NATIONAL CENTER FOR POLICY ANALYSIS

Medicare Drug Plans Need the Tools to Fight Prescription Drug Fraud

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Patients benefit enormously from safe and effective drug therapies. However, many of the drugs Americans take are not safe when they are taken recreationally, consumed in quantities larger than prescribed or diverted for illicit sale. More than 16,000 people die annually from prescription drug overdoses, according to the Centers for Disease Control and Prevention (CDC) — double the number that die abusing either cocaine or heroin, combined.

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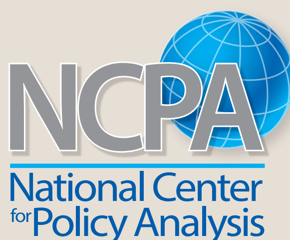

Executive Summary

Abuse of prescription pain relievers is a growing problem for Medicare drug plans, which have a limited ability to deal with this problem; even if they suspect fraud, drug plans are not allowed to restrict the availability of certain drugs — or restrict the drugstores that can supply benefits — to enrollees who abuse or resell them.

For the most part, questionable drug utilization typically involves addictive pain relievers that create a heroin-like euphoria. Some individuals seek drugs for their own recreational use, while others seek to capitalize on their value by selling drugs to others. Substantial numbers of Medicare drugs are diverted to the illicit market where their "street value" far exceeds their pharmacy cost. This is especially true of narcotic pain relievers derived from opioids. Drug diversion costs insurers nearly $75 billion per year — about two-thirds of it from public programs such as Medicare and Medicaid.

Barriers to Combating Fraud. The most common way Medicare fraudsters obtain large numbers of addictive, opioid pain relievers is by "doctor shopping" — seeing multiple doctors every month with bogus complaints about chronic pain. The unnecessary medical care required to fraudulently obtain drugs wastes far more money than the cost of the drugs themselves. For every $1 worth of drugs lost due to fraud, an additional $41 is wasted in unnecessary physician visits, redundant medical tests and unneeded visits to the emergency room to obtain the drugs.

Drug-seekers generally fill their multiple prescriptions at multiple pharmacies to avoid detection — hoping that no one pharmacy will track their behavior and question them. This tactic often fools individual doctors and pharmacies into believing their patients are not abusing prescription pain relievers. However, drug plans can easily detect drug-seeking behavior. Unfortunately, Medicare doesn't grant them the authority to stop this abuse. Under current law, Medicare drug plans are not allowed to restrict the benefits of enrollees thought to be abusing or reselling prescription drugs. At the very least, beneficiaries with high levels of narcotic pain reliever prescription fills

should be "locked in" to a program that assigns them one doctor, one pharmacy and one emergency room for the specific pain relievers being abused. Currently, 46 state Medicaid programs lock selected beneficiaries into specific providers.

Physician Fraud. There are about 894,000 physicians practicing in the United States, and nearly half provide primary care. Most are hurried and have little time to look for the subtle clues of addiction or scrutinize drug-seeking behavior on the part of their patients; they may not realize that the patient who comes in once a month to renew a prescription for oxycodone actually visits a dozen doctors every month for prescription pain relievers. But more worrisome are the doctors who turn a blind eye to likely drug abuse because drug-seeking patients can be lucrative customers.

Pharmacy Fraud. The problem of drug fraud goes beyond individuals seeking drugs. In 2009, the Office of the Inspector General within the U.S. Department of Health and Human Services identified 2,636 retail pharmacies with questionable billing patterns in 2009. Some pharmacies seemed to bill very high dollar amounts per beneficiary, while some billed for a high number of prescriptions per beneficiary. Others billed for a high number of prescriptions per physician prescriber. Such patterns could indicate the drugs were not medically necessary or possibly that they were never actually dispensed.

Significantly, submitting medical bills to insurers, health plans and pharmacy benefit managers requires only a limited amount of supporting documentation. Consequently, fraudulent claims are easy to disguise and submit for payment, as they are hard to detect amidst billions of legitimate claims. Companies that process electronic payments, however, have learned how to detect transaction patterns that deviate from the norm. If Medicare operated a lock-in program, drug plans could use this information to halt fraud.

It Is Not Just Painkillers. Although drug diversion is most closely associated with opioid pain relievers, there is tremendous potential for diversion to spill over into other lucrative drug classes. Increasingly, rare diseases are being treated with highly advanced specialty drugs and biological agents. The cost of specialty drug therapies ranges from tens of thousands of dollars to hundreds of thousands annually. As prescriptions worth thousands of dollars become increasingly common, so too will the number of people who attempt to divert these drugs for profit.

Fixing the Problem. In August 2014, the Office of the Inspector General within the U.S. Department of Health and Human Services issued recommendations to reduce the questionable usage of narcotic pain relievers by Medicare beneficiaries. One of its recommendations was to establish a lock-in program, which would allow drug plans to restrict Medicare enrollees' ability to access drugs through multiple pharmacies or physicians. In August 2014, the Chairman of the House Ways and Means Subcommittee on Health, Kevin Brady (R-Texas), circulated a draft of a bill designed to help Medicare drug plans reduce fraud. The "Protecting Integrity in Medicare Act of 2014" would give drug plans within Medicare Part D the authority to restrict certain beneficiaries to the use of a single doctor and pharmacy with respect to specific opioids and other high-risk drugs. Drug plans are currently hamstrung by regulations that prevent them from tackling drug abuse, and they need this type of flexibility in order to effectively combat fraud.

