

New Protections for Safe Prescribing of Opiates

DOVER – Continuing efforts to curb the abuse of opiate pain medication in Delaware, the state agency charged with regulating medical practice and drug prescription recently unveiled rules that will help doctors and pharmacists more closely monitor and control the use of opiates by patients under their care.

The new requirements contain expanded procedures related to prescribing opiates for acute episodes as well as for chronic, long-term pain management. Some components are at the discretion of the prescribing provider while other requirements are situation-based.

The result of an 18-month rulemaking process that included input from medical professionals, public health experts, the Attorney General, and other stakeholders, these regulations were published in the January issue of the Delaware Register of Regulations and will take effect on April 1.

“These regulations can save lives by helping to curb the abuse of opiates in our state. Delaware’s prescription rate for certain opiates is among the highest in the nation, according to the Centers for Disease Control, and we know what many users of heroin tell us: Their drug abuse can be traced back to a time when they were prescribed opiates for an injury or some other valid medical need,” said Secretary of State Jeff Bullock, whose department regulates and licenses prescribers of controlled substances in Delaware. “With these regulations, we are supporting the efforts of those seeking to break that cycle – including doctors, pharmacists, public health workers and our law enforcement agencies.”

Key elements of the new regulations are aimed at controlling

the amount of opiates given to new patients and aggressively monitoring their treatment. First-time opiate prescriptions may not exceed a one week supply under the new rules. If further opiate prescriptions are deemed necessary, further action is required, including a physical exam with discussion of relevant patient history and the risks of opiates, and a check of the statewide [Prescription Monitoring Program](#) database.

Prescribers statewide will receive an overview of the new regulations and also be directed to [HelpIsHereDE.com](#), which contains educational materials about identifying and fighting addiction, sample forms, and a link to access the Prescription Monitoring Program.

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FACT SHEET – New Opiate Regulations, Jan. 2016

Key elements related to prescribing for an acute episode (injury or procedure) include:

- A first-time prescription to an adult patient for an acute episode cannot exceed a 7-day supply
- No prescription to a minor can exceed a 7-day supply at any time If professional judgment dictates more than a 7-day supply is necessary
 - o Document the condition triggering the prescription
 - o Query the Prescription Monitoring Program to obtain a prescription history
 - o Indicate that a non-opiate alternative was not appropriate
 - o Obtain Informed Consent
 - o Administer a fluid drug screen, at the discretion of the provider
 - o Conduct a physical examination which must include a documented discussion to elicit relevant history, explain risks/benefits of opioid analgesics and possible

alternatives, and establish other treatments tried or considered

- o Schedule periodic follow-up visits and evaluations to monitor progress, whether there is an available alternative to opiate use, and whether to refer the patient for a pain management or substance abuse consultation

Key elements related to prescribing for chronic, long-term treatment with an opiate include:

- Those listed above
- Query the PMP
 - o At least every six months and more frequently if clinically indicated
 - o Whenever the patient is also being prescribed a benzodiazepine
 - o Whenever the patient is assessed to potentially be at risk for substance abuse or misuse
 - o Whenever the patient demonstrates loss of prescriptions, requests for early refills, or similar behavior
- Administer fluid drug screens at least every six months
- Obtain a signed Treatment Agreement

Informed Consent elements must include at least:

- The drug's potential for addiction, abuse, and misuse
- The risks of life-threatening respiratory depression associated with the drug
- Potential for fatal overdose as a result of accidental exposure, especially in children
- Neonatal opioid withdrawal symptoms
- Potential for fatal overdose when interacting with alcohol
- Other potentially fatal drug interactions, such as with benzodiazepines

Treatment Agreement elements must include:

- The patient's agreement to take medications at the dose and

frequency prescribed, with a specific protocol for lost prescriptions and early refills

- Reasons for which medication therapy may be re-evaluated, tapered or discontinued, including but not limited to violation of the Treatment Agreement or lack of effectiveness
- The requirement that all chronic pain management prescriptions are provided by a single practitioner or a limited, agreed-upon group of practitioners
- The patient's agreement to not abuse alcohol or use other medically unauthorized substances or medications
- Acknowledgment that a violation of the agreement may result in action as deemed appropriate by the prescribing practitioner such as a change in the treatment plan, a referral to a pain specialist, or referral to an addiction treatment programs
- The requirement that fluid drug screens be performed at random intervals at the practitioner's discretion, but no less than every six months.