4. What can be done to improve the value of CDS Connect to clinicians, patients, CDS developers, and other stakeholders?

Governance

5. What governance structure and framework does the submitting organization envision for the PPP (or other sustainment model)?

6. How would the PPP (or other sustainment model) operate, accounting for the involvement of AHRQ, other federal agencies, or other potential external partners?

Content

7. What suggestions (if any) would be proposed to modify or enhance the CDS Connect Repository, CDS artifacts within the CDS Connect Repository, and/or the CDS Connect Authoring Tool?

8. If submitting as an organization, what other suggestions does the submitting organization have to modify or enhance CDS Connect's content and/or capabilities?

9. What existing infrastructure can support these suggested modifications or enhancements, or what additional infrastructure would be needed? What are the barriers or general feasibility issues to implementation?

Business Model

10. What business model(s) can ensure that CDS Connect remains sustainable (*e.g.,* a PPP or other sustainment model)?

11. If submitting as an organization, what are the submitting organization's suggested mechanisms of models for generating revenue that will enable a sustainable PPP (or other sustainment model)?

12. What are the anticipated project start-up costs for the proposed business model?

General Questions About CDS

1. How can CDS become more shareable, interoperable, and reusable, in particular, please identify:

a. Enablers;

b. Barriers;

c. Potential role(s) for AHRQ and other federal agencies;

d. Sustainable models for collaborative relationships among government agencies, academic institutions, private industry, non-profit organizations, patient advocacy groups, and other stakeholders.

2. What are sustainable approaches for scaling CDS, including AI-based methods, to under-served settings that may not have the staff and resources to develop CDS on their own or to purchase CDS resources (*e.g.,* modules, services) from their EHR provider or other health IT providers?

Who Should Respond

AHRQ welcomes responses from any stakeholders interested in the continued sustainment and growth of CDS Connect. AHRQ is interested in perspectives from:

- Private industry
- Participants of similar public-private collaboratives
- Developers and users of CDS, including academic institutions, clinicians, patients, payers, and research organizations

ACRONYMS

Acronym	Definition
AHRQ	Agency for Healthcare Research and Quality.
AI	Artificial Intelligence.
CDS	Clinical Decision Support.
CMS	Centers for Medicare & Medicaid Services (HHS).
EHR	Electronic Health Record.
FFRDC	Federally Funded Research and Development Center.
HHS	U.S. Department of Health and Human Services.
LLM	Large Language Model.
PCOR	Patient-centered outcomes research.
PPP	Public Private Partnership.
RFI	Request For Information.

Dated: May 23, 2024.

Marquita Cullom,

Associate Director.

[FR Doc. 2024–11878 Filed 5–31–24; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10454 and CMS–10858]

Agency Information Collection Activities: Submission for OMB Review; 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 a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate 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 on the collection(s) of information must be received by the OMB desk officer by July 3, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

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 Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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 (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to publish a 30-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 that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of information Collection:* Disclosure of State Rating Requirements; *Use:* The final rule ''Patient Protection and Affordable Care Act; Health Insurance Market Rules; Rate Review'' implements sections 2701, 2702, and 2703 of the Public Health Service Act (PHS Act), as added and amended by the Affordable Care Act, and sections 1302(e) and 1312(c) of the Affordable Care Act. The rule directs that States submit to CMS certain information about State rating and risk pooling requirements for their individual, small group, and large group markets, as applicable. Specifically, States will inform CMS of age rating ratios that are narrower than 3:1 for adults; tobacco use rating ratios that are narrower than 1.5:1; a State-established uniform age curve; geographic rating areas; whether premiums in the small and large group market are required to be based on average enrollee amounts (also known as composite premiums); and, in States that do not permit any rating variation based on age or tobacco use, uniform family tier structures and corresponding multipliers. In addition, States that elect to merge their individual and small group market risk pools into a combined pool will notify CMS of such election. This information will allow CMS to determine whether State-specific rules apply or Federal default rules apply. It will also support the accuracy of the federal risk adjustment methodology. *Form Number:* CMS–10454 (OMB control number 0938–1258); *Frequency:* Occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 3; *Total Annual Responses:* 3; *Total Annual Hours:* 7.3. (For policy questions regarding this collection contact Russell Tipps at 301–869–3502.)

2. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Rebate Reduction Requests under Sections 11101 and 11102 of the Inflation Reduction Act; *Use:* Under the authority in sections 11101 and 11102 of the Inflation Reduction Act of 2022 (Pub. L. 117–169), the Centers for Medicare & Medicaid Services (CMS) is implementing the Medicare Part B Drug Inflation Rebate Program and the Medicare Part D Drug Inflation Rebate Program codified in section 1847A(i) and section 1860D–14B of the Social Security Act (''the Act''), respectively.

