



NOTICES OF FINAL RULEMAKING

This section of the *Arizona Administrative Register* contains Notices of Final Rulemaking. Final rules have been through the regular rulemaking process as defined in the Administrative Procedures Act. These rules were either approved by the Governor's Regulatory Review Council or the Attorney General's Office. Certificates of Approval are on file with the Office.

The final published notice includes a preamble and

text of the rules as filed by the agency. Economic Impact Statements are not published.

The Office of the Secretary of State is the filing office and publisher of these rules. Questions about the interpretation of the final rules should be addressed to the agency that promulgated them. Refer to Item #5 to contact the person charged with the rulemaking. The codified version of these rules will be published in the Arizona Administrative Code.

**NOTICE OF FINAL RULEMAKING
TITLE 9. HEALTH SERVICES
CHAPTER 4. DEPARTMENT OF HEALTH SERVICES
NONCOMMUNICABLE DISEASES**

[R18-75]

PREAMBLE

- 1. Article, Part, or Section Affected (as applicable)**

Article 6	<u>Rulemaking Action</u>
R9-4-601	New Article
R9-4-602	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 rules:**
 April 5, 2018
 The Arizona Department of Health Services (Department) requests an immediate effective date for this rule under A.R.S. § 41-1032 (A)(1) and (4). This rule is necessary to protect public health and safety and is less burdensome than the emergency rule currently in effect. Therefore, implementing the rule earlier than the usual 60-day time period will provide a benefit to both the regulated entities and the public. No additional penalties are assessed for a violation of this rule compared with the emergency rule.

- 4. Citations to all related notices published in the Register as specified in R1-1-409(A) that pertain to the record of the final rulemaking package:**
 Notice of Emergency Rulemaking: 23 A.A.R. 2857, October 13, 2017
 Notice of Rulemaking Docket Opening: 23 A.A.R. 3362, December 8, 2017
 Notice of Proposed Rulemaking: 24 A.A.R. 93, January 12, 2018

- 5. The agency's contact person who can answer questions about the rulemaking:**
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 or
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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:**
 Arizona Revised Statutes (A.R.S.) § 36-133 requires the Department to develop a chronic disease surveillance system for the



collection, management, and analysis of information on the incidence of chronic diseases in Arizona. The Department has implemented this statute in Arizona Administrative Code (A.A.C.) Title 9, Chapter 4. The Department believes that opioid use disorder, which can lead to opioid overdose and death, has become a chronic disease in Arizona. In the last 15 years, prescription opioid sales in the United States have risen by 300%, resulting in more than 33,000 opioid overdose deaths in 2015 nationwide. In Arizona, 790 individuals died in 2016 of an opioid overdose, a 74% increase since 2012.

To successfully prevent and combat opioid use disorder, overdoses, and deaths, the Department needs to be able to obtain complete and accurate data about these events in a timely fashion. Under Executive Order 2017-04, Enhanced Surveillance Advisory, issued by Governor Doug Ducey, on June 13, 2017, health care providers, pharmacists, emergency medical service providers, local and state law enforcement agencies, and others were directed to report data on specific opioid-related health conditions to the Department. This Executive Order was revised and renewed on August 10, 2017, when the Governor issued Executive Order 2017-05, and on October 9, 2017, when opioid-related reporting began under an emergency rule.

The Department has begun using the data being reported under the Executive Orders to monitor incidence patterns for opioid overdoses, and plans to 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. Since there is a continuing need for data to detect changes in opioid prescribing practices, as well as changes in the number of opioid overdoses and intervention activities, on a real-time basis, after the expiration of the emergency rule, the Department has sought and received an exception from the rulemaking moratorium established by Executive Order 2017-02 and is adopting rules for Opioid Poisoning-Related Reporting by regular rulemaking in 9 A.A.C. 4. 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 based the need for this rulemaking on the following two documents:

- a. The Department’s “2016 Arizona Opioid Report,” available at <http://azdhs.gov/documents/audiences/clinicians/clinical-guidelines-recommendations/prescribing-guidelines/arizona-opioid-report.pdf>; and
- b. The U.S. Centers for Disease Control and Prevention’s Morbidity and Mortality Weekly Report (MMWR) “Vital Signs: Changes in Opioid Prescribing in the United States, 2006-2015,” published July 7, 2017, available at https://www.cdc.gov/mmwr/volumes/66/wr/mm6626a4.htm?s_cid=mm6626a4_w.

Both documents present factual data describing the extent of the opioid epidemic in Arizona and the United States, respectively.

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:

Annual costs/revenues changes are designated as minimal when more than \$0 and \$1,000 or less, moderate when between \$1,000 and \$5,000, and substantial when \$5,000 or greater in additional costs or revenues. A cost is listed as significant when meaningful or important, but not readily subject to quantification. The Department anticipates that persons affected by the rulemaking include the Department; first response agencies, including ambulance services, emergency medical services providers, and law enforcement agencies; licensed health care institutions; health professionals; medical examiners; pharmacists/pharmacies; individuals experiencing an opioid overdose or neonatal abstinence syndrome (NAS) and their families; and the general public.

