

Estimated Total Annual Burden: 31,960 hours.

Request for Comments: OGE is publishing this first round notice of its intent to request paperwork clearance renewal for OGE Form 278e. Public comment is invited specifically on the need for and practical utility of this information collection, the accuracy of OGE's burden estimate, the enhancement of quality, utility and clarity of the information collected, and the minimization of burden (including the use of information technology). Comments received in response to this notice will be summarized for, and may be included with, the OGE request for extension of OMB paperwork approval. The comments will also become a matter of public record.

Approved: May 27, 2021.

Emory Rounds,

Director, U.S. Office of Government Ethics.

[FR Doc. 2021-11551 Filed 6-1-21; 8:45 am]

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OFFICE OF GOVERNMENT ETHICS

Agency Information Collection Activities; Information Collection Renewal; Comment Request for OGE Form 450 Executive Branch Confidential Financial Disclosure Report

AGENCY: Office of Government Ethics (OGE).

ACTION: Notice and request for comments.

SUMMARY: After this first round notice and public comment period, the Office of Government Ethics (OGE) plans to request that the Office of Management and Budget (OMB) renew its approval under the Paperwork Reduction Act for an existing information collection, entitled the OGE Form 450 Executive Branch Confidential Financial Disclosure Report.

DATES: Written comments by the public and agencies on this proposed extension are invited and must be received by August 2, 2021.

ADDRESSES: Comments may be submitted to OGE by any of the following methods:

Email: usoge@oge.gov. (Include reference to "OGE Form 450 paperwork comment" in the subject line of the message.)

Mail, Hand Delivery/Courier: Office of Government Ethics, 1201 New York Avenue NW, Suite 500, Attention: Grant Anderson, Assistant Counsel, Washington, DC 20005-3917.

Instructions: Comments may be posted on OGE's website, www.oge.gov.

Sensitive personal information, such as account numbers or Social Security numbers, should not be included. Comments generally will not be edited to remove any identifying or contact information.

FOR FURTHER INFORMATION CONTACT:

Grant Anderson at the U.S. Office of Government Ethics; telephone: 202-482-9318; TTY: 800-877-8339; Email: ganderso@oge.gov. An electronic copy of the OGE Form 450 is available on OGE's website at <https://www.oge.gov>. A paper copy may also be obtained, without charge, by contacting Mr. Anderson.

SUPPLEMENTARY INFORMATION:

Title: Executive Branch Confidential Financial Disclosure Report.

Agency Form Number: OGE Form 450.

Abstract: The OGE Form 450 collects information from covered department and agency employees as required under OGE's executive branch wide regulatory provisions in subpart I of 5 CFR part 2634. The basis for the OGE reporting regulation is section 201(d) of Executive Order 12674 of April 12, 1989 (as modified by Executive Order 12731 of October 17, 1990) and section 107(a) of the Ethics in Government Act, 5 U.S.C. app. sec. 107(a). OGE maintains the form in three formats on its website: a PDF version, a 508 compliant PDF version, and an Excel spreadsheet version. OGE seeks renewal of the OGE Form 450 without modification.

OMB Control Number: 3209-0006.

Type of Information Collection: Extension of a currently approved collection.

Type of Review Request: Regular.

Affected Public: Prospective Government employees, including special Government employees, whose positions are designated for confidential disclosure filing and whose agencies require that they file new entrant confidential disclosure reports prior to assuming Government responsibilities.

Estimated Annual Number of Respondents: 30,449.

Estimated Time per Response: 3 hours.

Estimated Total Annual Burden: 91,347 hours.

Request for Comments: OGE is publishing this first round notice of its intent to request paperwork clearance renewal for the OGE Form 450. Public comment is invited specifically on the need for and practical utility of this information collection, the accuracy of OGE's burden estimate, the enhancement of quality, utility and clarity of the information collected, and the minimization of burden (including

the use of information technology). Comments received in response to this notice will be summarized for, and may be included with, the OGE request for extension of OMB paperwork approval. The comments will also become a matter of public record.

Approved: May 27, 2021.

Emory Rounds,

Director, U.S. Office of Government Ethics.

[FR Doc. 2021-11553 Filed 6-1-21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10637 and CMS-10501]

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 (the 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 August 2, 2021.

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, you may make your request using one of following:

1. Access CMS’ website address at website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

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–10637 Marketplace Operations
CMS–10501 Healthcare Fraud
Prevention Partnership (HFPP) Data
Sharing and Information Exchange

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:* Extension of a currently approved collection; *Title of*

Information Collection: Marketplace Operations; *Use:* The data collections and third-party disclosure requirements will assist HHS in determining Exchange compliance with Federal standards and monitoring QHP issuers in FFEs for compliance with Federal QHP issuer standards. The data collection will also assist HHS in monitoring Web-brokers for compliance with Federal Web-broker standards. The data collected by health insurance issuers and Exchanges will help to inform HHS, Exchanges, and health insurance issuers as to the participation of individuals, employers, and employees in the individual Exchange, the SHOP, and the premium stabilization programs. *Form Number:* CMS–10637 (OMB control number 0938–1353); *Frequency:* Annually; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 3,902; *Total Annual Responses:* 3,902; *Total Annual Hours:* 2,336,190. (For policy questions regarding this collection contact: Nikolas Berkobien at 301–492–4400.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Healthcare Fraud Prevention Partnership (HFPP) Data Sharing and Information Exchange; *Use:* Section 1128C(a)(2) of the Social Security Act (42 U.S.C. 1320a–7c(a)(2)) authorizes the Secretary and the Attorney General to consult, and arrange for the sharing of data with, representatives of health plans for purposes of establishing a Fraud and Abuse Control Program as specified in Section 1128(C)(a)(1) of the Social Security Act. The result of this authority has been the establishment of the HFPP. The HFPP was officially established by a Charter in the fall of 2012 and signed by HHS Secretary Sibelius and US Attorney General Holder. In December 2020, President Trump signed into law H.R.133—Consolidated Appropriations Act, 2021, which amended Section 1128C(a) of the Social Security Act (42 U.S.C. 1320a–7c(a)) providing explicit statutory authority for the Healthcare Fraud Prevention Partnership including the potential expansion of the public-private partnership analyses.

Data sharing within the HFPP primarily focuses on conducting studies for the purpose of combatting fraud, waste, and abuse. These studies are intended to target specific vulnerabilities within the payment systems in both the public and private healthcare sectors. The HFPP and its committees design and develop studies in coordination with the TTP. The core function of the TTP is to manage and

execute the HFPP studies within the HFPP. *Form Number:* CMS–10501 (OMB control number: 0938–1251); *Frequency:* Occasionally; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 28; *Number of Responses:* 28; *Total Annual Hours:* 120. (For questions regarding this collection, contact Marnie Dorsey at (410–786–5942).

Dated: May 27, 2021.

William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2021–11591 Filed 6–1–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–P–0163]

Determination That SANDOSTATIN (Octreotide Acetate) Injection, Equal to 0.2 Milligrams Base/Milliliter and Equal to 1 Milligram Base/Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) has determined that SANDOSTATIN (octreotide acetate) injection, equal to (EQ) 0.2 milligrams (mg) base/milliliter (mL) and 1 mg base/mL, was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993–0002, 301–796–8363, Stacy.Kane@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that