In accordance with section 1847A(i) of the Act, for calendar quarters beginning January 1, 2023, a manufacturer of a Part B rebatable drug will owe a rebate, to be deposited in the Federal Supplementary Medical Insurance Trust Fund, if the amount specified in section 1847A(i)(3)(A)(ii)(I) of the Act exceeds the inflation-adjusted payment amount, which is calculated as set forth in section 1847A(i)(3)(C) of the Act. A ''Part B rebatable drug'' means a single-source drug or biological product (as defined section 1847A(c)(6)(D) of the Act), including a biosimilar biological product (as defined section 1847A(c)(6)(H) of the Act) but excluding a qualifying biosimilar biological product (as defined section 1847A(b)(8)(B)(iii) of the Act), for which payment is made under Medicare Part B, except such term shall not include such a drug or biological product if, as determined by the Secretary, the average total allowed charges for such drug or biological product under Part B for a year per individual that uses such a drug or biological product are less than the applicable threshold; or that is a vaccine described in subparagraph (A) or (B) of section 1861(s)(10) of the Act.

In accordance with section 1860D–14B of the Act, for each 12-month applicable period, starting with the applicable period beginning October 1, 2022, a manufacturer of a Part D rebatable drug will owe a rebate, to be deposited in the Federal Supplementary Medical Insurance Trust Fund, if the annual manufacturer price exceeds the inflation-adjusted payment amount. Section 1860D–14B(g)(1)(A) of the Act defines a ''Part D rebatable drug,'' in part, as a drug or biological described at section 1860D–14B(g)(1)(C) that is a ''covered Part D drug'' as that term is defined in section 1860D–2(e) of the Act. The definition of a Part D rebatable drug includes generic drugs that meet certain statutory criteria (effectively sole source generics). The definition of a Part D rebatable drug does not include a drug or biological if, as determined by the Secretary, the ''average annual total cost'' for such drug or biological under Part D for a year per individual that uses such a drug or biological is less than the applicable threshold.

Sections 1847A(i)(3)(G)(ii) and 1860D–14B(b)(1)(C)(ii) of the Act require that CMS reduce or waive the inflation rebate amount owed (if any) for a Part B rebatable biosimilar biological product and generic Part D rebatable drug or biosimilar when CMS determines there is a severe supply chain disruption during a calendar quarter or applicable period, respectively, such as that caused by a natural disaster or other unique or unexpected event. CMS must also reduce or waive the inflation rebate amount owed (if any) for a generic Part D rebatable drug if CMS determines that without such reduction or waiver, the drug is likely to be in shortage in a subsequent applicable period, as required by section 1860D–14B(b)(1)(C)(iii) of the Act.

CMS does not have information necessary to determine whether manufacturers of Part B and Part D rebatable drugs should have their rebate amount reduced due to either a severe supply chain disruption or a likely shortage as required by sections 1847A(i)(3)(G)(ii), 1860D–14B(b)(1)(C)(ii), and 1860D–14B(b)(1)(C)(iii) of the Act. Some of the information and supporting documentation needed for CMS to make a determination regarding a severe supply chain disruption and the likelihood of a future shortage are held by manufacturers and are not available to CMS. As such, for CMS to determine whether there is a severe supply chain disruption or likelihood of future shortage, in accordance with sections 1847A(i)(3)(G)(ii), 1860D–14B(b)(1)(C)(ii), and 1860D–14B(b)(1)(C)(iii) of the Act, a manufacturer must submit to CMS a

request for a rebate reduction along with supporting documentation. *Form Number:* CMS–10858 (OMB control number: 0938–new); *Frequency:* Once; *Affected Public:* Private Sector and Business or other for-profits; *Number of Respondents:* 10; *Total Annual Responses:* 10; *Total Annual Hours:* 310. (For policy questions regarding this collection contact Elisabeth Daniel at 667–290–8793.)

William N. Parham, III,

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

[FR Doc. 2024–12122 Filed 5–31–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–5023]

Shanif Abdul Punjani: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Shanif Abdul Punjani 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. Punjani was convicted of one felony count under Federal law for Conspiracy to Defraud the United States. The factual basis supporting Mr. Punjani's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Punjani 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 March 6, 2024 (30 days after receipt of the notice), Mr. Punjani had not responded. Mr. Punjani'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 June 3, 2024.

ADDRESSES: Any application by Mr. Punjani for termination of debarment under section 306(d)(1) of the FD&C Act (21 U.S.C. 335a(d)(1)) may be submitted at any time 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–5023. 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, between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500. 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 August 16, 2023, Mr. Punjani was convicted as defined in section 306(l)(1) of the FD&C Act in the U.S. District Court for the Northern District of Georgia-Atlanta Division, when the court accepted his plea of guilty and entered judgment against him for the offense of Conspiracy to Defraud the United States in violation of 18 U.S.C. 371. The underlying facts supporting the conviction are as follows: As contained in the Information and the Government's Sentencing Statement from Mr. Punjani's case, in or about March 2019, and continuing until February 2021, he imported thousands of Aurogra 100mg Sildenafil tablets, which were male enhancement pills manufactured in India, but not authorized for sale in the United States. Sildenafil is the same active pharmaceutical ingredient (API) as that in the prescription drug Viagra. The FDA approved drugs containing the active ingredient sildenafil are only