Ambulance services, emergency medical services providers, and law enforcement agencies currently report to the Department through the AZ-PIERS data system, while health care institutions, health professionals, and medical examiners report through the MEDSIS data system. Pharmacists report the dispensing of naloxone through the Arizona Board of Pharmacy’s Controlled Substances Prescription Monitoring Program (CSPMP) data system. The Department estimates that it cost the Department approximately \$8,000 to modify the MEDSIS data system and approximately \$3,600 to modify the AZ-PIERS data system. The cost to permanently update AZ-PIERS is estimated to be approximately \$12,000. The Department also paid \$10,500 to modify the CSPMP to accommodate the reported data. Therefore, the cost to the Department to modify the data systems used for collection of the reported information is expected to be substantial. The Department anticipates that de-duplication of information reported by multiple submitters in separate data systems, requesting additional information to complete reports, and entering medical examiner data from Maricopa County may impose a substantial annual cost on the Department. Costs to compile, analyze, and produce reports on the data, as well as to disseminate other information derived from the data, may impose a further substantial annual cost on the Department.

The Department may receive a significant benefit from the information submitted due to the rule in implementing the activities proposed in the Opioid Action Plan, developed by the Department in compliance with the Governor’s Declaration of Emergency and Notification of Enhanced Surveillance Advisory on the Opioid Overdose Epidemic. In addition to the significant intrinsic benefit of having a healthier and safer general public as a result of public health activities undertaken by the Department to address the opioid overdose epidemic, the Department has been able to obtain federal funds to help combat the opioid overdose epidemic. The Department may receive up to a substantial benefit if the data derived through the rules enable the Department to obtain additional federal funds.

The new rules may impose a minimal-to moderate-cost on first response agencies, including ambulance services, emergency medical services providers, and law enforcement agencies, for reporting the required information to the Department. The Department is also providing reports derived from the submitted information back to first response agencies, enabling them to improve



performance and the effectiveness of their activities. Through the provision of continuing timely data, the Department anticipates that a first response agency may receive a significant benefit from the new rules.

Reports of opioid overdose deaths are required by the new rules to be reported by medical examiners to the Department. To lessen the burden on the Maricopa County medical examiner, which has by far the largest number of opioid overdose deaths, the Department has been entering this data. The Department anticipates that the medical examiners of the other counties may experience a minimal cost to report on these deaths. Medical examiners may also receive a significant benefit from the reports of compiled data provided by the Department, derived from information submitted under the new rules.

Licensed health care institutions are required by the new rules to report suspected non-fatal opioid overdoses, suspected fatal opioid overdoses, and suspected cases of NAS. The Department estimates that 80% of health care institutions would incur minimal costs for this reporting, while the largest reporting health care institutions may experience a minimal-to-moderate annual cost for reporting. Health care institutions may also receive a significant benefit from the reports that may be disseminated by the Department, based on the information received under the new rules. Health professionals may be expected to incur a minimal burden due to reporting, and may receive a significant benefit from additional resources available to them and their patients as a result of the public health response to the opioid overdose epidemic, which is driven by data derived through the reporting.

The emergency rules are not consistent with reporting requirements for naloxone dispensing specified by the Arizona Board of Pharmacy. This inconsistency may cause confusion as to what information must be provided and in what timeframe. To address the discrepancy, the Department has included in the new rules a citation to A.R.S. § 32-1979. The Department believes this change from the requirements in the emergency rules may provide a significant benefit to a pharmacist/pharmacy by reducing confusion about reporting requirements.

The requirements in the rules were designed to provide the data that will allow a public health response to be implemented to improve the health and safety of the citizens of Arizona, including individuals experiencing an opioid overdose or NAS. Therefore, the Department anticipates that individuals experiencing an opioid overdose or NAS and their families may receive a significant benefit from the requirements in the rules. The Department anticipates that the timely monitoring of suspected opioid overdoses, and the effects that public health programs may have on them, may help reduce the number of opioid overdose deaths in Arizona and the number of individuals suffering an opioid overdose as a result of prescribed opioids. Therefore, the Department estimates that this rule may provide a significant benefit to the general public.

10. A description of any changes between the proposed rulemaking, to include supplemental notices, and the final rulemaking:

The following changes were made to the rule between the proposed rulemaking and the final rulemaking:

- A definition of “first response agency” has been added to R9-4-601; and
- Where applicable, the phrase “an ambulance service, an emergency medical services provider, or a law enforcement agency” has been replaced with “a first response agency” in R9-4-602.

