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 9. HEALTH SERVICES

CHAPTER 27. ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM (AHCCCS) HEALTH CARE GROUP COVERAGE

Editor's Note: The following Notice of Final Rulemaking was reviewed per Executive Order 2012-03 as issued by Governor Brewer. (See the text of the executive order on page 824.) The Governor's Office authorized the notice to proceed through the rulemaking process on August 14, 2013.

[R14-43]

PREAMBLE

1. Article, Part, or Section Affected (as applicable) — **Rulemaking Action:**

Chapter 27	Repeal
Article 1	Repeal
R9-27-101	Repeal
Article 2	Repeal
R9-27-202	Repeal
R9-27-203	Repeal
R9-27-204	Repeal
R9-27-210	Repeal
Article 3	Repeal
R9-27-301	Repeal
R9-27-302	Repeal
R9-27-303	Repeal
R9-27-307	Repeal
R9-27-310	Repeal
R9-27-311	Repeal
R9-27-312	Repeal
Article 5	Repeal
R9-27-509	Repeal
Article 7	Repeal
R9-27-702	Repeal
R9-27-703	Repeal
R9-27-704	Repeal

2. Citations to the agency's statutory rulemaking authority to include both the authorizing statute (general) and the implementing statute (specific):

Authorizing statute: A.R.S. § 36-2903.01

Implementing statute: A.R.S. § 36-2912.01 and Laws 2013, First Special Session, Chapter 10, §§ 8 and 42

3. The effective date of the rule:

May 3, 2014

4. Citations to all related notices published in the *Register* to include the *Register* as specified in R1-1-409(A) that pertain to the record of the final rulemaking package:

Notice of Rulemaking Docket Opening: 19 A.A.R. 3582, November 15, 2013

Notice of Proposed Rulemaking: 19 A.A.R. 3561, November 15, 2013

5. The agency's contact person who can answer questions about the rulemaking:

Name: Mariaelena Ugarte

Address: 701 E. Jefferson St.

Telephone: (602) 417-4693

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6. An agency's justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking:

The Administration is proposing repealing the HCG program rules since the program ceased to operate as of December 31, 2013. The HCG program has been impacted by the changes made from the Affordable Care Act: both the increase in the percentage of the federal poverty level that qualifies individuals for Medicaid (AHCCCS) and the availability of individual and small group health care coverage through the Exchange operated by the federal government make health insurance more available to persons who would have been covered under the HCG program.

Laws 2013, First Special Session, Ch. 10 § 42, prohibited the Administration from enrolling any new businesses or new employees to an existing Geographical Service Area (GSA) into the Healthcare Group program. Laws 2013, First Special Session, Ch. 10 § 8 repealed the HCG program (by repealing A.R.S. §§ 36-2912, 36-2912.02, 36-2912.03, and 36-2912.04) effective from and after December 31, 2013 which requires this rulemaking to repeal the rules that implemented the HCG program.

This provision is necessary to comply with state requirements that contain dates certain for compliance (that is, the December 31, 2013 repeal of the program). The HCG program as described under A.R.S. § 36-2912 and ceased to exist January 1, 2014. New enrollment into HCG program ceased August 1, 2013.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on 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:

A study was not referenced or relied upon when repealing the HCG coverage rules.

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

Not applicable.

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

The HCG program has been repealed from and after December 31, 2013. The HCG program was self-sustained through the premiums collected from participating employers. Individuals and small employer-based groups who were covered under the HCG program will be able to obtain health insurance on a guaranteed, community rated basis through the Exchange operated by the federal government and may qualify for advanced premium tax credits through the Exchange. There were 1787 employer groups covering 5203 members (counting dependents) enrolled as of December, 2013.

The Administration believes most of these groups/members will qualify for health care coverage through the Health Care Exchange and benefit from the tax subsidies. And as a result, little to no impact is expected on small business and consumers; they will pay premiums (and in some cases subsidized premiums) to private insurers through the federally-operated Exchange rather than to the Healthcare Group program.

10. A description of any changes between the proposed rulemaking, to include supplemental notices, and the final rulemaking:

No changes were made between the proposed rulemaking and the final rulemaking.

11. An agency's summary of the public or stakeholder comments made about the rulemaking and the agency response to the comments:

No comments were received as of the close of the comment period of December 30, 2013.

12. All agencies shall list other matters prescribed by statute applicable to the specific agency or to any specific rule or class of rules. Additionally, an agency subject to Council review under A.R.S. §§ 41-1052 and 41-1055 shall respond to the following questions:

No other matters are applicable.

a. Whether the rule requires a permit, whether a general permit is used and if not, the reasons why a general permit is not used:

Not applicable.

b. Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than federal law and if so, citation to the statutory authority to exceed the requirements of federal law:

Not applicable.

c. Whether a person submitted an analysis to the agency that compares the rule's impact of the competitiveness of business in this state to the impact on business in other states:

No analysis was submitted.

13. A list of any incorporated by reference material as specified in A.R.S. § 41-1028 and its location in the rule:
None

14. Whether the rule was previously made, amended or repealed as an emergency rule. If so, cite the notice published in the *Register* as specified in R1-1-409(A). Also, the agency shall state where the text was changed between the emergency and the final rulemaking packages:
Not applicable

15. The full text of the rules follows:

TITLE 9. HEALTH SERVICES

CHAPTER 27. ~~ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM~~ ~~HEALTHCARE GROUP COVERAGE~~ REPEALED

ARTICLE 1. ~~DEFINITIONS~~ REPEALED

Section
R9-27-101. ~~Location of Definitions~~ Repealed

ARTICLE 2. ~~SCOPE OF SERVICES~~ REPEALED

Section
R9-27-202. ~~Covered Services~~ Repealed
R9-27-203. ~~Exclusions and Limitations~~ Repealed
R9-27-204. ~~Emergency Medical Services~~ Repealed
R9-27-210. ~~Pre-existing Conditions~~ Repealed

ARTICLE 3. ~~ELIGIBILITY AND ENROLLMENT~~ REPEALED

Section
R9-27-301. ~~Eligibility Criteria for Employers~~ Repealed
R9-27-302. ~~Eligibility and Enrollment Criteria for Employees~~ Repealed
R9-27-303. ~~Dependent Eligibility Criteria~~ Repealed
R9-27-307. ~~Enrollment; Effective Date of Coverage~~ Repealed
R9-27-310. ~~Termination of HCG Coverage; Denial of Enrollment; Exclusion from Eligibility and Enrollment~~ Repealed
R9-27-311. ~~Effective Date of Termination of HCG Coverage~~ Repealed
R9-27-312. ~~Continuation Coverage~~ Repealed

ARTICLE 5. ~~GENERAL PROVISIONS AND STANDARDS~~ REPEALED

Section
R9-27-509. ~~Information to Subscribers~~ Repealed

ARTICLE 7. ~~STANDARDS FOR PAYMENTS~~ REPEALED

Section
R9-27-702. ~~Charges to Members~~ Repealed
R9-27-703. ~~Payments by an HCG Plan~~ Repealed
R9-27-704. ~~Liability of an HCG Plan to a Noncontracting Hospital for the Provision of Emergency and Post-stabilization Services to Members~~ Repealed

ARTICLE 1. ~~DEFINITIONS~~ REPEALED

R9-27-101. ~~Location of Definitions~~ Repealed

~~A.~~ ~~Location of definitions. Definitions applicable to this Chapter are found in the following:~~

~~Definition~~	~~Section or Citation~~
~~"Accountable health plan"~~	~~A.R.S. § 20-2301~~
~~"ADHS"~~	~~R9-27-101~~
~~"AHCCCS"~~	~~R9-27-101~~
~~"Ambulance"~~	~~A.R.S. § 36-2201~~
~~"Certification"~~	~~29 U.S.C. 1181~~
~~"Clean claim"~~	~~A.R.S. § 36-2904~~
~~"COBRA continuation provisions"~~	~~A.R.S. § 36-2912~~
~~"Coinsurance"~~	~~R9-27-101~~
~~"Copayment"~~	~~R9-27-101~~