About the Author

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Herrick received a Doctor of Philosophy in Political Economy degree and a Master of Public Affairs degree from the University of Texas at Dallas with a concentration in economic development. He also holds a Master of Business Administration degree with a concentration in finance from Oklahoma City University and an M.B.A. from Amber University, as well as a Bachelor of Science degree in accounting from the University of Central Oklahoma.

Introduction

By almost any measure, the prescription medications Americans take are a bargain compared to the alternatives. Drug therapy often substitutes for more expensive hospital and surgical treatments. Patients benefit enormously from safe and effective drug therapies. [See the sidebar, "Drug Therapy."] However, some of the drugs Americans take are not safe when they are consumed in quantities larger than prescribed, taken recreationally or diverted for illicit sale. Medicare has a drug problem — though only a tiny minority of Medicare beneficiaries abuse prescription drugs. Those who do abuse prescription drugs, however, risk their own health, harm public health and drive up costs for their fellow Medicare drug plan enrollees — all of whom pay higher premiums as a result. Medicare drug plans need the tools to fight prescription drug abuse and fraud.

America is facing an epidemic of prescription drug abuse. More than 16,000 people die annually from abusing pain relievers, according to the Centers for Disease Control and Prevention (CDC). This is double the number who die from cocaine and heroin abuse combined. Abuse of prescription pain relievers is a growing problem for Medicare drug plans.

Drug Therapy

Americans spend nearly $300 billion on prescription drug therapies annually.[1] This is a significant increase from the $40 billion spent on prescription drugs in 1990.[2] By any measure, drug therapy is a bargain — comprising only about 10 percent of total medical expenditures. By contrast, expenditures on physician services account for twice as much as drugs, and inpatient hospital care accounts for three times the cost of drug therapy. [See Figure I.]

Medicare Part D Drug Plans

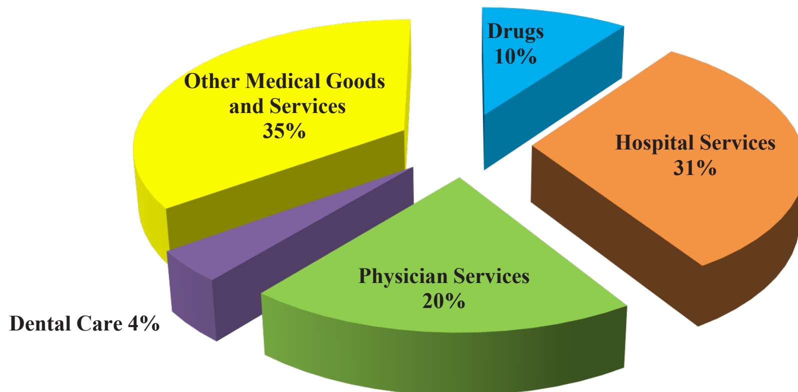
Nearly 39 million Medicare beneficiaries, including seniors and the disabled, have subsidized drug coverage through the Medicare Modernization Act (MMA) of 2003. All but a few of these individuals are enrolled in drug plans known as Medicare Part D. Medicare Part D plans are popular with seniors. Ninety percent of all seniors take a prescription drug in any given year, and the bulk of drugs consumed are generally prescribed for chronic conditions.[3] Although subsidized by Medicare, Part D plans are offered by private insurers and compete with each other for seniors' patronage.

Medicare drug plans are allowed to use a variety of techniques to keep premiums affordable. Some of the common methods include using preferred-drug lists, tiered formularies and mail-order drug suppliers. Drug plan sponsors negotiate prices with drug companies and drug distributors and contract with pharmacy network providers to secure seniors the lowest possible drug prices. Some seniors select plans that steer them to a preferred pharmacy network in return for lower premiums. Preferred pharmacy networks are more restrictive than open pharmacy network plans but generally offer a wide range of pharmacy choices while saving seniors money.

However, there are other cost-saving techniques which drug plans are not permitted to use. Medicare Part D drug plans are not allowed to restrict the availability of some drugs — or restrict the drugstores that can supply benefits (or selected benefits) — to enrollees who abuse drugs or who acquire drugs they don't need and resell them. This is a tool that most state Medicaid programs have implemented to combat fraud and protect public health. In August 2014, the Office of the Inspector General for the U.S. Department of Health and Human Services (HHS) issued several recommendations to alleviate the problems caused by the small number of Medicare enrollees who have questionable patterns of drug use. One of its recommendations was to establish a lock-in program, which would allow drug plans to restrict Medicare enrollees' ability to access drugs through multiple pharmacies or physicians in order to better monitor and control potential drug fraud.[4] [See the sidebar, "Medicaid Lock-in Program."]

