NOTICE OF EMERGENCY RULEMAKING
TITLE 9. HEALTH SERVICES
CHAPTER 4. DEPARTMENT OF HEALTH SERVICES
NONCOMMUNICABLE DISEASES
PREAMBLE

1.	Sections Affected	Rulemaking Action
	Article 6	New Article
	R9-4-601	New Section
	R9-4-602	New Section

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

Authorizing statutes: A.R.S. §§ 36-132(A)(1), 36-136(G)

Implementing statutes: A.R.S. § 36-133

3. The effective date of the rule:

The rule will take effect upon the filing of the Approval of Emergency Rulemaking and the Notice of Emergency Rulemaking with the Office of the Secretary of State by the Office of the Attorney General. An exception from the effective date provisions in A.R.S. § 41-1032(A) is necessary to preserve public health by immediately addressing the epidemic of opioid overdose deaths occurring in Arizona.

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

None

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 An agency's justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking:

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 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. The Department estimates that hundreds of opioid prescriptions are issued each day in Arizona, each having the potential to lead to an opioid overdose death. More than 33% of individuals experiencing an opioid overdose since June 15, 2017, had an opioid prescription filled in the two months before the overdose, and 62% of those prescriptions were for a period longer than six days. 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 response to the emergency situation created by the opioid overdose epidemic, Governor Doug Ducey, on June 13, 2017, issued Executive Order 2017-04, Enhanced Surveillance Advisory, in which health care providers, pharmacists, emergency medical service providers, local and state law enforcement agencies, and others were directed to report data on specific health conditions to the Department. This Executive Order was revised and renewed on August 10, 2017, when the Governor issued Executive Order 2017-05. The enhanced surveillance being undertaken by the Department as a result of the Governor's Executive Orders 2017-04 and 2017-05 has begun to provide more robust and more accurate data that will help shape the public health response to the opioid overdose epidemic. Since reporting began, there have been 1,961 reports of a suspected opioid overdose, and 263 Arizonans have died as a result. Executive Order 2017-05 will be expiring shortly, but the Department's need for data will continue after its expiration.

The Department believes that opioid use disorder, which can lead to opioid overdose and death, has become a chronic disease in Arizona. To successfully prevent and combat opioid use disorder, overdoses, and deaths, the Department needs to be able to obtain complete and accurate data in a timely fashion. The Department has begun using the data being reported under the Executive Orders to monitor incidence patterns for opioid overdoses, assess the success of intervention strategies being deployed to combat the opioid overdose epidemic, identify population subgroups at high risk for morbidity and mortality due to opioid overdoses, and identify regions of the state that are in particular need of intervention programs to reduce the incidence of opioid overdoses. However, continued reporting is necessary to obtain the data necessary to shape, implement, and assess the success of a public health response to the opioid overdose epidemic.

The Department has already adopted emergency rules in 9 A.A.C. 10, effective July 28, 2017, to strengthen requirements for health care institutions that prescribe, order, or administer opioids. 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. However, these changes only affect licensed health care institutions by requiring them to report deaths related to opioid prescription or administration as part of treatment. In response to the Executive Orders, the majority of suspected overdose and death reports being submitted, as well as reports of dispensed and administered doses of naloxone, are coming from healthcare professionals, law enforcement agencies, emergency medical services providers, and pharmacies. This real time data is critical for identifying and implementing public health strategies, including targeted prevention activities. Therefore, the Department is adopting emergency rules in 9 A.A.C. 4 to establish a surveillance system for opioid overdose-related events, similar to other non-communicable diseases.

In this emergency rulemaking, the Department seeks to protect the health and safety of the residents of Arizona by adopting rules to establish a surveillance system for opioid overdose-related events under A.R.S. § 36-133. Specifically, these rules require continued reporting of suspected opioid deaths, suspected opioid overdoses, naloxone doses administered in response to a suspected opioid overdose, naloxone doses dispensed, and neonatal abstinence syndrome cases. In this way, the Department may be able to detect changes in opioid prescribing practices, as well as changes in the number of opioid overdoses and intervention activities, in a time-frame during which new intervention activities may be initiated and changes to existing strategies made in order to save lives.