"Covered services"	R9-27-101
"Creditable coverage"	A.R.S. § 36-2912
"Day"	R9-27-101
"Deductible"	R9-27-101
"Dependent"	R9-27-101
"Disability"	R9-27-303
"Effective date of coverage"	R9-27-101
"Eligible employee"	A.R.S. § 36-2912
"Emergency ambulance service"	R9-27-101
"Emergency medical services"	R9-27-101
"Employee"	R9-27-101
"Employer"	R9-27-101
"Employer group"	R9-27-101
"Enrollment"	R9-27-101
"Experimental services"	R9-27-101
"Full-time employee"	R9-27-101
"GSA"	R9-27-101
"HCG"	R9-27-101
"HCGA"	R9-27-101
"HCG plan"	R9-27-101
"Health care coverage"	R9-27-101
"Health care practitioner"	R9-27-101
"Hospital"	R9-27-101
"Inpatient hospital services"	R9-27-101
"Late enrollee"	R9-27-101
"Medical services"	A.R.S. § 36-401
"Medically necessary"	R9-27-101
"Member"	R9-27-101
"Member handbook and evidence of coverage" or "member handbook"	R9-27-101
"Network"	R9-27-101
"Network provider"	R9-27-101
"Political subdivision"	R9-27-101
"Post-stabilization services"	R9-27-101
"Pre-existing condition"	A.R.S. § 36-2912
"Pre-existing condition exclusion"	A.R.S. § 36-2912
"Premium"	R9-27-101
"Pre-payment"	R9-27-101
"Prior authorization"	R9-27-101
"Qualifying event"	R9-27-101
"Scope of services"	R9-27-101
"Spouse"	R9-27-101
"Subcontract"	R9-27-101
"Subscriber"	R9-27-101
"Subscriber enrollment form"	R9-27-101
"Substantial gainful activity"	R9-27-303
"United States"	R9-27-101
"Waiting period"	A.R.S. § 36-2912

B. Definitions. In addition to the definitions contained in A.R.S. Title 36, Chapter 29, the words and phrases in this Chapter have the following meanings unless the context explicitly requires another meaning:

"ADHS" means the Arizona Department of Health Services, the state agency mandated to serve the public health needs of all Arizona residents.

"AHCCCS" means the Arizona Health Care Cost Containment System, which provides health services to an eligible member through the Administration, contractors, and other arrangements.

"Coinsurance" means a predetermined percentage of the cost of a covered service as specified in the GSA that a member agrees to pay for the provision of that service.

"Copayment" means a fixed-dollar amount that a member is required to pay directly to a provider at the time the services are rendered in order to receive the services.

"Covered services" means the health and medical services described in Article 2 of this Chapter, the GSA, and the mem-

~~ber handbook.~~
~~"Day" means a calendar day unless otherwise specified.~~
~~"Deductible" means the annual fixed-dollar amount of covered expenses that the member must pay before the HCG Plan starts to pay for covered services, subject to copayments and coinsurance.~~
~~"Dependent" means the eligible child and spouse of a subscriber under Article 3 of this Chapter.~~
~~"Effective date of coverage" means the date on which a subscriber or dependent can receive HCG coverage.~~
~~"Emergency ambulance service" means transportation by a ground or an air ambulance company for a member requiring emergency medical services in which the emergency medical services are provided by a person certified or licensed by a state to provide the services before, during, or after the member is transported by a ground or an air ambulance company.~~
~~"Emergency medical services" means covered medical services provided after the sudden onset of a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) that a prudent layperson, who possesses an average knowledge of health and medicine, may reasonably expect the absence of immediate medical attention to result in:~~
~~Placing a patient's health in serious jeopardy,~~
~~Serious impairment to bodily functions, or~~
~~Serious dysfunction of any bodily organ.~~
~~"Employee" means a person employed by an employer, a person who is self-employed, or a person who is eligible for a federal health coverage tax credit under 26 U.S.C. 35. A self-employed person shall meet the criteria specified in R9-27-301.~~
~~"Employer" means a business within this state that employs at least one but not more than 50 eligible full-time employees on the effective date of the first GSA with an HCG Plan, or an eligible political subdivision of this state. An employer includes a person who is self-employed.~~
~~"Employer group" means all eligible enrolled subscribers and eligible enrolled dependents, who receive HCG coverage through a contract with the employer.~~
~~"Enrollment" means the process in which an eligible employee and any eligible dependents are qualified to receive HCG covered services by selecting HCG coverage and completing and submitting all necessary and required documentation specified by HCGA under R9-27-302, provided that HCGA receives the full required premium for the entire employer group no later than the date specified in the employer group GSA.~~
~~"Experimental services" means services that are associated with treatment or diagnostic evaluation and that are not generally and widely accepted as a standard of care in the practice of medicine in the United States unless:~~
~~The weight of evidence in peer-reviewed articles in medical journals published in the United States supports the safety and effectiveness of the service; or~~
~~In the absence of such articles, for services that are rarely used, novel, or relatively unknown in the general professional medical community, the weight of opinions from specialists who provide the service attests to the safety and effectiveness of the service.~~
~~"Full-time employee" means an employee or a self-employed person who works at least 20 hours per week.~~
~~"GSA" means Group Service Agreement, a contract between an employer and HCGA or between HCGA and a person eligible for the federal health coverage tax credit.~~
~~"HCG" means Healthcare Group of Arizona, the program within the Administration authorized by A.R.S. § 36-2912 that allows HCG Plans to provide pre-paid health care coverage to subscribers of small businesses and political subdivisions within the state of Arizona through contracts with HCGA.~~
~~"HCGA" means Healthcare Group of Arizona Administration, which directs, determines eligibility, and regulates the continuous development and operation of the HCG program.~~
~~"HCG Plan" means a health plan offered by HCGA or by an entity under contract with the HCGA that establishes networks, manages the provision of covered services, and arranges for, and pays for HCG covered services through subcontracts with providers.~~
~~"Health care coverage" means a hospital or medical service corporation policy or certificate, a health care services organization contract, a multiple-employer welfare arrangement, or any other arrangement under which health services or health benefits are provided to two or more persons. Health care coverage does not include the following:~~
~~Accident only, dental only, vision only, disability income only or long-term care only insurance, fixed or hospital indemnity coverage, limited benefit coverage, specified disease coverage, credit coverage, or Taft-Hartley trusts;~~
~~Coverage that is issued as a supplement to liability insurance;~~
~~Medicare supplemental insurance;~~
~~Workers' compensation insurance; or~~
~~Automobile medical payment insurance.~~
~~"Health care practitioner" means a person who is licensed or certified under Arizona law to deliver health care services.~~
~~"Hospital" means a health care institution licensed as a hospital by the ADHS under A.R.S. Title 36, Chapter 4, Article 2, and certified as a provider under Title XVIII of the Social Security Act, as amended, or is determined by AHCCCS to meet the requirements for certification under Title XVIII of the Social Security Act, as amended.~~

~~"Inpatient hospital services" means services provided to a member who is admitted to a hospital for medical care and treatment. An inpatient hospital service is provided by or under the direction of a physician or other health care practitioner upon referral from a member's primary care provider.~~
~~"Late enrollee" means a member who enrolls 31 days after the effective date of the employer's initial GSA, or 31 days after a qualifying event, or outside of the open enrollment period.~~
~~"Medically necessary" means a covered service is determined by the HCG Plan or HCGA Medical Director, and a physician or other licensed health care practitioner within the scope of the physician's or other health care practitioner's practice under state law to:~~
~~Prevent disease, disability, or other adverse health condition or its progression; or~~
~~Prolong life.~~
~~"Member" means a subscriber and the subscriber's dependents who are enrolled with an HCG Plan for health care coverage.~~
~~"Member handbook and evidence of coverage" or "member handbook" means the written description that HCGA provides to each subscriber on enrollment, of the rights and responsibilities of members, as well as a list of covered services, limitations, exclusions, coinsurance, copayments, and deductibles that apply to the member's choice of coverage.~~
~~"Network" means the affiliation of physicians, hospitals and other providers that provide health care services to members through contracts with HCGA or HCG Plans.~~
~~"Network provider" means a provider who has a subcontract with HCGA or an HCG Plan and renders covered services to the member.~~
~~"Political subdivision" means the state of Arizona or a county, city, town, or school district within the state, or an entity whose employees are eligible for hospitalization and medical care under Arizona Revised Statutes, Title 38, Chapter 4, Article 4.~~
~~"Post-stabilization services" means covered services related to an emergency medical condition provided after the condition is stabilized.~~
~~"Premium" means the entire monthly pre-payment amount due to HCGA by the employer for coverage of medical benefits for all subscribers and dependents.~~
~~"Pre-payment" means the monthly submission by the employer or any eligible employee of the full premium payment at least 30 days in advance of coverage under the GSA.~~
~~"Prior authorization" means the process by which the HCGA or the HCG Plan informs a provider that it has made a preliminary determination that a requested service is medically necessary, appropriate, and is a covered service. Prior authorization is not a guarantee of payment.~~
~~"Qualifying event" means a situation as described in the GSA that enables a person to enroll outside a designated open enrollment period without being considered a late enrollee, or to obtain continuation coverage, if applicable.~~
~~"Scope of services" means the covered, limited, and excluded services listed in Article 2 of this Chapter, the GSA, and the member handbook.~~
~~"Spouse" means a husband or a wife of an HCG subscriber who has entered into a marriage recognized as valid by the state of Arizona.~~
~~"Subcontract" means an agreement entered into by HCGA or an HCG Plan with any of the following:~~
~~A provider of health care services who agrees to furnish covered services to members,~~
~~A marketing organization, or~~
~~Any other organization to serve the needs of the HCG Plan.~~
~~"Subscriber" means an enrolled HCG employee, including a person who meets the eligibility requirements for the federal health coverage tax credit under 26 U.S.C. 35 (Section 35 of the Internal Revenue Code of 1986).~~
~~"Subscriber enrollment form" means the form that a subscriber fills out to select and enroll in an HCG Plan and to choose a deductible.~~
~~"United States" means the 50 states, the District of Columbia, and includes the territorial waters adjoining these entities. A ship or an aircraft, even of American registry, is not considered to constitute American territory when it is not within or above the land area or territorial waters of the United States.~~

