

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

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ARTICLE 1. DEFINITIONS

R9-4-101. Definitions, General

In this Chapter, unless otherwise specified:

1. “Admitted” means the same as in A.A.C. R9-10-101.
2. “Business day” means any day of the week other than a Saturday, a Sunday, a state legal holiday, or a day on which the Department is authorized or obligated by law or executive order to close.
3. “Calendar day” means any day of the week, including a Saturday or a Sunday.
4. “Clinical laboratory” means a facility that:
 - a. Meets the definition in A.R.S. § 36-451;
 - b. Holds a certificate of accreditation or certificate of compliance issued by the United States Department of Health and Human Services under the 1988 amendments to the Clinical Laboratories Improvement Act of 1967; and
 - c. Is located within Arizona.
5. “Code” means a single number or letter, a set of numbers or letters, or a set of both numbers and letters that represents specific information.
6. “Dentist” means an individual licensed under A.R.S. Title 32, Chapter 11, Article 2.
7. “Department” means the Arizona Department of Health Services.
8. “Diagnosis” means the identification of a disease or injury, by an individual authorized by law to make the identification.
9. “Discharge” means the same as in A.A.C. R9-10-101.
10. “Discharge date” means the month, day, and year of an individual’s discharge from a hospital.
11. “Electronic” means the same as in A.R.S. § 44-7002.
12. “Guardian” means a person appointed as a legal guardian by a court of competent jurisdiction.
13. “Health care institution” means the same as in A.R.S. § 36-401.
14. "Health-related services" means the same as in A.R.S. § 36-401.
15. “Hospital” means the same as in A.A.C. R9-10-101.
16. “International Classification of Diseases Code” or “ICD Code” means a code, such as the ICD-9-CM or ICD-10-CM codes, which is used by a hospital for billing or reporting purposes.
17. "Medical records" means the same as in A.R.S. § 12-2291.
18. “Medical services” means the same as in A.R.S. § 36-401.

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19. “Nursing services” means the same as in A.R.S. § 36-401.
20. "Ordered" means instructed by a physician, registered nurse practitioner, or physician assistant to perform a test on an individual.
21. “Parent” means the:
 - a. Biological or adoptive father of an individual; or
 - b. Woman who:
 - i. Gave birth to an individual; or
 - ii. Adopts an individual.
22. “Pathology laboratory” means a clinical laboratory in which human cells or tissues are examined for the purpose of diagnosing diseases.
23. “Physician” means an individual licensed as a doctor of allopathic medicine under A.R.S. Title 32, Chapter 13, or as a doctor of osteopathic medicine under A.R.S. Title 32, Chapter 17.
24. “Physician assistant” has the same meaning as in A.R.S. § 32-2501.
25. “Registered nurse practitioner” means an individual who meets the definition of registered nurse practitioner in A.R.S. § 32-1601, and is licensed under A.R.S. Title 32, Chapter 15.
26. “Treatment” means the same as in A.A.C. R9-10-101.

ARTICLE 2. PESTICIDE ILLNESS

R9-4-201. Definitions

In this Article, unless otherwise specified:

1. “Cluster illness” means pesticide illness in two or more individuals that is caused by or may be related to one pesticide exposure incident.
2. “Documented” means evidenced by written information such as pesticide applicator reports, statements of individuals with pesticide illness, or medical records.
3. “Health care professional” means a physician, a registered nurse practitioner, a physician assistant, or any other individual who is authorized by law to diagnose human illness.
4. “Medical director” means the individual designated by a poison control center as responsible for providing medical direction for the poison control center or for approving and coordinating the activities of the individuals who provide medical direction for the poison control center.
5. “Pesticide” means the same as in A.R.S. § 3-361, but does not include an antimicrobial agent, such as a disinfectant, sanitizer, or deodorizer, used for cleaning.
6. “Pesticide illness” means any sickness reasonably believed by a health care professional or medical director to be caused by or related to documented exposure to any pesticide, based upon professional judgment and:
 - a. The history, signs, or symptoms of the sickness;
 - b. Laboratory findings regarding the individual; or
 - c. The individual’s response to treatment for the sickness.
7. “Poison control center” means an organization that is a member of and may be certified by the American Association of Poison Control Centers.

R9-4-202. Pesticide Illness Reporting Requirements

- A.** A health care professional who believes that an individual has pesticide illness shall submit a report to the Department, either personally or through a representative:
 1. Except as specified in subsections (A)(2) and (C), within five business days after the health care professional determines that the individual may have pesticide illness; and
 2. Within one business days after the individual is admitted to a hospital or dies due to pesticide illness.
- B.** Except as specified in subsection (C), a medical director who believes that an individual has pesticide illness shall submit a report to the Department, either personally or through a representative at least once each month.

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- C.** A health care professional or medical director who believes that an individual is part of a cluster illness shall submit a report to the Department, either personally or through a representative, within one business day after determining that the individual has pesticide illness.
- D.** A health care professional or medical director shall ensure that the report required in subsection (A), (B), or (C) includes the following information:
1. The name, address, and telephone number of the individual with pesticide illness;
 2. The date of birth of the individual with pesticide illness;
 3. The gender, race, and ethnicity of the individual with pesticide illness;
 4. The date symptoms of pesticide illness began;
 5. The date the health care professional or medical director determined that the individual may have pesticide illness;
 6. The occupation of the individual with pesticide illness;
 7. The name of the pesticide, if known;
 8. The symptoms reported by the individual with pesticide illness;
 9. Whether any laboratory tests were performed for the individual with pesticide illness and, if so, for each test:
 - a. The type of specimen collected,
 - b. The date the specimen was collected,
 - c. The type of test performed,
 - d. The results of the test, and
 - e. What results of the test would be considered normal;
 10. A description of any treatment provided to the individual with pesticide illness;
 11. On what basis the health care professional or medical director believes the individual has pesticide illness;
 12. The name and telephone number of the health care professional or medical director who believes that the individual has pesticide illness;
 13. The name and address of the health care institution or poison control center at which the health care professional or medical director determined that the individual may have pesticide illness; and
 14. A description of the type of health care institution or poison control center specified in subsection (D)(13).
- E.** A health care professional or medical director, either personally or through a representative, shall submit the report required in subsection (A), (B), or (C):
1. By telephone;

2. In person;
3. In a document sent by fax, delivery service, or mail; or
4. Through an electronic reporting system authorized by the Department.

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ARTICLE 3. BLOOD LEAD LEVELS

R9-4-301. Definitions

In this Article, unless otherwise specified:

1. “Adult” means an individual 16 years of age or older.
2. “Child” means an individual younger than 16 years of age.
3. “Patient” means the individual whose blood has been tested for lead content.
4. "Point-of-care test for blood lead" means an analysis to screen an individual for exposure to lead:
 - a. That is performed outside a clinical laboratory, and
 - b. For which the results of the analysis are available before the individual leaves the location at which the analysis was performed.
5. “Whole blood” means human blood from which plasma, erythrocytes, leukocytes, and thrombocytes have not been separated.

