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TESTIMONY

Statement of

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"The Opioid Epidemic: Implications for the Federal Employees' Compensation Act"

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Chairman Byrne, Ranking Member Takano, and Members of the Subcommittee on Workforce Protections, my name is Scott Szymendera and I am an analyst at the Congressional Research Service (CRS). Thank you for inviting CRS to testify before the subcommittee on the Federal Employees' Compensation Act (FECA) and the implications of the nation's ongoing opioid epidemic on this workers' compensation program.[1]

Since 1916, federal employees have been protected from economic losses associated with employment-related injuries and illnesses and their families have been protected in cases of employment-related deaths by FECA, in much the same way that private-sector employees are afforded these protections by state workers' compensation systems. Like these state systems, FECA and the other federal workers' compensation programs are facing increasing pressure from the nation's opioid epidemic.

The testimony of CRS begins with an overview of the FECA program, including the statutory requirement that the federal government provide medical treatment for workplace injuries and illnesses that it considers "likely to cure, give relief, reduce the degree or the period of disability, or aid in lessening the amount of the monthly compensation."[2] Included in this section is a discussion of the availability of complementary and alternative treatments, such as acupuncture, that have been the subject of recent research examining their efficacy as alternatives to opioids for patients with chronic pain but which must be prescribed or recommended by a physician to be eligible for FECA reimbursement.

As the focus of today's hearing is the opioid crisis, this testimony concludes with a discussion of efforts by the Office of Workers' Compensation Programs (OWCP) to limit access to certain classes of drugs, beginning with limitations placed on the availability of the opioid OxyContin in the Black Lung program through the current FECA program restrictions on the opioid fentanyl, other Schedule II drugs (many of which are opioids), compounded drug medications which frequently include opioids as ingredients, and the policy instituted in 2017 to limit the duration prescriptions for all opioids.

Overview of the FECA Program

Statutory and Regulatory Authorities

The FECA program is authorized in statute at 5 U.S.C. §§8101 *et seq*. Regulations implementing FECA are provided at 20 C.F.R. §§10.00-10.826. The FECA program is administered by the Department of Labor (DOL), Office of Workers' Compensation Programs (OWCP).

Program Financing

Benefits under FECA are paid out of the federal Employees' Compensation Fund. This fund is financed by appropriations from Congress that are used to pay current FECA benefits and that are ultimately reimbursed by federal agencies through the chargeback process in which the costs of benefits are annually charged back to each beneficiary's host agency. The FECA statute requires that each agency and instrumentality of the federal government include in its annual budget estimate for the next FY a request

[1] For additional information on FECA, see CRS Report R42107, *The Federal Employees' Compensation Act (FECA): Workers' Compensation for Federal Employees*. For additional information on the nature and scope of the issues surrounding the use of opioids and related drugs, see CRS Report R44987, *The Opioid Epidemic and Federal Efforts to Address It: Frequently Asked Questions* and the website of the Department of Health and Human Services (HHS) at: https://www.hhs.gov/opioids/about-the-epidemic/.

[2] 5 U.S.C. §5103(a).

for an appropriation in the amount of its chargeback benefit costs.[3] Thus, the ultimate cost of injuries, illnesses, and deaths of federal employees falls on each employee's host agency, not DOL.

The administrative costs associated with the FECA program are provided to the DOL through the appropriations process. In addition, the U.S. Postal Service (USPS) and certain other non-appropriated entities of the federal government are required to pay for the "fair share" of the costs of administering benefits for their employees.

FECA Benefit Costs

During the period between July 1, 2016, and June 30, 2017 (Chargeback Year 2017), the FECA program paid out $2.946 billion in benefits to 222,616 beneficiaries. These benefits included approximately $1.852 billion in disability benefits, $936 million in medical benefits, and $157 million in benefits to the survivors of federal employees killed on the job.[4] **Table 1** provides data on FECA benefit costs.

Table 1. FECA Benefit Costs, July 1, 2016, Through June 30, 2017

	Cost (in millions of dollars)	Percentage of Total Benefit Costs
Disability Benefits	1,852	62.9
Medical Benefits	936	31.8
Death Benefits	157	5.3
Total Benefits	**2,946**	**100.0**

Source: Department of Labor, *FY 2019 Congressional Budget Justification*, February 2018, p. OWCP-FPWC-13.

Note: Numbers may not add due to rounding.

Employees Covered by FECA

The FECA program covers all civilians employed by the federal government, including employees in the executive, legislative, and judicial branches of the government. Both full-time and part-time workers are covered, as are certain volunteers and all persons serving on federal juries. Coverage is also extended to certain groups, including state and local law enforcement officers acting in a federal capacity, Peace Corps volunteers, students participating in Reserve Officer Training Corps (ROTC) programs, and members of the Coast Guard Auxiliary and Civil Air Patrol.

