

award up to \$50 million in additional universal service funding to Tribal Areas, including Alaska, to accelerate mobile broadband availability in these remote and underserved areas. In its May 2012 *Third Order on Reconsideration* (FCC 12–52), the Commission revised certain rules adopted in the *USF/ICC Transformation Order*, including the deadline by which MF–I and TMF–I support recipients must file their annual reports pursuant to 47 CFR 54.1009(a). The information being collected under this information collection will be used by the Commission to ensure that MF–I and TMF–I support recipients are meeting the public interest obligations associated with receiving such support. Federal Communications Commission.

Katura Jackson,

Federal Register Liaison Officer.

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OFFICE OF GOVERNMENT ETHICS

Agency Information Collection Activities; Information Collection Renewal; Comment Request for OGE Form 319 Request for a Medical Exception to the Covid–19 Vaccination Requirement

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 319 Request for a Medical Exception to the Covid–19 Vaccination Requirement. The form was originally granted emergency clearance on November 19, 2021.

DATES: Written comments by the public and agencies on this proposed extension are invited and must be received by April 11, 2022.

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

Email: usoge@oge.gov (Include reference to “OGE Form 319 Request for a Medical Exception to the Covid–19 Vaccination Requirement comment” in the subject line of the message.)

Mail, Hand Delivery/Courier: Office of Government Ethics, 1201 New York Avenue NW, Suite 500, Attention:

Jennifer Matis, Associate 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:

Jennifer Matis at the U.S. Office of Government Ethics; telephone: 202–482–9216; TTY: 800–877–8339; Email: jmatis@oge.gov. A copy of the form may be obtained, without charge, by contacting Jennifer Matis.

SUPPLEMENTARY INFORMATION:

Title: Request for a Medical Exception to the Covid–19 Vaccination Requirement.

Agency Form Number: OGE Form 319.

Abstract: The OGE Form 319 collects information necessary to document the consideration, decision, and implementation of OGE employee requests for reasonable accommodation from the COVID vaccination requirement set forth in Executive Order 14043, Requiring Coronavirus Disease 2019 Vaccination for Federal Employees (Sept. 9, 2021).

OMB Control Number: 3209–0011.

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

Type of Review Request: Regular.

Affected public: Medical providers who are asked to provide documentation in support of an employee’s request for a medical exception to the requirement for COVID–19 vaccination.

Estimated Annual Number of Respondents: 1 (based on an estimate of five respondents over a ten year period, rounded up).

Estimated Time per Response: 10 minutes.

Estimated Total Annual Cost Burden (in dollars): 17.

Request for Comments: OGE is publishing this first round notice of its intent to request paperwork clearance renewal for the OGE Form 319. 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 included with the OGE request for extension of OMB paperwork approval.

The comments will also become a matter of public record.

A Notice Regarding Injunctions: The vaccination requirement issued pursuant to E.O. 14043 is currently the subject of a nationwide injunction. While that injunction remains in place, OGE will not process requests for a medical exception from the COVID–19 vaccination requirement pursuant to E.O. 14043. OGE will also not request the submission of any medical information related to a request for an exception from the vaccination requirement pursuant to E.O. 14043 while the injunction remains in place. But OGE may nevertheless receive information regarding a medical exception. That is because, if OGE were to receive a request for an exception from the COVID–19 vaccination requirement pursuant to E.O. 14043 during the pendency of the injunction, OGE will accept the request, hold it in abeyance, and notify the employee who submitted the request that implementation and enforcement of the COVID–19 vaccination requirement pursuant to E.O. 14043 is currently enjoined and that an exception therefore is not necessary so long as the injunction is in place. In other words, during the pendency of the injunction, any information collection related to requests for medical exception from the COVID–19 vaccination requirement pursuant to E.O. 14043 is not undertaken to implement or enforce the COVID–19 vaccination requirement.

Approved: February 7, 2022.

Emory Rounds,

Director, U.S. Office of Government Ethics.

