

TITLE 9. HEALTH SERVICES

CHAPTER 4. DEPARTMENT OF HEALTH SERVICES
NONCOMMUNICABLE DISEASES

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July 18, 2000 (Supp. 00-3). Amended by final rulemaking at 12 A.A.R. 179, effective March 11, 2006 (Supp. 06-1).

R9-4-102. Repealed**Historical Note**

Adopted effective August 15, 1989 (Supp. 89-3). Amended effective April 9, 1993 (Supp. 93-2). Section repealed by final rulemaking at 6 A.A.R. 2948, effective July 18, 2000 (Supp. 00-3).

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Adopted effective August 15, 1989 (Supp. 89-3). Amended effective March 4, 1993 (Supp. 93-1). Section repealed by final rulemaking at 7 A.A.R. 55, effective December 12, 2000 (Supp. 00-4).

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Adopted effective January 1, 1992, filed September 25, 1991 (Supp. 91-3). "Register" corrected to "Registry" in subsection (1) (Supp. 93-1). Repealed by final rulemaking at 12 A.A.R. 179, effective March 11, 2006 (Supp. 06-1).

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Adopted effective September 25, 1991 (Supp. 91-3). Section repealed by final rulemaking at 7 A.A.R. 712, effective January 17, 2001 (Supp. 01-1).

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ARTICLE 2. PESTICIDE ILLNESS

R9-4-201. Definitions

In this Article, unless otherwise specified:

1. "Cluster illness" means sickness in two or more individuals that is caused by or may be related to one pesticide exposure incident, as determined by the history, signs, or symptoms of the sickness; laboratory findings regarding the individuals; the individuals' responses to treatment for the sickness; or the geographic proximity of the individuals.
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. "Pest" has the same meaning as in A.R.S. Title 3, Chapter 2, Article 5 or as used in A.R.S. Title 3, Chapter 2, Article 6 and A.R.S. Title 32, Chapter 22.
6. "Pesticide" means any substance or mixture of substances, including inert ingredients, intended for preventing, destroying, repelling, or mitigating any pest or

ARTICLE 1. DEFINITIONS

R9-4-101. Definitions, General

In this Chapter, unless otherwise specified:

1. "Dentist" means an individual licensed under A.R.S. Title 32, Chapter 11, Article 2.
2. "Department" means the Arizona Department of Health Services.
3. "Diagnosis" means the identification of a disease or injury, by an individual authorized by law to make the identification, that is the cause of an individual's current medical condition.
4. "Hospital" means the same as in A.A.C. R9-10-201.
5. "ICD-9-CM" means the version of the ICD-9-CM: International Classification of Diseases codes used by a hospital for billing purposes.
6. "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.

Historical Note

Adopted effective September 25, 1991 (Supp. 91-3). Amended by final rulemaking at 6 A.A.R. 2948, effective

- intended for use as a plant regulator, defoliant, or desiccant, but does not include an antimicrobial agent, such as a disinfectant, sanitizer, or deodorizer, used for cleaning.
7. "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.
 8. "Physician assistant" has the same meaning as in A.R.S. § 32-2501.
 9. "Poison control center" means an organization that is a member of and may be certified by the American Association of Poison Control Centers.
 10. "Registered nurse practitioner" has the same meaning as in A.R.S. § 32-1601.

Historical Note

Adopted effective August 15, 1989 (Supp. 89-3).

Amended effective April 9, 1993 (Supp. 93-2). Former Section R9-4-201 renumbered to R9-4-202; new Section R9-4-201 adopted by final rulemaking at 6 A.A.R. 2948, effective July 18, 2000 (Supp. 00-3).

R9-4-202. Pesticide Illness Reporting Requirements

A health care professional or medical director who participates in the diagnosis of or identifies an individual with pesticide illness shall file a report of pesticide illness with the Department as follows:

1. The health care professional or medical director shall report a pesticide illness within five working days from the date of diagnosis or identification, except:
 - a. The health care professional or medical director shall report a pesticide illness where the individual with pesticide illness is hospitalized or dies no later than one working day from the time of hospital admission or death; and
 - b. The health care professional or medical director shall report cluster illnesses no later than one working day from the time the second individual with pesticide illness is diagnosed or identified.
2. The health care professional or medical director shall submit the report to the Department by telephone; in person; in a writing sent by fax, delivery service, or mail; or by an electronic reporting system if an electronic reporting system is developed by the Department. The report shall contain the following information:
 - a. The name, address, and telephone number of the individual with pesticide illness;
 - b. The date of birth of the individual with pesticide illness;
 - c. The gender of the individual with pesticide illness;
 - d. The occupation of the individual with pesticide illness, if the documented pesticide exposure is related to the occupation;
 - e. The dates of onset of illness and of diagnosis or identification as pesticide illness;
 - f. The name of the pesticide, if known;
 - g. The name, business address, and telephone number of the health care professional or medical director making the report;
 - h. A statement specifying whether the illness is caused by a documented pesticide exposure or is related to a documented pesticide exposure; and
3. The health care professional or medical director may designate a representative to make the report to the Department on behalf of the health care professional or medical director.
 - i. The health care professional's or medical director's reason for believing that the illness is caused by or related to documented exposure to a pesticide.

