NOTICES OF FINAL RULEMAKING

The Administrative Procedure Act requires the publication of the final rules of the state's agencies. Final rules are those which have appeared in the *Register* first as proposed rules and have been through the formal rulemaking process including approval by the Governor's Regulatory Review Council or the Attorney General. The Secretary of State shall publish the notice along with the Preamble and the full text in the next available issue of the *Register* after the final rules have been submitted for filing and publication.

NOTICE OF FINAL RULEMAKING

TITLE 3. AGRICULTURE

CHAPTER 9. DEPARTMENT OF AGRICULTURE
AGRICULTURAL COUNCILS AND COMMISSIONS

[R06-01]

PREAMBLE

1. Sections Affected | **Rulemaking Action**
R3-9-506 | New Section

2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statute: A.R.S. § 3-468

Implementing statute: A.R.S. § 3-468.02(C)(9)

3. The effective date of the rules:

March 11, 2006

4. A list of all previous notices appearing in the *Register* addressing the final rule:

Notice of Rulemaking Docket Opening: 10 A.A.R. 1166, March 26, 2004

Notice of Proposed Rulemaking: 11 A.A.R. 736, February 18, 2005

Notice of Public Information: 11 A.A.R. 4147, October 21, 2005

5. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:

Name: Rebecca Nichols, Rules Analyst

Address: Arizona Department of Agriculture
1688 W. Adams, Room 235
Phoenix, AZ 85007

Telephone: (602) 542-0962

Fax: (602) 542-5420

E-mail: rnichols@azda.gov

6. An explanation of the rule, including the agency's reason for initiating the rule:

This rulemaking codifies the process under which the Arizona Citrus Research Council ("ACRC") will award grants as prescribed under A.R.S. § 3-468.02(C)(5). The ACRC received a statutory exemption from Chapter 24 of A.R.S. Title 41, which applies to the solicitation of grants. A.R.S. § 41-2706.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on in its evaluation of or justification for the rule or did not rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

The agency did not review any study relevant to the rules.

8. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

9. The summary of the economic, small business, and consumer impact:

A. *The Arizona Citrus Research Council and the Arizona Department of Agriculture*.
The ACRC and the Department will incur modest expenses related to educating the regulated community on the new Sections.

B. *Political Subdivision.*
Other than the ACRC and the Department, the Office of Administrative Hearings may be affected by this rulemaking if a party requests a hearing.

C. *Businesses Directly Affected by the Rulemaking.*
Citrus producers, grower-shippers, handlers, researchers, and universities are the beneficiaries of the grants programs developed by the ACRC.
The regulated community, as well as the ACRC itself, will benefit from the use of the grant rules.

10. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

The following list only reflects the major changes where language was either removed from or moved within the rules.

- At R3-9-506(A), the definition of "applicant" was removed.
- At R3-9-506(B)(3)(a), the language describing the types of research the ACRC can statutorily fund was removed because it is defined in the statute cited.
- At R3-9-506(B)(4)(a) through (e), the language was removed due to duplication in subsection (F) Awards and Project Monitoring.
- At R3-9-506(B)(4)(f), the language was moved to the end of subsection (B)(3).
- At R3-9-506(B)(3)(g), the language is now contained in subsection (B)(4).
- At R3-9-506(D), this subsection was relabeled from "No Confidentiality" to "Public Participation" as it addresses the public's participation in the grant award making process.
- At R3-9-506(D)(1), the language was removed due to duplication in subsection (B)(3)(b).
- At R3-9-506(E)(1), the language was removed due to duplication in the previous subsection (D).
- At R3-9-506(E)(2), the language was removed as it is covered in statute under A.R.S. § 38-502, 38-503 and 38-510.
- At R3-9-506(E)(4) and (5), the language was removed as it is covered in open meeting law, A.R.S. § 38-431 et seq.
- At R3-9-506(F)(2), the language was moved to subsection (B)(3)(e).
- Grammatical and technical changes have been made to the rules based on suggestions from the Department and G.R.R.C. staff.

11. A summary of the comments made regarding the rule and the agency response to them:

None

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

The ACRC received a statutory exemption from Chapter 24 of A.R.S. Title 41, which applies to the solicitation of grants. A.R.S. § 41-2706.