Conditions Covered by FECA

Under FECA, workers' compensation benefits are paid to any covered employee for any disability or death caused by any injury or illness sustained during the employee's work for the federal government. There is no list of covered conditions nor is there a list of conditions that are not covered. However, no injury, illness, or death may be compensated by FECA if the condition was

- caused by the willful misconduct of the employee;
- caused by the employee's intention to bring about the injury or death of himself or another person; or

[3] 5 U.S.C. §8147(b).

[4] Department of Labor, *FY 2019 Congressional Budget Justification*, February 2018, p. OWCP-FPWC-13.

- proximately caused by the intoxication of the employee.

In addition, any person convicted of a felony related to the fraudulent application for or receipt of FECA benefits forfeits his or her rights to all FECA benefits for any injury that occurred on or before the date of conviction. The benefits of any person confined in jail, prison, or an institution pursuant to a felony conviction are suspended for the duration of the incarceration and may not be recovered.

FECA Compensation Benefits

Continuation of Pay

In the case of a traumatic injury, an employee is eligible for continuation of pay.[5] Continuation of pay is paid by the employing agency and is equal to 100% of the employee's rate of pay at the time of the traumatic injury. Since continuation of pay is considered salary and not compensation, it is taxed and subject to any deductions normally made against the employee's salary. Any lost work time beyond 45 days, or lost time due to a latent condition, is considered either a partial or total disability under FECA.

Employees of the USPS must satisfy a three-day waiting period before becoming eligible for continuation of pay. All other employees must satisfy this waiting period before receiving disability benefits. The waiting periods are waived in cases of permanent disability or temporary disability exceeding 14 days.

Partial Disability

If an employee is unable to work full-time at his or her previous job, but is able to work either part-time or at a job in a lower pay category, then he or she is considered partially disabled and eligible for the following compensation benefits:

- if the employee is single, a monthly benefit equal to two-thirds of the difference between the employee's pre-disability and post-disability monthly wage, or
- if the employee has at least one dependent, a monthly benefit equal to 75% of the difference between the employee's pre-disability and post-disability monthly wage.

The compensation benefits paid for partial disability are capped at 75% of the maximum basic pay at rate GS-15 (GS-15, step 10), are not subject to federal taxation, and are subject to an annual cost-of-living adjustment. Benefits are paid for the duration of the disability or the life of the beneficiary.

If an employee's actual wages do not accurately represent his or her true wage-earning capacity, or if he or she has no wages, then his or her partial disability benefit is based on his or her wage-earning capacity as determined by OWCP using a combination of vocational factors and "degree of physical impairment."

Scheduled Benefits

In cases in which an employee suffers a permanent partial disability, such as the loss of a limb, he or she is entitled to a scheduled benefit. The scheduled benefit is in addition to any other partial or total disability benefits received. An employee may receive a scheduled award even if he or she has returned to full-time work.[6] A scheduled award is generally paid on a periodic basis, but may be paid as a lump sum

[5] A traumatic injury for the purposes of eligibility for continuation of pay is defined in the regulations at 20 C.F.R. §10.5(ee) as "a condition of the body caused by a specific event or incident, or series of events or incidents, within a single workday or shift." Certain groups, including federal jurors, Peace Corps volunteers, and Civil Air Patrol members, are not eligible for continuation of pay.

[6] The list of the Federal Employees' Compensation Act (FECA) scheduled benefits are provided in statute at 5 U.S.C. §8107(c)
(continued...)

in certain circumstances. If an employee suffers a disfigurement of the face, head, or neck that is of such severity that it may limit his or her ability to secure or retain employment, the employee is entitled to up to $3,500 in additional compensation.

Total Disability

If an employee is unable to work at all, then he or she is considered totally disabled and eligible for the following compensation benefits:

- if the employee is single, a monthly benefit equal to two-thirds of the employee's pre-disability monthly wage, or
- if the employee has at least one dependent (including a spouse),[7] a monthly benefit equal to 75% of the employee's pre-disability monthly wage.

The compensation benefits paid for total disability are capped at 75% of the maximum basic pay at rate GS-15 (GS-15, step 10), are not subject to federal taxation, and are subject to an annual cost-of-living adjustment. Benefits are payable until it is determined that the employee is no longer totally disabled and may continue until the employee's death.

A FECA beneficiary who is blind, paralyzed, or otherwise disabled such that he or she needs constant personal attendant care may receive an additional benefit of up to $1,500 per month.

Death

If an employee dies in the course of employment or from a latent condition caused by his or her employment, the employee's survivors are eligible for the following compensation benefits:[8]

- if the employee had a spouse and no children, then the spouse is eligible for a monthly benefit equal to 50% of the employee's monthly wage at the time of death or
- if the employee had a spouse and one or more children, then the spouse is eligible for a monthly benefit equal to 45% of the employee's monthly wage at the time of death and each child is eligible for a monthly benefit equal to 15% of the employee's monthly wage at the time of death, up to a maximum family benefit of 75% of the employee's monthly wage at the time of death.

Special rules apply in cases in which an employee dies without a spouse or children or with only children.

