NOTICE OF FINAL EXPEDITED RULEMAKING
TITLE 9. HEALTH SERVICES
CHAPTER 10. DEPARTMENT OF HEALTH SERVICES
HEALTH CARE INSTITUTIONS: LICENSING

PREAMBLE

1. Articles, Part, and Sections Affected (as applicable) — **Rulemaking Action**

R9-10-120 — Amend

2. Citations to the agency's statutory rulemaking authority to include authorizing statutes (general) and the implementing statutes (specific):

Authorizing statute: A.R.S. §§ 36-132(A)(1) and 36-136(G)

Implementing statutes: A.R.S. §§ 36-405, 36-406, and 32-3248.01, as revised by Laws 2022, Ch. 134

3. The effective date of the rules:

The rule is effective the day the Notice of Final Expedited Rulemaking is filed with the Office of the Secretary of State.

4. Citations to all related notices published in the *Register* as specified in R1-1-409(A) that pertain to the record of the proposed rule:

Notice of Rulemaking Docket Opening: 28 A.A.R. 1984, August 5, 2022

Notice of Proposed Expedited Rulemaking: 28 A.A.R. 2202, September 2, 2022

5. The agency's contact person who can answer questions about the rulemaking:

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6. **An agency's justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking:**

In order to ensure public health, safety, and welfare, Arizona Revised Statutes (A.R.S.) §§ 36-405 and 36-406 require the Arizona Department of Health Services (Department) to adopt rules establishing minimum standards and requirements for construction, modification, and licensure of health care institutions. The Department has adopted rules for licensing health care institutions in Arizona Administrative Code (A.A.C.) Title 9, Chapter 10. A.C.C. Title 9, Chapter 10, Article 1, contains the rules that apply to more than one class of health care institutions. The Department has become aware that certain requirements for opioid prescribing and treatment in A.A.C. R9-10-120 may be unnecessary and impose an undue burden on health care institutions related to the ordering of opioids in an in-patient setting. In addition, the rule should be revised to comply with changes to A.R.S. § 32-3248.01, as revised by Laws 2022, Ch. 134. After receiving an exception from the rulemaking moratorium established by Executive Order 2022-01, the Department is revising R9-10-120 to reduce the burden on regulated entities, while preserving the health and safety of patients. The Department believes that these changes are consistent with the purpose for A.R.S. § 41-1027 in that this rulemaking does not increase the cost of regulatory compliance, does not increase a fee, or reduce a procedural right of regulated persons. In fact, the rulemaking will not only make the rules compliant with Legislative requirements, but also reduce the regulatory burden on regulated entities. The new rules will conform to rulemaking format and style requirements of the Governor's Regulatory Review Council and the Office of the Secretary of State.

7. **A reference to any study relevant to the rule that the agency reviewed and proposes either to rely on or not to rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:**

The Department did not review or rely on any study for this rulemaking.

8. **A showing of good cause why the rulemaking is necessary to promote a statewide interest if the rulemaking will diminish a previous grant of authority of a political subdivision of this state:**

Not applicable

9. **A summary of the economic, small business, and consumer impact:**

Under A.R.S. § 41-1055(D)(2), the Department is not required to provide an economic, small business, and consumer impact statement.

10. **A description of any changes between the proposed expedited rulemaking, including supplemental notices, and the final expedited rulemaking:**

Between the proposed expedited rulemaking and the final expedited rulemaking, no changes were made to the rulemaking.

11. **Agency's summary of the public or stakeholder comments or objections made about the rulemaking and the agency response to the comments:**

The Department did not receive public or stakeholder comments about the rulemaking.

