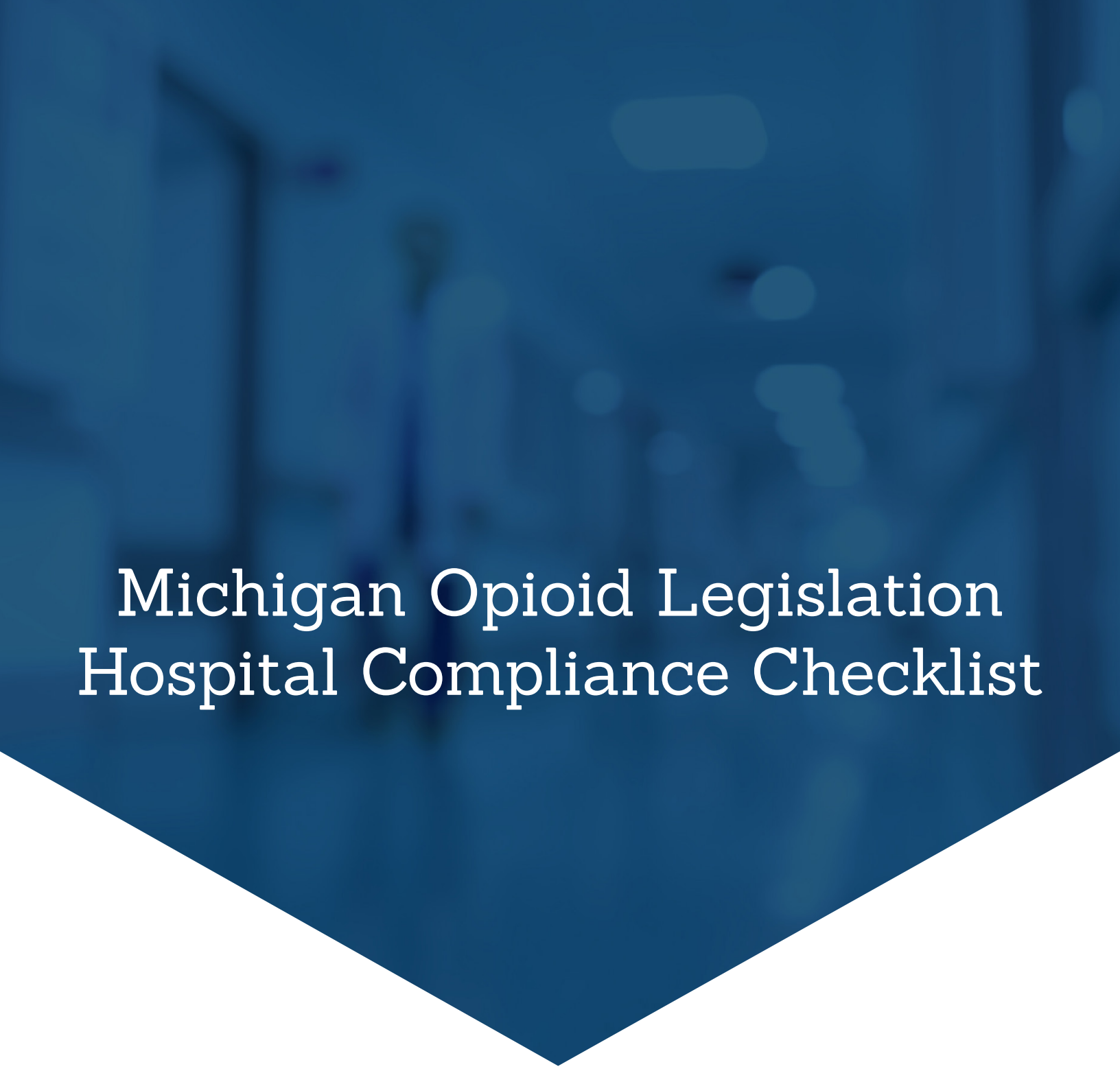

Michigan Opioid Legislation Hospital Compliance Checklist

MHA Keystone Center

A Certified Patient Safety Organization

MHA KEYSTONE CENTER
MICHIGAN OPIOID LEGISLATION
HOSPITAL COMPLIANCE CHECKLIST

The Michigan Opioid Legislation Hospital Compliance Checklist was created by the Michigan Health & Hospital Association to help guide its member hospitals through the requirements of a package of bills signed into law in December 2017 in response to the opioid epidemic.

