



MARK BRNOVICH
ATTORNEY GENERAL

OFFICE OF THE ARIZONA ATTORNEY GENERAL

July 27, 2017

Cara M. Christ, M.D., Director
Arizona Department of Health Services
150 N. 18th Ave., Ste. 510
Phoenix, Arizona 85007

RE: A.G. Rule No. AGR17-0005; A.A.C. R9-10-120

Dear Dr. Christ,

We have reviewed the above-referenced rule and the facts surrounding the adoption of the rule as an emergency measure by the Arizona Department of Health Services. We have determined that the rule is in proper form, is clear, concise and understandable, within the power of the agency to adopt and within legislative standards, and was adopted in compliance with procedures required by A.R.S. § 41-1026. In addition, we have determined that the requisite conditions constituting an emergency as provided in A.R.S. § 41-1026 exist so as to warrant approval as an emergency measure. In addition, we have determined that the Arizona Department of Health Services has demonstrated that the rule needs to be effective immediately in accordance with A.R.S. §41-1032.

The Attorney General's approval of the rule shall not be construed as an endorsement of policy issues relating to or resulting from the rulemaking. Policy decisions relating to the rulemaking are those of the Department of Health Services and not the Office of the Attorney General.

Accordingly, pursuant to A.R.S. § 41-1026, I have affixed my signature to the original Approval of Emergency Rules and have forwarded it together with the original rule, preamble, and three copies of each to the Secretary of State.

We have enclosed a copy for your reference

Sincerely,

A handwritten signature in blue ink that reads "Mark Brnovich".

Mark Brnovich
Attorney General

Enclosure

ATTORNEY GENERAL APPROVAL OF EMERGENCY RULES

JUL 28 PM 3:04

FILED

1. Agency Name: Department of Health Services
2. Chapter Heading: Department of Health Services
3. Code Citation for the Chapter: 9 A.A.C. 10
4. The Articles and the Sections involved in the rulemaking, listed in alphabetical and numerical order:

Sections

Action

A.A.C. R9-10-120

New Section

1. The rules contained in this package are approved as emergency rules pursuant to the standards set forth in A.R.S. § 41-1026. The Attorney General's approval of the rule shall not be construed as an endorsement of policy issues relating to or resulting from the rulemaking. Policy decisions relating to the rulemaking are those of Department of Health Services and not the Office of the Attorney General. The rules are effective immediately upon filing.

Mark Brnovich 28 July 17
 Mark Brnovich Date
 Attorney General

**AGENCY CERTIFICATE
NOTICE OF EMERGENCY RULEMAKING**

SECRETARY OF STATE

2017 JUL 28 PM 3:04

FILED

1. **Agency name:** Department of Health Services
2. **Chapter heading:** Department of Health Services – Health Care Institutions: Licensing
3. **Code citation for the Chapter:** 9 A.A.C. 10
4. **The Subchapters, if applicable; the Articles; the Parts, if applicable; and the Sections involved in the rulemaking listed in numerical order:**

Article, Part, or Section Affected

R9-10-120

Rulemaking Action

New Section

5. **The rules contained in this package are true and correct as made.**

6. 

Signature of Agency Director's Designee

Robert Lane

Printed or typed name of signer

7/10/17

Date of Signing

Chief, Administrative Counsel and Rules

Title of signer

SECRETARY OF STATE

AGENCY RECEIPT
NOTICE OF EMERGENCY RULEMAKING

2017 JUL 28 PM 3: 03

FILED

1. **Agency name:** Department of Health Services

2. **The Articles and the Sections involved in the rulemaking, listed in numerical order:**

Articles/Sections

Action

R9-10-120

New Section

PREAMBLE

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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:

Over the past 15 years, prescription opioid sales in the United States have risen by an astonishing 300%. Not surprisingly, this surge in the availability of prescription opioids has paralleled a simultaneous increase in opioid-related overdose deaths nationwide. In 2015, prescription opioid overdose deaths reached a new high water mark, claiming 33,000 American lives nationwide and leading to several states adopting more stringent regulations regarding opioid prescription and use. In 2016, 790 Arizonans died after suffering prescription opioid overdoses, a figure accounting for over *half* of all drug overdoses in Arizona. This equates to an average of more than two Arizonans per day dying as a result of opioid use. With opioid-related deaths increasing by 74% between 2012 and 2016, Arizona is now in the midst of a full-blown public health emergency that demands immediate attention.

In addition to the catastrophic human toll, opioid overdoses are slated to have a massive impact on Arizona's medical care system due to the volume and cost of overdose encounters. In 2015 alone, opioid-related encounters cost Arizona hospitals nearly \$350 million, representing a 26% jump from the previous year. While 2016 data is still forthcoming, the Department estimates that the costs will continue to rise so long as opioid prescribing practices remain the same. The Department estimates that hundreds of opioid prescriptions are issued each day in Arizona by health care providers in licensed health care institutions, each having the potential to lead to an opioid overdose death.