Problem: Chronic Pain. Unrelieved chronic pain is a widespread problem in most countries.[5] One estimate puts the economic costs of unrelieved pain at $635 billion per year in lost productivity and medical care.[6] Chronic pain can occur from any number of diseases or injuries, and it is estimated that up to 100 million Americans experience chronic or unrelieved pain daily.[7] This problem led to a laissez-faire attitude toward pain management that downplayed

Figure I
Drug Spending as a Proportion of All Health Care Expenditures
(2012)



Source: "National Health Expenditures by Type of Service and Source of Funds, CY 1960-2012," Centers for Medicare & Medicaid Services, U.S. Department of Health and Human Services, page last modified January 7, 2013. Available at http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/NHE201.zip.

the potential for addiction to pain medications. The most powerful pain medications are derived from the opium poppy plant — the same plant from which the illegal drug heroin is derived. Recently, many former advocates of opioid pain management have begun changing their minds about the drugs as opioids become better understood. Some experts are coming to the conclusion that opioid pain medications are more addictive, or pain management more complicated, than once thought.[8]

Problem: Prescription Drug Abuse. Some individuals seek drugs for their own recreational purposes, while others seek to capitalize on their value by selling them to others. The Centers for Medicare and Medicaid Services (CMS) defines drug diversion as "the diversion of licit drugs for illicit purposes."[9] Substantial numbers of Medicare drugs are diverted to the illicit market where their "street value" far exceeds their pharmacy cost. This is especially true of narcotic pain relievers derived from opioids. The reason drugs are diverted is easy to understand. The HHS Office of the Inspector General (OIG) reports the "street" price of Oxycodone is a dozen times the normal retail price at a pharmacy. Its agents report that a bottle of Oxycodone is worth $1,100 to $2,400 per bottle if sold on the streets of Northern California.[10] [See Figure II.]

In some cases, recipients themselves are abusing the drugs. In other cases, recipients attempt to obtain drugs they don't need in order to profit by reselling them. The OIG reports that drug diversion involves a variety of individuals: patients who are addicted, patients who profit from unneeded prescriptions, drug dealers who deal in prescription pain medications and unscrupulous providers. An estimated 80 percent of abused controlled substances are obtained by prescription and legally dispensed to the abuser, an abuser's friend or a family member.[11] While opioid pain relievers are the most common drugs diverted for resale, anxiety drugs and antipsychotic medications are also commonly diverted to the illicit market.

The problem is one familiar to health plan administrators. A recent report estimates that 20 million people abuse prescription drugs in a given year, and not without consequences; nearly one-in-five insured drivers in fatal accidents in 2009 tested positive for drugs.[12] Additionally, the costs of drug diversion include unnecessary office visits and 1.2 million expensive emergency room visits.[13] [See Figure III.] One report estimated drug diversion costs insurers nearly $75 billion per year — about two-thirds of it from public programs such as Medicare and Medicaid.[14] It is not uncommon for addicts to show up at the ER asking for painkillers, complaining of intense pain. Indeed, pain medications are the most commonly dispensed drug in the emergency room, and three-fourths of ER visits result in a dispensed drug.[15]

Over the past few years, Medicare Part D drug plans have increasingly adopted preferred pharmacy networks, giving drug plans leverage to negotiate the lowest possible drug prices from pharmacies competing to be included in preferred networks. In January 2014, the Centers for Medicare and Medicaid Services (CMS) proposed new regulations that would limit the ability of drug plans to offer seniors enhanced safety and lower premiums in exchange for patronizing preferred networks.[16] Fortunately, after a public discussion period, the agency tabled the proposal. The rule would have been a step in the wrong direction, given the growing problem of drug

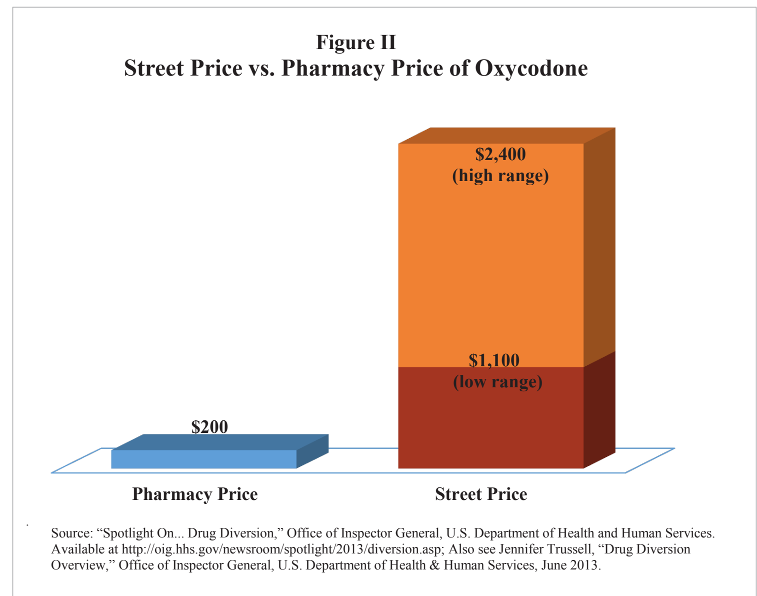
diversion and resale. Open pharmacy networks are a recipe for disaster, as unscrupulous pharmacy operators — and drug-seeking beneficiaries — can more easily steal from taxpayers. Laws that restrict drug plans from building exclusive networks increase the number of pharmacies for which claims must be adjudicated and paid, boosting administrative costs and limiting drug plans' ability to oversee pharmacy activity.[17] When plans are forced to reimburse any drugstore that submits a claim, fraud becomes a distinct possibility. Additionally, fraudulent drug stores can buy stolen identities or collaborate with dishonest enrollees to file claims for drugs not actually dispensed.[18]