ARTICLE 2. ~~SCOPE OF SERVICES~~ REPEALED

R9-27-202. ~~Covered Services~~ Repealed

~~Covered services. HCGA or an HCG Plan shall provide covered services to members as specified in the GSA.~~

R9-27-203. ~~Exclusions and Limitations~~ Repealed

~~A.~~ ~~Excluded services. An HCG Plan shall not cover the following:~~
~~1. Excluded services as specified in the GSA and the member handbook;~~
~~2. Services not covered in the member's choice of HCG benefit options;~~
~~3. Services that require prior authorization for which the member does not obtain prior authorization;~~
~~4. Care for a health condition for which a state or local law requires the member to be treated in a public facility;~~
~~5. Care for military service disabilities treatable through governmental facilities if the member is legally entitled to treat-~~

~~ment and the facilities are available;~~
~~6. Pregnancy termination, except when required by law to be covered;~~
~~7. Treatment of gender dysphoria including gender reassignment surgeries and reversal of voluntarily induced infertility (sterilization);~~
~~8. Services that HCGA, through its Medical Director, deems not to be medically necessary;~~
~~9. Charges for injuries incurred as the result of:~~
~~a. Participating in a riot,~~
~~b. Committing or attempting to commit a felony or assault,~~
~~c. Committing intentional acts of self-inflicted injury, or~~
~~d. Attempting suicide.~~
~~10. Infertility testing, in-vitro fertilization, and all other fertilization treatments;~~
~~11. Experimental services; and~~
~~12. Medications not approved by the FDA.~~
~~**B.** Limitations. When providing covered services, the HCG Plan shall adhere to the coverage limitations in this Article and the following:~~
~~1. Inpatient hospital accommodations are covered as specified in the GSA and the member handbook.~~
~~2. Alternative levels of care instead of hospitalization are covered if cost-effective and medically necessary.~~
~~3. Dialysis is limited to services not covered by Title XVIII, of the Social Security Act, as amended.~~

R9-27-204. ~~Emergency Medical Services~~ Repealed

~~**A.** Emergency medical services provided at a medical facility in the United States are covered when a member presents for emergency medical services regardless of whether the services are provided within or outside the network if the member or provider notifies the selected HCG Plan no later than 48 hours from the day that the member presents for the emergency service. Failure to provide timely notice constitutes cause for denial of payment unless the member or provider shows good cause. All emergency medical services are subject to review after services are received to ensure that the services are emergent and are covered, medically necessary services.~~
~~**B.** Emergency medical services provided outside the United States are not covered.~~

R9-27-210. ~~Pre-existing Conditions~~ Repealed

~~**A.** Pre-existing conditions exclusions. Except as provided in subsection (B), any health and medical services related to a pre-existing condition are not covered as specified in A.R.S. § 36-2912 and the GSA.~~
~~**B.** Pre-existing conditions coverage. Health and medical services relating to pre-existing conditions for the following individuals are covered:~~
~~1. Newborns from the time of birth, adopted children, and children placed for adoption, if enrolled within the timeframes set forth in the GSA;~~
~~2. A subscriber eligible under R9-27-302 who meets the aggregate periods of creditable coverage as calculated under A.R.S. § 36-2912 of 12 months or 18 months in the case of a late enrollee.~~
~~**C.** Credit for prior health coverage. A member shall receive a credit toward meeting the 12-month or 18-month pre-existing condition exclusion period of one month for each month of continuous coverage that a member received from HCG/HCGA or an accountable health plan under A.R.S. § 36-2912. Upon request, an HCG Plan that provided continuous coverage to a person shall disclose the coverage provided.~~

ARTICLE 3. ~~ELIGIBILITY AND ENROLLMENT~~ REPEALED

R9-27-301. ~~Eligibility Criteria for Employers~~ Repealed

~~**A.** Criteria for employers.~~
~~1. To be eligible for health care coverage through HCG, an employer shall:~~
~~a. Conduct business in the state of Arizona for at least 60 days before applying to HCGA.~~
~~b. Have a minimum of one (self-employed) and a maximum of 50 eligible full-time employees on the effective date of the first GSA with HCGA.~~
~~2. R9-27-301(A)(1)(b) does not apply to political subdivisions.~~
~~**B.** Employer's prior health care coverage. HCGA shall not enroll an employer in Healthcare Group sooner than 180 days after the date that the employer's health care coverage under an accountable health plan is discontinued. An employer's enrollment in HCG is effective on the first day of the month after the 180-day period. The 180-day enrollment restriction does not apply to an employer if the employer's accountable health plan discontinues offering the health plan of which the employer is a member.~~
~~**C.** Required initial enrollment of a minimum percentage of eligible employees. An employer other than a political subdivision shall meet the following enrollment percentages on the effective date of the first GSA with HCGA:~~
~~1. An employer with five or fewer eligible full-time employees shall enroll 100 percent of these employees in an HCG Plan, or~~
~~2. An employer with six or more eligible full-time employees shall enroll at least 80 percent of these employees in an~~

~~HCG Plan.~~

~~**D.** Full-time employees with proof of other health care coverage. Full-time employees with proof of existing health care coverage who elect not to participate in HCG shall not be considered when determining the required percentage of enrollees, specified in subsection (C), if the health care coverage is one of the following:~~

~~1. Group coverage provided through a spouse, parent, legal guardian; or~~
~~2. Medical assistance provided by a government-subsidized health care program; or~~
~~3. Medical assistance provided under A.R.S. § 36-2982; or~~
~~4. Individual coverage or health care coverage through another employer.~~

~~**E.** Post-enrollment changes in employer size. Changes in employer size that occur during the term of the GSA or during any renewal periods do not affect eligibility.~~

~~**F.** Review and verification of eligibility. HCGA may conduct random reviews for continued eligibility of an employer and the members.~~

R9-27-302. ~~Eligibility and Enrollment Criteria for Employees~~ Repealed

~~**A.** Eligibility criteria for employees. An eligible employee shall:~~

~~1. Be eligible for a federal health coverage tax credit under 26 U.S.C. 35 as specified in A.R.S. § 36-2912 (AA)(4)(d); or~~
~~2. Be employed by an enrolled employer with a contract with HCG as specified in R9-27-301; and~~
~~a. Work at least 20 hours per week for the employer; and~~
~~b. Meet other requirements as specified in the GSA.~~

~~**B.** Enrollment criteria for eligible employees. An eligible employee and an eligible dependent may receive HCG coverage if all of the following occur:~~

~~1. An eligible employee selects health care coverage through HCG;~~
~~2. An eligible employee completes and submits all necessary documentation specified by HCGA, including the subscriber enrollment form and health history forms; for the eligible employee and each applying family member; and~~
~~3. HCGA receives the full required premium no later than the date specified in the GSA.~~

~~**C.** After completion of the actions in subsection (B), HCGA shall send written notification of the effective date of coverage to the subscriber and dependent.~~