In response to this epidemic, Governor Doug Ducey, on June 5, 2017, issued a Declaration of Emergency (Opioid Overdose Epidemic), in which the Department is directed to "initiate emergency rule making with the Arizona Attorney General's Office in order to develop rules for opioid prescribing and treatment within health care institutions pursuant to A.R.S. § 36-405."

The Department believes that many opioid overdoses are preventable; however the Department requires more robust and more accurate data to successfully combat the opioid overdose epidemic and reduce the number of opioid overdose deaths. The enhanced surveillance being undertaken by the Department as a result of the Governor's Executive Order 17-04 will provide that data and help shape the public health response to the opioid overdose epidemic. To

reduce the number of opioid overdose deaths in Arizona and the number of individuals suffering an opioid overdose as a result of opioids prescribed, ordered, or administered as part of treatment in licensed health care institutions, the rules in A.A.C. Title 9, Chapter 10, need to be revised to strengthen requirements for health care institutions that prescribe, order, or administer opioids. To accomplish this and in compliance with the Governor's directive in the Opioid Overdose Epidemic Declaration of Emergency, the Department sought and obtained an exception from the rulemaking moratorium to conduct rulemaking related to opioid prescribing or use in treatment in licensed health care institutions.

In this emergency rulemaking, the Department, to protect the health and safety of a patient, is adopting rules to require licensed health care institutions to establish, document, and implement policies and procedures for prescribing, ordering, or administering opioids as part of treatment; to include specific processes related to opioids in a health care institution's quality management program; and to notify the Department of the death of a patient from an opioid overdose. The Department is also specifying requirements with which an individual will need to comply before prescribing opioids, ordering opioids, or administering opioids in the treatment of a patient. To reduce the burden on licensed health care institutions, the Department is exempting the prescription, ordering, or administration of opioids as part of treatment for a patient with a terminal condition.

Concurrent with this emergency action, the Department is initiating a regular rulemaking to address the alarming rise in prescription opioid-related deaths. The anticipated regular rulemaking does not negate the need for an emergency rulemaking, however. If the current rate of opioid-related deaths continues, nearly 600 Arizonan lives may be lost due to an opioid overdose in the time it takes to initiate and complete a regular rulemaking. It is, therefore, imperative that the Department act immediately through emergency rulemaking to devise and implement a public health response to the opioid crisis. By providing licensed health care institutions with comprehensive requirements related to the prescription and use of opioids in treatment as part of the emergency rulemaking, the Department anticipates an immediate effect on opioid prescribing practices, a decrease in the number of unnecessary opioid prescriptions, and an attendant reduction in overdose-related events thereafter. Accordingly, in light of the human and economic costs posed by opioid crisis, the Department submits that an emergency rulemaking is both justified and proper.

7. A reference to any study relevant to the rules that the agency reviewed and either relied on or did not rely on in its evaluation of or justification for the rules, 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 related to this rulemaking package.

- 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:**

Not applicable. Pursuant to A.R.S. § 41-1055(D)(1), this rulemaking is exempt from the requirements to prepare and file an economic, small business and consumer impact statement.

- 10. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules. When applicable, matters shall include but are not limited to:**

- 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:**

Not applicable

- 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:**

The rule is not more stringent than federal law.

- 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 analysis comparing competitiveness was received by the Department.

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

None

- 12. An agency explanation about the situation justifying the rulemaking as an emergency rule:**

The Department tracks deaths of individuals who die of an opioid overdose and recently reported a significant increase in prescription and illicit drug overdose deaths in 2016, as published in a report available at: <http://azdhs.gov/documents/audiences/clinicians/clinical-guidelines-recommendations/prescribing-guidelines/arizona-opioid-report.pdf>. In response to the significant increase in drug overdose deaths and to comply with the Governor's directive, the Department has immediately initiated this emergency rulemaking to address the public health epidemic. This situation was not caused by the Department's delay or inaction. In addition, given the additional

time necessary to conduct a regular rulemaking, the current situation cannot be averted by a regular rulemaking (which at a minimum could take an additional six to eight months to complete).

13. The date the Attorney General approved the rule:

14. The full text of the rules follows:

ARTICLE 1. GENERAL

Section

R9-10-120. Opioid Prescribing and Treatment

ARTICLE 1. GENERAL

R9-10-120. Opioid Prescribing and Treatment

A. For purposes of this Section, the following definitions apply:

1. “Benzodiazepine” means any one of a class of drugs that have sleep-inducing, anti-anxiety, anti-convulsant, and muscle-relaxing properties and are commonly used in the treatment of anxiety.
2. “Opioid” means the same as “opiate” in A.R.S. § 36-2501.
3. “Opioid antagonist” means a drug approved by the U.S. Department of Health and Human Services, Food and Drug Administration, that, when administered, negates or neutralizes, in whole or in part, the pharmacological effects of an opioid in the body.
4. “Substance abuse risk assessment” means an evaluation of an individual’s unique likelihood for addiction, abuse, misuse, diversion, or another adverse consequence resulting from the individual being prescribed or receiving treatment with opioids.
5. “Terminal condition” means the final stage of an incurable or irreversible ailment, caused by injury, disease, or illness and from which, to a reasonable degree of medical certainty, there is no recovery.

