NOTICES OF PROPOSED RULEMAKING

Unless exempted by A.R.S. § 41-1005, each agency shall begin the rulemaking process by first submitting to the Secretary of State's Office a Notice of Rulemaking Docket Opening followed by a Notice of Proposed Rulemaking that contains the preamble and the full text of the rules. The Secretary of State's Office publishes each Notice in the next available issue of the *Register* according to the schedule of deadlines for *Register* publication. Under the Administrative Procedure Act (A.R.S. § 41-1001 et seq.), an agency must allow at least 30 days to elapse after the publication of the Notice of Proposed Rulemaking in the *Register* before beginning any proceedings for making, amending, or repealing any rule. (A.R.S. §§ 41-1013 and 41-1022)

NOTICE OF PROPOSED RULEMAKING

TITLE 3. AGRICULTURE

CHAPTER 4. DEPARTMENT OF AGRICULTURE
PLANT SERVICES DIVISION

[R05-330]

PREAMBLE

1. Sections Affected **Rulemaking Action**

R3-4-220	Amend
R3-4-226	Amend
R3-4-238	Amend

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. § 3-107(A)(1)

Implementing statute: A.R.S. §§ 3-201.01 and 3-202

3. A list of all previous notices appearing in the *Register* addressing the proposed rule:

Notice of Rulemaking Docket Opening: 11 A.A.R. 1289, April 1, 2005

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

Name: Rebecca A. 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

5. An explanation of the rule, including the agency's reasons for initiating the rule:

R3-4-220 is being amended to accomplish the following:

(1) Remove Vein Enation from the list of "Viral diseases" since it is no longer considered a threat to the Arizona citrus industry.
(2) Remove all whitefly and scale pests from the list of "Arthropods", now covered in R3-4-226 and R3-4-238.
(3) Revise the language of the "Restriction" subsection in order to clarify the requirements and bring them into harmony with other states' quarantines.

R3-4-226 is being amended to accomplish the following:

(1) To allow flexibility in treatment options. Currently, the chemicals used for regulatory treatments are listed in rule, which does not allow for rapid changes in options when more effective treatments become available. With this rule amendment, rather than being restricted to a chemical listed in rule, a specific chemical used for treatment will be approved by the Director prior to shipment.

(2) If the commodity originates from a nursery with a pest management program recognized and monitored by the origin state and approved by the Director, the commodity may enter the state without treatment prior to shipment. R3-4-238 rulemaking will make the following changes:
   (a) Remove the common names from the list of regulated commodities;
   (b) Allow for certification of certain commodities by visual inspection;
   (c) Allow flexibility in treatment options. Currently, the chemicals used for regulatory treatments are listed in rule, which does not allow for rapid changes in options when more effective treatments are available. With this rule amendment, rather than being restricted to a chemical listed in rule, a specific chemical used for treatment will be approved by the Director prior to shipment.
   (d) Harmonize this rule with similar host lists contained in other rules.

6. A reference to any study relevant to the rule that the agency reviewed and either proposes to rely on or 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:

None

7. 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

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

A. *The Arizona Department of Agriculture*.
The Department will incur modest expenses related to educating staff and the regulated community regarding the new regulations.

B. *Political Subdivision.*
None

C. *Businesses Directly Affected by the Rulemaking.*
Out-of-state nurseries will incur modest expenses to meet the certification process outlined in these rules. These expenses will include the cost of chemical treatment, virus testing, and implementation of pest management programs. The cost to in-state nurseries would be negligible.

9. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:

Name:	Rebecca A. 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

10. The time, place, and nature of the proceedings for the making, amendment, or repeal of the rule, or if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rule:

An oral proceeding is not scheduled for these proposed rules. To request an oral proceeding or to submit comments, please contact the rules analyst listed in item #4 between the hours of 8:00 a.m. and 5:00 p.m., Monday through Friday, except Arizona legal holidays. If a request for an oral proceeding is not made, the public record in this rulemaking will close at 5:00 p.m. on October 24, 2005.

