Prescription Medication Policy in the FECA Program

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The FECA Statute

The FECA Statute (§8103) describes the provision of medical services and provides discretion to the Secretary of Labor as follows:

"The United States shall furnish to an employee who is injured while in the performance of duty, the services, appliances, and supplies prescribed or recommended by a qualified physician, which the *Secretary of Labor considers* likely to cure, give relief, reduce the degree or the period of disability, or aid in the lessening the amount of monthly compensation."

The FECA Regulations

The governing regulations indicate that:

- The employee is entitled to receive all medical services appliances and supplies (including prescribed medications) which a qualified physician prescribes and which OWCP considers necessary to treat the work-related injury. 20 C.F.R. §10.310(a)
- The regulations indicate that pharmacies should bill for prescriptions and itemize the charges on electronic or paper-based bills. The bills must include the NDC, the generic or trade name of the drug, the prescription number, quantity provided, and date of fill. 20 C.F.R. §10.801(c)(2)

The FECA Regulations

Payment for prescription medications is set forth in 20 C.F.R. §10.809:

- Payment determined by multiplying average wholesale price (AWP) by the quantity provided plus a dispensing fee. OWCP may contract for specific providers.
- AWP determined by the product's nationally recognized wholesale price as determined by surveys of manufacturers and wholesalers, or by other method designated by OWCP. Dispensing fee set by the Director.
- The AWP and dispensing fee will be reviewed and updated as necessary.
- OWCP may require the use of generic equivalents

FECA Policies and Procedures

The Secretary of Labor delegated his statutory discretion to the Director of OWCP. The FECA program has put some constraints around the approval of prescription medications over the past several years beginning with the institution of a pharmacy fee schedule and extending to the recent changes on compounds and opioids to aid the program in approving medications that are safe, appropriate for the diagnosed condition, and cost effective. Some of these changes have been codified by regulations, some by procedure and others with notice via our public facing website.

FECA Policies and Procedures

- Changes to billing and payment procedures for prescription medications are largely announced via a posting on the DFEC website.
- Changes to what medications will be provided and the process for obtaining authorizations for those medications are largely set forth in FECA Procedure documents (which are also posted online).

FECA Policies and Procedures

- In 1999, a Bulletin was issued describing the actions to be taken when a prescribed medication does not match the accepted condition based on program criteria.
- In 2009, all Schedule II medications became subject to early refill limitations and days' supply limitations (75% and 30 days).
- In 2011, OWCP placed strict limits on the use of the narcotic drug Fentanyl for FECA claims. For new claims without a cancer diagnosis, this medication is not approved. Extensive provider outreach was conducted to eliminate/reduce usage on existing cases. See FECA Bulletin 11-05
- In 2012, non-pharmacy prescriptions (like those filled by the physician's office) require NDC, days supply, line item charge and/or NPI number.
- In 2013, limitations were placed for reimbursement for injection codes.

FECA Policies and Procedures

In 2012, the program issued a Circular that outlined existing billing practices/restrictions and provided additional details concerning the responsibilities of claimants and providers in regard to billing and reimbursement. The Circular covered a number of medical billing issues and some specific to prescription medications:

1. Mechanics of billing to include the use of certain codes and the application of AWP
2. The criteria for dispensing generic medication automatically in most instances
3. The restrictions on Fentanyl

FECA Policies and Procedures

The program has made regular updates to the fee schedule as required in the regulations.

- In 2015, the maximum allowable fee for brand name drugs will be calculated at 85% of the average wholesale price (AWP - 15%) plus a $4.00 dispensing fee. The maximum allowable fee for generic drugs and non-drug items is not changing and is calculated at 70% of the average wholesale price (AWP - 30%) plus a $4.00 dispensing fee.
- In 2016 – the maximum allowable fee for generic medications is set at 60% of AWP plus a dispensing fee.

FECA Policies and Procedures

The FECA regulations allow OWCP some flexibility in the authorization and payment of prescription medications in part to allow the program to respond to emerging trends.

There have been two significant trends that the program has addressed with policy:

1. The use of compounded medications
2. Opioid medication use and related addiction in the United States

Compounded Medications

Medical compounding is the process of combining or altering two or more drugs or their ingredients to create a hybrid that is tailored to the specific need of a patient. Compounding is normally done by licensed physicians or licensed pharmacists with the oversight of the states' boards of pharmacy. Compounded medications may be appropriate in limited circumstances to include dosage requirements, route of administration, and allergy considerations.

Compounded Medications

However, the use of compounded medications has associated risks because they suffer from poor quality, adulteration, counterfeiting, misbranding, and the lack of safety and effectiveness enjoyed by FDA approved drugs. They are sometimes created by profit-driven manufacturers who may be biased in their choice of ingredients in order to maximize returns.

Compounded Medications

The FECA program experienced an exponential increase in payments for compound medications between 2011 and 2016 (from just over $2 million per year to nearly $263 million). OWCP was first alerted to this issue by partner agencies and worked throughout 2016 to address the cost, efficacy, and safety concerns around compounded medications.