11. An agency’s summary of the public stakeholder comments made about the rulemaking and the agency response to the comments:

The Department had a conversation with a representative of a hospital who expressed concern that a hospital might consider itself to be an “emergency medical services provider,” due to having an emergency department, and believe the hospital had to report under R9-4-602(A) as well as subsections (C) and (D). To reduce the chance of confusion, the Department is changing the rule as described under paragraph 10.

The Department received a written comment about the rulemaking from a representative of the Health System Alliance of Arizona after the close of record for this rulemaking but is addressing the concerns expressed in the written comment. A summary of the concerns and the Department’s responses follows:

Comment	Department’s Response
The commenter asked that the Department exclude providers covered under Title 42 Code of Federal Regulations, Chapter I, Subchapter A, Part 2 from reporting under R9-4-602(A).	R9-4-602(A) requires reporting from law enforcement agencies, ambulance services, and emergency medical services providers. This federal regulation is not applicable to these “first response agencies” and should not be included as part of the subsection. The Department is not changing the rule based on this comment.
The commenter asked that the Department clarify R9-4-602(A)(6) to state that hospitals do not have to provide additional reporting of naloxone administration prior to a patient’s arrival at the hospital.	R9-4-602(A)(6) does not pertain to hospitals. The Department is not changing the rule based on this comment.
The commenter asked the Department to clarify that the information required in R9-4-602(C)(3) and (5) must be reported “when known and available.”	The Department understands that sometimes information required in rule may not be available for every patient and includes the choice of “Unknown” in most fields in the database in which reported data is collected. However, the Department believes that most of the information required in these subsections includes information a hospital should be collecting on any patient or information that may be pertinent to treatment or referral decisions. The Department believes that a hospital should make the effort to obtain it. Subsection (C)(5)(f) includes the “if known” qualifier. The Department is not changing the rule based on this comment.



<p>The commenter asked the Department to clarify R9-4-602(C)(6)(b) to state that the requirement for date of death is applicable to deaths that occur “at the facility.”</p>	<p>The rule subsection requires the reporting of “Whether the individual with the suspected opioid overdose: b. Died and, if so, the date of death; and.” The Department does not anticipate that a hospital would continue to follow a patient after discharge to determine if and when the individual dies, sometime in the future. The Department believes that a hospital should report on a suspected opioid overdose death occurring at the hospital or pronounced at the hospital. The Department is not changing the rule based on this comment.</p>
<p>The commenter asked the Department to clarify that the information required in R9-4-602(D)(3), (4)(b), (d), and (e), and (5) must be reported if “known or available.”</p>	<p>As stated above, the Department believes that most of the information required in these subsections includes information a hospital should be collecting on any patient or information that may be pertinent to treatment or referral decisions. The Department believes that a hospital should make the effort to obtain it. Subsection (D)(5) includes the “if known” qualifier. The Department is not changing the rule based on this comment.</p>
<p>The commenter expressed concern that the required reports be submitted in a Department-provided format and wanted the information to be submitted electronically to avoid hospitals having “to dedicate considerable resources in order to comply with these new reporting requirements.”</p>	<p>The reporting requirements in the rule are not new, but are an extension of the reporting already being done by hospitals under the emergency rules. The term “Department-provided format” used in the rule refers to the existing data systems already being used for the collection of reported information. As stated in the economic, small business, and consumer impact statement, it currently takes between three and five minutes to enter a record. The Department estimates that an individual health care institution may incur less than \$1,000 in costs per year for reporting. The Department is not changing the rule based on this comment.</p>

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:

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:

The rules do not require a permit.

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:

Notice of Emergency Rulemaking: 23 A.A.R. 2857

Between the emergency rulemaking and the final rulemaking packages, the rule was changed by:

- Adding or revising definitions in R9-4-601;
- Changing R9-4-602(A)(3) to address situations in which:
 - The location of the encounter does not have a street address or is in an unincorporated location in a county, rather than in a city; or
 - The reporting entity does not have complete/correct information about the individual with a suspected opioid overdose or who died of a suspected opioid overdose;
- Changing R9-4-602(A)(6) and (7), (C)(3) to include an opioid antagonist other than naloxone;
- Clarifying requirements in R9-4-602(A)(8) into subsections (A)(8) and (9) related to the disposition of the individual with a suspected opioid overdoses;
- Clarifying exceptions from reporting requirement;
- Removing requirements in R9-4-602(C)(2) and (D)(2) for the address of the point of contact;
- Changing R9-4-602(C)(6) to include requirements related to discharge to a correctional facility and to simplify reporting information about the individual’s death;
- Changing subsection (E) to avoid conflicts with rules adopted by the Arizona Board of Pharmacy for pharmacists/pharmacies;
- Removing reporting requirements for clinical laboratories and related cross-references;
- Clarifying the authorities under which the information reported to the Department is confidential; and
- Making the changes described in paragraph 10

