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COMBATING OPIATE ABUSE ACROSS THE DRUG SUPPLY CHAIN

Stronger Regulation of Drug Wholesalers Provides Better Tools to Find and Stop Illegal Distribution of Prescription Drugs in Ohio

Ohio has helped lead the way in the national response to the opiate epidemic by practicing an aggressive, agile and coordinated approach to its law enforcement interventions, policy and regulatory actions, treatment efforts and prevention outreach.

OHIO'S PROGRESS TO DATE

- **Fighting Prescription Drugs:** Upon taking office, Gov. Kasich launched the most aggressive efforts Ohio had ever seen to combat prescription opiate abuse by shutting down pill mills and going after crooked health care providers. Coordinated efforts between the Administration, local officials, regulatory boards and other leaders led to the closure of pill mills and enforcement actions against more than 300 health care professionals. Prescribing guidelines and new mandatory restrictions on opiate prescribing for acute pain has reduced the number of opiate prescriptions by 162 million doses, 20.4 percent, from 2012 to 2016.
- **Heroin and Fentanyl:** As the epidemic pivoted toward cheap heroin and fentanyl, aggressive interventions by law enforcement resulted in a record number of drug seizures over the past five years and an increase in drug arrests of more than 100 percent.
- **Drug Treatment:** 500,000 low-income adults are now getting mental health and addiction treatment through Medicaid expansion. Ohio has funded more than 1,500 new recovery housing beds to assist Ohioans seeking sober environments post-treatment; 140 specialized docket courts in 42 counties receive funding for jail-based treatment and diversion programming; and expanded treatment programs inside Ohio's prisons provided more than 3,500 individuals a seamless link with post-release programs.
- **Prevention and Education:** The most effective efforts against the epidemic, however, are prevention, which is why the governor launched, *Start Talking!*, a drug-prevention program aimed to keep young people from abusing drugs to begin with. Combining a variety of already-proven outreach tools programs, *Start Talking!* has engaged more than 182,000 students and has provided parent tips to more than 60,000 adults.
- **Better Information:** Ohio has built the nation's leading electronic system for monitoring and tracking opiate prescribing and dispensing, which has dramatically increased the ability for law enforcement and regulatory officials to make sure that Ohio's laws are being followed and to respond to problems quickly.

NEW REGULATIONS FOR DRUG WHOLESALERS

Now Ohio is expanding its monitoring and tracking tools to the more than 500 wholesale pharmaceutical distributors doing business in the state, the companies that buy drugs from manufacturers and resell them to the some 20,000 Ohio pharmacies, doctors, clinics and hospitals that, in turn, sell and dispense and administer directly to patients. Wholesalers often have substantial information about the overall flow of drugs, and large spikes in their shipments hint at problematic activity that could be illegal. Giving law enforcement and regulatory officials a better, more consistent and more accurate understanding of these kinds of shipments – and giving them better tools to ensure compliance – will only help make Ohio safer from the opiate epidemic and those who would seek to profit from it. With these new regulations in place, Ohio will have one of – if not the most – comprehensive and rigorous approaches to combating the opiate epidemic of any state in the nation.

To help fill in the gap created by increasingly weak federal laws and regulations, Gov. Kasich and Ohio's Board of Pharmacy have worked together to develop new regulations on drug wholesalers in order to give officials better tools to combat prescription abuse. Highlights include:

- **Suspicious Orders Reporting – More Uniform, Detailed and Timely:** Orders that wholesalers believe to be suspicious must be reported to the federal Drug Enforcement Administration. Most states, including Ohio, model their own reporting regulations on those used by the DEA, but it is clear that improvements can be made. Instead of waiting on the federal

government to act, Ohio will create new requirements with detailed definitions and uniform, electronic reporting formats, to make sure officials are alerted to emerging problems before they get out of control.

- **Due Diligence – Requiring Wholesalers to Better Research Their Customers:** Wholesalers will be required to obtain more detailed, precise information on those to whom they sell opiates and other controlled substances, including conducting site-visits and reviewing drug utilization reports so that they have deeper data sets to use when evaluating if an order is suspicious or not.
- **Shipping Controls – Holding Suspicious Orders Until All Questions Are Answered:** No wholesaler will be permitted to ship any order that is deemed to be suspicious under the new requirements. Wholesalers will be responsible for reviewing all suspicious orders to determine if orders are reasonable prior to sale. Orders that are not deemed reasonable based upon the required review criteria are prohibited from being sold.
- **Developing Additional Enforcement Penalties for Violations:** New enforcement penalties will be created to address violations for failing to comply with these new rules.

In order to effectively use its current and new data in enforcement activities, the Board of Pharmacy is developing data analytics tools to monitor wholesale drug sales with the help of experts in the field. These new capabilities will be an important compliment to existing and new regulatory authority in order to help safeguard Ohioans from the opiate epidemic.

BOTTOM LINE: Wholesalers are a critical central link in the drug supply chain and can play an important role in alerting officials to problems on the frontlines. New regulations will help define that role more clearly and create uniform, consistent guidelines for what is expected from wholesalers and how they can comply. With additional data from wholesalers, Ohio regulatory and law enforcement officials will be able to make Ohio's work to combat prescription drug abuse even more effective and save more lives from the addiction epidemic.