An analysis by the Government Accountability Office (GAO) identified 170,000 Medicare beneficiaries who had received commonly abused drugs from five or more physicians in 2008. These 170,000 individuals represented nearly 2 percent of all Medicare Part D beneficiaries who had received drugs from 14 commonly abused classes during the year observed. Of the 170,000 individuals, most — 71 percent — were eligible for Medicare based on a disability rather than age.[19]

Problem: Barriers to Combating Fraud. Health care fraud is a problem faced by all third party payers — drug plans are no exception. Some Obama Administration experts believe improper payments (that is, waste and fraud) in the Medicare program overall approaches 10 percent.[20] The precise estimate of fraudulent or abusive claims in the Medicare Part D program, however, is very difficult to estimate with any precision. Most estimates place the fraud in Medicare Part D at only a fraction of Medicare's overall fraud level. However, fraud in Medicare is undoubtedly a significant burden for taxpayers and for drug plans, and it is likely to get much worse if drug plans are not given the necessary tools to deal with abusive enrollees with questionable claims. And, unfortunately, a few drug-seeking beneficiaries with questionable utilization are not the only problem. Dishonest physicians, unscrupulous pharmacies and bogus pharmacies add to the challenge. [See the sidebar, "Private Sector Solution to Fraud."]

Regulations requiring Medicare drug plan administrators to pay claims within 14 days also make it

Figure II
Street Price vs. Pharmacy Price of Oxycodone



Source: "Spotlight On... Drug Diversion," Office of Inspector General, U.S. Department of Health and Human Services. Available at http://oig.hhs.gov/newsroom/spotlight/2013/diversion.asp; Also see Jennifer Trussell, "Drug Diversion Overview," Office of Inspector General, U.S. Department of Health & Human Services, June 2013.

Private-Sector Solution to Fraud

Express Scripts is a pharmaceutical benefit management (PBM) company that administers drug plans for Medicare Part D and Medicaid, as well as for numerous insurers and employers. Express Scripts is the largest drug plan administrator in the country. It has developed a program using more than 290 indicators to predict the likelihood of fraud. Some of these include:

- Number of physicians visited;
- Distance traveled to either physicians or pharmacies;
- Frequency of prescriptions;
- Type and mix of drugs dispensed;
- Geographic characteristics; and
- Patient demographics.

According to industry research, for every $1 in fraudulent drug claims, an additional $41 dollars is spent on associated medical claims — unnecessary physician visits, redundant medical tests, unnecessary emergency room visits and the like — to obtain the drugs.[21] [See Figure IV.] Express Scripts estimates its collaborative approach — working with its clients to identify and prevent fraud — saved about $1.5 billion dollars in medical costs from 881 cases of fraud in 2013.[22]

difficult to detect fraudulent billing before claims have been paid, and current Medicare Part D regulations make it all but impossible to prevent dispensing narcotic pain relievers from multiple prescriptions at multiple pharmacies. At the very least, drug plans need the authority to identify suspicious activity and monitor beneficiaries with suspect drug utilization. Beneficiaries with high levels of narcotic pain reliever prescription fills could be locked in to a program that assigns them one doctor, one pharmacy and one emergency room for the specific pain relievers being abused. This not only saves money, but it is safer for the individual who could accidently overdose on a legally obtained narcotic. Such reforms would give drug plans greater authority to exclude or suspend suspected fraudulent providers from their networks and conduct routine audits of participating pharmacies.

The Centers for Medicare and Medicaid Services (CMS) requires drug utilization review. However, this review occurs after drugs have been dispensed. And although it allows drug plans to identify Medicare beneficiaries abusing drugs, federal law does not allow drug plans to restrict those individuals' access to drugs. Moreover, beneficiaries who "doctor shop" change drug plans more frequently than other beneficiaries. For a program of retrospective drug utilization analysis to be truly effective, Part D plans would need to share information on suspected enrollees — something that is not currently allowed.[23] Because of these limitations, the Obama

Medicaid Lock-in Program

Unlike Medicare Part D plans, state Medicaid agencies have the authority to restrict enrollees from obtaining drugs from any provider, except those designated by the state.[24] Beginning in 2001, state Medicaid programs began to look for ways to restrict individuals who were obtaining drugs in quantities that exceeded medical necessity.[25] Some state programs lock enrollees in to a specific pharmacy, while other state programs assign beneficiaries to one pharmacy and one prescribing physician.[26] Indeed, CMS actually encourages states to establish lock-in programs to restrict the ability of Medicaid recipients to over-utilize controlled substances.[27] Currently, 46 states have programs to lock selected beneficiaries into specific providers.[28] Prescription drug monitoring programs are operational in 48 states.[29]

The purpose of these programs is both safety and cost control. Opioid-abusing Medicaid enrollees cost nearly twice as much to care for annually as enrollees not abusing controlled substances.[30] Overall, the evidence of the effectiveness of the programs is positive: preliminary findings indicate that Medicaid lock-in programs produce significant cost savings, reducing narcotic drug use without affecting patients' need for medications to treat chronic conditions.[31] For example:

Missouri. The state of Missouri reviews the activities of enrollees participating in the state Medicaid program to assess whether they are abusing the program or may be engaging in activities that are wasteful or fraudulent. The factors that Missouri uses in its assessment include: services received, number of ER visits, prescription refill frequency and overlapping prescriptions, the number of different pharmacies where an enrollee obtains prescriptions and the number of prescribing physicians. Individuals with suspect patterns of drug utilization are locked in to a specific prescriber, a specific pharmacy or both for a two-year period, during which time the enrollee's case is periodically reviewed and monitored. Missouri currently has 1,521 active cases for people who are locked in to a specific provider.[32]

Iowa. Iowa analyzes providers to identify those who may have unsafe or unscrupulous prescribing patterns. The state has a program that assigns enrollees whose utilization suggests they are abusing drugs to a specific pharmacy, primary care physician and hospital emergency room.[33]

Louisiana. Enrollees in Louisiana's Medicaid program suspected of abusing pharmacy or physician services are restricted to one provider, one pharmacy or both. Those facing restrictions are asked to choose the doctor and the pharmacy to which they would like to be assigned. Louisiana providers who treat locked-in enrollees that are not assigned to them are not reimbursed for their services.[34]

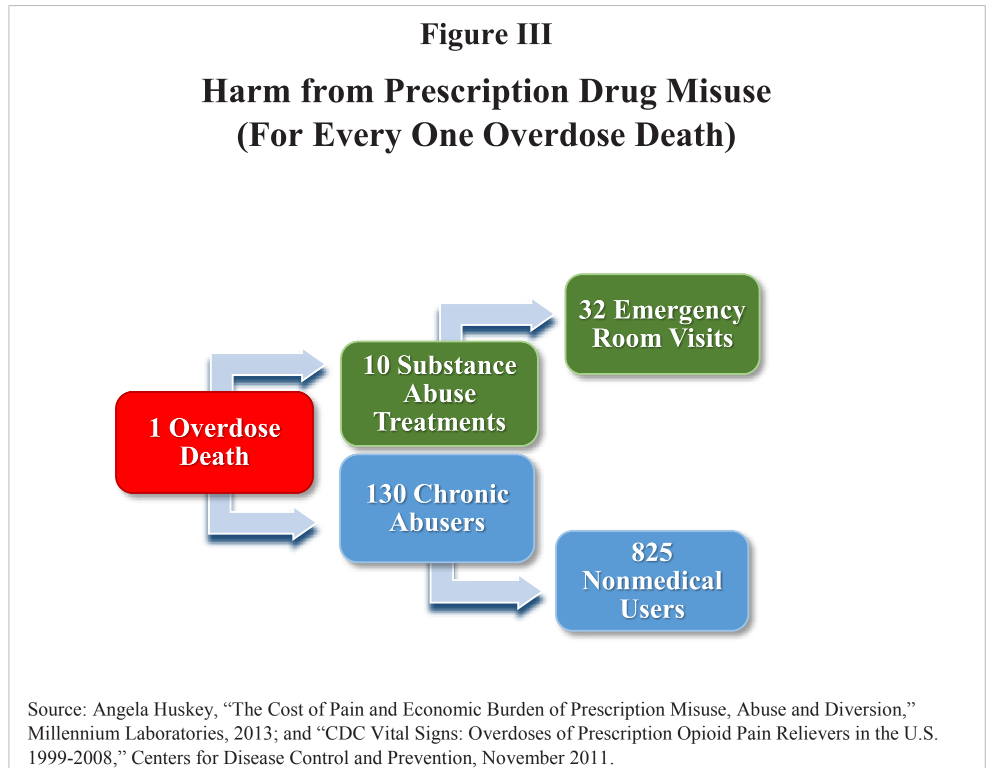
administration now supports allowing drug plans the flexibility to combat fraud using the approach virtually all state Medicaid programs use — a lock-in program.

Problem: Physician Fraud. There are about 894,000 physicians practicing in the United States, and nearly half provide primary care. Though not a significant proportion of physicians, a recent investigation by HHS's Office of the Inspector General found 736 primary care physicians with questionable billing patterns.[35] Some are hurried and have little time to look for the subtle clues of addiction or scrutinize drug-seeking behavior on the part of their patients. Many doctors are likely somewhat naïve about the degree to which they become targets of drug seekers who want prescription narcotics to feed an addiction or resell for profit. The patient who comes in once a month to renew a prescription for oxycodone may appear to have a legitimate need for daily relief from chronic pain; a physician may not realize he is only one of a dozen doctors the patient sees for prescription pain relievers.

In some cases, ignoring or remaining willfully ignorant of blatant drug-seeking behavior is a money-making endeavor. Drug seekers who are addicted (as well as those who resell drugs) are willing to go to great lengths to obtain their drugs — and pay great sums for access to opioid pain relievers. Physicians employed by one Florida pain management clinic earned nearly $1,000 per hour for their time writing prescriptions.[36] Physicians who own their own pain clinic or sell painkillers themselves may earn even more.

Figure III

Harm from Prescription Drug Misuse (For Every One Overdose Death)



Source: Angela Huskey, "The Cost of Pain and Economic Burden of Prescription Misuse, Abuse and Diversion," Millennium Laboratories, 2013; and "CDC Vital Signs: Overdoses of Prescription Opioid Pain Relievers in the U.S. 1999-2008," Centers for Disease Control and Prevention, November 2011.

