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DEPARTMENT OF LABOR

Office of the Worker's Compensation Programs

[OMB Control No. 1240-0055]

Proposed Extension of Information Collection; [Authorization and Certification/Letter of Medical Necessity (CA-26/CA-27)

AGENCY: Division of Federal Employees' Longshore and Harbor Workers' Compensation, Office of Workers' Compensation, (OWCP/DFELHWC), Labor.

ACTION: Request for public comments.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance request for comment to provide the general public and Federal agencies with an opportunity to comment on proposed collections of information in accordance with the Paperwork Reduction Act of 1995. This request helps to ensure that: requested data can be provided in the desired format; reporting burden (time and financial resources) is minimized; collection instruments are clearly understood; and the impact of collection requirements on respondents can be properly assessed. Currently, OWCP/DFELHWC is soliciting comments on the information collection for Authorization and Certification/Letter of Medical Necessity, CA-26/CA-27.

DATES: All comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**].

ADDRESSES: You may submit comment as follows. Please note that late, untimely filed comments will not be considered.

Written/Paper Submissions: Submit written/paper submissions in the following way:

- Mail/Hand Delivery: Mail or visit DOL- OWCP/DFELHWC, Office of Workers' Compensation Programs, Division of Federal Employees' Longshore and Harbor

Workers' Compensation, U.S. Department of Labor, 200 Constitution Ave., NW, Room S-3323, Washington, DC 20210.

- OWCP/DFELHWC will post your comment as well as any attachments, except for information submitted and marked as confidential, in the docket at *https://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Anjanette Suggs, Office of Workers' Compensation Programs, Division of Federal Employees Longshore, and Harbor Workers' Compensation, OWCP/DFELHWC, at suggs.anjanette@dol.gov (email); (202) 354-9660.

SUPPLEMENTARY INFORMATION:

I. Background

In 2013, the President of the United States, Barack Obama, signed a law which provides greater Federal oversight over compounding pharmacies that custom mix medication in bulk for patients who may benefit from prescriptions that are specific to their individual medical needs. *See* Compounding Quality Act, Public Law 113-54, 127 Stat. 587 (2013). Compounded medications (which may contain opioids) have two or more ingredients and are offered as an alternative to FDA-approved medications that do not meet an individual patient's health needs, such as when a patient has an allergy that requires a medication to be made without a certain dye. *See Compounding and the FDA: Questions and Answers*, FDA, http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm.

The President had previously announced in October 2015 that several initiatives would be undertaken by the Federal Government as it related to opioid abuse and the heroin epidemic, noting that the Centers for Disease Control and Prevention (CDC) reported that overdose deaths involving prescription opioids quadrupled

between 1999 and 2013, with more than 16,000 deaths in 2013. The CDC has identified addiction to prescription pain medication as the strongest risk factor for heroin addiction.

On March 23, 2016, the President, responding to the escalation of prescription opioid abuse and the heroin epidemic, announced several actions taken by his Administration to address the epidemic, including steps to expand access for treatment, prevent overdose deaths and increase community prevention strategies.

Compounded drugs are not FDA-approved. This means that the FDA does not verify the safety or effectiveness of compounded drugs. Consumers and health professionals rely on the drug approval process to ensure that drugs are safe and effective and made in accordance with Federal quality standards. Compounded drugs also lack an FDA finding of manufacturing quality before such drugs are marketed.

Health risks associated with compounded drugs include the use of ingredients that may be sub- or super-potent, contaminated, or otherwise adulterated. Additionally, patients may use ineffective compounded drugs instead of FDA-approved drugs that have been shown to be safe and effective.

Impacts on the FECA Program

The Federal Employees' Compensation Act (FECA), 5 U.S.C. 8101 et seq., provides compensation benefits to Federal employees for work-related injury/illness and to their surviving dependents if a work-related injury/illness results in the employee's death. Section 8145 provides the Secretary of Labor the authority to delegate the responsibility to administer the FECA program to OWCP;

through this delegation OWCP has the authority and the responsibility to decide all questions arising under the FECA. 5 U.S.C. 8145.

