

collection, contact Adam Pellillo at 667-290-9621.)

2. Type of Information Collection Request: Revision of a currently approved collection; **Title of Information Collection:** Blueprint for Approval of State-based Exchange; **Use:** The Patient Protection and Affordable Care Act (ACA) and its implementing regulations provide states with flexibility in the design and operation of Exchanges to ensure states are implementing Exchanges that best meet the needs of their consumers. States can choose to establish and operate a State-based Exchange (SBE) or a State-based Exchange on the Federal Platform (SBE-FP). To ensure a state can operate a successful and compliant SBE or SBE-FP, it is critical that states provide CMS with a complete and thorough Exchange Blueprint Application, Declaration of Intent Letter, and attest to demonstrate operational readiness. The information collected from states will be used by CMS, IRS, SSA and reviewed by other Federal agencies to determine if a state can implement a complete and fully operational Exchange. **Form Number:** CMS-10416 (OMB control number: 0938-1172); **Frequency:** Annually; **Affected Public:** State, Local, or Tribal governments; **Number of Respondents:** 2; **Total Annual Responses:** 21; **Total Annual Hours:** 106. (For policy questions regarding this collection contact Tiffany Y. Animashaun at Tiffany.Animashaun@cms.hhs.gov.)

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

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-R-71 and CMS-855B]

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 February 14, 2025.

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:** Quality Improvement Organization (QIO) Assumption of Responsibilities and Supporting Regulations; **Use:** The Peer Review Improvement Act of 1982 amended Title XI of the Social Security Act to create the Utilization and Quality Control Peer Review Organization (PRO) program which replaces the Professional Standards Review Organization (PSRO) program and streamlines peer review activities. The term PRO has been renamed Quality Improvement Organization (QIO). This information collection describes the review functions to be performed by the QIO. It outlines relationships among QIOs, providers, practitioners, beneficiaries, intermediaries, and carriers. **Form Number:** CMS-R-71 (OMB control number: 0938-0445); **Frequency:** Yearly; **Affected Public:** Business or other for-profit and Not-for-profit institutions; **Number of Respondents:** 6,120; **Total Annual Responses:** 502,246; **Total Annual Hours:** 1,091,597. (For policy questions regarding this collection contact Cheryl Lehane at 617-461-4888.)

2. Type of Information Collection Request: Reinstatement with change of a previously approved collection; **Title of Information Collection:** Medicare Enrollment Application for Clinics/ Group Practices and Other Suppliers; **Use:** Various sections of the Act, the United States Code (U.S.C.), Internal Revenue Service (IRS) Code, and the CFR require providers and suppliers to furnish information concerning the amounts due and the identification of individuals or entities that furnish medical services to beneficiaries before payment can be made. The Form CMS-855B application is submitted when the applicant first requests Medicare enrollment. The application is used by the MACs to collect data to ensure the applicant has the necessary credentials to provide the health care services for which they intend to bill Medicare; this includes data that allows the Medicare contractor to correctly price, process, and pay the applicant's claims. It also gathers information that enables MACs to ensure that the supplier is neither excluded from the Medicare program nor debarred, suspended, or excluded from any other Federal agency or program. The application is also used by

enrolled suppliers when they are reporting a change in their ownership, a change in their current Medicare enrollment information, or are revalidating or reactivating their Medicare enrollment. *Form Number:* CMS-855B (OMB control number: 0938-1377); *Frequency:* Occasionally; *Affected Public:* Private Sector; Business or other for-profits, and Not-for Profits; *Number of Respondents:* 132,800; *Number of Responses:* 132,800; *Total Annual Hours:* 155,884. (For questions regarding this collection, contact Frank Whalen at 410-786-1302 or Frank.Whalen@cms.hhs.gov.)

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

Food and Drug Administration

[Docket No. FDA-2021-P-0168]

Growing, Harvesting, Processing, and Distribution of Poppy Seeds—Industry Practices Related to Opiate Alkaloids; Request for Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for information.

SUMMARY: The Food and Drug Administration (FDA or we) is requesting information on industry practices related to poppy seeds, such as information about growing, harvesting, processing, and distribution of poppy seeds, including industry practices to reduce the opiate alkaloid content of poppy seeds. We are taking this action, in part, because we have received reports of adverse events related to the use of some poppy seed products. We intend to use the information to help determine what type(s) of actions, if any, we should take to help ensure that poppy seed products do not pose a health risk when consumed.

DATES: Either electronic or written comments on the notice must be submitted by April 15, 2025.

ADDRESSES: You may submit comments and information as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 15, 2025. Comments received by mail/hand delivery/courier (for written/

paper submissions) will be considered timely if they are received on or before that date.

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-2021-P-0168 for "Growing, Harvesting, Processing, and Distribution of Poppy Seeds—Industry Practices related to Opiate Alkaloids; Request for Information." Received comments, those filed in a timely manner (see **ADDRESSES**), 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." We will review this copy, including the claimed confidential information, in our 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.

FOR FURTHER INFORMATION CONTACT: Jesse Lunzer, Office of Food Chemical Safety, Dietary Supplements, and Innovation, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2879, or Holli Kubicki, Office of Policy, Regulations, and Information, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is requesting information on industry practices related to poppy seeds, such as information about growing, harvesting, processing, and distribution of poppy seeds, including industry practices to reduce the opiate alkaloid content of poppy seeds. The opium poppy (*Papaver somniferum*), or the "poppy plant," is cultivated for food use, decorative use, ornamental use, and