13. Incorporations by reference and their location in the rules:

None

14. Was this rule previously made as an emergency rule?

No.

15. The full text of the rules follows:

TITLE 3. AGRICULTURE

CHAPTER 9. DEPARTMENT OF AGRICULTURE
AGRICULTURAL COUNCILS AND COMMISSIONS

ARTICLE 5. ARIZONA CITRUS RESEARCH COUNCIL

Section
R3-9-506. Grants

ARTICLE 5. ARIZONA CITRUS RESEARCH COUNCIL

R3-9-506. Grants

A. Definitions.
1. "ACRC" means the Arizona Citrus Research Council.
2. "Authorized signature" means the signature of an individual authorized to receive funds on behalf of the applicant and responsible for the execution of the applicant's project.
3. "Awardee" means a successful applicant to whom the ACRC awards grant funds for research on a specific project.
4. "Grant" means an award of financial support to an applicant according to A.R.S. § 3-468.02(B) and (C)(5).
5. "Grant award agreement" means a document advising the applicant of the amount of money awarded following receipt by the ACRC of the applicant's signed acceptance.

B. Grant application process.
1. The ACRC shall award grants according to the competitive grant solicitation requirements of this Article.
2. The ACRC shall post the grant application and manual on the ACRC's web site at least four weeks before the due date of a grant application.
3. The ACRC shall ensure that the grant application manual contains the following items:
   a. Grant topics related to ACRC programs specified by A.R.S. § 3-468.02(B) and (C)(5);
   b. A statement that the information contained in an application is not confidential;
   c. A statement that the ACRC funding source is primarily from per carton assessments on citrus grown in Arizona;
   d. An application form including sections about the description of the grant project, scope of work to be performed, an authorized signature line, and a sample budget form;
   e. A statement that the applicant shall not include overhead expenses in the budget for the proposed project.
   f. The criteria that the ACRC shall use to evaluate an application;
   g. The date and time by which the applicant shall submit an application;
   h. The anticipated date of the ACRC award;
   i. A copy of the ACRC grant solicitation rules; and
   j. Any other information necessary for the grant application.
4. The ACRC shall not consider an application received by the ACRC after the due date and time.

C. Criteria. The ACRC shall consider the following when reviewing a grant application and deciding whether to award ACRC funds:
1. The applicant's successful completion of prior research projects,
2. The extent to which the proposed project identifies solutions to current issues facing the citrus industry,
3. The extent to which the proposed project addresses future issues facing the citrus industry,
4. The extent to which the proposed project addresses the findings of any industry surveys conducted within the previous year,
5. The appropriateness of the budget request in achieving the project objectives,
6. The appropriateness of the proposal time-frame to the stated project objectives, and
7. Relevant experience and qualifications of the applicant.

D. Public participation.
1. The ACRC shall make all applications available for public inspection by the business day following the application due date.
2. Before awarding a grant, the ACRC shall discuss and evaluate grant applications and proposed projects at a meeting conducted under A.R.S. § 38-431 et seq.

E. Evaluation of grant applications.
1. The ACRC may allow applicants to make oral or written presentations at the public meeting if time, applicant availability, and meeting space permit.
2. The ACRC may modify an applicant's proposed project in awarding funding.
3. The ACRC shall notify an applicant in writing of the ACRC's decision to fund, modify, or deny funding for a proposed project within 10 business days of the ACRC decision. The ACRC shall notify applicants by the U.S. Postal Service, commercial delivery, electronic mail, or facsimile.

F. Awards and project monitoring.
1. Before releasing grant funds, the ACRC shall execute a grant award agreement with the awardee. The awardee shall agree to accept the grant's legal requirements and conditions and authorize the ACRC to monitor the progress of the project by signing a grant award agreement.
2. The ACRC shall pay no more than 50% of the grant in the initial payment to the awardee.
3. During the term of the project, the awardee shall inform the ACRC of changes to the awardee's address, telephone number, or other contact information.
4. The ACRC may require an interim written report or oral presentation from the awardee during the pendency of the project.
5. The ACRC shall not award the grant funds remaining after the initial payment until the awardee submits to the

ACRC:
a. A final research report, and
b. An invoice for actual final project expenses not exceeding the remaining portion of the award.

