This order is applicable February 23, 2024.

ADDRESSES: Any application by Mr. McLaren for termination of debarment under section 306(d)(1) of the FD&C Act (21 U.S.C. 335a(d)(1)) may be submitted as follows:

Electronic Submissions

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. An application submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application 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 application, that information will be posted on *https://www.regulations.gov.*

• If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

• *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 a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All applications must include the Docket No. FDA–2023–N–2113. Received applications 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 an application with confidential information that you do not wish to be made publicly available, submit your application 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 your application. 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. 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, 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, between 9 a.m. and 4 p.m., Monday through Friday. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Compliance and Enforcement, Office of Policy, Compliance, and Enforcement, Office of Regulatory Affairs, Food and Drug Administration, at 240–402–8743 or *debarments@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(D) of the FD&C Act permits debarment of an individual from importing or offering for import any drug into the United States if FDA finds, as required by section 306(b)(3)(C) of the FD&C Act, that the individual has been convicted of a felony for conduct relating to the importation into the United States of any drug or controlled substance.

On March 2, 2023, Mr. McLaren was convicted as defined in section 306(l)(1) of the FD&C Act, in the U.S. District Court for Western District of Michigan when the court accepted his plea of guilty and entered judgment against him for the offense of conspiracy to smuggle goods into the United States in violation of 18 U.S.C. 371 and 545.

The underlying facts supporting the conviction are as follows: As contained in the indictment and plea agreement from his case, filed on March 1, 2022, and August 22, 2022, respectively, Brendon Gagne owned and operated *www.ExpressPCT.com*, which sold misbranded prescription drugs, obtained from overseas suppliers, and sold to customers in the United States without requiring a prescription. Mr. McLaren was recruited by Brendon Gagne to receive, repackage, and reship prescription drugs Mr. McLaren received from co-conspirators outside of the United States that were purchased by customers on the website *www.ExpressPCT.com.* In Mr. McLaren's plea agreement, he acknowledged he knew that receiving and reshipping prescription drugs in this manner was illegal. Later on, Mr. McLaren recruited at least one other person to be involved in the scheme by