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CHIEF HUMAN RESOURCES OFFICER
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UNITED STATES
POSTAL SERVICE

October 4, 2016

Office of Information and Regulatory Affairs
Attn: OMB Desk Officer for DOL - OWCP
Office of Management and Budget, Room 10235
725 17th Street, NW
Washington, DC 20503-0009

Subject: Response to September 6, 2016, Public Notice – Authorization Request Forms/Certification/Letter of Medical Necessity

Dear Sir/Madam:

This letter responds to your September 6, 2016, public notice. In that notice, you announced that the Department of Labor, Office of Workers' Compensation Programs (DOL/OWCP) plans to require a letter of medical necessity for all new compound drug prescriptions reimbursed under the Federal Employees Compensation Act (FECA). In general, the United States Postal Service (Postal Service) supports that plan. However, in order to effectively control compound drug costs, the letter must be sufficiently thorough to establish real medical necessity, and the process for reviewing submitted letters must be sufficiently robust to ensure that only medically necessary compound drug prescriptions are reimbursed. We offer the following comments and recommendations.

Background

It is crucial that the letter and the review process accomplish their principal goal—reigning in out-of-control compound drug costs. Over the last three years, compound drug costs have skyrocketed, both for the Postal Service and for other public organizations. As a nonappropriated federal entity, the Postal Service pays to the DOL/OWCP an annual "chargeback" fee. That fee covers the costs the DOL/OWCP incurs on the Postal Service's behalf in providing FECA benefits to ill and injured Postal Service employees. The chargeback fee includes the cost of compound drugs. In fiscal year 2013, the Postal Service's total chargeback amount attributable to compound drugs was only $9 million. But in 2014, that amount more than tripled to $30 million. In 2015, the amount surged again, reaching $99 million. Finally, in 2016, it soared to a staggering $173.4 million—amounting to an increase of more than 1,800 percent in just three years.

The Postal Service has not been alone in experiencing sharp increases; other large public entities have felt them as well. For example, between May 2014 and May 2015, the Department of Defense's TRICARE program saw its compound drug costs balloon from $42 million per month to $300 million per month, more than 610 percent.[1] Similarly, between 2006 and 2015, Medicare Part D's spending on compound drugs rose from $70 million to $508 million—a 625 percent increase.[2]

There is reason to believe that those increases were caused, at least in part, by fraud and abuse. The Department of Defense officials, for example, have publically attributed much of TRICARE's

[1] Jim Axelrod & Emily Rand, *"Free" Pain Meds for Veterans Cost Taxpayers Big Bucks*, CBS News (May 5, 2015), http://www.cbsnews.com/news/free-pain-meds-for-veterans-cost-taxpayers-big-bucks/.
[2] U.S. Dep't of Health & Human Serv., Office of Inspector Gen., High Part D Spending on Opioids and Substantial Growth in Compounded Drugs Raise Concerns, No. OEI-02-00290, at 4 (2016).

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increases to widespread kickback schemes, under which pharmacy compounders paid physicians to prescribe expensive compound drugs to TRICARE beneficiaries.[3] The Department of Health and Human Service's Office of the Inspector General (OIG) recently noted "a growing number of fraud cases" associated with compound drugs.[4] That fraud has drawn the attention of the Department of Justice, which in June of this year announced a $900 million takedown related to compound drug fraud.[5] Likewise, in March of this year, the Postal Service's own OIG issued a report finding that at least some of the Postal Service's increased costs were attributable to fraud and abuse.[6]

Many of the entities victimized by these fraudulent billing practices have adopted commonsense administrative controls. TRICARE, for one, has implemented a new screening process for compound drugs.[7] Through a private contractor, TRICARE now screens each compound drug ingredient to determine whether it is medically necessary.[8] TRICARE also maintains a "commercial reject list," which is a list of ingredients that it has determined are not worthy of coverage.[9] With these measures, TRICARE reduced its compound drug costs from $1 billion in the first four months of 2015 to just $4 million in May 2015—savings approaching 95 percent.[10] And it was able to achieve those savings while preserving patients' access to truly necessary medications.

Recommendations and Comments

We recently received a copy of the DOL/OWCP's proposed "medical necessity" letter which is titled "Authorization Request Form and Certification/Letter of Medical Necessity for Compound Drugs."[11] While we see the proposed letter as a good first step, we believe it could be stronger. As such, we recommend that the DOL/OWCP adopt the following improvements to the letter:

- *National Drug Code pricing.* We recommend that you require the DOL/OWCP to add a requirement that the prescribing physician provide National Drug Code pricing information for each compound drug ingredient. That requirement will ensure that ingredients are not billed to the DOL/OWCP at an inflated price.

- *Patient allergies.* We recommend that you require the DOL/OWCP to add a field to indicate any patient allergies. That field will ensure that the patient is not prescribed any ingredient to which he or she could have an allergic reaction.