The laws include provisions that require prescribers to review patient medical records and history, create and maintain records of a patient's medical condition, and ensure a plan for follow-up care is in place before prescribing Schedule II-V controlled substances to a patient. The MHA was a member of Gov. Snyder's Michigan Prescription Drug and Opioid Abuse Taskforce and understands that the misuse of prescription drugs is a national problem that has reached epidemic proportions. Michigan hospitals remain committed to being part of the solution while ensuring patients receive the most appropriate care and treatment for their individual healthcare needs.

Additional information and resources are available on the MHA's Opioid Epidemic webpage at mha.org.

DISCLAIMER

Updated May 17, 2018
This document was created by the MHA to support its member hospitals and does not constitute legal advice. Please note that guidance from the state of Michigan is subject to change, and organizations are encouraged to contact legal counsel for legal advice.

MHA KEYSTONE CENTER
MICHIGAN OPIOID LEGISLATION
HOSPITAL COMPLIANCE CHECKLIST
May 2018

Controlled Substance ("CS") and Opioid Antagonist Dispensing The hospital has in place policies, procedures and recordkeeping systems that accomplish the following objectives.	
___	Block the pharmacist's ability to dispense "additional quantities" of a CS (except CS 5 that do not contain an opioid).
___	Prohibit filling a CS 2 prescription more than 90 days after the date on which prescription was issued.
___	Permit partial filling of CS 2 prescriptions in compliance with federal law and regulations. (References to partial filling for "terminally ill patients" is removed from policies, procedures and recordkeeping systems.) Federal law permits partial fill of CS 2 prescriptions provided the following conditions are met: 1. The prescription is written and filled in accordance with federal and state law. 2. The partial fill is requested by the prescriber or the patient. 3. The total quantity dispensed in all partial fills does not exceed the total quantity prescribed. 4. Except in emergency situations involving non-written prescriptions, remaining portions are filled within 30 days of the date the prescription is written. 5. For emergency situations involving non-written prescriptions, remaining portions are filled within 72 hours after the prescription is issued.
___	Prohibit filling or refilling a CS 3 or 4 prescription more than 6 months after the date of the prescription.
___	Prohibit filling or refilling a CS 3 or 4 prescription that does not contain specific instructions from the prescriber regarding refills.

___	Prohibit refilling a CS 3 or 4 prescription more than 5 times; a new or renewed prescription is required after the 5th refill.
___	Prohibit distributing or dispensing a CS 5 drug for other than a medical purpose.
___	Require all CS prescriptions to contain the quantity of CS prescribed in both written and numerical terms. (This may include pre-printed amounts to be checked by the prescriber.)
___	Facilitate receipt of electronically transmitted CS prescriptions in a manner that does not alter, modify, or extract data during the transmission process.
___	Prevent dispensing more than a 7-day supply of an opioid within a 7-day period for a patient being treated for *acute pain*.[1] (To accomplish this, consider default categorization of all inpatient/outpatient opioid orders as treatment for "acute pain," and/or requiring prescribers to note on the prescription/order when a CS prescription is not for purposes of treating acute pain.) (Effective Date 7-1-18)**
___	If the hospital pharmacy plans to dispense opioid antagonists under the standing order of the chief medical officer of the Department of Health and Human Services ("DHHS"), the hospital is registered with DHHS to do so.
___	Each hospital pharmacist who dispenses an opioid antagonist under the DHHS standing order has received training in the proper use and administration of opioid antagonists and training on opioid overdose response.
___	A hospital pharmacist who dispenses opioid antagonists under the DHHS standing order provides to each indivdiual seeking an opioid antagonist, the DHHS-approved educational materials on the proper administration of opioid antagonists, and documents same.
___	A hospital pharmacist who dispenses opioid antagonists under the DHHS standing order provides to each indivdiual seeking an opioid antagonist resource information regarding referral for substance use disorder services ("SUDS"), and documents same.