If a spouse remarries before the age of 55, then he or she is entitled to a lump-sum payment equal to 24 months of benefits, after which all benefits cease. If a spouse remarries at the age of 55 or older, benefits continue for life. A child's benefits end at the age of 18, or age 23 if the child is still in school. A child's benefits continue for life if the child is disabled and incapable of self-support.

The compensation benefits paid for death are capped at 75% of the maximum basic pay at rate GS-15, are not subject to federal taxation, and are subject to an annual cost-of-living adjustment.

(...continued)

and in regulation at 20 C.F.R. §10.404(a).

[7] A dependent can be a spouse, unmarried child under the age of 18, unmarried child 18 or older who is incapable of self-support, a student up to age 23 or until he or she completes four years of school beyond high school, or a dependent parent.

[8] The death must be related to the person's work. For example, a person who dies of an unrelated medical condition in the workplace would not be eligible for FECA benefits.

Additional Death Benefits

The personal representative of the deceased employee is entitled to reimbursement, up to $200, of any costs associated with terminating the deceased employee's formal relationship with the federal government. The personal representative of the deceased employee is also entitled to a reimbursement of funeral costs up to $800, and the federal government will pay any costs associated with shipping a body from the place of death to the employee's home. An employee killed while working with the military in a contingency operation is also entitled to a special gratuity payment of up to $100,000 payable to his or her designated survivors.

Vocational Rehabilitation

The Secretary of Labor may direct any FECA beneficiary to participate in vocational rehabilitation, the costs of which are paid by the federal government. While participating in vocational rehabilitation, the beneficiary may receive an additional benefit of up to $200 per month. However, any beneficiary who is directed to participate in vocational rehabilitation and fails to do so may have his or her benefit reduced to a level consistent with the increased wage earning capacity that likely would have resulted from participation in vocational rehabilitation.

FECA Medical Benefits

Under FECA, all medical costs—including medical devices, therapies, and medications—associated with the treatment of a covered injury or illness are paid for, in full, by the federal government. A FECA beneficiary is not responsible for any coinsurance or any other costs associated with his or her medical treatment, and does not have to use any personal insurance for any covered medical costs. A published fee schedule is used by OWCP to determine the rate or reimbursement paid to medical providers.[9]

Generally, a beneficiary may select his or her own medical provider and is reimbursed for the costs associated with transportation to receive medical services. Medical providers must be authorized by OWCP and can have their authorization removed if it is determined that they are violating program rules or are involved in fraud.

Statutory Requirement of Necessity for Medical Benefits

The FECA statute includes the following specific language regarding the scope of medical benefits that are to be provided to injured workers:

> 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 lessening the amount of the monthly compensation...[10]

In its implementing regulations for this provision, DOL provides the following regarding the entitlement of FECA beneficiaries to medical benefits:

[9] A copy of the current OWCP medical fee schedule can be found on the DOL website at http://www.dol.gov/owcp/regs/feeschedule/fee.htm.

[10] 5 U.S.C. §5103(a).

> The employee is entitled to receive all medical services, appliances or supplies which a qualified physician prescribes or recommends and which OWCP considers necessary to treat the work-related injury...[11]

In a 2016 notice in the *Federal Register*, OWCP provided the following explanation of the medical necessity provision in regards to the provision of medical benefits under FECA:

> The FECA statute grants OWCP discretion to provide an injured employee the ''services, appliances, and supplies prescribed or recommended by a qualified physician'' which OWCP considers ''likely to cure, give relief, reduce the degree or the period of disability, or aid in lessening the amount of the monthly compensation.'' *In other words, OWCP is mandated to provide medical supplies and services—including prescription drugs such as opioids and compounded drugs—that it considers medically necessary* (emphasis added).[12]

Provision of Complementary and Alternative Treatments for Pain

There is a growing body of literature examining the role of complementary and alternative treatments, including nonpharmacologic treatments, for pain and the effectiveness of these treatments as alternatives to the use of opioids. The National Center for Complementary and Integrative Health (NCCIH) of the National Institutes of Health (NIH) supports and conducts research into alternative treatments for pain and states on its website:

> A growing body of evidence suggests that some complementary approaches, such as acupuncture, hypnosis, massage, spinal manipulation, and yoga, may help to manage some painful conditions.[13]

In 2017, the National Academies of Sciences, Engineering, and Medicine issued a consensus study report on pain management and the opioid epidemic.[14] This report was requested by the Food and Drug Administration (FDA) to "update the state of the science on pain research, care, and education."[15] In a section of the report on complementary and alternative treatments for pain, the report provides the following summary of the existing research:

> Nonpharmacologic interventions for pain treatment, including acupuncture, physical therapy and exercise, CBT (cognitive behavioral therapy), and mindfulness meditation, represent powerful tools in the management of chronic pain. Many are components of successful self-management. While further research is needed to better understand the mechanism of action and the appropriate dosage and delivery for some nonpharmacologic approaches, they may provide effective pain relief for many patients in place of or in combination with pharmacologic approaches.[16]

Certain complementary and alternative treatments may be authorized by the FECA program. The only alternative treatment addressed in the FECA statute is chiropractic services which are "limited to treatment consisting of manual manipulation of the spine to correct a subluxation as demonstrated by X-ray to exist..."[17] For all other medical treatments, including complementary and alternative treatments not normally provided by doctors or nurses, the statute and regulations require the prescription or

[11] 20 C.F.R. §10.310(a).