~~**D.** Eligibility for government-subsidized health care programs. HCGA shall provide written information to members who may be eligible for a government-subsidized health care program.~~

R9-27-303. ~~Dependent Eligibility Criteria~~ Repealed

~~**A.** Eligible dependents. An eligible dependent of an employee member includes:~~

~~1. A legal spouse;~~
~~2. An unmarried child less than the age of 19 or less than the age of 24 if the child is a full-time student, and is:~~
~~a. A natural child,~~
~~b. An adopted child or a child who is placed for adoption,~~
~~c. A step-child, or~~
~~d. A child for whom the subscriber or enrolled spouse is a legal guardian.~~
~~3. An unmarried child, as specified in subsection (A)(2), of any age with a disability that existed before the child's 19th birthday, as determined by HCGA through the HCGA Medical Director.~~

~~**B.** For the purposes of this Section:~~

~~1. "Disability" means the inability to do any substantial gainful activity by reason of any impairment or combination of impairments that HCGA through the HCGA Medical Director expects to be permanent and continuous. The impairment must result from anatomical, physiological, or psychological abnormalities that can be shown by medically acceptable clinical and laboratory diagnostic techniques. Medical evidence consisting of signs, symptoms, and laboratory findings, not only the member's statement of symptoms, establishes an impairment.~~
~~2. "Substantial gainful activity" means work that:~~
~~a. Involves doing significant and productive physical or mental duties, and~~
~~b. Is done or intended for pay or profit.~~

R9-27-307. ~~Enrollment; Effective Date of Coverage~~ Repealed

~~**A.** Enrollment. A member who meets the eligibility requirements may select and enroll in HCG coverage under the terms of the GSA at any time. In order not to be considered a late enrollee, an eligible member shall enroll during the qualifying event periods specified in the GSA:~~

~~1. Within 31 days following the effective date of the initial GSA with the employer;~~
~~2. Within 31 days after the qualifying event occurs;~~
~~3. When the open enrollment period occurs as specified in the GSA; or~~
~~4. Within 31 days following the termination of health care coverage for an eligible subscriber or dependent.~~

~~**B.** Effective date of coverage. The HCGA shall establish the effective date of coverage for an employer group or a subscriber or dependent and shall provide written notice of the effective date of coverage to the employer as provided under this Chapter.~~

R9-27-310. ~~Termination of HCG Coverage; Denial of Enrollment; Exclusion from Eligibility and Enrollment~~ Repealed

~~**A.** Immediate termination of a member's coverage. HCGA may terminate a member's coverage effective immediately for any of the following reasons:~~
- ~~1. Clear and convincing evidence of fraud or misrepresentation regarding enrollment or factors listed in A.R.S. § 36-2912 when the member applies for coverage or obtains services;~~
- ~~2. Committing or threatening to commit violence toward an employee or an agent of HCGA, an employee or an agent of an HCG Plan, including a network provider or an out-of-network provider.~~

~~**B.** Written notice. For immediate termination of a member's coverage under subsection (A), HCGA shall mail a notice of termination of coverage to the member's last known address within one business day after HCGA terminates a member's coverage. The notice shall state the date and time coverage was terminated and the reason for termination.~~

~~**C.** Termination of a member's coverage with 30-day notice. HCGA may terminate a member's coverage 30 days from the date of the notice for any of the following reasons:~~
- ~~1. Repeated and unreasonable demands for unnecessary or uncovered medical services;~~
- ~~2. Failure to pay any copayment, coinsurance, or deductible;~~
- ~~3. Violation of a material provision of the member handbook;~~
- ~~4. Termination of employment;~~
- ~~5. Change in status of the member that is required for eligibility under R9-27-302; or~~
- ~~6. Changes to the eligibility criteria for a dependent under R9-27-303.~~

~~**D.** Written notice. For termination of a member's coverage with 30 days notice under subsection (C), HCGA shall mail a notice of proposed termination to the member's last known address. The notice shall state the reason for proposed termination and the date coverage will be terminated.~~

~~**E.** Termination of an employer group. If HCGA does not receive the full premium payment from an employer for an employer group by the premium due date specified in the GSA, HCGA shall send notice of the final due date to the employer at the employer's last known address. The notice shall advise the employer that HCGA must receive the full premium payment by the final due date contained in the notice and state the reason and date for the termination of coverage for the employer group if the full premium is not received by the final due date.~~

~~**F.** Exclusion of member from eligibility and enrollment. HCGA may exclude, as ineligible to enroll or re-enroll, any member whose prior health care coverage has been terminated by HCGA for any of the following reasons:~~
- ~~1. Clear and convincing evidence of fraud or misrepresentation regarding enrollment or criteria listed in R9-27-302 and R9-27-303 when the member applies for coverage or obtains services;~~
- ~~2. Committing or threatening to commit violence toward an employee or an agent of HCGA, an employee or an agent of an HCG Plan, including a network provider, or an out-of-network provider;~~
- ~~3. Repeated and unreasonable demands for unnecessary or uncovered medical services;~~
- ~~4. Failure to pay any copayment, coinsurance, or deductible;~~
- ~~5. Violation of a material provision of the member handbook.~~

~~**G.** Exclusion of an employer from eligibility and enrollment. HCGA may exclude, as ineligible to enroll or re-enroll, an employer whose prior health care coverage has been terminated by HCGA for any of the following reasons:~~
- ~~1. Violating a provision of the GSA;~~
- ~~2. Committing or threatening to commit violence toward an employee or an agent of HCGA, an employee or an agent of an HCG Plan, including a network provider, or an out-of-network provider;~~
- ~~3. Clear and convincing evidence of fraud or misrepresentation regarding eligibility and enrollment criteria for an employer in R9-27-301.~~

R9-27-311. ~~Effective Date of Termination of HCG Coverage~~ Repealed

~~**A.** Except as specified in subsection (B), HCG coverage for a member shall terminate on the date specified in the notice mailed to the member as provided in R9-27-310(B), (D), or (E).~~

~~**B.** HCGA shall provide and pay for health care services for a member who is an inpatient on the effective date of termination of coverage until the HCG Plan Medical Director or designee determines that care in the hospital is no longer medically necessary, provided that HCGA continues to receive timely paid premiums for the member. Coverage for all other members, except the member who is an inpatient, shall terminate as provided in subsection (A).~~

R9-27-312. ~~Continuation Coverage~~ Repealed

~~A member who is entitled to continuation coverage under A.R.S. § 36-2912(AA)(2) may retain HCG coverage until the benefit expires, the continuation coverage ends, or the premium is not paid by the member, whichever is earlier.~~

ARTICLE 5. ~~GENERAL PROVISIONS AND STANDARDS~~ REPEALED

R9-27-509. ~~Information to Subscribers~~ Repealed

~~**A.** Member handbook. HCGA shall produce and distribute a printed member handbook to each subscriber by the effective date of coverage or as otherwise stated in the GSA. The member handbook shall include the following:~~

1. ~~A description of all available services and an explanation of any service limitations, exclusions from coverage, and charges for services, when applicable;~~
2. ~~An explanation of the procedure for obtaining covered services, including a notice stating that the HCG Plan is only liable for services authorized by a member's primary care provider or the HCG Plan;~~
3. ~~Procedures for obtaining emergency medical services;~~
4. ~~An explanation of the procedure for obtaining emergency medical services outside the network of an HCG Plan;~~
5. ~~Circumstances under which a member may lose coverage;~~
6. ~~A description of the grievance and request for hearing procedures;~~
7. ~~Copayment, coinsurance, and deductible schedules;~~
8. ~~Information on obtaining health services and on the maintenance of personal and family health; and~~
9. ~~Information regarding medically necessary emergency transportation offered by an HCG Plan.~~

~~B.~~ ~~Notification of changes in services. HCGA shall prepare and distribute to members a printed member handbook endorsement describing any changes, including changes to deductibles, coinsurance, and copayments that HCGA proposes to make in services provided within the HCG network. HCGA shall distribute the endorsement to all affected members and dependents at least 14 days before a planned change. HCGA shall provide notification as soon as possible when unforeseen circumstances require an immediate change in services or service locations.~~

ARTICLE 7. ~~STANDARDS FOR PAYMENTS~~ REPEALED

R9-27-702. ~~Charges to Members~~ Repealed

~~If a member notifies a provider that the member is covered by HCG, the provider shall not charge, submit a claim to, or demand or otherwise collect payment from the member or a person acting on behalf of the member for any covered service, except the provider may collect from or bill the member:~~