Historical Note

New Section renumbered from R9-4-201 and amended by final rulemaking at 6 A.A.R. 2948, effective July 18, 2000 (Supp. 00-3).

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. "Clinical laboratory" has the same meaning as in A.R.S. § 36-451.
4. "Patient" means the individual whose blood has been tested for lead content.
5. "Public" means funded by and operated under the direction of the federal or state government or a political subdivision of the state.
6. "Public insurance" means a public program, such as the Arizona Health Care Cost Containment System, Kids-Care, Indian Health Services, or TRICARE, that pays for medical services.
7. "Whole blood" means human blood from which plasma, erythrocytes, leukocytes, and thrombocytes have not been separated.

Historical Note

Adopted effective August 15, 1989 (Supp. 89-3).

Amended effective March 4, 1993 (Supp. 93-1). Former Section R9-4-301 renumbered to R9-4-302; new Section R9-4-301 adopted by final rulemaking at 7 A.A.R. 55, effective December 12, 2000 (Supp. 00-4).

R9-4-302. Reporting Significant Blood Lead Levels

- A. A physician who receives a laboratory result showing a level of lead equal to or greater than 10 micrograms of lead per deciliter of whole blood for a child or 25 micrograms of lead per deciliter of whole blood for an adult shall report the blood lead level to the Department as follows:
 1. The physician shall report the blood lead level within five working days from the date of receipt of the laboratory result if the blood lead level is less than 45 micrograms of lead per deciliter of whole blood for a child or less than 60 micrograms of lead per deciliter of whole blood for an adult.
 2. The physician shall report the blood lead level within one working day from the date of receipt of the laboratory result if the blood lead level is equal to or greater than 45 micrograms of lead per deciliter of whole blood for a child or equal to or greater than 60 micrograms of lead per deciliter of whole blood for an adult.
 3. A physician may designate a representative to make the report to the Department on behalf of the physician.
- B. A clinical laboratory director shall report to the Department the results of all tests for lead in whole blood as follows:
 1. The clinical laboratory director shall report the blood lead test result within five working days from the date of completing the test if the blood lead level is equal to or greater than 10 but less than 45 micrograms of lead per deciliter

- of whole blood for a child or equal to or greater than 25 but less than 60 micrograms of lead per deciliter of whole blood for an adult.
2. The clinical laboratory director shall report the blood lead test result within one working day from the date of completing the test if the blood lead level is equal to or greater than 45 micrograms of lead per deciliter of whole blood for a child or equal to or greater than 60 micrograms of lead per deciliter of whole blood for an adult.
 3. The clinical laboratory director shall report blood test results that are less than 10 micrograms of lead per deciliter of whole blood for a child or less than 25 micrograms of lead per deciliter of whole blood for an adult at least once each month.
 4. A clinical laboratory director may designate a representative to make the report to the Department on behalf of the clinical laboratory director.
- C. A physician or clinical laboratory director shall submit each report to the Department by telephone; in a writing sent by fax, delivery service, or mail; or by an electronic reporting system authorized by the Department.
- D. A report shall include the following information:
1. The patient's name, address, and telephone number;
 2. The patient's date of birth;
 3. The patient's gender;
 4. If the patient is an adult, the patient's occupation and the name, address, and telephone number of the patient's employer;
 5. An indication of the patient's funding source and the specific health plan name, if applicable:
 - a. Public insurance,
 - b. Private insurance,
 - c. Self-pay,
 - d. Workplace monitoring program,
 - e. Other, or
 - f. Unknown;
 6. The type of blood draw used (venous or capillary);
 7. The date the blood was drawn;
 8. The blood lead level;
 9. The date the blood lead level was received by the physician or determined by the laboratory;
 10. The name, address, and telephone number of the laboratory that tested the blood; and
 11. The name, practice name, address, and telephone number of the physician who ordered the test.
- Historical Note**
- New Section renumbered from R9-4-301 and amended by final rulemaking at 7 A.A.R. 55, effective December 12, 2000 (Supp. 00-4).
- ARTICLE 4. CANCER REGISTRY**
- R9-4-401. Definitions**
- In this Article, unless otherwise specified:
1. "Accession number" means a unique number, separate from a medical record number, assigned by a hospital's cancer registry to a patient for identification purposes.
 2. "Admitted" means the same as in A.A.C. R9-10-201.
 3. "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.
 4. "Basal cell" means a cell of the inner-most layer of the skin.
 5. "Behavioral health service agency" means the same as "agency" in A.A.C. R9-20-101.
 6. "Business day" means any day of the week other than a Saturday, a Sunday, a legal holiday, or a day on which the Department is authorized or obligated by law or executive order to close.
 7. "Calendar day" means any day of the week, including a Saturday or a Sunday.
 8. "Calendar year" means January 1 through December 31.
 9. "Cancer" means a group of diseases characterized by uncontrolled cell growth and the spread of abnormal cells.
 10. "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.
 11. "Carcinoma" means a type of cancer that is characterized as a malignant tumor derived from epithelial tissue.
 12. "Carcinoma in situ" means a cancer that is confined to epithelial tissue within the site of origin.
 13. "Case report" means an electronic or paper document that includes the information in R9-4-403 for a patient.
 14. "Chemotherapy" means the treatment of cancer using specific chemical agents or drugs that are selectively destructive to malignant cells and tissues.
 15. "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, or
 - c. An outpatient radiation treatment center.
 16. "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.
 17. "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.
 18. "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.
 19. "Cytology" means the microscopic examination of cells.
 20. "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.
 21. "Date of last contact" means the day, month, and year that a reporting facility last knew a patient to be alive.
 22. "Designee" means a person assigned by the governing authority 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.
 23. "Discharge" means the same as in A.A.C. R9-10-201.