___	A hospital that is registered with DHHS to dispense opioid antagonists under the DHHS standing order submits the following information to DHHS each quarter, in the manner established by DHHS: 1. Total number of opioid antagonist doses dispensed under the standing order. 2. Total number of opioid antagonist doses dispensed under any type of order, including the standing order. 3. The number of each type of formulation dispensed. 4. Any other information required by DHHS.

Patient Care and Prescribing

The hospital has developed and implemented policies, procedures, educational materials and recordkeeping systems that accomplish the following objectives.

NOTE: For purposes of this Checklist, "prescriber" refers only to a practitioner legally authorized to prescribe who is prescribing for a registered hospital patient, or who is prescribing as part of his/her duties under an employment or independent contractor arrangement with the hospital.

___	The hospital has available educational materials describing SUDS available in the hospital's service area.
___	The hospital provides to patients who come to the hospital for treamtment of an *opioid-related overdose*[2] and to their families or representatives, information on SUDS, and documents same.
___	Each prescriber who writes a CS 2-5 prescription is in a compliant *bona fide prescriber-patient relationship*[3] with the patient for whom the CS 2-5 prescription is written. (Effective Date 3-31-19, or earlier date of implementing rule)
___	Each prescriber who writes a CS 2-5 prescription provides follow-up care to the patient to monitor the efficacy of the CS as a treatment for the patient's medical condition. If the prescriber is unable to provide follow-up care, the prescriber refers the patient to the patient's primary care provider for follow-up care, or, if the patient has no primary care provider, refers the patient to another licensed prescriber who is geographically accessible to the patient for follow-up care. (Effective Date 3-31-19, or earlier date of implementing rule)
___	Each prescriber documents in the patient's record the arrangement for follow-up care after prescribing a CS 2-5 prescription for a patient. (Effective Date 3-31-19, or earlier date of implementing rule)

___	Each prescriber who writes a CS prescription containing an opioid for a minor limits the prescription to no more than a single, 72-hour supply of the CS containing an opioid when the individual signing the required *Opioid Start Talking* form is not the minor's parent or guardian, but is another adult authorized to consent to the minor's medical treatment. (Effective Date 6-1-18)
___	A prescriber who is treating an inpatient or outpatient for acute pain does not prescribe more than a 7-day supply of an opioid within a 7-day period. (Effective Date 7-1-18)

	<u>Michigan Automated Prescribing System (MAPS) Requirements</u> **The hospital has in place policies, procedures and recordkeeping systems that accomplish the following objectives.** (Effective Date 6-1-18)
___	Each prescriber who may write CS 2-5 prescriptions and the prescriber's delegates are registered with MAPS prior to 6-1-18.
___	Each prescriber who writes a CS 2-5 prescription in a quantity that exceeds a 3-day supply to obtains and reviews a MAPS report concerning that patient prior to prescribing. *<u>Exemption</u>*: A MAPS query is not required if the dispensing <u>and</u> administration of the CS to the patient occurs in a licensed hospital or freestanding surgical outpatient facility.
___	Each prescriber who writes a CS prescription documents performance of the required MAPS query in the patient's medical record.
___	Each pharmacist or dispensing prescriber who dispenses a CS reports the required data elements to MAPS for each CS prescription dispensed. *<u>Exemption</u>*: A licensed hospital that administers the CS to an individual who is an inpatient is not required to report the CS dispensing/administration to MAPS. *<u>Exemption</u>*: A health facility or agency licensed under Article 17 of the Public Health Code is not required to report to MAPS a CS that is dispensed by a dispensing prescriber in a quantity adequate to treat the patient for not more than 48 hours.
___	(If the hospital operates a *SUDS program*[4]) Each prescriber, obtains and reviews a MAPS report before prescribing or dispensing buprenorphine or a drug containing buprenorphine or methadone to a patient in the hospital SUDS program.
___	(If the hospital operates a SUDS program) Each dispensing prescriber reports the required data elements to MAPS in connection with dispensing any drug containing buprenorphine or methadone to a patient in the hospital SUDS program, provided federal law does not prohibit reporting of data concerning the patient.