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

None

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

None

13. The full text of the rules follows:

TITLE 3. AGRICULTURE

CHAPTER 4. DEPARTMENT OF AGRICULTURE
PLANT SERVICES DIVISION

ARTICLE 2. QUARANTINE

Section
R3-4-220. Citrus Nursery Stock Pests
R3-4-226. Scale Insect Pest
R3-4-238. Whitefly Pests

ARTICLE 2. QUARANTINE

R3-4-220. Citrus Nursery Stock Pests

A. Definitions. "Pest" means any of the following viral diseases or arthropods:
1. Viral diseases:
Cachexia (CVd-II),
Citrus Exocortis Virus (CEVd),
Citrus Psorosis Virus (CPsV),
Citrus Tristeza Virus (CTV), or
~~Vein Enation, also known as Woody Gall, or~~
2. Arthropods. All life stages of:
Aceria sheldoni, Citrus bud mite;
~~*Aleurothrixus floccosus*, Woolly whitefly;~~
~~*Aonidiella aurantii*, California red scale;~~
~~*Aonidiella citrina*, Yellow scale;~~
~~*Chrysomphalus aonidum*, Florida red scale;~~
~~*Dialeurodes citri*, Citrus whitefly;~~
~~*Dialeurodes citrifolii*, Cloudy-winged whitefly;~~
Maconellicoccus hirsutus, Pink hibiscus mealybug;
Phyllocoptruta oleivora, Citrus rust mite;
Pseudococcus comstocki, Comstock mealybug; or
~~*Pulvinaria psidii*, Green shield scale.~~

B. Area under quarantine. All states, territories, and districts of the United States, except the state of Arizona.

C. Regulated commodities and appliances.
1. Commodities. A plant or plant part, except seed or attached green fruit, of all species, varieties, or hybrids of the genera *Citrus*, *Eremocitrus*, *Fortunella*, *Poncirus*, and *Microcitrus*.
2. Appliances. An appliance used in a citrus grove, citrus nursery, or other area to handle citrus nursery stock listed in subsection (C) (1).

D. Restrictions.
1. A person may ship a regulated commodity into Arizona from an area under quarantine if the regulated commodity is accompanied by a~~n original~~ certificate issued by a plant regulatory official ~~of the state of~~ from the origin state attesting that the commodity:
~~a. The regulated commodity originated from an area:~~
~~i. Designated free from every disease listed in subsection (A)(1); or~~
~~ii. Where a designated suppression or eradication program for the diseases listed in subsection (A)(1) exists; and~~
~~b. The regulated commodity:~~
~~i. Originated from a source tree that was tested annually at a state-of-origin approved laboratory;~~
~~ii. Is free from every disease listed in subsection (A)(1);~~
~~iii. Was propagated from a bud, cutting, or scion from a tested and disease-free source tree; and~~
~~iv. Is free from every arthropod listed in subsection (A)(2), in accordance with a method approved by the Director.~~

a. Originated from an area not under quarantine for citrus tristeza virus, and
b. Originated from a source tree that:
i. Was tested for Cachexia, citrus exocortis virus and citrus psorosis virus, or
ii. Originated from budwood that was tested for Cachexia, citrus exocortis virus, and citrus psorosis virus, and
iii. Is tested annually for citurs tristeza virus, and
c. Is treated within 5 days before shipment with a chemical to kill the arthropod pests listed in subsection (A)(2), and that the commodity is free of all live life stages of the arthropod pests listed in subsection (A)(2).

2. A person shall not ship a Meyer lemon plant or plant part, except fruit, into Arizona. An exception is allowed for the selection Improved Meyer lemon plant or plant part, which may be shipped into Arizona in compliance with this Section.
3. A person shipping a regulated commodity into Arizona shall attach a single tag or label to each plant or plant part, or to each individual container containing a plant or plant part, that is intended for resale by an Arizona receiver. The tag or label shall contain the following information separately provided for each scion variety grafted to a single rootstock:
a. Name and address of the nursery that propagated the plant,
b. Scion variety name,
c. Scion variety registration number, and
d. Rootstock variety name.
4. A person shipping a regulated commodity into Arizona shall ensure the commodity is also in compliance with the entry requirements prescribed in A.A.C. R3-2-226 (Scale Insect Pests) and R3-4-238 (Whitefly Pests).
5. A person may ship a regulated appliance into Arizona if the appliance is accompanied by a certificate issued by a plant regulatory official of the origin state attesting that the appliance was treated within 5 days before shipment with a chemical to kill the arthropod pests listed in subsection (A)(2), and that the appliance is free of all live life stages of the arthropod pests listed in subsection (A)(2).

E. Disposition of regulated commodity or appliance not in compliance. A regulated commodity or appliance shipped into Arizona in violation of this Section shall be destroyed, treated, or transported out of state as prescribed at A.R.S. Title 3, Chapter 2, Article 1.

R3-4-226. Scale Insect Pest

A. Definitions.
"Pest" means all life stages of the following:
Aonidiella aurantii, California red scale;
Aonidiella citrine, Yellow scale;
Chrysomphalus aonidum, Florida red scale; or
Pulvinaria psidi, Green shield scale.

B. Area under quarantine. The entire states of Alabama, Arkansas, California, Florida, Georgia, Hawaii, Louisiana, Mississippi, and Texas, and the Commonwealth of Puerto Rico.