R9-4-302. Blood Lead Level Reporting Requirements

- A. For each patient, a physician shall submit a report to the Department, either personally or through a representative, for the levels of lead and within the time periods specified in Table 3.1.

Table 3.1: Criteria for Physician Reporting of Blood Lead Levels

| | Child | Adult |
|---|--|---|
| Within One Business Day After Performing a Point-of-Care Test for Blood Lead or Receiving the Result of a Test for Blood Lead from a Clinical Laboratory | ≥ 45 µg of lead per dL of whole blood | ≥ 60 µg of lead per dL of whole blood |
| Within Five Business Days After Performing a Point-of-Care Test for Blood Lead or Receiving the Result of a Test for Blood Lead from a Clinical Laboratory | ≥ 10 µg to < 45 µg of lead per dL of whole blood | ≥ 25 µg to <60 µg of lead per dL of whole blood |
| At Least Once Each Month After Performing a Point-of-Care Test for Blood Lead | < 10 µg of lead per dL of whole blood | < 25 µg of lead per dL of whole blood |

- B.** A physician shall ensure that the report required in subsection (A) includes the following information:
1. The patient's name, address, and telephone number;
 2. The patient's date of birth;
 3. The patient's gender, race, and ethnicity;
 4. If the patient is an adult, the patient's occupation and the name, address, and telephone number of the patient's employer;
 5. Whether the blood collected from the patient was venous blood or capillary blood;
 6. The date the blood was collected;
 7. The results of the blood lead level test;
 8. The date of the test result;
 9. If the test result indicates a blood lead level greater than or equal to 25 µg of lead per dL of whole blood for an adult or greater than or equal to 10 µg of lead per dL of whole blood for a child:
 - a. The funding source for the medical services provided to the patient and, if applicable, the name of the patient's health plan and the identification number for the patient assigned by the health plan;
 - b. The language predominantly spoken in the patient's home, if known; and
 - c. If the patient is a child, the name of the patient's parent or guardian;
 10. The date the physician performed the point-of-care test for blood lead or received the test result from a clinical laboratory;
 11. If applicable, the name, address, and telephone number of the clinical laboratory that tested the blood; and
 12. The name, practice name, address, and telephone number of the physician who performed the point-of-care test for blood lead or received the test result from the clinical laboratory.
- C.** For each blood lead level test, a clinical laboratory director shall submit a report to the Department, either personally or through a representative, for the levels of lead and within the time periods specified in Table 3.2.

Table 3.2: Criteria for Clinical Laboratory Director Reporting of Blood Lead Levels

| | Child | Adult |
|--|--|---|
| Within One Business Day After Completing the Test | ≥ 45 µg of lead per dL of whole blood | ≥ 60 µg of lead per dL of whole blood |
| Within Five Business Days After Completing the Test | ≥ 10 µg to < 45 µg of lead per dL of whole blood | ≥ 25 µg to <60 µg of lead per dL of whole blood |
| At Least Once Each Month | < 10 µg of lead per dL of whole blood | < 25 µg of lead per dL of whole blood |

D. A clinical laboratory director shall ensure that the report required in subsection (C) includes the following information:

1. The patient’s name, address, and telephone number;
2. The patient’s date of birth;
3. The patient’s gender, race, and ethnicity;
4. If the patient is an adult, the patient’s occupation and the name, address, and telephone number of the patient’s employer if known;
5. The name, practice name, address, and telephone number of the physician who ordered the test;
6. If known, the funding source for the test for blood lead, the name of the patient’s health plan, and the identification number for the patient assigned by the health plan;
7. Whether the blood collected from the patient was venous blood or capillary blood;
8. The date the blood was collected;
9. The results of the blood lead level test;
10. The date of the test result;
11. The name and address of the clinical laboratory that tested the blood; and
12. The name and telephone number of the clinical laboratory director.

E. A physician or clinical laboratory director, either personally or through a representative, shall submit the report required in subsection (A) or (C):

1. By telephone;
2. In person;
3. In a document sent by fax, delivery service, or mail; or
4. Through an electronic reporting system authorized by the Department.

ARTICLE 4. CANCER REGISTRY

R9-4-401. Definitions

In this Article, unless otherwise specified:

1. “Analytic patient” means a patient, who is:
 - a. Diagnosed at a facility, or
 - b. Administered any part of a first course of treatment at the facility.
2. “Calendar year” means January 1 through December 31.
3. “Cancer” means a group of diseases characterized by uncontrolled cell growth and the spread of abnormal cells.
4. “Cancer registry” means a unit within a hospital or clinic that collects, stores, summarizes, distributes, and maintains information specified in R9-4-403 about patients who:
 - a. Are admitted to the hospital;
 - b. Receive diagnostic evaluation at, or cancer-directed treatment from, the hospital or clinic; or
 - c. Show evidence of cancer, carcinoma in situ, or a benign tumor of the central nervous system while receiving treatment from the hospital or clinic.
5. “Carcinoma” means a type of cancer that is characterized as a malignant tumor derived from epithelial tissue.
6. “Carcinoma in situ” means a cancer that is confined to epithelial tissue within the site of origin.
7. “Case report” means an electronic or paper document that includes the information in R9-4-403 for a patient.
8. “Chemotherapy” means the treatment of cancer using specific chemical agents or drugs that are selectively destructive to malignant cells and tissues.
9. “Clinic” means a facility that is not physically connected to or affiliated with a hospital, where a physician, doctor of naturopathic medicine, dentist, or registered nurse practitioner provides cancer diagnosis, cancer treatment, or both, and that is:
 - a. An outpatient treatment center, as defined in A.A.C. R9-10-101;
 - b. An outpatient surgical center, as defined in A.A.C. R9-10-101;
 - c. An outpatient radiation treatment center; or
 - d. A private office of one or more physicians, doctors of naturopathic medicine, dentists, or registered nurse practitioners that:
 - i. Is exempt from licensing under A.R.S. § 36-402(A)(3), and

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- ii. Treats 50 or more cancer patients per year.
- 10. “Clinical evaluation” means an examination of the body of an individual for the presence of disease or injury to the body, and review of any laboratory test results for the individual by a physician, doctor of naturopathic medicine, dentist, or registered nurse practitioner.
- 11. “Clinical or pathological” means an analysis of evidence either acquired solely before a first course of treatment was initiated, or acquired both before a first course of treatment, and supplemented or modified by evidence acquired during and subsequent to surgery or other treatment.
- 12. “Cytology” means the microscopic examination of cells.
- 13. “Date of first contact” means the day, month, and year a reporting facility first began to provide cancer-related medical services, nursing services, or health-related services, as defined in A.R.S. § 36-401, to a patient.
- 14. “Date of last contact” means the day, month, and year that a reporting facility last knew a patient to be alive.
- 15. “Designee” means a person assigned by the governing authority, as defined in A.R.S. § 36-401, of a hospital or clinic or by an individual acting on behalf of the governing authority to gather information for or report to the Department, as specified in R9-4-403 or R9-4-404.
- 16. “Distant lymph node” means a lymph node that is not in the same general area of a human body as the primary site of a tumor.
- 17. “Distant site” means an area of a human body that is not adjacent to or in the same general area of the human body as the primary site of a tumor.
- 18. “Doctor of naturopathic medicine” means an individual licensed under A.R.S. Title 32, Chapter 14.
- 19. “First course of treatment” means the initial set of cancer- or non-cancer-directed treatment that is planned and administered to the patient when a cancer is diagnosed.
- 20. “Follow-up report” means an electronic document that includes the information stated in R9-4-404(A)(2) for a patient.
- 21. “Inpatient beds” means the same as in A.R.S. § 36-401.
- 22. “Licensed capacity” means the same as in A.R.S. § 36-401.
- 23. “Lymph” means the clear, watery, sometimes faintly yellowish fluid that circulates throughout the lymphatic system.

