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Implications of recent controlled substance policy initiatives

by

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Abbreviations: acetaminophen (APAP), Centers for Disease Control and Prevention (CDC), Center for Medicare and Medicaid Services (CMS), Center for Program Integrity (CPI), Controlled Substance Act (CSA), Drug Enforcement Agency (DEA), Food and Drug Administration (FDA), Food, Drug and Cosmetic Act (FDCA), morphine equivalent dose (MED), National Associations of Boards of Pharmacy (NABP), opioid pain relievers (OPR), Overutilization Monitoring System (OMS), Pharmacy and Therapeutics (P&T), prescription drug monitoring program (PDMP), prescription monitoring program (PMP).

Introduction

Recent legislative and regulatory activity designed to address controlled substance diversion and overuse of narcotics is having a significant impact on prescription drug utilization and patient care in the United States. Although providers and patients are the focus of these new requirements, the designers and implementers of formularies and medication use protocols need to be aware of salient features of these initiatives.

Formulary drug product selection, prior authorization procedures and drug utilization strategies should be reconsidered in accordance with the changes in controlled substance oversight.

The primary focus of this article involves recent approaches to controlling the illegal acquisition of licit prescriptions, particularly opioid pain relievers (OPR). According to the Centers for Disease Control and Prevention (CDC), in 2008 OPRs were involved in 74% of the 20,000 fatal prescription drug overdoses in the United States. This represents an increase of over 300% since 1999 and these fatalities now exceed death by cocaine and heroin combined. [1] Interestingly, the death rate varied five-fold by state, largely reflecting different levels of opioid regulation and oversight. They also noted that sales of OPRs quadrupled between 2000 and 2010 and that OPR abuse cost health insurers over \$72 billion annually in healthcare costs. [2]

Federal legislative and policy strategies

The federal government controls the distribution and access to these dangerous and addictive drugs through the Controlled Substances Act (CSA) and the Food, Drug and

Cosmetic Act (FDCA) as enforced by the Drug Enforcement Agency (DEA). The CSA regulates controlled prescription medication through a tiered system reflecting current accepted medical use of the substance and increased danger for abuse or misuse. [3] Formulary treatment of Schedule II through V varies considerably among ambulatory and institutional healthcare organizations. The overuse and diversion of newer opioid preparations has led to considerable legislative and regulatory activity.

The Center for Medicare and Medicaid Services (CMS) has taken a lead in managing the overuse of opioids and acetaminophen in its beneficiary populations. CMS created the Medicare Part D Overutilization Monitoring System (OMS) that uses claims data to identify individuals at risk. CMS will use OMS to ensure plan sponsors' drug utilization review (DUR) programs are effective in preventing overuse as required in 42 C.F.R §423.153 et seq. Their guidance offers methodology for identifying those outliers at risk for opioid and acetaminophen overutilization. CMS will use the following identifying criteria to define outliers for overuse:

1. Opioid outliers: Excluding patients with cancer or receiving hospice care, beneficiaries whose daily morphine equivalent dose ("MED") is greater than 120 mg for at least 90 consecutive days, and who used more than 3 prescribers and more than 3 pharmacies.
2. Acetaminophen (APAP) outliers: Beneficiaries who may be taking more than 4 g of APAP per day for more than 30 days.

3. Center for Program Integrity (CPI) referral outliers: Beneficiaries referred by the Medicare CPI for review of possible utilization issues. These referrals involve potential fraud or abuse of prescriptions in the Part D program and may include non-opioid cases.

The OMS quarterly reports on overutilization will be available to sponsors through a web portal. Sponsors are required to respond to CMS within 30 days as to the implemented initiatives to address each case. Plan sponsors may include point-of-service (POS) edits in collaboration with prescribers for identified beneficiary. However, if the prescriber is non-responsive to inquiries by the sponsor, the sponsor may proceed without collaboration. [4]

During the current 113th United States Congress, approximately 75 bills have been submitted related to controlled substances. The most viable of these legislative initiatives attempt to address narcotic diversion by encouraging the creation of national registries of controlled substance prescribing, limiting opioid selection by reclassifying certain narcotics to a higher or more regulated classification and enhancing controlled substance reporting and audit requirements at the federal level. Some attempt to preserve liberal opioid prescribing protocols for terminally ill patients and those in intractable pain. [5]

The pharmaceutical manufacturers have been under a great deal of pressure to assist in the overutilization of their products. In January 2013, the Food and Drug Administration (FDA) drafted guidance for manufacturers on abuse-deterrent opioids, evaluation and labeling. [6] In November 2013 the FDA stated that it plans to request

reclassification of hydrocodone combination products from Schedule III to Schedule II as early as December 2013. These products are among the most prescribed pain medications in the country and among the most abused and diverted. [7] This scheduling change certainly may affect pain management protocols and formulary placement of hydrocodone products as the regulatory burden of prescribing hydrocodone increases. A possible unintended consequence of this action might include prescribing shifts to other opioids, including more expensive branded products.