Compounded Medications

- July 2016 – reductions to the pharmacy fee schedule so that compounded medications with three or fewer ingredients pay at 50% of AWP. Those with more then three pay at 30% of AWP. Initial prescriptions are limited to a period of 90 days.
- This occurred at the same time that the max fee for generics was lowered to 60% of AWP.

Compounded Medications

October 2016:

- Compounded drug prescriptions limited to 90 days and initial fills and refills are issued in 30 day supplies.
- A prior authorization process is instituted and no compounded medications are approved unless the physician has completed a Letter of Medical Necessity and a Claims Examiner has undertaken the necessary medical development and approved the prescription.

Compounded Medications

FECA Bulletin 17-01 details the program's policy on requiring a CA-26 a Letter of Medical Necessity (LMN) and provides guidance to claims staff in processing them.

The CA-26 and has been successful in significantly decreasing usage and payment for compounded medications. It requires that a doctor certify (under civil and criminal penalty) that they are the injured worker's treating physician and that each ingredient in the compounded medication is medically necessary and cost effective. The form also explicitly states that herbal drugs will not be approved on the CA-26 in compounded medications.

Compounded Medications - Herbals

In March of 2017, OWCP issued a policy related to compounded medications but not exclusive to it (see FECA Bulletin 17-03). This Bulletin concerns herbal supplements and explains that the program's policy is to not authorize payment for herbal supplements unless a claimant's treating physician acquires prior authorization by submitting rationalized medical evidence that supports the herbal supplement's safety, effectiveness, and necessity.

Fill Limits on Non-Maintenance Drugs

Beginning May 2017, DFEC instituted a new policy on filling non-maintenance medications for the treatment of work-related injury or illness. The program's policy limits the fill of non-maintenance medications to 30 day increments. Additionally, refills cannot be obtained until 75% of the prescription timeline has passed. Maintenance medications (such as those used to treat chronic conditions like high blood pressure and asthma) will not be subject to these limitations. In determining what constitutes a maintenance medication, DFEC will be relying primarily on First Data Bank classifications.

Capturing Prescriber Data

Effective May 31, 2017, the prescribing provider's National Provider Identification (NPI) number is a mandatory field for all point of sale (POS) transactions for claimants seeking pharmacy benefits under the Federal Employees' Compensation Act. POS transactions will be denied for: claims that do not reflect the prescribing provider's NPI number and/or for claims that reflect an NPI number but the NPI format is not valid.

Upcoming Policy – Opioid Medication

When used appropriately, opioid drugs can provide necessary and safe pain relief to injured workers. However, opioids carry a risk of substance use disorder and accidental overdose. The FDA has developed a comprehensive action plan to address what it calls an opioid crisis facing the United States. Additionally, the agency is encouraging the development of opioid formulations with abuse-deterrent properties to combat the opioid epidemic. The FDA is working with many drug makers to support advancements in this area and help drug makers navigate the regulatory path to market as quickly as possible.

Upcoming Policy – Opioid Medication

Because the FECA program has safety concerns regarding opioid drugs, we are instituting new procedures to comprehensively review opioid prescriptions for FECA beneficiaries. This policy will be administered in two phases:

1. The first addresses FECA claims with newly prescribed opioid use (i.e. claims where an opioid has not been prescribed within the past 180 days, if ever). This policy for newly prescribed opioid use will be implemented in August of 2017. If a claimant goes six months without opioid use and starts again, this policy will also apply to them.
2. The second phase will address legacy opioid claims where an opioid claim has been prescribed within the past 180 days. Details on this phase will be forthcoming.

Upcoming Policy – Opioid Medication

Opioid Policy, Phase I (see FECA Bulletin 17-07)

- Initial 60 day grace period
- Following that, an LMN (form CA-27) is required to be submitted, reviewed, and approved by OWCP.
- Authorizations will be limited to 60 days and fills limited to 30 days (with the non-maintenance medication fill limits)
- New LMN and auth required every 60 days
- No more than 2 opioids at a time
- Opioid medications in compounded drugs have no grace period and all prescriptions require an LMN and prior authorization.

Upcoming Policy – Opioid Medication

The FECA Bulletin lays out specific medical development to be undertaken before authorization of opioids can be provided.

- The initial 60 day authorization may be provided based on existing medical documentation from the treating physician.
- Opioid use beyond the initial authorization can only be approved if the CE concurrently writes to the physician to specifically address the issue of opioid use.
- Cases with continued opioid use should be reviewed by a District Medical Adviser or second opinion physician before additional authorization is provided and every six months thereafter.

Upcoming Policy – Opioid Medication

Opioid Policy, Phase II

This second phase will address injured workers who have been receiving opioids from the program – most of them for much longer periods than 180 days. These claims will be run through a risk model which looks at factors such as case attributes (anatomical location of injury) and history of opioid usage. Based on these factors, each of these cases is assigned to one of three risk categories which indicates their likelihood of remaining on opioid drugs one year out (not likely, likely, and very likely). Based on the risk model, different review intervals will be recommended for these cases. This policy is slated to be deployed in FY 2018, Q3.

Upcoming Policy – Opioid Medication

DO WE WANT TO DO A SLIDE THAT DISCUSSES THE ALTERNATIVE TREATMENTS THAT DFEC WILL AUTHORIZE? IF SO – SAVE SPACE HERE.

QUESTIONS?