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24. “Lymph node” means any of the small bodies located along lymphatic vessels, particularly at the neck, armpit, and groin, that filter bacteria and foreign particles from lymph.
25. “Lymphatic system” means the organ system that consists of lymph, lymph nodes, and vessels or channels that contain and convey lymph throughout a human body.
26. “Malignant” means an inherent tendency of a tumor to sequentially spread to areas of a human body beyond the site of origin.
27. “Medical record number” means a unique number assigned by a hospital, clinic, physician, doctor of naturopathic medicine, dentist, or registered nurse practitioner to an individual for identification purposes.
28. “Melanocyte” means a skin cell that makes melanin, which is a dark pigment.
29. “Melanoma” means a dark-pigmented, malignant tumor arising from a melanocyte and occurring most commonly in the skin.
30. “Metastasis” means the spread of a cancer from a primary site into a regional site or a distant site.
31. “Narrative description” means a written text describing an act, occurrence, or course of events.
32. “Organ” means a somewhat independent part of a human body, such as a heart or a kidney, that performs a specific function.
33. “Organ system” means one or more organs and associated tissues that perform a specific function, such as the circulatory system.
34. “Outpatient radiation treatment center” means a facility regulated under 9 A.A.C. 7 that provides radiation treatment.
35. “Patient” means an individual who has been diagnosed with a cancer, carcinoma in situ, or benign tumor of the central nervous system:
 - a. Including melanoma; and
 - b. Excluding skin cancer that:
 - i. Is confined to the primary site, or
 - ii. Was diagnosed after January 1, 2003.
36. “Primary site” means a specific organ or organ system within a human body where the first cancer tumor originated.
37. “Principal diagnosis” means the primary condition for which an individual is admitted to a hospital or treated by the hospital.

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38. “Radiation treatment” means the exposure of a human body to a stream of particles or electromagnetic waves for the purpose of selectively destroying certain cells or tissues.
39. “Reconstructive surgery” means a medical procedure that involves cutting into a body tissue or organ with instruments to repair damage or restore function to, or improve the shape and appearance of, a body structure that is missing, defective, damaged, or misshapen by cancer or cancer-directed therapies.
40. “Reference date” means the date on which the hospital’s cancer registry began reporting patient information to the Department.
41. “Regional lymph node” means a lymph node that is in the same general area of a human body as the primary site of a tumor.
42. “Regional site” means an area of a human body that is adjacent to or in the same general area of the human body as the primary site of a tumor.
43. “Release” means to transfer care of a patient from a hospital to a physician, a doctor of naturopathic medicine, a registered nurse practitioner, an outpatient treatment center, another hospital, the patient, the patient’s parent if the patient is under 18 years of age and unmarried, or the patient’s legal guardian.
44. “Reporting facility” means a hospital, clinic, physician, doctor of naturopathic medicine, dentist, or registered nurse practitioner that submits a case report to the Department.
45. “Secondary diagnosis” means all other diagnoses of an individual that may be related to cancer made after the principal diagnosis.
46. “Skin cancer” means cancer of any of the following types:
 - a. Papillary tumor, a tumor of the skin producing finger-like projections from the skin surface;
 - b. Squamous cell, a flat, scale-like skin cell that forms part of the surface of the skin;
 - c. Basal cell, a cell of the inner-most layer of the skin; or
 - d. Other carcinoma of the skin, where a specific diagnosis has not been determined.
47. “Stage group” means a scheme for categorizing a patient, based on the staging classification of the patient’s cancer, to enable a physician, doctor of naturopathic medicine, or registered nurse practitioner to provide better treatment and outcome information to the patient.
48. “Staging classification” means the categorizing of a cancer according to the size and spread of a tumor from its primary site, based on an analysis of three basic components:
 - a. The tumor at the primary site,

- b. Regional lymph nodes, and
 - c. Metastasis.
49. “Tumor” means an abnormal growth of tissue resulting from uncontrolled multiplication of cells and serving no physiological function.

R9-4-402. Exceptions

This Article does not apply to a hospital that is a special hospital, as defined in A.A.C. R9-10-101, that:

- 1. Is only licensed to provide psychiatric services, or
- 2. Limits admission to individuals requiring rehabilitation services, as defined in A.A.C. R9-10-101.

R9-4-403. Case Reports

A. A physician, doctor of naturopathic medicine, dentist, registered nurse practitioner, or the designee of a clinic shall:

- 1. Prepare a case report in a format provided by the Department;
- 2. Include the following information in the case report:
 - a. The name, address, and telephone number of, or the identification number assigned by the Department to, the reporting facility;
 - b. The patient’s name, and, if applicable, the patient’s maiden name and any other name by which the patient is known;
 - c. The patient’s address at the date of last contact, and address at diagnosis of cancer;
 - d. The patient’s date of birth, Social Security number, sex, race, and ethnicity;
 - e. The date of first contact with the patient for the cancer being reported, as applicable;
 - f. If the patient is an adult, the:
 - i. Primary type of activity carried out by the business where the patient was employed for the most number of years of the patient’s life before the diagnosis of cancer, and
 - ii. Kind of work performed by the patient for the most number of years of the patient’s life during which the patient was employed for a salary or wages before the diagnosis of cancer;
 - g. The patient’s medical record number, if applicable;
 - h. The date of diagnosis of the cancer being reported;

