Congress of the United States
House of Representatives
Washington, DC 20515

October 5, 2016

The Honorable Howard Shelanski
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Attn: OMB Desk Officer for DOL-OWCP
Room 10235

Re: Comment for DOL Form CA-26 "Authorization Request Form and Certification /Letter of Medical Necessity for Compounded Drugs". OMB ICR Reference No: 201606-1240-003.

Dear Administrator Shelanski:

As Ranking Members of the Committee on Education and the Workforce and the Committee on Oversight and Government Reform, we believe that federal employees injured on the job should have ready access to prescription drugs that are medically necessary. At the same time, serious concerns have been raised about exorbitant prices being charged to the Federal Employees' Compensation Act (FECA) program for "compounded drugs" that lack demonstrated efficacy for the condition for which they are prescribed.

We are encouraged that the Department of Labor is proposing ways to address these concerns, and we would like to offer our assistance. We submit these comments with respect to the September 6, 2016 Notice in the *Federal Register* (81 Fed. Reg. 61255) regarding the "Authorization Request Form and Certification /Letter of Medical Necessity for Compounded Drugs."

The FECA program has experienced an explosive growth in costs for compounded pharmaceuticals in recent years. The lack of adequate programmatic safeguards – including the open-ended payment for compounded drugs that lack demonstrated efficacy for the diagnosed conditions – has allowed costs to skyrocket from an estimated $2.5 million to $400 million over the past five years, according to data provided by the Department of Labor (DOL) and the DOL Inspector General.

For example, the Office of Workers' Compensation Programs (OWCP) has approved as much as $67,077.00 for a tube of ointment containing a mixture of common pain relievers and a muscle relaxant. The Postal Inspector General (IG) has identified at least 6,000 compound drug prescriptions that exceeded $10,000 apiece and several hundred that exceeded $30,000 each.[1] DOL has paid more than $32,000.00 per prescription for a compounded cream containing resveratrol, a phenol compound found in red wine. The Food and Drug Administration (FDA) has not approved resveratrol for any use. The Postal Inspector General provided data which show payments for over 5,000 prescriptions for resveratrol totaling more than $16 million. Thus, it appears DOL has been paying exorbitant prices for medically unsubstantiated compounded drugs.

While there is a medical need for a narrow range of compounded drugs, questions have been raised about the efficacy and medical necessity for almost all of the payments made by the FECA program for compounded drugs. Further, fraud investigations by Inspectors General found that kickbacks are being paid by compounding pharmacies to doctors to write prescriptions for compounded drugs that have no demonstrated medical benefit – with middlemen being paid a commission for each prescription written. The programmatic weaknesses revealed by these fraudulent schemes need to be addressed.

We note that CVS/Caremark has established an ingredient "exclusion list" for compounded drugs where they have determined that "efficacy and safety are unknown" for given conditions. We are troubled that the DOL has paid out tens of thousands of claims at exorbitant prices for ingredients on the CVS/Caremark exclusion list, many of which were folded into compounded lotions and creams.[2] Similarly, the TRICARE program found that it was paying for compounded drugs with "dubious clinical evidence." Working with Express Scripts, a pharmacy benefit manager, TRICARE has created its own exclusion list.[3]

We are pleased to see that the DOL is taking initial actions to limit payment for compounded drugs that have no medical value or for which there is a less costly commercial alternative. These actions are consistent with the framework set forth in the FECA Act, which limits payment to those medical expenses "likely to cure, give relief, or reduce the degree or period of disability." Consistent with that mandate, and in the interest of ensuring that the preauthorization process is effective in eliminating payment for drugs lacking efficacy, we offer the following comments:

1) Form CA-26 has a number of ambiguities that merit clarification:
   - There is no definition of "compounded drug" listed on Form CA-26. When including a definition of a compounded drug, the DOL is encouraged to include both

---

[1] Postal Service OIG Data, Compound Pharmaceuticals Data Analysis of Compound Medications, July 1, 2013 - March 24, 2016.
[2] CVS, *Coverage Strategy for Compounds: Ingredient Exclusion List* (Aug. 26, 2014) (online at www.caremark.com/portal/asset/compoundexclusionlist.pdf).
[3] Decision Paper on Implementing ESI Commercial Reject List and Prior Authorization For All Compound Medication Prescriptions, Director Defense Health Agency, May 8, 2015.

compounded drugs with multiple ingredients, in which each ingredient has its own NDC code, as well as compounded drugs made up of multiple ingredients, but only listed under a single NDC code. Further, if there is only one active ingredient and one inactive ingredient, clarification would be required to determine whether this would qualify as a "compounded drug."

- On page two of Form CA-26, item #28, there is a line that states: "Herbal supplements cannot be authorized on this form and will cause the form to deny."
    - There is no definition of "herbal supplements" on Form CA-26. For example, resveratrol is a dietary supplement which has been prescribed for use in compounded drug creams for back pain, but resveratrol can come from a fermented grape, which is a fruit, not an herb.
    - The phrase "will cause the form to deny" is not clear. We infer that the intended meaning may be "will cause the authorization to be denied." This requires clarification in order to be readily understandable to physicians, pharmacists, and patients.
- Please clarify whether Form CA-26 is required to be approved before the pharmacy can dispense the compounded drug to the patient.
- The form does not explain whether physicians must complete this form for both new and refill prescriptions.

2) The screening criteria DOL will use to determine whether a compounded drug should be covered is not delineated in the form. Without knowing the screening criteria, it is difficult to understand if there is sufficient information being gathered.

3) The *Federal Register* notice stated that OMB is particularly interested in comments that "[m]inimize the burden of the collection of information on those who are to respond[.]" TRICARE has simplified the screening process by incorporating, along with a letter of medical necessity, a list of excluded ingredients or a commercial reject list for those ingredients that lack clinical benefit for the particular diagnosis. An exclusion list would preclude the need for wasteful submissions. We encourage DOL to examine whether an exclusion list as part of its screening process could help achieve this goal.

Thank you for your consideration of these comments. Please contact Richard Miller at the Committee on Education and the Workforce at richard.miller@mail.house.gov, or Lena Chang or Alexandra Golden at the Committee on Oversight and Government Reform at lena.chang@mail.house.gov or alexandra.golden@mail.house .gov.

Sincerely,

ROBERT C. "BOBBY" SCOTT
Ranking Member
Committee on Education and the Workforce

ELIJAH E. CUMMINGS
Ranking Member
Committee on Oversight and Government Reform

CC: The Honorable T. Michael Kerr, Assistant Secretary, Office of the Assistant Secretary for Administration and Management (OASAM), Department of Labor

The Honorable Chris P. Lu, Deputy Secretary of Labor, Department of Labor