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 continue to monitor both opioid overdoses and the availability and use of naloxone, as one aspect of the public health response to the opioid overdose crisis, while gathering data to better shape, implement, and assess the success of a public health response to the opioid overdose epidemic. Accordingly, in light of the human and economic costs posed by the opioid overdose crisis, the Department believes 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. However, until the initiation of enhanced surveillance under Executive Orders 2017-04 and 2017-05, this data was not being collected in a time-frame that enabled the Department to respond in a timely manner. Because the data being submitted under enhanced surveillance has helped the Department to better understand the extent of this public health epidemic, the Department and community partners have initiated strategies, including intervention activities, to address the epidemic. It is now imperative that these and future intervention activities be monitored so new public health strategies may be developed. 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:

TITLE 9. HEALTH SERVICES

CHAPTER 4. DEPARTMENT OF HEALTH SERVICES

NONCOMMUNICABLE DISEASES

ARTICLE 6. OPIOID POISONING-RELATED REPORTING

Section

R9-4-601. Definitions

R9-4-602. Opioid Poisoning-Related Reporting Requirements

ARTICLE 6. OPIOID POISONING-RELATED REPORTING

R9-4-601. Definitions

A. In this Article, unless otherwise specified:

1. "Administrator" means the individual who is a senior leader in a health care institution or correctional facility.
2. "Ambulance service" has the same meaning as in A.R.S. § 36-2201.
3. "Business day" means the period from 8:00 a.m. to 5:00 p.m. on a Monday, Tuesday, Wednesday, Thursday, or Friday that is not a state holiday.
4. "Clinical laboratory" has the same meaning as in in A.R.S. § 36-451.
5. "Correctional facility has the same meaning as in A.A.C. R9-6-101.
6. "Dispense" has the same meaning as in A.R.S. § 32-1901.
7. "Emergency medical services provider" has the same meaning as in in A.R.S. § 36-2201.
8. "Health care institution" has the same meaning as in A.R.S. § 36-401.
9. "Health professional" has the same meaning as in A.R.S. § 32-3201.
10. "Law enforcement agency" has the same meaning as in A.A.C. R13-1-101.
11. "Medical examiner" has the same meaning as in A.R.S. § 36-301.
12. "Naloxone" means a prescription medication, as defined in A.R.S. § 32-1901, that is used to block the effects of an opioid in an individual.
13. "Neonatal abstinence syndrome" means a set of signs of opioid withdrawal occurring in an individual shortly after birth that are indicative of opioid exposure while in the womb.
14. "Opioid" means the same as "opiate" in A.R.S. § 36-2501.
15. "Opioid overdose" means respiratory depression, slowing heart rate, or unconsciousness or mental confusion caused by the administration, including self-administration, of an opioid to an individual.
16. "Pharmacist" has the same meaning as in A.R.S. § 32-1901.

R9-4-602. Opioid Poisoning-Related Reporting Requirements

A. An ambulance service, an emergency medical services provider, or a law enforcement agency shall, either personally or through a representative, submit a report to the Department, in a Department-provided format and within five business days after an encounter with an individual with a suspected opioid overdose, that includes:

1. The following information about the ambulance service, emergency medical services provider, or law enforcement agency:

a. Name;

b. Street address, city, county, and zip code;

c. Whether the entity reporting is:

i. An ambulance service,

ii. An emergency medical services provider, or

iii. A law enforcement agency; and

d. If applicable, the certificate number issued by the Department to the ambulance service; and

2. The name, title, telephone number, and email address of a point of contact for the entity required to report;

3. The street address, city, county, state, and zip code of the location at which the ambulance service, emergency medical services provider, or law enforcement agency encountered the individual;

4. If applicable, the date and time the ambulance service, emergency medical services provider, or law enforcement agency was dispatched to the location specified according to subsection (A)(3);

5. The following information about the individual with a suspected opioid overdose or who died of a suspected opioid overdose:

a. Name,

b. Date of birth,

c. Age in years,

d. Gender,

e. Race and ethnicity, and

f. Reason for suspecting that the individual had an opioid overdose;

6. Whether naloxone was administered to the individual before the ambulance service, emergency medical services provider, or law enforcement agency encountered the individual and, if so:

a. The number of doses of naloxone administered to the individual; and

b. As applicable, that the naloxone was administered to the individual by:

i. Another individual; or

ii. Another entity and, if so the type of entity that administered the naloxone to the individual;

7. Whether naloxone was administered to the individual by the ambulance service, emergency medical services provider, or law enforcement agency and, if so, the number of doses of naloxone administered to the individual;

8. The following information about the disposition of the individual:

   a. Whether the individual was pronounced dead at the location specified according to subsection (A)(3);

   b. Whether the individual was transported to a hospital and; if so:

      i. The name of the hospital to which the individual was transported, and

      ii. The type of entity that transported the individual to the hospital; and

   c. If known, whether the individual:

      i. Survived the suspected opioid overdose,

      ii. Died from the suspected opioid overdose, or

      iii. Died from another cause after experiencing a suspected opioid overdose; and

9. The date of the report.

B. An administrator of a health care institution licensed under 9 A.A.C. 10 or a pharmacist, as applicable, is not required to submit a report to the Department under this Article for:

1. An opioid overdose resulting from the administration of the opioid to a patient in the health care institution if the opioid overdose is addressed through the health care institution's quality management program; or

2. Naloxone dispensed in connection with a surgical procedure, as defined in A.A.C. R9-10-101, performed in the health care institution.