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- i. If the diagnosis was not made at the reporting facility, the name and address of the facility at which the diagnosis was made;
- j. The primary site and the specific subsite area within the primary site for the cancer being reported;
- k. The following characteristics of the tumor at diagnosis:
 - i. Size;
 - ii. Histology, the microscopic structure of the tumor cells and surrounding tissues in relation to their function;
 - iii. Grade, the degree of resemblance of the tumor to normal tissue, as an indication of the severity of the cancer; and
 - iv. Laterality, the side of a paired organ or the side of the body in which the primary site of the tumor is located;
- l. A code that describes the presence or absence of malignancy in a tumor;
- m. Whether the cancer had spread from the primary site at the time of diagnosis and, if so, to where;
- n. The extent to which the cancer has spread from the primary site;
- o. A narrative description of the extent to which the cancer had spread at diagnosis, as applicable;
- p. The method or methods by which the diagnosis was made, or whether the method by which the diagnosis was made is unknown;
- q. Whether the patient's laboratory results show the presence of specific substances, derived from tumor tissue, whose detection in the blood, urine, or tissues of a human body indicates the presence of a specific type of tumor, if applicable;
- r. Any other physiological symptoms or diagnostic criteria that may indicate the presence of a specific type of tumor, if applicable;
- s. For each treatment the patient received, the type of treatment, date of treatment, and the name of the facility where the treatment was performed;
- t. Whether any residual tumor cells were left at the edges of a surgical site, after surgery to remove a tumor at the primary site;
- u. Whether the patient is alive or dead, including:
 - i. The date of last contact if the patient is alive, and
 - ii. The date of death if the patient is dead;

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- v. Whether or not the patient has evidence of a current cancer, carcinoma in situ, or benign tumor of the central nervous system as of the date of last contact or death, or whether this information is unknown;
 - w. The name of the physician, nurse practitioner, or doctor of naturopathic medicine providing medical services to the patient; and
 - x. Whether the patient has a history of other cancers, and if so, identification of the primary site and the date the other cancer was diagnosed; and
3. Use codes and a coding format supplied by the Department for data items specified in subsection (A)(2) that require codes on the case report.
- B.** The cancer registry of a hospital that reports as specified in R9-4-404(A) shall:
- 1. Prepare a case report in a format provided by the Department;
 - 2. Include the information specified in subsection (A) and the following information in the case report:
 - a. The patient's unique accession number, separate from a medical record number, that was assigned by the hospital's cancer registry to the patient for identification purposes;
 - b. The unique sequence number assigned by the cancer registry to the specific cancer within the body of the patient being reported;
 - c. The date the patient was admitted to the hospital for diagnostic evaluation, cancer-directed treatment, or evidence of cancer, carcinoma in situ, or a benign tumor of the central nervous system, if applicable;
 - d. The date the patient was discharged from the hospital after the patient received diagnostic evaluation or treatment at the hospital, if applicable;
 - e. The source of payment for diagnosis or treatment of cancer, or both;
 - f. The level of the facility's involvement in the diagnosis or treatment, or both, of the patient for cancer;
 - g. The year in which the hospital first provided diagnosis or treatment to the patient for the cancer being reported;
 - h. The patient's county of residence at diagnosis of cancer;
 - i. The patient's marital status and age at diagnosis of cancer, place of birth, and, if applicable, name of the patient's spouse;
 - j. If the patient is under 18 years of age and unmarried, the name of the patient's parent or legal guardian;

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- k. A narrative description of how the cancer was diagnosed, including a description of the primary site and the microscopic structure of the tumor cells and surrounding tissues;
- l. The number of regional lymph nodes examined and the number in which evidence of cancer was detected;
- m. The clinical, pathological, or other staging classification, based on the analysis of tumor, lymph node, and metastasis;
- n. The patient's clinical, pathological, or other stage group;
- o. If the cancer was diagnosed before 2018, the code for the person who determined the stage group of the patient;
- p. A narrative description of the clinical evaluation of x-ray diagnostic films and scans of the patient, and the dates of the films or scans;
- q. A narrative description of laboratory tests performed for the patient, including the date, type, and results of any of the patient's laboratory tests;
- r. A narrative description of the results of the patient's clinical evaluation;
- s. The procedures used by the reporting facility to obtain a diagnosis and staging classification, including:
 - i. The dates on which the procedures were performed; and
 - ii. The name of the facilities where the procedures were performed, if different from the reporting facility;
- t. A narrative description of any cancer-related surgery on the patient, including the:
 - i. Date of surgery;
 - ii. Name of the facility where the surgery was performed, if different from the reporting facility; and
 - iii. Type of surgery;
- u. The code associated with the type of surgery performed on the patient and the date of surgery;
- v. The codes associated with the:
 - i. Extent of lymph node surgery;
 - ii. Number of lymph nodes removed;
 - iii. Surgery of regional sites, distant sites, or distant lymph nodes; and
 - iv. Reason for no surgery or that surgery was performed;

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- w. Whether reconstructive surgery on the patient was performed as a first course of treatment, delayed, or not performed;
- x. A narrative description of cancer-related radiation treatment administered to the patient, including the:
 - i. Date of radiation treatment;
 - ii. Name of the facility where the radiation treatment was performed, if different from the reporting facility; and
 - iii. Type of radiation;
- y. As applicable, the code specifying that radiation treatment was administered or associated with the reason for no radiation treatment;
- z. The code associated with the type of radiation treatment administered to the patient and the date of radiation treatment;
- aa. A narrative description of cancer-related chemotherapy administered to the patient, including the:
 - i. Date of cancer-related chemotherapy;
 - ii. Name of the facility that administered the chemotherapy, if different from the reporting facility; and
 - iii. Type of chemotherapy;
- bb. The code associated with the type of chemotherapy administered to the patient and the date of chemotherapy;
- cc. The code associated with any other types of cancer- or non-cancer-directed first course of treatment, not otherwise coded on the case report for the patient, including:
 - i. Hormone therapy, immunotherapy, hematologic transplant, or endocrine procedures administered to the patient;
 - ii. Additional surgery, radiation, or chemotherapy administered to the patient; or
 - iii. Other treatment administered to the patient;
- dd. If applicable, a narrative description of any other types of cancer or non-cancer-directed first course of treatment, including:
 - i. The dates of the treatment;
 - ii. The names of the facilities where the treatment was performed, if different from the reporting facility; and
 - iii. The type of treatment;

- ee. If the patient's treatment included both surgery and another type of treatment, the sequence of the two treatments;
 - ff. The code for the status of the patient's treatment, including whether the patient received any treatment or the tumor was being actively observed and monitored;
 - gg. The code for whether the patient has had a reappearance of a cancer, carcinoma in situ, or benign tumor of the central nervous system, and, if additional cancer of the type diagnosed at the primary site is found after cancer-directed treatment:
 - i. The date of the reappearance; and
 - ii. A narrative description of the nature of the reappearance, including whether the additional cancer was found at the primary site, a regional site, or a distant site;
 - hh. If the patient has died, the place and cause of death and whether an autopsy was performed;
 - ii. The name of the individual or the code that identifies the individual completing the case report;
 - jj. The type of records used by the reporting facility to complete the case report;
 - kk. If applicable, a code that indicates the reason for a required date not to be included in the case report required in subsection (B)(1); and
 - ll. If applicable, a code that indicates that an apparently inconsistent code has been reviewed and is correct; and
3. Use codes and coding format supplied by the Department for data items specified in subsection (B)(2) that require codes in the case report.