[12] Department of Labor, Office of Workers' Compensation Programs, "Proposed Collection of Information; Comment Request," 81 *Federal Register* 40722, June 22, 2016.

[13] National Center for Complementary and Integrative Health, *Chronic Pain: In Depth*, https://nccih.nih.gov/health/pain/chronic.htm.

[14] National Academies of Sciences, Engineering, and Medicine, *Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use*, Washington: National Academies Press, 2017.

[15] Ibid., p. 1.

[16] Ibid., p. 91.

[17] 5 U.S.C. §8101(3).

recommendation of a "qualified physician."[18] The statute defines "physician" to include "surgeons, podiatrists, dentists, clinical psychologists, optometrists, chiropractors, and osteopathic practitioners within the scope of their practice as defined by State law" with the caveat that chiropractors are limited to using spinal manipulation to treat subluxations.[19] The FECA regulations permit "non-physician providers" to provide medical services to the extent permitted by state and federal laws.[20]

The OWCP FECA procedure manual provides guidance on several complementary and alternative treatments including physical therapy and acupuncture, and provides for the reimbursement of membership fees at a health club or spa if a specific program of exercise is prescribed or recommended by a physician.[21]

OWCP Efforts to Limit Payments for Certain Prescription Drugs, Including Opioids

The FECA statute and regulations do not include specific provisions limiting the ability of DOL to pay for any specific prescription drugs, provided these drugs are medically necessary and are properly prescribed by an authorized physician. Rather, the FECA statute and regulations, and OWCP policy, tend to grant deference to a beneficiary's treating physician in determining which specific prescription drugs should be authorized for payment. In its 2016 *Federal Register* notice, OWCP provided the following summary of its policies regarding the limitation on payment of certain drugs:

> The FECA statute and implementing regulations are not primarily focused on managing doctor/patient decisions relating to medication therapy and, with the exception of few limitations on fentanyl (an opioid) and other controlled substances, the FECA program policy on pharmacy benefits has generally been a policy of payment for prescribed medications in accordance with a fee schedule based on a percentage of the average wholesale price (AWP) for drugs identified by a National Drug Code (NDC).[22]

However, despite this general policy of deference to the treating physician, OWCP has used its discretion to implement the medical necessity provision of the FECA statute to institute policies that limit payment for certain types of drugs including fentanyl, compounded drug medications, and other opioids. OWCP has also limited access to OxyContin for federal Black Lung program participants.

In addition, in 2017, OWCP instituted a policy limiting fills of FECA non-maintenance medications to 30 days and requiring that 75% of a prescription's timeline (i.e. 75% of 30 days for a 30-day supply) pass before a refill may be filled.[23]

Any attempts to limit access to a specific class of drug must be balanced against the legitimate needs of FECA beneficiaries who may benefit from this type of drug and the traditional deference given by OWCP to the physician-patient relationship and the treatment recommendations of the beneficiary's treating physician. In addition, per the FECA statute's medical necessity provision, OWCP must make decisions

[18] 5 U.S.C. §8103(a) and 20 C.F.R. §10.310(a).

[19] 5 U.S.C. §8101(2).

[20] 20 U.S.C. §10.310(b).

[21] Department of Labor, Office of Workers' Compensation Programs, *Division of Federal Employees' Compensation: Procedure Manual*, Chapter 3-400, https://www.dol.gov/owcp/dfec/regs/compliance/DFECfolio/FECA-PT3/.

[22] Department of Labor, Office of Workers' Compensation Programs, "Proposed Collection of Information; Comment Request," 81 *Federal Register* 40722, June 22, 2016.

[23] Department of Labor, Office of Workers' Compensation Policy, *Division of Federal Employees' Compensation: New Policy on Filling Non-Maintenance Medications*, April 12, 2017, https://www.dol.gov/owcp/dfec/FillingNonmaintenanceMeds.htm.

on the availability of specific treatments, including treatments with opioids, within the context of whether the treatment is "likely to cure, give relief, reduce the degree or the period of disability, or aid in lessening the amount of the monthly compensation."[24]

OxyContin

OxyContin is the brand-name of a sustained-release formulation of the opioid drug oxycodone. OxyContin was introduced in 1995 as the first sustained-release formulation of oxycodone, allowing patients to dose every 12 hours instead of every four to six hours. In the early 2000's concerns were raised that some patients were misusing OxyContin, in some cases by crushing the tablets to defeat the sustained-release properties and then snorting or injecting the crushed tablets. Concerns were also raised that OxyContin was being illegally diverted. Congress held its first hearings on OxyContin in 2001[25] and 2002[26] and in 2003 the Government Accountability Office (GAO), at the request of Congress, issued a report on OxyContin abuse and diversion.[27]

OWCP Policy

In 2001, OWCP issued a new policy regarding reimbursement for OxyContin in the federal Black Lung program. Under this policy, OxyContin is only reimbursed if it is prescribed for pain alleviation for pneumoconiosis and its sequelae as defined in the Black Lung Benefits Act, not for any comorbid or other conditions.[28]

Schedule II Drugs

The Controlled Substances Act (CSA) establishes five schedules for various types of drugs, plants, and chemicals.[29] Substances are placed on one of the schedules based on their medical use, potential for abuse, and potential for dependence. Substances may be placed on a schedule through legislation or administrative rulemaking. Various federal regulations, including manufacturing limits for Schedule I and II drugs, are associated with each of the CSA schedules.