24. "Discharge date" means the month, day, and year when a patient is discharged from a hospital.
25. "Disease progression" means the process of a disease becoming more severe or spreading from one area of a human body to another area of the human body.
26. "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.
27. "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.
28. "Doctor of naturopathic medicine" means an individual licensed under A.R.S. Title 32, Chapter 14.
29. "Electronic" means the same as in A.R.S. § 44-7002.
30. "First course of treatment" means the initial set of cancer- or non-cancer-directed treatment that is planned when a cancer is diagnosed and administered to the patient before disease progression or recurrence.
31. "Follow-up report" means an electronic document that includes the information stated in R9-4-404(A)(2) for a patient.
32. "Governing authority" means the same as in A.R.S. § 36-401.
33. "Grade" means the degree of resemblance of a tumor to normal tissue, and gives an indication of the severity of the cancer.
34. "Health care institution" means the same as in A.A.C. R9-10-101.
35. "Histology" means the microscopic structure of cells, tissues, and organs in relation to their function.
36. "Inpatient beds" means the same as in A.R.S. § 36-401.
37. "Laterality" means the side of a paired organ or the side of the body in which the primary site of a tumor is located.
38. "Licensed capacity" means the same as in A.R.S. § 36-401.
39. "Lymph" means the clear, watery, sometimes faintly yellowish fluid that circulates throughout the lymphatic system.
40. "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.
41. "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.
42. "Malignant" means an inherent tendency of a tumor to sequentially spread to areas of a human body beyond the site of origin.
43. "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.
44. "Melanocyte" means a skin cell that makes melanin, which is a dark pigment.
45. "Melanoma" means a dark-pigmented, malignant tumor arising from a melanocyte and occurring most commonly in the skin.
46. "Metastasis" means the spread of a cancer from a primary site into a regional site or a distant site.
47. "Narrative description" means a written text describing an act, occurrence, or course of events.
48. "Organ" means a somewhat independent part of a human body, such as a heart or a kidney, that performs a specific function.
49. "Organ system" means one or more organs and associated tissues that perform a specific function, such as the circulatory system.
50. "Outpatient radiation treatment center" means a facility in which a person, licensed as specified in 12 A.A.C. 1, Article 7, provides radiation treatment.
51. "Papillary tumor" means a benign tumor of the skin producing finger-like projections from the skin surface.
52. "Pathology laboratory" means a facility in which human cells or tissues are examined for the purpose of diagnosing cancer and that is licensed under 9 A.A.C. 10, Article 1.
53. "Patient" means an individual who has been diagnosed with a cancer, carcinoma in situ, or benign tumor of the central nervous system, including melanoma, but excluding skin cancer that is:
 - a. Confined to the primary site; or
 - b. Present at regional sites or distant sites, but was diagnosed on or after January 1, 2003.
54. "Primary site" means a specific organ or organ system within a human body where the first cancer tumor originated.
55. "Principal diagnosis" means the primary condition for which an individual is admitted to a hospital or treated by the hospital.
56. "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.
57. "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.
58. "Recurrence" means the reappearance of a tumor after previous removal or treatment of the tumor, after a period in which the patient was believed to be free of cancer.
59. "Reference date" means the date on which the hospital's cancer registry began reporting patient information to the Department.
60. "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.
61. "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.
62. "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.
63. "Rehabilitation services" means the same as in A.A.C. R9-10-201.
64. "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.
65. "Reporting facility" means a hospital, clinic, physician, doctor of naturopathic medicine, dentist, or registered nurse practitioner that submits a case report to the Department.
66. "Secondary diagnosis" means all other diagnoses of an individual made after the principal diagnosis.