6. The ACRC shall make research findings and reports resulting from any grant awarded by the ACRC available to Arizona citrus producers.

G. Repayment. If the awardee does not complete the project as specified in the grant award agreement, the awardee shall return all unexpended grant funds within 30 days after receipt a written request by the ACRC.

NOTICE OF FINAL RULEMAKING

TITLE 9. HEALTH SERVICES

CHAPTER 4. DEPARTMENT OF HEALTH SERVICES
NONCOMMUNICABLE DISEASES

[R06-07]

PREAMBLE

1. Sections Affected — **Rulemaking Action**

R9-4-101	Amend
R9-4-104	Repeal
R9-4-401	Repeal
R9-4-401	New Section
R9-4-401.01	Repeal
R9-4-402	Repeal
R9-4-402	New Section
R9-4-403	Repeal
R9-4-403	New Section
R9-4-404	New Section
R9-4-405	New Section

2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statute: A.R.S. § 36-136(A)(7) and (F)

Implementing statutes: A.R.S. §§ 36-133 and 36-606

3. The effective date of the rules:

March 11, 2006

4. A list of all previous notices appearing in the *Register* addressing the final rule:

Notice of Rulemaking Docket Opening: 10 A.A.R. 3665, September 3, 2004

Notice of Proposed Rulemaking: 11 A.A.R. 3553, September 23, 2005

5. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:

Name: Georgia Yee, Office Chief

Address: Arizona Department of Health Services
Bureau of Public Health Statistics
150 N. 18th Ave., Suite 550
Phoenix, AZ 85007

Telephone: (602) 542-7321

Fax: (602) 364-0296

E-mail: yeega@azdhs.gov

or

Name: Kathleen Phillips, Rules Administrator

Address: Arizona Department of Health Services
Office of Administrative Rules
1740 W. Adams, Suite 202
Phoenix, AZ 85007

Telephone: (602) 542-1264
Fax: (602) 364-1150
E-mail: phillik@azdhs.gov

6. An explanation of the rule, including the agency's reason for initiating the rule:

A.R.S. § 36-133 requires the Arizona Department of Health Services to develop a cancer registry for the collection, management, and analysis of information on the incidence of cancer in Arizona. *Arizona Administrative Code* Title 9, Chapter 4, Articles 1 and 4 implement the statute by providing definitions and reporting requirements for hospitals, clinics, pathology laboratories, physicians, dentists, doctors of naturopathic medicine and registered nurse practitioners to follow, when reporting cancer cases or responding to requests for information from a hospital or the Department. The rules allow the Department to collect information needed to monitor incidence patterns; identify population subgroups at risk; analyze data relating to the detection, diagnosis, and treatment of persons with cancer; and identify areas that need intervention or prevention programs. Data collected is also used to perform studies and to provide epidemiological information to the medical community.

The rulemaking corrects awkward syntax, unclear reporting requirements, ineffective organization, and undefined words and phrases. All changes conform to rulemaking format and style requirements of the Governor's Regulatory Review Council (Council) and the Office of the Secretary of State.