C. Regulated commodities. Plants and all plant parts, except seed, of the genera listed below:
Camellia ~~spp.,~~
Chrysalidocarpus ~~spp.,~~
Citrus ~~spp.,~~
Cycas ~~spp.~~,
Dracaena ~~spp.,~~
Eremocitrus ~~spp.,~~
Euonymus ~~spp.~~,
Ficus ~~spp.,~~
Fortunella ~~spp.,~~
Ilex ~~spp.,~~
Ligustrum ~~spp.,~~
Microcitrus ~~spp.,~~
Poncirus ~~spp.,~~ and
Rosa ~~spp.~~

D. Restrictions. A person ~~shall not~~ may ship ~~into Arizona~~ a regulated commodity to Arizona from an area under quarantine ~~*unless*~~ if each shipment is accompanied by a certificate issued by a plant regulatory official of the origin state ~~or commonwealth of origin~~ attesting that within 5 days before shipment:

1. The regulated commodity of the genera *Citrus*, *Eremocitrus*, *Fortunella*, *Microcitrus*, *and Poncirus* was treated ~~as prescribed in subsection (F).~~ with a chemical to kill the pests listed in subsection (A), and was visually inspected and found free of all live life stages of the pests listed in subsection (A).

2. The regulated commodity not listed in subsection (D)(1):
   a. Was treated with a chemical to kill the pests listed in subsection (A), and was visually inspected and found free of all live life stages of the pests listed in subsection (A), or
   b. Originated from a nursery with a pest management program recognized and monitored by the origin state to control the pests listed in subsection (A), and was visually inspected and found to be free of all live life stages of the pests listed in subsection (A).

~~E.~~ ~~Exemptions.~~
1. ~~A bare root rose free of all soil and foliage is exempt from treatment if a regulatory official of the state or commonwealth of origin visually inspected the commodity and found it free from the pests in subsection (A).~~
2. ~~A miniature rose is exempt from treatment if a regulatory official of the state or commonwealth of origin visually inspected the commodity and found it free from the pest.~~
3. ~~The Director shall issue a permit to allow a regulated commodity from an area under quarantine to enter Arizona without treatment as prescribed in subsection (F) if:~~
   a. ~~A plant regulatory official of the state or commonwealth of origin attests that the area is free from the pests in subsection (A) based on a detection survey, and~~
   b. ~~The applicant complies with all conditions of the permit.~~

~~F.~~ ~~Treatment. A foliar application of a narrow range oil and one of the following chemicals, applied at label rates:~~
1. ~~Acephate,~~
2. ~~Buprofezin,~~
3. ~~Imidacloprid,~~
4. ~~Pyriproxyfen, or~~
5. ~~Thiamethoxam.~~

~~G.~~**E.** Disposition of regulated commodity not in compliance. A regulated commodity shipped into Arizona in violation of this Section shall be destroyed, treated, or transported out of state as prescribed at A.R.S. Title 3, Chapter 2, Article 1.

R3-4-238. Whitefly Pests

A. Definition. "Pest" means:
1. Citrus whitefly, Dialeurodes citri (Ashm.);
2. Cloudy-winged whitefly, *Dialeurodes citrifolii* (Morgan);
3. Woolly whitefly, *Aleurothrixus floccosus* (Maskell).

B. Area under quarantine. Alabama, Arkansas, California, Florida, Georgia, Hawaii, Louisiana, Mississippi, North Carolina, South Carolina, Texas, and Virginia.

C. Commodities covered. Plants and all plant parts, except fruit and seed, of the following genera and species:
Ailanthus ~~spp.~~ ~~(Tree of Heaven),~~
Amplopsis ~~spp.~~ ~~(Boston Ivy),~~
Bignonia capreolata ~~spp.~~ ~~(Cross Vine),~~
Choisya ternata ~~(Mexican Orange),~~
Citrus ~~spp.,~~
Diospyros ~~spp.~~ ~~(Persimmon),~~
Eremocitrus
Feijoa spp. ~~(Pineapple guava),~~
Ficus macrophyll ~~(Ficus),~~
Fortunella spp. ~~(Kumquat),~~
Gardenia spp. ~~(Gardenia or Cape Jasmine),~~
Ilex spp. ~~(Holly),~~
Jasminum ~~spp.~~ ~~(Jasmine),~~
Lagerstroemia ~~spp.~~ ~~(Crape Myrtle),~~
Ligustrum ~~spp.~~ ~~(Privet),~~
Maclura pomifera ~~(Osage Orange),~~
Melia ~~spp.~~ ~~(Chinaberry),~~
Microcitrus
Musa ~~spp.~~ ~~(Banana Shrub),~~
Osmanthus ~~(Osmanthus) (Not tolerant to methyl bromide fumigation),~~
Plumaria ~~spp.~~ ~~(Frangipani, temple tree),~~
Poncirus ~~spp.~~ ~~(Trifoliate orange),~~
Prunus caroliniana ~~(Carolina Cherry Laurel),~~
Psidum ~~spp.~~ ~~(Guava),~~
Punica granatum ~~(Pomegranate),~~
Pyrus communis ~~(Pear),~~

Sapindus mukorossi ~~(Chinese Soapberry),~~
Smilax ~~spp.~~ (Sarsparilla),
Syringa vulgaris ~~(Common Lilac), and~~
Viburnum ~~spp.~~ (Viburnum).