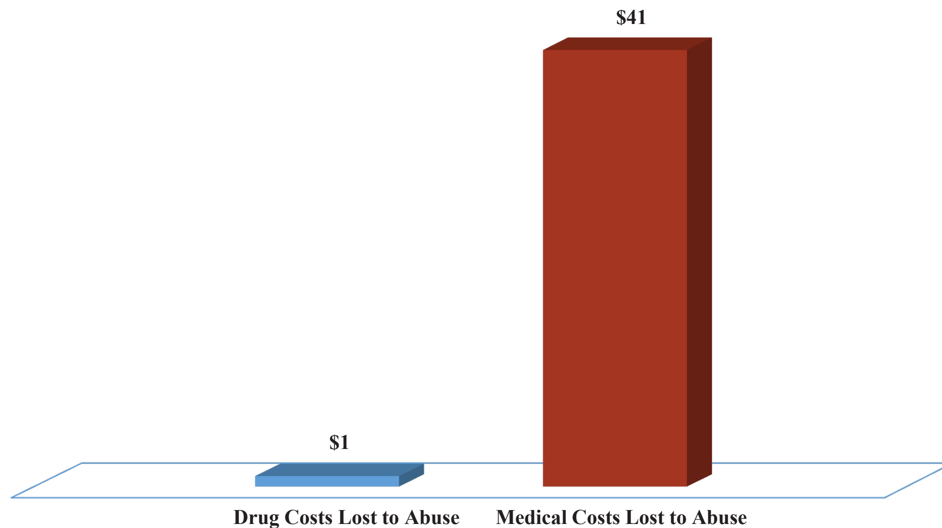
Problem: Florida Pain Clinics. Florida experienced a proliferation of pain management clinics that authorities believe functioned more like illicit drug dealers than medical clinics. Nine states have passed laws regulating pain clinics and so-called pill mills.[37] Under the guise of medical treatment, virtually anyone could go to a Florida pain clinic and obtain powerful narcotic pain relievers regardless of their medical condition. Among the most popular offerings were the opioid pain relievers oxycodone and hydrocodone. In 2010, about 90 percent of the top 100 physicians buying and dispensing oxycodone were located in Florida. The state's pain clinics were thought to be the source of narcotic pain relievers that were resold and made their way into regions as far away Appalachia.[38]

The number of patients a given doctor sees in a day varies with the type of medical practice and the types of medical conditions the doctor normally treats. Consider:

- A family doctor in a typical primary care practice has about 19 patient encounters per day — each lasting an average of about 22 minutes.[39]
- The physicians who were employed by one Florida pain clinic often saw about 100 patients per day.[40]
- At 100 patients per eight-hour day, a physician could only spend less than five minutes with each patient.

When the logistics of getting patients in and out of an exam room is taken into consideration, the doctor would barely have time to do anything more than listen to whatever flimsy excuse the patient contrived as a pretext for needing high-powered painkillers.

To expedite the prescription-writing process, the physicians at



Source: "Prescription for Peril: How Insurance Fraud Finances Theft and Abuse of Addictive Prescription Drugs," Coalition Against Insurance Fraud, December 2007.

this pain clinic used a standardized rubber stamp. Physicians typically dispensed 180 painkillers at a time that had a retail value of about $360. In addition, returning patients generally paid $150 for each office visit.[41] Thus, each doctor working at the pain clinic expected to generate about $50,000 per day in revenue for the clinic. A back-of-the-envelope analysis finds that after compensating the doctor and paying for the wholesale drug costs, the clinic owners might realize $25,000 to $30,000 in profit per day for each doctor they employed.

Solution: Tough Laws in Florida. The lucrative pill mill business model began to crumble after Florida took decisive action to reduce the scourge of drug dealing masquerading as pain management. In 2010, Florida tightened regulations and oversight of pain clinics.[42] The state put into place a statewide prescription-monitoring program, which included a database that tracked the number of prescription painkillers doctors prescribed, as well as the number and identity of drugs dispensed to patients. Physicians who practiced pain management were required to receive special training, and all pain clinics were required to register with the Department of Health. Failure to register a clinic is a felony. It is also a crime for a doctor at an unregistered pain clinic to prescribe drugs or for a pharmacy to dispense drugs prescribed by an unregistered clinic. Additionally, pain management physicians and pain clinics cannot advertise specific drug therapies, such as oxycodone or hydrocodone. Patients paying out-of-pocket for prescription narcotics are limited to a 72-hour supply; providers who violate that regulation are subject to a felony charge.

The state continued its efforts to crack down on the drug business the following year. In 2011, Florida passed House Bill 7095, which prohibited pain management doctors from bypassing pharmacies and dispensing pain relievers directly to patients. After these laws were passed, the number of pain clinics quickly declined by a third, from around 800 to about 500. It could easily be argued that legitimate patients' ability to access painkillers has not been reduced under the new laws. Patients actually suffering chronic pain need the services of a pain management specialist who can help them alleviate that pain, while protecting them from addiction or accidental overdose. It is clear that pain management clinics had little time for those safety measures prior to the reforms. After these changes to the law, the number of Florida residents dying from overdoses fell, according to the CDC.[43]