- *Conversion plan.* We recommend that you require the DOL/OWCP to include a field for the physician to describe a conversion plan; i.e., a plan to move the patient off expensive compound drugs to cheaper, commercially available products. Often, physicians

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[3] *See 25 Arrested for Fraud Related to TRICARE and Compound Drugs*, Health.mil (July 18, 2016), http://www.health.mil/News/Articles/2016/07/18/25-arrested-for-fraud-related-to-TRICARE-and-compound-drugs (DHA's website) (reporting on prosecutions for "widespread and blatant fraud" linked to compound drugs, many of which "were of dubious or no clinical value" or "dangerous"); *see also* Delvin Barrett, *U.S. Probes Possible Fraud Linked to Compounding Creams*, Wall Street Journal (Feb. 7, 2016), http://www.wsj.com/articles/u-s-probes-possible-fraud-linked-to-compounding-creams-1454790501 (reporting that Tricare paid $1.75 billion for compound drugs in fiscal year 2015 and that "[i]nvestigators suspect most of those bills [were] fraudulent").

[4] U.S. Dep't of Health & Human Serv., Office of Inspector Gen., High Part D Spending on Opioids and Substantial Growth in Compounded Drugs Raise Concerns, No. OEI-02-00290, at 8 (2016).

[5] Press Release, Dep't of Justice, National Health Takedown Results in Charges Against 301 Individuals for Approximately $900 Million in False Billing (June 22, 2016).

[6] U.S. Postal Serv. Office of Inspector Gen., Workers' Compensation Compound Drug Costs, No. HR-MA-16-003 (March 14, 2016).

[7] *Compound Drugs Q&A*, Health.mil, http://www.health.mil/CompoundDrugs (last visited Sept. 30, 2016) (describing TRICARE's compound screening process).

[8] *Id.*

[9] *Id.*

[10] Patricia Kime, *Tricare: Compound Medication Orders Fall Sharply*, Military Times (June 18, 2015), http://www.militarytimes.com/story/military/benefits/health-care/2015/06/18/tricare-compounded-medications-update-defense-health-agency-dha-prescription-express-scripts/28914815/.

[11] A copy of the proposed DOL/OWCP letter of medical necessity is attached as Appendix A.

prescribe compound drugs because a comparable commercial product is unavailable. In such a case, the physician should also plan to transition the patient to the commercial product when that product becomes available.

- *Return deadline.* The proposed letter no longer requires the physician to complete and return it within a definite time frame. As such, we recommend that you require the DOL/OWCP to add a return deadline; for example, "If this letter is not returned within 24 hours, reimbursement will be denied."

- *Condition certification.* Compound drugs are often prescribed because the patient suffers from a condition that cannot be treated with commercially available products—products that tend to be less expensive than compound drugs. However, those conditions should be rare. With that in mind, we recommend that the letter require the prescribing physician to identify whether the patient has such a condition, and if so, what that condition is and why commercially available products are inadequate to treat it.

These improvements will help to accomplish the principal goal of requiring the letter: reducing unnecessary compound drug costs. However, even with the improvements, the letter cannot itself ensure that only medically necessary compound drugs are prescribed to ill and injured employees. Accomplishing that goal will also require a robust review process. Your public notice did not describe the DOL/OWCP's planned review process, so we ask that you clarify certain aspects of that process now:

- The DOL/OWCP should clarify whether it plans to require that a copy of the original prescription be included with the completed letter. If so, that requirement could clash with existing electronic-billing processes, which do not allow for PDF attachments. The DOL/OWCP should also explain how it plans to accommodate those billing processes—for example, by providing a rejection code explaining that a letter of medical necessity is required, then allowing for the submission of a physical form before the compound drug is reimbursed.

- The DOL/OWCP should explain its approval process. It should specify who will initially review the letter, whether there will be any additional review, and how it will prevent premature reimbursements (i.e., reimbursements before the form is approved).

- The DOL/OWCP should state how long an initial approval will last. Will the DOL/OWCP automatically approve valid prescriptions for a specified period of time, or will it approve prescriptions for varying periods on a case-by-case basis? Also, will the DOL/OWCP require a new letter of medical necessity for refills, or will it simply rely on the initial letter?

The Postal Service, like all federal entities covered by the FECA, shares an interest with the DOL/OWCP in creating a robust review process for letters of medical necessity related to compound drugs. By providing these details, the DOL/OWCP will allow the Postal Service to review that process and, if necessary, provide additional feedback and recommendations.

We are pleased that the DOL/OWCP is now taking steps to limit out-of-control compound drug costs. But we urge the DOL/OWCP not to stop here. Additional steps can and should be taken. Ms. Megan Brennan, Postmaster General, outlined some of those steps in a recent letter to Mr. Thomas Perez, Secretary of Labor.[12] We continue to believe that those steps are necessary to bring compound drug costs under control, and we encourage the DOL/OWCP to adopt them as well.

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[12] A copy of Postmaster General Brennan's September 14, 2016 letter to Secretary Perez is attached as Appendix B.

Thank you for your consideration. We look forward to reading your response.

Jeffrey C. Williamson

Attachments

cc: Ronald A. Stroman
Joseph Corbett
Thomas J. Marshall
Michel Smyth