D. Restrictions. A person may ship a regulated commodity to Arizona from an area under quarantine if each shipment is accompanied by a certificate issued by a plant regulatory official of the state of origin attesting that within five days before shipment:

~~1. All covered commodities with foliage listed in subsection (C) shall be treated as prescribed in subsection (E) immediately before shipment and certified by an authorized official from the state of origin; or~~

~~2. The Director may issue a permit admitting a covered commodity subject to specific limitations, conditions, and provisions which eliminate the risk of the pest.~~

1. The regulated commodity of the genera *Citrus*, *Eremocitrus*, *Fortunella*, *Microcitrus*, *and Poncirus* was treated with a chemical to kill the pests listed in subsection (A), and was visually inspected and found free of all live life stages of the pests listed in subsection (A).
2. The regulated commodity not listed in subsection (D)(1):
   a. Was treated with a chemical to kill the pests listed in subsection (A), and was visually inspected and found free of all live life stages of the pests listed in subsection (A), or
   b. Originated from a nursery with a pest management program recognized and monitored by the origin state and to control the pests listed in subsection (A), and was visually inspected and found to be free of all live life stages of the pests listed in subsection (A), or
   c. The regulated commodity is completely devoid of foliage and is exempt from treatment for the pests listed in subsection (A).

~~**E.** Treatment.~~

~~1. Methyl bromide fumigation. 2 1/2 pounds of methyl bromide per 1000 cu. ft. of chamber space for two hours at 80° F or more.~~

~~2. Sodium cyanide 99% chamber fumigation. 25cc HCN gas per 100 cu. ft. for one hour at not less than 18.3° C (60° F) or more than 29.4° C (85° F). Circulation shall be maintained during the entire fumigation period. Fruit fumigated with HCN gas shall be dry.~~

~~3. Chlorpyrifos. 4 lb. per gallon of Chlorpyrifos (4E) formulation in an emulsion of narrow range spray-oil (petroleum) oil, NR-415, emulsive.~~

~~a. 4.7 ml of Chlorpyrifos (4E), plus 19 ml of narrow range 415 oil per gallon of water, or~~
~~b. 16 fl. oz. of Chlorpyrifos (4E), plus 64 fl. oz. narrow range 415 oil per 100 gallons water.~~
~~c. Methods of treatment:~~
~~i. Dip. Totally submerge plant material for two minutes, remove for one minute, and submerge again for one minute. Then remove and let dry.~~
~~ii. Spray. Apply to all plant parts. Thoroughly drench all surfaces of leaves and all other aerial plant parts.~~

E. Disposition of regulated commodity not in compliance. A regulated commodity shipped into Arizona in violation of this Section shall be destroyed, treated, or transported out of state as prescribed at A.R.S. Title 3, Chapter 2, Article 1.

NOTICE OF PROPOSED RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

[R05-333]

PREAMBLE

1. Sections Affected — **Rulemaking Action**

R4-23-402	Amend
R4-23-408	Amend

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. § 32-1904(A)(1)

Implementing statute: A.R.S. § 32-1904(A)(1)