R9-4-404. Requirements for Submitting Case Reports and Follow-up Reports and Allowing Review of Hospital Records

- A.** The cancer registry of a hospital with a licensed capacity of 50 or more inpatient beds shall ensure that:
- 1. An electronic case report, prepared according to R9-4-403(B), is submitted to the Department within 180 calendar days after the date a patient is first released from the hospital;
 - 2. An electronic follow-up report, for correcting information previously submitted according to R9-4-403(A)(2)(j) through (l), or (B)(2)(a), (b), (m), (n), or (w), is submitted to the Department:

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- a. Within 30 calendar days after identifying the correct information and at least annually,
 - b. For all patients for whom applicable corrected information is obtained,
 - c. That includes patient identifying information and the information to be corrected, and
 - d. In a format provided by the Department; and
3. An electronic follow-up report for analytic patients, in a format provided by the Department:
- a. Is submitted to the Department at least annually for:
 - i. All living analytic patients in the hospital's cancer registry database, and
 - ii. All analytic patients in the hospital's cancer registry database who have died since the last follow-up report; and
 - b. Includes, as applicable:
 - i. A change of patient address;
 - ii. A summary of additional first course of treatment; and
 - iii. The information in R9-4-403(A)(2)(s), (u), (v), and (w) and R9-4-403(B)(2)(gg).
- B.** The cancer registry or other designee of a hospital with a licensed capacity of fewer than 50 inpatient beds shall either report as specified in subsection (A), or shall at least once every six months:
1. Prepare and submit to the Department, in a format provided by the Department:
 - a. For all individuals:
 - i. Released by the hospital since the last report was prepared, and
 - ii. Whose medical records include ICD Codes specified in a list provided to the hospital by the Department;
 - b. The following information for each individual:
 - i. The individual's medical record number assigned by the hospital,
 - ii. The individual's date of birth,
 - iii. The individual's admission and discharge dates,
 - iv. All applicable ICD Codes for the individual that are in the list in subsection (B)(1)(a)(ii), and
 - v. Whether the ICD Code reflects the individual's principal or secondary diagnosis; and

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2. Allow the Department to review the records listed in R9-4-405(A) to obtain the information specified in R9-4-403 about a patient.
- C.** If the designee of a clinic submitted 100 or more case reports to the Department in the previous calendar year or expects to submit 100 or more case reports in the current calendar year, the designee of the clinic shall:
1. Submit to the Department a case report, prepared according to R9-4-403(A), for each patient who is not referred by the clinic to a hospital for the first course of treatment; and
 2. Ensure that the case report in subsection (C)(1) is submitted in electronic format within 90 calendar days after:
 - a. Initiation of treatment of the patient at the clinic; or
 - b. Diagnosis of cancer in the patient, if the clinic did not provide treatment and did not refer to a hospital for the first course of treatment.
- D.** If the designee of a clinic submitted fewer than 100 case reports to the Department in the previous calendar year and expects to submit fewer than 100 case reports in the current calendar year, the designee of the clinic shall submit to the Department an electronic or paper case report, prepared according to R9-4-403(A), for each patient, within 30 calendar days after the date of diagnosis of cancer in the patient, if the clinic:
1. Diagnoses cancer in the patient, and
 2. Does not refer the patient to a hospital for the first course of treatment.
- E.** A physician, doctor of naturopathic medicine, dentist, or registered nurse practitioner who diagnoses cancer in or provides treatment for cancer for fewer than 50 patients per year shall submit an electronic or paper case report to the Department for each patient, within 30 calendar days after the date of diagnosis of cancer in the patient, if the physician, doctor of naturopathic medicine, dentist, or registered nurse practitioner does not refer the patient to a hospital or clinic for the first course of treatment.
- F.** A clinic, physician, dentist, registered nurse practitioner, or doctor of naturopathic medicine that receives a letter from the Department, requesting any of the information specified in R9-4-403 about a patient, shall provide to the Department the requested information on the patient within 15 business days after the date of the request.
- G.** A clinic, physician, dentist, registered nurse practitioner, or doctor of naturopathic medicine that receives a letter from a hospital, requesting any of the information specified in R9-4-403 about a patient, shall provide to the hospital the requested information on the patient within 15 business days after the date of the request.
- H.** A pathology laboratory shall:

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1. At least once every 90 calendar days, provide to the Department electronic copies of pathology reports of patients; and
2. Include in a pathology report the following information:
 - a. The patient's name, address, and telephone number;
 - b. The patient's date of birth;
 - c. The patient's gender, race, and ethnicity;
 - d. Clinical information about the patient, if available;
 - e. The type of tissue collected;
 - f. The procedure by which the tissue was collected;
 - g. The date the tissue was collected;
 - h. The code number assigned by the clinical laboratory to the tissue collected for pathological analysis;
 - i. The results of the pathological analysis of the tissue, including the pathologist's interpretation of the results;
 - j. The date of the results;
 - k. The name, practice name, address, and telephone number of the physician who ordered the pathological analysis of the tissue;
 - l. The name and address of the clinical laboratory that performed the pathological analysis of the tissue; and
 - m. The name and telephone number of the clinical laboratory director.

R9-4-405. Data Quality Assurance

- A. To ensure completeness and accuracy of cancer reporting:
 1. Upon notice from the Department of at least five business days, a hospital, clinic, physician, doctor of naturopathic medicine, dentist, or registered nurse practitioner required to report under R9-4-404 shall allow the Department to review any of the following records, as are applicable to the facility:
 - a. A report meeting the requirements of R9-4-404(B)(1);
 - b. Patient medical records;
 - c. Medical records of individuals not diagnosed with cancer;
 - d. Pathology reports;
 - e. Cytology reports;
 - f. Logs containing information about surgical procedures, as specified in A.A.C. R9-10-215(6) or A.A.C. R9-10-911(A); and

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- E.** Upon receiving a case report returned under subsection (D), a hospital, clinic, physician, doctor of naturopathic medicine, dentist, or registered nurse practitioner shall submit the revised case report to the Department within 15 business days after the date the Department requests the revision.
- F.** Upon written request by the Department, a hospital shall:
 - 1. Prepare a case report based on a simulated medical record provided by the Department for the purpose of demonstrating the variability with which data is reported, and
 - 2. Submit the case report to the Department within 15 business days after the date of the request.