12. **All agencies shall list other matters prescribed by statute applicable to the specific agency or to any specific rule or class of rules. Additionally, an agency subject to Council review under A.R.S. §§ 41-1052 and 41-1055 shall respond to the following questions:**

There are no other matters prescribed by statutes applicable specifically to the Department or this specific rulemaking.

a. **Whether the rule requires a permit, whether a general permit is used and if not, the reasons why a general permit is not used:**

Although licensing of health care institutions is not addressed in this rulemaking, A.R.S. § 36-407 prohibits a person from establishing, conducting, or maintaining "a health care institution or any class or subclass of health care institution unless that person holds a current and valid license issued by the [D]epartment specifying the class or subclass of health care institution the person is establishing, conducting or maintaining." A health care institution license is specific to the licensee, class or subclass of health care institution, facility location, and scope of services provided. As such, a general permit is not applicable and is not used.

b. **Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than federal law and if so, citation to the statutory authority to exceed the requirements of federal law:**

Not applicable

c. **Whether a person submitted an analysis to the agency that compares the rule's impact of the competitiveness of business in this state to the impact on business in other states:**

No business competitiveness analysis was received by the Department.

13. **A list of any incorporated by reference material as specified in A.R.S. § 41-1028 and its location in the rules:**

Not applicable

14. **Whether the rule was previously made, amended, or repealed as an emergency rule. If so, cite the notice published in the Register as specified in R1-1-409(A). Also, the agency shall state where the text was changed between the emergency and the final rulemaking packages:**

The rule was not previously made as an emergency rule.

15. **The full text of the rules follows:**

TITLE 9. HEALTH SERVICES
CHAPTER 10. DEPARTMENT OF HEALTH SERVICES
HEALTH CARE INSTITUTIONS: LICENSING

ARTICLE 1. GENERAL

Section

ARTICLE 1. GENERAL

R9-10-120. Opioid Prescribing and Treatment

A. This Section does not apply to a health care institution licensed under Article 20 of this Chapter.

B. In addition to the definitions in A.R.S. § §§ 32-3248.01 and 36-401(A) and R9-10-101, the following definitions apply in this Section:

1. "Episode of care" means medical services, nursing services, or health-related services provided by a health care institution to a patient for a specific period of time, ending in discharge, ~~or~~ the completion of the patient's treatment plan, or 90 days from the start of service provision to the patient, whichever is later.
2. "Order" means to issue written, verbal, or electronic instructions for a specific dose of a specific medication in a specific quantity and route of administration to be obtained and administered to a patient in a health care institution.

C. An administrator of a health care institution where opioids are prescribed or ordered as part of treatment shall:

1. Establish, document, and implement policies and procedures for prescribing or ordering an opioid as part of treatment, to protect the health and safety of a patient, that:
   a. Cover which personnel members may prescribe or order an opioid in treating a patient and the required knowledge and qualifications of these personnel members;
   b. As applicable and except when contrary to medical judgment for a patient, are consistent with A.R.S. § 32-3248.01 and the Arizona Opioid Prescribing Guidelines or national opioid-prescribing guidelines, such as guidelines developed by the:
      i. Centers for Disease Control and Prevention, or
      ii. U.S. Department of Veterans Affairs and the U.S. Department of Defense;
   c. ~~Include~~ As applicable, include how, when, and by whom:
      i. A patient's profile on the Arizona Board of Pharmacy Controlled Substances Prescription Monitoring Program database is reviewed;
      ii. An assessment is conducted of a patient's substance use risk;
      iii. The potential risks, adverse outcomes, and complications, including death, associated with the use of opioids are explained to a patient or the patient's representative;

iv. Alternatives to a prescribed or ordered opioid are explained to a patient or the patient's representative;

v. Informed consent is obtained from a patient or the patient's representative and, if applicable, in what situations, described in subsection (G), ~~or~~ (H), or (I), informed consent would not be obtained before an opioid is prescribed or ordered for a patient;

vi. A patient receiving an opioid is monitored; and

vii. The actions taken according to subsections (C)(1)(c)(i) through (vi) are documented;

d. Address conditions that may impose a higher risk to a patient when prescribing or ordering an opioid as part of treatment, including:

i. Concurrent use of a benzodiazepine or other sedative-hypnotic medication,

ii. History of substance use disorder,

iii. Co-occurring behavioral health issue, or

iv. Pregnancy;

e. Cover the criteria for co-prescribing a short-acting opioid antagonist for a patient who is not an inpatient, as defined in R9-10-201;

f. Include that, if continuing control of a patient's pain after discharge is medically indicated due to the patient's medical condition, a method for continuing pain control will be addressed as part of discharge planning;

g. Include the frequency of the following for a patient being prescribed ~~or ordered~~ an opioid for longer than a 30-calendar-day period:

i. Face-to-face interactions with the patient,

ii. Conducting an assessment of a patient's substance use risk,

iii. Renewal of a prescription ~~or order~~ for an opioid without a face-to-face interaction with the patient, and

iv. Monitoring the effectiveness of the treatment;

h. If applicable according to A.R.S. § 36-2608, include documenting a dispensed opioid in the Arizona Board of Pharmacy Controlled Substances Prescription Monitoring Program database;

i. ~~Cover~~ As applicable and consistent with A.R.S. § 32-3248.01, cover the criteria and procedures for tapering opioid prescription or ordering as part of treatment; and

j. Cover the criteria and procedures for offering or referring a patient for treatment for substance use disorder;

2. Include in the plan for the health care institution's quality management program a process for:

a. Review of known incidents of opioid-related adverse reactions or other negative outcomes a patient experiences or opioid-related deaths, and

b. Surveillance and monitoring of adherence to the policies and procedures in subsection (C)(1);

3. Except as prohibited by Title 42 Code of Federal Regulations, Chapter I, Subchapter A, Part 2, or as provided in subsection (H)(1), ensure that, if a patient's death may be related to an opioid prescribed or ordered as part of treatment, written notification, in a Department-provided format, is provided to the Department of the patient's death within one working day after the health care institution learns of the patient's death; and

4. Ensure that informed consent, if required from a patient or the patient's representative, includes:

a. The patient's:

i. Name,

ii. Date of birth or other patient identifier, and

iii. Condition for which opioids are being prescribed;

b. That an opioid is being prescribed or ordered;

c. The potential risks, adverse reactions, complications, and medication interactions associated with the use of an opioid;

d. If applicable, the potential risks, adverse outcomes, and complications associated with the concurrent use of an opioid and a benzodiazepine or another sedative-hypnotic medication;

e. Alternatives to a prescribed or ordered opioid;

f. The name and signature of the individual explaining the use of an opioid to the patient; and

g. The signature of the patient or the patient's representative and the date signed.

D. Except as provided in subsection (H) or (I), an administrator of a health care institution where opioids are prescribed as part of treatment shall ensure that a medical practitioner authorized by policies and procedures to prescribe an opioid in treating a patient:

1. Before prescribing an opioid for a patient of the health care institution:

a. Conducts a physical examination of the patient or reviews the documentation

from a physical examination conducted during the patient's same episode of care;

b. Except as exempted by A.R.S. § 36-2606(G), reviews the patient's profile on the Arizona Board of Pharmacy Controlled Substances Prescription Monitoring Program database;

c. Conducts an assessment of the patient's substance use risk or reviews the documentation from an assessment of the patient's substance use risk conducted during the same episode of care by an individual licensed under A.R.S. Title 32 and authorized by policies and procedures to conduct an assessment of the patient's substance use risk;

d. Explains to the patient or the patient's representative the risks and benefits associated with the use of opioids or ensures that the patient or the patient's representative understands the risks and benefits associated with the use of opioids, as explained to the patient or the patient's representative by an individual licensed under A.R.S. Title 32 and authorized by policies and procedures to explain to the patient or the patient's representative the risks and benefits associated with the use of opioids;

e. ~~Explains~~ If applicable, explains alternatives to a prescribed opioid; and

f. Obtains informed consent from the patient or the patient's representative that meets the requirements in subsection (C)(4), including the potential risks, adverse outcomes, and complications associated with the concurrent use of an opioid and a benzodiazepine or another sedative-hypnotic medication, if the patient:

   i. Is also prescribed or ordered a sedative-hypnotic medication, or

   ii. Has been prescribed a sedative-hypnotic medication by another medical practitioner;