- R9-4-101 contains definitions used throughout Chapter 4 and is being amended.
- R9-4-104 contains definitions applicable to the cancer registry requirements set forth in Article 4. Both R9-4-104 and the current R9-4-401 are being repealed and a more complete cancer registry definitions section is being placed in R9-4-401.
- R9-4-401.01 defines "pathology laboratory" and provides reporting requirements for pathology laboratories. R9-4-401.01 is being repealed and the information contained in the section is being placed in the new R9-4-401 and R9-4-404.
- The current R9-4-402 is repealed and a new R9-4-402, Exceptions, is added to specify the types of hospitals that are excluded from the requirements of Article 4.
- The current R9-4-403 is being repealed and a new R9-4-403, Case Reports, is being added to list the information required in case reports.
- A new R9-4-404 is being added to specify procedures and time-frames for reporting sources to follow regarding the filing of case reports and follow-up reports, and to require reporting sources to allow the Department to review medical records.
  The Department is requiring hospitals with a licensed capacity of 50 or more inpatient beds to report electronically. Currently, only hospitals with a licensed capacity of 150 or more inpatient beds are required to report electronically.
  The Department is also adding a new category of individuals required to report. Currently, registered nurse practitioners are not required to report to the Department, however, they were recently added to the list of individuals who are allowed to state a cause of death on a death certificate. Since registered nurse practitioners can now state a cause of death from cancer for the patients under their care, they are being added to the sources required to report. Registered nurse practitioners are also being added as a source for information about a patient being reported by a hospital or for whom the Department is preparing a case report.
  Doctors of naturopathic medicine are not being required to report to the Department, however, they are being added as a source for information about a patient being reported by a hospital or for whom the Department is preparing a case report.
- A new R9-4-405 is being added to specify standards to ensure complete reporting and accuracy of data reported. The records that the Department may review to assess compliance are specified, as are the time-frames for correcting case reports and completing case reports with simulated data. The Department is also changing the annual follow-up report requirements to reduce the burden on hospitals. Rather than submitting a follow-up report for 90% of the total number of cancer cases reported by a hospital, as currently required in rule, a hospital is required to submit a follow-up report at least annually for: (1) 80% of all analytic patients, from the hospital's reference date; and (2) 90% of all analytic patients diagnosed within the last five years or from the hospital's reference date, whichever is shorter. The reference date is the date the hospital began reporting to the Department, and an analytic patient is a patient who received a diagnosis or treatment from the hospital.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on in its evaluation of or justification for the rule or did not rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

The Department did not review or rely on any study related to this rulemaking package.

8. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

9. The summary of the economic, small business, and consumer impact:

As used in this summary, annual costs/revenues are designated as minimal when less than $1,000, moderate when between $1,000 and $10,000, and substantial when greater than $10,000.

Cost Bearers

- The Department will incur minimal costs associated with educating the staff of hospitals, clinics and health care providers about the new requirements.
- Hospitals with a licensed capacity of more than 50 and less than 150 inpatient beds are affected by the new requirement for reporting electronically. All hospitals with a licensed capacity of 50 or more inpatient beds, including the 18 hospitals in the affected category, as well as all clinics submitting 100 or more case reports per year, already report electronically, but a hospital in this category that did not report electronically would incur minimal to substantial costs to do so.
- Practices operated by physicians or dentists, and clinics that submit fewer than 100 case reports per year will continue to prepare and submit case reports within 30 calendar days, as under the current rules, but they will now be required to provide requested information to the Department or to a hospital required to report, within 15 business days. This change, which makes requirements for providing requested information more consistent, is expected to cause minimal costs for the affected businesses.
- Nurse practitioners are expected to incur minimal costs due to the requirements to submit case reports on the few patients who are not referred to a hospital or clinic for treatment, and to respond to requests for information about patients in their care, and doctors of naturopathic medicine are expected to incur minimal costs due to the requirement to respond to requests for information about patients in their care.

Beneficiaries

- Hospitals with a licensed capacity of fewer than 50 inpatient beds are unaffected by the case reporting requirements of the rule changes, because all hospitals with a licensed capacity of fewer than 50 inpatient beds are currently permitting the Department to review medical records. These hospitals, as well as the larger hospitals, will benefit from the clarification of the reporting requirements and from the change in requirements for follow-up reports.
- The public will benefit substantially from a complete population-based cancer reporting system that may lead to a reduction in the number of individuals who develop cancer and who may die of cancer. The information gathered and compiled by the Department is used by researchers to perform studies and is used by other health care professionals to provide intervention programs for individuals with cancer.

The Department has determined that the benefits related to public health outweigh any potential costs associated with this rulemaking.

10. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) now requires those who bill for medical services to use the version of a national medical code set, which is revised annually, that is in effect on the date that medical services are rendered. Hospitals already follow the HIPAA requirement, as a standard of practice. In R9-4-101, the definition of "ICD-9-CM" was changed to clarify that hospitals are to use the information they are already collecting for billing purposes, rather than recoding information to a specific version of a document that may contain obsolete codes. The definition was changed from:

> "ICD-9-CM" means ICD-9-CM: International Classification of Diseases, 9th Revision, Clinical Modification (5th ed. 2000), incorporated by reference, on file with the Department ~~and the Office of the Secretary of State~~, including no future editions or amendments, and available at http://pmiconline.site.yahoo.net and from Practice Management Information Corporation, 4727 Wilshire Boulevard, Suite 300, Los Angeles, CA 90010. ~~and from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161. This incorporation by reference contains no future editions or amendments.~~

to:

> "ICD-9-CM" means the version of the ICD-9-CM: International Classification of Diseases codes used by a hospital for billing purposes. ~~, 9th Revision, Clinical Modification (5th ed. 2000), incorporated by reference, on file with the Department and the Office of the Secretary of State, and available from Practice Management Information Corporation, 4727 Wilshire Boulevard, Suite 300, Los Angeles, CA 90010 and from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161. This incorporation by reference contains no future editions or amendments.~~

In R9-4-401, the introductory phrase "In this Article, unless otherwise specified:" was added to adhere to format requirements.