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ARTICLE 5. BIRTH DEFECTS MONITORING PROGRAM

R9-4-501. Definitions

In this Article, unless otherwise specified:

1. “Birth defect” means an abnormality:
 - a. Of body structure, function, or chemistry, or of chromosomal structure or composition;
 - b. That is present at or before birth; and
 - c. That may be diagnosed before or at birth, or later in life.
2. “Clinic” means:
 - a. A person under contract or subcontract with the Arizona Health Care Cost Containment System to provide the services specified in 9 A.A.C. 22, Article 13;
 - b. An outpatient treatment center, as defined in A.A.C. R9-10-101;
 - c. An outpatient surgical center, as defined in A.A.C. R9-10-101; or
 - d. A birth center, as defined in A.A.C. R9-13-201.
3. “Clinical evaluation” means an examination of the body of an individual and review of the individual’s laboratory test results to determine the presence or absence of a medical condition that may be related to a birth defect.
4. “Conception” means the formation of an entity by the union of a human sperm and ovum, resulting in a pregnancy.
5. “Co-twin” means a sibling of a patient, who was born to the same mother as the patient and as a result of the same pregnancy as the patient.
6. “Date of first contact” means the day, month, and year a physician, clinic, or other person specified in R9-4-503(A) first began to provide medical services, nursing services, or health-related services to a patient or the patient’s mother.
7. “Date of last contact” means the day, month, and year:
 - a. Of a patient’s death; or
 - b. That a physician, clinic, or other person specified in R9-4-503(A) last clinically evaluated, diagnosed, or provided treatment to a patient or the patient's mother.
8. “Designee” means an individual assigned by the governing power of a hospital, high-risk perinatal practice, genetic testing facility, or prenatal diagnostic facility or by another individual acting on behalf of the governing power to gather information for or report to the Department, as specified in R9-4-502, R9-4-503, or R9-4-504.
9. “Estimated date of confinement” means an approximation of the date on which a woman will give birth, based on the clinical evaluation of the woman.

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10. “Estimated gestational age” means an approximation of the duration of a pregnancy, based on the date of the last menstrual period of the pregnant woman.
11. “Facility” means a building and associated personnel and equipment that perform or are used in connection with performing a particular service or activity.
12. “Family medical history” means an account of past and present illnesses or diseases experienced by individuals who are biologically related to a patient.
13. “Genetic testing facility” means an organization, institution, corporation, partnership, business, or entity that conducts tests to detect, analyze, or diagnose a ~~genetic condition~~ disease or other abnormal state present at birth or before birth, as a result of an alteration of DNA, that may impair normal physiological functioning in an individual, including an evaluation to determine the structure of an individual’s chromosomes.
14. “Governing power” means the individual, agency, group, or corporation appointed, elected, or otherwise designated, in which the ultimate responsibility and authority for the conduct of a hospital, high-risk perinatal practice, genetic testing facility, or prenatal diagnostic facility are vested.
15. “High-risk perinatal practice” means a clinic or physician that routinely provides medical services prenatally to a patient or a patient’s mother with perinatal risk factors to prevent, clinically evaluate, diagnose, or treat the patient for a possible birth defect.
16. “Log” means a chronological list of individuals for or on whom medical services, nursing services, or health-related services were provided by a designated unit of a hospital or by another person specified in R9-4-503(A).
17. “Medical condition” means a disease, injury, other abnormal physiological state, or pregnancy.
18. “Medical record number” means a unique number assigned by a hospital, clinic, physician, or registered nurse practitioner to an individual for identification purposes.
19. “Midwife” means an individual licensed under A.R.S. Title 36, Chapter 6, Article 7, or certified under A.R.S. Title 32, Chapter 15.
20. “Mother” means the woman:
 - a. Who is pregnant with or gives birth to a patient, or
 - b. From whose fertilized egg a patient develops.
21. “Multiple gestation” means a pregnancy in which a patient is not the only fetus carried in a mother’s womb.
22. “Patient” means an individual, regardless of current age:

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- a. Who, from conception to one year of age, was clinically evaluated for a possible birth defect or a medical condition that may be related to a birth defect:
 - i. By a physician, midwife, registered nurse practitioner, or physician assistant; or
 - ii. At a hospital or clinic;
 - b. Whose mother was clinically evaluated during her pregnancy with the individual:
 - i. For a medical condition that may be related to a possible birth defect, and
 - ii. By an individual or facility specified in subsection (22)(a);
 - c. Who, from conception to one year of age, was tested by a genetic testing facility or other clinical laboratory;
 - d. Whose mother was tested during her pregnancy with the individual by a:
 - i. Genetic testing facility or other clinical laboratory, or
 - ii. Prenatal diagnostic facility;
 - e. Who, from conception to one year of age, was provided treatment or whose mother during her pregnancy with the individual was provided treatment by a hospital, clinic, physician, registered nurse practitioner, or other person specified in R9-4-503(A) for a medical condition that may be related to a possible birth defect; or
 - f. Who has received a diagnosis of having a medical condition that may be related to a birth defect.
23. “Perinatal risk factor” means a situation or circumstance that may increase the chance of an individual being born with a birth defect, such as:
- a. A family medical history of birth defects or other medical conditions;
 - b. The exposure of the individual or the individual’s mother or biological father to radiation, medicines, chemicals, or diseases before the individual’s birth; or
 - c. An abnormal result of a test performed for the individual or the individual’s mother by a prenatal diagnostic facility or clinical laboratory, including a genetic testing facility.
24. “Prenatal diagnostic facility” means an organization, institution, corporation, partnership, business, or entity that conducts diagnostic ultrasound or other medical procedures that may diagnose a birth defect in a human being.
25. “Principal diagnosis” means the primary reason for which an individual is:
- a. Admitted to a hospital;

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- b. Treated by a hospital, clinic, midwife, physician, registered nurse practitioner, or physician assistant; or
 - c. Tested by a genetic testing facility or prenatal diagnostic facility.
26. “Procedure” means a set of activities performed on a patient or the mother of a patient that:
- a. Are invasive;
 - b. Are intended to diagnose or treat a disease, illness, or injury;
 - c. Involve a risk to the patient or patient’s mother from the activities themselves or from anesthesia; and
 - d. Require the individual performing the set of activities to be trained in the set of activities.
27. “Refer” means to provide direction to an individual or the individual’s parent or guardian to obtain medical services or a test for assessment, diagnosis, or treatment of a birth defect or other medical condition.
28. “Routinely” means occurring in the regular or customary course of business.
29. “Secondary diagnosis” means all other diagnoses that may be related to a birth defect for an individual besides the principal diagnosis.
30. “Singleton gestation” means a pregnancy in which a patient is the only fetus carried in a mother’s womb.
31. “Support services” means activities, not related to the diagnosis or treatment of a birth defect, intended to maintain or improve the physical, mental, or psychosocial capabilities of a patient or those individuals biologically or legally related to the patient.
32. “Surgical procedure” means making an incision into an individual’s body for the:
- a. Correction of a deformity or defect,
 - b. Repair of an injury,
 - c. Excision of a part of the individual’s body, or
 - d. Diagnosis, amelioration, or cure of a disease.
33. “Test” means:
- a. An analysis performed on body fluid, tissue, or excretion by a genetic testing facility or other clinical laboratory to evaluate for the presence or absence of a disease; or
 - b. A procedure performed on the body of a patient or the patient’s mother that may be used to evaluate for the presence or absence of a birth defect.

~~56.34.~~ “Transfer” means for a hospital to discharge a patient or the patient’s mother and send the patient or the patient’s mother to another hospital for inpatient medical services without the intent that the patient or the patient’s mother will return to the sending hospital.