[FR Doc. 2022–02826 Filed 2–9–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2022–0024]

Proposed 2022 CDC Clinical Practice Guideline for Prescribing Opioids

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services (HHS), announces the opening of a docket to obtain comment on the proposed clinical practice guideline, *CDC Clinical Practice Guideline for*

Prescribing Opioids—United States, 2022 (the clinical practice guideline). The clinical practice guideline updates and expands the *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, and provides evidence-based recommendations for clinicians who provide pain care, including those prescribing opioids, for outpatients age 18 years and older with acute pain (duration less than 1 month), subacute pain (duration of 1–3 months), or chronic pain (duration of 3 months or more), not including sickle cell disease-related pain management, cancer pain treatment, palliative care, and end-of-life care. The clinical practice guideline includes recommendations for primary care clinicians (including physicians, nurse practitioners, and physician assistants) as well as for outpatient clinicians in other specialties (including those managing dental and postsurgical pain in outpatient settings and emergency clinicians providing pain management for patients being discharged from emergency departments). This voluntary clinical practice guideline provides recommendations and does not require mandatory compliance; and the clinical practice guideline is intended to be flexible so as to support, not supplant, clinical judgment and individualized, patient-centered decision-making.

DATES: Written comments must be received on or before April 11, 2022.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2022–0024, by either of the following methods.

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Mail:* National Center for Injury Prevention and Control, Centers for Disease Control and Prevention, 4770 Buford Highway NE, Mailstop S106–9, Atlanta, GA 30341, Attn: Docket No. CDC–2022–0024.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to <http://regulations.gov>, including any personal information provided. Do not submit comments by email. CDC does not accept comments by email. For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Arlene I. Greenspan, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention, 4770 Buford Highway NE, MS S106–9, Atlanta, GA 30341; Telephone: 770–488–4696. Email: opioids@cdc.gov.

SUPPLEMENTARY INFORMATION:

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data. Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on <https://www.regulations.gov>. Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. Do not submit comments by email. CDC does not accept comments by email. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign.

Background

In the *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, CDC communicated the intent to evaluate and reassess evidence and recommendations as new evidence became available and to determine when new evidence would prompt an update. To achieve these aims, CDC funded the Evidence-based Practice Centers at the Agency for Healthcare Research and Quality (AHRQ) to conduct systematic reviews of the scientific evidence in the following five areas: (1) Noninvasive nonpharmacological treatments for chronic pain; (2) nonopioid pharmacologic treatments for chronic pain; (3) opioid treatments for chronic pain; (4) treatments for acute pain; and (5) acute treatments for episodic migraine. Based upon the new evidence described in these reviews, an update to the *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016* was warranted.

CDC developed the clinical practice guideline using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) framework, which specifies the systematic review of scientific evidence and offers a transparent approach to grading quality of evidence and strength of recommendations. Recommendations were made based on systematic reviews of the available scientific evidence

while considering benefits and harms; patients', caregivers', and clinicians' values and preferences for pain treatment; and resource allocation (e.g., costs to patients or health systems, including clinician time). CDC drafted recommendation statements in the clinical practice guideline focused on assisting clinicians in determining whether to initiate opioids for pain; opioid selection and dosage; opioid duration and follow-up; and assessing risk and addressing potential harms of opioid use.

This clinical practice guideline is voluntary; it provides recommendations and does not require mandatory compliance. It is intended to be flexible to support, not supplant, clinical judgment and individualized, patient-centered decision-making. This clinical practice guideline *is not* intended to be applied as inflexible standards of care across patient populations by healthcare professionals, health systems, third-party payers, organizations, or governmental jurisdictions. The clinical practice guideline is intended to achieve the following: Improved communication between clinicians and patients about the risks and benefits of pain treatment, including opioid therapy for pain; improved safety and effectiveness for pain treatment, resulting in improved function and quality of life for patients experiencing pain; and a reduction in the risks associated with long-term opioid therapy, including opioid use disorder, overdose, and death.

To help assure the clinical practice guideline's integrity, credibility, and consideration of patients', caregivers', and providers' values and preferences, CDC obtained input from patients, caregivers, experts, clinicians, the public, and a federally chartered advisory committee, the Board of Scientific Counselors of the National Center for Injury Prevention and Control (BSC/NCIPC). CDC is also currently obtaining feedback from a panel of external peer reviewers who are experts in topic areas related to opioid prescribing. The panel of external peer reviewers' feedback will be addressed and incorporated into the final clinical practice guideline at the same time that public comments received in response to this Notice are considered.

For more information about the clinical practice guideline or the process of updating it, please visit <https://www.cdc.gov/opioids/guideline-update/index.html>.