3. A list of all previous notices appearing in the *Register* addressing the proposed rule:

Notice of Rulemaking Docket Opening: 11 A.A.R. 3128, August 12, 2005

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

Name: Dean Wright, Compliance Officer

Address: Board of Pharmacy
4425 W. Olive Ave., Suite 140
Glendale, AZ 85302

Telephone: (623) 463-2727, ext. 131

Fax: (623) 934-0583

E-mail: rxcop@cox.net

5. An explanation of the rule, including the agency's reasons for initiating the rule:

Section R4-23-402 (Pharmacist, Graduate Intern, and Pharmacy Intern) was amended effective August 6, 2005. The changes implemented when this rule was amended included a requirement that a pharmacist or graduate intern or pharmacy intern under the supervision of a pharmacist shall document both the circumstance and reason for not providing oral consultation. It was the Board's intent to allow a pharmacist or graduate intern or pharmacy intern under the supervision of a pharmacist to delegate the actual documentation to a pharmacy technician or pharmacy technician trainee under the pharmacist's supervision. During final approval by G.R.R.C., the G.R.R.C. staff recommended grammar changes that took out the language that allowed a pharmacist to delegate the documentation required when counseling does not occur. The proposed rule adds language to allow a pharmacist or graduate intern or pharmacy intern under the supervision of a pharmacist to delegate the documentation of both the circumstance and reason for not providing oral consultation. The Board feels these changes are necessary to maintain the consistency of the proposed rules with existing Board rules [see R3-23-402(A)] and allow pharmacists more flexibility and control in the use of technology, their personnel, and their own time. The Board determined that the rule should be further amended to clarify when and what documentation is required based on the usual circumstances encountered in a pharmacy. Language is added in subsection (H) to specify the documentation requirements. The Board added language in subsection (I) to require that when a prescription meets the conditions of subsection (B), a pharmacist or graduate intern or pharmacy intern under the supervision of a pharmacist shall personally give the prescription to the patient or the patient's care-giver whether or not oral consultation is provided.

Several Arizona pharmacies are now using electronic imaging recordkeeping systems, and existing Board rules do not specifically address these systems. The Board determined that R4-23-408 (Computer Records) should be amended to include requirements for prescription records and retention, specifically addressing the issue of prescription imaging. A new subsection (H) is added to R4-23-408 detailing requirements for computer prescription records and retention and specifically the use of an electronic imaging recordkeeping system. The amended rules will include format, style, and grammar necessary to comply with the current rules of the Secretary of State and Governor's Regulatory Review Council.

The Board believes that approval of these rules benefits the public and the pharmacy community by clearly establishing the standards for patient counseling provided by pharmacists and pharmacy interns and graduate interns under pharmacist supervision and the use of electronic imaging recordkeeping systems.

6. A reference to any study relevant to the rule that the agency reviewed and either proposes to rely on or 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:

None

7. 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

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

The amended rules will impact the Board, pharmacies, pharmacists, pharmacy interns, graduate interns, and the public. The amended rules' impact on the Board will be the usual rulemaking-related costs which are minimal. The Board estimates the amended rules will have minimal economic impact on pharmacies. The amended rules simply clarify the documentation requirements of the patient counseling in R4-23-402 and clearly establish standards for electronic imaging recordkeeping systems in R4-23-408. The amendments to R4-23-402 may reduce actual costs for pharmacies by only requiring documentation of the circumstance and reason for not counseling when the pharmacist chooses not to counsel and not when the patient refuses or someone other than the patient picks up the prescription. The amendments to R4-23-408 will not require the use of electronic imaging recordkeeping systems, but will merely establish minimum standards for the use of such systems. The amended rules have no economic impact on the public.

The public, Board, pharmacists, pharmacy interns, graduate interns, and pharmacies benefit from rules that are clear, concise, and understandable. The amended rules benefit the public and the pharmacy community by clearly establish-

ing the standards for patient counseling provided by pharmacists and pharmacy interns and graduate interns under pharmacist supervision and the use of electronic imaging recordkeeping systems.

9. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:

Name:	Dean Wright, Compliance Officer
Address:	Board of Pharmacy 4425 W. Olive Ave., Suite 140 Glendale, AZ 85302
Telephone:	(623) 463-2727, ext. 131
Fax:	(623) 934-0583
E-mail:	rxcop@cox.net

10. The time, place, and nature of the proceedings for the making, amendment, or repeal of the rule, or if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rule:

Comments may be written or presented orally. Written comments must be received by 5 p.m., Monday, October 24, 2005. An oral proceeding is scheduled for:

Date:	October 24, 2005
Time:	10:00 a.m.
Location:	4425 W. Olive Ave., Suite 140 Glendale, AZ 85302

A person may request information about the oral proceeding by contacting the person listed in item #9.

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

Not applicable

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

None

13. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 4. PROFESSIONAL PRACTICES

Section
R4-23-402. Pharmacist, Graduate Intern, and Pharmacy Intern
R4-23-408. Computer Records

ARTICLE 4. PROFESSIONAL PRACTICES

R4-23-402. Pharmacist, Graduate Intern, and Pharmacy Intern

A. No change
B. No change
C. No change
D. When, in the professional judgment of the pharmacist or graduate intern or pharmacy intern under the supervision of a pharmacist, or when circumstance precludes it, oral consultation may be omitted if the pharmacist, graduate intern, or pharmacy intern:
1. Personally provides written information to the patient or patient's care-giver that summarizes the information that would normally be orally communicated;
2. Documents, or assumes responsibility to document, both the circumstance and reason for not providing oral consultation ~~is documented~~ by a method approved by the Board or its designee; and

3. Offers the patient or patient's care-giver the opportunity to communicate with a pharmacist, graduate intern, or pharmacy intern at a later time and provides a method for the patient or patient's care-giver to contact a pharmacist, graduate intern, or pharmacy intern at the pharmacy.

