

OHIO STATE BOARD OF PHARMACY

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-Equal Opportunity Employer and Service Provider-

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Ohio House Bill 314: Prescribing Opioids to Minors Effective September 17, 2014

Effective September 17, 2014, HB 314 requires all prescribers (physicians, PAs, APRNs, optometrists, dentists and podiatrists) to obtain explicit informed consent, in the absence of a medical emergency or other specified circumstances (see below), if they intend to prescribe to minors controlled substances containing opioids.

The informed consent requirement has three components: assessing the minor's mental health and substance abuse history; discussing with the minor and the minor's parent, guardian, or another authorized adult certain risks and dangers associated with taking controlled substances containing opioids; and obtaining the signature of the parent, guardian, or authorized adult on a consent form. Additionally, the new law limits to not more than a 72-hour supply the quantity of a controlled substance containing an opioid that a prescriber may prescribe to a minor when another adult authorized by the minor's parent or guardian gives the required consent.

Please note: HB 314 requires written documentation of informed consent when prescribing opioids to a minor. A signed "Start Talking" consent form must be maintained in the minor's medical record and the form must be separate from any other document the prescriber uses to obtain informed consent for other treatment provided to the minor.

To assist prescribers with this requirement, the State Medical Board of Ohio has developed a "Start Talking" Consent Form, which can be accessed here:

http://www.med.ohio.gov/pdf/NEWS/Start%20Talking!%20Model%20Consent%20Form%20-%20Med%20Bd%20August%202014.pdf

To assist with the processing of the prescription at the pharmacy, prescribers are strongly encouraged to either include a signed copy of the informed consent document with the prescription or document on the prescription itself that consent was obtained. If informed consent was not obtained, prescribers are further requested to document on the prescription which of the statutory exemptions applies (see below). **Exemptions**

The law specifies that the informed consent requirement does not apply when any of the following is the case:

- (1) The minor's treatment is associated with or incident to a medical emergency;
- (2) The minor's treatment is associated with or incident to surgery, regardless of whether the surgery is performed on an inpatient or outpatient basis;

- (3) In the prescriber's professional judgment, fulfilling the bill's informed consent requirement would be a detriment to the minor's health or safety;
- (4) The minor's treatment is rendered in a hospital, ambulatory surgical facility, nursing home, pediatric respite care program, residential care facility, freestanding rehabilitation facility, or similar institutional facility. This exemption does not apply, however, when the treatment is rendered in a prescriber's office that is located on the premises of or adjacent to any of the foregoing facilities or locations; OR
- (5) The prescription is for a compound that is a controlled substance containing an opioid that a prescriber issues to a minor at the time of discharge from a facility or other location described in (4), above.

Definitions

"Another adult authorized to consent to the minor's medical treatment" means an adult to whom a minor's parent or guardian has given written authorization to consent to the minor's medical treatment.

A "medical emergency" is a situation that in the prescriber's good faith medical judgment creates an immediate threat of serious risk to the life or physical health of a minor.

A "minor" is a person under 18 years of age who is not emancipated. (For purposes of the law's informed consent requirement only, the law specifies that a person under 18 years of age is to be considered emancipated only if the person has married, entered the armed services of the United States, became employed and self-sustaining, or has otherwise become independent from the care and control of the person's parent, guardian, or custodian.)

What is the role of the pharmacist in enforcing this new law?

Pharmacists have a corresponding responsibility to ensure that a prescription issued by a prescriber is compliant with all state and federal laws. If the minor meets any of the exemptions listed in this document, then the pharmacist can safely assume, using professional judgment, that no consent form is required. If, however, they receive a prescription for a minor that does not meet the exemptions under the law (using professional judgment or indicated on the script) and no consent is indicated on the prescription (or no copy of the signed consent is included), then the pharmacist should verify with the doctor that a consent form was completed (or was not required) prior to dispensing. It is recommended that the pharmacist document the informed consent or the reason why it is not required in the patient record.

What is an Opioid?

The Ohio State Board of Pharmacy considers an opioid (analgesic) as a drug derived from or related to opium used in the management of pain through the activation of the mu receptor. It may also be utilized for its antitussive effects. Opioid analgesics include, but are not limited to, the following drugs:

Generic Name	Brand Name	Schedule
Buprenorphine	BUTRANS, BUPRENEX	Schedule III
Butorphanol	BUTORPHANOL NS	Schedule IV
Codeine (acetaminophen and	TYLENOL W. CODEINE #3, TYLENOL	Schedule III

¹Used to prevent or relieve a cough. Updated 9.3.2014

other combination products)	W. CODEINE #4	
Dihydrocodeine/ASA/caffeine	SYNALGOS-DC	Schedule III
Fentanyl	DURAGESIC, ACTIQ, ABSTRAL, LAZANDA, FENTORA, SUBSYS, SUBLIMAZE, ONSOLIS, IONSYS	Schedule II
Hydrocodone	ZOHYDRO ER	Schedule II
Hydrocodone (acetaminophen combination products)	XODOL, MAXIDONE, ZYDONE, LORCET, HYCET, ZAMICET, CO- GESIC, ZOLVIT, STAGESIC, LIQUICET, LORTAB, VICODIN, NORCO	Schedule II (Effective October 6, 2014)
Hydrocodone (ibuprofen combination products)	IBUDONE, REPREXAIN, VICOPROFEN	Schedule II
Hydromorphone	DILAUDID, EXALGO	Schedule II
Meperidine	DEMEROL	Schedule II
Methadone	DOLOPHINE, METHADOSE	Schedule II
Morphine Sulfate	MS CONTIN, AVINZA, DURAMORPH, KADIAN, DEPODUR, ASTRAMORPH, IMFUMORPH	Schedule II
Oxycodone	OXECTA, ROXICODONE, OXYCONTIN	Schedule II
Oxycodone (acetaminophen, aspirin and other combination products)	PERCODAN, PERCOCET, ROXICET, ENDOCET, XOLOX, TYLOX, PRIMLEV, MAGNACET, XARTEMIS XR	Schedule II
Oxymorphone	OPANA, NUMORPHAN	Schedule II
Tapentadol	NUCYNTA	Schedule II
Tramadol	ULTRAM, ULTRACET, RYZOLT, CONZIP, RYBIX	Schedule IV

More Information

For more information on the law, see the following links:

Law Text: http://www.legislature.state.oh.us/bills.cfm?ID=130_HB_314

Legislative Service Commission Bill Analysis:

http://www.lsc.state.oh.us/analyses130/h0314-rs-130.pdf

Questions

If you are a pharmacist, pharmacy intern or location licensed as a terminal distributor of dangerous drugs, please contact the Ohio State Board of Pharmacy at 614-466-4143. If you are a prescriber, please contact your respective regulatory board using the information below.

State Medical Board of Ohio: (614) 466-3934

Ohio Board of Nursing: (614) 728-2504

Ohio State Dental Board: (614) 466-2580

Ohio State Optometry Board: (614) 466-5115