1. ~~For any copayment, coinsurance, or deductible as described in the GSA;~~
2. ~~If the member requests the provision of services, other than emergency medical services, that are excluded under the GSA or have not been authorized by an HCG Plan; or~~
3. ~~For the difference between any payments the provider receives from an HCG Plan and billed charges for services if the provider has obtained, prior to the delivery of the service, the written agreement of the member to accept financial responsibility for the difference.~~

R9-27-703. ~~Payments by an HCG Plan~~ Repealed

~~A.~~ ~~Neither HCGA nor an HCG Plan is responsible for reimbursing a provider for services that are:~~

1. ~~Excluded under the GSA; or~~
2. ~~In the case of non-emergency services, services not authorized by an HCG Plan or that did not result from a referral.~~

~~B.~~ ~~An HCG Plan shall reimburse a network provider for covered services as specified in the subcontract between the HCG Plan and the provider.~~

~~C.~~ ~~If a member receives emergency medical services from a provider other than a network provider, or if an HCG Plan authorizes services to be delivered by, or refers a member to a provider other than a network provider, the HCG Plan shall reimburse the provider for covered services at the lesser of billed charges or an amount negotiated with the provider less any copayment, coinsurance, or deductible as described in the GSA.~~

~~D.~~ ~~An HCG Plan shall adjudicate claims from providers within 60 days of receipt of a clean claim from the provider unless a different time is specified in the subcontract between the HCG Plan and the provider.~~

R9-27-704. ~~Liability of an HCG Plan to a Noncontracting Hospital for the Provision of Emergency and Post-stabilization Services to Members~~ Repealed

~~An HCG Plan shall reimburse a noncontracting hospital for the provision of emergency and post-stabilization services to a member in accordance with the terms of the HCG Plan's contract with HCGA and the GSA. Unless the GSA or contract with HCGA states otherwise, the HCG Plan shall meet the following requirements:~~

1. ~~Liability to noncontracting hospitals. An HCG Plan shall reimburse a noncontracting hospital for a member's emergency medical services until the member's condition is stabilized and the member is transferable to a contracting hospital or is discharged after the member's condition is stabilized.~~
2. ~~Member refusal of transfer. If a member refuses transfer from a noncontracting hospital to a contracting hospital, neither HCGA nor an HCG Plan is liable for any costs incurred after the date of refusal when:~~
   a. ~~The HCG Plan consulted with the member and the member continued to refuse the transfer; and~~
   b. ~~The member is provided and signs a written statement of liability on or before the date of consult by which the member indicates the member is aware of the financial consequences of refusing to transfer, or two witnesses sign a statement indicating that the member was provided the statement of liability but refused to sign.~~

NOTICE OF FINAL RULEMAKING

TITLE 12. NATURAL RESOURCES

CHAPTER 1. RADIATION REGULATORY AGENCY

Editor's Note: The following Notice of Final Rulemaking was reviewed per Executive Order 2012-03 as issued by Governor Brewer. (See the text of the executive order on page 824.) The Governor's Office authorized the notice to proceed through the rulemaking process on April 2, 2013.

[R14-44]

PREAMBLE

1. Article, Part, or Section Affected (as applicable) **Rulemaking Action:**

R12-1-611.01	New Section
R12-1-611.02	New Section

2. Citations to the agency's statutory rulemaking authority to include the authorizing statute (general) and the implementing statute (specific):

Authorizing statute: A.R.S. § 30-654(B)(5)

Implementing statutes: A.R.S. §§ 30-651, 30-654, 30-657, 30-671, 30-672, 30-673, 30-681, 30-687, 30-688, and 30-689.

3. The effective date of the rule:

May 3, 2014

4. Citations to all related notices published in the *Register* as specified in R1-1-409(A) that pertain to the record of the proposed rule:

Notice of Rulemaking Docket Opening: 19 A.A.R. 895, April 26, 2013

Notice of Proposed rulemaking: 19 A.A.R. 1475, June 7, 2013

Notice of Supplemental Proposed rulemaking: 19 A.A.R. 3217, October 18, 2013

5. The agency's contact person who can answer questions about the rulemaking:

Name:	Jerry W. Perkins
Address:	Radiation Regulatory Agency 4814 S. 40th St. Phoenix, AZ 85040
Telephone:	(602) 255-4845, ext. 272
Fax:	(602) 437-0705
E-mail:	jperkins@azrra.gov
Website:	www.azrra.gov

6. An agency's justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking:

This rulemaking package adds two rules to ensure that Arizona radiation compliance addresses recent safety issues related to therapeutic doses of radiation significantly higher than those experienced from diagnostic x-ray exposure. The dose is being delivered by FDA approved e-brachytherapy devices that recently gained market clearance.

7. A reference to any study relevant to the rule that the agency reviewed and proposes either to rely on or not to 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

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

Not applicable

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

There is little or minimal economic impact from any of the proposed rules in this rulemaking. Currently, all registrants pay an annual fee which covers the administrative cost and inspection fees for each facility registration number. This package has no fee increase or new requirements that would markedly change the way businesses operate with radiation safety concerns in mind. The amendments in this rulemaking address safety issues related to therapeutic

doses of radiation significantly higher than those experienced from diagnostic x-ray exposure. The dose is being delivered by FDA approved e-brachytherapy devices that recently gained market clearance. No new FTE's were needed for this rulemaking package so additional notice was not sent to Joint Legislative Budget Committee (JLBC).

10. A description of any changes between the proposed rulemaking, to include supplemental notices, and the final rulemaking:

Several grammatical, clarifying, and formatting changes were made to the proposed rules following the suggestions of the Office of the Secretary of State. A modification of the heading of R12-1-611.02 was made for clarification. Several subsection cross references were corrected as a result of the re-lettering that occurred in the supplemental notice that was not adjusted in the text of the rules. In addition, the certifying physicist's college in Canada was corrected to its appropriate name to "Canadian College of Physicists in Medicine" in R12-1-611.01(M)". Clarification to R12-1-611.01(A) language was made to match the modification of the heading for the rule. This same modification to match the intended language of the heading of R12-1-611.02 was made in the first paragraph as well. In addition, the heading in R12-1-611.01 was modified to include the clarifying term "therapeutic" to match similar language used in the heading for R12-1-611.02.

11. An agency's summary of the public or stakeholder comments made about the rulemaking and the agencies response to the comments:

Agency received comments that were used to begin the rulemaking process as well as the request of the governor's office. Additional comments were received after the docket was opened and before the first oral hearing took place. The first comment received was from the Cancer Treatment Services Arizona on March 5, 2012. Ajay Bhatnager, M.D. wrote a letter on behalf of the company requesting that the Agency adopt authorized training requirements similar to those recommended by the CRCPD. The comment was considered and the rule making package includes the Suggested State Regulations from the CRCPD where appropriate within the laws of Arizona. Several individuals representing the Arizona Radiological Society submitted a letter in June 14, 2012 with significantly similar language as the previous comment and the comment was considered as additional support for the adoption of Suggested State Regulations specific to electronic brachytherapy. On July 17, 2013 Dr. Stephen Sapareto presented a written letter on behalf of Banner MD Anderson Cancer Center that used significantly the same language as the first two comments. Similar consideration was given as previously stated. Only one comment related to the rules in this rulemaking was made during the oral hearing on July 17, 2013. The comment requested that "before next patient use" be the terminology used instead of "two days" to ensure the unit is calibrated for each new patient and not used more often on multiple patients before calibration. This modification was made in the supplemental notice to R12-1-611.01(J)(5)(b). A written comment by Albert Mesa, DABR, was supplied to the agency encouraging the idea that electronic brachytherapy was safer than traditional brachytherapy and less regulation was needed. The comment was considered as a portion of the reason to re-hear comments on the two proposed rules.

