MAY 2019 DRAFT RULES FOR ARTICLE 5

Underlines = new language being added **Yellow Highlight = Change**
~~Strikeouts~~ = existing language being removed **Green Highlight = Comment**

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.~~ **[Moved to R9-4-101]**

~~2.~~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.

~~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.~~ **[Moved to R9-4-101]**

~~4. "Calendar day" means any day of the week, including a Saturday or a Sunday.~~ **[Moved to R9-4-101]**

~~5.~~2. "Clinic" means:

a. A person under contract or subcontract with ~~CRS~~ the Arizona Health Care Cost Containment System to provide the medical services specified in ~~9 A.A.C. 7, Article 4~~ 9 A.A.C. 22, Article 13; **[CRS is no longer part of ADHS]**

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;

d. An abortion clinic, as defined in A.R.S. § 36-449.01; or

e. A birth center, as defined in A.A.C. R9-13-201.

~~6.~~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. **[also in R9-4-401, but that definition is specific to ACR; this definition is now specific to ABDMP]**

~~7. "Clinical laboratory" means a facility that:~~ **[Now in R9-4-101]**

~~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.~~ **[Now in R9-4-101]**

~~9.~~4. "Conception" means the formation of an entity by the union of a human sperm and ovum, resulting in a pregnancy.

~~10.~~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.

~~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.~~ **[Not be needed. Term only used in the definitions for "clinic" and "enrolled" and in R9-4-503(B)(2)(w), so the term could be described there.]**

~~12.~~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. **[Only used in one place – in R9-4-503(B)(2)(b) but keep in definitions]**

~~13.~~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.

~~14.~~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.

~~15. "Discharge" means the same as in A.A.C. R9-10-201.~~ **[moved to R9-4-101]**

~~16. "Discharge date" means the month, day, and year of an individual's discharge from a hospital.~~ **[moved to R9-4-101]**

~~17. "Electronic" means the same as in A.R.S. § 44-7002.~~ **[moved to R9-4-101]**

~~18. "Enrolled" means approved to receive services specified in 9 A.A.C. Chapter 7 from CRS.~~ **[no longer used in R9-4-503(B)(2)(w)]**

~~19.~~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.

~~20.~~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.

~~21.~~11. "Facility" means a building and associated personnel and equipment that perform or are used in connection with performing a particular service or activity.

~~22.~~12. "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:~~ **[only used once - in R9-4-503(B)(2)(x); no longer needed]**

~~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.~~ **[only used once - in the definition below]**

~~25.~~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. **[combined definitions]**

~~26.~~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. **[only used in the definition of designee]**

~~27. "Guardian" means an individual appointed as a legal guardian by a court of competent jurisdiction.~~ **[Moved to R9-4-101]**

~~28. "Health-related services" means the same as in A.R.S. § 36-401.~~

~~29.~~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.

~~30.~~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).

~~31.~~17. "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.~~ **[moved to R9-4-101]**

~~33.~~18. "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.~~ **[moved to R9-4-101]**

~~35.~~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.

~~36.~~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.

~~37.~~21. "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.~~ **[Now in R9-4-101]**

~~39. "Ordered" means instructed by a physician, registered nurse practitioner, or physician assistant to perform a test on an individual.~~ **[Now in R9-4-101]**

~~40.~~22. "Parent" means the:

a. Biological or adoptive father of an individual; or

b. Woman who:

i. Is the mother of an individual; or

ii. 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.~~ **[Now in R9-4-101]**

~~42.~~23. "Patient" means an individual, regardless of current age:

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:

(1) A physician,

(2) A midwife,

(3) A registered nurse practitioner, or

(4) A 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 ~~(42)(a)~~ (23)(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; or

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.

~~43.~~24. "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.

~~44. "Physician assistant" means an individual licensed under A.R.S. Title 32, Chapter 25.~~ **[Now in R9-4-101]**

~~45.~~25. "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.~~26. "Principal diagnosis" means the primary reason for which an individual is:

a. Admitted to a hospital;

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.

~~47.~~27. "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.

~~48.~~28. "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.~~29. "Routinely" means occurring in the regular or customary course of business.

~~51.~~30. "Secondary diagnosis" means all other diagnoses that may be related to a birth defect for an individual besides the principal diagnosis.