Supporting and Related Material in the Docket

The docket contains the following supporting and related materials to help

inform public comment: (1) The draft clinical practice guideline; (2) the GRADE tables; (3) the Opioid Workgroup (OWG) Report, prepared at the request of the BSC/NCIPC and which the BSC/NCIPC unanimously voted to have CDC adopt, and CDC's response to observations outlined in the OWG Report; and (4) an Overview of Community Engagement and Public Comment Opportunities, which describes key themes that emerged about stakeholders' values and preferences regarding pain management, as well as CDC's response to input obtained from these efforts. The GRADE tables include clinical evidence review ratings of the evidence for the key clinical questions. The OWG Report describes the workgroup's findings and observations about the initial draft clinical practice guideline as presented to the BSC/NCIPC at a public meeting on July 16, 2021. The OWG, comprising three BSC/NCIPC members in accordance with federal advisory committee policy, as well as patients with pain, caregivers, and family members of patients with pain, and clinicians and subject matter experts with a variety of relevant pain management expertise, was designed to provide independent, broad, external, transparent input to the BSC/NCIPC on the diverse and complex issues addressed in the clinical practice guideline. OWG meetings were coordinated by an NCIPC subject matter expert who served as the Designated Federal Official. CDC's response to the OWG Report reflects and describes how CDC incorporated OWG observations and comments in the revised draft of the clinical practice guideline. The *Overview of Community Engagement and Public Comment Opportunities* document provides a summary of efforts implemented throughout the clinical practice guideline update process to better understand the lived experiences and perspectives of community members that we serve and to ensure additional input from patients, caregivers, clinicians, and the public. CDC's response to the themes and findings that emerged throughout the community engagement and public comment opportunities describes how CDC carefully considered and incorporated diverse perspectives and input from multiple sources and stakeholders into the clinical practice guideline.

Dated: February 7, 2022.

Angela K. Oliver,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2022-02802 Filed 2-9-22; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-1030]

Brenda K. Marmas: 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) debarment Brenda K. Marmas 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 Ms. Marmas engaged in a pattern of importing or offering for import misbranded drugs (*i.e.*, in an amount, frequency, or dosage that is inconsistent with her personal or household use) that are not designated in an authorized electronic data interchange system as products regulated by FDA. Ms. Marmas was given notice of the proposed debarment and was given an opportunity to request a hearing to show why she should not be debarred. As of December 12, 2021 (30 days after receipt of the notice), Ms. Marmas had not responded. Ms. Marmas' failure to respond and request a hearing constitutes a waiver of her right to a hearing concerning this matter.

DATES: This order is applicable February 10, 2022.

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, or at <https://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Enforcement (ELEM-4029), Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240 402-8743, or at debarments@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(D) of the FD&C Act (21 U.S.C. 335a(b)(1)(D)) 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)(D) of the FD&C Act, that the individual has engaged in a pattern of importing or offering for import misbranded drugs (*i.e.*, in an amount, frequency, or dosage that is inconsistent with personal or household use by the importer), and the shipments are not designated in an entry in an authorized electronic data exchange system as products regulated by FDA.

After an investigation, FDA discovered that Ms. Marmas has engaged in numerous instances of importing or offering for import misbranded drugs; all the parcels containing the misbranded drugs serving as the basis for this action, described in further detail below, were intercepted by FDA at either the John F. Kennedy International Airport (JFK), San Francisco International Airport (SFO), or Chicago International Airport Mail Facilities (MF) and were addressed to Ms. Marmas at an address connected to her.

On or about March 3, 2020, Ms. Marmas offered for import a parcel intercepted and processed by FDA at JFK MF that was addressed to her. This parcel contained multiple products. FDA determined that one of the products contained in this parcel was 1,000 tablets of levofloxacin IP and was a misbranded drug for a number of reasons: (1) The article was determined to be a prescription drug but did not include the symbol "Rx only" on its label; (2) the article had been determined to lack adequate directions for use; (3) the drug was not included in a list required by section 510(j) of the FD&C Act (21 U.S.C. 360(j)); and (4) the drug was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 510 of the FD&C Act. FDA also determined that another product contained in this parcel was 900 tablets of moxifloxacin hydrochloride and was a misbranded drug for a number of reasons: (1) The article was determined to be a prescription drug but did not include the symbol "Rx only" on its label; (2) the article had been determined to lack adequate directions for use; (3) the drug was not included in a list required by section 510(j) of the FD&C Act; and (4) the drug was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 510 of the FD&C Act. Both products were refused entry on March 26, 2020.