15. 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. DefinitionsR9-4-602. Opioid Poisoning-Related Reporting Requirements

ARTICLE 6. OPIOID POISONING-RELATED REPORTING

R9-4-601. Definitions

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 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 A.R.S. § 36-2201.
8. “First response agency” means:
 - a. An ambulance service.
 - b. An emergency medical services provider, or
 - c. A law enforcement agency.
9. “Health care institution” has the same meaning as in A.R.S. § 36-401.
10. “Health professional” has the same meaning as in A.R.S. § 32-3201.
11. “Law enforcement agency” has the same meaning as in A.A.C. R13-1-101.
12. “Medical examiner” has the same meaning as in A.R.S. § 36-301.
13. “Naloxone” means a specific opioid antagonist that has been used since 1971 to block the effects of an opioid in an individual.
14. “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.
15. “Opioid” means the same as “opiate” in A.R.S. § 36-2501.
16. “Opioid antagonist” means a prescription medication, as defined in A.R.S. § 32-1901, that:
 - a. Is approved by the U.S. Department of Health and Human Services, Food and Drug Administration; and
 - b. When administered, reverses, in whole or in part, the pharmacological effects of an opioid in the body.
17. “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.
18. “Pharmacist” has the same meaning as in A.R.S. § 32-1901.

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

- A.** A first response 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 first response agency:
 - a. Name;
 - b. Street address, city, county, and zip code;
 - c. Whether the first response agency 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;
 2. The name, title, telephone number, and email address of a point of contact for the first response agency required to report;
 3. The following information about the location at which the first response agency encountered the individual:
 - a. Street address or, if the location at which the first response agency encountered the individual does not have a street address, another indicator of the location at which the encounter occurred;
 - b. City, if applicable;
 - c. County;
 - d. State; and
 - e. Zip code;
 4. If applicable, the date and time the first response agency was dispatched to the location specified according to subsection (A)(3);



- 5. The following information, as known, 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 or another opioid antagonist designated according to A.R.S. § 36-2228 was administered to the individual before the first response agency encountered the individual and, if so:
 - a. The number of doses of naloxone or other opioid antagonist administered to the individual; and
 - b. As applicable, that the naloxone or other opioid antagonist was administered to the individual by:
 - i. Another individual; or
 - ii. Another first response agency and, if so the type of first response agency that administered the naloxone or other opioid antagonist to the individual;
 - 7. Whether naloxone or another opioid antagonist designated according to A.R.S. § 36-2228 was administered to the individual by the first response agency and, if so, the number of doses of naloxone or other opioid antagonist administered to the individual;
 - 8. Whether the disposition of the individual was that the individual:
 - a. Survived the suspected opioid overdose; or
 - b. Was pronounced dead:
 - i. At the location specified according to subsection (A)(3), or
 - ii. After leaving the location specified according to subsection (A)(3);
 - 9. If the individual was transported by a first response agency:
 - a. The type of first response agency that transported the individual; and
 - b. Whether the individual was transported to:
 - i. A hospital and, if so, the name of the hospital to which the individual was transported;
 - ii. Another class of health care institution and, if so, the name of the health care institution to which the individual was transported; or
 - iii. A correctional facility and, if so, the name of the correctional facility to which the individual was transported; and
 - 10. The date of the report.
- B.** The following are not required to submit a report under this Article:
- 1. An administrator of a health care institution licensed under 9 A.A.C. 10, for 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. A pharmacist for naloxone or another opioid antagonist that is dispensed in connection with a surgical procedure, as defined in A.A.C. R9-10-101, or other invasive procedure performed in a 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, 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 or another opioid antagonist designated according to A.R.S. § 36-2228 was administered to the individual before the health professional or health care institution encountered the individual and, if so:
 - i. The type of first response agency that administered the naloxone or other opioid antagonist to the individual, or
 - ii. That the naloxone or other opioid antagonist 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. 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 a first response agency and, if so, the type of first response agency 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 or correctional facility and, if so, the name of the law enforcement agency or correctional facility;
 - iv. Was discharged to home; or
 - v. Left the health care institution against medical advice; or
 - b. Died 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, 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. 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.** A pharmacist who dispenses naloxone or another opioid antagonist to an individual according to A.R.S. § 32-1979 shall, either personally or through a representative, submit a report as required in A.R.S. § 32-1979 to document the dispensing.
- 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 or another opioid antagonist was administered to the deceased individual before the deceased individual's death and, if known:
 - i. The type of first response agency that administered the naloxone or other opioid antagonist to the deceased individual,
or
 - ii. That the naloxone or other opioid antagonist 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.** Information collected on individuals pursuant to this Article is confidential according to:
- 1. A.R.S. § 36-133(F); and
 - 2. If applicable, A.R.S. §§ 36-2401 through 36-2403.