

PRESCRIBING OPIOIDS TO MINORS

Updated 12-30-2014

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), prior to issuing a minor an initial prescription for any drug classified as an opioid.

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.

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/DNN/PDF-Folders/Center-Panel/Start-Talking-Model-Consent-Form.pdf

(Please note: This specific consent form is not required by law. A prescriber or health care facility can develop their own form as long as it contains the three required components listed in the previous paragraph).

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 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;

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- (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, emergency facility¹, 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.)

"Hospital" is defined as an institution for the care and treatment of the sick and injured that is certified by the department of health and approved by the state board of pharmacy as proper to be entrusted with the custody of controlled substances and the professional use of controlled substances.

What is the role of the pharmacist in enforcing this new law? (UPDATED 9.9.2014)

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 informed consent by the prescriber is required. If, however, they receive a prescription for a minor that does not meet the exemptions under the law (using professional judgment) and no consent is indicated on the prescription (or no copy of the signed consent is included), then the pharmacist should verify with the prescriber 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. Please note: The pharmacist must ultimately decide what is in the best interest of the patient and the lack of informed consent does not preclude a pharmacist from dispensing an opioid prescription to a minor.

¹ "Emergency facility" means a hospital emergency department or any other facility that provides emergency care.

What is an Opioid?

Effective March 20, 2015, section 3719.01 of the Ohio Revised Code defines an "opioid analgesic" as a controlled substance that has analgesic pharmacologic activity at the opioid receptors of the central nervous system, including the following drugs and their varying salt forms or chemical congeners:

Generic Name	Brand Name	Schedule
Buprenorphine	BUTRANS, BUPRENEX	Schedule III
Butorphanol	BUTORPHANOL NS	Schedule IV
Codeine (acetaminophen and other combination products)	TYLENOL W. CODEINE #3, TYLENOL W. CODEINE #4	Schedule III
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 (Effective

More Information

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

Law Text: http://archives.legislature.state.oh.us/bills.cfm?ID=130 HB 314

Legislative Service Commission Bill Analysis: http://www.lsc.ohio.gov/analyses130/14-hb314-130.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 State Dental Board: (614) 466-2580

Ohio Board of Nursing: (614) 728-2504 Ohio State Optometry Board: (614) 466-5115