E. No change

F. Nothing in subsection (B) requires a pharmacist, graduate intern, or pharmacy intern to provide oral consultation if a patient or patient's care-giver refuses the consultation.

G. Using a method approved by the Board or its designee, a pharmacist, graduate intern, or pharmacy intern shall~~:~~ document, or assume responsibility to document, that oral consultation is or is not provided.

H. Oral consultation documentation. When oral consultation is required as specified in subsection (B), a pharmacist, graduate intern, or pharmacy intern shall:

1. Document, or assume responsibility to document, that oral consultation is ~~or is not~~ provided; ~~and~~ or
2. When a patient refuses oral consultation or a person other than the patient or patient's care-giver picks up a prescription and oral consultation is not provided, document, or assume responsibility to document, that oral consultation is not provided; or
3. ~~If~~ When a pharmacist, graduate intern, or pharmacy intern determines to omit oral consultation under subsection (D) and oral consultation is not provided, document, or assume responsibility to document, both the circumstance and reason that oral consultation is not provided.

I. When a prescription meets the conditions of subsection (B), a pharmacist or graduate intern, or pharmacy intern under the supervision of a pharmacist shall personally give the prescription to the patient or the patient's care-giver whether or not oral consultation is provided.

~~**G.**~~**J.** No change

~~**H.**~~**K.** No change

~~**I.**~~**L.** No change

~~**J.**~~**M.** No change

R4-23-408. Computer Records

A. No change

B. No change

C. No change

D. No change

E. No change

F. No change

G. No change

H. Prescription records and retention.

1. Except as specified in subsection (H)(2), a pharmacy permittee or pharmacist-in-charge shall ensure that each original prescription is:
   a. Reduced to a hard copy if not received in written form, and
   b. Filed for a period of not less than seven years from the date the prescription is last dispensed.
2. In lieu of filing the actual original hard-copy prescription, a pharmacy permittee or pharmacist-in-charge may use an electronic imaging recordkeeping system, if:
   a. The system is capable of capturing, storing, and reproducing the exact image of a prescription, including the reverse side of the prescription if necessary;
   b. Any notes of clarification of and alterations to a prescription are directly associated with the electronic image of the prescription;
   c. The prescription image and any associated notes of clarification to or alterations to a prescription are retained for a period not less than seven years from the date the prescription is last dispensed;
   d. Policies and procedures for the use of an electronic imaging recordkeeping system are developed and implement in the same manner as specified in subsection (A); and
   e. The prescription is not for a schedule II controlled substance.

NOTICE OF PROPOSED RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

[R05-332]

PREAMBLE

1. Sections Affected | **Rulemaking Action**

R4-23-601	Amend
R4-23-1003	Amend

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. § 32-1904(A)(1)

Implementing statutes: A.R.S. §§ 32-1904(B)(3) and 36-2523

3. A list of all previous notices appearing in the *Register* addressing the proposed rule:

Notice of Rulemaking Docket Opening: 11 A.A.R. 2657, July 15, 2005

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

Name:	Dean Wright, Compliance Officer
Address:	Board of Pharmacy 4425 W. Olive Ave., Suite 140 Glendale, AZ 85302
Telephone:	(623) 463-2727, ext. 131
Fax:	(623) 934-0583
E-mail:	rxcop@cox.net

5. An explanation of the rule, including the agency's reasons for initiating the rule:

During the 2003 legislative session, the Legislature changed A.R.S. § 32-1064 to require that prescription records be maintained for at least seven years instead of three. Since that statutory change occurred, the Board has been moving to change all citations within the Board's rules pertaining to records maintenance from three years to seven years. During the Board's June 2005 five-year rule review, the Board determined that R4-23-1003 (Records and Order Forms) contained two subsections with a three-year records retention clause. The amended rules will change R4-23-1003(A)(1)(f) and (A)(4) to require that controlled substance inventory records be available for seven years instead of three. The Board staff identified R4-23-601 (General Provisions) as containing a subsection with a three-year records retention clause. The amended rules will change R4-23-601(D)(2) to require that records of receipt and disposal of drugs be kept for seven years instead of three. The Board feels these changes are necessary to maintain the consistency of the amended rules with the existing Board statutes and rules. The amended rules will include format, style, and grammar necessary to comply with the current rules of the Secretary of State and Governor's Regulatory Review Council.