Opioid Consent and Information Forms

The hospital has in place policies, procedures and recordkeeping systems that require the use and retention of the following two forms, or the single, LARA-prepared Opioid Start Talking Form that combines the elements of these two forms**:**

- (a) Start Talking Form and (b) Opioid Information Form

or

- LARA Opioid Start Talking Form (MDHHS 5730)

NOTE: A hospital is required to use a LARA-approved *Opioid Information* form to satisfy the opioid information requirements of the Code, but is permitted to develop its own *Start Talking Form*. Because use of the LARA Opioid Start Talking Form will satisfy both the *Start Talking* form and the *Opioid Information* form requirements, this Checklist assumes the hospital will use the LARA Opioid Start Talking Form.

(Effective Date 6-1-18)

___	Before issuing a prescription for a CS that contains/is an opioid, each prescriber (for *minor*[5] patients) or another *health professional*[6] (permitted for non-minor patients only) shall provide the information listed on the LARA Opioid Start Talking Form to, and obtain the dated signature of the patient/*patient representative*[7]/parent/guardian/other *adult authorized to consent to a minor's treatment*,[8] as appropriate.
___	For opioid prescriptions for minors, the prescriber also signs and dates the LARA Opioid Start Talking Form where indicated, prior to issuing the prescription.
___	The health professional who provides opioid information to an adult patient is not required to sign the LARA Opioid Start Talking Form; only the adult patient's/patient's representative's dated signature is required.
___	The hospital retains a copy of the signed and dated LARA Opioid Start Talking Form in the patient's medical or clinical record.

___	The hospital is not required to use the LARA Opioid Start Talking Form in the following situations: 1. The CS is being prescribed for inpatient use with any patient who is not a minor. 2. The CS is being prescribed for inpatient use with any patient who is a minor in one of the following situations: • Minor's treatment is associated with or incident to a *medical emergency*.[9] • Minor's treatment is associated with or incident to inpatient surgery. • In the prescriber's professional medical judgement, using the form and/or process would be detrimental to the minor's health or safety. • The minor's treatment is rendered in a hospice or in the oncology department of a licensed hospital. • The prescriber is issuing the prescription when the minor is being discharged from a hospice or from the oncology department of a licensed hospital. • Consent of the minor's parent/guardian is not legally required for the minor to obtain treatment.

****Note: All checklist requirements are currently in effect unless a different Effective Date is given.**

[1] *Acute pain* means pain that is the normal, predicted physiological response to a noxious chemical or a thermal or mechanical stimulus and is typically associated with invasive procedures, trauma, and disease and usually lasts for a limited amount of time.

[2] *Opioid-related overdose* means a condition, including, but not limited to, extreme physical illness, decreased level of consciousness, respiratory depression, coma, or death, that results from the consumption or use of an opioid or another substance with which an opioid was combined or that a layperson would reasonably believe to be an opioid-related overdose that requires medical assistance.

[3] *Bona fide prescriber-patient relationship* means a treatment or counseling relationship between a prescriber and a patient in which both of the following are present:

(1) The prescriber has reviewed the patient's relevant medical or clinical records and completed a full assessment of the patient's medical history and current medical condition, including a relevant medical evaluation of the patient conducted in person or via telehealth; and
(2) The prescriber has created and maintained records of the patient's condition in accordance with medically accepted standards.

[4] *Substance use disorder or SUDS program* means a substance use disorder program as defined under the Michigan Mental Health Code, an approved service program as defined under the Michigan Mental Health Code, a nonregulated substance use disorder services program, a federal certified substance use disorder services program, or a federally-regulated substance use disorder services program.

[5] *Minor* means an individual under 18 years of age who is not legally emancipated.

[6] *Health professional* means an individual who is licensed, registered or otherwise authorized to engage in a health profession under Article 15 of the Michigan Public Health Code.

[7] *Patient's representative* means a guardian of a patient, if appointed, or a parent, guardian or person acting in loco parentis, if the patient is a minor, unless the minor lawfully obtained health care without the consent or notification of a parent, guardian or other person acting in loco parentis.

[8] *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.

[9] *Medical emergency* means 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 the minor.

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