2. Includes the following information in the patient's medical record, an existing treatment plan, or a new treatment plan developed for the patient:

   a. The patient's diagnosis;

   b. The patient's medical history, including co-occurring disorders;

   c. The opioid to be prescribed;

   d. Other medications or herbal supplements being taken by the patient;

   e. If applicable:

      i. The effectiveness of the patient's current treatment,

      ii. The duration of the current treatment, and

      iii. Alternative treatments tried by or planned for the patient;

f. The expected benefit of the treatment and, if applicable, the benefit of the new treatment compared with continuing the current treatment; and

g. Other factors relevant to the patient's being prescribed an opioid; and

3. If applicable, specifies in the patient's discharge plan how medically indicated pain control will occur after discharge to meet the patient's needs.

E. Except as provided in subsection (G) or (H), an administrator of a health care institution where opioids are ordered for administration to a patient in the health care institution as part of treatment shall ensure that a medical practitioner authorized by policies and procedures to order an opioid in treating a patient:

1. Before ordering an opioid for a patient of the health care institution:

a. Conducts a physical examination of the patient or reviews the documentation from a physical examination conducted:

i. During the patient's same episode of care; or

ii. Within the previous 30 calendar days, at a health care institution transferring the patient to the health care institution or by the medical practitioner who referred the patient for admission to the health care institution;

b. Except as exempted by A.R.S. § 36-2606(G), reviews the patient's profile on the Arizona Board of Pharmacy Controlled Substances Prescription Monitoring Program database;

c. ~~Conducts an assessment of~~ If medically appropriate based on the physical examination in subsection (E)(1)(a) and the patient's medical history, assesses the patient's substance use risk or reviews the documentation from an assessment of the patient's substance use risk conducted within the previous 30 calendar days by an individual licensed under A.R.S. Title 32 and authorized by policies and procedures to conduct an assessment of the patient's substance use risk;

d. ~~Explains to the patient or the patient's representative the risks and benefits associated with the use of opioids or ensures~~ Ensures that the patient or the patient's representative understands the risks and benefits associated with the use of opioids, as explained to the patient or the patient's representative ~~by an individual licensed under A.R.S. Title 32 and authorized by~~ according to policies and procedures ~~to explain to the patient or the patient's representative the risks and benefits associated with the use of opioids~~; and

e. If applicable, explains alternatives to an ordered opioid; and

f. ~~Obtains informed consent from the patient or the patient's representative, according to subsection (D)(1)(f); and~~

2. Includes the following information in the patient's medical record, an existing treatment plan, or a new treatment plan developed for the patient:
   a. The patient's diagnosis;
   b. The patient's medical history, including co-occurring disorders;
   c. The opioid being ordered and the reason for the order;
   d. Other medications or herbal supplements being taken by the patient; and
   e. If applicable:
      i. The effectiveness of the patient's current treatment,
      ii. The duration of the current treatment,
      iii. Alternative treatments tried by or planned for the patient,
      iv. The expected benefit of a new treatment compared with continuing the current treatment, and
      v. Other factors relevant to the patient's being ordered an opioid.