The Board believes that approval of these rules benefits the public and the pharmacy community by clearly establishing uniform standards for maintaining the records for receipt, disposal, and inventory of drugs and controlled substances in Arizona.

6. A reference to any study relevant to the rule that the agency reviewed and either proposes to rely on or 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:

None

7. 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

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

The amended rules will impact the Board, pharmacies, and the public. The amended rules' impact on the Board will be the usual rulemaking-related costs that are minimal. The Board estimates the amended rules will have minimal economic impact on pharmacies. A pharmacy's cost of storing the records may increase to comply with the longer records retention requirement, however the change is due to a statutory mandate and cannot be helped. Many pharma-

cies are beginning to image their records. The use of this technology may reduce the storage costs. The amended rules have no economic impact on the public.

The public, Board, and pharmacies benefit from rules that are clear, concise, and understandable. The amended rules benefit the public and the pharmacy community by clearly establishing uniform standards for maintaining the records for receipt, disposal, and inventory of drugs and controlled substances in Arizona.

9. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:

Name:	Dean Wright, Compliance Officer
Address:	Board of Pharmacy 4425 W. Olive Ave., Suite 140 Glendale, AZ 85302
Telephone:	(623) 463-2727, ext. 131
Fax:	(623) 934-0583
E-mail:	rxcop@cox.net

10. The time, place, and nature of the proceedings for the making, amendment, or repeal of the rule, or if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rule:

Comments may be written or presented orally. Written comments must be received by 5 p.m., Monday, October 24, 2005. An oral proceeding is scheduled for:

Date:	October 24, 2005
Time:	10:00 a.m.
Location:	4425 W. Olive Ave., Suite 140 Glendale, AZ 85302

A person may request information about the oral proceeding by contacting the person listed in item #9.

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

Not applicable

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

None

13. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

Section
R4-23-601. General Provisions

ARTICLE 10. UNIFORM CONTROLLED SUBSTANCES AND DRUG OFFENSES

Section
R4-23-1003. Records and Order Forms

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

R4-23-601. General Provisions

A. No change
B. No change
C. No change
D. Record of receipt and disposal of drugs.

1. No change
2. Every person receiving, selling, delivering, or disposing of a drug shall record and retain for not less than ~~three~~ seven years the following information:
   a. No change
   b. No change
   c. No change
   d. No change
3. No change
4. No change

E. No change

ARTICLE 10. UNIFORM CONTROLLED SUBSTANCES AND DRUG OFFENSES

R4-23-1003. Records and Order Forms

A. Records
1. If the pharmacist-in-charge of a pharmacy is replaced by another pharmacist-in-charge, the new pharmacist-in-charge shall complete an inventory of all controlled substances in the pharmacy within 10 days of assuming the responsibility. This inventory and any other required controlled substance inventory shall:
   a. No change
   b. No change
   c. No change
   d. No change
      i. No change
      ii. No change
   e. No change
   f. Be available in the pharmacy for inspection by the Board or its designee for not less than ~~three~~ seven years.
2. No change
   a. No change
   b. No change
   c. No change
   d. No change
   e. No change
3. No change
4. Every person receiving, selling, delivering, or disposing of any controlled substance shall record and retain for not less than ~~three~~ seven years the following information:
   a. No change
   b. No change
   c. No change
   d. No change

B. No change

NOTICE OF PROPOSED RULEMAKING

TITLE 9. HEALTH SERVICES

CHAPTER 4. DEPARTMENT OF HEALTH SERVICES NONCOMMUNICABLE DISEASES

[R05-342]

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

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

4. 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

5. An explanation of the rule, including the agency's reasons 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 that 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 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 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.
  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 changing the annual follow-up report requirements. Currently, each year following the date of last contact, a hospital is required to submit a follow-up report for 90% of the total number of cancer cases reported by the institution. Since many hospitals have been reporting for several years now, the Department is proposing a change to reduce the burden on hospitals whose reference date, the date the hospital began reporting to the Department, is more than five years before the date of a follow-up report. The Department is proposing to require a hospital 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. An analytic patient is a patient who received a diagnosis or treatment from the hospital.

6. A reference to any study relevant to the rule that the agency reviewed and either proposes to rely on or 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.

7. 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

8. The preliminary 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.

Small businesses unaffected by the rule changes include hospitals with a licensed capacity of fewer than 50 inpatient beds. All hospitals with a licensed capacity of fewer than 50 inpatient beds are currently permitting the Department to review medical records. Practices operated by physicians or dentists, and clinics that submit fewer than 100 case reports per year may be small businesses affected by the rule changes. Although physicians, dentists, and clinics that submit fewer than 100 case reports per year will continue to prepare and submit case reports within 30 calendar days, under the proposed rules, they will 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 small businesses.