In R9-4-403, the descriptions of three items of information on case reports were changed to improve clarity.

- Subsection (A)(2)(l) was changed from "Whether the tumor behaves as if it is benign, borderline, a carcinoma in situ, or malignant;" to "A code that describes the presence or absence of malignancy in a tumor;".
- Subsection (B)(2)(x) was changed from:
  "The surgical approach; extent of lymph node surgery; number of lymph nodes removed; surgery of other regional sites, distant sites, or distant lymph nodes; or reason for no surgery;"
  to:
  "The codes associated with the:
  i. Surgical approach;
  ii. Extent of lymph node surgery;
  iii. Number of lymph nodes removed;
  iv. Surgery of other regional sites, distant sites, or distant lymph nodes; or
  v. Reason for no surgery;".
- Subsection (B)(2)(ee) was changed from:
  "A narrative description of any other types of cancer or non-cancer directed first course of treatment, including additional surgery, chemotherapy, radiation, or other treatment, administered to the patient, including the dates of the treatment, names of the facilities where the treatment was performed, if different from the reporting facility, and type of treatment;"
  to:
  "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;".

In R9-4-404, subsection (B)(1) was changed to improve readability and to clarify that the Department is providing a list of cancer-related ICD-9 codes to the hospital, from:

"1. Prepare and submit a written report to the Department, for all ICD-9-CM codes provided by the Department, of all individuals released by the hospital since the last report was prepared, containing:
  a. ICD-9-CM diagnosis codes, arranged in numeric order, which are associated with an individual's medical records;
  b. 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"

to:

"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 from 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".

Minor technical and grammatical changes were also made at the suggestion of staff of the Council.

11. A summary of the comments made regarding the rule and the agency response to them:

There were no oral comments at the Oral Proceeding. The Department received one written comment. The comment was a question as to who needs to report cancer treatments.

Department's response: Those who are required to report are specified in R9-4-404.

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable

13. Incorporations by reference and their location in the rules:
None

14. Was this rule previously made as an emergency rule?
No.

15. The full text of the rules follows:

TITLE 9. HEALTH SERVICES

CHAPTER 4. DEPARTMENT OF HEALTH SERVICES
NONCOMMUNICABLE DISEASES

ARTICLE 1. DEFINITIONS

Section
R9-4-101. Definitions, General
R9-4-104. ~~Definitions, Cancer Registry~~ Repealed

ARTICLE 4. CANCER REGISTRY

Section
R9-4-401. ~~Case Reporting~~ Definitions
R9-4-401.01. ~~Pathology Laboratory Reporting~~ Repealed
R9-4-402. ~~Filing Requirements~~ Exceptions
R9-4-403. ~~Data Quality Assurance~~ Case Reports
R9-4-404. ~~Repealed~~ Requirements for Submitting Case Reports and Allowing Review of Hospital Records
R9-4-405. Data Quality Assurance

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 a health care institution licensed by the Department as a general hospital, a rural general hospital, or a special hospital under 9 A.A.C. 10.~~
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. ~~, 9th Revision, Clinical Modification (5th ed. 2000), incorporated by reference, on file with the Department and the Office of the Secretary of State, and available from Practice Management Information Corporation, 4727 Wilshire Boulevard, Suite 300, Los Angeles, CA 90010 and from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161. This incorporation by reference contains no future editions or amendments.~~
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.