67. “Sequence number” means a unique number assigned by a cancer registry to a specific cancer within the body of a patient.
68. “Skin cancer” means cancer of any of the following types:
- Papillary tumor;
 - Squamous cell;
 - Basal cell; or
 - Other carcinoma of the skin, where a specific diagnosis has not been determined.
69. “Special hospital” means the same as in A.A.C. R9-10-201.
70. “Squamous cell” means a flat, scale-like skin cell.
71. “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.
72. “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:
- The tumor at the primary site,
 - Regional lymph nodes, and
 - Metastasis.
73. “Subsite” means a specific area within a primary site where a cancer tumor originated.
74. “Substantiate stage” means a narrative describing the stage group of a cancer at the time of diagnosis.
75. “Treatment” means the administration to a patient of medical services, nursing services, or health-related services, as defined in A.R.S. § 36-401, that are intended to relieve illness or injury.
76. “Tumor” means an abnormal growth of tissue resulting from uncontrolled multiplication of cells and serving no physiological function.
77. “Usual industry” means the primary type of activity carried out by the business where a patient was employed for the most number of years of the patient’s working life before the diagnosis of cancer.
78. “Usual occupation” means the kind of work performed during the most number of years of a patient’s working life before the diagnosis of cancer.
79. “Working life” means that portion of a patient’s life during which the patient was employed for a salary or wages.

Historical Note

Adopted effective January 1, 1992, filed September 25, 1991 (Supp. 91-3). Section repealed; new Section made by final rulemaking at 12 A.A.R. 179, effective March 11, 2006 (Supp. 06-1). Amended by final rulemaking at 3708, effective November 11, 2006 (Supp. 06-3).

R9-4-401.01. Repealed

Historical Note

New Section made by final rulemaking at 9 A.A.R. 1859, effective June 3, 2003 (Supp. 03-2). Section repealed by final rulemaking at 12 A.A.R. 179, effective March 11, 2006 (Supp. 06-1).

R9-4-402. Exceptions

This Article does not apply to a hospital that is:

- Licensed as a special hospital and a behavioral health service agency, or
- A special hospital that limits admission to individuals requiring rehabilitation services.

Historical Note

Adopted effective January 1, 1992, filed September 25, 1991 (Supp. 91-3). Section repealed; new Section made by final rulemaking at 12 A.A.R. 179, effective March 11, 2006 (Supp. 06-1).