F. For a health care institution where opioids are administered as part of treatment or where a patient is provided assistance in the self-administration of medication for a prescribed opioid, including a health care institution in which an opioid may be prescribed or ordered as part of treatment, an administrator, a manager as defined in R9-10-801, or a provider, as applicable to the health care institution, shall:

1. Establish, document, and implement policies and procedures for administering an opioid as part of treatment or providing assistance in the self-administration of medication for a prescribed opioid, to protect the health and safety of a patient, that:
   a. Cover which personnel members may administer an opioid in treating a patient and the required knowledge and qualifications of these personnel members;
   b. Cover which personnel members may provide assistance in the self-administration of medication for a prescribed opioid and the required knowledge and qualifications of these personnel members;
   c. Include how, when, and by whom a patient's need for opioid administration is assessed;
   d. Include how, when, and by whom a patient receiving an opioid is monitored; and
   e. Cover how, when, and by whom the actions taken according to subsections (F)(1)(c) and (d) are documented;
2. Include in the plan for the health care institution's quality management program a process

for:

a. Review of incidents of opioid-related adverse reactions or other negative outcomes a patient experiences or opioid-related deaths, and

b. Surveillance and monitoring of adherence to the policies and procedures in subsection (F)(1);

3. Except as prohibited by Title 42 Code of Federal Regulations, Chapter I, Subchapter A, Part 2, or as provided in subsection (H)(1), ensure that, if a patient's death may be related to an opioid administered as part of treatment, written notification, in a Department-provided format, is provided to the Department of the patient's death within one working day after the patient's death; and

4. Except as provided in subsection (H), ensure that an individual authorized by policies and procedures to administer an opioid in treating a patient or to provide assistance in the self-administration of medication for a prescribed opioid:

a. Before administering an opioid or providing assistance in the self-administration of medication for a prescribed opioid in compliance with an order as part of the treatment for a patient, identifies the patient's need for the opioid;

b. Monitors the patient's response to the opioid; and

c. Documents in the patient's medical record:

i. An identification of the patient's need for the opioid before the opioid was administered or assistance in the self-administration of medication for a prescribed opioid was provided, and

ii. The effect of the opioid administered or for which assistance in the self-administration of medication for a prescribed opioid was provided.

G. A medical practitioner authorized by a health care institution's policies and procedures to order an opioid in treating a patient is exempt from the requirements in subsection (E), if:

1. The health care institution's policies and procedures, required in subsection (C)(1) or the applicable Article in 9 A.A.C. 10, contain procedures for:

a. Providing treatment without obtaining the consent of a patient or the patient's representative,

b. Ordering and administering opioids in an emergency situation, and

c. Complying with the requirements in subsection (E) after the emergency is resolved;

2. The order for the administration of an opioid is:

a. Part of the treatment for a patient in an emergency, and

b. Issued in accordance with policies and procedures; and

3. The emergency situation is documented in the patient's medical record.

H. The requirements in subsections (D), (E), and (F)(4), as applicable, do not apply to a health care institution's:

1. Prescribing, ordering, or administration of an opioid as part of treatment for a patient with an end-of-life condition or pain associated with an active malignancy;

2. Prescribing an opioid as part of treatment for a patient when changing the type or dosage of an opioid, which had previously been prescribed by a medical practitioner of the health care institution for the patient according to the requirements in subsection (D):

   a. Before a pharmacist dispenses the opioid for the patient; or

   b. If changing the opioid because of an adverse reaction to the opioid experienced by the patient, within 72 hours after the opioid was dispensed for the patient by a pharmacist;

3. Ordering an opioid as part of treatment for no longer than three calendar days for a patient remaining in the health care institution and receiving continuous medical services or nursing services from the health care institution; or

4. Ordering an opioid as part of treatment:

   a. For a patient receiving a surgical procedure or other invasive procedure; or

   b. When changing the type, dosage, or route of administration of an opioid, which had previously been ordered by a medical practitioner of the health care institution for a patient according to the requirements in subsection (E), to meet the patient's needs.

I. The requirements in subsections (D)(1)(c) through (f) do not apply to a health care institution's prescribing an opioid as part of treatment for a patient with chronic, intractable pain who has had an established health professional-patient relationship with the prescribing medical practitioner for at least 90 days before the opioid is prescribed.