Problem: Pharmacy Fraud. Most pharmacies are there to serve their customers and fill and dispense prescriptions. But not all pharmacy operators that bill Medicare have honorable intentions — or are even actual pharmacies. The HHS OIG identified 2,636 retail pharmacies with questionable billing patterns in 2009.[44] The types of questionable billing varied — some pharmacies seemed to bill very high dollar amounts per beneficiary, while some billed for a high number of prescriptions per beneficiary. Others billed for a high number of prescriptions per physician prescriber. Such patterns could indicate the drugs were not medically necessary or possibly that they were never actually dispensed. Whatever the case, pharmacy fraud has become a widespread problem in Florida.[45] The number of Medicare Part D fraud investigations has quadrupled in South Florida since 2009, according to OIG testimony before the Senate Committee on Aging.[46]

For example, a couple of secretaries in a Florida physician's office were paid $100 apiece for bogus paper prescriptions that local pharmacies billed to Medicare for drugs that were never actually dispensed. The doctor was not implicated in wrongdoing, but staffers used her office to defraud Medicare. Her office experienced a spike in Medicare prescriptions that jumped from less than $300,000 in 2010 to $5 million in 2012.[47]

In another case, a small pharmacy on the outskirts of Miami had recently been sold but was "reopened" for business under new owners a few weeks later. The previous owners' Medicare billing activity was about $1,000 per week. On a day when OIG investigators observed no customers or employees entering or leaving the storefront, the store billed Medicare about $100,000 for drugs that were never dispensed. One doctor later learned the bogus pharmacy had billed more than $100,000 under his prescribing authority. Within nine days of being reopened under new management, the small pharmacy with no customers had billed Medicare $776,298 for drugs.[48] [See the sidebar, "Bogus Claims Masquerade as Legitimate Claims."]

Problem: It Is Not Just Painkillers. Although drug diversion is most closely associated with opioid pain relievers, there is tremendous potential for diversion to spill over into other lucrative drug classes. Increasingly, highly advanced specialty drugs and biological agents are used to treat rare diseases and disorders that had no treatment (or relatively ineffective treatments) only a few years ago.[52] Some examples of conditions treated with specialty drugs include cancer, multiple sclerosis, HIV, hepatitis C, rheumatoid arthritis and infertility.[53] As newer therapies are developed, highly advanced specialty drugs are increasingly supplanting conventional drug therapies. Spending on prescription drugs has grown tremendously over the past two decades.

A specialty drug is not a therapeutic class or an official designation of the U.S. Food and Drug Administration (FDA). Rather, the term describes some of the latest high-tech therapies. The cost of specialty drug therapies ranges from tens of thousands of dollars to hundreds of thousands annually. A drug regimen using a specialty drug can easily approach $15,000 per year; the most expensive therapy reportedly costs $750,000 per year.[54] Specialty drugs comprised only about 1 percent of prescriptions in 2012, yet spending on these drugs was about one-fourth of all prescription drug spending.[55] [See Figure V.]

Specialty drug expenditures are growing nearly three times faster than spending on conventional drug therapies. In 2011, expenditures on specialty pharmacy were $92 billion.[56] The actuarial consultancy Milliman expects this to increase to $235 billion by 2018.[57] In just a few short years — before the end of the decade — specialty drug therapies could grow to nearly half of all drug expenditures.[58] Pharmaceutical experts predict spending on specialty drugs will gradually displace traditional drug therapies as the major component of drug spending.

Bogus Claims Masquerade as Legitimate Claims

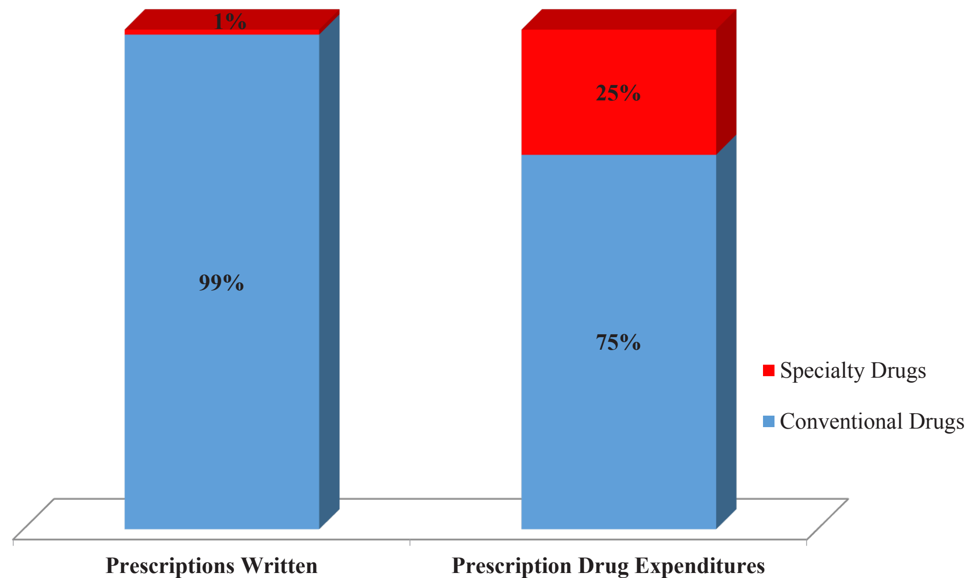
Health care expenditures totaled nearly $3 trillion dollars in 2012.[49] Providers do most of their billing electronically, and claims are typically paid the same way. Submitting medical bills to insurers, health plans and PBMs requires only a limited amount of supporting documentation. Consequently, fraudulent claims are easy to disguise and submit for payment. Concealed among the billions of claims submitted to more than one million providers, fraudulent claims often look just like legitimate claims.[50] Medicare processes about 4.5 million claims on a daily basis — the sheer volume of claims making it easy to disguise fraud.[51]