Schedule I drugs are those that have a high potential for abuse, and "no currently accepted medical use for treatment in the United States."[30] Examples of Schedule I drugs include marijuana, heroin, lysergic acid diethylamide (LSD), and methaqualone (i.e. the brand name Quaalude).[31]

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[24] 5 U.S.C. §5103(a).

[25] U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, *OxyContin: Its Use and Abuse*, 107th Cong., 1st sess., August 28, 2001, Serial No. 107-54 (Washington: GPO, 2001); and U.S. Congress, House Committee on Appropriations, Subcommittee on Commerce, Justice, State, and Judiciary, *Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies for 2002: Part 10: OxyContin*, 107th Cong., 1st sess., December 11, 2001 (Washington: GPO, 2002).

[26] U.S. Congress, Senate Committee on Health, Education, Labor, and Pensions, *OxyContin: Balancing Risks and Benefits*, 107th Cong., 2nd sess., February 12, 2002, S. Hrg. 107-287 (Washington: GPO, 2002).

[27] U.S. Government Accountability Office, *Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem*, GAO-04-110, December 2003.

[28] Department of Labor, Office of Workers' Compensation Programs, *Division of Coal Mine Workers' Compensation: Announcement for Physicians and Pharmacy Providers of Medical Care to Qualified Recipients of Federal Black Lung Miner's Benefits*, June 11, 2001, https://www.dol.gov/owcp/dcmwc/regs/compliance/providerannox.htm.

[29] 21 U.S.C. §812. For additional information on the CSA and drug schedules see CRS Report RL34635, *The Controlled Substances Act: Regulatory Requirements*; and CRS Report R45164, *Legal Authorities Under the Controlled Substances Act to Combat the Opioid Crisis*.

[30] 21 U.S.C. §812(b)(1).

Schedule II drugs are available by prescription unlike Schedule I drugs. A drug must meet all of the following conditions for placement in Schedule II:

- the drug has a high potential for abuse;
- the drug has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions; and
- abuse of the drug may lead to severe psychological or physical dependence.[32]

Examples of Schedule II drugs include combination drugs with less than 15 mg of hydrocodone per dose (i.e. the brand name Vicodin), methadone, cocaine, and fentanyl.[33]

By definition, Schedule II drugs have the highest potential for abuse and dependence of any drugs available by prescription. Thus, there is a legitimate concern for the welfare of patients who are prescribed these drugs. Within the FECA program, the potential analgesic benefits of these drugs must be weighed against the risk of abuse, dependence, and addiction, and the impacts this may have on the beneficiary's overall health and ability to ultimately return to the federal workforce.

OWCP Policy

On December 1 2009, OWCP began implementing limits on the payment for Schedule II drugs in the FECA program.[34] This policy included the following provisions:

- beneficiaries with cancer are eligible for an unlimited number of refills of Schedule II drugs, but must use at least 75% of the previous supply of drugs before a refill will be authorized; and
- beneficiaries without cancer are only eligible for a thirty-day supply of any Schedule II drug, and no more than three additional refills of the drug within a 90-day period after the initial fill.

Fentanyl

Fentanyl is a synthetic opioid analgesic that is 50 to 100 times more potent than morphine and is classified as a Schedule II drug under the CSA.[35] Fentanyl is often prescribed for breakthrough pain after surgery, for patients with cancer, or for chronic pain in patients who are physically tolerant to other opioids. Fentanyl is administered via injection, transdermal patch, tablet, or lozenge, and is available in fast-acting (i.e. the brand names Actiq and Fentora) and sustained-release (i.e. the brand name Duragesic) formulations. Fentanyl may also be produced illicitly, such as in a powdered form, which can be mixed with heroin, cocaine, or other illicit drugs.

In testimony before the House Committee on Energy and Commerce in 2017, the director of the National Center for Injury Prevention and Control of the Centers for Disease Control and Prevention (CDC) stated that the fentanyl associated with recent drug overdoses is produced in illegal laboratories and distributed

(...continued)

[31] Drug Enforcement Administration, *Drug Scheduling*, https://www.dea.gov/druginfo/ds.shtml.

[32] 21 U.S.C. §812(b)(2).

[33] Drug Enforcement Administration, *Drug Scheduling*, https://www.dea.gov/druginfo/ds.shtml.