Section 8103 provides:

The United States shall furnish to an employee who is injured while in the performance of duty, the services, appliances, and supplies prescribed or recommended by a qualified physician, which the Secretary of Labor considers likely to cure, give relief, reduce the degree or the period of disability, or aid in lessening the amount of the monthly compensation. 5 U.S.C. 8103.

A number of injured workers receiving benefits under the FECA program are prescribed opioid medication. While most prescriptions are short term in nature, some patients remain on these habit-forming medications for a long period of time.

Statutorily, FECA is mandated to provide medically necessary supplies and services to treat work related injuries. However, the FECA statute gives broad discretionary authority to determine the medical necessity of supplies and services used to treat work related injuries. Due to the safety concerns for both compounded drugs and opioids, the Department of Labor has deemed it necessary to more closely review the medical necessity of these medications in FECA claims by instituting a pre-authorization process.

OWCP believes that the two forms used to monitor compound and opiate medication further strengthens medical management procedures for prescription drugs, assist our stakeholders in controlling costs from medically unnecessary treatments, and lessen the impact of potential drug addiction and medical fraud.

A major goal of the FECA program is to return an injured employee back to employment as soon as medically feasible. The forms that are in use serve as a means for injured workers to continue receiving opioids and compounded drugs

only where medically necessary and simultaneously give OWCP greater oversight in monitoring their use.

OWCP has issued regulations relating to its authority to require prior authorization for medical treatment which will now be applied through these forms to compounded drugs and opioids. (20 CFR 10.310, 10.800 & 10. 809). Requiring Prior Authorization will assist OWCP in determining whether the prescribed medication will assist in curing, giving relief, and lessening the degree of disability. FECA further provides OWCP the authority to conduct such investigation as necessary before making an award of compensation (including the need for medical treatment by certain prescription drugs). 5 U.S.C. 8124(a)(2). Finally, 5 U.S.C. 8149 provides OWCP the authority to prescribe rules and regulations necessary for the administration of FECA.

As such, the CA-26, Authorization Request form and Certification/Letter of Medical Necessity for Compounded Drugs, and CA-27, Authorization Request form and Certification/Letter of Medical Necessity or Opioid Medications, fulfill these requirements and obligations under the FECA.

II. Desired Focus of Comments

OWCP is soliciting comments concerning the proposed information collection (ICR) titled, "Authorization and Certification/Letter of Medical Necessity", CA-26/CA-27.

OWCP/DFELHWC is particularly interested in comments that:

- Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information has practical utility;

- Evaluate the accuracy of OWCP/DFELHWC's estimate of the burden related to the information collection, including the validity of the methodology and assumptions used in the estimate;
- Suggest methods to enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the information collection on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Background documents related to this information collection request are available at https://regulations.gov and at DOL-OWCP/DFELHWC located at 200 Constitution Avenue., NW, Room S-3323, Washington, DC 20210. Questions about the information collection requirements may be directed to the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

III. Current Actions

This information collection request concerns the Authorization and Certification/Letter of Medical Necessity, CA-26/CA-27.

OWCP/DFELHWC has updated the data with respect to the number of respondents, responses, burden hours, and burden costs supporting this information collection request from the previous information collection request.

Type of Review: Extension, without change, of a currently approved collection.

Agency: Office of Workers' Compensation Programs, Division of Federal Employees' Longshore, and Harbor Workers' Compensation, OWCP/DFELHWC

OMB Number: 1240-0055

Affected Public: Individuals or households; business or other for-profit

Number of Respondents: 1,104

Frequency: On occasion

Number of Responses: 4,212

Annual Burden Hours: 2,106 hours

Annual Respondent or Recordkeeper Cost: $241,685.00

OWCP Form CA-26/CA-27, Authorization and Certification/Letter of Medical Necessity

Comments submitted in response to this notice will be summarized in the request for Office of Management and Budget approval of the proposed information collection request; they will become a matter of public record and will be available at https://www.reginfo.gov.

Anjanette Suggs,

Certifying Officer.

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