B. Except as provided in subsection (E), a licensee of a health care institution where opioids are prescribed, ordered, or administered as part of treatment shall:

1. Establish, document, and implement policies and procedures for prescribing or ordering an opioid or administering 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 or administer an opioid in treating a patient and the required knowledge and qualifications of these personnel members;
 - b. Except when contrary to medical judgment for a patient, are consistent with the Arizona Opioid Prescribing Guidelines or national opioid-prescribing guidelines, such as guidelines developed by the:
 - i. Centers for Disease Control and Prevention,
 - ii. Substance Abuse and Mental Health Services Administration, or
 - iii. American Society of Addiction Medicine;
 - c. 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. A substance abuse risk assessment of a patient is conducted;
- 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 opioid are explained to a patient or the patient's representative;
- v. Informed consent is obtained from a patient or the patient's representative;
- vi. A patient receiving an opioid is monitored; and
- vii. The actions taken according to subsections (B)(1)(c)(i) through (vi) are documented;
- d. Cover conditions that may contraindicate prescribing an opioid or using an opioid in treatment, including:
 - i. Concurrent use of a benzodiazepine,
 - ii. History of opioid abuse,
 - iii. History of other substance abuse, or
 - iv. Pregnancy;
- e. Cover the criteria for co-prescribing an opioid antagonist for a patient;
- f. For a patient being prescribed an opioid, or for whom opioid administration is being ordered, for longer than a 30-calendar-day period, include the frequency of:
 - i. Face-to-face interactions with the patient,
 - ii. Conducting a substance abuse risk assessment of the patient,
 - iii. Renewal of a prescription for an opioid without a face-to-face interaction with the patient, and
 - iv. Monitoring the effectiveness of the treatment;
- g. If applicable, include documenting a dispensed opioid in the Arizona Board of Pharmacy Controlled Substances Prescription Monitoring Program database;
- h. Cover the criteria and procedures for tapering or discontinuing opioid prescription or administration as part of treatment; and
- i. Cover the criteria and procedures for offering or referring a patient for treatment for substance abuse;
- 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 (B)(1); and
- 3. Except as prohibited by Title 42 Code of Federal Regulations, Chapter I, Subchapter A, Part 2, ensure that, if a patient's death may be related to an opioid prescribed, ordered, or 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 health care institution learns of the patient's death.
- C. Except as provided in subsection (E), an administrator shall ensure that, before prescribing an opioid or ordering the administration of an opioid as part of the treatment for a patient, an individual authorized by policies and procedures to prescribe or order an opioid in treating a patient:
 - 1. Conducts a physical examination of the patient;
 - 2. Reviews the patient's profile on the Arizona Board of Pharmacy Controlled Substances Prescription Monitoring Program database;
 - 3. Conducts a substance abuse risk assessment of a patient;
 - 4. Develops a treatment plan for the patient based on the:
 - a. Patient's diagnosis;
 - b. Patient's medical history, including co-occurring disorders;
 - c. Opioid to be prescribed;
 - d. Other medications or herbal supplements being taken by the patient;
 - e. Effectiveness of the patient's current treatment;
 - f. Duration of the current treatment;
 - g. Alternative treatments tried by or planned for the patient;
 - h. Expected benefit of a new treatment compared with continuing the current treatment; and
 - i. Other factors relevant to the patient;
 - 5. Explains to the patient the risks and benefits associated with the use of opioids;
 - 6. Explains alternatives to a prescribed opioid; and
 - 7. Obtains informed consent from the patient or the patient's representative that includes:
 - a. The patient's:
 - i. Name;
 - ii. Date of birth;

- iii. Address;
 - iv. Condition for which opioids are being prescribed or used;
 - v. Telephone number; and
 - vi. E-mail address, if applicable;
 - b. The potential risks, adverse reactions, complications, and medication interactions associated with the use of opioids;
 - c. If the patient is also prescribed a benzodiazepine, the potential risks, adverse outcomes, and complications associated with the concurrent use of an opioid and benzodiazepine;
 - d. Alternatives to a prescribed opioid;
 - e. Name and signature of the personnel member explaining the use of an opioid to the patient; and
 - f. The signature of the patient or patient's representative and the date signed.
- D. Except as provided in subsection (E), an administrator shall ensure that an individual authorized by policies and procedures to administer an opioid in treating a patient:
 - 1. Before administering an opioid in compliance with an order as part of the treatment for a patient, identifies the patient's pain before the opioid is administered;
 - 2. Monitors the patient's response to the opioid; and
 - 3. Documents in the patient's medical record:
 - a. An identification of the patient's pain before the opioid was administered, and
 - b. The effect of the opioid administered.
- E. The requirements in subsections (B), (C), and (D) do not apply to a health care institution's prescription, ordering, or administration of opioids as part of treatment for a patient with a terminal condition.