R9-4-403. Case Reports

- A. A physician, doctor of naturopathic medicine, dentist, registered nurse practitioner, or the designee of a clinic shall:
- Prepare a case report in a format provided by the Department;
 - Include the following information in the case report:
 - The name, address, and telephone number, or the identification number assigned by the Department to the reporting facility;
 - The patient’s name, and if applicable, the patient’s maiden name and any other name by which the patient is known;
 - The patient’s address at the date of last contact, and address at diagnosis of cancer;
 - The patient’s date of birth, Social Security number, sex, race, and ethnicity;
 - The date of first contact with the patient for the cancer being reported;
 - The patient’s usual industry and usual occupation, if the patient is an adult;
 - The patient’s medical record number, if assigned;
 - The date of diagnosis of the cancer being reported;
 - If the diagnosis was not made at the reporting facility, the name and address of the facility at which the diagnosis was made;
 - The primary site and subsite of the cancer being reported;
 - The tumor size, histology, grade, and laterality at diagnosis;
 - A code that describes the presence or absence of malignancy in a tumor;
 - Whether the cancer had spread from the primary site at the time of diagnosis and if so, to where;
 - The extent to which the cancer has spread from the primary site;
 - A narrative description of the extent to which the cancer had spread at diagnosis;
 - Whether the diagnosis was made by histology, cytology, clinical evaluation, diagnostic x-ray, or any other method, or whether the method by which the diagnosis was made is unknown;
 - For each treatment the patient received, the type of treatment, date of treatment, and the name of the facility where the treatment was performed;
 - Whether any residual tumor cells were left at the edges of a surgical site, after surgery to remove a tumor at the primary site;
 - Whether the patient is alive or dead, including the date of last contact if the patient is alive, and the date, place, and cause of death if the patient is dead;
 - 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;
 - The name of the physician, nurse practitioner, or doctor of naturopathic medicine providing medical services, as defined in A.R.S. § 36-401, to the patient;
 - The name of the individual or the code that identifies the individual completing the case report;
 - The date the case report was completed; 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 with a licensed capacity of fewer than 50 inpatient beds that reports as specified in R9-4-404(A) and the cancer registry of a hospital with a licensed capacity of 50 or more inpatient beds 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 on the case report:
 - a. The patient's accession number;
 - b. The sequence number of the cancer 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;
 - k. The patient's religious preference, if applicable;
 - l. Whether the patient's laboratory results show the presence of specific substances known as Tumor Marker 1 and Tumor Marker 2, which are derived from tumor tissue and whose detection in the blood of a human body indicates the presence of a specific type of tumor;
 - m. A narrative description of how the cancer was diagnosed;
 - n. The number of regional lymph nodes examined and the number in which evidence of cancer was detected;
 - o. The clinical or pathological staging classification, based on the analysis of tumor, lymph node, and metastasis;
 - p. The patient's clinical or pathological stage group;
 - q. The occupation of the individual who determined the clinical or pathological stage group of the patient;
 - r. 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;
 - s. A narrative description of laboratory tests performed for the patient, including the date, type, and results of any of the patient's laboratory tests;
 - t. A narrative description of the results of the patient's clinical evaluation;
 - u. The procedures used by the reporting facility to obtain a diagnosis and staging classification, including the dates on which the procedures were performed, and the name of the facilities where the procedures were performed, if different from the reporting facility;
 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.
 - v. A narrative description of any cancer-related surgery on the patient, including the date of surgery, name of the facility where the surgery was performed, if different from the reporting facility, and type of surgery;
 - w. The code associated with the type of surgery performed on the patient and the date of surgery;
 - x. The codes associated with the:
 - i. Surgical approach;
 - ii. Extent of lymph node surgery;
 - iii. Number of lymph nodes removed;
 - iv. Surgery of regional sites, distant sites, or distant lymph nodes; and
 - v. Reason for no surgery or that surgery was performed;
 - y. Whether reconstructive surgery on the patient was performed as a first course of treatment, delayed, or not performed;
 - z. A narrative description of cancer-related radiation treatment administered to the patient, including the date of radiation treatment, name of the facility where the radiation treatment was performed, if different from the reporting facility, and type of radiation;
 - aa. The code associated with the type of radiation treatment administered to the patient and the date of radiation treatment;
 - bb. A narrative description of cancer-related chemotherapy administered to the patient, including the date of cancer-related chemotherapy, name of the facility that administered the chemotherapy, if different from the reporting facility, and type of chemotherapy;
 - cc. The code associated with the type of chemotherapy administered to the patient and the date of chemotherapy;
 - dd. If the patient's treatment included both surgery and radiation treatment, the sequence of the two treatments;
 - ee. If applicable, a narrative description of 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. Additional surgery, chemotherapy, radiation, or other treatment, administered to the patient;
 - ii. The dates of the treatment;
 - iii. The names of the facilities where the treatment was performed, if different from the reporting facility; and
 - iv. The type of treatment;
 - ff. If additional cancer of the type diagnosed at the primary site is found after cancer-directed treatment, the date and location of the additional cancer, and whether the additional cancer was found at the primary site, a regional site, or a distant site;
 - gg. If the patient has died, whether an autopsy was performed; and
 - hh. The type of records used by the reporting facility to complete the case report; and

Historical Note

Adopted effective January 1, 1992, filed September 25, 1991 (Supp. 91-3). Section repealed; new Section made by final rulemaking at 12 A.A.R. 179, effective March 11, 2006 (Supp. 06-1). Amended by final rulemaking at 12 A.A.R. 3708, effective November 11, 2006 (Supp. 06-3).

R9-4-404. Requirements for Submitting Case 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 is submitted to the Department within 180 calendar days from the date a patient is first released from the hospital; and
 2. An electronic follow-up report, including a change of patient address, if applicable, a summary of additional first course of treatment, if applicable, and the information in R9-4-403(A)(2)(q), (s), (t), and (u) and R9-4-403(B)(2)(gg), is submitted to the Department at least annually for:
 - a. All living analytic patients in the hospital's cancer registry database, and
 - b. All analytic patients in the hospital's cancer registry database who have died since the last follow-up report.
- 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 a written report to the Department:
 - a. For all individuals:
 - i. Released by the hospital since the last report was prepared, and
 - ii. Whose medical records include ICD-9-CM diagnosis codes specified in a list provided to the hospital by the Department,
 - b. Containing ICD-9-CM diagnosis codes that are arranged in numeric order, and
 - c. Including the following information associated with each ICD-9-CM diagnosis code:
 - i. The individual's medical record number assigned by the hospital,
 - ii. The individual's age,
 - iii. The individual's admission and discharge dates, and
 - iv. Whether the diagnosis code reflects the individual's principal or secondary diagnosis, and
 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 a case report to the Department 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 of:
 - 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.
- 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 an elec-

tronic or paper case report to the Department for each patient, within 30 calendar days from the date of diagnosis of cancer in the patient, if the clinic:

1. Diagnoses cancer in the patient without a pathology report from a pathology laboratory, 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 shall submit an electronic or paper case report to the Department for each patient, within 30 calendar days from the date of diagnosis of cancer in the patient, if the physician, doctor of naturopathic medicine, dentist, or registered nurse practitioner:
1. Diagnoses cancer in the patient without a pathology report from a pathology laboratory, and
 2. 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 from 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 from the date of the request.
- H.** A pathology laboratory shall:
1. Allow the Department to review pathology reports at least once every 90 calendar days to obtain the information specified in R9-4-403; and
 2. Provide to the Department copies, in electronic or written format, of pathology reports of patients.

