

Authorization Request Forms/Certification/Letter of Medical
Necessity (ICR Reference Number: 201606-1240-003)
Agency Response to 30-day FRN Public Comments
October 2016

A Federal Register Notice inviting written public comments on the CA 26 and 27 was published on September 6, 2016 (81 FR 61255). These comments were to be submitted to OMB by October 6, 2016. Two comments were received, one from a federal agency and the other from the Ranking Member of the House Committee on Education and the Workforce and the Ranking Member of the House Committee on Oversight and Government Reform. The commenters were supportive of the Department of Labor's efforts to address concerns about the safety and efficacy of compounded drugs; both offered suggestions for improvement of the process as well as suggestions on the form. Neither commenter made any recommendations concerning CA 27 addressing limitations on opioid usage. Summaries of the two comments are noted below.

Public Comment Number 1: The first comment was from the United States Postal Service (USPS). USPS stated that it generally supports the Department's plans to require a letter of medical necessity for all new compounded drug prescriptions, noting the increasing costs experienced by the Federal Employees' Compensation Act (FECA) program under the Office of Workers' Compensation Programs (OWCP) as well as for TRICARE and Medicare Part D. USPS expressed the view that this increase in costs is due in large part to fraud and widespread kickback schemes. USPS made the following recommendations:

1. Require the prescribing physician to provide National Drug Code pricing information for each compound ingredient to ensure ingredients are not billed at an inflated rate.
2. Require a field on the form for the physician to indicate any patient allergies to ensure the patient is not prescribed an ingredient to which he or she is allergic.
3. Require a field on the form for the physician to describe a conversion plan to cheaper commercially available products.
4. Require a condition certification—that the physician identify whether the patient has a condition that cannot be treated with commercially available products and why.
5. Require a return deadline within 24 hours or reimbursement will be denied

USPS also requested clarification of the Department's planned

Authorization Request Forms/Certification/Letter of Medical
Necessity (ICR Reference Number: 201606-1240-003)
Agency Response to 30-day FRN Public Comments
October 2016

review process as follows: 1) whether the Department planned to require a copy of the prescription be included with the completed form, expressing concern that this would clash with existing billing processes; 2) that the Department explain its approval process including who will review the form and how it will prevent premature reimbursements; and 3) how long the Department's approval will last.

OWCP Response: USPS overall agreed with and supported OWCP's proposal and highlighted concerns similar to those that we have noted related to increased cost, safety and efficacy with compounded drugs.

With respect to USPS's first suggestion to require the prescribing physician to provide pricing information, OWCP is instead requiring the prescribing physician to certify that each component of a compounded drug is medically necessary, further instructing the physician that only the most cost effective and medically necessary ingredients should be used. OWCP considers requiring the physician to list the price of each ingredient to be unduly burdensome and of limited practical utility, as OWCP will only pay for compounded drugs in accordance with its published fee schedules which already include percentage limitations on the Average Wholesale Price for compounds based on the number of ingredients.

With respect to USPS's second suggestion, OWCP considers it to be the responsibility of the treating physician to identify allergies. To the extent a patient's allergies could necessitate a compounded drug, the narrative box at the end of the form provides an opportunity for the physician to document and provide supporting rationale for that opinion.

With respect to the third and fourth suggestions that the form require a conversion process to move the patient off a compounded drug and explain whether/why the patient cannot be treated with commercially available products, OWCP has in response to USPS concerns modified question 25 to require the physician if the answer is "no" to explain in the narrative section of the form

Authorization Request Forms/Certification/Letter of Medical
Necessity (ICR Reference Number: 201606-1240-003)
Agency Response to 30-day FRN Public Comments
October 2016

why the patient has not tried to obtain relief through over the counter or other prescribed products for the diagnosis. The requirement that the physician certify that the patient tried and failed to obtain relief through non-compounded medications coupled with the requirement of a narrative explanation if they have not will accomplish the same result.

With respect to the fifth suggestion that the physician be required to return the form within a definite time frame (such as 24 hours) or be denied, such a step is unnecessary. Before authorization is even considered for further evaluation, the CA 26 must be fully and properly completed as to all fields or it will be returned to the provider. No compounded drug will be approved to be dispensed and paid for by the FECA program at point of sale unless and until authorization is granted by OWCP.