[34] Department of Labor, Office of Workers' Compensation Programs, *Division of Federal Employees Compensation: Pharmacy Schedule II Policy*, December 1, 2009, https://www.dol.gov/owcp/dfec/pharmacy-schedule-II-policy.htm.

[35] National Institute on Drug Abuse, *Fentanyl*, Drug Facts, June 3, 2016, https://www.drugabuse.gov/publications/drugfacts/fentanyl.

through illicit channels rather than through legal prescriptions. This testimony cited an investigation of fentanyl-related overdoses in Massachusetts in 2014 and 2015 in which the CDC, the Massachusetts Department of Public Health, the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Drug Enforcement Administration (DEA) determined that 82% of fentanyl-related overdose deaths in this period were suspected to involve illicitly-manufactured fentanyl while only 4% were suspected to involve pharmaceutical fentanyl, with the remaining 14% of cases lacking sufficient evidence to make a determination.[36]

While much of the fentanyl that is contributing to the current problem of drug overdoses comes from illicit channels rather than legitimate prescriptions, the use of legally-prescribed fentanyl can result in addiction, fatal overdose from intentional or accidental ingestion, and life-threatening respiratory depression. Because of these risks, fentanyl products are required by the Food and Drug Administration (FDA) to carry a "boxed warning" with information on these risks.[37]

OWCP Policy

On May 3, 2011, OWCP issued a new policy regarding payment for fast-acting formulations of fentanyl under the FECA program.[38] Under this policy, a FECA beneficiary must have an employment-related cancer, except for non-melanoma cancer of the skin or carcinoma in situ (also known as stage 0 cancer), to be eligible for a prescription for a fast-acting fentanyl product.

Compounded Drug Medications

Compounded drug medications are customized medications in which a physician or pharmacist mixes two or more commercially available medications or ingredients to create a new medication. In workers' compensation, compounding is most frequently used to create non-sterile topical medications for the treatment of neuropathic, muscle, or joint pain, which are often provided by sources other than traditional retail pharmacies. These compounded medications in many cases contain an opioid as an ingredient.

In addition to concerns over the safety and efficacy of compounded drug medications, especially when compared against commercially available medications, the DOL, USPS, and some Members of Congress have raised concerns about the costs associated with compounded drug medications in the FECA program. In Congressional testimony in March 2017, the DOL Inspector General reported that costs for compounded drug medications in the FECA program rose from approximately $2 million in FY2011 to $263 million in FY2016, with costs rising from $80 million to $214 million in FY2015 alone. In FY2015, total costs for compounded drug medications ($214 million) surpassed costs for all other medications ($199 million) provided by the FECA program.[39]

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[36] U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, *Fentanyl: The Next Wave of the Opioid Crisis*, 115th Cong., 1st sess., March 21, 2017, testimony of Debra Houry, Director, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention.

[37] See for example the FDA-approved drug label for the fentanyl drug Fentora at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/021947s024s025lbl.pdf. For additional information on the FDA's role in responding to the opioid epidemic, see CRS Legal Sidebar LSB10049, *Responding to the Opioid Epidemic: Legal Developments and FDA's Role*.

[38] Department of Labor, Office of Workers' Compensation Programs, *Usage Guidelines for Fentanyl Products*, FECA Bulletin No. 11-05, May 3, 2011, https://www.dol.gov/owcp/dfec/regs/compliance/DFECfolio/FECABulletins/FY2011-2015.htm#FECAB1105.

[39] U.S. Congress, House Committee on Appropriations, Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, *Management Challenges at the Departments of Labor, Health and Human Services, Education, and the Social Security Administration: Views from the Inspectors General*, 115th Cong., 1st sess., March 9, 2017 (statement of Scott S. Dahl, Inspector General, Department of Labor).

The USPS Office of Inspector General found similar cost increases associated with compounded medications for postal workers in the FECA program with compounded drug costs rising from $4.9 million in chargeback year 2011 to $98.7 million in chargeback year 2015. In addition, in chargeback year 2015, compounded medications made up 34% of USPS FECA prescriptions and 53% of associated prescription costs.[40] In response to these increases, in 2015, the USPS took the unprecedented step of formally requesting to DOL that the USPS chargeback be reduced by $68 million (from a total chargeback of $1.4 billion) to account for increased costs associated with what the agency felt was the improper use of compounded medications.[41] This request was denied by DOL.[42]

In a letter to the Office of Management and Budget, the ranking members of House Committees on Education and the Workforce and Oversight and Government Reform expressed their concerns over costs associated with compounded medications in the FECA program and cited, as examples, a single tube of a compounded ointment that cost over $67,000 and a compounded cream containing resveratrol[43] that cost over $32,000 per prescription.[44]

OWCP Policy

On October 14, 2016, OWCP announced new guidelines for the prescribing and dispensing of compounded drug medications in the FECA program.[45] These new guidelines require that all compounded drug prescriptions receive prior authorization from OWCP based on a Letter of Medical Necessity (LMN) submitted by the claimant's treating physician. Each compounded prescription may be authorized for no more than a 30-day supply for a total of 90 days. After 90 days, a new LMN and authorization is required to continue the use of the compounded medication.

