



September 14, 2016

The Honorable Thomas E. Perez
Secretary of Labor
U.S. Department of Labor
200 Constitution Avenue, NW
Washington, DC 20210-0001

SUBJECT: Uncontrolled Pharmacy-Compounding Costs

Dear Mr. Secretary:

I am writing to you today concerning a matter that has significant negative monetary impact on the United States Postal Service (Postal Service). Over the last four years, the Postal Service's medical costs have increased exponentially, largely because of sharply rising pharmacy-compounding costs. As a non-appropriated agency, the Postal Service must reimburse the DOL/OWCP for the cost of medical services, treatment, and supplies provided to eligible claimants out of its own generated operating revenues. In fiscal years 2013, 2014, 2015, and 2016 those costs were largely flat—with the notable exception of pharmacy-compounding costs, which increased by a factor of nineteen in just four short years without any apparent justification. In fiscal year 2013, the Postal Service's pharmacy-compounding costs totaled only \$9 million. But in 2014, they rose to \$30 million; a single-year increase of \$21 million. In 2015, they inflated to nearly \$99 million; a single-year increase of approximately \$69 million. Finally in 2016, the Postal Service's pharmacy-compounding costs ballooned to \$173.4 million; a single-year increase of \$74.4 million.

The Postal Service has not been alone in seeing its pharmacy-compounding costs skyrocket. Rather, both private and public insurers have been saddled with ever-increasing pharmacy-compounding costs. For example, over the last two years, Blue Cross and Blue Shield and UnitedHealth both saw their pharmacy-compounding costs quintuple.

Similarly, between May 2014 and May 2015, the Department of Defense (TRICARE)¹, saw its pharmacy-compounding costs balloon from \$42 million per month to \$300 million per month. Department of Defense officials have publically said that most of TRICARE's increased costs were the result of nationwide kickback schemes, under which pharmacy compounders paid physicians to prescribe expensive compound drugs to TRICARE beneficiaries.² Likewise, in several high-profile cases, pharmacy compounders have victimized state workers' compensation

¹ TRICARE is the federally funded health care program for uniformed service members and their families that is managed by the Defense Health Agency (DHA) under leadership of the Assistant Secretary of Defense (Health Affairs).

² 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").

programs. For instance, in June 2015, fifteen chiropractors, pharmacists, and financial brokers were indicted for participating in a scheme to bill California's workers' compensation program for millions of dollars in fraudulent pharmacy-compounding charges. Further, on June 22, 2016, a joint Department of Justice/Health Services taskforce announced a \$900 million health fraud takedown, which included a number of cases of fraudulent pharmacy-compounding charges. According to Attorney General Loretta Lynch, the high costs of these compound drugs make them more attractive for criminals. The Postal Service has no reason to conclude that the exploding costs we are incurring related to pharmacy-compounding charges are legitimate.

Many of the entities targeted by such schemes have reacted by adopting commonsense safeguards. For example, in May 2015, after seeing its pharmacy compounding charges explode, TRICARE adopted a new claim-screening process, eliminated certain compounding pharmacies from its network, and began tracking spending on a daily basis. Likewise, in 2011, California reformed its workers'-compensation-reimbursement process to reduce pharmacy-compounding costs. Among other things, it required that compound drugs be billed on an individual-ingredient basis. It also pegged reimbursement rates to the prescribing physician's office's "Documented Paid Price." Other workers' compensation programs have also acted to reign in pharmacy-compounding. For example, Ohio capped reimbursements for compound drugs through its workers' compensation program to \$600. And Louisiana required compound drugs to be billed under the same reimbursement formula as generic drugs.

The Postal Service lacks the authority to adopt similar reforms. Instead, we must rely on the DOL/OWCP to police the FECA-claims process and to reign in fraudulent charges. The DOL/OWCP, however, has over the last four years consistently failed to control—or even recognize—exploding pharmacy-compounding costs. We have worked diligently with your staff over the last year to address the need for the DOL/OWCP to implement reasonable and commonsense steps to control pharmacy-compounding costs and to prevent fraud, waste, and abuse. After the Postal Service received our first-quarter chargeback report for fiscal year 2015, and on numerous occasions thereafter, we asked the DOL/OWCP why our medical costs had risen so quickly. However, the DOL/OWCP failed to explain or address the increases. It was only once the Postal Service conducted our own investigation that we determined the increased costs were due almost entirely to surging pharmacy-compounding charges.

Recently, the DOL/OWCP did take steps to implement three remedial measures that it believes will control the rising costs of pharmacy-compounding costs. According to a letter sent by a member of your staff—Leonard J. Howie, III, Director, OWCP, to House Committee on Education and the Workforce Ranking Member Robert Scott on June 23, 2016, the DOL/OWCP was scheduled to implement three initial remedial measures on July 1, 2016. The remedial measures include reducing reimbursement for generic ingredients by 10 percent, creating a tiered reimbursement structure, and limiting initial prescriptions for compound drugs to a period not to exceed 90 days. While we are encouraged by this step, we do not consider these measures to be adequate to effectively control spiraling compound-drug costs.

