Rx Ipsa Loquitur

Volume 42 Number 4
July/August 2015

AN OFFICIAL PUBLICATION OF THE AMERICAN SOCIETY FOR PHARMACY LAW

PharMerica Settlements Highlight Potential for Dual False Claims Act and Controlled Substances Act Liability for Invalid Prescriptions

By Barbara Rowland and Matt Newcomer

In a development with significant potential consequences for pharmacies dispensing controlled substances, PharMerica Corporation recently entered into dual federal settlement agreements with the Drug Enforcement Administration (DEA) and the U.S. Department of Health and Human Services (HHS) arising out of the same alleged conduct – dispensing Schedule II controlled substances to long-term care facility patients without DEA-compliant prescriptions and causing Medicare Part D to be billed for the noncompliant prescriptions. These settlements reflect the first major government effort to recover damages and penalties under the federal False Claims Act, 31 U.S.C. §§ 3729-3733, for violations of the Controlled Substances Act (CSA), 21 U.S.C. §§ 801 *et seq*., and its regulations.

In May, PharMerica, a long-term care pharmacy supplying medication to nursing homes and other health care facilities, agreed to pay a total of $31.5 million in civil damages and penalties -- $8 million under the CSA for invalid prescriptions and $23.5 million under the False Claims Act for related Medicare Part D billings. The settlements came after a Wisconsin federal court denied PharMerica's motion to dismiss holding the government's theory of liability that Schedule II drug prescriptions, not compliant with the CSA and its regulations, could constitute false claims to Medicare when billed under the Part D program.

Triggered by a former PharMerica pharmacist's whistleblower action, the Department of Justice filed a complaint-in-intervention alleging that PharMerica violated the CSA and its regulations by providing Schedule II drugs to long-term care facility patients without obtaining a valid prescription from a prescriber within the requisite time period. The specific facts alleged were:

- Employees of long-term care facilities contacted PharMerica closed-door pharmacies by either telephone or facsimile with non-emergency requests for Schedule II drugs for patients. Order forms transmitted by the facilities did not contain prescribers' signatures or the requested drug quantities.
- The pharmacies dispensed the drugs to the facilities while simultaneously preparing and sending templates for completion to patients' physicians identifying the quantities supplied.
- Templates were not returned to PharMerica in many instances, and in others, they were returned after drugs were dispensed.

The government also alleged that PharMerica supplied long-term care facilities with narcotic boxes for emergency situations but did not require prescribers to contact a PharMerica pharmacist before dispensing Schedule II drugs from the narcotics boxes

"No Duty to Warn"

Continued from page 1

or to follow up with written prescriptions for the drugs dispensed within the requisite time period.

Combining these alleged CSA violations with the False Claims Act's remedies available to federal health care programs, the government further alleged that PharMerica violated the False Claims Act by submitting Prescription Drug Event (PDE) claims data to Medicare Part D plan sponsors that inaccurately or incompletely (1) designated the drugs as covered Part D drugs, (2) represented that the drugs were dispensed upon a valid prescription, and (3) identified the prescriber and the prescriber's instructions. The government contended that as a subcontractor provider for Part D plan sponsors, PharMerica was required to comply with all federal laws and regulations including the CSA and its regulations defining a valid prescription.

PharMerica's principal argument in seeking dismissal was that under the Part D program, Medicare pays the plan sponsors a fixed monthly fee not tied to the submission of PDEs. The district court rejected that argument, finding that Medicare annually reconciles its payments to plan sponsors with the actual costs of PDEs for covered Part D drugs and that Medicare's decision to reimburse relies on PDEs accurately representing that prescriptions were for covered Part D drugs.

In addition to the $31.5 million settlement amount, PharMerica entered into a five-year Corporate Integrity Agreement (CIA) with HHS that focused on compliance with the CSA, as well as the more typical obligation of compliance with federal health care program requirements. It is noteworthy that, among other obligations, the CIA requires PharMerica's Board of Directors and senior executives to certify annually that the Company's compliance program and business practices meet CSA regulations, as well federal health care program requirements.

Practice Tips

The PharMerica settlement exemplifies the current interest of the government, and whistleblowers, in using the False Claims Act to recover substantial damages and penalties for not uncommon violations of the CSA and its regulations – violations that until now typically had been resolved by DEA through civil penalties or administrative remedies.

To minimize the dual risk of CSA and False Claims Act liability, pharmacies – retail, mail order, specialty or long-term care – must have in place business practices and compliance programs that establish the proper safeguards for dispensing controlled substances, train employees in those safeguards, and test the safeguards periodically through monitoring and auditing. A well-executed compliance program will go far to demonstrate the pharmacy's good faith, integrity, and commitment to meeting legal requirements and persuade the government that False Claims Act and CSA recoveries are unwarranted.

Barbara Rowland, JD, and Matt Newcomer, JD, are Principals in the Internal Investigations and White Collar Defense Group at Post & Schell, PC's Washington D.C. and Philadelphia offices, respectively.