Other small businesses affected by the rule changes include registered nurse practitioners and doctors of naturopathic medicine. Under the proposed rules, the Department will require nurse practitioners to: (1) submit a case report to the Department for each patient whom they diagnose with cancer without a pathology report from a pathology laboratory and do not refer to a hospital or clinic for treatment; and (2) respond to requests for information about patients in their care. Although not being required to initiate a case report to the Department, doctors of naturopathic medicine are being required to respond to requests for information about patients in their care. The Department expects registered nurse practitioners and doctors of naturopathic medicine to incur minimal costs due to these changes in the rules.

Large businesses affected by the rule changes include 18 hospitals with a licensed capacity of more than 50 and less than 150 inpatient beds that will be required to report electronically. All hospitals with a licensed capacity of 50 or more inpatient beds, including the 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.

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.

9. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:

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

10. The time, place, and nature of the proceedings for the making, amendment, or repeal of the rule, or if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rule:

The Department has scheduled the following oral proceeding:

Date:	October 27, 2005
Time:	1:00 p.m.
Location:	1740 W. Adams, Room 101A Phoenix, AZ 85007
Close of record:	4:00 p.m., October 27, 2005

A person may submit written comments on the proposed rules no later than the close of record to either of the individuals listed in items #4 and #9.

A person with a disability may request a reasonable accommodation, such as a sign language interpreter, by contacting Ruthann Smejkal at (602) 364-3959 or smejkar@azdhs.gov. Requests should be made as early as possible to allow time to arrange the accommodation.

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

Not applicable

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

Not applicable

13. 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 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.~~
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.~~

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,
   b. Administered any of a first course of treatment at the facility, or
   c. Diagnosed and administered any of the 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 therapy 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, a dentist or a registered nurse practitioner provides cancer diagnosis, treatment of cancer, 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 of the individual 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 based either solely on evidence acquired before a first course of treatment was initiated or on evidence acquired both before a first course of treatment, supplemented or modified by the addition of 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 the 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 was 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 a 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 therapies, 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 a tumor that has an inherent tendency 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, a clinic, a physician, a dentist, or a registered nurse practitioner to an individual for identification purposes.
42. "Melanocyte" means a skin cell that makes the dark pigment, melanin.
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 or occurrence, or a course of events.
46. "Organ" means a somewhat independent part of a human body, such as a heart or a kidney, which 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, which consists of the heart, veins, arteries, and capillaries.
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 tissue are examined for the purpose of diagnosing cancer and that is licensed under A.A.C. 9 Chapter 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, restore function, or improve the shape and appearance to body structures that are 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, as defined in A.R.S. § 32-1601, who 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, a clinic, a physician, a dentist, or a 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, and is 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 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 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 of the reporting facility;
   b. The patient's name, and the patient's maiden name and any other name by which the patient is known, if applicable;
   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. Whether the tumor behaves as if it is benign, borderline, a carcinoma in situ, or malignant;
   m. Whether the cancer had spread from the primary site at the time of diagnosis, and to where;
   n. The extent to which the cancer has spread from the primary site;
   o. A narrative description of the substantiate extent of cancer 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, what the primary site was 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. In addition to the information in subsection (A), a hospital with a licensed capacity of fewer than 50 inpatient beds that chooses to submit case reports 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 following information on the case report:
   a. The accession number assigned to the patient by the hospital's cancer registry;
   b. The sequence number of the cancer being reported;
   c. The date the patient was admitted to the hospital for diagnostic evaluation, cancer-directed therapy, 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 a period during which the patient received diagnostic evaluation or treatment, 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, age at diagnosis of cancer, and place of birth, and the name of the patient's spouse, if applicable;
   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 showed 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. An identification 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 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;
   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. 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;
ff. If additional cancer of the type diagnosed at the primary site is found after cancer-related 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, 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
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 for a patient 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 refer the patient to a hospital and 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 a 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 a 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. A hospital, clinic, physician, dentist, or registered nurse practitioner required to report under R9-4-404 shall submit a case report to the Department for at least 97% of the patients meeting the criteria in R9-4-404 during a calendar year.

B. To ensure compliance with R9-4-405(A) and completeness and accuracy of cancer reporting, and 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 prepared as and containing the information specified in 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 above that contain information about diagnostic evaluation, cancer-directed therapy, or other treatment provided to an individual by the hospital, clinic, physician, dentist, or registered nurse practitioner.

C. The Department shall return a case report not prepared according to R9-4-403 to the hospital, clinic, physician, dentist, or registered nurse practitioner who submitted the case report, stating what revisions 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 requested the revision.

D. Upon written request by the Department, a hospital shall prepare a case report based on a simulated medical record 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.

E. A hospital shall submit the 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.