Historical Note

Adopted effective January 1, 1992, filed September 25, 1991 (Supp. 91-3). Section repealed by final rulemaking at 9 A.A.R. 1859, effective June 3, 2003 (Supp. 03-2). New Section made by final rulemaking at 12 A.A.R. 179, effective March 11, 2006 (Supp. 06-1). Amended by final rulemaking at 12 A.A.R. 3708, effective November 11, 2006 (Supp. 06-3).

R9-4-405. Data Quality Assurance

- A.** To ensure completeness and accuracy of cancer reporting, 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:
1. A report meeting the requirements of R9-4-404(B)(1);
 2. Patient medical records;
 3. Medical records of individuals not diagnosed with cancer;
 4. Pathology reports;
 5. Cytology reports;
 6. Logs containing information about surgical procedures, as specified in A.A.C. R9-10-214(A)(6) or A.A.C. R9-10-1709(A); and
 7. Records other than those specified in subsections (A)(1) through (A)(6) that contain information about diagnostic evaluation, cancer-directed treatment, or other treatment provided to an individual by the hospital, clinic, physician, doctor of naturopathic medicine, dentist, or registered nurse practitioner.

- B.** The Department shall consider a hospital, clinic, physician, doctor of naturopathic medicine, dentist, or registered nurse practitioner required to report under R9-4-404 as meeting the criteria in R9-4-404 if the hospital, clinic, physician, doctor of naturopathic medicine, dentist, or registered nurse practitioner submits a case report to the Department for at least 97% of the patients for whom a case report is required under R9-4-404 during a calendar year.
- C.** The Department shall consider a hospital required to report under R9-4-404(A)(2) as meeting the criteria in R9-4-404(A)(2) if the hospital submits a follow-up report specified in R9-4-404(A)(2) to the Department once each calendar year for at least:
1. Eighty percent of all analytic patients from the hospital's reference date; and
 2. Ninety percent of all analytic patients diagnosed within the last five years or from the hospital's reference date, whichever is shorter.
- D.** The Department shall return a case report not prepared according to R9-4-403 to the hospital, clinic, physician, doctor of naturopathic medicine, dentist, or registered nurse practitioner that submitted the case report, identifying the revisions that are needed in the case report. The 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 from the date the Department requests the revision.
- E.** Upon written request by the Department, a hospital shall 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. The hospital shall return the case report to the Department within 15 business days from the date of the request.

Historical Note

New Section made by final rulemaking at 12 A.A.R. 179, effective March 11, 2006 (Supp. 06-1). Amended by final rulemaking at 12 A.A.R. 3708, effective November 11, 2006 (Supp. 06-3).

ARTICLE 5. BIRTH DEFECTS MONITORING PROGRAM

R9-4-501. Definitions

In this Article, unless otherwise specified:

1. "Admitted" means the same as in A.A.C. R9-10-201.
2. "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.
3. "Business day" means any day of the week other than a Saturday, a Sunday, a legal holiday, or a day on which the Department is authorized or obligated by law or executive order to close.
4. "Calendar day" means any day of the week, including a Saturday or a Sunday.
5. "Clinic" means:
 - a. A person under contract or subcontract with CRS to provide the medical services specified in 9 A.A.C. 7, Article 4;
 - b. An outpatient treatment center, as defined in A.A.C. R9-10-101, or
 - c. An outpatient surgical center, as defined in A.A.C. R9-10-101.
6. "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.
7. "Clinical laboratory" means a facility that:
 - a. Meets the definition in A.R.S. § 36-451;
 - b. Is operated, licensed, or certified by the U.S. government; and
 - c. Is located within Arizona.
8. "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.
9. "Conception" means the formation of an entity by the union of a human sperm and ovum, resulting in a pregnancy.
10. "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.
11. "CRS" means the Children's Rehabilitative Services program, established within the Department as specified in A.R.S. Title 36, Chapter 2, Article 3.
12. "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.
13. "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.
14. "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.
15. "Discharge" means the same as in A.A.C. R9-10-201.
16. "Discharge date" means the month, day, and year of an individual's discharge from a hospital.
17. "Electronic" means the same as in A.R.S. § 44-7002.
18. "Enrolled" means approved to receive services specified in 9 A.A.C. Chapter 7 from CRS.
19. "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.
20. "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.
21. "Facility" means a building and associated personnel and equipment that perform or are used in connection with performing a particular service or activity.
22. "Family medical history" means an account of past and present illnesses or diseases experienced by individuals who are biologically related to a patient.
23. "Follow-up services" means activities intended to assist the parent or guardian of a patient who has a birth defect to:
 - a. Learn about the birth defect and, if applicable, how the birth defect may be prevented; or
 - b. Obtain applicable medical services, nursing services, health-related services, or support services.
24. "Genetic condition" means a disease or other abnormal state present at birth or before birth, as a result of an alteration of DNA, that impairs normal physiological functioning of a human body.