R9-4-104. ~~Definitions, Cancer Registry~~ Repealed
~~In Article 4, unless the context otherwise requires:~~

1. ~~"Arizona Cancer Registry" (ACR) means the unit of the Department authorized to conduct cancer surveillance.~~
2. ~~"Cancer clinic" means every health care institution, whether organized for profit or not, which is not a hospital and which provides outpatient cancer diagnosis and treatment of 100 or more cancer cases per year, including outpatient surgical facilities, staff-based health maintenance organizations, multispecialty clinics, and outpatient radiation therapy facilities.~~
3. ~~"Cancer registry" means a program authorized to receive, collect and maintain information on persons diagnosed with cancer.~~
4. ~~"Case" means any person with a cancer, or carcinoma in situ, or benign tumor of the central nervous system. This~~

~~does not include localized skin cancer of the following types: papillary, squamous cell, basal cell, or carcinoma not otherwise specified.~~

5. ~~"Date of last contact" means the date the case was last known to be alive.~~
6. ~~"Doctor" means physician or dentist.~~
7. ~~"Follow-up report" means a standard ACR-supplied form or a diskette that conveys whether the case is alive or dead, the status of the disease and subsequent treatments received by the case.~~
8. ~~"Registrar" means a person who has two years of experience working in a cancer registry, or two years of experience in medical record discharge analysis, coding, or abstracting, or who has successfully completed a college-level course in anatomy and physiology, and a course in medical terminology.~~
9. ~~"Stage" means the categorization of the extent of cancer, using the TNM classification scheme.~~
10. ~~"TNM" means the Tumor size, lymph Node involvement, and distant Metastases codes and classification scheme promulgated by the American Joint Committee on Cancer, Manual for Staging of Cancer (3rd Ed.), J.B. Lippincott Company, East Washington Square, Philadelphia, PA 19105, incorporated herein by reference and on file with the Office of the Secretary of State.~~
11. ~~"Vital status" means whether the patient is alive or dead.~~

ARTICLE 4. CANCER REGISTRY

R9-4-401. ~~Case Reporting~~ Definitions

~~**A.** Case reports shall be submitted to the ACR by cancer clinics, doctors, and hospitals, except for behavioral and rehabilitation hospitals. Clinics seeing fewer than 100 cancer cases per year shall comply as per the requirements for doctors.~~

~~**B.** A case report shall be prepared on a form provided by the ACR and shall use standardized codes and coding format supplied by the ACR in the coding of the data items on the case report.~~

1. ~~A full case report shall contain narrative and coded data that includes patient identification, demographic and diagnostic information, a chronological summary of the disease, stage, extent of disease, treatment, recurrence, vital status, names of doctors, reporting registrar and facility.~~
2. ~~An abbreviated case report shall contain patient identification, demographic and diagnostic information, vital status and the names of the doctors.~~

~~**C.** Each year following the date of last contact, hospitals shall submit a follow-up report of each case to the ACR. Upon request of hospitals or the ACR, cancer clinics and doctors shall provide information available in office records for the follow-up report.~~

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, dentist, or registered nurse practitioner provides cancer diagnosis, cancer treatment, or both, and is:
    a. An outpatient treatment center, as defined in A.A.C. R9-10-101, or

b. An outpatient surgical center, as defined in A.A.C. R9-10-101.

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, 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. "Discharge" means the same as in A.A.C. R9-10-201.
23. "Discharge date" means the month, day, and year when a patient is discharged from a hospital.
24. "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.
25. "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.
26. "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.
27. "Doctor of naturopathic medicine" means an individual licensed under A.R.S. Title 32, Chapter 14.
28. "Electronic" means the same as in A.R.S. § 44-7002.
29. "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.
30. "Follow-up report" means an electronic document that includes the information stated in R9-4-404(A)(2) for a patient.
31. "Grade" means the degree of resemblance of a tumor to normal tissue, and gives an indication of the severity of the cancer.
32. "Health care institution" means the same as in A.A.C. R9-10-101.
33. "Histology" means the microscopic structure of cells, tissues, and organs in relation to their function.
34. "Inpatient beds" means the same as in A.R.S. § 36-401.
35. "Laterality" means the side of a paired organ or the side of the body in which the primary site of a tumor is located.
36. "Licensed capacity" means the same as in A.R.S. § 36-401.
37. "Lymph" means the clear, watery, sometimes faintly yellowish fluid that circulates throughout the lymphatic system.
38. "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.
39. "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.
40. "Malignant" means an inherent tendency of a tumor to sequentially spread to areas of a human body beyond the site of origin.
41. "Medical record number" means a unique number assigned by a hospital, clinic, physician, dentist, or registered nurse practitioner to an individual for identification purposes.
42. "Melanocyte" means a skin cell that makes melanin, which is a dark pigment.
43. "Melanoma" means a dark-pigmented, malignant tumor arising from a melanocyte and occurring most commonly in the skin.
44. "Metastasis" means the spread of a cancer from a primary site into a regional site or a distant site.
45. "Narrative description" means a written text describing an act, occurrence, or course of events.
46. "Organ" means a somewhat independent part of a human body, such as a heart or a kidney, that performs a specific function.
47. "Organ system" means one or more organs and associated tissues that perform a specific function, such as the circulatory system.
48. "Papillary tumor" means a benign tumor of the skin producing finger-like projections from the skin surface.
49. "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.
50. "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.