With respect to USPS concerns with the planned process, the form contemplates no attachments that would clash with the existing billing process. Regarding the Department's explanation of the approval process, OWCP has already begun wide dissemination of information about implementation of the CA 26 process including website postings, emails to a number of stakeholder list serves and letters to all claimants who recently received a compounded medication. The CA 26 will be initially screened by our medical billing processor; only fully and appropriately completed forms with all fields completed will be sent to OWCP for further consideration. As noted on the form, the need for the medication is subject to review by claims staff and medical professionals. Each form will be evaluated on a case-by-case basis but every prescription has an outside limit of 90 days. Each prescription will require a new CA 26 Certification of Medical Necessity completed by a physician who must be enrolled as a medical provider with the FECA program.

Public Comment Number 2: The second comment was a letter jointly signed by the Ranking Member of the House Committee on Education and the Workforce and the Ranking Member of the House Committee on Oversight and Government Reform. The Congressional letter generally supported OWCP's proposal and requested some

Authorization Request Forms/Certification/Letter of Medical
Necessity (ICR Reference Number: 201606-1240-003)
Agency Response to 30-day FRN Public Comments
October 2016

clarifications. More specifically, this comment also noted the increase in the cost of compounded drugs in the FECA program. The letter noted that CVS/Caremark has established an ingredient exclusion list and reported that TRICARE has created its own exclusion list working with its contractor Express Scripts. The Congressmen noted that while they were pleased DOL was taking initial action on compounded drugs, they noted a number of ambiguities meriting clarification: 1) the lack of a definition of compounded drug on the form, including whether a compounded drug with a single NDC would qualify as a compounded drug or if it contained only one inactive and one active ingredient; 2) the lack of definition of "herbal supplement" because of the concern that resveratrol might not be considered as an herbal supplement; 3) the term "will cause the form to deny" is unclear; 4) whether the CA 26 is required to be approved before the pharmacy can dispense the medication; and 5) whether the physician must complete the form for both new and refill prescriptions. Finally, the Congressmen encouraged the Department to further explain the screening criteria and to consider incorporating a list of excluded ingredients.

OWCP Response: With respect to item one, the form is modified to include a short definition of compounded drugs.

With respect to the commenters' concern that resveratrol might not be considered as an herbal supplement (item two), the form is modified to list a number of examples of herbal supplements and will explicitly list resveratrol as an example of an herbal supplement that cannot and will not be authorized on form CA 26.

Regarding the concern that the term "will cause the form to deny" (item three) is unclear, the language is clarified to make clear that an herbal supplement cannot be authorized using form CA 26 and the form will be returned to the physician if it includes an herbal ingredient.

With respect to item four, as we previously noted, no compounded drug will be approved to be dispensed and paid for by the FECA program at point of sale unless and until authorization is

Authorization Request Forms/Certification/Letter of Medical
Necessity (ICR Reference Number: 201606-1240-003)
Agency Response to 30-day FRN Public Comments
October 2016

granted by OWCP.

Regarding item five, as we previously noted, each prescription will require a new CA 26 Certification of Medical Necessity completed by a physician who is enrolled as a medical provider with the FECA program.

Regarding the commenters' suggestion that the screening criteria be further explained, as we noted in our response to USPS, the CA 26 will be initially screened by our medical billing processor; only fully and appropriately completed forms with all fields completed will be sent to OWCP for further consideration. As explained on the form, the need for the medication is subject to review by claims staff and medical professionals. Each form will be evaluated on a case-by-case basis, with every prescription having an outside limit of 90 days, meaning that the form is required for the initial 30-day prescription and is effective for two additional refills of 30 days each. With regard to utilization of an excluded ingredient list, OWCP continues to explore such additional enhancements to its pharmacy process and has reserved regulatory authority to contract for or require the use of specific providers for certain medications. In sequencing improvements to its pharmacy process generally, OWCP decided due to safety and cost concerns that it would be more efficacious to immediately institute a preauthorization process for compounded medications.