25. "Genetic testing facility" means an organization, institution, corporation, partnership, business, or entity that conducts tests to detect, analyze, or diagnose a genetic condition in an individual, including an evaluation to determine the structure of an individual's chromosomes.
26. "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.
27. "Guardian" means an individual appointed as a legal guardian by a court of competent jurisdiction.
28. "Health-related services" means the same as in A.R.S. § 36-401.
29. "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.
30. "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).
31. "Medical condition" means a disease, injury, other abnormal physiological state, or pregnancy.
32. "Medical records" means the same as in A.R.S. § 12-2291.
33. "Medical record number" means a unique number assigned by a hospital, clinic, physician, or registered nurse practitioner to an individual for identification purposes.
34. "Medical services" means the same as in A.R.S. § 36-401.
35. "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.
36. "Mother" means the woman:
- Who is pregnant with or gives birth to a patient, or
 - From whose fertilized egg a patient develops.
37. "Multiple gestation" means a pregnancy in which a patient is not the only fetus carried in a mother's womb.
38. "Nursing services" means the same as in A.R.S. § 36-401.
39. "Ordered" means instructed by a physician, registered nurse practitioner, or physician assistant to perform a test on an individual.
40. "Parent" means the:
- Biological or adoptive father of an individual; or
 - Woman who:
 - Is the mother of an individual; or
 - Adopts an individual.
41. "Pathology laboratory" means a facility in which human cells, body fluids, or tissues are examined for the purpose of diagnosing diseases and that is licensed under 9 A.A.C. 10, Article 1.
42. "Patient" means an individual, regardless of current age:
- 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:
 - By:
 - A physician,
 - A midwife,
 - A registered nurse practitioner, or
 - A physician assistant; or
 - At a hospital or clinic;
 - Whose mother was clinically evaluated during her pregnancy with the individual:
 - For a medical condition that may be related to a possible birth defect, and
 - By an individual or facility specified in subsection (42)(a);
 - Who, from conception to one year of age, was tested by a genetic testing facility or other clinical laboratory;
 - Whose mother was tested during her pregnancy with the individual by a:
 - Genetic testing facility or other clinical laboratory, or
 - Prenatal diagnostic facility; or
 - 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.
43. "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 family medical history of birth defects or other medical conditions;
 - 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
 - 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.
44. "Physician assistant" means an individual licensed under A.R.S. Title 32, Chapter 25.
45. "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.
46. "Principal diagnosis" means the primary reason for which an individual is:
- Admitted to a hospital;
 - Treated by a hospital, clinic, physician, registered nurse practitioner, or physician assistant; or
 - Tested by a genetic testing facility or prenatal diagnostic facility.
47. "Procedure" means a set of activities performed on a patient or the mother of a patient that:
- Are invasive;
 - Are intended to diagnose or treat a disease, illness, or injury;
 - Involve a risk to the patient or patient's mother from the activities themselves or from anesthesia; and
 - Require the individual performing the set of activities to be trained in the set of activities.
48. "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.
49. "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.

50. "Routinely" means occurring in the regular or customary course of business.
51. "Secondary diagnosis" means all other diagnoses for an individual besides the principal diagnosis.
52. "Singleton gestation" means a pregnancy in which a patient is the only fetus carried in a mother's womb.
53. "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.
54. "Surgical procedure" means making an incision into an individual's body for the:
- Correction of a deformity or defect,
 - Repair of an injury,
 - Excision of a part of the individual's body, or
 - Diagnosis, amelioration, or cure of a disease.
55. "Test" means:
- 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
 - 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. "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. "Treatment" means the same as in A.A.C. R9-10-101.
58. "Unit" means an area of a hospital designated to provide an organized service, as defined in A.A.C. R9-10-201.
- e. For each patient or the mother of the patient:
- The patient's or mother's medical record number;
 - 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;
 - The race and ethnicity of the patient or patient's mother;
 - The patient's gender and date of birth, if applicable;
 - The admission and discharge dates;
 - The principal and secondary diagnoses or the ICD-9-CM diagnosis codes for the principal and secondary diagnoses for the patient or patient's mother; and
 - The procedure codes for 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 end of the month for which the report is being prepared.
- B.** The designee of a high-risk perinatal practice shall:
- Prepare a written report each month in a format specified by the Department for all individuals:
 - Who are patients or the mothers of patients; and
 - Whose:
 - Date of last contact is within the month for which the report is being prepared, as specified in subsection (B)(2)(d); and
 - Medical record includes a principal or secondary diagnosis specified in a list provided to the high-risk perinatal practice by the Department;
 - Include the following information in the report specified in subsection (B)(1):
 - The name, address, and telephone number of the high-risk perinatal practice, or the identification number assigned by the Department to the high-risk perinatal practice;
 - The name and telephone number of the designee of the high-risk perinatal practice;
 - The date the report was completed;
 - The month for which the report is being prepared; and
 - For each patient or the mother of the patient:
 - The patient's or mother's medical record number, if assigned;
 - The mother's name;
 - The mother's date of birth;
 - The mother's estimated date of confinement;
 - The patient's gender, if known;
 - Whether the patient is from a singleton or multiple gestation;
 - The location and date of the patient's birth, if known;
 - Whether the patient was born alive or dead, if known;
 - The date of last contact with the mother;
 - The principal and secondary diagnoses for the patient or the patient's mother; and
 - If the principal and secondary diagnoses for the patient were made before the patient's birth, whether the principal and secondary diagnoses were confirmed at birth; and