Companies that process electronic payments have learned how to detect transaction patterns that deviate from the norm. Computer algorithms can examine thousands of medical claims for services or medications for obvious irregularities. For example, a company might red flag a pattern of oral contraceptives being prescribed to male Medicare beneficiaries, as these drugs are ordinarily used only by women of childbearing age. Ferreting out fraudulent claims often involves analysis of retrospective data — that is, a pattern may not emerge until long after a series of fraudulent claims have been processed and paid — and, even after fraud is identified, drug plans have little ability to deal with it. This is one reason why lock-in programs are so valuable.

As prescriptions worth thousands of dollars become increasingly common, so too will the number of people who attempt to divert these drugs for profit. A study by the HHS OIG on the diversion of costly HIV drugs in Medicare Part D identified Miami, Florida, as an area with an especially questionable pattern of HIV drug utilization.[59] [See "Case Study: Human Immunodeficiency Virus."]

Hepatitis C is a virus that attacks the liver and which, over time, can lead to cirrhosis of the liver and liver cancer. A new breakthrough hepatitis C therapy was recently approved by the FDA. The new drug, sofosbuvir, known by a trade name of Sovaldi, was shown to have a high rate of success in actually curing hepatitis C.[62] However, the 12-week course of treatment necessary to cure the disease costs more than $80,000.[63] At $1,000 per pill, it is arguably one of the most costly medications available in pill form. A pill with a retail price of $1,000 would potentially have significant resale value in the diversion market.

Figure V
Prescription Drug Utilization in 2012



Source: "Specialty Therapy Class Forecast 2012," Research and New Solutions Lab, Express Scripts Drug Trend Report, March 5, 2013. http://lab.express-scripts.com/insights/industry-updates/~/media/07e71c2358f244678d1812c80e273014.ashx

Although there are multiple ways to contract hepatitis C, the most common involves direct contact with contaminated blood. Intravenous drug use and sharing needles is a common way hepatitis C is transmitted. While only about 1 percent of the population is thought to have hepatitis C, this proportion skyrockets from 16 percent to 41 percent in the prison population. [64] According to the CDC, perhaps 3.2 million people are infected with hepatitis C. Estimates place the number of incarcerated people with hepatitis C at 1.9 million.[65] Up to a third of the people with hepatitis C cycle through prison or jails in a given year.[66] Many public health experts report that county jails and state prisons have few resources to combat the problem. This is especially true given that many hepatitis patients are asymptomatic and may not develop chronic conditions until years after they have left prison. Most will ultimately be released into the community. Those who are released may qualify for Medicaid, and most will likely be eligible for Medicare at some point.

A hepatitis C patient with a criminal history could easily acquire

Case Study: Human Immunodeficiency Virus

Infection with the Human Immunodeficiency Virus (HIV) is a serious medical condition that, if left untreated, leads to AIDS. The OIG performed an analysis in 2012 of HIV drug utilization. HIV drugs cost the Medicare program $2.8 billion in 2012. Although not a significant proportion of Medicare beneficiaries have HIV, the OIG found about 1,600 people had questionable HIV drug utilization. These beneficiaries used HIV drugs costing Medicare approximately $32 million, or an average of $25,000 piece. For more than half of the enrollees with questionable utilization of HIV drugs (about 900 individuals), there was no indication that they even had HIV. Many filled multiple prescriptions at different pharmacies far in excess of doses normally prescribed. Some utilized a high number of prescribers. It is also possible that the identities of beneficiaries were stolen by unscrupulous pharmacies and the prescriptions were never filled.[60] And purportedly, HIV drugs are sometimes abused to increase the effects of crystal meth.[61]

an excess supply of pills worth $1,000 apiece at retail by visiting numerous doctors for the same condition. The HHS OIG believes that drug fraud can involve a wide range of drugs — especially if those drugs are costly. Although most current lock-in programs primarily involve opioid drugs, the OIG suggests program integrity efforts go beyond opioids and limit beneficiaries from a wider range of inappropriate or unnecessary drugs.[67] Given the cost of Sovaldi and other drugs like it, the problem of diversion of non-narcotics is likely to persist in the future.

Conclusion

In August 2014, the Office of the Inspector General within the U.S. Department of Health and Human Services issued recommendations to reduce questionable drug use by Medicare beneficiaries. Such a program is currently being debated in Congress. In August 2014, the Chairman of the House Ways and Means Subcommittee on Health, Kevin Brady (R-Texas), circulated a draft of a bill designed to help Medicare drug plans reduce fraud. The "Protecting Integrity in Medicare Act of 2014" would give drug plans within Medicare Part D the authority to restrict certain beneficiaries to the use of a single doctor and pharmacy with respect to specific opioids and other high-risk drugs. Drug plans are currently hamstrung by regulations that prevent them from tackling drug abuse, and they need this type of flexibility in order to effectively combat fraud.

Notes

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