C. Except as prohibited by Title 42 Code of Federal Regulations, Chapter I, Subchapter A, Part 2 or as specified in subsection (B), a health professional or the administrator of a health care institution licensed under 9 A.A.C. 10 shall, either personally or through a representative, submit a report to the Department, in a Department-provided format and within five business days after an encounter with an individual with a suspected opioid overdose, that includes:

1. The name, street address, city, county, zip code, and telephone number of the health professional or health care institution;

2. If different from the person in subsection (C)(1), the name, title, street address, city, county, zip code, telephone number, and email address of the individual reporting on behalf of the person in subsection (C)(1);

3. The following information about the individual with a suspected opioid overdose:

   a. The individual's name;

b. The individual's street address, city, county, state, and zip code;

c. The individual's date of birth;

d. The individual's gender;

e. The individual's race and ethnicity;

f. Whether the individual is pregnant and, if so, the expected date of delivery;

g. If applicable, the name of the individual's guardian; and

h. Whether naloxone was administered to the individual before the health professional or health care institution encountered the individual and, if so:

i. The type of entity that administered the naloxone to the individual, or

ii. That the naloxone was administered to the individual by another individual;

4. The following information about the diagnosis of opioid overdose:

a. The reason for suspecting that the individual had an opioid overdose;

b. The date of the suspected opioid overdose;

c. The date of diagnosis; and

d. Except as provided in subsection (G), if the diagnosis was confirmed through one or more tests performed by a clinical laboratory, for each test:

i. The name, address, and telephone number of the clinical laboratory;

ii. The date a specimen was collected from the individual;

iii. The type of specimen collected;

iv. The type of laboratory test performed; and

v. The laboratory test result and date of the result;

5. The following information about the suspected opioid overdose:

a. Whether the opioid overdose appeared to be intentional or unintentional;

b. The location where the opioid overdose took place;

c. Whether the individual was alone at the time of the opioid overdose;

d. Whether the individual was transported to the health professional or health care institution by an ambulance service, an emergency medical services provider, or a law enforcement agency and, if so, the type of entity that transported the individual;

e. The specific opioid that appeared to be responsible for the opioid overdose; and

f. If known, whether:

i. The individual was prescribed an opioid within the 90 calendar days before the date of the suspected opioid overdose;

ii. The individual had been referred to receive behavioral health services, as defined in A.R.S. § 36-401; or

iii. The opioid overdose was the first time the individual had had an opioid overdose and, if not, the number of previous opioid overdoses the individual was known to have had;

6. Whether the individual with the suspected opioid overdose:

a. Survived the suspected opioid overdose and:

i. Was admitted to the health care institution;

ii. Was transferred to another health care institution and, if so, the name of the health care institution;

iii. Was discharged to a law enforcement agency;

iv. Was discharged to home; or

iv. Left the health care institution against medical advice;

b. Died from the suspected opioid overdose and, if so, the date of death; or

c. Died from another cause after experiencing a suspected opioid overdose and, if so, the date of death; and

7. The date of the report.

D. Except as prohibited by Title 42 Code of Federal Regulations, Chapter I, Subchapter A, Part 2, a health professional or the administrator of a health care institution licensed under 9 A.A.C. 10 shall, either personally or through a representative, submit a report to the Department, in a Department-provided format and within five business days after an encounter with an individual with suspected neonatal abstinence syndrome, that includes:

1. The name, street address, city, county, zip code, and telephone number of the health professional or health care institution;

2. If different from the person in subsection (D)(1), the name, title, street address, city, county, zip code, telephone number, and email address of the individual reporting on behalf of the person in subsection (D)(1);

3. The following information about the individual with suspected neonatal abstinence syndrome:

a. The individual's name;

b. The individual's date of birth;

c. The individual's gender;

d. The individual's race and ethnicity;

e. The name of the individual's mother; and

f. If not the individual's mother, the name of the individual's guardian;