~~57.35.~~ “Treatment” means the same as in A.A.C. R9-10-101.

~~58.36.~~ “Unit” means an area of a hospital designated to provide an organized service, as defined in A.A.C. R9-10-201.

R9-4-502. Reporting Sources; Information Submitted to the Department

A. The designee of a hospital shall:

1. Upon the request of the Department and no more often than once per month, prepare a report, in a format specified by the Department, identifying all individuals:
 - a. Who are patients or the mothers of patients; and
 - b. Whose:
 - i. Discharge date is within the time period for which the report is being prepared, as specified in subsection (A)(2)(d); and
 - ii. Medical records include for the principal diagnosis, a secondary diagnosis, or a procedure performed on the individual, an ICD Code for a diagnosis or a procedure code specified in a list provided to the hospital by the Department;
2. Include the following information in the report specified in subsection (A)(1):
 - a. The name, address, and telephone number of the hospital, or the identification number assigned by the Department to the hospital;
 - b. The name, telephone number, and e-mail address of the designee of the hospital;
 - c. The date the report was completed;
 - d. The time period for which the report is being prepared; and
 - e. For each patient or the mother of the patient:
 - i. The patient’s or mother’s medical record number;
 - ii. The name of the patient or patient’s mother, if available, and, if applicable, any other name by which the patient or patient’s mother is known;
 - iii. The patient’s gender and date of birth, if applicable;
 - iv. The admission and discharge dates;
 - v. The principal and secondary diagnoses or the ICD Codes for the principal and secondary diagnoses for the patient or patient’s mother; and

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- vi. The codes for procedures provided to the patient or patient's mother; and
 3. Submit the report specified in subsection (A)(1) to the Department, in a format specified by the Department, within 30 calendar days after the Department's request.
- B.** The designee of a prenatal diagnostic facility, high-risk perinatal practice, or clinic shall:
1. Upon the request of the Department and no more often than once per month, prepare a report, in a format specified by the Department, identifying all individuals:
 - a. For whom a specified test was conducted, with test results indicating a diagnosis in a list provided by the Department; or
 - b. Whose medical records include a principal diagnosis or secondary diagnosis specified in a list provided by the Department;
 2. Include the following information in the report specified in subsection (B)(1):
 - a. Either:
 - i. The name, address, and telephone number of the prenatal diagnostic facility, high-risk perinatal practice, or clinic; or
 - ii. The identification number assigned by the Department to the prenatal diagnostic facility, high-risk perinatal practice, or clinic;
 - b. The name, telephone number, and e-mail address of the designee of the prenatal diagnostic facility, high-risk perinatal practice, or clinic;
 - c. The date the report was completed;
 - d. The time period for which the report is being prepared;
 - e. The mother's name, date of birth, and medical record number;
 - f. The estimated gestational age of the patient at the time of the test or diagnosis, as applicable;
 - g. The mother's estimated date of confinement;
 - h. The outcome of the pregnancy, if known;
 - i. The location and date of the patient's birth, if known;
 - j. The patient's gender, if known;
 - k. The principal diagnosis and secondary diagnoses for the patient or the patient's mother, as applicable; and
 - l. Information about the test leading to the diagnosis, including:
 - i. The type of test performed,
 - ii. The date the test was completed, and
 - iii. The results of the test; and

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3. Submit the report specified in subsection (B)(1) to the Department, in a Department-provided format, within 30 calendar days after the Department's request.
- C. The designee of a genetic testing facility shall:
1. Prepare a report, in a format specified by the Department, for all individuals:
 - a. Who are patients or the mothers of patients, and
 - b. For whom the genetic testing facility performed a test specified in a list provided by the Department;
 2. Include the following information in the report specified in subsection (C)(1):
 - a. The name, address, and telephone number of the genetic testing facility, or the identification number assigned by the Department to the genetic testing facility;
 - b. The name, telephone number, and e-mail address of the designee of the genetic testing facility;
 - c. The date the report was completed;
 - d. The month for which the report is being prepared, if reporting according to subsection (C)(3)(a); and
 - e. For each patient or mother of a patient:
 - i. If the test was performed on the patient:
 - (1) The patient's name, date of birth, and gender; and
 - (2) The name of the patient's parent or guardian;
 - ii. If the test was performed on the mother of the patient:
 - (1) The mother's name and date of birth;
 - (2) The estimated gestational age of the patient when the test was performed, if available; and
 - (3) The mother's estimated date of confinement when the test was performed, if available;
 - iii. The name of the physician, registered nurse practitioner, or physician assistant who ordered the test for the patient or the patient's mother; and
 - iv. Information about the test, including:
 - (1) The type of test performed on the patient or the patient's mother,
 - (2) The date the test was completed, and
 - (3) The results of the test; and
 3. Submit to the Department the report specified in subsection (C)(1) and a copy of the test results within 30 calendar days after either:
 - a. The end of the month during which the test was completed, or

- b. The date of the test.

R9-4-503. Review of Records; Information Collected

A. Upon notice from the Department of at least five business days, the following persons or facilities shall allow the Department access to the facility and the electronic or written records specified in subsection (B)(1) to collect the information specified in subsection (B)(2):

- 1. A hospital,
- 2. A clinic,
- 3. A physician,
- 4. A midwife,
- 5. A registered nurse practitioner,
- 6. A genetic testing facility,
- 7. A prenatal diagnostic facility,
- 8. A physician assistant,
- 9. A clinical laboratory, or
- 10. A medical examiner.

B. The Department may:

- 1. Review any of the following records in electronic or written format, as are applicable to the person or facility specified in subsection (A):
 - a. Patient medical records;
 - b. Medical records for the mother of a patient;
 - c. Reports from:
 - i. Physicians or other individuals who clinically evaluated, diagnosed, or treated a patient or the patient's mother, including physical therapists, as defined in A.R.S. § 32-2001; occupational therapists, as defined in A.R.S. § 32-3401; podiatrists, as defined in A.R.S. § 32-801; and speech-language pathologists, licensed according A.R.S. Title 35, Chapter 17;
 - ii. High-risk perinatal practices;
 - iii. Prenatal diagnostic facilities;
 - iv. Genetic testing facilities;
 - v. Pathology laboratories; or
 - vi. Other facilities or clinical laboratories that performed a test for a patient or the patient's mother;