In the same letter, Director Howie indicated that the DOL/OWCP plans to implement a number of additional mid- and long-term actions to improve the management of compound-drug usage in the FECA program, including requiring physicians to issue a "letter of medical necessity" for each compound-drug refill, adopting a centralized Pharmacy Benefits Manager (PBM) program and requiring use of the universal claim form. Recently, my staff was advised that the DOL/OWCP may be in the process of preparing amended rules covering the mid- and long-term actions described by Director Howie in his June 23 letter, and that the DOL/OWCP may be currently going through the process to have these rules approved and published in the *Federal Register*.

At this point, in connection with the development of new rules concerning this, I would respectfully ask that the DOL/OWCP ensure that the following reasonable and effective remedial measures are included in any proposed amended rules. These measures represent concrete procedures

that have been adopted by other entities confronting this problem that will help the DOL/OWCP to effectively manage compound-drug costs:

Letter of Medical Necessity

A letter of medical necessity should be required for every compound-drug prescription submitted to the DOL/OWCP for reimbursement. The letter of medical necessity should be required for initial prescriptions as well as any refills. The letter of medical necessity should include;

- The diagnosis or condition that the compound drug will treat.
- A list of commercially available products that could be used as an alternative to the requested compound drug.
- A statement addressing whether there is a national drug shortage for the commercially available product.
- A list of each ingredient that will be used in the compound drug.
- Certification of the necessity for each ingredient used in the compound drug.
- Certification that there is not a U.S. Food and Drug Administration (FDA) approved drug that is more appropriate.
- The estimated length of the proposed therapy.
- Signature of the doctor certifying that the compound drug is medically necessary and cost-effective.

We would like the DOL/OWCP to require submission of a letter of medical necessity for every compound-drug prescription submitted to the DOL/OWCP for reimbursement.

Initial prescriptions cannot exceed 90 days

As noted above, on June 23 the DOL/OWCP issued a statement of action regarding initial prescriptions for compound drugs. Their action stated "initial prescriptions for compound drugs should be for a period not to exceed 90 days." We have no evidence this is being enforced.

We would therefore suggest a requirement that initial prescriptions for compound drugs cannot exceed 90 days.

Reimbursement Caps

We would like the DOL/OWCP to establish reimbursement caps for approved compound drugs that are prescribed to ill and injured postal employees who have accepted FECA claims.

Pharmacy Benefit Manager

Most workers' compensation programs establish mandatory use of Pharmacy Benefit Managers (PBMs) that are used to capture prescription network discounts, conduct drug utilization reviews, and administer formularies to reduce overall pharmacy costs. While we have our own PBM, our employees are not required to use it.

We would like the use of a PBM to be mandatory for all ill and injured postal employees who have accepted FECA claims.

Drug Formulary Lists

As you may know, a drug formulary is a list of prescription drugs, both generic and brand name, used by practitioners to identify drugs that offer the greatest overall value. Drugs considered for the formulary are evaluated by a committee of local experts and are chosen for their safety and effectiveness. Clinical expertise and input is also sought from many other local physicians who are not committee members. The formulary, preservice authorization parameters, and related procedures are updated as needed when new information becomes available.

We would like the DOL/OWCP to use a drug formulary list when assessing the use of approved compound drugs for ill and injured postal employees who have accepted FECA claims.

Commercial Reject List

A Commercial Reject List excludes reimbursement for compound-drug ingredients that the PBM considers to be overpriced with no additional clinical benefit.

We would like the DOL/OWCP to use a commercial reject list when assessing the use of approved compound drugs for ill and injured postal employees who have accepted FECA claims.

The above listed remedial measures have been endorsed by a national private sector health services company called OPTUM. OPTUM currently provides contract PBM services to the Postal Service. The identified remedial measures have also been endorsed by national insurance providers, state workers' compensation programs and federal government agencies that have been faced with the task of managing escalating compound-drug costs in recent years. These providers include TRICARE, who working through their pharmacy contractor, Express Scripts, have implemented a series of controls including prior authorization, limitations on reimbursement for certain preparations, use of commercial reject lists, use of drug formulary lists, and an assessment process during which they determine whether they will or will not cover certain active pharmaceutical ingredients. This is the role served by PBMs. After implementing these controls in May 2015, TRICARE was able to reduce its compound-drug costs from \$1 billion in the first four months of 2015 to just \$4 million in May 2015.

As the sole administrator for the FECA, DOL/OWCP plays a crucial gatekeeping function. It bears responsibility for policing the claims process and for preventing fraud, waste, and abuse. As noted above, in our view, the DOL/OWCP failed to perform this function when it did not detect or prevent dramatic year-over-year increases in pharmacy-compounding charges. As a result of that failure, the Postal Service incurred exponential increases to its 2014 and 2015 chargeback statements and the same result now exists with the even higher chargeback costs contained in the recent chargeback statement received from the DOL/OWCP for fiscal year 2016 chargeback costs.

I would be happy to meet with you to discuss these issues in person. Alternatively, I am happy to answer any questions you may have regarding the issues addressed in this letter.

I look forward to receiving your response to my two requests set forth in this letter.

Sincerely,


Megan J. Brennan