Historical Note

Adopted effective September 25, 1991 (Supp. 91-3).
 Former Section R9-4-501 renumbered to R9-4-502; new
 Section R9-4-501 adopted by final rulemaking at 7
 A.A.R. 712, effective January 17, 2001 (Supp. 01-1).
 Amended by final rulemaking at 13 A.A.R. 1702,
 effective June 30, 2007 (Supp. 07-2).

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

- A.** The designee of a hospital shall:
- Prepare a written report each month in a format specified by the Department identifying all individuals:
 - Who are patients or the mothers of patients; and
 - Whose:
 - Discharge date is within the month for which the report is being prepared, as specified in subsection (A)(2)(d); and
 - Medical record includes for the principal diagnosis, a secondary diagnosis, or a procedure performed on the individual, an ICD-9-CM diagnosis or procedure code specified in a list provided to the hospital by the Department;
 - Include the following information in the report specified in subsection (A)(1):
 - The name, address, and telephone number of the hospital, or the identification number assigned by the Department to the hospital;
 - The name and telephone number of the designee of the hospital;
 - The date the report was completed;
 - The month for which the report is being prepared; and

within 30 calendar days after the end of the month for which the report is being prepared.

- C. The designee of a genetic testing facility shall:
1. Prepare a written report each month, 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:
 - i. Completed within the month for which the report is being prepared, as specified in subsection (C)(2)(d); and
 - ii. Specified in a list provided by the Department to the genetic testing facility;
 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 and telephone number 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; 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 the report specified in subsection (C)(1) to the Department, in a format specified by the Department, within 30 calendar days after the end of the month for which the report is being prepared.
- D. The designee of a prenatal diagnostic facility shall:
1. Submit an electronic or paper report to the Department:
 - a. For each mother:
 - i. On whom the prenatal diagnostic facility conducts a test specified in a list provided by the Department to the prenatal diagnostic facility, and
 - ii. Whose test result indicates a diagnosis specified in a list provided by the Department to the prenatal diagnostic facility; and
 - b. Within 30 calendar days from the date of the test;
 2. Include the following information in the report specified in subsection (D)(1):
 - a. The name, address, and telephone number of the prenatal diagnostic facility, or the identification number assigned by the Department to the prenatal diagnostic facility;
 - b. The name and telephone number of the designee of the prenatal diagnostic facility;
 - c. The date the report was completed;
 - d. The mother's name and date of birth;
 - e. The estimated gestational age of the patient at the time of the test;
 - f. The mother's estimated date of confinement;
 - g. The outcome of the pregnancy, if known;
 - h. The name of the physician, registered nurse practitioner, or physician assistant who ordered the test for the mother; and
 - i. Information about the test, including:
 - i. The type of test performed on the mother,
 - ii. The date the test was completed, and
 - iii. The results of the test.

Historical Note

Adopted effective September 25, 1991 (Supp. 91-3). New Section R9-4-502 renumbered from R9-4-501 and amended by final rulemaking at 7 A.A.R. 712, effective January 17, 2001 (Supp. 01-1). Section repealed; new Section made by final rulemaking at 13 A.A.R. 1702, effective June 30, 2007 (Supp. 07-2).

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,
 - 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;
 - d. Logs and registers containing information about surgical procedures, as specified in A.A.C. R9-10-214(A)(6) or A.A.C. R9-10-1709(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;
 - 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 to or is enrolled in CRS and, if so, the date of referral or enrollment;
 - x. Whether the patient is receiving any other follow-up services, medical services, nursing services, or health-related services related to a birth defect, 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;
 - 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:
 - 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,

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- 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.

Historical Note

New Section made by final rulemaking at 13 A.A.R. 1702, effective June 30, 2007 (Supp. 07-2).

R9-4-504. Data Quality Assurance

- A. The Department may request a hospital, 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, 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 any of the entities specified in R9-4-503(A) to obtain additional information about a patient's diagnosis or treatment.

Historical Note

New Section made by final rulemaking at 13 A.A.R. 1702, effective June 30, 2007 (Supp. 07-2).