51. "Primary site" means a specific organ or organ system within a human body where the first cancer tumor originated.
52. "Principal diagnosis" means the primary condition for which an individual is admitted to a hospital or treated by the hospital.
53. "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.
54. "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.
55. "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.
56. "Reference date" means the date on which the hospital's cancer registry began reporting patient information to the Department.
57. "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.
58. "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.
59. "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.
60. "Rehabilitation services" means the same as in A.A.C. R9-10-201.
61. "Release" means to transfer care of a patient from a hospital to a physician, an outpatient treatment center, another hospital, the patient, or the patient's parent or legal guardian, if the patient is under 18 years of age and unmarried.
62. "Reporting facility" means a hospital, clinic, physician, dentist, or registered nurse practitioner that submits a case report to the Department.
63. "Secondary diagnosis" means all other diagnoses of an individual made after the principal diagnosis.
64. "Sequence number" means a unique number assigned by a cancer registry to a specific cancer within the body of a patient.
65. "Skin cancer" means cancer of any of the following types:
    a. Papillary tumor;
    b. Squamous cell;
    c. Basal cell; or
    d. Other carcinoma of the skin, where a specific diagnosis has not been determined.
66. "Special hospital" means the same as in A.A.C. R9-10-201.
67. "Squamous cell" means a flat, scale-like skin cell.
68. "Stage group" means a scheme for categorizing a patient, based on the staging classification of the patient's cancer, to enable a physician to provide better treatment and outcome information to the patient.
69. "Staging classification" means the categorizing of a cancer according to the size and spread of a tumor from its primary site, based on an analysis of three basic components:
    a. The tumor at the primary site,
    b. Regional lymph nodes, and
    c. Metastasis.
70. "Subsite" means a specific area within a primary site where a cancer tumor originated.
71. "Substantiate stage" means a narrative describing the stage group of a cancer at the time of diagnosis.
72. "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.
73. "Tumor" means an abnormal growth of tissue resulting from uncontrolled multiplication of cells and serving no physiological function.
74. "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.
75. "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.
76. "Working life" means that portion of a patient's life during which the patient was employed for a salary or wages.

R9-4-401.01. ~~Pathology Laboratory Reporting~~ Repealed

~~**A.** For the purposes of this Section, "pathology laboratory" means a location where human cells or tissue are examined for the purpose of diagnosing cancer.~~

~~**B.** A pathology laboratory shall permit the Department to review pathology reports once every 90 days to collect the information specified in R9-4-401(B) that is necessary for the Department to complete a case report.~~

R9-4-402. ~~Filing Requirements~~ Exceptions

~~**A.** A hospital with 50 or more licensed beds shall appoint one or more cancer registrars who shall complete and submit a full case report for each case, whether inpatient or outpatient, diagnosed or admitted for the first time. The case report shall be submitted within 180 days from the date the case is discharged.~~

~~**B.** A hospital with less than 50 licensed beds shall either report as specified in subsection (A) or shall permit the staff of the ACR access to, and review of, the medical records of all patients with cancer for the purpose of completing a case report form. If the latter method of reporting is employed, the hospital shall provide the medical records for review every six months.~~

~~**C.** Cancer clinics shall submit an abbreviated case report to the ACR for each cancer case not immediately referred to a hospital. They shall designate a doctor or a registrar to submit the case report, if required, within 90 days of diagnosis or initiation of treatment at the facility.~~