~~52.~~31. "Singleton gestation" means a pregnancy in which a patient is the only fetus carried in a mother's womb.

~~53.~~32. "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.~~33. "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.

~~55.~~34. "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.~~35. "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.~~36. "Treatment" means the same as in A.A.C. R9-10-101.

~~58.~~37. "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 ~~Prepare~~ a ~~written~~ report~~, each month~~ in a format specified by the Department, identifying all individuals: **[lessened burden by reducing the frequency of reporting]**
   a. Who are patients or the mothers of patients; and
   b. Whose:
      i. Discharge date is within the ~~month~~ time period for which the report is being prepared, as specified in subsection (A)(2)(d); and
      ii. Medical ~~record includes~~ records include for the principal diagnosis, a secondary diagnosis, or a procedure performed on the individual, an ~~ICD-9-CM~~ ICD Code for a diagnosis or 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~~, and~~ telephone number, and e-mail address of the designee of the hospital;
   c. The date the report was completed;
   d. The ~~month~~ 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 race and ethnicity of the patient or patient's mother;~~
      ~~iv.~~iii. The patient's gender and date of birth, if applicable;
      ~~v.~~iv. The admission and discharge dates;

~~vi.~~v. The principal and secondary diagnoses or the ~~ICD-9-CM diagnosis codes~~ ICD Codes for the principal and secondary diagnoses for the patient or patient's mother; and

~~vii.~~vi. 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~~ Department's request.

~~**B.** The designee of a high-risk perinatal practice shall:~~ **[combined with other types of facilities in new subsection (B)]**

~~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. Whose:~~

~~i. Date of last contact is within the month for which the report is being prepared, as specified in subsection (B)(2)(d); and~~

~~ii. Medical record includes a principal or secondary diagnosis specified in a list provided to the high-risk perinatal practice by the Department;~~

~~2. Include the following information in the report specified in subsection (B)(1):~~

~~a. 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;~~

~~b. The name and telephone number of the designee of the high-risk perinatal practice;~~

~~c. The date the report was completed;~~

~~d. The month 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, if assigned;~~

~~ii. The mother's name;~~

~~iii. The mother's date of birth;~~

~~iv. The mother's estimated date of confinement;~~

~~v. The patient's gender, if known;~~

~~vi. Whether the patient is from a singleton or multiple gestation;~~

~~vii. The location and date of the patient's birth, if known;~~

~~viii. Whether the patient was born alive or dead, if known;~~

~~ix. The date of last contact with the mother;~~

~~x. The principal and secondary diagnoses for the patient or the patient's mother; and~~

~~xi. 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~~

~~3. Submit the report specified in subsection (B)(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 prenatal diagnostic facility, high-risk perinatal practice, or clinic shall:

[consolidated reporting scheme for prenatal diagnostic facilities, high-risk perinatal practices, and clinics; lessened burden by reducing the frequency of reporting]

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

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 ~~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 specified in a list provided by the Department~~:~~;

~~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, 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)(4)(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;

3. A copy of the test results; and

~~3.~~4. Submit to the Department the report specified in subsection (C)(1), in a format specified by the Department, and the copy of the test results specified in subsection (C)(3) ~~to the Department, in a format specified by the Department,~~ within 30 calendar days after either:

a. ~~the~~ The end of the month ~~for which the report is being prepared~~ during which the test was completed, or

b. The date of the test.

~~**D.** The designee of a prenatal diagnostic facility shall:~~ **[combined with other types of facilities in new subsection (B)]**

~~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.~~

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;

d. Logs and registers containing information about surgical procedures, as specified in A.A.C. ~~R9-10-214(A)(6)~~ R9-10-215(A)(6) or A.A.C. ~~R9-10-1709(A)~~ 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;

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~~ approved to receive medical services from the Children's Rehabilitative Services program, established within the Arizona Health Care Cost Containment System, as specified in A.R.S. Title 36, Chapter 2, Article 3 and 9 A.A.C. 22, Article 13, and, if so, the date of referral or ~~enrollment~~ approval;

x. Whether the patient is receiving any other ~~follow-up services,~~ 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, 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,

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

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, 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~~ 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).