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Senate of Pennsylvania

JOHN H. EICHELBERGER, JR.
30TH DISTRICT

March 15, 2010

TO: All Senators
FROM: John H. Eichelberger, Jr. *JHE*
SUBJECT: Legislation on Methadone Diversion ("Karl's Law")

As I noted in an earlier memorandum, the use of methadone as a treatment for both opioid drug addiction and pain management has expanded dramatically. Prescriptions for methadone increased nearly 700 percent over the last decade alone. Corresponding to this increase in the use of methadone, the National Drug Intelligence Center in the U.S. Department of Justice reported a 109% increase (from 2003 through 2007) in the unlawful diversion of the drug.

Methadone is a drug with its own unique properties. It is potent and long-acting. Unlike other drugs, therapeutic and lethal concentrations overlap with methadone, particularly when someone is just starting to use the drug, giving uneducated, inexperienced users ample time to make deadly mistakes. A dose of the drug can begin to work slowly in the body and last from 12 hours to several days or more. One pill or one dose can kill a non or low opiate tolerant person. Even a day or two after the drug is taken, it has lead to deadly consequences for those who mix alcohol or other drugs.

It should come as no surprise that during this same timeframe of increased prescription and increased diversion, the number of poisoning deaths involving methadone increased 468 percent; and the rate of methadone deaths in younger individuals (age 15 to 24) increased 11-fold, according to the CDC National Center for Health Statistics.

One tragic example of the serious dangers of diverted methadone occurred in October of 2006 when a young man, Karl Hottenstein, sought treatment for an addiction to painkillers prescribed after an auto accident. He was turned down by a hospital and a standard drug treatment provider, and sought assistance from a friend who sold him a liquid dose of methadone diverted from a clinic. Soon thereafter, he was dead.

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According to the FDA, the short duration of analgesic effect with methadone combined with its significantly longer half-life, increase the risk for methadone toxicity. As noted by the Substance Abuse and Mental Health Services Administration (SAMHSA), deaths have occurred among children and adults who have accidentally taken methadone, and fatal intoxications have also occurred during the first weeks of treatment or adjustment of the methadone dose.

Currently, state guidelines in Pennsylvania with regard to methadone clinics are only found in regulation (28 Pa.Code 715.1, et. seq.), rather than in statute, as the General Assembly has yet to formally address this issue. As such, I plan to introduce a bill to address the issues arising from the increased diversion of methadone in the Commonwealth. Specifically, the legislation would amend the "Pennsylvania Drug and Alcohol Abuse Control Act" to do the following:

1. Require all methadone clinics to be open 7 days per week, 365 days per year to limit take-home dosages which can be diverted (currently, clinics only stay open 7 days on a voluntary basis).
2. Require that Narcan (an antidote used to counter the effects of opioid overdose), be given to all patients starting methadone treatment.
3. Require testing for Benzodiazepines. Require a patient who is using Benzodiazepines to obtain a signed waiver from a psychiatrist before providing methadone. (Benzodiazepines possess sedative, hypnotic, muscle relaxant and amnesic actions, and are frequently used by methadone users in combination with methadone to get "high." The drugs are typically used for conditions such as alcohol dependence, seizures, anxiety, panic, agitation and insomnia.)
4. Not allow methadone patients to receive permission to take methadone home for the first six months of treatment (current regulations provide for 3 months).
5. Require a 'peak and trough' test (PTT) for doses of methadone that exceed 150 mgs, for those exceeding 200mgs, also require an EKG. Individuals metabolize methadone differently. In a PTT, a sample is taken after a dose, and another before the next dose. (If the trough is greater than normal, the patient is at risk for adverse effects. Therefore, the doctor should expand the time interval before ordering the next dose or decrease drug dose.)
6. Require criminal investigation and reporting in all methadone-related deaths. According to SAMHSA: "Without reporting by [providers] of overdose events and deaths of patients, some key questions about methadone deaths will remain unanswered."
7. Develop protocols for determining when methadone is no longer an effective treatment for an individual enrolled in a methadone program.

If you would like to co-sponsor this legislation, or have any questions, please feel free to contact Lee Derr of my office by phone at 717-787-5490 or by e-mail at lderr@pasen.gov.

JHE/ld