~~**D.** Doctors shall utilize one of the following procedures to submit an abbreviated case report of any cancer case they diagnose but do not immediately refer for cancer treatment to a hospital or to a cancer clinic.~~

~~1. If a doctor receives a report form from the ACR, the doctor shall review the form, verify its accuracy, correct or complete any missing information, and resubmit it to the ACR within 30 days; or~~

~~2. If a doctor diagnoses cancer in an outpatient case without a record in a pathology laboratory licensed by the Department, the doctor shall initiate an abbreviated case report and submit it directly to the ACR within 30 days.~~

~~**E.** Within two years of the effective date of these rules, registrars at hospitals with 150 or more licensed beds, and cancer clinics submitting 100 or more case reports per year shall submit a paper copy of the case report and an IBM compatible 5 1/4 or 3 1/2 inch diskette that contains computer-readable data coded in accordance with R9-4-401. Diskettes from hospitals shall be submitted monthly. Diskettes from cancer clinics shall be submitted quarterly.~~

This Article does not apply to a hospital that is:

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

R9-4-403. ~~Data Quality Assurance~~ Case Reports

~~**A.** Upon notice of five business days in advance, records maintained by hospitals, cancer clinics and doctors shall be subject to review by the staff of the ACR to assure completeness and accuracy of the data reported.~~

~~**B.** Upon request by the ACR, hospital registrars shall abstract a standard medical record for the purpose of demonstrating the variability with which data is reported.~~

~~**C.** Reports not prepared in accordance with R9-4-401(B) shall be returned to the reporting entity for revision and resubmitted to the ACR within 15 days of date of receipt.~~

~~**D.** A hospital, cancer clinic or doctor shall satisfy the requirement for complete reporting of cases when 97% of the reportable cases in a calendar year are submitted to the ACR. The Department shall review the medical records to determine whether there has been compliance with this requirement.~~

~~**E.** Each hospital shall submit follow-up reports covering 90% of the total number of cases reported by that institution.~~

A. A clinic, physician, dentist, or registered nurse practitioner shall:

1. Prepare a case report in a format provided by the Department;
2. Include the following information in the case report:
   a. The name, address, and telephone number, or the identification number assigned by the Department to the reporting facility;
   b. The patient's name, and if applicable, the patient's maiden name and any other name by which the patient is known;
   c. The patient's address at the date of last contact, and address at diagnosis of cancer;
   d. The patient's date of birth, Social Security number, sex, race, and ethnicity;
   e. The date of first contact with the patient for the cancer being reported;
   f. The patient's usual industry and usual occupation, if the patient is an adult;
   g. The patient's medical record number, if assigned;
   h. The date of diagnosis of the cancer being reported;
   i. If the diagnosis was not made at the reporting facility, the name and address of the facility at which the diagnosis was made;
   j. The primary site and subsite of the cancer being reported;
   k. The tumor size, histology, grade, and laterality at diagnosis;
   l. A code that describes the presence or absence of malignancy in a tumor;
   m. Whether the cancer had spread from the primary site at the time of diagnosis and if so, to where;
   n. The extent to which the cancer has spread from the primary site;
   o. A narrative description of the extent to which the cancer had spread at diagnosis;
   p. 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;
   q. For each treatment the patient received, the type of treatment, date of treatment, and the name of the facility

where the treatment was performed;
r. Whether any residual tumor cells were left at the edges of a surgical site, after surgery to remove a tumor at the primary site;
s. 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;
t. 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;
u. 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;
v. The name of the individual or the code that identifies the individual completing the case report;
w. 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. A hospital with a licensed capacity of fewer than 50 inpatient beds that reports as specified in R9-4-404(A) and 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;
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; or
v. Reason for no surgery;

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

3. Use codes and coding format supplied by the Department for data items specified in subsection (A)(2) that require codes in the case report.

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

A. 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. 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(B) to obtain the information specified in R9-4-403 about a patient.

C. If 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 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 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 clinic 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 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, 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, 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.

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, 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, dentist, or registered nurse practitioner.

B. The Department shall consider a hospital, clinic, physician, 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, 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, dentist, or registered nurse practitioner that submitted the case report, identifying the revisions that are needed in the case report. The hospital, clinic, physician, 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.