Opioids

Opioids are drugs that bind to opioid receptors on nerve cells in the human body and brain. Through this action, opioids have an analgesic effect and are therefore most frequently prescribed and used for pain relief. As a class of drug, opioids include both natural derivatives of the opium poppy plant (referred to as opiates) and synthetic formulations that emulate the effect of opiates. Examples of opioids include heroin, fentanyl, morphine, oxycodone, hydrocodone, and codeine.

In addition to temporarily relieving pain, opioids can have other short-term effects including euphoria, drowsiness, confusion, nausea, constipation, and slowed breathing. Repeated use of opioids can result in an increased physical tolerance for the drug resulting in a user's need for higher doses to get the same effects. Users may also develop dependence on the drug such that its absence in the body will result in

[40] U.S. Postal Service, Office of Inspector General, *Workers' Compensation Compound Drug Costs*, Management Advisory Report Number HR-MA-16-003, March 3, 2016, p. 7.

[41] Ibid., pp. 17-19.

[42] Ibid. pp. 20-21.

[43] Resveratrol is a natural phenol found in grapes, wine, and other foods that has not been approved for any use by the Food and Drug Administration (FDA). There is no regulation or policy limiting FECA beneficiaries to only products approved by the FDA.

[44] Letter from Robert C. "Bobby" Scott, Ranking Member, House Committee on Education and the Workforce, and Elijah E. Cummings, Ranking Member, House Committee on Oversight and Government Reform, to Howard Shelanski, Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget, October 5, 2016, http://democrats-edworkforce.house.gov/imo/media/doc/10-05-16%20Letter%20from%20Reps%20%20R%20%20Scott%20and%20Cummings%20Regarding%20Compounded%20Drugs%20OMB%20ICR%20Reference%20No%20%20201606-1240-003%20(002).pdf.

[45] Department of Labor, Office of Workers' Compensation Programs, FECA Bulletin 17-01, October 14, 2016, https://www.dol.gov/owcp/dfec/regs/compliance/DFECfolio/FECABulletins/FY2016-2020.htm#FECAB1701.

withdrawal symptoms or an addiction to the drug in which the person compulsively seeks the drug despite increasing negative physical, psychological, or social consequences associated with its use.[46] Also of concern is the potential for overdose and death from the use of both illicit and prescription opioids. The increase in opioid-overdose deaths in recent years has been well-documented and the subject of significant attention from public health authorities, the public, and Congress.[47] Since March 2016, the FDA has required that all immediate-release opioids carry a boxed warning with information on the risks of misuse, abuse, addiction, overdose, and death associated with opioids.[48]

In part due to the nature of work injuries, which frequently involve pain, opioids make up a large portion of the total utilization of prescription drugs in workers' compensation programs. For example, the Pharmacy Benefits Manager (PBM) myMatrixx reports that, despite recent decreases in overall opioid use within workers' compensation, owing in part to legislative and regulatory changes made in the states, among workers' compensation prescriptions that it services opioids constitute the largest class of medications prescribed, making up approximately 23% of the utilization of medications and 24% of annual workers' compensation medication spending.[49] Research on workers' compensation prescriptions in California produced similar findings.[50] The National Council on Compensation Insurance (NCCI) reports that in 2016, workers' compensation beneficiaries who received at least one prescription received three times the national average number of opioid prescriptions.[51]

A 2018 working paper from the National Bureau of Economic Research (NBER) looks at the interaction of long-term opioid use and the duration of workers' compensation disability benefits and prospects for returning injured workers to the job.[52] In this study, which focused on individuals with employment-related low back pain, the authors conclude that long-term use of opioids is linked to longer disability durations, stating:

> We find that prolonged prescribing of opioids leads to longer duration of temporary disability benefits among workers with work-related low back injuries. Our estimates indicate that longer-term opioid prescriptions roughly triple the duration of temporary disability benefits, compared to similar workers with similar injuries who do not get opioid prescriptions. Thus, we do not find evidence, on average, of beneficial effects of opioids prescribed in workers' compensation cases—benefits that would need to be weighed against the costs of opioid use.[53]

[46] National Institute on Drug Abuse, *Prescription Opioids*, Drug Facts, January 2018, https://www.drugabuse.gov/publications/drugfacts/prescription-opioids.

[47] See for example Rose A. Rudd, Puja Seth, and Felicita David, et al., "Increases in Drug and Opioid-Involved Overdose Deaths-United States 2010-2015," *Morbidity and Mortality Weekly Report*, vol. 65, no. 50-51 (December 30, 2016), pp. 1145-1452. For information on the federal response to the opioid epidemic, see CRS Report R44987, *The Opioid Epidemic and Federal Efforts to Address It: Frequently Asked Questions*.

[48] Department of Health and Human Services, Food and Drug Administration, *FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death*, FDA News Release, March 22, 2016, https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm.