A second public hearing was scheduled following the supplemental notice of these two rules on November 21, 2013. Several comments were made during the hearing and considered by the board. The first comment considered was to clarify the low range of survey meters used for therapy units. The change to R12-1-611.01(B) was considered and approved. The second comment suggested a cross reference to shielding requirements be made to the rule R12-1-611.01(C)(4). The comment used a rule in Article 4, but the board agreed to use a cross reference to the rule in Article 6 as a more specific reference. A third comment was presented on restricting assistance to patients receiving therapy in R12-1-611.01(G)(5). The comment was withdrawn by the original maker after discussions on the medical necessity of allowing limited assistance in some cases. A forth comment to rule R12-1-611.01(H)(1) was made and considered to clarify who must wear dosimetry badges during therapy treatments. The rule language was rewritten to clarify that any person in the treatment room, other than the patient during treatment, is required to wear personnel monitoring devices. A fifth comment was made to rule R12-1-611.01(H)(2). The word "new" was added to the language to clarify that both an authorized user and a Qualified Medical Physicist would be present during the initiation of a treatment plan, but not required for each fractional dose after a lengthy debate and consideration of multiple oral comments on the written comment by Mr. Wong. A sixth written comment suggested that the Agency not use the antiquated term of art "misadministration" and adopt the current industry term "medical event". The term replacement was made where appropriate. Oral comments requested that the headings of R12-1-611.01 and R12-1-611.02 be modified for clarification of use of therapy units. The addition of the use term for "interstitial and intracavity" was added to R12-1-611.01 and "superficial" was added to R12-1-611.02. Other comments on the record were viewed as discussion for and opposed to the written comments of record. They were addressed with each of the written comments previously discussed.

There were multiple oral comments made by Tariq Mian that professional societies in medical physics promote the attendance of both the authorized user and the Qualified Medical Physicist at all fractions of therapy treatment for enhanced safety. These comments were heard by the Radiation Regulatory Board and staff of the Agency and considered in an effort to meet regulatory safety requirements without causing undue hardship to local business. Oral comments made that discussed safety issues by medical practitioners were heard but determined to be a medical practice issue and not a radiation safety issue.

12. All agencies shall list other matters prescribed by statute applicable to the specific agency or to any specific rule or class of rules. Additionally, an agency subject to Council review under A.R.S. §§ 41-1052 and 41-1055 shall respond to the following questions:

The Arizona Radiation Regulatory Hearing Board is required to review and approve rules and substantive policy statements adopted by the agency in accordance with A.R.S. § 30-655(D). The rules in this package were approved as mended based upon comments and factors discussed in an oral hearing on November 21, 2013.

a. Whether the rule requires a permit, whether a general permit is used and if not, the reasons why a general permit is not used:

The Agency believes that it is exempt from A.R.S. § 41-1037 due to paragraph (A)(2) as the issuance of an alternative type of permit is authorized under the statutory requirement of A.R.S. § 30-672 to protect the public health and safety.

b. Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than federal law and if so, citation to the statutory authority to exceed the requirements of federal law:

Currently the regulation of radiation producing equipment is conducted at the state level and federal regulations in Title 21 of the Code of Federal Regulations only govern the manufacture of radiation producing electronic devices described in this rulemaking.

c. Whether a person submitted an analysis to the agency that compares the rule's impact of the competitiveness of business in this state to the impact on business in other states:

No analysis has been submitted.

13. A list of any incorporated by reference material as specified in A.R.S. § 41-1028 and its location in the rules:

Not applicable

14. Whether the rule was previously made, amended or repealed as an emergency rule. If so, cite the notice published in the *Register* as specified in R1-1-409(A). Also, the agency shall state where the text was changed between the emergency and the final rulemaking packages:

Not applicable

15. The full text of the rules follows:

TITLE 12. NATURAL RESOURCES

CHAPTER 1. RADIATION REGULATORY AGENCY

ARTICLE 6. USE OF X-RAYS IN THE HEALING ARTS

Section

ARTICLE 6. USE OF X-RAYS IN THE HEALING ARTS

R12-1-611.01. Electronic Brachytherapy to Deliver Interstitial and Intracavity Therapeutic Radiation Dosage

A. Electronic brachytherapy devices used to deliver interstitial and intracavity therapeutic radiation dosage shall be subject to the requirements of this Section, and unless otherwise specified in this Section shall be exempt from the requirements of R12-1-611.

1. An electronic brachytherapy device that does not meet the requirements of this Section shall not be used for irradiation of patients; and
2. An electronic brachytherapy device shall only be utilized for human use applications specifically approved by the U.S. Food and Drug Administration (FDA), unless participating in a research study approved by the registrant's Institutional Review Board (IRB).

B. Each facility location authorized to use an electronic brachytherapy device in accordance with this Section shall possess appropriately calibrated portable monitoring equipment. At a minimum, such equipment shall include a portable survey instrument capable of measuring dose rates over the range 10 μSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The survey instrument shall be capable of measuring as low as 10 μSv (1 mrem) per hour in the energy range of the electronic brachytherapy unit for which the survey instrument is to be used. Published correction factors utilized in conjunction with the instrument's readings may be used to achieve sensitivity. The survey instrument or instruments shall be operable and calibrated before first use, at intervals not to exceed 12 months, and after survey instrument repairs.

C. Facility Design Requirements for Electronic Brachytherapy Devices. In addition to shielding adequate to meet requirements of R12-1-603(C), the treatment room shall meet the following design requirements:

1. If applicable, provision shall be made to prevent simultaneous operation of more than one therapeutic radiation machine in a treatment room.
2. Access to the treatment room shall be controlled by a door at each entrance.
3. Each treatment room shall have provisions to permit continuous oral communication and visual observation of the

patient from the treatment control panel during irradiation. The electronic brachytherapy device shall not be used for patient irradiation unless the patient can be observed.

4. For electronic brachytherapy devices capable of operating below 150 kVp, radiation shielding for the staff in the treatment room may be available, either as a portable shield or as localized shielded material around the treatment site or both, in lieu of the requirements for room shielding. The shielding shall meet the requirements of R12-1-603(C).
5. For electronic brachytherapy devices capable of operating at or greater than 150 kVp, the facility must meet the requirements of R12-1-611(B)(4).

D. Control Panel Functions. The control panel, in addition to the displays required by other provisions in this Section, shall:

1. Provide an indication of whether electrical power is available at the control panel and if activation of the electronic brachytherapy source is possible;
2. Provide an indication of whether x-rays are being produced;
3. Provide a means for indicating electronic brachytherapy source potential and current;
4. Provide the means for terminating an exposure at any time; and
5. Include an access control (locking) device that will prevent unauthorized use of the electronic brachytherapy device.

E. Timer. A suitable irradiation control device (timer) shall be provided to terminate the irradiation after a pre-set time interval or integrated charge on a dosimeter-based monitor.

1. A timer shall be provided at the treatment control panel. The timer shall indicate the planned setting and the time elapsed or remaining;
2. The timer shall not permit an exposure if set at zero;
3. The timer shall be a cumulative device that activates with an indication of "BEAM-ON" that retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;
4. The timer shall terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system has not previously terminated irradiation.
5. The timer shall permit setting of exposure times as short as 0.1 second; and
6. The timer shall be accurate to within one percent of the selected value or 0.1 second, whichever is greater.

F. Qualified Medical Physicist Support.

1. The services of a Qualified Medical Physicist shall be required in facilities having electronic brachytherapy devices. The Qualified Medical Physicist shall be responsible for:
   a. Evaluation of the output from the electronic brachytherapy source;
   b. Generation of the necessary dosimetric information;
   c. Supervision and review of treatment calculations prior to initial treatment of any treatment site;
   d. Establishing the periodic and day-of-use quality assurance checks and reviewing the data from those checks as required in subsection (J);
   e. Consultation with the authorized user in treatment planning, as needed; and
   f. Performing calculations/assessments regarding patient treatments that may constitute a medical event.
2. If the Qualified Medical Physicist is not a full-time employee of the registrant, then the operating procedures required by subsection (G) shall also specifically address how the Qualified Medical Physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the Qualified Medical Physicist can be contacted.

G. Operating Procedures.

1. Only individuals approved by the authorized user, Radiation Safety Officer, or Qualified Medical Physicist shall be present in the treatment room during treatment;
2. Electronic brachytherapy devices shall not be made available for medical use unless the requirements of subsections (A), (H), and (I) have been met;
3. The electronic brachytherapy device shall be inoperable, either by hardware or password, when unattended by qualified staff or service personnel;
4. During operation, the electronic brachytherapy device operator shall monitor the position of all persons in the treatment room, and all persons entering the treatment room, to prevent entering persons from unshielded exposure from the treatment beam;
5. If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used;
6. Written procedures shall be developed, implemented, and maintained for responding to an abnormal situation. These procedures shall include:
   a. Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions; and
   b. The names and telephone numbers of the authorized users, the Qualified Medical Physicist, and the Radiation Safety Officer to be contacted if the device or console operates abnormally.
7. A copy of the current operating and emergency procedures shall be physically located at the electronic brachytherapy device control console;

8. Instructions shall be maintained with the electronic brachytherapy device control console to inform the operator of the names and telephone numbers of the authorized users, the Qualified Medical Physicist, and the Radiation Safety Officer to be contacted if the device or console operates abnormally; and
9. The Radiation Safety Officer, or the Radiation Safety Officer's designee, and an authorized user shall be notified immediately if the patient has a medical emergency, suffers injury or dies. The Radiation Safety Officer or the Qualified Medical Physicist shall inform the manufacturer of the event.