4. The following information about a diagnosis of neonatal abstinence syndrome:

a. The reason for suspecting that the individual has neonatal abstinence syndrome;

b. The date of the onset of signs of neonatal abstinence syndrome;

c. The date of diagnosis;

d. Except as provided in subsection (G), if the diagnosis was confirmed through one or more tests performed by a clinical laboratory, for each test:

i. The name, address, and telephone number of the clinical laboratory;

ii. The date a specimen was collected from the individual;

iii. The type of specimen collected;

iv. The type of laboratory test performed; and

v. The laboratory test result and date of the result; and

e. Whether any of the following supported a diagnosis of neonatal abstinence syndrome:

i. A maternal history of opioid use,

ii. A positive laboratory test for opioid use by the individual's mother, or

iii. A positive laboratory test for opioids in the individual;

5. If known, the following information about the suspected neonatal abstinence syndrome:

a. The source of the opioid believed to have caused the neonatal abstinence syndrome; and

b. If the source of the opioid used by the individual's mother was not through a prescription order, as defined in A.R.S. § 32-1901, the specific opioid used by the individual's mother; and

6. The date of the report.

E. Except as specified in subsection (B), a pharmacist shall, either personally or through a representative, submit a report to the Department, in a format provided by the Arizona Board of Pharmacy and within five business days after dispensing naloxone to an individual, that includes:

1. The following information about the pharmacist:

a. Name;

b. Pharmacy street address, city, county, and zip code; and

c. The professional license number issued to the pharmacist under A.R.S. Title 32;

2. The number of doses of naloxone dispensed to the individual by the pharmacist;

3. The date the naloxone was dispensed; and

4. The date of the report.

F. A medical examiner shall, either personally or through a representative, submit a report to the Department, in a Department-provided format and within five business days after the completion of the death investigation required in A.R.S. § 11-594 on the human remains of a deceased individual with a suspected opioid overdose, that includes:

1. The following information about the medical examiner:
   a. Name; and
   b. Street address, city, county, and zip code;
2. The following information about the deceased individual with a suspected opioid overdose:
   a. The deceased individual's name;
   b. The deceased individual's date of birth;
   c. The deceased individual's gender;
   d. The deceased individual's race and ethnicity;
   e. Whether the deceased individual was pregnant and, if so, the expected date of delivery;
   f. If applicable, the name of the deceased individual's guardian; and
   g. Whether naloxone was administered to the deceased individual before the deceased individual's death and, if known:
      i. The type of entity that administered the naloxone to the deceased individual, or
      ii. That the naloxone was administered to the deceased individual by another individual;
3. The following information about the diagnosis of opioid overdose:
   a. The reason for suspecting that the deceased individual had an opioid overdose;
   b. The date of the opioid overdose;
   c. The date of diagnosis; and
   d. If the diagnosis was confirmed by clinical laboratory tests:
      i. The name, address, and telephone number of the clinical laboratory;
      ii. The date a specimen was collected from the deceased individual;
      iii. The type of specimen collected;
      iv. The type of laboratory test performed; and
      v. The laboratory test result and date of the result;
4. If applicable, a copy of the clinical laboratory test results;
5. If known, the following information about the suspected opioid overdose:

a. Whether the opioid overdose appeared to be intentional or unintentional;

b. The location where the opioid overdose took place;

c. Whether the deceased individual was alone at the time of the opioid overdose;

d. The specific opioid that appeared to be responsible for the opioid overdose;

e. Whether the deceased individual was prescribed an opioid within the 90 calendar days before the date of the opioid overdose; and

f. Whether the opioid overdose was the first time the deceased individual was known to have had an opioid overdose and, if not, the number of previous opioid overdoses the deceased individual had had;

6. Whether the deceased individual with the suspected opioid overdose:

a. Died from the suspected opioid overdose and, if so, the date of death; or

b. Died from another cause after experiencing a suspected opioid overdose and, if so, the date of death; and

7. The date of the report.

G. A director of a clinical laboratory, on the premises of a health care institution licensed as a hospital, as defined in A.A.C. R9-10-101, or performing laboratory tests under an arrangement with a hospital, shall submit a report to the Department, in a Department-provided format and within five business days after completing laboratory tests on one or more specimens from an individual that indicate a positive result for the presence of an opioid or an opioid metabolite, that includes:

1. The name and address of the clinical laboratory;

2. The name and telephone number of the director of the clinical laboratory;

3. The name and, if available, the address of the individual;

4. The date of birth of the individual;

5. The gender of the individual;

6. The laboratory identification number;

7. For each laboratory test performed:

a. The date of collection of the specimen;

b. The type of specimen collected;

c. The type of laboratory test performed on the specimen;

d. The laboratory test result, including quantitative values and reference ranges, if applicable; and

e. The date of the laboratory test result; and

8. The date of the report.

H. Information collected on individuals pursuant to this Article is confidential, subject to disclosure provisions in A.R.S. Title 12, Chapter 13, Article 7.1, and 9 A.A.C. 1, Article 3.