



This document is scheduled to be published in the Federal Register on 06/22/2016 and available online at <http://federalregister.gov/a/2016-14818>, and on FDsys.gov

DEPARTMENT OF LABOR

Office of Workers' Compensation Programs

Proposed Collection of Information; Comment Request

AGENCY: Division of Federal Employees' Compensation, Office of Workers' Compensation Programs, Department of Labor

ACTION: Notice

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506 (c) (2) (A)] This program 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, the Office of Workers' Compensation Programs is soliciting comments concerning the proposed collection: Authorization Request form and Certification/Letter of Medical Necessity for Compounded Drugs (CA-26) and Authorization Request form and Certification/Letter of Medical Necessity for Opioid Medications (CA-27). A copy of the proposed information

collection request can be obtained by contacting the office listed below in the addresses section of this Notice.

DATES: Written comments must be submitted to the office listed in the addresses section below on or before [INSERT 60-DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Ms. Yoon Ferguson, U.S. Department of Labor, 200 Constitution Ave., NW, Room S-3323, Washington, D.C. 20210, telephone/fax (202) 354-9647, Email ferguson.yoon@dol.gov. Please use only one method of transmission for comments (mail or Email).

SUPPLEMENTARY INFORMATION

I. Background:

The Department of Labor (DOL) is requesting an approval of a new information collection. This information collection is essential to the mission of DOL and the Office of Workers' Compensation Programs (OWCP), to monitor and assure the appropriate use of opioids and compounded drugs in treating employment-related injuries under the Federal Employees Compensation Act (FECA), 5 U.S.C. 8101 et seq.

The FECA statute grants OWCP discretion to provide an injured employee the "services, appliances, and supplies prescribed or

recommended by a qualified physician" which OWCP 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. In other words, OWCP is mandated to provide medical supplies and services - including prescription drugs such as opioids and compounded drugs - that it considers medically necessary. 20 C.F.R. 10.310. The FECA statute and implementing regulations are not primarily focused on managing doctor/patient decisions relating to medication therapy and, with the exception of few limitations on fentanyl (an opioid) and other controlled substances, the FECA program policy on pharmacy benefits has generally been a policy of payment for prescribed medications in accordance with a fee schedule based on a percentage of the average wholesale price (AWP) for drugs identified by a National Drug Code (NDC). See 20 C.F.R. 10.809. The FECA program does not currently have any limitations on payment for opioids generally or for compounded drugs. The FECA program is establishing a prior authorization policy for opioid and compounded drugs (at this time after first fill) utilizing the pre-authorization authority already contained in its regulations at 20 C.F.R. § 10.310(a) and § 10.800(b). In requiring the use of these forms for opioid and compounded drugs, OWCP is implementing a prior-authorization process based on medical necessity.

The forms, Authorization Request Form and Certification/Letter of Medical Necessity for Compounded Drugs (CA-26) and Authorization Request Form and Certification/Letter of Medical Necessity Certification/Letter of Medical Necessity for Opioid Medications (CA-27), require an injured worker's treating physician to answer a number of questions about the prescribed opioids and/or compounded drugs and certify that they are medically necessary to treat the work-related injury. The responses to the questions on the forms are intended to ensure that treating physicians have considered non-opioid and non-compounded drug alternatives, and are only prescribing the most cost effective and medically necessary drugs. The forms will also permit OWCP to more easily track the volume, type, and characteristics of opioids and compounded drugs authorized by the FECA program. The forms will 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 appropriate use and gather additional data about their use.

II. Review Focus: The Department of Labor is particularly interested in comments which:

* evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the

agency, including whether the information will have practical utility;

- * evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

- * enhance the quality, utility and clarity of the information to be collected; and

- * minimize the burden of the collection of information 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 submissions of responses.

III. Current Actions: The Department of Labor seeks the approval of this new information collection in order to carry out its responsibility to meet the statutory requirements of the Federal Employees' Compensation Act.

Agency: Office of Workers' Compensation Programs.

Type of Review: New Collection (Request for New OMB control Number).

Title: Authorization and Certification/Letter of Medical Necessity

OMB Number: 1240-0NEW.

Agency Number: CA-26 and CA-27.

Affected Public: Individuals or households; Businesses or other for-profit.

Total Respondents: 80,000.

Total Annual Responses: 65,600.

Estimated Total Burden Hours: 40,000.

Estimated Time Per Response: 30 minutes.

Frequency: On occasion

Total Burden Cost (capital/startup): \$0.

Total Burden Cost (operating/maintenance): \$0.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

DATED: June 16 2016

Yoon Ferguson
Agency Clearance Officer,
Office of Workers' Compensation Programs
US Department of Labor

Billing Code No. 4510-CH-P

[FR Doc. 2016-14818 Filed: 6/21/2016 8:45 am; Publication Date: 6/22/2016]