H. Safety Precautions for Electronic Brachytherapy Devices.
1. Any person in the treatment room, other than the person being treated, shall wear personnel monitoring devices;
2. An authorized user and a Qualified Medical Physicist shall be physically present during the initiation of all new patient treatments involving the electronic brachytherapy device;
3. After the first treatment one of the following individuals shall be physically present during continuation of all patient treatments involving the electronic brachytherapy device:
   a. A Qualified Medical Physicist, or
   b. An authorized user, or
   c. A certified therapy technologist (CTT) certified by the Arizona Medical Radiologic Technology Board of Examiners, under the direct supervision of an authorized user, who has been trained in the operation and emergency response for the electronic brachytherapy device;
4. When shielding is required by subsection (C)(4), surveys shall be conducted to ensure that the requirements of R12-1-408, R12-1-414, and R12-1-416 are met. Alternatively, a Qualified Medical Physicist shall designate shield locations sufficient to meet the requirements of R12-1-603(C) and R12-1-607(C) for any individual, other than the patient, in the treatment room; and
5. All personnel in the treatment room are required to remain behind shielding during treatment. A Qualified Medical Physicist shall approve any deviation from this requirement and shall designate alternative radiation safety protocols, compatible with patient safety, to provide an equivalent degree of protection.

I. Electronic Brachytherapy Source Calibration Measurements.
1. Calibration of the electronic brachytherapy source output shall be performed by, or under the direct supervision of, a Qualified Medical Physicist. If the control console is integral to the electronic brachytherapy device, the required procedures shall be kept where the operator is located during electronic brachytherapy device operation.
2. Calibration of the electronic brachytherapy source output shall be made for each electronic brachytherapy source, or after any repair affecting the x-ray beam generation, or when indicated by the electronic brachytherapy source quality assurance checks;
3. Calibration of the electronic brachytherapy source output shall utilize a dosimetry system appropriate for the energy output of the unit and calibrated by the National Institute for Standards and Technology (NIST) or by an American Association of Physicists in Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL). The calibration shall have been performed within the previous 24 months and after any servicing that may have affected system calibration;
4. Calibration of the electronic brachytherapy source output shall include, as applicable, determination of:
   a. The output within two percent of the expected value, if applicable, or determination of the output if there is no expected value;
   b. Timer accuracy and linearity over the typical range of use;
   c. Proper operation of back-up exposure control devices;
   d. Evaluation that the relative dose distribution about the source is within five percent of that expected; and
   e. Source positioning accuracy to within one millimeter within the applicator;
5. Calibration of the x-ray source output required shall be in accordance with current published recommendations from a recognized national professional association with expertise in electronic brachytherapy (when available). In the absence of a calibration protocol published by a national professional association, the manufacturer's calibration protocol shall be followed.
6. The registrant shall maintain a record of each calibration in an auditable form for the duration of the registration. The record shall include: the date of the calibration; the manufacturer's name, model number and serial number for the electronic brachytherapy device and a unique identifier for its electronic instrument or instruments brachytherapy source; the model numbers and serial numbers of the instrument or instruments used to calibrate the electronic brachytherapy device; and the name and signature of the Qualified Medical Physicist responsible for performing the calibration.

J. Periodic and Day-of-Use Quality Assurance Checks for Electronic Brachytherapy Devices.
1. Quality assurance checks shall be performed on each electronic brachytherapy device:
   a. At the beginning of each day of use;
   b. Each time the device is moved to a new room or site; and
   c. After each x-ray tube installation.
2. The registrant shall perform periodic quality assurance checks required in accordance with procedures established by

the Qualified Medical Physicist;

3. To satisfy the requirements of this subsection, radiation output quality assurance checks shall include at a minimum:
   a. Verification that output of the electronic brachytherapy source falls within three percent of expected values, as appropriate for the device, as determined by:
      i. Output as a function of time, or
      ii. Output as a function of setting on a monitor chamber.
   b. Verification of the consistency of the dose distribution to within three percent (or the manufacturer's or Qualified Medical Physicist's documented recommendation not to exceed five percent), observed at the source calibration required by subsection (I); and
   c. Validation of the operation of positioning methods to ensure that the treatment dose exposes the intended location within one millimeter; and
4. The registrant shall use a dosimetry system that has been intercompared within the previous 12 months with the dosimetry system described in this Section to make the quality assurance checks required in subsection (J)(3);
5. The registrant shall review the results of each radiation output quality assurance check to ensure that:
   a. An authorized user and Qualified Medical Physicist is immediately notified if any parameter is not within its acceptable tolerance, and the electronic brachytherapy device is not used until the Qualified Medical Physicist has determined that all parameters are within their acceptable tolerances;
   b. If all radiation output quality assurance check parameters appear to be within their acceptable range, the acceptable quality assurance checklist shall be reviewed and signed by either the authorized user or Qualified Medical Physicist prior to the next patient use of the unit. In addition, the Qualified Medical Physicist shall review and sign the results of each radiation output quality assurance check at intervals not to exceed 30 days.
6. To satisfy the requirements of subsection (J)(1), safety device quality assurance checks shall, at a minimum, assure:
   a. Proper operation of radiation exposure indicator lights on the electronic brachytherapy device and on the control console;
   b. Proper operation of viewing and intercom systems in each electronic brachytherapy facility, if applicable;
   c. Proper operation of radiation monitors, if applicable;
   d. The integrity of all cables, catheters or parts of the device that carry high voltages; and
   e. Connecting guide tubes, transfer tubes, transfer-tube-applicator interfaces, and treatment spacers are free from any defects that interfere with proper operation.
7. If the results of the safety device quality assurance checks required in subsection (J)(6) indicate the malfunction of any system, a registrant shall secure the control console in the OFF position and not use the electronic brachytherapy device except as may be necessary to repair, replace, or check the malfunctioning system.
8. The registrant shall maintain a record of each quality assurance check required by this Section in a legible form for three years.
   a. The record shall include the date of the quality assurance check; the manufacturer's name, model number and serial number for the electronic brachytherapy device; the name and signature of the individual who performed the periodic quality assurance check and the name and signature of the Qualified Medical Physicist who reviewed the quality assurance check;
   b. For radiation output quality assurance checks required by subsection (J)(3), the record shall also include the unique identifier for the electronic brachytherapy source and the manufacturer's name; model number and serial number for the instrument or instruments used to measure the radiation output of the electronic brachytherapy device.

K. Therapy-related Computer Systems. The registrant shall perform acceptance testing on the treatment planning system of electronic brachytherapy-related computer systems in accordance with current published recommendations from a recognized national professional association with expertise in electronic brachytherapy (when available). In the absence of an acceptance testing protocol published by a national professional association, the manufacturer's acceptance testing protocol shall be followed.

1. Acceptance testing shall be performed by, or under the direct supervision of a Qualified Medical Physicist. At a minimum, the acceptance testing shall include, as applicable, verification of:
   a. The source-specific input parameters required by the dose calculation algorithm;
   b. The accuracy of dose, dwell time, and treatment time calculations at representative points;
   c. The accuracy of isodose plots and graphic displays;
   d. The accuracy of the software used to determine radiation source positions from radiographic images; and
   e. If the treatment planning system is different from the treatment delivery system, the accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.
2. The position indicators in the applicator shall be compared to the actual position of the source or planned dwell positions, as appropriate, at the time of commissioning.
3. Prior to each patient treatment regimen, the parameters for the treatment shall be evaluated for correctness and approved by the authorized user and the Qualified Medical Physicist through means independent of that used for the

determination of the parameters.