[49] myMatrixx, *2017 Workers' Compensation Drug Trends Report*, April 2018, https://www.mymatrixx.com/wp-content/uploads/2018/04/myMatrixx-2017-Workers-Compensation-Drug-Trend-Report.pdf.

[50] Steve Hayes and Alex Swedlow, *Trends in the Use of Opioids in California's Workers' Compensation System*, California Workers' Compensation Institute, May 2016, https://www.cwci.org/document.php?file=2957.pdf.

[51] National Council on Compensation Insurance, *On Opioids: The Doctors' Perspective*, April 23, 2018, https://www.ncci.com/Articles/Pages/II_OnOpioids-Doctors.aspx.

[52] Bogdan Savych, David Neumark, and Randall Lea, "Do Opioids Help Injured Workers Recover and Get Back to Work? The Impact of Opioid Prescriptions on Duration of Temporary Disability," National Bureau of Economic Research Working Paper No. 24528, April 2018, http://www.nber.org/papers/w24528.pdf.

[53] Ibid., p. 31.

OWCP Policy

On June 16, 2017, OWCP issued guidelines for the prescription of opioids in the FECA program.[54] At this time, these guidelines only apply to cases in which no opioid has previously been prescribed within the past 180 days and do not apply to cancer cases.[55]

Maximum Allowable Opioid Prescriptions

FECA beneficiaries are limited to no more than two opioid prescriptions at any time, only one of which may be Schedule II drug. In supporting documentation to these guidelines, OWCP states that physicians should utilize "partial fills" for Schedule II and III opioids and should, to the extent possible, avoid the concurrent use of opioids and benzodiazepines.[56]

Initial Authorization

The 2017 guidelines do not require any LMN or prior authorization by OWCP before the initial fill of an opioid prescription. However, any fills after the initial 60-day period require an LMN and OWCP prior authorization. The beneficiary will be notified of this requirement at the point of sale when receiving the initial fill. When making the decision to grant the initial authorization, the OWCP Claims Examiner (CE) should review the medical evidence in the case and the justification for the prescription provided in the LMN. The CE should assess at least the following factors when making an initial authorization decision:

- whether the physician has enough knowledge of the claimant to arrive at a sound medical opinion;
- the medical rationale for the prescription provided by the physician; and
- whether the necessity of the prescription is based on objective clinical findings or subjective complaints.

If the CE determines that additional information is necessary before making an authorization decision, the claims examiner may:

- consult with an OWCP District Medical Advisor (DMA) to determine the appropriateness of the prescription and pain management plan, including any plan to address dependence on opioids;[57]
- require the beneficiary to undergo a second-opinion medical examination;[58] or
- if applicable, direct the case's Field Nurse (FN) to discuss the issue of ongoing opioid use with the physician.

The CE may provide authorization while this process is taking place.

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[54] Department of Labor, Office of Workers' Compensation Programs, FECA Bulletin 17-07, June 6, 2017, https://www.dol.gov/owcp/dfec/regs/compliance/DFECfolio/FECABulletins/FY2016-2020.htm#FECAB1707.

[55] OWCP reports that additional guidelines for cases in which an opioid has been prescribed in the past 180 days will be forthcoming [Department of Labor, Office of Workers' Compensation Programs, *Division of Federal Employees' Compensation: Opioid Medications*, June 6, 2017, https://www.dol.gov/owcp/dfec/NewFECAPolicyonOpioidMedications.htm].

[56] Department of Labor, Office of Workers' Compensation Programs, *Division of Federal Employees' Compensation: Opioid Medications*, June 6, 2017, https://www.dol.gov/owcp/dfec/NewFECAPolicyonOpioidMedications.htm. Benzodiazepines are drugs primarily used to treat anxiety and include the Schedule IV drugs diazepam (i.e. the brand name Valium) and alprazolam (i.e. the brand name Xanax).

[57] A DMA is a physician employed by OWCP to serve as a consultant to the CE on medical issues.

[58] The FECA statute at 5 U.S.C. § 8123 requires a FECA claimant to submit to a medical examination by a physician designated by DOL as frequently "as may be reasonably required."

Subsequent Authorizations

For each 60-day period after the initial fill, a new LMN and OWCP authorization is required with each subsequent authorization being valid for 60 days. Continued use of an opioid may only be authorized beyond 120 days from the initial fill if the CE has written to the physician requesting "rationalized medical justification" for the ongoing use of opioids, but may provide authorization while this process is taking place. All cases with continued opioid use should, per this OWCP policy, be reviewed every six months by either a DMA or a via a second-opinion examination of the beneficiary provided by OWCP.

It may be too early to determine the full impact of these policy changes on opioid use within the FECA program. In addition, these new policies on initial and subsequent authorizations currently only apply to beneficiaries with new opioid prescriptions rather than those who are currently involved in the long-term use of opioids. Thus, it remains to be seen how OWCP will address those beneficiaries who have been taking opioids for more than 180 days, especially in light of recent research showing links between long-term opioid use and disability duration.