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- d. Logs and registers containing information about surgical procedures, as specified in A.A.C. R9-10-215(6) or A.A.C. R9-10-911(A);
 - e. Other logs that may contain information about a patient or the mother of a patient with a birth defect, such as:
 - i. Labor and delivery unit logs,
 - ii. Nursery unit logs,
 - iii. Pediatric unit logs,
 - iv. Intensive care unit logs,
 - v. Autopsy logs, and
 - vi. Ultrasound logs;
 - f. Autopsy reports; and
 - g. Records other than those specified in subsections (B)(1)(a) through (f) that contain information about or may lead to information about:
 - i. A patient,
 - ii. The patient's mother, or
 - iii. The patient's biological sibling; and
2. Collect the following information from a person or facility specified in subsection (A), as applicable to a patient or the mother of a patient:
- a. The name, address, and telephone number of the person or facility, or the identification number assigned by the Department to the person or facility;
 - b. The date of first contact and the date of last contact;
 - c. The date the patient was admitted to a hospital;
 - d. The date the patient was discharged from a hospital;
 - e. The dates the mother of the patient was admitted to and discharged from a hospital for:
 - i. The birth of the patient, or
 - ii. Treatment related to a possible birth defect in the patient;
 - f. The name and address of the hospital or other location in which the patient was born;
 - g. The name and address of a hospital in which the patient or the mother of the patient was admitted for treatment related to a possible birth defect in the patient;
 - h. The specific unit of a hospital that provided medical services to the patient or the patient's mother;
 - i. The medical record number of the patient or the patient's mother;

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- j. The patient's name and any other name by which the patient is known;
- k. The names, addresses, and dates of birth of the patient's parents;
- l. The name, address and telephone number of the patient's guardian, if a parent of the patient does not have physical custody of the patient;
- m. The patient's date of birth and hour of birth;
- n. The estimated date of confinement for the pregnancy resulting in the patient's birth;
- o. The estimated gestational age, length, weight, and head circumference of the patient at birth;
- p. The patient's gender, race, and ethnicity;
- q. The race and ethnicity of the patient's biological mother and father;
- r. The address of the patient's mother at the time of the patient's birth;
- s. The address and telephone number of the patient at the date of last contact;
- t. The county in which the patient was born;
- u. The name of each physician, registered nurse practitioner, physician assistant, or other person that clinically evaluated, diagnosed, ordered a test for, or treated the patient or the patient's mother;
- v. The names of any facility from which or to which the patient or the patient's mother was transferred or referred;
- w. Whether the patient was referred for or approved to receive services under 9 A.A.C. 22, Article 13, and, if so, the date of referral or approval;
- x. Whether the patient is receiving any medical services, nursing services, ~~or~~ health-related services, or other services to support the patient or the patient's parent related to a birth defect, other than services under 9 A.A.C. 22, Article 13, and, if so, the name of the person providing the services and the date the provision of the services began;
- y. The name of the insurance company, if applicable, that:
 - i. Paid for the birth of the patient, and
 - ii. Is currently covering medical expenses for the patient or the patient's mother;
- z. Any perinatal risk factors documented in:
 - i. The patient's medical record,
 - ii. The patient's mother's medical record, or
 - iii. The patient's family medical history;

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- aa. Whether any tests were performed on the patient or the patient's mother by a genetic testing facility and, if so:
 - i. The types of tests performed,
 - ii. The test dates,
 - iii. The test results,
 - iv. The age or estimated gestational age of the patient at the time of each test,
 - v. The estimated date of confinement of the patient's mother at the time of each test,
 - vi. The name of the genetic testing facility that performed each test; and
 - vii. The names of the individuals who interpreted the test results;
- bb. Whether any tests were performed on the patient or the patient's mother by a prenatal diagnostic facility and, if so:
 - i. The types of tests performed,
 - ii. The test dates,
 - iii. The test results,
 - iv. The estimated gestational age of the patient at the time of each test,
 - v. The estimated date of confinement of the patient's mother at the time of each test,
 - vi. The name of the prenatal diagnostic facility that performed each test, and
 - vii. The names of the individuals who interpreted the test results;
- cc. Whether any other types of tests were performed on the patient or the patient's mother that may enable the diagnosis of a birth defect and, if so:
 - i. The types of tests performed,
 - ii. The test dates,
 - iii. The test results,
 - iv. The age or estimated gestational age of the patient at the time of each test,
 - v. The estimated date of confinement of the patient's mother at the time of each test,
 - vi. The names of the facilities that performed the tests, and
 - vii. The names of the individuals who interpreted the test results;
- dd. Whether any surgical procedures associated with a birth defect were performed on the patient or the patient's mother and, if so:

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- i. The types of surgical procedures performed,
- ii. The dates of the surgical procedures,
- iii. The results of the surgical procedures,
- iv. The ages or estimated gestational ages of the patient at the time of the surgical procedures,
- v. The estimated date of confinement of the patient's mother at the times of the surgical procedures, and
- vi. The names of the facilities at which the surgical procedures were performed, and
- vii. The names of the individuals who performed the surgical procedures;
- ee. For each diagnosis made for the patient or the patient's mother:
 - i. The diagnosis,
 - ii. Whether the diagnosis is a principal or secondary diagnosis,
 - iii. The facility at which the diagnosis was made,
 - iv. The date on which the diagnosis was made, and
 - v. The name of the individual who made the diagnosis;
- ff. The number of times the patient's mother has been pregnant;
- gg. The number of times a pregnancy of the patient's mother has lasted:
 - i. More than 37 weeks,
 - ii. Between 20 and 37 weeks, and
 - iii. Less than 20 weeks;
- hh. The number of children who were born as a result of the patient's mother's pregnancies, and whether the children were born alive or dead;
- ii. Whether the patient is from a singleton or multiple gestation, and, if from a multiple gestation, whether a co-twin of the patient:
 - i. Is identical or fraternal;
 - ii. Is alive, and, if not alive, the co-twin's date of death; and
 - iii. Has:
 - (1) The same birth defect as the patient,
 - (2) A different birth defect from that of the patient, or
 - (3) No birth defect;
- jj. If the patient is being adopted or living with a guardian rather than a parent;
- kk. If the patient is being adopted, the name, address, and telephone number of the individual who will adopt the patient;

- ll. The date of last contact; and
- mm. If the patient has died:
 - i. The patient's date and county of death,
 - ii. The facility in which the patient's death occurred, and
 - iii. Whether an autopsy was performed on the patient.

R9-4-504. Data Quality Assurance and Follow-up

- A. The Department may request a hospital, clinic, high-risk perinatal practice, genetic testing facility, or prenatal diagnostic facility to revise a report:
 - 1. That was submitted to the Department by the designee of the hospital, clinic, high-risk perinatal practice, genetic testing facility, or prenatal diagnostic facility under R9-4-502;
 - 2. That was not prepared according to R9-4-502; and
 - 3. By identifying the revisions that are needed in the report.
- B. If a person receives a request from the Department for revision of a report under subsection (A), the person shall return a revised report, containing the revisions requested by the Department, to the Department within 15 business days after the date of the Department's request, or by a date agreed to by the person and the Department.
- C. The Department may discuss the information submitted to the Department as specified in R9-4-502 or collected as specified in R9-4-503(B)(2) with:
 - 1. Any of the entities specified in R9-4-503(A) to obtain additional information about a patient's diagnosis or treatment;
 - 2. The Arizona Early Intervention Program, according to A.R.S. § 36-133(E); and
 - 3. The parent or guardian of a patient, as allowed by A.R.S. § 36-133(E).