L. Training for e-brachytherapy Authorized Users.

1. The registrant for any therapeutic radiation machine subject to this Section shall require the authorized user to be a physician who is certified in:
   a. Radiation oncology or therapeutic radiology by the American Board of Radiology or radiology (combined diagnostic and therapeutic radiology program) by the American Board of Radiology prior to 1976; or
   b. Radiation oncology by the American Osteopathic Board of Radiology; or
   c. Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or
   d. Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or
2. Is in the active practice of therapeutic radiology, and has completed 200 hours of instruction in basic radiation techniques applicable to the use of an external beam radiation therapy unit, 500 hours of supervised work experience, and a minimum of three years of supervised clinical experience.
   a. To satisfy the requirement for instruction, the classroom and laboratory training shall include:
      i. Radiation physics and instrumentation;
      ii. Radiation protection;
      iii. Mathematics pertaining to the use and measurement of ionization radiation; and
      iv. Radiation biology.
   b. To satisfy the requirement for supervised work experience, training shall be under the supervision of an authorized user and shall include:
      i. Review of the full calibration measurements and periodic quality assurance checks;
      ii. Evaluation of prepared treatment plans and calculation of treatment times or patient treatment settings or both;
      iii. Using administrative controls to prevent medical events as described in R12-1-444;
      iv. Implementing emergency procedures to be followed in the event of the abnormal operation of an external beam radiation therapy unit or console; and
      v. Checking and using radiation survey meters.
   c. To satisfy the requirement for a period of supervised clinical experience, training shall include one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user. The supervised clinical experience shall include:
      i. Examining individuals and reviewing their case histories to determine their suitability for external beam radiation therapy treatment, and any limitations or contraindications or both;
      ii. Selecting proper dose and how it is to be administered;
      iii. Calculating the therapeutic radiation machine doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed doses or treatment plans as warranted by patients' reaction to radiation or both; and
      iv. Post-administration follow-up and review of case histories.
3. Notwithstanding the requirements of this subsection, the registrant for any therapeutic radiation machine subject to this Section may also submit the training of the prospective authorized user physician for Agency review on a case-by-case basis if the training includes substantially equivalent training as that listed in subsection (L)(2) and the training includes dosimetry calculation training and experience.
4. A physician shall not act as an authorized user until such time as the physician's training has been reviewed and approved by the Agency.

M. Training for Qualified Medical Physicist. The registrant for any therapeutic radiation machine subject to this Section shall require the Qualified Medical Physicist to:

1. Be certified with the Agency, as a provider of radiation services in the area of calibration and compliance surveys of external beam radiation therapy units; and
2. Be certified by the American Board of Radiology in:
   a. Therapeutic radiological physics; or
   b. Roentgen-ray and gamma-ray physics; or
   c. X-ray and radium physics; or
   d. Radiological physics; or
3. Be certified by the American Board of Medical Physics in Radiation Oncology Physics; or
4. Be certified by the Canadian College of Physicists in Medicine; or
5. Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university, and have completed one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of a Qualified Medical Physicist at a medi-

cal institution. This training and work experience shall be conducted in clinical radiation facilities that provide high-energy external beam radiation therapy (photons and electrons with energies greater than or equal to one MV/one MeV). To meet this requirement, the individual shall have performed the tasks listed in this subsection under the supervision of a Qualified Medical Physicist during the year of work experience.

N. Qualifications of Operators. Individuals who will be operating a therapeutic radiation machine for medical use shall be certified by the Agency as a CTT by the Arizona Medical Radiologic Technology Board of Examiners.

O. Additional training requirements.

1. A registrant shall provide instruction, initially and at least annually, to all individuals who operate the electronic brachytherapy device, as appropriate to the individual's assigned duties, in the operating procedures identified in subsection (G). If the interval between patients exceeds one year, retraining of the individuals shall be provided.
2. In addition to the requirements of subsection (L) for therapeutic radiation machine authorized users and subsection (M) for Qualified Medical Physicists, these individuals shall also receive device-specific instruction initially from the manufacturer, and annually from either the manufacturer or other qualified trainer. The training shall be of a duration recommended by a recognized national professional association with expertise in electronic brachytherapy (when available). In the absence of any training protocol recommended by a national professional association, the manufacturer's training protocol shall be followed. The training shall include, but not be limited to:
   a. Device-specific radiation safety requirements;
   b. Device operation;
   c. Clinical use for the types of use approved by the FDA;
   d. Emergency procedures, including an emergency drill; and
   e. The registrant's quality assurance program.
3. A registrant shall retain a record of individuals receiving manufacturers instruction for three years. The record shall include a list of the topics covered, the date of the instruction, the name or names of the attendee or attendees, and the name or names of the individual or individuals who provided the instruction.

P. Mobile Electronic Brachytherapy Service. A registrant providing mobile electronic brachytherapy service shall, at a minimum:

1. Check all survey instruments before medical use at each address of use or on each day of use, whichever is more restrictive;
2. Account for the electronic brachytherapy x-ray tube in the electronic brachytherapy device before departure from the client's address; and
3. Perform, at each location on each day of use, all of the required quality assurance checks specified in this Section to assure proper operation of the device.

Q. Medical events shall be reported to the Agency. For purposes of this Section "medical event" means a therapeutic radiation dose from a machine:

1. Delivered to the wrong patient;
2. Delivered using the wrong mode of treatment;
3. Delivered to the wrong treatment site; or
4. Delivered in one week to the correct patient, using the correct mode, to the correct therapy site, but greater than 130 percent of the prescribed weekly dose; or

R. A therapeutic radiation dose from a machine with errors in the calibration, time of exposure, or treatment geometry that result in a calculated total treatment dose differing from the final, prescribed total treatment dose by more than 20 percent, except for treatments given in 1 to 3 fractions, in which case a difference of more than 10 percent constitutes a medical event.

S. Reports of therapy medical events:

1. Within 24 hours after discovery of a medical event, a registrant shall notify the Agency by telephone by speaking to an Agency staff member. The registrant shall also notify the referring physician of the affected patient and the patient or a responsible relative or guardian, unless the referring physician personally informs the registrant either that he or she will inform the patient, or that in his or her medical judgment, telling the patient or the patient's responsible relative or guardian would be harmful to one or the other, respectively. If the Agency staff member, referring physician, or the patient's responsible relative or guardian cannot be reached within 24 hours, the registrant shall notify them as soon as practicable. The registrant shall not delay medical care for the patient because of notification problems.
2. Within 15 days following the verbal notification to the Agency, the registrant shall report, in writing, to the Agency and individuals notified under subsection (S)(1). The written report shall include the registrant's name, the referring physician's name, a brief description of the event, the effect on the patient, the action taken to prevent recurrence, whether the registrant informed the patient or the patient's responsible relative or guardian, and if not, why not. The report shall not include the patient's name or other information that could lead to identification of the patient.
3. Each registrant shall maintain records of all medical events for Agency inspection. The records shall:
   a. Contain the names of all individuals involved in the event, including:
      i. The physician,

ii. The allied health personnel,
iii. The patient,
iv. The patient's referring physician,
v. The patient's identification number if one has been assigned,
vi. A brief description of the event,
vii. The effect on the patient, and
viii. The action taken to prevent recurrence.

b. Be maintained for three years beyond the termination date of the affected registration.

R12-1-611.02. Other Use of Electronically-Produced Radiation to Deliver Superficial Therapeutic Radiation Dosage

A person shall not utilize any device which is designed to electrically generate a source of ionizing radiation to deliver superficial therapeutic radiation dosage, and which is not appropriately regulated under any existing category of therapeutic radiation machine, until:

1. The applicant or registrant has, at a minimum, provided the Agency with:
   a. A detailed description of the device and its intended application or applications;
   b. Facility design requirements, including shielding and access control;
   c. Documentation of appropriate training for authorized user physician or physicians and qualified medical physicist or physicists;
   d. Methodology for measurement of dosages to be administered to patients or human research subjects;
   e. Documentation regarding calibration, maintenance, and repair of the device, as well as instruments and equipment necessary for radiation safety;
   f. Radiation safety precautions and instructions; and
   g. Other information requested by the Agency in its review of the application; and
2. The applicant or registrant has received written approval from the Agency to utilize the device in accordance with the regulations and specific conditions the Agency considers necessary for the medical use of the device; and
3. The applicant or registrant has submitted the application information and forms required by Article 2.
4. In addition to the requirements of this Section, a registrant using a device for x-ray radiation therapy shall meet the requirements of R12-1-611.01(Q), (R), and (S).