State policy strategies

While the federal government has embarked on numerous controlled substances initiatives under its purview, individual states have attempted to address the problem in a variety of ways. In February of this year, New York rescheduled hydrocodone combination products to CII thus tightening prescribing and eliminating refills. More common amongst the states is the creation of prescription drug monitoring program known as PDMP or PMPs. A typical PMP collects all state-wide controlled substances prescription dispensing data at predetermined intervals and stores it in an electronic database that is available for DUR. The agency responsible for collecting the data would be authorized to share that information with other agencies or individuals so designated by state law. [8] As of July 2013, 47 states had operational PMPs while two were currently operationalizing their PMPs and one state had PMP legislation pending. In addition, 21 of these states are working with the National Boards of Pharmacy (NABP) to integrate their data into NABP's PMP InterConnect that allows sharing of data. [9]

States are using the information in their databases to varying degrees. For example, Kentucky and New York require prescribers register for their PMPs and access the information before prescribing. Kentucky's prescribers must access the database before writing the initial prescription for controlled substances and throughout the patient's treatment. This diligence has seen Kentucky's nonmedical use of prescription pain medication ranking drop from 2nd to 31st in the nation.[10] In August 2013, New York required prescribers to register for PMP access as well as access the PMP before writing for control substances as part of their I-STOP, ACT 2012.[11] Many states generate threshold reports that are sent to prescribers and pharmacists to review. Prescribers and pharmacists are requested to review these reports and discuss with other prescribers/pharmacists who will be responsible for patient care.

Provider concerns related to legal exposure for failing to adhere to PMP regulations has prompted 26 states to specifically provide civil and/or criminal immunity to prescribers and dispensers. These statutes protect certain actions associated with accessing, failing to access, or reporting data to the prescription monitoring program database. [12]

Currently, Wyoming and New York require real time submission of controlled substances claims to their PMP while Delaware, Kansas, Kentucky, Minnesota, North Dakota and West Virginia require reporting within 24 hours. The remaining states vary in submission requirements up to 30 days. [12]

This move toward state PMPs was fostered by several federal policy initiatives and funding opportunities. The U.S. Department of Justice offers seed funding to plan, implement and enhance PMP efforts, while the Department of Health and Human Services administers a program to foster PMPs that meet consistent national criteria and allow for the interstate exchange of data. [11] There have been numerous federal legislative attempts to create a PMP on the national level. [12]

Discussion and Conclusion

Pharmacy has been in the legislative and regulatory forefront on multiple issues in 2013 including the continual battle to address prescription drug diversion. The Department of Justice, DEA, and other local law enforcement agencies have now gained new supporters as a result of the growing problem of legitimate controlled substance prescription diversion and overuse of narcotics across the U.S. The consequences of this diversion include adverse societal, clinical and economic impacts.

As a result of this high profile and recent legislative activity, Pharmacy and Therapeutics (P&T) committees need to discuss where this is leading to regarding assuring the provision of optimal patient care by their organization. Pharmacy organizations are reporting compelling and revealing responses concerning controlled substances to treat acute or chronic pain such as:

- Pharmacists turning away patients due to limits on monthly dispensing

- Wholesaler inspections to assure appropriate dispensing or risk being denied drug orders by that supplier due to past DEA imposed record keeping fines (see call out at end of document)
- Hesitancy by suppliers and other regulatory agencies to provide clear guidance that address many of the gray areas in real-world pharmacy dispensing situations.

Again, questions are being asked about DEA's position on this issue, and placing pharmacists in untenable roles that can conflict with their clinician responsibilities to patient care.

Regardless of individual positions, the high potential for political consensus will continue to drive more action in this area by elected officials at all levels. There is a prescription drug abuse problem in this country and legitimate patients are once again in danger of not having their medical pain needs met. The conflict among regulatory and enforcement agencies at every levels fuels the continuing lack of resolution to the country's drug abuse problem. This is evident in what we have seen with marijuana legislation; federal and state agencies are at odds with one another over its regulation as well as enforcement of legal justice.

Health care entities such as hospitals, health systems, and managed care organizations must be engaged in this complicated yet locally driven issue. The consequences to the systems for ignoring this problem will be exacerbated under reimbursement rules that are gaining momentum under health care reform. The direction of reform is to place the ultimate economic burden at the door of these health care entities. Similar to never

events and continuity of care initiatives, addressing community based health care issues can be an opportunity for health care entities employing effective population health efforts in local communities. The implementation and effect of various health policies around controlled substances remains uneven at best, but the opportunity for creating a better outcome can occur from grassroots efforts that begin with enlightened P&T members of these critically important health care entities.

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DEA Record Keeping Fines

Wifredo A. Ferrer, United States Attorney for the Southern District of Florida, and Mark R. Trouville, Special Agent in Charge, Drug Enforcement Administration (DEA), Miami Field Division, announced that Walgreens Corporation (Walgreens), the nation's largest drug store chain, has agreed to pay \$80 million in civil penalties, resolving the DEA's administrative actions and the United States Attorney's Office's civil penalty investigation regarding the Walgreens Jupiter Distribution Center and six Walgreens retail pharmacies (collectively "Registrants") in Florida. The settlement further resolves open civil investigations in the District of Colorado, Eastern District of Michigan, and Eastern District of New York, as well as civil investigations by DEA field offices nationwide, pursuant to the Controlled Substances Act (the Act).

April 3, 2013 CVS Pharmacy, Inc., and Oklahoma CVS Pharmacy, L.L.C., (collectively "CVS"), have agreed to pay \$11,000,000 to the United States to settle civil penalty claims for record-keeping violations under the Controlled Substances Act and related regulations, announced Administrator Michele M. Leonhart of the Drug Enforcement Administration (DEA) and Sanford C. Coats, United States Attorney for the Western District of Oklahoma.