



Highlights of [GAO-09-341](#), a report to congressional requesters

Why GAO Did This Study

Prescription drug abuse is a growing public health problem. In particular, methadone-associated overdose deaths—those in which methadone may have caused or contributed to the death—have risen sharply. Before the late 1990s, methadone was used mainly to treat opioid addiction but has since been increasingly prescribed to manage pain. Taken too often, in too high a dose, or with other drugs or alcohol, methadone can cause serious side effects and death. Methadone-associated overdose deaths can occur under several different scenarios, including improper dosing levels by practitioners, misuse by patients who may combine methadone with other drugs, or abuse—using the drug for nontherapeutic purposes.

This report examines the regulation of methadone, factors that have contributed to the increase in methadone-associated overdose deaths, and steps taken to prevent methadone-associated overdose deaths.

GAO reviewed documents, laws and regulations, data, and research from relevant state and federal agencies, including the Drug Enforcement Administration (DEA) and the Substance Abuse and Mental Health Services Administration (SAMHSA). GAO also interviewed federal officials, officials in five selected states, officials from professional associations and advocacy groups, and experts in pain management, addiction treatment, and forensic sciences.

View [GAO-09-341](#) or [key components](#). For more information, contact Kathleen King at (202) 512-7114 or kingk@gao.gov.

METHADONE-ASSOCIATED OVERDOSE DEATHS

Factors Contributing to Increased Deaths and Efforts to Prevent Them

What GAO Found

Methadone is regulated as a controlled substance, under federal and state laws and regulations, when used for pain management and addiction treatment. When methadone is used for pain management, it is regulated under federal and state laws and regulations that apply to controlled substances generally and that do not impose requirements unique to methadone. For addiction treatment, however, federal and state laws and regulations impose additional requirements that are specific to the use of methadone in opioid treatment programs (OTP), which treat and rehabilitate people addicted to heroin or other opioids. GAO, however, only reviewed relevant state laws and regulations for five selected states.

Although information on methadone-associated overdose deaths is limited, available data suggest that methadone's growing use for pain management has made more of the drug available, thus contributing to the rise in methadone-associated overdose deaths. Methadone prescriptions for pain management grew from about 531,000 in 1998 to about 4.1 million in 2006—nearly eightfold. Methadone has unique pharmacological properties that make it different from other opioids, and as a result, a lack of knowledge about methadone among practitioners and patients has been identified as a factor contributing to these deaths. DEA data suggest that abuse of methadone diverted from its intended purpose has also contributed to the rise in overdose deaths as the number of methadone drug items seized by law enforcement and analyzed in forensic laboratories increased 262 percent, from 2,865 in 2001 to 10,361 in 2007. Nonetheless, data and research from five states GAO reviewed suggest that the specific circumstances of these deaths are variable because of drug combinations and unknown sources of methadone.

GAO identified selected efforts to prevent methadone abuse and overdose deaths that focused on education, safety, and monitoring. For example, to educate practitioners about using methadone for pain management and addiction treatment, SAMHSA is establishing a physician clinical support system for methadone. To improve safety, in 2006, the Food and Drug Administration (FDA) approved a revised label for methadone tablets that included new safety information regarding the use of methadone for pain and modified dosage instructions for those beginning pain management treatment with methadone. Additionally, to prevent diversion and abuse of controlled substances such as methadone, DEA reports that as of February 2009, 31 states have established prescription monitoring programs. Some officials and experts cautioned that any prevention efforts focused on methadone alone might unintentionally shift similar problems to a different drug.

GAO received comments from the Department of Health and Human Services stating that FDA recently notified manufacturers of certain opioid drug products, such as methadone, that they must take certain steps to ensure that the benefits of these drugs continue to outweigh the risks. The Department of Justice provided GAO with technical comments.